DEVELOPMENT AND FEASIBILITY TESTING OF A MULTI-COMPONENT SMOKING CESSATION INTERVENTION FOR SMOKERS LIVING WITH DIABETES MELLITUS

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Abstract

Background: Tobacco smoking increases the risk of macro- and micro-vascular complications for individuals living with diabetes. While smoking cessation has been recognised as an integral part of diabetes management, evidence of effective interventions is limited, and often this is overlooked by diabetes educators. Smokers with diabetes tend to be less motivated to stop, leading to low participation and abstinence rates.

Aim: To develop a multi-component smoking cessation intervention grounded in theory and evidence, tailored for smokers with diabetes, and to assess its feasibility, acceptability, and potential effectiveness in preparation for a future definitive trial.

Methods: In the development phase, a scoping review on the smoking cessation interventions that have been utilised amongst individuals with diabetes, and the faced challenges, and barriers was undertaken. A systematic review of effectiveness of the identified promising interventions followed, for identifying the components of the successful interventions. A qualitative descriptive study on the views of Maltese individuals living with diabetes of the identified components and their needs to quit smoking led to the development of the intervention. In the feasibility phase, a feasibility trial and its pilot were undertaken. A randomised trial with a nested qualitative descriptive study was undertaken to assess the feasibility and acceptability of the intervention amongst individuals with type 1 and type 2 diabetes (n=91) and two diabetes nurse educators (intervention providers) at a Maltese acute public hospital, comparing intervention acceptability and potential effectiveness to standard care.

Results: A unique multi-component smoking cessation intervention consisting of 3-4 behavioural support sessions and a 6-week provision of Nicotine Replacement Therapy (NRT) was developed. Minor revisions were required following the pilot study, mainly the addition of a final follow-up session for continuing smokers. While treatment discontinuation was high in both groups in the feasibility trial, the intervention was found to be feasible, acceptable to the individuals with diabetes and the diabetes nurse educators, and potentially effective. The provision of NRT was identified as a crucial component of the intervention.

Conclusions: The developed intervention is feasible and acceptable and may improve smoking quit rates when compared to standard care. To improve participation rates for a definitive trial, telephone-based follow-up support should be provided to those who struggle to

attend further. Given NRT's contributing role, the cost coverage or provision of NRT to smokers with diabetes is also recommended.

Keywords: Diabetes Mellitus; Tobacco Use Cessation; Medical Research Council Framework; Information Motivation Behavioral Skills Model; Feasibility Studies

To Bill. B.

Thank you for sharing your story.

May you rest in peace.

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Chapter 1: Introduction

1.1 Introduction

This thesis describes the development and feasibility testing of a multi-component smoking cessation intervention for individuals living with diabetes mellitus. This chapter provides the background and rationale to this research project. Section 1.2 provides an overview on diabetes and tobacco smoking, outlining the effects of smoking in diabetes. Conversely, section 1.3 presents the evidence on the effects of smoking cessation on diabetes management. Section 1.4 provides an overview of the tobacco cessation guidelines for individuals with diabetes, along with the evidence in relation to the efficacy of smoking cessation interventions for individuals living with diabetes at the starting time of the doctoral research project. This section also discusses the provision of smoking cessation support within diabetes practice, in view of the associated barriers and challenges to smoking cessation and outlines the Maltese National Health Service's smoking cessation pathway for individuals living with diabetes. Gaps in evidence are identified, leading to the research implications for the doctoral research project. Section 1.5 presents the overall aims of this doctoral research project and the main research question. The research framework which was utilised is briefly discussed in section 1.6. An outline of the thesis' structure follows in section 1.7 with a conclusion summarising the chapter in section 1.8.

1.2 Diabetes and tobacco smoking

Diabetes mellitus is a major public health concern. Based on the International Diabetes Federation Diabetes Atlas's latest figures, it is estimated that worldwide 589 million adults between the ages of 20–79 years had diabetes in 2024 (Magliano et al., 2025). Unmanaged diabetes can result in serious complications and consequences. High levels of blood glucose in diabetes can lead to the development of various macro- and micro-vascular complications such as cardiovascular disease, nephropathy, neuropathy and retinopathy, increasing the risk of morbidity and even death (Boyko et al., 2021). Diabetes is also of concern for national public health (Calleja et al., 2016). Although the European region has the third-lowest diabetes

prevalence (at 9.8%), Malta has a high diabetes prevalence, estimated at 11.5% (Magliano et al., 2025). The latest published Maltese National Health Interview Survey of 2019/20 reported that 7.9% of the participants aged 15 years and over had reported having diabetes during their life (England et al., 2022). However, a health examination survey carried out amongst 18 to 70 year old individuals between 2014 and 2016 reported a higher prevalence of individuals with type 2 diabetes, at 10.4%, 95% Confidence Interval, CI [9.5-11.4] (Cuschieri et al., 2016).

Tobacco smoking is another public health issue. Tobacco smoking is associated with increased morbidity and mortality in the general population (Drope & Schluger, 2018), including a higher risk of type 2 diabetes (Durlach et al., 2022; Pan, Wang, Talaei, Hu, et al., 2015). Among those living with diabetes who smoke, increasing evidence demonstrates an increased risk of complications and mortality. In addition to causing endothelial dysfunction and alteration of the plasma viscosity by interfering via the coagulation pathway, tobacco smoking, likely mediated by the effects of nicotine, contributes to metabolic deregulations – greater insulin resistance, worsened beta-cell function and impaired insulin secretion, resulting in a higher risk for vascular complications (Durlach et al., 2022; Kar et al., 2016; Rouland et al., 2024).

In a recent prospective cohort study, Yang et al. (2022) reported that compared to never smokers, heavy smokers (≥20 cigarettes/day) with diabetes had a greater risk of cardiovascular events than heavy smokers without diabetes (multi-variable-adjusted Hazard Ratio [aHR]: 1.45, 95% CI [1.17-1.78] vs. aHR: 1.20, 95% CI [1.01-1.42]). In another prospective cohort study, Barengo et al. (2017) found that compared to never smokers without diabetes, both men and women with type two diabetes who smoke had a higher all-cause mortality than smokers without diabetes (aHR amongst men: 3.76, 95% CI [2.95-4.78] vs. 2.63, 95% CI [2.33-2.97]; aHR amongst women: 4.51, 95% CI [2.91-7.00] vs. 2.37, 95% CI [2.02-2.78]). Furthermore, when compared to never smokers without diabetes, the coronary heart disease (CHD) mortality risk for male smokers with diabetes was higher than in male smokers without diabetes (aHR: 6.15, 95% CI [4.22-8.96] vs. aHR: 3.11, 95% CI [2.48-3.92]; Barengo et al., 2017). A similar trend was also observed in females (aHR: 6.92, 95% CI [2.79-17.19] vs 3.84, 95% CI [2.65-5.55]; Barengo et al., 2017).

Whilst few studies have compared the effects of tobacco smoking on patients with diabetes to the general population, several researchers have studied the association between smoking and the risk of diabetes complications among patients with diabetes, providing accumulating substantial evidence. Individuals with diabetes who smoke have been found to have an

increased risk for CHD (pooled Relative Risk [RR]: 1.51, 95% CI [1.41-1.62]; 21 studies), cardiovascular disease (RR: 1.44, 95% CI [1.34-1.54]; 16 studies), stroke (RR: 1.54, 95% CI [1.41-1.69]; 15 studies), heart failure (RR: 1.43, 95% CI [1.19-1.72]; four studies), and peripheral arterial disease (RR: 2.15, 95% CI [1.62-2.85]; three studies) when compared to individuals with diabetes who do not smoke (Pan, Wang, Talaei, & Hu, 2015). Additionally, when compared to non-smoking individuals with diabetes, individuals with diabetes who smoke have an increased risk of diabetic foot amputations (Odds Ratio [OR]: 1.65, 95% CI [1.09-2.50]; seven studies) (Liu et al., 2018). When compared to never smokers, a higher risk for total mortality (RR: 1.48, 95% CI [1.34-1.64]; 27 studies), and for cardiovascular mortality (RR: 1.36, 95% CI [1.22-1.52]; nine studies) has also been identified amongst smokers with diabetes (Qin et al., 2013).

While both smokers with type 1 and type 2 diabetes are at risk of these macrovascular complications, the relationship between smoking and microvascular complications such as nephropathy, retinopathy and neuropathy is less evident among individuals with type 2 diabetes, as few rigorous studies are available (Campagna et al., 2019; Durlach et al., 2022; Rouland et al., 2024; Walicka et al., 2024). In their systematic review and meta-analysis, Clair et al. (2015) found that smoking may be associated with diabetic neuropathy amongst individuals with diabetes (OR: 1.26, 95% CI [0.86-1.95]), identifying a significant association in patients with type 1 diabetes (OR: 1.74, 95% CI [1.48-2.04]), but not for patients with type 2 diabetes. Similarly, while both smokers with type 1 and type 2 diabetes were found to have an increased risk for developing diabetic nephropathy (Hazard Ratio [HR]: 1.07, 95% CI [1.01-1.13]), the increased risk was significant in the type 1 diabetes sub-group (HR: 1.05, 95% CI [1.00-1.11]), but not in the type 2 diabetes sub-group (Liao et al., 2019). Additionally, when compared to non-smokers, smokers with type 1 diabetes had an increased risk of diabetic retinopathy (RR: 1.23, 95% CI [1.14-1.33] and of proliferative diabetic retinopathy (RR: 1.48, 95% CI [1.20-1.81]), however this was not observed amongst individuals with type 2 diabetes (Cai et al., 2018).

As stated earlier, smoking does not only enhance vascular complications amongst individuals with diabetes, but has also been found to impair glucose metabolism and lipid control, which in turn also lead to a worse cardiovascular outcome (Kar et al., 2016). In their systematic review and meta-analysis Kar et al. (2016) observed a mean difference in HbA1c of −0.61%, 95% CI [-0.88 to -0.33] between non-smokers and smokers with diabetes. Dyslipidaemia, often associated with diabetes, was also found to be aggravated by smoking. An HDL-cholesterol

difference of 0.12mmol/l, 95% CI [0.08-0.15], and an LDL-cholesterol difference of -0.11mmol/l 95% CI [-0.21 to -0.01] were also observed between non-smokers and smokers (Kar et al., 2016). It is thus evident that the harmful effects of smoking amongst individuals with diabetes extend beyond the concomitant vascular complications to metabolic deregulations resulting in poor diabetes management.

Despite the increased health risk associated with tobacco use, having diabetes does not necessarily encourage individuals to quit smoking (Clement et al., 2023; Gaggero et al., 2022; Holm et al., 2017). Worldwide, the mean prevalence of tobacco use amongst individuals with type 2 diabetes was estimated to be 20.8%, 95% CI [18.93-22.76] (Roderick et al., 2019). On the other hand, Durlach et al. (2022) estimated the average smoking prevalence among individuals with type 1 diabetes at 30%. The prevalence of tobacco use amongst individuals with diabetes can vary substantially across countries (Pan, Wang, Talaei, & Hu, 2015; Roderick et al., 2019) and seems to reflect the smoking habits of the nation (Lotrean, 2017). In Malta, the latest published National Health Interview Survey reported that 21% of the participants aged 18 years and over were daily smokers in 2019 (Borg et al., 2023). Analysis of unpublished raw data from this Survey revealed that the smoking prevalence rate amongst those who reported having diabetes was at 15.2%, i.e., one in six/seven individuals with diabetes smokes on a daily basis (Directorate for Health Information and Research, 2023). Malinovská et al. (2025), who utilised data from the 2019/20 Survey of Health, Ageing and Retirement in Europe on individuals aged 50 years and over who reported having/having had diabetes, reported a prevalence of current smokers of 12.2% in 27 European countries, including Malta, observed at 9.3%. These observations warrant the need to understand better the connection between diabetes and tobacco smoking to implement more targeted and appropriate anti-smoking strategies.

1.3 Smoking cessation and diabetes outcomes

Individuals with diabetes who smoke need to quit to avoid the above-mentioned tobacco-specific complications and to reduce their higher risk of mortality. Smoking cessation presents a decreased risk for premature death, cardiovascular mortality and morbidity (Durlach et al., 2022), namely myocardial infarction and ischaemic stroke (Walicka et al., 2024). However, while improvement in lipid profile is immediate, within three weeks (Kar et al., 2016), in the

short-term quitting smoking may be associated with a negative impact on diabetes management, posing a challenge for both the patient and his/her clinician (Campagna et al., 2019; Walicka et al., 2022).

Weight gain is a well-known side-effect following smoking cessation. Compared with continuing smoking, quitting smoking is significantly associated with an absolute weight gain of 2.61 kg, 95% CI [1.61-3.60] and BMI gain of 0.63 kg/m^2, 95% CI [0.46-0.80] (Tian et al., 2015). This may potentially present health concerns for those with diabetes, such as an increased risk of developing cardiovascular disease (Liu et al., 2020). Although when compared with current smokers the multivariable-adjusted HRs for incidence of cardiovascular disease (within 6 years of quitting) were significantly reduced amongst individuals with diabetes who quit without weight gain (0.77, 95% CI [0.62-0.95]), these were higher for those who quit with weight gain, (0.94 [0.73-1.20]) with similar trends noted for risk of developing CHD and stroke (Liu et al., 2020).

Smoking cessation is also associated with a deterioration in glycaemic control following quitting. This may not be linked to weight gain post cessation (Campagna et al., 2019). For example, in Lycett et al.'s (2015) study, participants' HbA1c increased by 0·21%, 95% CI [0·17–0·25]; 2·34 mmol/mol, 95% CI [1·91–2·77] within the first year after quitting, which was not mediated by weight change. Glycaemic control also tends to remain poor in the first 10 years following quitting (Kar et al., 2016; Peng et al., 2018). Compared to non-smokers, former smokers who had quit smoking in the past ten years were still found at risk of poor glycaemic control (multivariable-adjusted Odds Ratio [aOR]: 1.23, 95% CI [1.06–1.42]; Peng et al., 2018). Evidence suggests that this increased risk only levels off after 10 years from quitting (aOR for former smokers who had quit for 10-19 years was 0.97, 95% CI [0.80-1.19]; Peng et al., 2018).

Nonetheless, smoking cessation amongst individuals with diabetes who smoke still presents various health benefits, which outweigh these short-term challenges. When compared to current smokers, the increased risk of poor glycaemic control was found to be significantly less amongst former smokers; aORs for former smokers who had quit for <10, 10-19, and ≥20 years were 0.84, 95% CI [0.72-0.98], 0.67, 95% CI [0.54-0.83]), and 0.79, 95% CI [0.61-1.00], respectively (Peng et al., 2018). When compared to current smokers, former smokers were still found to have a significant lower risk for coronary heart disease; RR: 1.03 [0.84-1.26] vs. 1.66 [1.40-1.97]; (Qin et al., 2013). Former smokers also had a significant lower risk for total

mortality (RR: 1.28, 95% CI [1.09-1.51] vs. 1.58, 95% CI [1.42-1.77]) and mortality from cardiovascular disease (RR: 1.19 [1.02-1.39] vs. 1.56 [1.34-1.81]; Qin et al., 2013). Despite possible weight gain following quitting, smoking cessation amongst individuals with diabetes still results in a reduction of all-cause mortality risk. Compared with current smokers, the multivariable-adjusted HRs were 0.84, 95% CI [0.71-0.99] amongst those without weight gain within 6 years of quitting, 0.73, 95% CI [0.43-1.24] amongst those with a weight gain between 0.1-5.0kg, and 0.46, 95% CI [0.26-0.83] amongst those with a weight gain of more than 5.0kg, with similar trends noted for cardiovascular disease and cancer mortality (Liu et al., 2020).

Despite the short-term potential negative impact on glycaemic control and weight management post-cessation, evidence still supports the position that quitting smoking provides clear benefits in terms of reducing the risk of cardiovascular morbidity, mortality, and overall mortality in people with diabetes as it does for the general population. Smoking cessation is therefore recommended for all smokers with diabetes.

1.4 Smoking cessation for individuals with diabetes

Just as all tobacco users should be encouraged to quit smoking, individuals with diabetes who smoke should also be supported. Smoking cessation support has been recommended as an essential component of diabetes care (Durlach et al., 2022; Karuranga et al., 2019; Lotrean, 2017; Seidu et al., 2022). It is also one of the key recommendations outlined in the Malta National Diabetes Strategy to help delay the onset or the progression of diabetes complications amongst individuals with diabetes (Calleja et al., 2016).

Smoking cessation interventions however vary widely in terms of the content, intensity, and methods of delivery. They can range from a one-off brief tobacco cessation advice or behavioural support session from a health care professional, or printed information material, to more intensive approaches involving multiple support sessions, with or without additional components, such as pharmacotherapy for smoking cessation or other interacting smoking cessation measures (Hartmann-Boyce et al., 2021). Smoking cessation interventions can also be based on common specific frameworks or approaches, such as the 5As (and 5Rs) for smoking cessation (World Health Organization, 2014), the stages of change as outlined in the Transtheoretical model of change (DiClemente et al., 1991), and motivational interviewing (Miller & Rollnick, 2002), amongst others. The tobacco cessation guidelines for individuals

with diabetes recommend the provision of at least brief tobacco cessation advice, and/or a combination of intensive behavioural support and pharmacotherapy for smoking cessation (Durlach et al., 2022; Lotrean, 2017; Rouland et al., 2024).

This section provides an overview of the main treatment approaches used in the general population of smokers, along with the evidence in relation to the efficacy of smoking cessation interventions for individuals with diabetes at the starting time of the doctoral research project. This section also discusses the provision of smoking cessation support within diabetes practice, in view of the associated barriers and challenges, and outlines the Maltese National Health Service's smoking cessation pathway for individuals with diabetes. Gaps in evidence are identified, leading to the research implications for the doctoral research project.

1.4.1 Brief smoking cessation advice

The identification of individuals with diabetes who smoke, and the subsequent provision of brief advice, has been recommended as a first line of smoking cessation support for individuals with diabetes in clinical settings (Durlach et al., 2022; Lotrean, 2017). This proves to be opportunistic, as the identified smokers might not be seeking tobacco cessation support, but might become interested in quitting smoking during such encounters (European Network for Smoking and Tobacco Prevention, 2020). When compared to no advice or usual care (i.e. routine care/practice; Lamb & Altman, 2015), brief advice, i.e., smoking cessation advice lasting no more than 20 minutes and an additional follow-up session, was reported to significantly increase the rate of quitting in the general population of smokers (RR: 1.66, 95% CI [1.42-1.94]; Stead et al., 2013).

The 5As (Ask, Advise, Assess, Assist, Arrange) and 5Rs (Relevance, Risks, Rewards, Roadblocks, Repetition) algorithm is one of the most evidence-based frameworks used for the provision of brief tobacco cessation advice amongst all tobacco users (Durlach et al., 2022; European Network for Smoking and Tobacco Prevention, 2020; Fiore et al., 2008; World Health Organization, 2014). This includes: Asking all patients about their smoking status; Advising those who smoke to quit; Assessing readiness to quit; Assisting them with making a quit plan by providing brief behavioural counselling and recommending/prescribing smoking cessation medications, (or providing brief counselling to non-motivated smokers to encourage them to quit by following the 5Rs); and Arranging a follow-up (European Network for Smoking and Tobacco Prevention, 2020; Fiore et al., 2008; World Health Organization, 2014).

The 5Rs algorithm (which is followed for non-motivated smokers) includes encouraging patients to talk about how quitting is relevant to them (Relevance), discussing perceived Risks and Rewards to quitting, discussing possible barriers to quitting smoking (Roadblocks) and finally re-assessing readiness to quit smoking (Repetition) (European Network for Smoking and Tobacco Prevention, 2020; Fiore et al., 2008; World Health Organization, 2014). Albeit being renown for brief encounters, this framework has also been followed for the provision of intensive behavioural support (Lancaster & Stead, 2017). Compared to smokers who received one or none of the 5As, smokers who reported receiving all 5As during a health care professional consultation were more likely to access counselling services (OR: 11.2, 95% CI [7.1-17.5]), take stop smoking medications (OR: 6.2, 95% CI [4.3-9.0]), or a combination of both (OR: 14.6, 95% CI [9.3-23.0]) (Kruger et al., 2016).

1.4.2 Intensive behavioural support and pharmacotherapy for smoking cessation

Intensive behavioural support may help counter any ambivalence about quitting and help individuals with diabetes who smoke develop new strategies to deal with the challenges and barriers to quitting (Campagna et al., 2019; Durlach et al., 2022; Lotrean, 2017; Rouland et al., 2024). The provision of intensive behavioural support and pharmacological treatment are recommended as part of advanced cessation interventions for individuals with diabetes (Durlach et al., 2022; Lotrean, 2017; Rouland et al., 2024).

1.4.2.1 Intensive behavioural support

Compared to brief advice, intensive behavioural support, such as counselling, is found to be more effective for smoking cessation in the general population (RR: 1.29, 95% CI [1.09-1.53]; Lancaster & Stead, 2017). Intensive behavioural support commonly includes reviewing the participant's smoking history and motivation to quit, the identification of high-risk smoking situations and the generation of problem-solving strategies to deal with the barriers in quitting (Lancaster & Stead, 2017). Intensive behavioural support is typically provided through repeated contacts led by professionals such as social workers, psychologists, health educators and nurses trained in smoking cessation (Lancaster & Stead, 2017). Intensive behavioural support for smoking cessation can be provided in group or individual format, with no significant difference being identified between them (RR: 0.99, 95% CI [0.76-1.28]; Stead & Lancaster, 2017).

1.4.2.2 Motivational Interviewing (MI)

A commonly used behavioural support approach is MI which was developed by Miller and Rollnick in 1991. MI is defined as a directive client-centred approach which aims to elicit behaviour change while inviting clients to explore and resolve any ambivalence to behaviour change (Miller, 1983). The main underlying principles are: empathy; developing the discrepancy between the current behaviour and the desired behaviour; rolling with any resistance and supporting self-efficacy (Miller & Rollnick, 2002). While previous meta-analyses showed that MI interventions are effective for smoking cessation in the general population (OR comparing likelihood of abstinence in the MI group versus control was 1.45, 95% CI [1.14-1.83]; Heckman et al., 2010; RR comparing MI to brief advice or usual care was 1.26, 95% CI [1.16-1.36]; Lindson-Hawley et al., 2015), a recent systematic review and meta-analysis by Lindson et al. (2019) has concluded that the effectiveness of this approach appears to be uncertain, recommending further research.

1.4.2.3 Stage based interventions

In planning and providing intensive smoking cessation interventions, some practitioners prefer to consider the current stage of change an individual is in, thus being able to provide tailored interventions. The transtheoretical model (DiClemente et al., 1991; Prochaska & Velicer, 1997; Prochaska, Velicer, Prochaska, & Johnson, 2004), is the most widely known stage-based theory of behavioural change. It suggests that smokers go through a series of motivational stages to stop smoking. These are the *precontemplation* (no thoughts of quitting in the foreseeable future, usually measured as the next six months), *contemplation* (thinking about quitting probably within the next six months), *preparation* (planning to quit usually measured as the next 30 days while having made a quit attempt in the past year), *action* (quitting successfully within the past six months), and *maintenance* stages (no smoking for more than six months) (DiClemente et al., 1991; Prochaska et al., 2004). Given that the individual's stage of change can be defined, the interventions that take into account the current stage of the individual are generally thought to be more effective and efficient (Cahill et al., 2010). Nonetheless, the effectiveness in adapting the smoking cessation intervention in accordance to the smoker's stage of change still appears to be uncertain (Cahill et al., 2010; Riemsma et al., 2003).

1.4.2.4 Pharmacological treatment

Conversely, there is sufficient evidence which demonstrates that smoking cessation interventions that combine pharmacological treatment and behavioural support increase

smoking cessation success when compared to a brief smoking cessation intervention or usual care in the general population (RR: 1.83, 95% CI [1.68-1.98]; Stead et al., 2016). The use of pharmacotherapy, such as Nicotine Replacement Therapy (NRT), bupropion, and varenicline, has also been found to improve the odds of quitting smoking with a low risk of harm, reducing cravings and withdrawal symptoms related to quitting (Cahill, Stevens, Perera, & Lancaster, 2013). Varenicline is shown to be superior to any single type of NRT and to bupropion but is not more effective than combination NRT; i.e. a constant dose of NRT through the use of the nicotine patch, and a fast-acting type of NRT, such as through the use of the gum, inhaler or spray (OR: 1.06; 95% CI [0.75-1.48]; Cahill et al., 2013).

1.4.2.5 Multi-component smoking cessation interventions

Research evidence suggests that multi-component smoking cessation interventions, i.e., interventions with two or more interacting components, such as intensive behavioural counselling, pharmacotherapy, and the provision of more follow-up appointments, can help improve cessation rates in the general population (Cantera et al., 2015; Papadakis et al., 2010). In their systematic review, Cantera et al. (2015) found that in primary care, the more support the smoker receives, in terms of more components, more follow-ups, the use of intensive interventions and pharmacotherapy, the greater the effect is in terms of smoking cessation (Cantera et al., 2015). Such strategies were found to be more effective when the smoker had set a quit date and when pharmacotherapy was provided for free (Cantera et al., 2015). Similarly, in a systematic review and meta-analysis by Papadakis et al. (2010) it was found that multi-component smoking cessation interventions, which included smoking cessation counselling and free NRT, were more effective in achieving smoking abstinence when compared to no intervention or usual care (OR: 2.19, 95% CI [1.71-2.79]).

The above-mentioned evidence suggests a notable benefit in combining smoking cessation pharmacotherapy to intensive behavioural support (as well as the consideration of additional smoking cessation components) as part of a targeted smoking cessation strategy for individual living with diabetes.

1.4.3 Efficacy of smoking cessation interventions for individuals with diabetes

Despite the potential health benefits for those who quit smoking and have diabetes, there has been limited research on the development and evaluation of targeted smoking cessation

interventions for individuals with diabetes (Nagrebetsky et al., 2014). Furthermore, due to mixed findings, there is limited evidence so far for recommending intensive behavioural support and pharmacotherapy for smoking cessation for individuals with diabetes (Durlach et al., 2022).

The systematic review and meta-analysis by Nagrebetsky et al. (2014), which compared the effectiveness of more intensive to less intensive stand-alone smoking cessation interventions amongst individuals with diabetes, found no evidence calling for the use of more intensive smoking cessation interventions. When compared to less intensive interventions such as, usual care or brief smoking cessation advice, intensive smoking cessation interventions (i.e., pharmacological and/or non-pharmacological behavioural interventions) which were not part of a broader intervention for improving diabetes management only resulted in a non-significant increase in self-reported (RR: 1.85, 95% CI [0.81-4.22]) and biochemically verified (RR: 1.32, 95% CI [0.23-7.43]) smoking abstinence (Nagrebetsky et al., 2014). Conversely, in the meta-analysis by Zhan, Song, & Liu (2016), where the authors assessed the effectiveness of psychological interventions smoking cessation, including both stand-alone smoking cessation interventions and interventions in which smoking cessation was part of a broader intervention for improving diabetes management in their review, and compared these to usual care, found that psychological interventions were more effective, however significance was short-lived, up till three months of follow-up (RR: 2.52, 95% CI [1.32-4.80] vs. 1.73, 95% CI [0.84-3.55] at six months). Furthermore, this analysis was based on self-reported data. Notwithstanding these inconsistencies, it is worth noting that both reviews suffered from substantial heterogeneity; I^2=76% (Nagrebetsky et al., 2014) and I^2=69% and 74% for pooled studies measuring smoking abstinence at three and six months follow-up, respectively (Zhan et al., 2016), warranting caution in the interpretation of findings and application to clinical practice.

The ability to draw conclusions regarding the efficacy of smoking cessation interventions for individuals with diabetes is further compounded as none of the reviewers provided robust recommendations in terms of the specific smoking cessation interventions or components for use amongst individuals with diabetes, again limiting application to clinical practice. Given the higher level of self-management required for diabetes, Nagrebetsky et al. (2014) suggest the integration of smoking cessation interventions within diabetes routine care, rather than addressing tobacco use in isolation. In view of the identified gap in research, further research on the development and evaluation of smoking cessation interventions for individuals with diabetes has also been recommended (Nagrebetsky et al., 2014).

1.4.4 Smoking cessation support within diabetes care and the associated barriers and challenges

When compared to the general population, patients with diabetes are more likely to see health care professionals more often, offering the opportunity for health care professionals to integrate tobacco cessation support (Lotrean, 2017). Nevertheless, the literature suggests that individuals with diabetes are less likely to be advised against smoking and less likely to be supported towards quitting (Lotrean, 2017). While in two national representative surveys in the United States, 78.6% and 84.5% of those with diabetes reported receiving advice to quit smoking versus 54.2% and 72.8% without a condition (OR: 1.89, 95% CI [1.50-2.37]; Keith et al., 2013; and OR: 1.9, 95% CI [1.3-2.6]; Schauer et al., 2013; respectively), evidence suggests that individuals with diabetes are less likely to be advised to quit smoking when compared to patients with other chronic conditions. Analysis of data from the PINNACLE register (the Practice Innovation and Clinical Excellence register which collects data from ambulatory cardiology practices in the United States), revealed that those with diabetes were less likely to be provided with smoking cessation assistance when compared to other chronic conditions (OR: 0.84, 95% CI [0.82-0.87] ; Sardana et al., 2016). Furthermore, amongst adults attending primary care clinics, it was found that the odds of receiving smoking cessation counselling and medication were lower amongst those with diabetes (OR: 0.85; 95% CI [0.79-0.92]) unlike those with other chronic conditions, e.g., asthma or chronic obstructive pulmonary disease, coronary artery disease, hyperlipidaemia, and hypertension (Bailey et al., 2018).

The literature suggests that diabetes specialists and diabetes educators tend to focus their educational efforts on other aspects of diabetes management, rather than on smoking cessation (Camilleri et al., 2021; Lotrean, 2017). In a representative survey amongst Chinese residents aged 45 years and over it was found that amongst those who were provided with diabetes education (79.8%), only 42.5% of the smokers were provided with smoking cessation advice (Xu et al., 2016). In another study held amongst primary care nurses who played a major role in the care of individuals with diabetes, it was found that only half of their patients (who wished to stop smoking) were advised to take NRT (Daly et al., 2014).

Diabetologists and diabetes educators have also reported feeling inadequately prepared in discussing smoking cessation amongst individuals with diabetes (Lotrean, 2017). In the study by Berlin et al. (2024) only 13.3% of the diabetologists who answered a survey on smoking

and diabetes, reported feeling competent to support smokers with diabetes to quit smoking. Similarly in the study by Jansink et al. (2010), primary care nurses, who worked with patients with diabetes, remarked not having enough knowledge and skills to help individuals with diabetes to quit, thus feeling inadequate in their approach.

Besides the psychological (the smoking habit) and tobacco addiction, individuals with diabetes tend to present with diabetes-specific barriers/challenges which makes it even more challenging for the assisting health care professional (Campagna et al., 2019; Durlach et al., 2022; Lotrean, 2017). Weight gain and poor glycaemic control, both of which can independently occur on quitting smoking, can be a concern for individuals with diabetes in attempting to quit smoking (Campagna et al., 2019; Durlach et al., 2022; Kar et al., 2016; Rouland et al., 2024). Comorbidities commonly associated with diabetes, such as anxiety (Smith et al., 2013) and depression (Rotella & Mannucci, 2013), are known to hinder efforts in quitting smoking (Richards et al., 2013). Notably, the risk of depression is higher among individuals with type 2 diabetes who smoke (Durlach et al., 2022). Irrespective of such comorbidities, individuals with diabetes may also experience 'diabetes distress,' the negative emotional or affective experience when struggling to keep up with the demands of diabetes, possibly due and/or being exacerbated by negative social interactions (such as with family/friends, health care providers, etc.), resulting in decreased self-care and emotional wellbeing (Skinner et al., 2020). Emerging evidence also suggests that individuals with diabetes may be more likely to suffer from nicotine addiction (Keith et al., 2019; Yammine et al., 2019). Individuals with type 2 diabetes may metabolise nicotine faster, possibly because of diabetes-induced changes to the liver resulting in fatty liver disease, which is associated with an increased nicotine metabolite ratio, making them smoke more during their life, possibly increasing their nicotine addiction (Keith et al., 2019).

Given these barriers and challenges to smoking cessation among individuals with diabetes, further research in this subject area was deemed to be required.

1.4.5 The National Health Service's smoking cessation pathway for individuals with diabetes locally

According to the current Malta National Diabetes Strategy, all adults with type 1 diabetes are under the care of the diabetologists, who attend the diabetes outpatients' department at the two acute public hospitals (Calleja et al., 2016). Individuals with type 2 diabetes attend the

respective departments when complications arise or at prescribed time intervals, at least once annually (Calleja et al., 2016). According to the Malta National Diabetes Strategy, all newly diagnosed patients, who are mainly diagnosed with type 2 or type 1 diabetes, are advised to quit smoking and subsequently referred to the Maltese National Health Service's general smoking cessation services (Calleja et al., 2016). Both individuals with type 1 and type 2 diabetes may also be referred to the diabetes nurse specialists (referred to as diabetes practice nurses or diabetes nurse educators) for diabetes education within the respective outpatients' departments (Calleja et al., 2016). However, despite the potential integration of smoking cessation interventions into diabetes education, these sessions focus on achieving glycaemic control by enhancing diabetes health literacy and self-management, rather than addressing smoking cessation.

1.4.6 Implications for the doctoral research project

In view of the limited evidence on the efficacy of smoking cessation interventions for individuals with diabetes, the low involvement of diabetes educators in treating tobacco use, and the barriers and challenges to smoking cessation faced by individuals with diabetes, further research in this subject area was deemed to be required. A more comprehensive review (a scoping review) of the available literature on different types of smoking cessation interventions that have been utilised amongst individuals with diabetes (including those that are part of a wider diabetes management intervention), taking into consideration the challenges, and the barriers to smoking cessation that were identified amongst individuals with diabetes, was thus carried out and is reported in chapter three. This helped to identify the smoking cessation interventions that looked most promising, and which were examined in more detail, in terms of their effectiveness in a systematic review, reported in chapter four. Feedback from individuals with diabetes on the identified smoking cessation components was also sought, leading to the development of a unique promising multi-component smoking cessation intervention for individuals with diabetes. The developed intervention was then presented to the diabetes educators, i.e., to the diabetes practice nurses who provide formal diabetes education at Malta's acute public hospitals, as potential intervention providers. Given that the success of a health care intervention, such as a smoking cessation intervention, is dependent on stakeholder engagement, patients and providers alike (Skivington et al., 2021), its feasibility, and acceptability, along with its potential effectiveness, were assessed before future evaluation or implementation.

1.5 Overall research aims and main research question

This doctoral research project aimed to develop a multi-component smoking cessation intervention grounded in theory and research evidence, tailored for smokers with diabetes, and to assess its feasibility, acceptability, and its potential effectiveness in preparation for a future definitive trial. The aims were to:

- Develop a smoking cessation intervention, based on evidence and theory, tailored for people with diabetes who smoke.
- Improve the design and delivery of the intervention using feedback from diabetes nurse educators and current smokers with diabetes.
- Evaluate the feasibility and acceptability of this intervention using feedback from diabetes nurse educators and current smokers with diabetes and assess its potential effectiveness.

The overarching research question for this doctoral research project is as follows:

Is a multi-component smoking cessation intervention developed for persons living with diabetes who smoke feasible, acceptable to diabetes nurse educators and their patients, and potentially effective?

Specific aims and objectives for the different phases of this doctoral research project are provided in the methodology chapter, chapter two.

1.6 The developmental framework

To reach the overall aims, a guiding framework was required. Interventions such as the proposed smoking cessation intervention that consist of interacting components are known as complex interventions (Craig et al., 2008, 2013; Skivington et al., 2021). This doctoral research project is based on the Medical Research Council (MRC) 2021 framework for the development and evaluation of complex interventions in health care (Skivington et al., 2021). The MRC framework consists of four distinctive phases for the development-evaluation-implementation process of complex interventions which may not always be linear in action

(Craig et al., 2008, 2013; Skivington et al., 2021). These are: development (the development or identification of an already established intervention); feasibility (for reducing uncertainties that relate to the intervention or its evaluation); evaluation (looking at the intervention's effectiveness); and implementation (to help ensure that the complex intervention is implemented in clinical practice) (Skivington et al., 2021). In addition to these four distinctive phases, the latest MRC guidelines recommend the consideration of a set of core elements which look at efficacy, effectiveness, theory base, and systems throughout the research process (Skivington et al., 2021). At each phase, the researcher/s should also consider the context, develop and/or refine the intervention and the programme theory (which describes how the model of the intervention works within its context), engage stakeholders, identify key uncertainties, and consider alternative courses of actions (Skivington et al., 2021).

The MRC framework guides the researcher to develop an intervention in a systematic manner, testing it out prior to moving on to a definitive evaluation and implementation (Craig et al., 2008, 2013; Skivington et al., 2021). Through this process, the research can identify and strengthen the weak links earlier on, understand fully how the intervention works, in terms of the active ingredients and their exerted effects, and avoid bias in rejecting an ineffective intervention given that the intervention is meticulously developed and refined throughout (Craig et al., 2008, 2013; Skivington et al., 2021). This research investigates the first two phases: the developmental and the feasibility stages. The use of both quantitative and qualitative methods may be necessary for exploring complex interventions beyond their effectiveness (Skivington et al., 2021), as in this case. The use of mixed methods, i.e., the integration of qualitative and quantitative approaches at any point in the research process, can help to understand and improve the proposed intervention within its context (Borglin, 2015; Skivington et al., 2021). This approach provides important implications for research, policy and practice, ultimately offering a comprehensive answer to the posed research question (Borglin, 2015; Skivington et al., 2021). Further details on the MRC framework, which was followed in this doctoral research project, is provided in chapter two.

1.7 The organisation of the thesis

This thesis describes a doctoral research project consisting of several complementary research studies undertaken to fulfil the development and feasibility phases of the framework for reaching the overall aims of this doctoral project.

Chapter one provided the background and rationale for the development and feasibility assessment of the doctoral intervention and an overview of the aims of this research. Chapter two is the methodology chapter, providing an overview of the research design and methods adopted to reach the aims of this doctoral research project. Chapter three, four and five report the work carried out to develop the smoking cessation intervention. Chapter three, a scoping review, maps out the literature on the smoking cessation interventions utilised amongst individuals with diabetes mellitus, and on the challenges, and barriers to smoking cessation that were identified amongst such individuals. This led to the identification of the smoking cessation methods which looked most promising for use amongst individuals with diabetes. These were examined in more detail, in terms of their effectiveness, in a systematic review, reported in chapter four. Apart from examining and comparing the effectiveness of the identified interventions, this systematic review also aimed to identify the components of the successful interventions for the development of a smoking cessation intervention for individuals with diabetes. Chapter five reports a study which was undertaken to help further develop the smoking cessation intervention based on the needs of individuals with diabetes. Chapter five describes a qualitative descriptive study which explored former and current smokers with diabetes' smoking cessation needs, and their views of the proposed intervention's characteristics.

Chapter six outlines the developed smoking cessation intervention (and the programme theory) for use amongst individuals with diabetes and a training programme which was offered to the diabetes nurse educators. Chapter seven details the development of the research tools that were used in the feasibility study and a pilot study undertaken to test and refine the methods of the feasibility study with a small sample of individuals with diabetes.

Chapter eight describes the work undertaken to evaluate the feasibility and acceptability of the multi-component smoking cessation intervention amongst the diabetes nurse educators, and the participants, the individuals with diabetes, and to assess its potential effectiveness in preparation for a future definitive trial. Chapter eight reports the findings of a randomised

feasibility trial which investigated the feasibility and acceptability of the intervention with a sample of adult smokers with diabetes, its potential effectiveness, and the findings from the nested qualitative descriptive study carried out with a sample of participants to explore their experience of the smoking cessation intervention. The main feasibility and acceptability elements included the recruitment rate, and study uptake, and the nurses' perceived challenges and facilitators to implementation, and the nurses' and participants' satisfaction with the smoking cessation intervention and the participants' perceived usefulness of the intervention provided.

Chapter nine is an overall discussion and conclusion of the doctoral research project. The main findings of the doctoral research project are outlined and discussed in the context of the research conducted prior to the development and feasibility assessment of the intervention and more recent studies. The strengths and limitations of this doctoral project are also discussed. Furthermore, recommendations for research, policy and practice are proposed.

1.8 Conclusion

Despite the short-term potential negative impact on diabetes management, the evidence presented in this chapter supports the position that quitting smoking provides clear benefits for those with diabetes, necessitating the provision of smoking cessation support as part of diabetes management. Nonetheless, current evidence-based practice was found to be inconclusive and limited in terms of its applicability for clinical practice, thus indicating the need for further research in this subject area. This led to the development and feasibility testing of a multi-component smoking cessation intervention for individuals with diabetes, which formed this doctoral research project. The following chapter is the methodology chapter, providing an overview of the research design and methods adopted to reach the overall aims of the Ph.D.

Chapter 2: Methods

2.1 Introduction

This chapter reports the overall study design of this doctoral research project. This research was guided by the Medical Research Council (MRC) framework for complex interventions (Skivington et al., 2021). The complementing philosophical framework of the doctoral research project is presented in section 2.2. The overall aims of the entire research project are restated in section 2.3, with the addition of the specific study objectives for the developmental and feasibility phases of the MRC framework. In section 2.4, a summary on the MRC framework is provided. The elements of research undertaken within the MRC development stage are then presented in section 2.5. These include a scoping review, a systematic review and a qualitative descriptive research study which included individuals living with diabetes. In section 2.6, the research from the feasibility phase of the MRC framework is then presented. This includes the randomised feasibility trial of the intervention and its pilot. Section 2.7 provides the timings of the various phases of the research process, while section 2.8 provides a conclusion to the chapter. Whilst this chapter provides an overview of the doctoral project's research methods, further detail about the individual studies' methods, their findings and the implications for the doctoral project are reported in the respective chapters.

2.2 The Philosophical framework of the doctoral research project

2.2.1 Philosophy in research

All research is founded in philosophy and hence researchers need to be aware of the philosophical assumptions they make to gain knowledge from their study (Creswell & Plano Clark, 2018). These set of assumptions, stemming from beliefs and values, which guide the researcher's inquiry, are also known as the research paradigm or worldview, the latter usually refers to when the researcher takes a more complex approach by considering all-encompassing perspectives of the experiences and thoughts about the world (Allemang et al., 2022; Creswell

& Plano Clark, 2018; Morgan, 2007). According to Creswell & Plano Clark (2018), while there are several philosophical paradigms or worldviews, they all include the following common elements:

- Ontology – The study of the nature of reality - What is considered real in the world?
- Epistemology – The study of knowledge and understanding - How do we gain knowledge of what we know?
- Axiology – The study of values in research - What is valuable or important in research?
- Methodology – The processes and principles to conduct research - What methods should be used to investigate the research question?
- And Rhetoric – The art of persuasive and effective communication - How do we effectively convey ideas or results?

As was stated in section 1.6, the use of pure quantitative or qualitative approaches are not recommended for complex intervention research whose focus is beyond investigating an intervention's effectiveness (Skivington et al., 2021). Hence, the use of mixed methods was recommended for answering the posed research question.

According to Creswell & Plano Clark (2018), there are four main worldviews for informing mixed methods research – post positivism, constructivism, transformism and pragmatism. While post positivism is typically associated with quantitative approaches, constructivism is often associated with qualitative approaches. On the other hand, transformism focuses on the need for social justice and human rights. In pragmatism, researchers use the best methods to investigate problems in real-world situations, allowing the use of various sources of data and knowledge to best answer their posed research question and objective (Allemang et al., 2022). The philosophy of pragmatism, which is most commonly associated with mixed methods research (Allemang et al., 2022; Borglin, 2015; Creswell & Plano Clark, 2018; Kaushik & Walsh, 2019; Morgan, 2007, 2014), guided this doctoral research project.

2.2.2 Pragmatism as the research paradigm for this doctoral research project

Pragmatism originates from the Greek word for 'action' (Morgan, 2014). The founding principle in the philosophy of pragmatism is that human action cannot be separated from the

individuals' experiences or the beliefs that have been shaped in such experiences (Kaushik & Walsh, 2019; Morgan, 2014). Hence, knowledge is linked to experience and individuals act based on perceived consequences (Allemang et al., 2022). The philosophy of pragmatism also implies that actions and the intended consequences cannot be separated from the situation or the context (Morgan, 2014). Actions and consequences are thus context-specific and hence no objective concept of truth can be assigned to specific actions (Morgan, 2014). If situations of the action change, their consequences would also change and hence there is no universal truth but unique experiences, consequences and beliefs that can take shape as individuals repeatedly take action in different situations (Kaushik & Walsh, 2019). While no two people will have an identical experience, pragmatists believe that researchers will identify some degree of shared experiences leading to different degrees of shared beliefs (Morgan, 2014). Hence, worldviews are both individually unique and also socially shared at a broader level (Morgan, 2014).

In view of this, pragmatism as a research paradigm does not focus on metaphysical concepts such as truth and reality, as it accepts that there are singular or multiple realities that need to be researched in specific circumstances (Creswell & Plano Clark, 2018; Kaushik & Walsh, 2019; Morgan, 2014). Thus, in terms of ontology, reality is dynamic and shaped by the users' experience, i.e., socially constructed (Creswell & Plano Clark, 2018; Morgan, 2014). With regards to epistemology, in pragmatism knowledge is not neutral, as it is based on experience (Borglin, 2015; Morgan, 2014). Hence, researchers need to value both objective and subjective knowledge (Borglin, 2015; Creswell & Plano Clark, 2018). Pragmatism also means that research has to take place in a context of value, investigating questions of importance for the greater good of the majority – axiology (Borglin, 2015). As regards to methodology, it is the research objective that governs the adoption of the methods of inquiry (Allemang et al., 2022; Creswell & Plano Clark, 2018). While pragmatism has been commonly associated with mixed methods research, it does not privilege one method over the another (Allemang et al., 2022; Morgan, 2014), however, it is understood that the adoption of different methods of inquiry are required to address the research problem in a comprehensive manner (Allemang et al., 2022; Creswell & Plano Clark, 2018). As regards to rhetoric, in pragmatism researchers use both formal and informal ways to communicate ideas and results (Allemang et al., 2022; Borglin, 2015). While being pragmatic does not require one to follow the philosophy of pragmatism, research based on pragmatism should be pragmatic, i.e. it should follow methods or approaches that can lead to the best evidence in view of the study's real-world problem to understand 'what works' (Borglin, 2015; Morgan, 2014).

In summary, pragmatism as a worldview emphasises the nature of the individuals' (participants) experiences and the outcomes of action, rather than the nature of reality or of truth. While individual beliefs are not disregarded, pragmatism as a research paradigm is more concerned in examining shared beliefs usually by adopting a mix of quantitative and qualitative methods, led by the study's research question and aim and objectives to identify what works within a specific situation.

2.3 Overall research aims and the specific objectives for the two phases of the research project

As was stated in section 1.6, the overall aims of this doctoral research project were to:

- Develop a smoking cessation intervention, based on evidence and theory, tailored for people with diabetes who smoke.
- Improve the design and delivery of the intervention using feedback from diabetes nurse educators and current smokers with diabetes.
- Evaluate the feasibility and acceptability of this intervention using feedback from diabetes nurse educators and current smokers with diabetes and assess its potential effectiveness.

The specific objectives (SO) for the developmental phase of this doctoral research project were to:

SO1 Review the literature to identify the most promising smoking cessation methods for persons living with diabetes, taking in consideration the barriers and challenges to quitting, and any gaps in evidence.

SO2 Review the literature which assessed the effectiveness of the identified promising smoking cessation methods (stand-alone smoking cessation interventions), identifying the critical features of the successful smoking cessation interventions.

SO3 Explore the views of individuals living with diabetes of the acceptability of the identified promising smoking cessation components and their needs to quit smoking.

SO4 Develop a tentative model of a smoking cessation intervention for individuals with diabetes in consultation with the doctoral research project's advisors and the diabetes practice nurses who were invited to deliver the intervention.

The specific objectives for the feasibility phase of this doctoral research project were to:

SO5 Train the diabetes practice nurses in delivering the smoking cessation intervention to ensure that the intervention is delivered as intended.

SO6 Test and refine the intervention, the feasibility study's recruitment and implementation processes, and the data collection methods amongst a small sample of individuals living with diabetes.

SO7 Assess the feasibility of the intervention for a future definitive trial, by analysing the recruitment and study uptake, and the nurses' perceived challenges and facilitators to implementation.

SO8 Investigate the acceptability of the intervention, by analysing the participants' and the providers' satisfaction with the smoking cessation intervention provided, and the participants' perceived usefulness of the intervention.

SO9 Compare the participants' satisfaction with and perceived usefulness of the smoking cessation intervention provided to standard care (i.e. optimal care, the best care possible; Köpke et al., 2015) – the provision of general smoking cessation support.

SO10 Determine the preliminary evidence of the intervention's effectiveness.

SO11 Undergo a preliminary process evaluation, by exploring the intervention's functioning and assessing whether the intervention was delivered as intended.

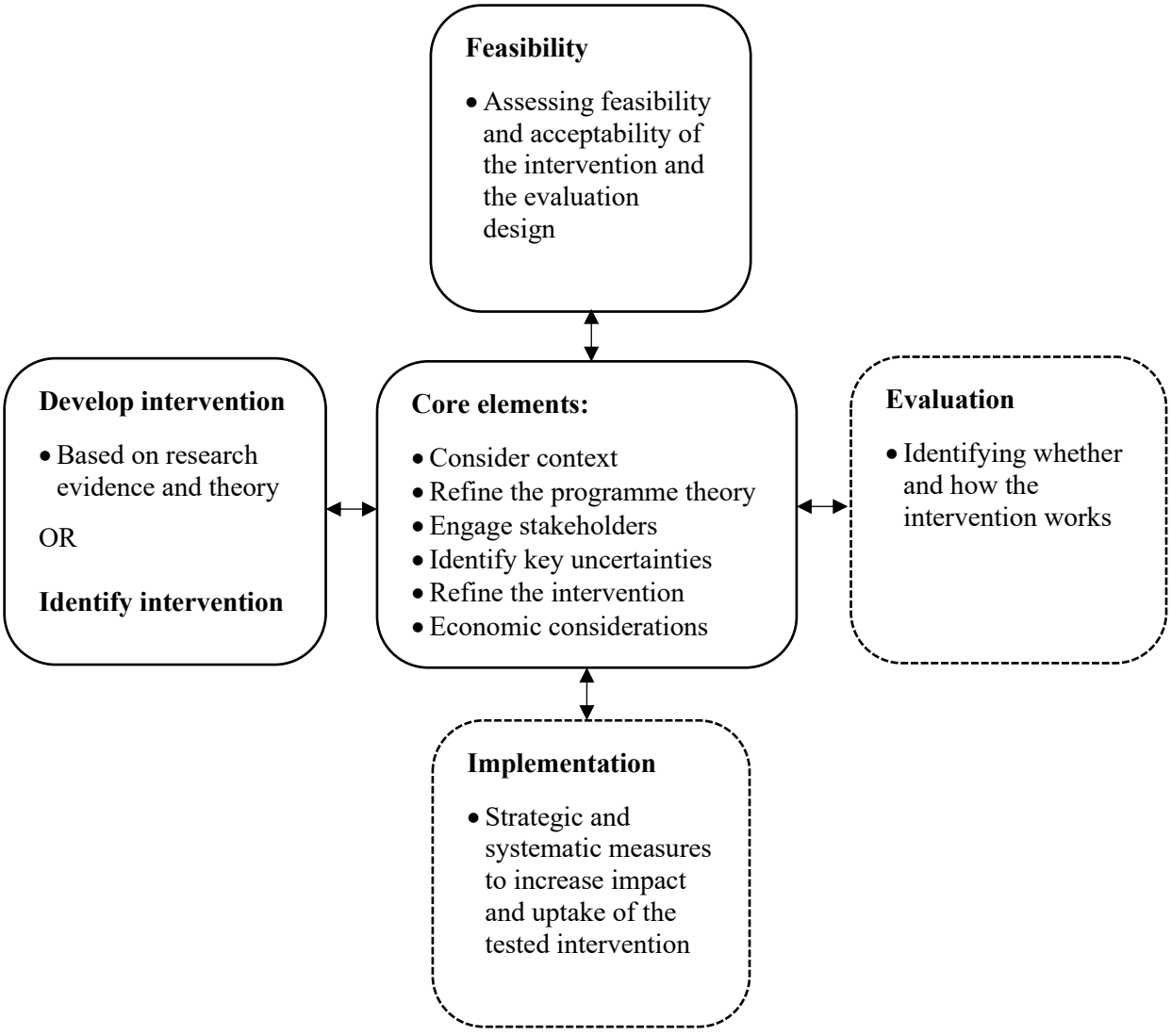
The elements of research undertaken within the MRC development and feasibility phases, based on the specific objectives (SO) of the doctoral research project, are outlined in figure 2.2, after an explanation of the MRC framework (section 2.4).

2.4 The MRC framework

As was remarked in section 1.6, the MRC framework – figure 2.1 (Skivington et al., 2021), was selected to guide the development and feasibility assessment of this multi-component

intervention. The MRC framework has been widely used in research on complex interventions; i.e. interventions that consist of interacting components, as it helps researchers to identify and address any key uncertainties throughout the four-stage process of the development, feasibility, evaluation and implementation of a complex intervention (Skivington et al., 2021).

Figure 2.1: The MRC framework (Skivington et al., 2021, pg. 4)



The developmental phase refers to the whole process in the design and planning of the complex intervention, starting from initial design of the research endeavour, the development or identification of an already established intervention, through to feasibility, pilot, or evaluation study (Skivington et al., 2021). In the developmental phase the researchers also construct a

model of their intervention, based on the identified evidence and theory of the problem (Richards, 2015a). The programme theory describes how the model works, i.e., how the intervention (its key components) is expected to work within a particular context (Skivington et al., 2021).

Following the development of a complex intervention, a feasibility study helps to reduce any key uncertainties prior to a thorough evaluation of the developed intervention (Richards, 2015a). The terms feasibility studies (research studies that aim to provide information on the study processes and/or design for compiling a plan for the future trial) and pilot studies (small replicas of the proposed study) tend to be used interchangeably in research, as they both aim to guide the development and conduct of a future definitive trial (Giangregorio & Thabane, 2015). In fact, Eldridge, Lancaster, et al. (2016) view feasibility as an overarching concept, that encompasses all type of studies which are conducted in preparation for a future definitive trial. These may include randomised and non-randomised pilot studies and feasibility studies that are not small-scale studies. A feasibility study may can be carried out to help reduce uncertainties that relate to the evaluation design of a complex intervention as outlined in the MRC framework. These may include uncertainties around potential challenges with recruitment and attrition, or issues with the intervention itself, e.g., uncertainties regarding content, delivery, acceptability and likelihood of its effectiveness (Giangregorio & Thabane, 2015; Skivington et al., 2021). Further work might be required before embarking on a full-scale evaluation.

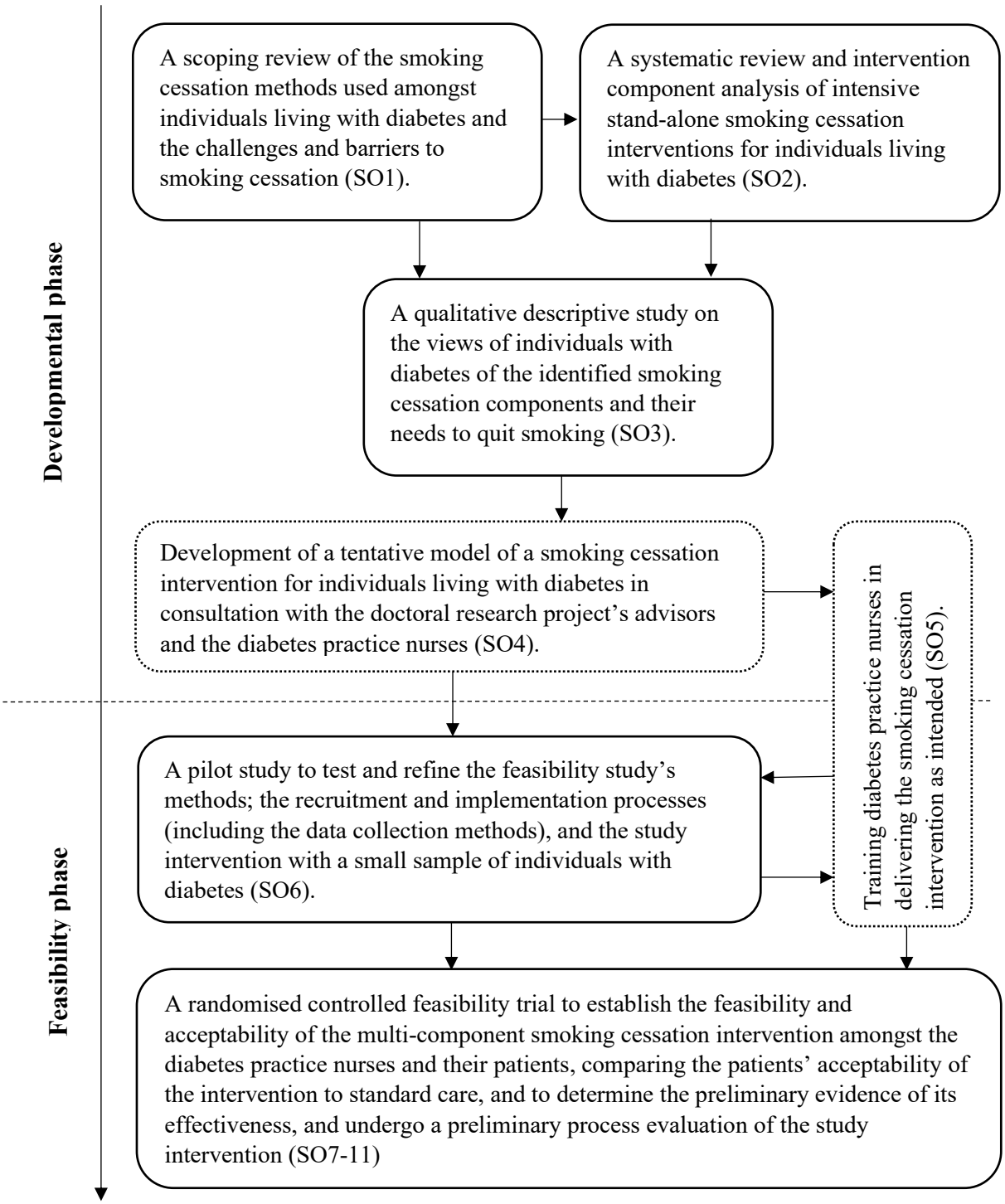
In the evaluation phase, researchers aim to establish causality, i.e. the link between the intervention and its expected effects (Richards, 2015a). Researchers are also expected to go beyond identifying whether an intervention works, to understanding and theorising how its components interact and work within the context in which it is implemented (Skivington et al., 2021).

Following evaluation, researchers are also expected to take a strategic and systematic approach to help ensure that the complex intervention is implemented in clinical practice (Richards, 2015a; Skivington et al., 2021). In the MRC framework, the implementation phase is considered as a distinct phase, however, it is recommended that implementation measures are considered throughout the phases of the intervention development, feasibility testing, and evaluation to increase the potential of having the intervention adopted and integrated in clinical practice (Skivington et al., 2021).

In addition to these four distinctive phases, the latest MRC guidelines also recommend the consideration of a set of core elements which look at efficacy, effectiveness, theory base, and systems throughout the research process (Skivington et al., 2021). Researchers should identify any key uncertainties throughout the process, consider the context in which the intervention is expected to be implemented, any economic considerations (a comparative analysis of an alternative course of action), engage with stakeholders (those individuals who are targeted by the intervention, such as patients and providers), develop and refine the programme theory and the intervention (Skivington et al., 2021).

According to Skivington et al. (2021) a research project can begin at any phase, depending on the key uncertainties about the intervention in question. Given the uncertainties as regards to evidence-based smoking cessation practice for individuals with diabetes (highlighted in section 1.4.3), this research project commenced at the developmental phase. Thus, this research was located within the first two phases of the framework: the development and feasibility phases, as outlined in figure 2.1. The elements of research undertaken within the MRC development and feasibility phases, based on the specific objectives (SO) of the doctoral research project, are outlined in figure 2.2 and presented in sections 2.5 and 2.6, respectively.

Figure 2.2: Elements of research undertaken within the MRC development and feasibility stages, based on the specific objectives (SO) of the doctoral research project



2.5 The MRC development stage (SO1-4)

According to Craig et al. (2008, 2013) the first step in developing a complex intervention is to evaluate current evidence by reviewing the literature for any similar interventions. Furthermore, by drawing on existing evidence and theory, researchers are to explore the likely process of change, looking at the changes that are expected and how these are to be achieved. This helps to model out the intervention's processes and outcomes providing important information about the design of both the intervention and the evaluation prior to full-scale evaluation (Craig et al., 2008, 2013). In the development phase, the following research was undertaken:

- A scoping review on the smoking cessation interventions that have been utilised amongst individuals with diabetes mellitus, and on the challenges, and barriers to smoking cessation that were identified amongst such individuals.
- A systematic review of effectiveness of the identified promising interventions from the scoping review; comparing the effectiveness of the identified interventions and identifying the components of the successful interventions.
- A qualitative descriptive study on the views of individuals with diabetes of the identified smoking cessation components and their needs to quit smoking.

2.5.1 The scoping review

As was outlined in section 1.4.3 and is further explained in section 3.2, the lack of robust recommendations for evidence-based practice called for a new, more comprehensive review of the literature. A scoping review of the literature was thus carried out to map the literature on smoking cessation interventions delivered to individuals living with diabetes, and on the challenges and barriers to smoking cessation that were identified amongst such individuals (SO1). This review thus helped to identify the most promising smoking cessation methods for this study population and provide research recommendations based on the identified gaps in evidence. This scoping review is presented in chapter three.

2.5.2 The systematic review

As is further explained in section 3.8, while the scoping review helped to identify the most promising smoking cessation interventions for tackling the identified diabetes-specific challenges and barriers to quitting, this review could not determine their effectiveness. These uncertainties necessitated the need to carry out a systematic review of the identified promising interventions with a component-level analysis of the successful interventions. Thus, a systematic review which assessed the effectiveness of the identified promising smoking cessation methods (stand-alone smoking cessation interventions) and identified the critical features of the successful interventions was conducted (SO2). This systematic review is presented in chapter four.

2.5.3 The qualitative descriptive study

To validate the reviews' findings, address the identified uncertainties and engage the most relevant stakeholders, the intended recipients of the proposed intervention, further research was conducted. A qualitative descriptive study was carried out to explore the views of individuals with diabetes of the identified promising smoking cessation components as well as their needs to quit smoking (SO3). This study is presented in chapter five.

This study was guided by the Information, Motivation and Behavioural skills (IMB) model for achieving and sustaining behaviour change (Fisher et al., 2006; Fisher et al., 2003). Apart from helping to understand the smoking cessation needs of individuals living with diabetes, this model has also been recommended for the development of behaviour change complex interventions (Abraham et al., 2015). Thus, following this study, a tentative model of a smoking cessation intervention for individuals with diabetes was developed in consultation with the doctoral research project's advisors (SO4). This was then presented to the proposed providers, the diabetes practice nurses who run the diabetes education clinics. Further details on the use of the IMB model are presented in section 5.3, while the proposed intervention is described in section 6.2.

2.6 The MRC feasibility stage (SO5-11)

Following the development of the intervention, and the training of the intervention providers, it was important to identify and address any problems which could affect the acceptability and delivery of the intervention (O'Cathain et al., 2015). Feasibility studies are required to determine whether an intervention is appropriate prior to further testing (Bowen et al., 2009). In the feasibility phase, researchers can identify potential obstacles that could prevent the trial from succeeding, such as low recruitment, high attrition, or poor adherence to the protocol (Giangregorio & Thabane, 2015), or significant problems with the intervention itself, which may necessitate the researchers to return to the development phase (Cathain et al., 2019). While a feasibility study may not necessarily be a randomised trial (Giangregorio & Thabane, 2015), a comparative analysis of an alternative course of action in terms of resources and outcomes helps to provide more information to make decisions about progressing to the next stage of the MRC framework, as part of the economic considerations (Skivington et al., 2021). Feasibility studies can use quantitative methods for analysing issues with recruitment and retention and the acceptability of the intervention, however, appropriate and well conducted qualitative research can make an additional contribution to the quantitative assessments, providing a better understanding of the intervention functioning on a small scale (O'Cathain et al., 2015).

In the feasibility phase of this doctoral research project, a randomised controlled feasibility study was undertaken; this was piloted beforehand. The pilot study was carried out to test and refine the intervention, the feasibility study processes, and the data collection methods. On the other hand, the feasibility study was carried out to: assess the feasibility and acceptability of the smoking cessation intervention amongst the diabetes nurse educators and their patients, comparing the patients' acceptability of the intervention to standard care; determine the potential effectiveness of the intervention; and undergo a preliminary process evaluation of the study intervention.

2.6.1 The pilot study

Initially a pilot study was carried out. The feasibility study was piloted with individuals with diabetes who smoke to test and refine the study processes, the intervention and the study methods prior to the main feasibility study. Furthermore, the pilot study was also carried out

to assess the reliability of the tools which were then used amongst the participants in the feasibility study (SO6).

After developing a training programme and training the diabetes practice nurses to deliver the proposed smoking cessation intervention (SO5; further outlined in chapter six), a small sample of individuals living with diabetes who smoked was purposively recruited to the study from the acute public hospitals in Malta and provided with the study intervention. Furthermore, the developed and translated questionnaires, were also assessed for their reliability (internal consistency). Feedback, to help refine the recruitment and implementation processes, including the design and delivery of the intervention, was also sought by asking the providers to keep an intervention log, audio-recording the provided sessions, and by conducting interviews with the nurses. Additional feedback was also sought from the study participants by conducting interviews. More details about the methods taken to fulfil the aims of the pilot study are presented in chapter seven.

2.6.2 The feasibility study

The randomised controlled feasibility study was carried out to:

- assess the feasibility of the intervention for a future definitive trial, by analysing the recruitment and study uptake, and the nurses' perceived challenges and facilitators to implementation (SO7);
- assess the acceptability of the intervention, by analysing the participants' and the nurses' satisfaction with the smoking cessation intervention provided, and the participants' perceived usefulness of the intervention (SO8), comparing the patients' acceptability of the intervention to standard care – the provision of general smoking cessation support by the National Health Service (SO9);
- determine the potential effectiveness of the intervention, by comparing the smoking cessation and reduction outcomes achieved in both groups (SO10).

Additionally, in the feasibility study a preliminary process evaluation was carried out, by exploring the intervention's functioning as experienced by the participants and by assessing whether the intervention was delivered as intended (SO11).

The feasibility study's methods followed closely those of its pilot study. Prior to carrying out the study, the study intervention and the recruitment and implementation processes were refined based on the pilot study's recommendations, while remedial training was given to the nurses. Participants (n=91) were randomly assigned to the intervention or control groups on a 1:1 basis. Quantitative measures of the intervention's feasibility, acceptability and potential effectiveness included the study's questionnaires, and the recruitment and intervention logs. Conversely, qualitative measures of the intervention's acceptability and the feasibility of implementing the intervention in practice (and for exploring the intervention's functioning) were explored through interviews. These were held with the nurses (n=2) and a purposive sample of patients (n=20), who were selected based on their participation experience. As was done in the pilot study, the nurses were asked to audio-record the sessions provided for assessing treatment fidelity. More details on the methods adopted in the randomised controlled feasibility study are provided in chapter eight.

2.7 The timings of this doctoral research project

The scoping review (followed by the systematic review), as part of the developmental phase, was initially carried out in August 2020. These were later updated in May 2022 and published. The qualitative descriptive research study followed, with the analysis being completed in August 2021. Following this study, the building of the intervention commenced. The initial study intervention was devised in February 2022. This was then discussed with the supervisors and the study advisors in the subsequent months. The feasibility phase, consisting of the randomised controlled feasibility study and its pilot, began in November 2022. Following analysis of the findings obtained from the pilot study, the main feasibility study commenced in August 2023. Data collection was concluded by October 2024 while analysis was concluded by December 2024.

Given that over the duration of the project, especially after the scoping and systematic reviews searches were conducted (May 2022), studies on smoking cessation interventions amongst individuals with diabetes and on their challenges and barriers to smoking cessation were published, any relevant literature was reviewed in the subsequent months. The identified literature is briefly presented in chapter nine to place the development and feasibility assessment of the intervention in the context of current research.

2.8 Conclusion

This chapter reported the overall study design of this doctoral research project, guided by the developmental and feasibility phases of the MRC framework for complex interventions (Skivington et al., 2021) and the philosophy of pragmatism. The overall aims of this doctoral research project and the specific objectives for the developmental and feasibility phases of the project were outlined. Furthermore, the elements of research undertaken were briefly described. In the next chapter, a scoping review of the literature on the smoking cessation methods utilised amongst individuals with diabetes mellitus, and on the challenges, and barriers to smoking cessation for such individuals is presented.

Chapter 3: Mapping the research on smoking cessation interventions in persons living with diabetes, and the faced challenges and barriers to cessation – a scoping review

3.1 Introduction

This chapter reports a scoping review that identifies the most promising smoking cessation methods for use amongst individuals with diabetes, as part of the developmental stage of this doctoral research project. This chapter presents the literature on the smoking cessation interventions utilised amongst individuals with diabetes mellitus, and on the challenges, and barriers to smoking cessation that were identified amongst such individuals. In the next section the rationale for opting for a scoping review to achieve the above aim is provided. The methodological framework followed is illustrated in section 3.3, while the research question posed for this review is presented in section 3.4. This chapter also includes a detailed section (section 3.5) on the methods followed in conducting this review. The results section (section 3.6) provides an overview of the selection process of the relevant studies, from which data was extracted, charted, and summarised in view of the posed research questions. The findings obtained are then discussed in section 3.7. Furthermore, in this section, the most promising interventions which can assist smokers with diabetes to quit are identified, taking into consideration the identified challenges and barriers in quitting and gaps in evidence. Section 3.8 outlines this review's implications for the doctoral research project/development of the smoking cessation intervention, while section 3.9 is a conclusion to this chapter.

3.2 A scoping review

As was remarked in sections 1.6 and 2.4, the first step of the developmental phase of a complex intervention is to identify the available evidence. This is usually done by carrying out a systematic review of the literature (Craig et al., 2008, 2013; Skivington et al., 2021), unless a systematic review is already available and of relevance to the undertaken research (Petticrew & Roberts, 2006). Two systematic reviews and meta-analyses on smoking cessation

interventions amongst individuals with diabetes (Nagrebetsky et al., 2014; Zhan et al., 2016) were identified, however as reported in section 1.4, these were of limited value to this project and to clinical practice due to the substantial heterogeneity in the meta-analyses and the lack of robust recommendations. Given these limitations, a new, more comprehensive review of the literature was recommended (Petticrew & Roberts, 2006). In line with the philosophy of pragmatism, a scoping review provides more flexibility than a traditional systematic review, bridging quantitative and qualitative research by drawing on multiple evidence sources, based on the research problem (Peters et al., 2015; Peterson et al., 2017). A scoping review takes a wider approach to a research problem, mapping out and appraising existing relevant literature, exploring and describing concepts and research gaps providing evidence-based recommendations (Munn et al., 2018; Peters et al., 2020; Petticrew & Roberts, 2006). Scoping reviews are also carried out to provide a wider overview of the research previously undertaken to identify the area for a future systematic review or other types of evidence synthesis (Peters et al., 2020). Thus, a scoping review which aimed to map out the existing literature on this subject matter, i.e. the range of smoking cessation interventions that have been utilised amongst individuals with diabetes (including those that are part of a wider diabetes management intervention) whilst taking note of the challenges and barriers to quitting, and research gaps in this area, was undertaken. This helped to identify the most promising smoking cessation interventions for tackling the identified diabetes-specific challenges and barriers to quitting, thus leading to further exploration with a focused research question based on evidence, for identifying the required evidence-based interventions.

3.3 The methodological framework

To map out all relevant literature (and information), to provide unbiased reproducible results, a scoping review requires a robust structured framework which will guide the researcher in the process (Sucharew & Macaluso, 2019). Arksey & O'Malley (2005)'s framework, which mainly consists of five stages: identification of the research question; identification of relevant studies; selection of studies; charting of data; and collation, and summarising and reporting of results, has been widely utilised in planning scoping reviews and was followed in the carrying out of this scoping review.

Before the undertaking of a scoping review, the writing of a study protocol is also recommended (Khalil et al., 2016; Peters et al., 2015; Peters et al., 2020; Sucharew & Macaluso, 2019; Tricco et al., 2018). A study protocol provides the plan for a scoping review, providing guidance for this systematic piece of work (Peters et al., 2020). Before carrying out this scoping review, a draft protocol was devised. This was reviewed by the researcher's supervisors, updated and finalised. The study protocol is included in Appendix 3.1.

3.4 Identification of the research question

Scoping reviews typically use the PCC (population, concept, context) framework to develop the research question (Munn et al., 2018; Peters, 2016; Peters et al., 2020; Tricco et al., 2018). In this review, the population included individuals living with diabetes mellitus, concept referred to smoking cessation, and context implied any geographical locations and/or health care setting. The main research question for this scoping review therefore was:

Which smoking cessation interventions are most promising in helping smokers with diabetes quit?

The following secondary research questions were identified:

What type of smoking cessation interventions have been used amongst individuals with diabetes?

What challenges and barriers to smoking cessation were identified amongst individuals with diabetes?

What are the gaps in evidence?

3.5 Methods

Following the identification of the scoping review's objective and research question, inclusion and exclusion criteria were formulated. Furthermore, the methods taken to search, select, extract, and chart the data were devised.

3.5.1 Inclusion and exclusion criteria

The established inclusion and exclusion criteria based on the PCC framework are outlined in Table 3.1.

Table 3.1: Scoping review - inclusion and exclusion criteria

PCC framework	Inclusion criteria	Exclusion criteria
Population	Individuals diagnosed with diabetes mellitus who smoke tobacco.	Individuals diagnosed with pre-diabetes. Studies in which only a proportion of the patients had diabetes.
Concept	Studies which assess the effect of smoking cessation interventions on achieving smoking abstinence and/or identify the challenges and barriers to smoking cessation.	Studies which focus exclusively on cessation and/or the challenges and barriers to smoking cessation of smokeless tobacco products, such as chewing tobacco.
Context	Any context (any geographical locations and health care settings).	No limiter
Type of studies	All types of research studies and reviews of the literature which report findings on the above concept amongst the specified population.	Opinion articles.

3.5.1.1 Population

As shown in Table 3.1, the studies included had to be specific to individuals diagnosed with diabetes mellitus. While this helped to ensure that the study was adequately represented, it also helped to ensure that the approach taken to design/deliver the smoking cessation intervention and/or explore any challenges and barriers in quitting, factored in the specific needs and characteristics of this population, to identify the most promising smoking cessation interventions for these individuals. Studies in which only a proportion had diabetes or reports on analysis of data (of individuals with diabetes) from studies which were not specific to individuals with diabetes were thus deemed ineligible.

3.5.1.2 Concept

Studies which evaluated smoking cessation interventions in terms of the effect on smoking cessation were included. Smoking cessation interventions which were part of a broader diabetes management intervention were also included. Papers which focused on the challenges

and barriers to smoking cessation, were also included. Studies which focused exclusively on the cessation and/or the challenges and barriers to cessation of smokeless tobacco products, such as chewing tobacco, were deemed ineligible as these were not in line with the project's aim.

3.5.1.3 Context

No restrictions were set for the context of studies identified.

3.5.1.4 Type of studies

All types of primary and secondary research studies, including unpublished studies (grey literature), such as conference proceedings, were included. Both quantitative and qualitative studies were included as both types of studies could provide relevant information to answer the set research questions. Opinion articles, being not based on research, were excluded.

3.5.2 Search strategy

The overall search strategy was drafted by the author and reviewed by his supervisors.

3.5.2.1 Search methods

A selection of appropriate databases was used to maximise the yield of relevant studies. Grey literature databases were also included. The search methods outlining the selected databases and their respective interfaces, and search dates are displayed in table 3.2. The search was run first in August 2020 and updated on the 28th of May 2022.

Table 3.2: Search methods

Database name	Interface	Year range	Date searched
CINAHL Complete, Cochrane Central Register of Controlled Trials, Cochrane Clinical Answers, Cochrane Database of Systematic Reviews, Cochrane Methodology Register, MEDLINE Complete, APA PsycInfo	EBSCOhost	From inception	28/05/2022
ProQuest Dissertations & Theses A&I	ProQuest	From inception	28/05/2022
Public Health Database	ProQuest	From inception	28/05/2022
PubMed	U.S. National Library of Medicine (NLM)	From inception	28/05/2022
Scopus	Elsevier	From inception	28/05/2022
System for Information on Grey Literature in Europe (OpenGrey)	Exalead	From inception	28/05/2022
Web of Science (All Databases)	Web of Science	From inception	28/05/2022

3.5.2.2 Search tools

The keywords used in this scoping review included the main terms from the PCC framework together with other identified relevant keywords and synonyms obtained by using the MeSH browser and an English language thesaurus. The list of the keywords and synonyms searched by means of the words with wildcards are illustrated in table 3.3 below.

Table 3.3: Keywords and synonyms used

Elements of the PCC framework		Key terms	Other keywords and synonyms	Words with wildcards
Population	Individuals who have diabetes mellitus	diabetes mellitus	diabetic, diabetes mellitus DM, type 1 diabetes T1DM (insulin dependent diabetes mellitus IDDM), type 2 diabetes T2DM (non-insulin dependent diabetes mellitus NIDDM)	diabet*, DM, T1DM, T2DM
Concept	Smoking cessation	smoking	smoke/s, smoked, smoking, tobacco use, use of tobacco	smok*, tobacco
		cessation	smoking cessation, tobacco cessation, tobacco use cessation products, tobacco use cessation devices, quit, stop, avoid, avoidance, refrain, cessation, abstinent, abstain, give up, gave up, cease, discontinue, discontinued, discontinuation, terminate, terminated, termination, break off, broke off, put an end to	quit*, stop*, avoid* refrain*, cessation, abst*, "give up", "gave up", cease*, discontinu*, termin*, "break off", "broke off"
Context	Any context	NA	NA	NA
Type of studies	Research studies and reviews	NA	NA	NA

The selected words (with wildcards) were searched in the databases outlined in table 3.2. These were combined by using Boolean operators 'AND' and 'OR', and searched in titles ('ti'), abstracts ('ab'), and subject headings ('su', 'MeSH terms', 'key', AK) accordingly. Furthermore, where available, proximity searching ('N5', 'NEAR/5', and 'W/5') was carried out for searching two or more words within a range of five words from each other (e.g. quit* N5 smok*), thus narrowing the number of hits. Expanders (apply equivalent subjects & apply related words) was also used when using the EBSCOhost, while the limiter 'limit to human' was used to narrow down the results in the Public Health Database. No language restrictions or time limiters were applied. The minimum requirement for non-English papers was that the title and/or abstract had to be translated into English in the bibliographic database. The search strategy adopted for searching in the EBSCOhost interface is outlined in table 3.4, while the search strategies adopted for the remaining interfaces (as listed in table 3.2) are outlined in Appendix 3.2.

Table 3.4: EBSCOhost search strategy

Search strings	Search terms	Search options	Hits
S1	SU "smoking cessation" OR SU "tobacco cessation" OR SU "tobacco use cessation"	Expanders - apply equivalent subjects & apply related words	84,832
S2	SU "diabetes mellitus"	Expanders - apply equivalent subjects & apply related words	649,125
S3	S1 AND S2		1,441
S4	TI (diabet* OR DM OR T1DM OR T2DM) OR AB (diabet* OR DM OR T1DM OR T2DM)	Expanders - apply equivalent subjects & apply related words	375,736
S5	TI (smok* OR tobacco) OR AB (smok* OR tobacco)	Expanders - apply equivalent subjects & apply related words	601,789
S6	TI (quit* OR stop* OR avoid* OR refrain* OR cessation OR abst* OR "give up" OR "gave up" OR cease* OR discontinu* OR termin* OR "break off" OR "broke off" OR "put an end to") OR AB (quit* OR stop* OR avoid* OR refrain* OR cessation OR abst* OR "give up" OR "gave up" OR cease* OR discontinu* OR termin* OR "break off" OR "broke off" OR "put an end to")	Expanders - apply equivalent subjects & apply related words	5,128,671
S7	S6 N5 S5		104,998
S8	S4 AND S7		1,567
S9	S3 OR S8		2,173

3.5.3 Screening

Following the execution of the search strategy, the identified records were collated in a reference manager (Mendeley) for de-duplication. The remaining records were screened by reading titles and abstracts. The retained articles were then assessed for eligibility for inclusion basing decisions on the inclusion and exclusion criteria, which reflected the main research question, listed in table 3.1. On the identification of the studies which were included in this review, the reference lists of these studies were examined for the identification of other possible relevant studies. These were also included in the review.

3.5.4 Data extraction and charting

A data extraction form was developed to capture the required information from the eligible articles and present the data in table form. This was devised by the author and reviewed by the author's supervisors. The information extracted from the studies included: the study's author/s and year of publication; study design; origin of study (country); the method, including details on the smoking cessation intervention, if applicable (characteristics of the intervention and comparator, provider/s, study setting, and follow-up period); the sample characteristics (sample size, type of diabetes, gender, and age); and relevant findings (response at follow-up, smoking cessation outcome and/or the identified challenges and barriers to smoking cessation).

3.5.5 Synthesis of results

Once data was extracted and charted, a narrative approach to report the results followed. The aim was to map out the relevant studies' details to answer the set secondary research questions, while identifying limitations and research gaps.

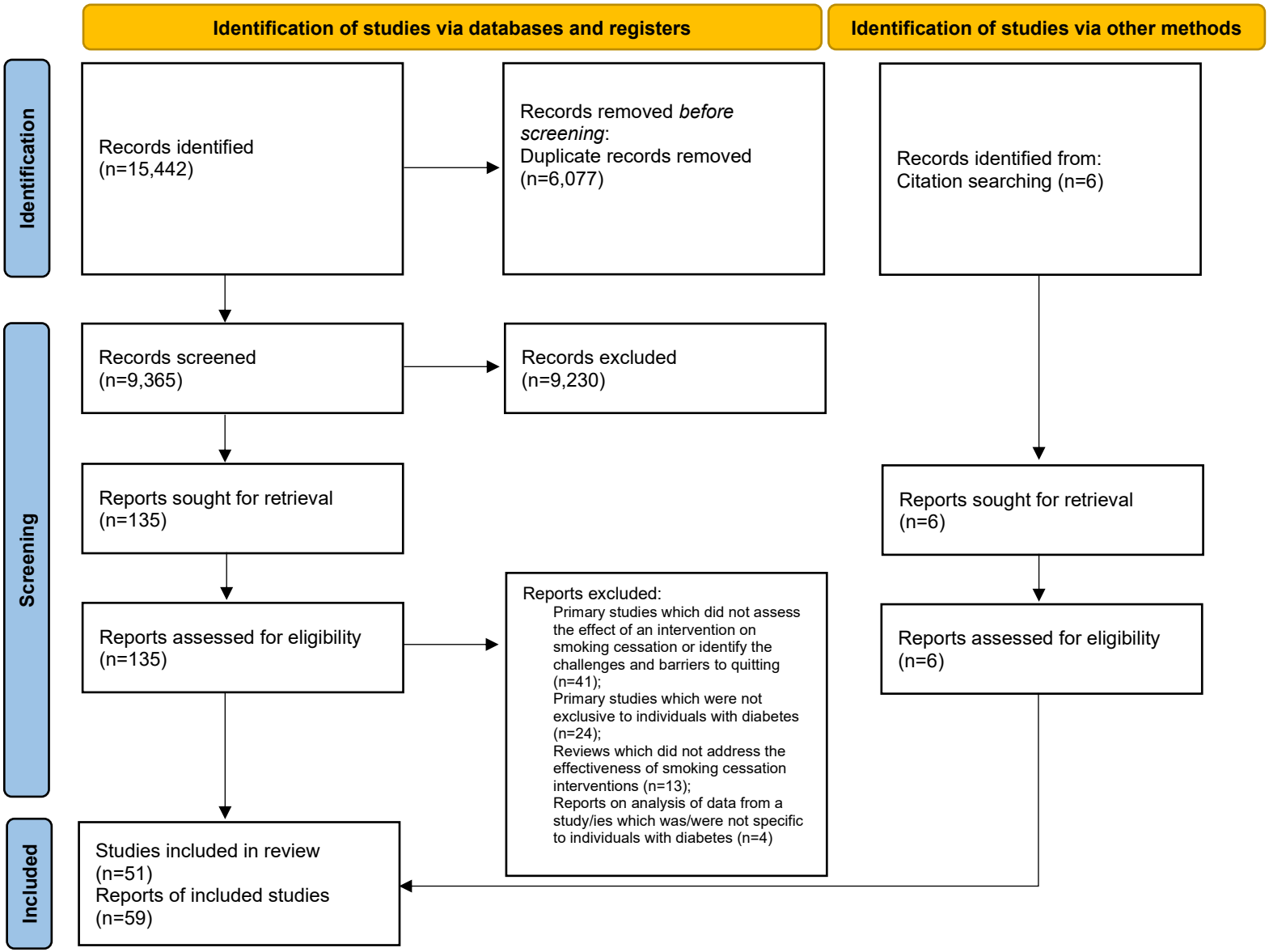
3.6 Results

3.6.1 Selection of sources of evidence

The Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) 2020 flow diagram (Page et al., 2021) was utilised to outline the selection process, providing details on the exclusion reasons at the full-text level of screening (figure 3.1). The number of records identified amounted to 15,442 of which 6,007 were duplicates. After removing duplicates, the remaining records (n=9,365) were screened for relevance by reading titles and abstracts. One hundred and thirty-five reports were found to be possibly relevant and eligible for full-text screening. On matching these publications to the inclusion criteria, 82 reports were found to be ineligible. These studies (listed in Appendix 3.3) were excluded as they did not assess the effect of an intervention on smoking cessation or identify the challenges and barriers to quitting or were not specific to individuals with diabetes. Conversely, 53 reports were deemed eligible to the review. In addition to these reports, an additional six reports, which were obtained from citation searching, were also included. This led to a total number of 59 reports being identified.

Some of the identified reports referred to the same study. Both Rubak et al. (2009) and Rubak et al. (2011) reported findings from the ADDITION study, while Albaroodi et al. (2018) and Albaroodi et al. (2021) reported findings from the same randomised control trial. Lam et al. (2017) and Thankappan (2013a) reported the findings from the randomised control trials by Li et al. (2017) and Thankappan (2013b), in a conference proceeding and abstract, respectively, Thankappan et al., (2014) and Nichter, Mini, & Thankappan (2017) followed up participants from Thankappan et al. (2013b)'s trial for a total of one and two years, respectively. Mini et al. (2015) reported the cotinine measurements from the study by Thankappan et al. (2013b) in a separate publication. Similarly, in the publication by Khunti et al.'s (2012) study, the participants who had been enrolled in Davies et al.'s (2008) trial were followed up for an additional two years. Thus, a total number of 51 studies were identified.

Figure 3.1: Scoping review – PRISMA flow diagram



3.6.2 General characteristics of the identified studies

The general characteristics and the relevant findings of the identified publications are outlined in tables 3.5, 3.6 and 3.7. Most of the identified papers reported randomised control trials (n=29). Studies were frequently conducted in the United Kingdom (n=7), or the United States (n=7). Most reports (n=25) focused on individuals with type 2 diabetes, who were mostly men (n=39), in their 50s (n=25).

Most reports evaluated a smoking cessation intervention/s which was provided on its own (n=25; table 3.5), or which was part of a broader intervention for improving diabetes management (n=20; table 3.6). The reviews by Daly et al. (2017), Ekong & Kavookjian (2016), Zhan et al. (2016), and Tricco et al. (2012) included both types of studies (included in table 3.6). Typically, the provided diabetes-specific smoking cessation support consisted of behavioural support, such as counselling, commonly based on the 5As (and 5Rs) algorithm, or motivational interviewing, or were education-based. Pharmacotherapy for smoking cessation was also provided/recommended in some of the identified studies. The identified interventions were mostly delivered by nurses, or doctors, at general practices/primary care settings or at diabetic clinics. Further details on the studies' interventions are outlined in sections 3.6.3 and 3.6.4, respectively.

In some of the identified studies, the authors aimed to identify or explore the barriers and challenges to smoking cessation for individuals with diabetes (table 3.7). Abu Ghazaleh et al. (2018), Chau et al. (2015), Georges et al. (2019), Haire-Joshu et al. (1994), Mishu et al. (2021), Wakefield et al. (1997, 1998) explored the perceived or the experienced challenges and barriers to smoking cessation for individuals with diabetes, whilst Albaroodi et al. (2018), Ardron et al. (1988), and Bodmer et al. (1990) specifically explored the challenges and barriers which were experienced by individuals with diabetes who attended a smoking cessation intervention. Javelot et al. (2009) and Kristensen et al. (2008) reported the side-effects experienced by individuals with diabetes who utilised pharmacotherapy to quit smoking. More details on these studies are available in section 3.6.5.

The key findings drawn from all the identified studies are provided in the sub-sections below. The next sub-section (3.6.3) provides information on the interventions' characteristics and the relevant findings of the studies whose intervention focused on smoking cessation. This is then followed by a similar sub-section (3.6.4) on the studies whose intervention was part of a broader intervention for diabetes management (including the reviews by Daly et al., 2017;

Ekong & Kavookjian, 2016; Zhan et al., 2016; Register et al., 2016; Tricco et al., 2012). The final sub-section (3.6.5) presents more information on the methods and reports on the findings of the studies who identified barriers and challenges to smoking cessation for individuals with diabetes.

3.6.3 Interventions' characteristics and relevant findings of the studies whose intervention was focused on smoking cessation

This section reports on the characteristics of the smoking cessation interventions and the relevant findings of the studies whose intervention was focused on smoking cessation. The characteristics of the identified studies and the relevant findings are listed in table 3.5 below.

Table 3.5: Characteristics and relevant findings of the studies whose intervention was focused on smoking cessation

Author/s (date)	Country	Study design	Intervention's main characteristic/s	Control's main characteristic/s (if any)	Study setting; Provider	Sample characteristics,[a]	Follow-up period, months	Percentage followed up, %	Biochemically verified smoking cessation outcome at follow-up		Other key findings/ comments
									Intervention group, n (%)	Control group, n (%)	
Albareda et al. (2009)	Spain	Prospective cohort study (PCS)	American Diabetes Association recommendations Tailored to the participants' stage of change Smoking cessation programme Nicotine replacement therapy (NRT) accordingly.		Physicians' diabetes care offices; Health professionals	n=156: T1DM=54, T2DM=99, and other=3; mean age 62.5 years (SD 15.9); 49.9% male participants	12	90.4	65 (46.1)*		19 participated in the programme Use of NRT not reported
Albaroodi et al. (2021)	Malaysia	Randomised controlled trial (RCT)	Counselling based on the 5As algorithm (Ask, Advise, Assess, Assist, Arrange)	Routine care	Out-patient diabetes clinic; Physicians and nurses	n=140: T1DM=13, T2DM=35, and unknown=78; mean age - 47.6 years (SD 13.6); 95.2% male participants	6	90	4	4	Preprint - not peer reviewed
Ardron et al. (1988)	United Kingdom	RCT	Brief advice Counselling	Brief advice	Diabetes clinic; Doctor and diabetes health visitor	n=60: T1DM=50, and T2DM=10; mean age - 29.1 years (SD 7.4); 48.3% male participants	6	100	0	1	
Bodmer et al. (1990)	United Kingdom	PCS	Brief advice		Diabetes clinic	n=43: T1DM=6, and T2DM=37; mean age - 53 years; 58.1% male participants	3	84.2	6		
Canga et al. (2000)	Spain	RCT	Counselling (consideration of participants' stage of change and readiness to quit) NRT accordingly	Usual care	Primary care centres and hospitals; Nurse	n=280: T1DM=85, and T2DM=195; mean age - 55 years (SD 15.0); 86.0% male participants	6	99.3	25 (17.0)	3 (2.3)	25/105 accepted NRT but only 10 completed it Smoking cessation outcome of those who took NRT is not reported

Author/s (date)	Country	Study design	Intervention's main characteristic/s	Control's main characteristic/s (if any)	Study setting; Provider	Sample characteristics,[a]	Follow-up period, months	Percentage followed up, %	Biochemically verified smoking cessation outcome at follow-up		Other key findings/ comments
									Intervention group, n (%)	Control group, n (%)	
Fowler et al. (1989)	Australia	RCT	Educational sessions using coloured photographs	Usual care	Diabetes clinics	n=34: T1DM=12, and T2DM=22; mean age of newly diagnosed patients - 47 years (SD 9.0) and those with pre-existing diabetes - 53 years (SD 13.0)	6	100			Three quit smoking Drop-outs from the programme were very high
Hokanson et al. (2006)	United States	RCT	Counselling based on motivational interviewing (MI), stage of change (readiness to quit) NRT or bupropion accordingly	Information about cessation programmes	Diabetes centre; Nurses	n=114 (T2DM); mean age - 54 years (SD 9.0); 57.0% male participants	6	63.2	4 (7.0)	2 (3.5)	Similar numbers in both groups utilised pharmacotherapy
Ismail et al. (2000)	United Kingdom	PCS	Brief advice		Diabetes centre; Doctor and nurse	n=93: T1DM=74, and T2DM=19; mean age - 30; 59.0% male participants	24	100	3		
Katsaounou et al. (2019)	Greece	Pre-experimental study: one group, pre- and post-intervention (PES)	Smoking cessation programme Varenicline		Not reported; A respiratory physician, endocrinologist, dietitian and behavioural psychologist	n=17 (T2DM); mean age - 57.6 years; 85.0% male participants	3	100	12 (70.5)		
Korkontzelou et al. (2020)	Greece	PES	Smoking cessation programme Varenicline		Not reported; Multidisciplinary team	n=41 (T1DM AND T2DM); mean age - 59; 65.9% male participants	3	100	25 (61)		
Lam et al. /Li et al. (2017)	China	RCT	Counselling based on the 5As algorithm (matched to the participants' stage of change)	Usual care	Diabetes clinics; Nurse counsellor	n=557 (T2DM); mean age - 56 years (SD 11.4); 88.3% male participants	12	79.1	9 (3.2)	14 (5.1)	

Author/s (date)	Country	Study design	Intervention's main characteristic/s	Control's main characteristic/s (if any)	Study setting; Provider	Sample characteristics,[a]	Follow-up period, months	Percentage followed up, %	Biochemically verified smoking cessation outcome at follow-up		Other key findings/ comments
									Intervention group, n (%)	Control group, n (%)	
Nagrebetsky et al. (2014)	Various	Systematic review and meta-analysis	Pharmacological or nonpharmacological intensive interventions	Less intensive interventions	Primary, secondary and tertiary care	n=872 (T1DM and T2DM)	6				Relative risk: 1.32, 95% CI [0.23-7.43]; four trials Substantial heterogeneity between studies (I2=76%, p=0.006)
Ng et al. (2010)	Indonesia	Pilot RCT	Counselling session based on the 5As (and 5Rs) algorithm Control intervention	Brief advice using visuals of smoking associated diabetic complications	Diabetic clinics in hospitals and smoking cessation clinic; Doctor and counsellor	n=71 (T2DM); mean age - 56 years (SD 9.0); 100% male participants	6	78.9	14 (36.8)*	10 (30.3)*	A significant decrease in smoking prevalence in both groups $p<0.001$
Perez-Tortosa et al. (2015)	Spain	Cluster RCT	Counselling based on MI (and participants' stage of change) Pharmacotherapy	Usual care	Primary care practices; General practitioners and nurses	n=948 (T1DM and T2DM); mean age - 59.7 years (SD 11.3); 75.7% male participants	12	76.2	90 (26.1)	67 (17.8)	Use of pharmacological treatment not reported
Persson and Hjalmarson (2006)	Sweden	Cluster non-randomised control trial	Smoking cessation programme (group-based) based on MI Pharmacotherapy recommended	Letter	Primary health centres; Nurses	n=368 (T2DM); mean age - 59.4-60.6 years; 57.0% male participants	12	95.4	42 (20)*	10 (7)*	29 participants from the intervention group used pharmacotherapy but use was not significant 50/241 (21%) accepted to participate in the smoking cessation programme
Persson et al. (2000)	Sweden	PES	Smoking cessation programme (group-based) NRT		Primary health care; Nurses	n=14; ages - 30-75 years; 42.9% male participants	18		9 (64)*		Use of NRT not reported

Author/s (date)	Country	Study design	Intervention's main characteristic/s	Control's main characteristic/s (if any)	Study setting; Provider	Sample characteristics,[a]	Follow-up period, months	Percentage followed up, %	Biochemically verified smoking cessation outcome at follow-up		Other key findings/ comments
									Intervention group, n (%)	Control group, n (%)	
Sawicki et al. (1993)	Germany	RCT	Smoking cessation behavioural therapy programme NRT accordingly	Brief advice NRT accordingly	Diabetes clinic; Psychotherapist	n=89: T1DM=72 and T2DM=17; mean age - 38 years (SD 12.0); 61% male participants	6	100	2	7	57% participated to the programme
Scemama et al. (2006)	France	PES	Counselling NRT prescription		Diabetes unit (in patient); Physician	n=38: T1DM=18, and T2DM=20; mean age - 42.5 (SD 14.5); 73.7% male participants	9	7	1*		16 (45.7%) agreed to take NRT Very high attrition rate
Thankappan et al. (2013a,b) (2014) Mini et al. (2015) Nicther et al. (2017)	India	Pilot RCT with follow-up studies	Counselling based on the 5As (and 5Rs) algorithm Control intervention	Brief advice using visuals of smoking associated diabetic complications	Diabetic clinics; Doctor and counsellor	n=224; mean age - 53 years; 100% male participants	6-24	87.5	58 (51.8)*	14 (12.5)*	Adjusted Odds Ratio: 3.35; 95% CI [1.82–6.18] at 12 months (self-reported confirmed in 86%) Five were abstinent at 24 months
Tien and Tu (2016)	Taiwan	Cross-sectional study	Counselling based on the 5As algorithm		Health centre	n=73	6		26(35.6)		

a: Type one diabetes – T1DM, Type two diabetes – T2DM;. *self-reported data. SD – standard deviation, CI – confidence interval

3.6.3.1 Characteristics of the smoking cessation interventions

Most studies adopted a one-to-one approach for smoking cessation. While in all studies the smoking cessation intervention was provided face to face, in four studies (Albareda et al., 2009; Canga et al., 2000; Hokanson et al., 2006; Persson & Hjalmarson, 2006) telephone counselling follow-up sessions were also provided.

The complexity and intensity of the smoking cessation interventions varied, with most consisting of various components in terms of the smoking cessation support provided and/or being more intense (session/s of longer duration and/or consisting of follow-up appointments), with or without the provision of pharmacotherapy for smoking cessation (e.g. Nicotine Replacement Therapy NRT, bupropion or varenicline). For example, in Thankappan et al.'s (2013b) study the participants in the intervention group were provided with a smoking cessation intervention consisting of four components (brief smoking cessation advice, portrayal of visual messages of smoking related diabetic complications, educational material on the harm of tobacco on diabetes, and counselling sessions based on the 5As algorithm). Furthermore, the intervention was also more intensive than brief advice as three additional counselling sessions (30 minutes each) were provided during the study.

In all studies except two (Bodmer et al., 1990; Ismail et al., 2000), in which the researchers only provided brief advice on smoking cessation and informational material, the researchers provided more intensive behavioural support as part of the smoking cessation intervention. Albaroodi et al., (2021), Li et al. (2017), Ng et al. (2010), Thankappan et al. (2013b) and Tien and Tu (2016) provided behavioural support based on the 5As algorithm, while in the studies by Hokanson et al. (2006), Pérez-Tortosa et al. (2015) and Persson and Hjalmarson (2006) the behavioural support sessions were based on motivational interviewing. Albareda et al., (2009), Canga et al. (2000), Hokanson et al. (2006), Li et al. (2017) and Pérez-Tortosa et al. (2015) also designed their intervention on the stages of change model (Trans-theoretical model of change) and/or on the participants' readiness to change. Generally, smokers who were in the pre-contemplation were advised and encouraged to quit smoking, while more intensive behavioural support was provided to those who were in the contemplation or preparation stage of change. NRT, buproprion, or varenicline were provided to some participants in ten studies (Albareda et al., 2009; Canga et al., 2000; Hokanson et al., 2006; Katsaounou et al., 2019; Korkontzelou et al., 2020; Pérez-Tortosa et al., 2015; Persson et al., 2000; Sawicki et al., 1993) depending on the set eligibility criteria. In Scemama et al.'s (2006) study, participants were

provided with a prescription for NRT, while use of NRT was recommended in Persson & Hjalmarson's (2006) study.

Various researchers also provided participants with informational material, such as leaflets (Albareda et al., 2009; Ardron et al., 1988; Bodmer et al., 1990; Ismail et al., 2000; Li et al., 2017; Ng et al., 2010; Thankappan et al., 2013b). In three studies, the researchers also included visual aids of diabetic related complications to motivate participants to quit (Fowler et al., 1989; Ng et al., 2010; Thankappan et al., 2013b). While follow-up varied, generally it was for one year or less. Generally, smoking abstinence was biochemically verified; by measuring cotinine (a derivative of nicotine following tobacco use) in blood, saliva or urine, and/or by measuring carbon monoxide (a by-product of tobacco combustion). However, in some studies the findings were only based on self-reported data (Albareda et al., 2009; Ng et al., 2010; Nichter et al., 2017; Scemama et al., 2006; Thankappan et al., 2013b, 2014; Tien & Tu, 2016).

Besides these studies, Nagrebetsky et al. (2014) compared various intensive interventions to usual care/less intensive interventions in a systematic review and meta-analysis.

3.6.3.2 Relevant findings

Despite observing commonalities amongst the studied interventions, such as the use of counselling, the effect on smoking cessation was found to vary across the identified studies. The efficacy of specific behavioural support approaches, such as the 5As (and 5Rs) algorithm, or motivational interviewing, and the tailoring of the study intervention according to the participants' stage of change, is not clear. While Albareda et al. (2009), Canga et al. (2000), and Pérez-Tortosa et al. (2015), whose interventions took into consideration the participants' stages of change, identified a significant improvement in smoking abstinence, Hokanson et al. (2006) and Li et al. (2017), who also considered the participants' stage of change, did not report significant findings. Tien and Tu (2016) and Thankappan et al. (2013b) who delivered their intervention using the 5As (and 5Rs) algorithm reported a significant impact in tobacco abstinence in their studies. Furthermore, Thankappan et al. (2014) found out that quit rates achieved in Thankappan et al.'s (2013b) study remained significantly higher for an additional six months (but not maintained at two years follow-up (Nichter et al., 2018). Conversely, Albaroodi et al. (2021), Li et al. (2017) and Ng et al. (2010), whose intervention was also based on the 5As (and 5Rs) algorithm, did not identify higher quit rates amongst the intervention group. Nonetheless, Ng et al. (2010), who like Thankappan et al. (2013b) provided all participants with brief smoking cessation advice, visual messages of smoking related diabetic

complications and educational materials on the harm of tobacco in diabetes, still identified a significant decrease in smoking prevalence in both groups at follow-up. The use of motivational interviewing also appears to be uncertain. While Pérez-Tortosa et al., 2015) and Persson and Hjalmarson (2006) reported positive findings in using motivational interviewing for smoking cessation, Hokanson et al. (2006) who also based their intervention on motivational interviewing, did not report significant differences between the studied groups at six months follow-up.

Nonetheless, it appears that the addition of pharmacotherapy to smoking cessation support was more likely to be associated with success. With the exception of the studies by Nagrebetsky et al. (2014), which did not compare pharmacological to non-pharmacological interventions, Hokanson et al. (2006), in which similar numbers in both groups utilised pharmacotherapy, and Sawicki et al. (1993) and Scemama et al. (2006), who both suffered from poor participation and response rates (respectively), in all studies (Albareda et al., 2009; Canga et al., 2000; Katsaounou et al., 2019; Korkontzelou et al., 2020; Pérez-Tortosa et al., 2015; Persson & Hjalmarson, 2006; Persson et al., 2000) in which the authors included NRT, bupropion or varenicline as part of the smoking cessation intervention, a significant improvement in tobacco cessation amongst the study's participants was reported.

3.6.4 Interventions' characteristics and relevant findings of the studies whose smoking cessation intervention was part of a broader intervention for diabetes management

This section reports on the characteristics of the smoking cessation interventions and the relevant findings of the studies which investigated the impact of a smoking cessation intervention which was part of a broader intervention for achieving diabetes management. The characteristics of the identified studies and the relevant findings are listed in table 3.6 below.

Table 3.6: Characteristics and relevant findings of the studies whose smoking cessation intervention was part of a broader intervention for diabetes management

Author/s (date)	Country	Study design	Intervention's main characteristic/s	Control's main characteristic/s (if any)	Study setting; Provider	Sample characteristics,[a]	Follow-up period, months	Percentage followed up, %	Self-reported smoking cessation outcome at follow-up		Other key findings/ comments
									Intervention group, n (%)	Control group, n(%)	
Bluml et al. (2014)	United States	Pre-experimental study: one group, pre- and post-intervention	Educational consultations		Diabetes care teams; Pharmacists	n=1,836 of whom 270 were smokers; mean age - 54.1 years (SD 11.1); 42.8% male participants	12	84.9	26 (9.3)		Variability of interventions and providers
Cohen et al. (2011)	United States	Randomised controlled trial (RCT)	Group-based educational programme Education on tobacco cessation was based on the participants' stage of change	Standard care	Veteran Affairs Medical Centre; A nurse, a nutritionist a physical therapist and a pharmacist	n=99 (T2DM) of whom 11 were smokers; mean age - 67.2-69.8 years; 98.0% male participants	6	97			Abstinence at follow-up not significant
Daly et al. (2017)	Various	Systematic review (SR) and meta-analysis	Active nurse-led interventions	Usual care	Various - by telephone, smoking cessation clinic, letter, face to face; Nurses	n=1,890 (smokers)	6				Relative Risk (RR): 6.65, 95% CI [2.24-19.70]; two trials (biochemical verified)
Davies et al. (2008), Khunti et al. (2012)	United Kingdom	Cluster RCT and follow-up study	Group-based educational programme	Usual care	General practices; Health professionals	n=824 (T2DM) of whom 110 were smokers; mean age - 59-60 years; 54.9% male participants	12-36	68.2	25 (43.9)	16 (30.2)	Significant reduction in smoking prevalence not maintained at 36 months
Ekong and Kavookijan (2016)	Various	SR	Motivational Interviewing (MI) based interventions	Usual care (non MI interventions)	Outpatient sites	n=994 smokers (T2DM)	6-16				No significant differences in abstinence were observed (three trials) MI intervention varied across studies

Author/s (date)	Country	Study design	Intervention's main characteristic/s	Control's main characteristic/s (if any)	Study setting; Provider	Sample characteristics,[a]	Follow-up period, months	Percentage followed up, %	Self-reported smoking cessation outcome at follow-up		Other key findings/ comments
									Intervention group, n (%)	Control group, n(%)	
Griffin et al. (2014)	United Kingdom	RCT	Behaviour change educational intervention Control intervention	Nurse-led intensive interventions in routine care	General practices; Lifestyle trainers and nurses	n=478 (T2DM) of whom 65 were smokers; mean age - 59.5-59.8 years; 62.3% male participants	12	92.9	0	5*	Use of taught skills were lowest amongst those who were trying to quit smoking
Jones et al. (2003)	Canada	RCT	Health coaching (based on the participants' stage of change)	Physician visits and/or diabetes education	By mail or telephone; Counsellors	n=1,029 of whom 148 were smokers; mean age - 54-55 years; 52.4% male participants	12		39 (23.3)	19 (11.6)	Difference not significant
Kirkman et al. (1994)	United Kingdom	RCT	Health coaching	Usual care	By telephone; Nurse	n=275 (T2DM) of whom 65 were smokers; mean age - 63.7 years; 99.0% male participants	12		4*	0	
McDermott et al. (2015)	Australia	Cluster RCT	Home visits Out-of-clinic care	Waiting list	Community health services; Trained health workers	n=213 (T2DM) of whom 72 were smokers; mean age - 47.9 years; 38% male participants	18	89.7	0	5	The authors report that a major health system reform impacted on the study
McGloin et al. (2015)	Ireland	Longitudinal mixed method case study design	Health coaching based on MI (based on the participants' stage of change)		By telephone (Skype)	n=10 (T2DM) of whom 3 were smokers; mean age - 54.5 years (SD 6.9); 50.0% male participants	12	80	1		
Nkansah et al. (2008)	United States	Retrospective time series study	Educational consultations		Pharmacy clinic within physician practice; Pharmacist	n=77 of whom 7 were smokers; mean age - 64 years (SD 10.9); 55.0% male participants	6		0		
Ramallo-Fariña et al. (2021)	Spain	Cluster RCT	Three arms: educational programme for patients (PTI), providers (PFI), or both (CBI)	Usual care	Primary care practices; Nurse and health professionals	n=2,334 of whom 524 were smoker	24		PTI-47 (41.5) CBI-46 (42.3) PFI-37 (23.4)	31 (21.2)	Significant differences for PTI or CBI versus control (p=0.012)

Author/s (date)	Country	Study design	Intervention's main characteristic/s	Control's main characteristic/s (if any)	Study setting; Provider	Sample characteristics,[a]	Follow-up period, months	Percentage followed up, %	Self-reported smoking cessation outcome at follow-up		Other key findings/ comments
									Intervention group, n (%)	Control group, n(%)	
Register et al. (2016)	Various	SR	Pharmacists/podiatrists/optometrists/dentists-led intensive smoking cessation	Usual care	Various	n=1,124 (T1DM and T2DM)	4 - 18				A significant decrease in smoking was only observed in one out of six studies
Rubak et al. (2009)	Denmark	Cluster RCT	MI in clinical practice	Usual care	GP practices	n=265 (T2DM) (number of smokers at baseline not reported)	12	88.3			Abstinence at follow-up not significant In both groups GPs were encouraged to act as counsellors in their practice
Rubak et al. (2011)	Denmark	Cluster RCT	MI in clinical practice	Usual care	GP practices	n=628 (T2DM) of whom 82 were smokers; mean age - 61 years; 58.0% male participants	12	88.6			Abstinence at follow-up not significant Intervention was not implemented systematically
Smith et al. (2011)	Ireland	Cluster RCT	Peer support group sessions Control intervention	Introduction of a diabetes care system	General practices; Trained peers	n=395 (T2DM) of whom 71 were smokers; mean age - 63.2-66.1 years; 54.5% male participants	24	85	6 (19.4)	11 (28.0)	4/29 peer supporters were smokers
Taveira et al. (2010)	United States	RCT	Group-based educational programme Education on tobacco cessation was based on the participants' stage of change	Standard care	Veteran Affairs Medical Centre; A nurse, a nutritionist a physical therapist and a pharmacist	n=109 (T2DM) of whom 27 were smokers; mean age - 62.2-66.8 years; 95.4% male participants	4	92.4	3	0	

Author/s (date)	Country	Study design	Intervention's main characteristic/s	Control's main characteristic/s (if any)	Study setting; Provider	Sample characteristics,[a]	Follow-up period, months	Percentage followed up, %	Self-reported smoking cessation outcome at follow-up		Other key findings/ comments
									Intervention group, n (%)	Control group, n(%)	
Toobert et al. (2011)	United States	RCT	Group-based educational programme	Usual care	NR	n=280 (T2DM) of whom 30 were smokers; mean age - 57.1 years (SD 10.1); all participants were female	12	63.5	0	1	
Tranche et al. (2005)	Spain	Prospective multicentre cohort study	Smoking cessation in clinical practice		Primary care centres	n=3,466 (T2DM) of whom 596 were smokers; mean age - 58.3 years (SD 7.5); 48.7% male participants	12	68.6	24 (4)		Intervention was not implemented systematically
Tricco et al. (2012)	Various	SR and meta-analysis	Quality Improvement initiatives (e.g., counselling)	Usual care	NR	n=3,231 (smokers); mean age - 56.4-62.4 years; 52.0% male participants	12				Non-significant reduction in smoking (RR:1.13, 95% CI [0.99-1.29]; 13 trials)
Ukoha-Kalu et al. (2021)	Nigeria	RCT	Group-based educational programme	No intervention	Hospital clinic; Pharmacist	n=284 (T2DM) of whom 37 were smokers; mean age - 46-55 years; 52.8% male participants	9	72.9	11 (69.0)	7 (33.3)	
Yasmin et al. (2020)	Bangladesh	RCT	Health coaching	Usual care	Outpatients centre	n=320 (T2DM) of whom 11 were smokers; mean age - 32-51 years; 32.2% male participants	12	85.3	2	4	
Zhan et al. (2016)	Various	SR and meta-analysis	Psychological smoking cessation interventions	Usual care	Various	n=2,089 smokers (T1DM and T2DM)	1 - 12				At three months RR: 2.52, 95% CI [1.32-4.80]; four trials Not significant at longer follow-up periods

a: Type one diabetes – T1DM, Type two diabetes – T2DM. *biochemically verified. SD – standard deviation, CI – confidence interval

3.6.4.1 Characteristics of the smoking cessation interventions

Most studies provided the smoking cessation component on a one-to-one basis. The use of group-based interventions was mentioned in seven of the identified studies (Cohen et al., 2011; Davies et al., 2008; Ramallo-Fariña et al., 2021; Smith et al., 2011; Taveira et al., 2010; Toobert et al., 2011; Ukoha-Kalu et al., 2021). While in most studies, the authors assessed the impact of a multi-component intervention for improving diabetes management, which was additional to standard/usual care, in three publications, the authors assessed the effect of an intervention which was integrated within clinical care (Rubak et al., 2009; Rubak et al., 2011; Tranche et al., 2005). In the studies by Rubak et al. (2009) and Rubak et al. (2011), the authors assessed the effect of training general practitioners in motivational interviewing for integrating this approach in clinical practice, while in Tranche et al.'s (2005) study, general practitioners provided a multifactorial intervention during routine care.

The other studies' interventions varied. In six studies (Cohen et al., 2011; Davies et al., 2008; Ramallo-Fariña et al., 2021; Taveira et al., 2010; Toobert et al., 2011; Ukoha-Kalu et al., 2021), the authors assessed the impact of structured educational programmes, which also covered smoking cessation, in improving diabetes management. Ramallo-Fariña et al. (2021) assessed the impact of an educational group programme for health professionals (for improving diabetes management) as an intervention on its own and in conjunction with the structured educational programme for patients. Griffin et al. (2014), who also provided participants with educational meetings, assessed the impact of a behavioural change intervention based on the Leventhal's Common-Sense Model and the Theory of Planned Behaviour on diabetes management. Conversely, in McGloin et al.'s (2015) study the health coaching intervention was based on motivational interviewing. While in most studies the intervention was provided face to face, Jones et al. (2003), Kirkman et al. (1994) and Yasmin et al. (2020) coached participants on diabetes management (and smoking cessation) over the phone. Toobert et al. (2011) provided smokers with smoking cessation leaflets while Ramallo-Fariña et al. (2021) provided individuals with diabetes with continuous personalised feedback via text messages.

As seen in table 3.6, several studies (n=7) were carried out in general practices/primary care settings (Davies et al., 2008; Griffin et al., 2014; Nkansah et al., 2008; Rubak et al., 2009; Rubak et al., 2011; Smith et al., 2011; Tranche et al., 2005). Various professionals/workers delivered the designed intervention. For example, in the studies by Bluml et al. (2014) and Nkansah et al. (2008), the provided educational consultations were pharmacist-led.

Conversely, in Smith et al.'s (2011) study, trained peers provided group sessions to participants for peer support, while in McDermott et al.'s (2015) study health workers provided home visits and out of clinic care to individuals with diabetes.

As seen in table 3.6, in some studies the authors tailored the intervention to the participants' stage of change. In both Jones et al.'s (2003) and McGloin et al.'s (2015) studies the authors tailored the diabetes management intervention to the participants' stage of change. Conversely, Cohen et al. (2011), and Taveira et al. (2010) tailored the smoking cessation component according to the stage of change of the participating smokers.

The studies' follow-up period varied according to the type of study, however this usually lasted 12 months. Khunti et al. (2012) followed up the participants in Davies et al.'s (2008) study for an additional 24 months.

Besides these interventions, two systematic reviews (Ekong & Kavookjian, 2016; Register et al., 2016), and three systematic reviews with meta-analyses (Daly et al., 2017; Tricco et al., 2012; Zhan et al., 2016) were also identified. Zhan et al. (2016) compared the effect of psychological (intensive) interventions on achieving smoking abstinence to usual care, while Ekong & Kavookjian (2016) compared the effect of motivational interviewing based interventions (for improving diabetes management) to non-motivational interviewing interventions. Daly et al. (2017) compared the effect of nurse-led interventions on diabetes management to usual care, while Register et al. (2016) assessed the effect of pharmacist, podiatrist, optometrist, or dentist-led smoking cessation interventions amongst individuals with diabetes. Conversely, in the systematic review and meta-analysis by Tricco et al. (2012), the authors compared quality improvement initiatives (such as provision of smoking cessation counselling) to usual care, for improving diabetes management.

Smoking abstinence was measured objectively only in Griffin et al.'s (2014) study, who analysed plasma cotinine levels and in Kirkman et al.'s (1994) study, who measured the exhaled carbon monoxide levels of those who claimed to quit. In the reviews by Zhan et al. (2016), Ekong & Kavookjian (2016), and Daly et al. (2017), some of the included studies also included objective measures of smoking abstinence.

3.6.4.2 Relevant findings

As outlined in table 3.6, most of the identified studies were not successful in helping smokers quit. Rubak et al. (2009), Rubak et al. (2011) and Tranche et al. (2005), who integrated their

intervention within routine clinical care, did not report any significant improvements in smoking cessation. While Davies et al. (2008), Ukoha-Kalu et al. (2021), and Ramallo-Fariña et al. (2021), who adopted an educational approach to smoking cessation, reported a significant smoking cessation outcome, the other study authors who took a similar approach (Bluml et al., 2014; Griffin et al., 2014; Nkansah et al., 2008; Taveira et al., 2010; Toobert et al., 2011), did not. Furthermore, the significant reduction in the number of smokers within the intervention group reported in Davies et al.'s (2008) study was no longer sustained after two years (Khunti et al., 2012). Jones et al. (2003), Kirkman et al. (1994) and Yasmin et al. (2020), who coached participants on diabetes management (and smoking cessation) over the phone, also did not observe significant findings at follow-up.

While Zhan et al. (2016) found that psychological (intensive) interventions, which included smoking cessation, were superior to usual care, findings were only significant up until three months of follow-up. Quality improvement strategies which included tobacco cessation interventions such as counselling, were also not associated with a significant increase in smoking cessation rates (Tricco et al., 2012). In their review, Ekong & Kavookjian (2016) also found that motivational interviewing based diabetes management interventions (which included smoking cessation) were not more effective than non-motivational interviewing interventions. This finding was also observed in McGloin et al.'s (2015) study, whose behavioural change intervention was also based on motivational interviewing.

No significant difference was observed in Smith et al.'s (2011) study, which was led by peers, and in McDermott et al.'s (2015) study which was delivered by trained health workers. Register et al. (2016) reported a lack of evidence on the effectiveness of pharmacist, podiatrist, optometrist, or dentist-led tobacco cessation interventions amongst individuals with diabetes in their review. On the other hand, Daly et al. (2017) found that active nurse led interventions were more likely to help smokers with diabetes quit as compared to usual care. This finding was still significant when the analysis was limited to the two trials which verified smoking abstinence objectively.

3.6.5 Characteristics and relevant findings of the studies which explored barriers and/or challenges to quitting

This section provides more details on the studies which explored the barriers or challenges to quitting amongst smokers with diabetes and their relevant findings. The characteristics of the identified studies and the relevant findings are listed in table 3.7 below.

Table 3.7: Characteristics and relevant findings of the studies who explored barriers and/or challenges to quitting smoking

Author/s (date)	Country	Study design	Method	Sample characteristics,[a]	Identified challenges/barriers	
Abu Ghazaleh et al. (2018)	United Kingdom	Qualitative descriptive study	Interviews on experiences and beliefs towards smoking and quitting	n=12 (T1DM); mean age - 33.7 years (SD 13.3); 66.7% male participants	Smoking habit and addiction; lack of will-power and social support; smoking as a stress/emotional coping mechanism; adverse effects when using NRTs	
Albaroodi et al. (2018)	Malaysia	Randomised controlled trial (RCT)	Questionnaires on factors affecting smoking cessation pre- and post-intervention	n=140: T1DM=13, T2DM=35, and unknown=78; mean age - 47.6 years (SD 13.6); 95.2% male participants	Pre-intervention: Smoking habit (n=82, 58.6%); stress (n=22, 15.7%)	Post-intervention: Smoking habit (n=74, 58.7%); stress (n=24, 19.0%)
Ardron et al. (1988)	United Kingdom	RCT	Reported reasons for continuing smoking following an intervention	n=60: T1DM=50, and T2DM=10; mean age - 29.1 years (SD 7.4); 48.3% male participants	Cravings (n=31, 51.7%); unconvinced by the health hazards (n=13, 21.7%); too restricted by the diabetic treatment regime (n=10, 16.7%)	
Bodmer et al. (1990)	United Kingdom	Prospective cohort study	Reported reasons for continuing smoking following an intervention	n=43: T1DM=6, and T2DM=37; mean age - 53 years; 58.1% male participants	Lack of will-power; like smoking too much	
Chau et al. (2015)*	China	Qualitative descriptive study	Focus-groups and interviews on perceptions about quitting	n=42 (T2DM); mean age - 60.3 years (SD 11.3); 92.9% male participants	Lack of will-power; psychological addiction; weight gain after quitting; smoking peers; misconceptions about smoking and diabetes management; minimisation of the harmful effects of smoking	
Georges et al. (2019)	Switzerland	Qualitative descriptive study	Focus-groups and interviews on needs and beliefs towards quitting	n=21 (T2DM); mean age - 59.4 years (SD 8.0); 57.1% male participants	Smoking addiction and habit; peers/partners who smoke; misconceptions about smoking and diabetes management; minimisation of the harmful effects of smoking	
Haire-Joshu et al. (1994)	United States	Cross-sectional study	Questionnaire on beliefs about smoking and diabetes	n=64 (T1DM); mean age - 41 years (SD 14); male participants 48.0%	Weight gain after quitting (n=31, 49%); too restricted by the diabetic treatment regime (n=27, 42%); misconceptions about smoking and diabetes management	
Javelot et al. (2009)	France	Case report	Reported the glycaemic imbalance of a patient who took nicotine replacement therapy	n=1 (T2DM); 68-year-old male	Hyper and hypoglycaemia on taking nicotine lozenges and patches	
Kristensen et al. (2008)	Denmark	Case report	Reported the glycaemic imbalance of a patient who took varenicline	n=1 (T1DM); 53-year-old female	Hypoglycaemia on taking varenicline	
Mishu et al. (2021)	Bangladesh	Cross-sectional study	Interviews on barriers of implementing a tobacco cessation intervention	n=15	Lack of knowledge on the effects of tobacco use; tobacco addiction; disinterest; lack of time	
Wakefield et al. (1997)	Australia	Qualitative descriptive study	Focus-groups on beliefs about smoking and diabetes and barriers to quitting	n=18 (T1DM); age - 15-40 years; 55.6% male participants	Smoking to cope with stress/manage nicotine withdrawal; little social support; misconceptions about smoking and diabetes management	
Wakefield et al. (1998)	Australia	Cross-sectional study	Questionnaire on smoking and barriers to quitting	n=54 (T1DM); mean age - 27.9 years (SD 7.0); 50.9% male participants	Having too many stressful things happening (n=16, 30%); gaining weight/glycaemic imbalance on quitting (n=16, 30%); having already given up on several things due to diabetes (n=14, 26%).	

a: Type one diabetes - T1DM, Type two diabetes - T2DM. *included also former smokers. SD – standard deviation.

3.6.5.1 Methods

In most studies (n=7) (Abu Ghazaleh et al., 2018; Chau et al., 2015; Georges et al., 2019; Haire-Joshu et al., 1994; Mishu et al., 2021; Wakefield et al., 1997, 1998), the authors explored the barriers and challenges to smoking cessation, asking recruited participants about smoking, smoking cessation, and diabetes. Albeit Haire-Joshu et al. (1994) and Wakefield et al. (1998), who made use of structured questionnaires, these researchers adopted a qualitative approach; semi-structured individual or focus group interviews. Conversely, in three studies (Albaroodi et al., 2018; Ardron et al., 1988; Bodmer et al., 1990), participants were provided with a smoking cessation intervention and then reasons/barriers to quitting were investigated. In the studies by Javelot et al. (2009) and Kristensen et al. (2008), both authors report the adverse effects experienced by a smoker after taking pharmacotherapy for smoking cessation. In the majority of the studies identified (n=8), smoking patients were identified from diabetic clinics (Abu Ghazaleh et al., 2018; Albaroodi et al., 2018; Ardron et al., 1988; Bodmer et al., 1990; Chau et al., 2015; Georges et al., 2019; Haire-Joshu et al., 1994; Wakefield et al., 1997).

3.6.5.2 Relevant findings

Various barriers to smoking cessation were outlined by the studies' participants. In most studies, participants remarked finding it difficult to quit because of the smoking habit/addiction (Abu Ghazaleh et al., 2018; Albaroodi et al., 2018; Ardron et al., 1988; Chau et al., 2015; Georges et al., 2019; Mishu et al., 2021; Wakefield et al., 1997) and stress, which was relieved by smoking (Abu Ghazaleh et al., 2018; Albaroodi et al., 2018; Haire-Joshu et al., 1994; Wakefield et al., 1997, 1998). Participants also remarked lacking willpower (Abu Ghazaleh et al., 2018; Bodmer et al., 1990; Chau et al., 2015) and social support (Abu Ghazaleh et al., 2018; Georges et al., 2019; Wakefield et al., 1997) to quit smoking.

Further to these commonly reported barriers, various challenges towards quitting were identified by the authors of these studies. Having diabetes proved to be a challenge to quit smoking for most participants. Many participants tended to believe that smoking helped them manage diabetes (such as glycaemic control, adherence to diet or weight management), or its impact (such as stress or suffering) on the individual (Chau et al., 2015; Georges et al., 2019; Haire-Joshu et al., 1994; Wakefield et al., 1997, 1998), thus making it difficult to quit smoking. Others claimed that they were already too restricted because of the diabetic treatment regime (Ardron et al., 1988; Haire-Joshu et al., 1994; Wakefield et al., 1998), or that their condition

(i.e. diabetes) incurred health priorities which preceded smoking cessation (Abu Ghazaleh et al., 2018).

Minimization of the harmful effects of smoking by participants were also identified in some studies (Ardron et al., 1988; Chau et al., 2015; Georges et al., 2019; Wakefield et al., 1997), undermining the importance of quitting. Even though most participants knew that smoking was associated with health problems, they did not perceive themselves to be at a great risk (Ardron et al., 1988; Chau et al., 2015; Georges et al., 2019; Wakefield et al., 1997), as they were not currently experiencing complications (Chau et al., 2015; Georges et al., 2019; Wakefield et al., 1997). Being informed by health professionals to quit smoking, or being told about the additional health risks when smoking with diabetes failed to instil in some participants an urgency to decide to quit, with participants undervaluing smoking cessation (Ardron et al., 1988; Chau et al., 2015; Wakefield et al., 1997).

In three studies, adverse effects, such as hypoglycaemia (Javelot et al., 2009; Kristensen et al., 2008) and skin irritation (Abu Ghazaleh et al., 2018), when using pharmacotherapy were reported, making their use seem counterproductive.

3.7 Discussion

In the following sub-sections, the relevant data, which was extracted, charted, and summarised in the previous section, is discussed in view of the posed research questions.

3.7.1 What type of smoking cessation interventions have been used amongst adults with diabetes mellitus?

This scoping review identified a wide array of studies which have either assessed the effects of smoking cessation interventions on their own or as part of a diabetes management intervention.

As suggested in the literature (Lancaster & Stead, 2017), most of the researchers adopted an intensive approach for encouraging smoking cessation, mainly by providing face-to-face individual-based behavioural support sessions or structured educational sessions to their participants. Similar to what was found in the systematic review and meta-analyses by Zhan

et al. (2016), and Nagrebetsky et al. (2014), most of the intensive interventions identified were similar to those provided to the general population (i.e., being based on the commonly used 5As (and 5Rs) framework and/or the stages of change model, and/or including common counselling approaches, such as, motivational interviewing) with most adding a diabetes-specific educational component on the increased risk of smoking. While in some studies participants were verbally advised on the increased risk for diabetic complications, and even provided with educational printed material, some researchers also utilised visual aids of diabetic related complications to depict such information and to further motivate participants to quit smoking. The use of visual aids, such as the use of pictorial warnings, has been found to elicit negative attitudes towards smoking, effectively increasing intentions to quit (Noar et al., 2016). While various researchers who assessed the effect of stand-alone smoking cessation interventions included pharmacotherapy for smoking cessation, none of the study authors who assessed the effect of broader interventions for improving diabetes management (that included a smoking cessation component) did. This suggests that smoking cessation interventions which are part of a broader intervention tend to be limited in terms of scope and intensity.

The identified smoking cessation interventions were mostly delivered by doctors and nurses who have both been identified in the literature as being effective smoking cessation practitioners (nurses - Rice et al., 2017; physicians - Stead et al., 2013). Most studies were carried out in diabetic clinics and general practices/primary care. This proved to be quite practical and appropriate since individuals with diabetes tend to be seen more frequently in such settings.

3.7.2 What challenges and barriers to smoking cessation were identified amongst individuals with diabetes?

The commonly reported barriers, outlined in section 3.6.5.2, have also been identified in studies which looked at barriers to smoking cessation amongst the general smoking population. Smokers who were recruited from a primary care setting in Malaysia (Chean et al., 2019), and others recruited from general practices in the Netherlands (Dieleman et al., 2021), have also remarked finding it difficult to quit smoking because of the smoking habit/nicotine addiction, social cues to smoking/lack of social support, and lack of willpower/motivation. In Dieleman et al.'s (2021) study most participants also found that emotional and stressful events were a barrier to smoking cessation.

Having focused on individuals with diabetes, this review however identified additional challenges to smoking cessation which are specific to this population. Several misconceptions and attempts to minimize the harmful effects of smoking on diabetes were identified by the studies' authors. While some participants in Chean et al.'s (2019) study (whose study explored challenges and barriers amongst the general smoking population) remarked general misconceptions on smoking and smoking cessation, such as believing that the effects of smoking cessation might be harmful to health, in this review identified false beliefs were mostly specific to having diabetes.

Given that being informed by health professionals to quit smoking, or being told about the additional health risks when smoking with diabetes failed to instil in some participants an urgency to decide to quit (Ardron et al., 1988; Chau et al., 2015; Wakefield et al., 1997), more influential methods for encouraging smoking cessation are required. The use of stronger warnings about the risks of smoking to diabetes have been in fact recommended as a strategy to motivate smokers with diabetes to quit (Li et al., 2017). Such warnings may be based on the personal experiences of tobacco associated harm and diseases, which are more likely to be influential than the information provided by health professionals (Georges et al., 2019).

In addition to these diabetes-specific challenges, in three of the identified studies (Abu Ghazaleh et al., 2018; Javelot et al., 2009; Kristensen et al., 2008), a few adverse events on using varenicline or NRT were reported, which discouraged smoking cessation. Nonetheless, it is worth noting that two of these studies (Javelot et al., 2009; Kristensen et al., 2008) were just case reports. Mild adverse effects, such as those reported in Abu Ghazaleh et al.'s (2018) study, have also been reported in the literature which investigated adverse effects in using NRT for smoking cessation amongst the general population (Cahill et al., 2013; Hartmann-Boyce et al., 2018). Such adverse events can usually be minimised or avoided by applying the treatment correctly. Significant hyper- or hypoglycaemic events were not reported in these studies, however, the number of individuals with diabetes who were included in these reviews might have been too small to observe an effect. Nonetheless, none of the identified studies which studied the effect of a smoking cessation intervention which included the provision of pharmacotherapy for smoking cessation reported such adverse effects.

3.7.3 What are the gaps in evidence?

The identified studies suffered from various limitations resulting in gaps in evidence. Several studies, most of which assessed the impact of a smoking cessation component as part of a complex intervention, had a small number of participating smokers. This could have affected statistical power. Hence, future research should carry out power calculations to ensure an adequate number of participating smokers for data analysis. This would provide a more valid picture of the effect of smoking cessation components, as part of broader interventions for diabetes management.

Another limitation, particularly amongst studies where the smoking cessation intervention was part of a diabetes management intervention, was the use of self-reported data to assess the effectiveness of the intervention in achieving smoking abstinence. As remarked by Benowitz et al. (2020), biochemical verification of smoking abstinence increases scientific rigor. In fact in two of the identified studies (Bodmer et al., 1990; Kirkman et al., 1994), self-reported data on smoking abstinence differed when compared to biochemically verified data. Thus future research should also aim to verify tobacco abstinence by testing for free cotinine in plasma, saliva, and urine or exhaled carbon monoxide for self-reported quitters (Benowitz et al., 2020).

As was identified in this review, smoking cessation interventions for individuals with diabetes should continue to inform participants about the link between tobacco use and diabetes complications. This review found that this has been done by health professionals who in some studies have used printed educational material or visual images of such harm to relay such information and motivate smokers further to stop smoking. Despite such efforts, this review also highlighted that some smokers were still unconvinced of such hazards, or were not concerned, recommending the use of stronger, more influential warnings such as those based on the real personal experiences of tobacco harm of former smokers.

The use of such warnings has been found to increase awareness of tobacco related harm, quit attempts and smoking cessation amongst the general population. The first flight of the 'Tips From Former Smokers' or 'Tips' campaign in 2012, a mass media campaign which features television and internet broadcasted video messages by former smokers who narrate their stories of suffering from smoking related disease, was found to be associated with a relative increase of 12% in the number of smokers reporting a quit attempt (adjusted Odds Ratio [aOR]: 1.20, 95% CI [1.02-1.40]; Mcafee et al., 2013). Furthermore, the prevalence of smoking abstinence of those who reported a quit attempt was 13.4% (95% CI [9.7-17.2] (Mcafee et al., 2013). In

another study on the second flight of the 'Tips' campaign, Huang et al. (2015) also assessed awareness of two lesser-known tobacco-related health risks; amputation and blindness. Knowledge of these lesser-known tobacco-related health risks significantly increased from baseline to follow-up (33% to 46% for amputation, $p<0.001$; 11% to 18% for blindness, $p<0.001$, respectively; (Huang et al., 2015). Furthermore, participants' recall of the campaign's advertisements was associated with greater odds of reporting having visited cessation websites (OR: 1.62, 95% CI [1.27-2.06]), having called a Quitline (OR: 2.28, 95% CI [1.61-3.24]), and having made a quit attempt (OR: 1.18, 95% CI [1.00-1.39]) (Huang et al., 2015).

An analysis of the successful features of the Tips campaign by Skubisz et al. (2016) found that featuring lay spokespersons with similar characteristics to those of the target audience, enhanced relatability, and receptivity of the relayed messages. Former smokers conveyed information about the experienced tobacco-related harm in the form of a narrative, using fear and guilt appeals and their first-hand knowledge, making the messages more credible to the target audience (Skubisz et al., 2016). Furthermore, the former smokers also narrated their ability on how they quit smoking, thus communicating self-efficacy (Skubisz et al., 2016).

Despite the absence of randomised control trials on the impact of such video messages including those that feature former smokers with diabetes' true emotional stories of experiencing smoking related disease, the positive findings outlined above suggest that such messages can be influential in raising awareness on the effects of smoking on health amongst those with diabetes, encouraging quit attempts. The promising use of such video messages as an educational tool, part of a smoking cessation intervention for individuals with diabetes, thus merited further investigation, as part of this doctoral research project.

3.7.4 Which smoking cessation methods are most promising in helping smokers with diabetes quit?

Compared to the interventions which included smoking cessation as part of a broader intervention for improving diabetes management, smoking cessation interventions which were provided on their own seem to have been more successful in helping smokers quit. This is line with a recent systematic review and meta-analysis which showed that while targeting more than one behaviour at a time is effective in chronic disease management, such interventions were not successful in supporting smoking cessation (Silva et al., 2024). Griffin et al. (2014) who assessed the impact of a broad intervention to address physical activity levels, dietary

change, medication adherence and smoking cessation, found that having participants focus on various behaviours at once did not help them achieve the desired results. Furthermore, Rubak et al. (2011) and Tranche et al. (2005), found that when smoking cessation was integrated within clinical care, the smoking cessation intervention was not implemented systematically, thus undermining the study's effort. Given the various behavioural changes required by most individuals with diabetes, such as losing weight, dietary and treatment adherence and increasing levels of physical activity, and the number of challenges and barriers to smoking cessation observed, a comprehensive intervention on diabetes management may not be appropriate to successfully encourage and support smokers to quit their habit and addiction.

While not all stand-alone interventions which focused solely on smoking cessation reported significant smoking cessation outcomes, it appears that the addition of pharmacotherapy to behavioural support was more likely to be associated with successful results. The use of pharmacotherapy for smoking cessation, which has been associated with increased smoking cessation success in the general smoking population (Cantera et al., 2015; Lancaster & Stead, 2017; Papadakis et al., 2010; Stead et al., 2016), may be particularly useful for individuals with diabetes in light of the evidence which suggests that individuals with diabetes may have an increased nicotine addiction compared to other smokers (Keith et al., 2019; Yammine et al., 2019), and in view of tobacco addiction being identified as a challenge by many of the participants of the included studies. Both NRT and varenicline have been identified in this review to support individuals with diabetes to quit smoking. Analysis of data of individuals with diabetes who participated in general smoking cessation studies in which participants were provided with NRT (Folan et al., 2014), or varenicline (Tonstad & Lawrence, 2017), also suggest this, having both reported significant smoking cessation outcomes. Nonetheless, given the concerns about the possible links between varenicline use and neuropsychiatric events, including depression (Cahill et al., 2013), the use of NRT may be preferable, particularly amongst individuals with diabetes who are known to more likely to suffer from depression (Rotella & Mannucci, 2013). Additionally, at the time of this scoping review, the neuropsychiatric safety of varenicline for use among individuals with diabetes had not been assessed. This is because in the analysis by Tonstad & Lawrence (2017), in all studies except for one, participants were excluded if they had a diagnosis or were taking treatment for depression during the previous 12 months. Furthermore, varenicline was unavailable in Europe during the doctoral research project. In 2021, Pfizer stopped and recalled varenicline due to a nitrosamine impurity (Lang & Berlin, 2023).

Despite these observations, calling for the addition of NRT to behavioural support, it is however worth noting that in Persson & Hjalmarson's (2006) study (which was identified in this review), smoking abstinence was not significantly different between those who used pharmacotherapy or not. Conversely, few participants took NRT in Canga et al.'s (2000) study (also included in this review), whose intervention was still found to be effective. Therefore, further research is recommended to establish the significance of pharmacotherapy for smoking cessation amongst individuals with diabetes.

The efficacy of the behavioural support approaches used, and the use of any additional smoking cessation components (e.g. the use of informational leaflets) remains uncertain. Given such uncertainties, a more focused and rigorous review, a systematic review of effectiveness which includes an Intervention Component Analysis (ICA), a pragmatic approach to identify the effective characteristics, or the 'active ingredients', of the assessed interventions (Sutcliffe et al., 2015), was deemed required. A systematic review of randomised controlled trials which assessed the effectiveness of the identified promising smoking cessation methods (stand-alone smoking cessation interventions) and identified the critical features of the successful smoking cessation interventions was thus carried out. This is reported in chapter four.

3.7.5 Strengths and limitations of the scoping review

The strength of the review was that it comprised a systematic and comprehensive search of the literature on the subject matter, utilising a wide range of databases and literature. This scoping review is more comprehensive than the systematic reviews carried out by Nagrebetsky et al. (2014) and Zhan et al. (2016). In this review, the literature on smoking cessation interventions were compared to literature on complex interventions for diabetes management which included a smoking cessation component. Furthermore, for a more pragmatic understanding of the research problem, in identifying the most promising smoking cessation interventions, the most common barriers and challenges experienced by individuals with diabetes in quitting smoking were taken into consideration. While the studies selected had to be focused on individuals diagnosed with diabetes thus excluding studies in which only a proportion had a diabetes, this helped ensure that the designed/delivered interventions and/or the challenges/barriers identified factored in the specific needs of this population for identifying the most promising smoking cessation interventions. To ensure a comprehensive approach for mapping out the literature on this subject matter, all types of literature which utilised quantitative or qualitative

research methods were included, in line with the philosophy of pragmatism. Furthermore, no time or language restrictions were applied.

Nonetheless, the search was only conducted by the author. This falls short of the recommendation provided by Peters, Marnie, et al. (2020), who state that source selection (both at the title/abstract and full-text screening) should be performed by a minimum of two reviewers, independently. Notwithstanding this limitation, a detailed search strategy protocol was devised, which was reviewed by the supervisors. This review is not conclusive. The identified promising smoking cessation methods are based on the judgement of the candidate of the available literature, which suffered from various limitations. Therefore, more research is required, particularly on the effect of smoking cessation interventions as part of broader interventions for diabetes management.

3.8 Implications for the doctoral research project/development of the intervention

As discussed in section 3.7.5, while stand-alone smoking cessation interventions which included pharmacotherapy were found to be more successful in helping smokers with diabetes quit, when compared to diabetes management interventions (which included smoking cessation), this review could not determine the efficacy of the behavioural support approaches used, and the use of any additional smoking cessation components for recommending practice. This is because scoping reviews do not provide conclusions about effectiveness (Chang, 2018), but are more appropriate to assess and understand the extent of the knowledge on the subject area, identifying areas for subsequent research (Munn et al., 2018; Peters et al., 2020; Petticrew & Roberts, 2006). Hence, a more focused and rigorous review, a systematic review of effectiveness with the addition of an ICA, was considered necessary before developing the smoking cessation intervention.

This review also recommends the need of using more influential methods for communicating tobacco related harm, such as by drawing on the personal experiences of individuals with diabetes. Given the absence of randomised control trials on the impact of messages from former smokers who experienced smoking related disease (as depicted in the 'Tips' campaign (Centers for Disease Control and Prevention, 2022), the use of such messages as an educational

tool, part of a smoking cessation intervention for individuals with diabetes, was deemed to merit further investigation, as part of the doctoral research project.

The next chapter reports a systematic review of randomised controlled trials which assessed the effectiveness of stand-alone smoking cessation interventions amongst individuals with diabetes, with the addition of an ICA, for identifying the most effective components for smoking cessation. Chapter five reports a study which was undertaken to explore the needs of individuals with diabetes to quit smoking, and their views of the identified promising smoking cessation components, for the development of a smoking cessation intervention for individuals with diabetes.

3.9 Conclusion

The scoping review reported in this chapter sought to identify the most promising smoking cessation interventions for helping smokers with diabetes quit. Compared to the interventions which included smoking cessation as part of a broader intervention for improving diabetes management, stand-alone smoking cessation interventions which included pharmacotherapy seem to have been more successful in helping smokers quit. These findings and the uncertainties as regard to the efficacy of the behavioural support approaches used, and the use of any additional smoking cessation components call for a more focused and rigorous review; a systematic review of effectiveness with the addition of an ICA for identifying the 'active ingredients' of the effective interventions. This review also indicates the need for the use of more influential methods for communicating tobacco related harm, such as by drawing on the personal experiences (of tobacco related harm) of individuals with diabetes. Given the absence of randomised control trials on the impact of messages from former smokers who experienced smoking related disease (as depicted in the 'Tips' campaign), the use of such messages as an educational tool, part of a smoking cessation intervention for individuals with diabetes, was also recommended, as part of this doctoral research project.

The next chapter presents a systematic review which assessed the effectiveness of stand-alone smoking cessation interventions amongst individuals with diabetes and identified the critical features of the successful interventions.

Chapter 4: Assessing the effectiveness of stand-alone smoking cessation intervention for individuals living with diabetes – a systematic review

4.1 Introduction

This chapter reports on the work which followed the scoping review; the examination of stand-alone smoking cessation interventions for individuals with diabetes in terms of their effectiveness. Apart from examining and comparing the effectiveness of stand-alone smoking cessation interventions to less intensive interventions, such as brief tobacco cessation advice or usual care, this systematic review aimed to identify the components of the successful interventions for the development of a smoking cessation intervention for individuals with diabetes, as part of the developmental stage of this doctoral research project. In the next section (section 4.2) the rationale for opting for a systematic review with the addition of an Intervention Component Analysis (ICA) to achieve the above set aim is provided. The research questions posed for this review are outlined in section 4.3, while the methods for conducting this review are detailed in section 4.4. The results section (section 4.5) follows, providing an overview of the selection process of the relevant studies, the characteristics of the identified studies, their quality ratings using the Cochrane Risk of Bias tool and a narrative synthesis of the studies' outcomes of interest. Furthermore, the review was extended with an analysis of the components of the successful smoking cessation interventions for the identification of the 'active ingredients' for the development of a smoking cessation intervention. The findings obtained from this systematic review of the literature are then discussed in section 4.6. Section 4.7 outlines this review's implications for the doctoral research project/development of the intervention, while section 4.8 is a conclusion to this chapter.

4.2 A systematic review of effectiveness

As was explained in section 3.8, the scoping review's findings and the uncertainties as regards to the efficacy of the behavioural support approaches used, and the use of any additional

smoking cessation components, called for a more focused and rigorous review; a systematic review of effectiveness, the 'gold standard' for determining evidence-based practice (Aromataris & Riitano, 2014). Systematic reviews, being more analytical in nature (Peters et al., 2020), attempt to collate all the empirical evidence available according to pre-set eligibility criteria to answer specific research questions for evidence-based information (Lasserson et al., 2022). Systematic reviews of effectiveness help researchers to study and compare the effectiveness of different interventions, informing them on the most appropriate intervention for a particular situation (Lasserson et al., 2022). Furthermore, the findings of a systematic review have greater validity than those of other types of reviews, as the systematic methods employed aim to minimise bias and increase rigor throughout the research process, providing quality evidence-based recommendations (Aromataris & Riitano, 2014). Thus, following the identification of the promising smoking cessation interventions for tackling the identified diabetes-specific challenges and barriers to quitting, a systematic review for assessing the effectiveness of these interventions was found to be required for identifying evidence-based practice.

In developing a multi-component intervention, in addition to a systematic review of effectiveness, Higgins et al. (2019) also recommend a component-level analysis of the successful interventions. This helps in identifying the critical features of these interventions which can then be combined, forming a promising multi-component intervention (Higgins et al., 2019). Synthesis methods such as network meta-analyses, meta-regression, and sub-group analyses can help identify the reviewed studies interventions' successful characteristics, however these require a number of studies with very similar interventions to operate effectively (Sutcliffe et al., 2015). In the case of systematic reviews in which the studies' interventions differ from one another (such as in this case, as was identified in the scoping review), which limit the ability to explore meaningful numbers of mediators and moderators of intervention effect, Sutcliffe et al. (2015) recommends carrying out an Intervention Component Analysis (ICA). Based on the philosophy of pragmatism, an ICA takes a pragmatic approach to identify what an effective intervention 'looks like' when facing such challenges, thus providing more information about the critical features of interventions for the application to practice (Sutcliffe et al., 2015). Thus, further to a systematic review of effectiveness, an ICA of the successful interventions was also conducted.

Before the undertaking of a systematic review, the writing of an a priori study protocol with defined objectives, and the methods of the systematic review that need to be undertaken, is

recommended (Aromataris & Riitano, 2014; Lasserson et al., 2021; Tufanaru et al., 2020). While the protocol provides the plan for the systematic review, it promotes transparency of methods and processes prior to the undertaking of the review, limiting the occurrence of bias (Lasserson et al., 2022). Before carrying out this systematic review, a draft protocol was devised as means of guidance to this systematic work. This was reviewed by the researcher's supervisors, updated and finalised. The study protocol is reported in Appendix 4.1.

4.3 Identification of the research question

As with any type of research, the first and most important step in preparing for a systematic review is to determine its focus, by framing the review objective/s, and/or the research questions the review needs to answer (Aromataris & Riitano, 2014; Thomas et al., 2021). In systematic reviews, researchers generally use the PICO mnemonic (participants, intervention, comparator and outcome) to articulate a clear and meaningful review objective or question for quantitative evidence on effectiveness of interventions (Thomas et al., 2022; Tufanaru et al., 2020). The PICO framework should be addressed by the study's objective and research question, which guide the development of the inclusion and exclusion criteria (Tufanaru et al., 2020).

This systematic review aimed to assess the effectiveness of stand-alone smoking cessation interventions amongst individuals with diabetes, and to identify the critical features of the successful interventions. This was done by examining and comparing the effectiveness of stand-alone smoking cessation interventions to less intensive interventions, such as brief tobacco cessation advice or usual care, and by identifying the critical features of the successful interventions. Taking into consideration the PICO framework, where population stands for individuals with diabetes mellitus, intervention refers to intensive stand-alone smoking cessation intervention, comparator refers to less intensive interventions (or usual care), and the outcome investigated is smoking cessation, the following main research question was formulated:

Compared to less intensive smoking cessation interventions such as brief tobacco cessation advice or usual care, are stand-alone smoking cessation interventions more effective in helping individuals with diabetes who smoke to quit?

Furthermore, to identify the 'active ingredients' of the successful interventions, the following research question was formulated:

What are the critical components of successful smoking cessation interventions?

4.4 Methods

4.4.1 Inclusion and exclusion criteria

Following the identification of the study's objective and research question, inclusion and exclusion criteria were formulated. The established inclusion and exclusion criteria per PICO framework are outlined in Table 4.1.

Table 4.1: Systematic review - inclusion and exclusion criteria

PICO framework	Inclusion criteria	Exclusion criteria
Population	Individuals diagnosed with diabetes mellitus who smoke tobacco.	Individuals diagnosed with pre-diabetes. Studies in which only a proportion of the patients had diabetes.
Interventions	Pharmacological or non-pharmacological (such as counselling/behavioural support or educational interventions) smoking cessation interventions.	Smoking cessation interventions which are part of a broader intervention for improving diabetes management.
Comparators	Usual care or a less intensive smoking cessation intervention.	No care.
Outcome	Smoking cessation (self-reported and/or biochemically verified smoking abstinence).	Cessation of smokeless tobacco products.
Study design	Randomised controlled trials.	Systematic reviews, non-randomised controlled trials and other types of studies.

4.4.1.1 Population

As shown in Table 4.1, and was explained in section 3.5.1.1, the studies included had to be specific to individuals diagnosed with diabetes mellitus. Studies in which only a proportion had diabetes were thus deemed ineligible.

4.4.1.2 Intervention and Comparator

Studies which assessed smoking cessation interventions by comparing the studied intervention to a less intensive intervention or usual care (comparator), were included. Given that smoking cessation interventions which were part of a broader diabetes management intervention were not identified as promising smoking cessation interventions for use amongst individuals with diabetes, these were excluded.

4.4.1.3 Outcome

Studies which evaluated smoking cessation interventions in terms of the effect on smoking cessation were included. As was explained in section 3.5.1.2, studies which focused exclusively on the cessation of smokeless tobacco products, such as chewing tobacco, were deemed ineligible to the review.

4.4.1.4 Type of studies

In this review, only randomised controlled trials were included. Non-randomised trials were excluded as these tend to produce effect estimates that indicate increased benefits when compared to randomised trials (McKenzie et al., 2022). Conversely, randomised trials provide the most convincing evidence about the effects of interventions as randomisation aims to prevent systematic differences between the characteristics of participants within the intervention groups which may confound the outcome of interest (Higgins et al., 2019; McKenzie et al., 2021). Systematic reviews were also not considered for inclusion in this review. While systematic reviews which include a network meta-analysis, meta-regression, and sub-group analyses can help identify the reviewed studies interventions' successful characteristics, none of the identified systematic reviews (from the scoping review) were found to have carried out such analyses. Furthermore, none of the systematic reviews provided sufficient detail on the critical features of the successful intervention/s for informing the development of a multi-component smoking cessation intervention. Thus, only published, or unpublished reports of randomised controlled trials were included in the review.

4.4.2 Selection of studies

Since this systematic review followed on the scoping review a new search of the literature was not required. This review included all 59 reports of the 51 identified studies, identified in the scoping review. These records were assessed for eligibility for inclusion basing decisions on

the inclusion and exclusion criteria, which reflected the set research questions for the systematic review, listed in table 4.1.

4.4.3 Data extraction

On identifying the studies for inclusion in the review, further to the data that was collected and extracted as part of the scoping review (method outlined in section 3.5.4), additional information was extracted for carrying out the systematic review of effectiveness. This included: information for assessment of risk of bias as outlined in the revised version of the Cochrane tool risk-of-bias tool, known as RoB 2 tool (Sterne et al., 2019); time points of collection of smoking cessation outcome and reporting methods; and the information required for carrying out the ICA pragmatic approach for identifying the critical features of complex interventions as outlined by Sutcliffe et al. (2015). The latter included detailed information of the included interventions' characteristics, and information about the researchers' reflections and accounts of their experience in evaluating the intervention, drawn from discussion sections of the trial reports (Sutcliffe et al., 2015).

4.4.4 Critical appraisal

The retrieved studies were critically appraised to assess the methodological quality of each study and determine the extent to which each study had excluded or reduced the chance of bias within its methods (Tufanaru et al., 2020). As recommended by Higgins et al. (2021), RoB 2 by Sterne et al. (2019) was utilised for critical appraisal. According to Higgins et al. (2021), the domains included in RoB 2 cover all types of bias that are known to affect the results of randomised controlled trials. These are:

- bias arising from the randomisation process
- bias arising from identification or recruitment of participants within clusters (cluster randomised controlled studies only)
- bias due to deviations from intended interventions
- bias due to missing outcome data
- bias in the measurement of the outcome of interest
- bias in selection of the reported result

Within each domain, a series of questions are provided to guide the researcher in judging the risk of bias for that domain. An algorithm also facilitates the judgement about the risk of bias of each domain. Free text boxes are also available so that the reviewer/s can justify responses to the signalling questions and risk-of-bias judgements (Higgins, Savovic, et al., 2021). Following the judgement about the risk of bias of each domain, an overall risk-of-bias judgement can also be calculated as per criteria provided (Higgins, Savovic, et al., 2021).

In this review the RoB 2 for randomized parallel-group trials and the RoB 2 tool specific to cluster-randomized trials were utilised. As recommended by Higgins et al. (2021), the information obtained was presented as part of the review's findings and also reflected in the analysis and conclusions of the review. The 'robvis' tool (McGuinness & Higgins, 2020) was also used to visualise the risk-of-bias assessments.

4.4.5 Synthesis of results

While a meta-analysis of effect estimates (using the random effect analysis) was the preferred method of synthesis, given the incompletely reported outcomes/effect estimates in some of the identified studies (outlined in section 4.5.2.3), and the significant diversity in the interventions utilised by the study authors (outlined in section 4.5.2.2), this was not recommended. Other methods of synthesis, such as a narrative synthesis, are recommended in case of incompletely reported outcome/effect estimates (McKenzie & Brennan, 2022) and when studies do not compare the same or sufficiently similar interventions (experimental and comparator interventions) in a similar situation (Cullum & Dumville, 2015). Thus, once data was extracted and charted, by providing a tabular form of the studies' characteristics, a narrative approach to analyse the results followed.

For the second part of the synthesis, the ICA, the method outlined by Sutcliffe et al. (2015), was followed. The critical features of the interventions were mapped, taking note of the variation in the studies' smoking cessation outcome, thus helping to identify which of the differences in the interventions' characteristics appeared to be of significance. Furthermore, the informal data, the researchers' reflections and accounts of their experience in evaluating the intervention, was coded using inductive thematic analysis. This was done to help understand the association between the intervention features and the success or failure of the intervention, and to re-examine the conclusions drawn from the effectiveness synthesis.

4.5 Results

The following section outlines the results of the systematic review. This section provides an overview of the selection process of the relevant studies, the characteristics of the identified studies, their quality ratings using RoB 2, a narrative synthesis of the studies' smoking cessation outcome/s and a narrative analysis of the components of the studies' interventions.

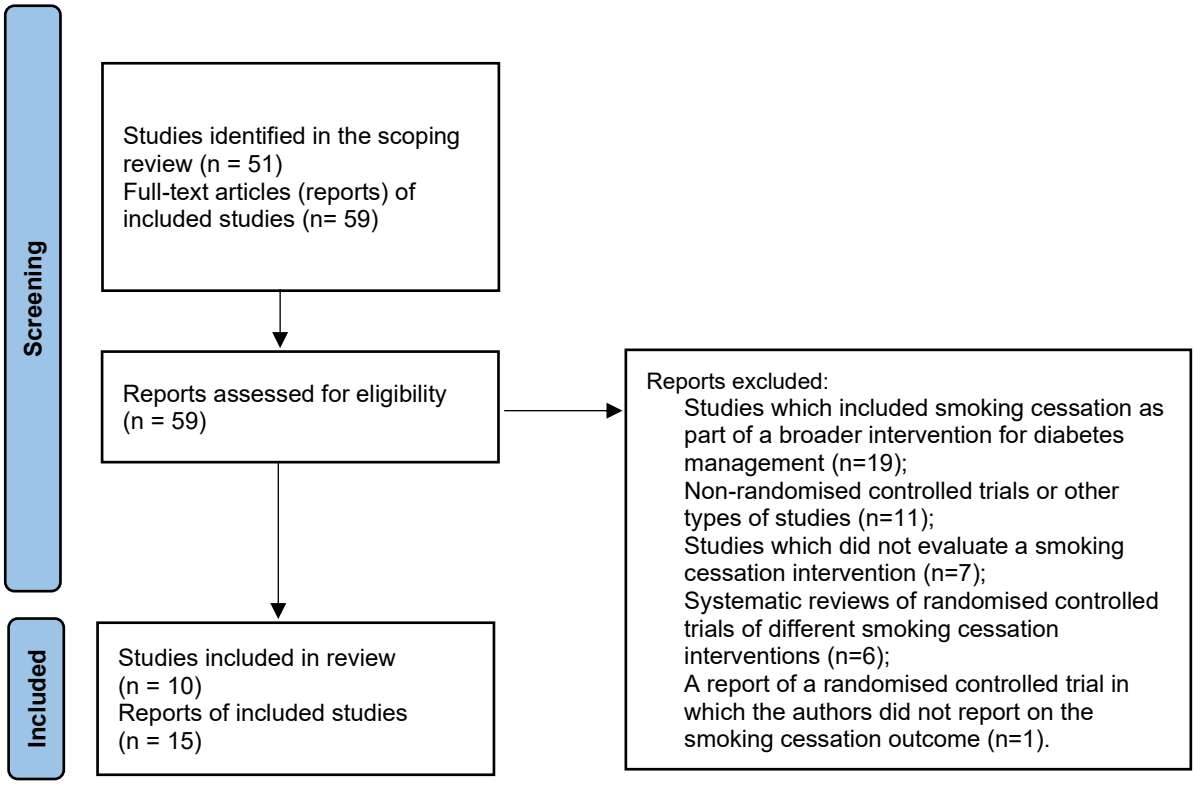
4.5.1 Selection of sources of evidence

As was explained in section 4.4.2, a new search was not conducted, but rather the studies included in the scoping review were assessed for eligibility for inclusion for this review. A modified PRISMA flow diagram was thus utilised to outline the selection process, providing details on the exclusion reasons at the full-text level of screening (Figure 4.1).

On matching the 59 reports, which were identified in the scoping review, to the inclusion and exclusion criteria, 44 reports were found to be ineligible. These studies (listed in Appendix 4.2) were excluded as they were not randomised controlled trials which assessed the effectiveness of stand-alone smoking cessation interventions on smoking cessation. Conversely, 15 reports were deemed eligible to the review.

As was also identified in the scoping review (outlined in section 3.6.1), some of the identified reports however referred to the same study, resulting in a different number of studies being identified. Both Lam et al. (2017) and Thankappan (2013a) published the findings from the randomised control trials by Li et al. (2017) and Thankappan (2013b), respectively, in conference proceedings. Furthermore, in the publications by Thankappan et al., (2014) and Nichter, Mini, & Thankappan (2018), the authors followed up participants from Thankappan et al. (2013b)'s trial for a total of one and two years, respectively, without providing them with additional interventions. Mini et al. (2015) also reported the cotinine measurements from the study by Thankappan et al. (2014) in their publication. Thus, the total number of identified studies was 10 studies.

Figure 4.1: Systematic review – PRISMA flow diagram



4.5.2 Characteristics of the identified studies

The characteristics of the identified studies as per the PICO framework together with the reported smoking cessation outcome/s are listed in table 4.2 below. Almost all the identified papers reported findings from individually randomised parallel-group trials. Pérez-Tortosa et al. (2015) reported the findings from a cluster-randomised parallel-group trial. All studies were published in journals except for the study by Albaroodi et al. (2021) which was available as a preprint (not peer reviewed). The studies were held in Malaysia (Albaroodi et al., 2021), England (Ardron et al., 1988; Fowler et al., 1989), Spain (Canga et al., 2000; Pérez-Tortosa et al., 2015), United States (Hokanson et al., 2006), China (Lam et al., 2017; Li et al., 2017), Indonesia (Ng et al., 2010), Ireland (Sawicki et al., 1993), and India (Mini et al., 2015; Nichter et al., 2018; Thankappan et al., 2013a, 2013b, 2014).

4.5.2.1 Population

As seen in table 4.2, most of the studies (n=5) included individuals with both type one and type two diabetes as study participants (Albareda et al., 2009; Albaroodi et al., 2021; Ardron et al., 1988; Canga et al., 2000; Sawicki et al., 1993). Fowler et al. (1989) specifically investigated

smoking cessation interventions amongst newly diagnosed individuals with diabetes. Most of the studies participants were men. While mean ages varied, most participants were in their fifties. Only two of the identified studies focused on young adults – mean age less than 40 years (Ardron et al., 1988; Fowler et al., 1989).

Sample sizes varied across the studies; from n=34 (Fowler et al., 1989) to n=948 (Pérez-Tortosa et al., 2015). Both Ardron et al. (1988) and Hokanson et al. (2006) argued that their sample size might have been too small to detect a statistically significant effect. A priori power calculations based on a primary outcome to inform sample size were reported in only four of the identified studies (Albaroodi et al., 2021; Canga et al., 2000; Li et al., 2017; Pérez-Tortosa et al., 2015). However, while Canga et al. (2000), Li et al. (2017) and Pérez-Tortosa et al. (2015) carried out power calculations to detect a difference in smoking abstinence, Albaroodi et al. (2021) did not specify on which primary outcome they based the power calculations for informing sample size. The percentage of participants followed up varied from 63.2% (n=72) (Hokanson et al., 2006) to 100% (Ardron et al., 1988; Fowler et al., 1989; Sawicki et al., 1993). While Thankappan et al. (2014) and Nichter et al. (2018) aimed to follow all the participants registered in Thankappan et al.'s (2013b) trial, Mini et al. (2015) only contacted 60 participants out of the 76 self-reported former smokers for confirming smoking abstinence biochemically.

4.5.2.2 Interventions

The characteristics of the assessed interventions and their comparators are also outlined in table 4.2. While in some studies (n=6) the authors based their intervention on a similar theoretical framework or followed a specific behaviour change intervention, namely the 5As algorithm (Albaroodi et al., 2021; Li et al., 2017; Ng et al., 2010; Thankappan et al., 2013b) and motivational interviewing (Hokanson et al., 2006; Pérez-Tortosa et al., 2015), taking into consideration the participants' stage of change and/or readiness to quit (Canga et al., 2000; Hokanson et al., 2006; Li et al., 2017; Pérez-Tortosa et al., 2015), the characteristics of the studied interventions, such as the number of sessions provided, the duration of each encounter and the use of additional (possibly interacting) components, as part of the smoking cessation intervention, varied at large. In addition to behavioural support, in four of the identified studies (Canga et al., 2000; Hokanson et al., 2006; Pérez-Tortosa et al., 2015; Sawicki et al., 1993), pharmacotherapies for smoking cessation were provided to some participants depending on the set eligibility criteria. The provision of informational material, such as leaflets was also part of the smoking cessation interventions in four studies (Ardron et al., 1988; Li et al., 2017; Ng et al., 2010; Thankappan et al., 2013b). Visual aids of diabetic related complications were also

used in three studies (Fowler et al., 1989; Ng et al., 2010; Thankappan et al., 2013b), to motivate smokers to quit.

The study authors compared their experimental intervention to brief advice (Ardron et al., 1988; Hokanson et al., 2006; Ng et al., 2010; Sawicki et al., 1993; Thankappan et al., 2013b) or usual care (Albaroodi et al., 2021; Canga et al., 2000; Fowler et al., 1989; Li et al., 2017). However, as seen in table 4.2, these also tended to vary across the identified studies. Furthermore, in some of the studies the study authors also made use of educational material (Li et al., 2017; Ng et al., 2010; Thankappan et al., 2013b) or provided NRT (Sawicki et al., 1993) to the participants in the control group as was provided to those assigned to the intervention group.

Various professionals were involved in the provision of the smoking cessation interventions. These included nurses (Albaroodi et al., 2021; Canga et al., 2000; Hokanson et al., 2006; Li et al., 2017; Pérez-Tortosa et al., 2015), doctors (Albaroodi et al., 2021; Ardron et al., 1988; Ng et al., 2010; Pérez-Tortosa et al., 2015; Thankappan et al., 2013b), counsellors (Ng et al., 2010; Thankappan et al., 2013b), a diabetes health visitor (Ardron et al., 1988), a psychotherapist (Sawicki et al., 1993) and unspecified health care professionals (Fowler et al., 1989).

As seen in table 4.2, most studies were carried out in diabetes centres/clinics (Albaroodi et al., 2021; Fowler et al., 1989; Hokanson et al., 2006; Li et al., 2017; Ng et al., 2010; Sawicki et al., 1993; Thankappan et al., 2013b).

4.5.2.3 Outcome

As seen in table 4.2, in most studies the authors assessed the impact of the studied intervention on smoking cessation at six months follow-up. Conversely, Pérez-Tortosa et al. (2015) only reported on the smoking cessation rates at 12 months of follow-up. Li et al. (2017) followed up their participants for up to 12 months while Thankappan et al. (2014) and Nichter et al. (2018) followed up the participants from Thankappan et al.'s (2013b) trial for one and two years, respectively.

In most studies smoking abstinence was based on a designated time period; a seven-day point prevalence abstinence (Hokanson et al., 2006; Li et al., 2017; Ng et al., 2010; Thankappan et al., 2013b, 2014), a 30-day point prevalence abstinence (Mini et al., 2015), continuous abstinence at six months (Pérez-Tortosa et al., 2015), and prolonged abstinence (up till 2 years) after having quit smoking (Nichter et al., 2018). Generally, self-reported smoking abstinence was biochemically verified at the end of the study; by measuring exhaled carbon monoxide

(Albaroodi et al., 2021; Ardron et al., 1988; Li et al., 2017; Pérez-Tortosa et al., 2015), and/or cotinine in saliva (Hokanson et al., 2006; Li et al., 2017), urine (Ardron et al., 1988; Canga et al., 2000), or blood plasma (Fowler et al., 1989; Sawicki et al., 1993). In Ng et al.'s (2010) and Thankappan et al.'s (2013b) trials, the findings were only based on self-reporting. Mini et al. (2015) attempted to validate the self-reported smoking cessation rate in Thankappan et al.'s (2013b) trial, by matching self-reported smoking abstinence to salivary cotinine levels at one year follow-up (86% of the sample's self-reported smoking abstinence was biochemically confirmed). Nonetheless, it is worth noting that only 35 participants (46.1%) out of 76 non-smokers participated in this study.

While in all studies the authors reported the smoking cessation outcome per intervention group in Fowler et al.'s (1989) Mini et al.'s (2015) and Nichter et al.'s (2018) studies the overall number of individuals who quit smoking/sustained their smoking abstinence was reported. Unlike most of the studies, where the authors provided the absolute number of individuals who quit smoking, Thankappan et al. (2014) only reported the odds ratio.

Table 4.2: Characteristics and reported smoking cessation outcome of the identified studies

Author/s (date)	Country	Study setting	Sample characteristics[a]	More intensive intervention	Less intensive intervention	Follow-up period, months	Percentage followed up, %	Biochemically verified smoking abstinence at six months follow-up		Other relevant findings/ comments
								Intervention group, n (%)	Control group, n (%)	
Albaroodi et al. (2021)	Malaysia	Diabetes clinic	n=140: T1DM=13, T2DM=35, and unknown=78; mean age - 47.6 years (SD 13.6); 95.2% male participants	Brief (5 minutes) three diabetes-specific tobacco cessation counselling sessions based on the 5As algorithm over 3-4 months delivered by physicians and nurses.	Three routine diabetes care counselling sessions over 3-4 months (routine care).	6	90	4	4	Preprint - not peer reviewed.
Ardron et al. (1988)	England (United Kingdom)	Diabetes clinic	n=60: T1DM=50, and T2DM=10; mean age - 29.1 years (SD 7.4); 48.3% male participants	Same advice provided in comparator group and a lengthier intensive counselling session, a smoking cessation leaflet and a home visit by a diabetes health visitor within two weeks.	A brief (5 minutes) diabetes-specific smoking cessation advice consultation by a medical registrar.	6	100	0	1	
Canga et al. (2000)	Spain	Primary care centres and hospitals	n=280: T1DM=85, and T2DM=195; mean age - 55 years (SD 15.0); 86.0% male participants	An initial 40-minute counselling session focused on diabetes-specific smoking cessation advice by a nurse, provision of self-help written material, and negotiation of a cessation date . Five follow up contacts (a letter, a telephone call or a visit) provided over six months. Consideration of participants' stage of change and readiness to quit. Optional transdermal NRT for heavy smokers and those who did not succeed in quitting.	Usual care provided at the care centres/hospitals, including advice to quit.	6	99.3	25 (17.0)	3 (2.3)	NRT was offered to 105 participants, of whom 25 accepted, but only ten completed it.

Author/s (date)	Country	Study setting	Sample characteristics[a]	More intensive intervention	Less intensive intervention	Follow-up period, months	Percentage followed up, %	Biochemically verified smoking abstinence at six months follow-up		Other relevant findings/ comments
								Intervention group, n (%)	Control group, n (%)	
Fowler et al. (1989)	England (United Kingdom)	Diabetes clinic	n=34: T1DM= 12, and T2DM= 22; mean age of Newly Diagnosed (ND) patients - 47 years (SD 9.0) and those with Pre-Existing (PE) diabetes - 53 years (SD 13.0)	Intervention for ND patients and those with PE diabetes: the Smokescreen protocol (four half-hour educational visits with the use of visual-coloured photographs delivered by health professionals over six months).	Intervention for ND patients: usual care with late access to the intervention. Intervention for patients with PE diabetes: counselling about the interaction between smoking and diabetic complications (same number of visits).	6	100			It is not known in which group the smokers who quit smoking (n=3) pertained. Drop-outs from the programme were high.
Hokanson et al. (2006)	United States	Diabetes centre	n=114 (T2DM); mean age - 54 years (SD 9.0); 57.0% male participants	A motivational interviewing-based smoking cessation counselling session of 20-30 minutes (20 minutes duration) and 3-6 telephone counselling sessions, based on the participant's readiness to quit (an average of 3.5 10-minute sessions) by trained research nurses, and the provision of NRT or bupropion to those interested in quitting.	Provision of information about local smoking cessation programmes.	6	63.2	4 (7.0)	2 (3.5)	Similar numbers in both groups utilised smoking cessation therapies/medications.
Lam et al. (2017) / Li et al. (2017)	China	Diabetic clinics	n=557 (T2DM); mean age - 56 years (SD 11.4); 88.3% male participants	A brief (20 minutes) counselling session based on the 5As framework and matched to the participants' stage of change delivered by a nurse counsellor, two 30-minutes telephone follow-up assessments (included brief booster sessions) at one week and one month follow-up, a self-help and diabetes specific smoking cessation leaflets.	Usual care, brief smoking cessation advice and a self-help smoking cessation leaflet.	12	79.1	38 (13.4)*	39 (14.2)*	At 12 months follow-up, nine (3.2%) vs.14 participants (5.1%) from the intervention and control groups, respectively, were abstinent from smoking (bio-chemically verified; p=0.25).

Author/s (date)	Country	Study setting	Sample characteristics[a]	More intensive intervention	Less intensive intervention	Follow-up period, months	Percentage followed up, %	Biochemically verified smoking abstinence at six months follow-up		Other relevant findings/ comments
								Intervention group, n (%)	Control group, n (%)	
Ng et al. (2010)	Indonesia	Diabetic clinics and smoking cessation clinic	n=71 (T2DM); mean age - 56 years (SD 9.0); 100% male participants	Same intervention as provided to the control group and an active referral to a smoking cessation counselling session based on the 5As algorithm.	Brief smoking cessation advice, use of visual messages of smoking related diabetic complications and provision of educational materials on the harm of tobacco in diabetes by a doctor.	6	78.9	14 (36.8)*	10 (30.3)*	A significant decrease in smoking prevalence in both groups.
Perez-Tortosa et al. (2015)	Spain	Primary care practices	n=948 (T1DM and T2DM); mean age - 59.7 years (SD 11.3); 75.7% male participants	An intensive intervention based on the participant's stage of change using motivational interviewing, therapies and medications, delivered by GPs and nurses. Participants attended a median of four visits (IQR: 2-6). Median total cumulative time of visits - 100 minutes (IQR: 48.8-183.3). Median time spent/visit - 22.1 minutes (IQR: 15.0-37.7).	Usual care.	12	76.2			Per protocol analysis. At 12 months follow-up, 67 (17.8%) and 90 (26.1%) participants from the control and intervention groups were found to be abstinent from smoking (bio-chemically verified; *p*=0.007).
Sawicki et al. (1993)	Ireland	Diabetes clinic	n=89: T1DM=72 and T2DM=17; mean age - 38 years (SD 12.0); 61% male participants	Ten weekly 90-minutes structured smoking cessation sessions (based on behavioural therapy) by a psychotherapist. Nicotine gum was offered to patients with 'severe' tobacco addiction.	A brief 15-minutes unstructured smoking cessation advice session by a physician. Nicotine gum was offered to patients with 'severe' tobacco addiction.	6	100	2	7	Only 25 (57%) attended the support sessions.

Author/s (date)	Country	Study setting	Sample characteristics[a]	More intensive intervention	Less intensive intervention	Follow-up period, months	Percentage followed up, %	Biochemically verified smoking abstinence at six months follow-up		Other relevant findings/ comments
								Intervention group, n (%)	Control group, n (%)	
Thankappan et al. (2013, 2014), Mini et al. (2015) and Nichter et al. (2018)	India	Diabetic clinics	n=224; mean age - 53 years; 100% male participants	Same intervention as provided to the control group with the addition of three intensive (30 minutes) counselling sessions based on the 5As algorithm by a counsellor at baseline, one month and three months.	Brief smoking cessation advice, use of visual messages of smoking related diabetic complications and provision of educational materials on the harm of tobacco in diabetes by a doctor.	6-24	87.5	58 (51.8)*	14 (12.5)*	Adjusted Odds Ratio at 6 months: 8.4, 95% CI [(4.1-17.1], and at 12 months: 3.35; 95% CI [1.82–6.18] (self-reported data was confirmed in 86%). At 24 months only five were abstinent.

a: T1DM - type 1 diabetes, T2DM - type 2 diabetes; * self-reported data; NRT – Nicotine Replacement Therapy SD – standard deviation, IQR – interquartile range, CI – confidence interval

4.5.3 Assessment for risk of bias

A risk-of-bias assessment was carried out on the endpoint reported smoking cessation outcome of each study/report. The RoB 2 tool for randomized parallel-group trials and the RoB 2 tool specific to cluster-randomized trials, were utilised. The assessments using the templates provided are available in Appendices 4.3 (RoB 2 for randomized parallel-group trials) and 4.4 (RoB 2 for cluster-randomized trials). The risk-of-bias assessments performed were visualised using the 'robvis' tool (McGuinness & Higgins, 2020). The risk-of-bias assessments using RoB 2 are displayed in figure 4.2, while the risk-of-bias assessment using the RoB 2 tool for cluster-randomized trials is displayed in figure 4.3.

Figure 4.2: Summary of risk-of-bias assessments performed using the RoB 2 for randomized parallel-group trials

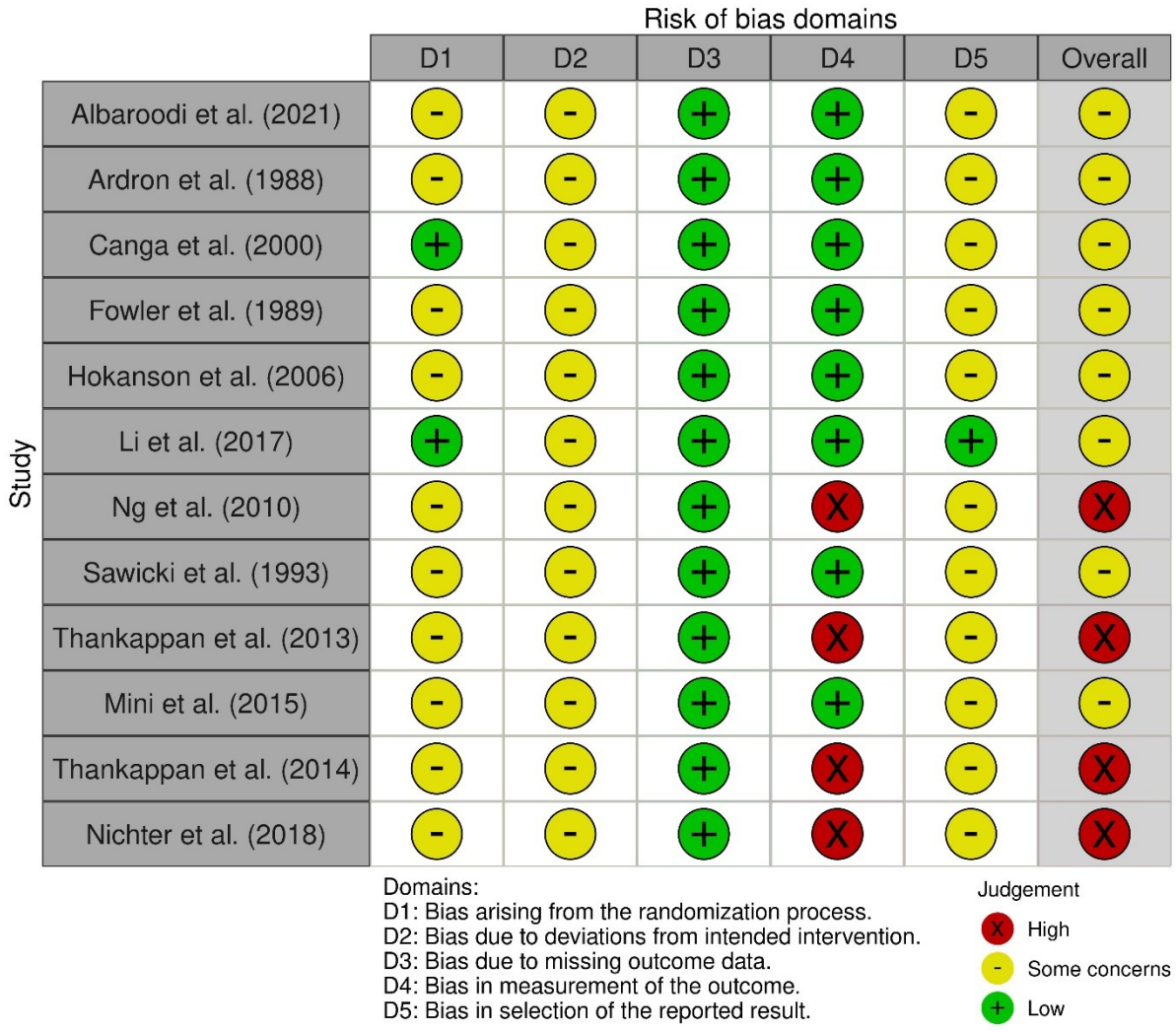
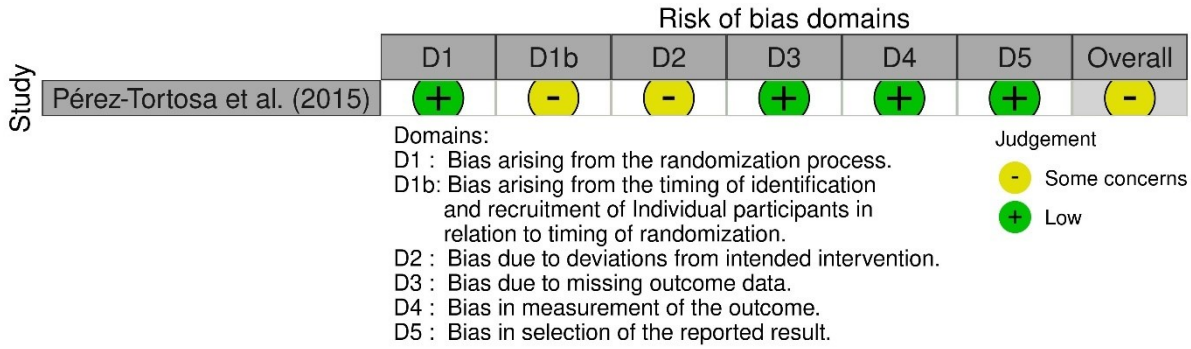


Figure 4.3: Summary of risk-of-bias assessment performed using the RoB 2 for cluster-randomized trials



4.5.3.1 Bias arising from the randomization process

According to Higgins et al. (2021) randomised controlled trials which are judged to be at low risk-of-bias arising from the randomization process should have an adequate method for generating the allocation sequence and for concealing the allocation sequence from the personnel involved in enrolling participants. As seen in figures 4.2 and 4.3, only three studies (Canga et al., 2000; Li et al., 2017; Pérez-Tortosa et al., 2015) were found to be at low risk of bias arising from the randomization process. In most studies (Albaroodi et al., 2021; Ardron et al., 1988; Fowler et al., 1989; Hokanson et al., 2006; Ng et al., 2010; Sawicki et al., 1993; Thankappan et al., 2013b) no information on concealment of allocation sequence was provided, while in some studies (Ardron et al., 1988; Fowler et al., 1989; Ng et al., 2010; Sawicki et al., 1993) no information on randomisation methods were reported. Thus, these studies were judged as having 'some concerns.'

4.5.3.2 Bias arising from the timing of identification and recruitment of individual participants in relation to the timing of the cluster randomization

According to Higgins, Eldridge, et al. (2021) in cluster-randomised trials if identification or recruitment of any participants happens after randomization of the cluster, then there is the possibility that recruitment could have been affected by knowledge of the intervention, introducing bias. In Pérez-Tortosa et al.'s (2015) cluster-randomised study, it is reported that individual participants were identified/recruited after the randomisation selection. Furthermore, there is no information on whether the selection of individual participants was affected by knowledge of the intervention assigned to the cluster. Thus, this study was judged as having 'some concerns' for this type of bias.

4.5.3.3 Bias due to deviations from the intended interventions (effect of assignment to intervention)

According to Higgins et al. (2021) lack of blinding in randomised controlled trials may cause bias if it leads to changes in the provision of the intervention. In some of the identified studies there is no information on whether participants and/or providers were aware of their assigned intervention, while in the other studies no information on blinding was reported. Furthermore, none of the authors reported whether there were any deviations from the intended intervention because of this. Nonetheless, in all studies an appropriate analysis was used to estimate the effect of assignment to intervention (i.e., intention-to-treat analyses or modified intention-to-treat analyses excluding participants with missing outcome data (Higgins, Savovic, et al., 2022). Thus, all the identified studies were judged as having 'some concerns.'

4.5.3.4 Bias due to missing outcome data

All studies were deemed at low risk-of-bias due to missing outcome data. This is because in some studies (Albaroodi et al., 2021; Ardron et al., 1988; Canga et al., 2000; Fowler et al., 1989; Sawicki et al., 1993), data on smoking abstinence at the end of the study were available for all or nearly all participants, while in others (Hokanson et al., 2006; Li et al., 2017; Ng et al., 2010; Nichter et al., 2018; Thankappan et al., 2013b), analysis methods that correct for bias (such as intention-to-treat analysis) were used. In Mini et al.'s (2015) and Thankappan et al.'s (2014) reports, all missing outcome data occurred for documented reasons which were unrelated to the assessed outcome. On the other hand, Pérez-Tortosa et al. (2015) compared the baseline data of those included in the analysis to those with missing data, finding minimal differences.

4.5.3.5 Bias in measurement of the outcome

According to Higgins et al. (2021) it is very important that outcomes are measured using appropriate methods. In all studies except in the studies by Ng et al. (2010) and Thankappan et al. (2013b) and in the reports by Thankappan et al. (2014) and Nichter et al. (2018), the self-reported smoking cessation outcome was biochemically confirmed using objective methods, and so were judged to be of low risk of bias. Conversely the smoking cessation outcome reported in Ng et al.'s (2010) study and in Thankappan et al.'s (2013b, 2014) and Nichter et al.'s (2018) studies/reports was considered at 'high risk' of bias.

4.5.3.6 Bias in selection of the reported result

As recommended by Higgins et al. (2021), for each trial, the trial registry entry, trial protocol or the published study protocol were sought so that any pre-specified outcome measures or analyses which were omitted in the studies could be identified. Only Li et al. (2017) and Pérez-Tortosa et al. (2015) had registered their trial prospectively, thus providing their pre-specified analysis intentions (thus classified at low risk-of-bias). The other studies did not provide any information on whether the result was analysed in accordance with a pre-specified analysis plan. Nonetheless, none of the available studies' results were found to have been probably selected from multiple outcome measurements or multiple analyses of the data. Thus, none of the studies were judged at high risk-of-bias, but of some concern.

4.5.3.7 Overall risk-of-bias judgement

The judgement of the overall risk-of-bias for each study's reported smoking cessation outcome was also based on Higgins et al.'s (2021) guide. Given that all studies were judged to be of concern of risk-of-bias in at least one domain, most studies' overall risk-of-bias was also judged to be of some concern. On the other hand, the overall risk-of-bias of the remaining studies/reports (Ng et al., 2010; Nichter et al., 2018; Thankappan et al., 2013b, 2014) was judged at 'high risk,' as these were found to be at high risk-of-bias in the measurement of the smoking cessation outcome.

4.5.4 Narrative analysis of the studies' findings

As was discussed in section 4.4.5, given the heterogeneity of the identified studies, a narrative synthesis was carried out. As seen in table 4.2, significant differences in smoking cessation between the intervention and comparators groups were only identified in Canga et al.'s (2000) study (17% vs. 2.3%; $p<0.001$), and in Thankappan et al.'s (2013b) study (51.8% vs. 12.5% $p<0.001$) at six months follow-up, and in Pérez-Tortosa et al.'s (2015) study (26.1% vs. 17.8% $p=0.007$), and in Thankappan et al.'s (2014) study (adjusted Odds Ratio aOR: 3.35; 95% CI [1.82–6.18]) at one year follow-up. The other study authors (Albaroodi et al., 2021; Ardron et al., 1988; Fowler et al., 1989; Hokanson et al., 2006; Li et al., 2017; Ng et al., 2010; Nichter et al., 2018; Sawicki et al., 1993) did not identify a significant improvement in the smoking cessation rate of the intervention group when compared to the control group. Nonetheless, in Ng et al.'s (2010) study, a significant decrease in the self-reported smoking prevalence in both the intervention and control groups (intervention 36.8%, control 30.3%; $p<0.001$) was reported.

It is worth noting that in both studies which focused on young adults (mean less than 40 years), the authors did not report a significant impact on tobacco cessation in both intervention groups (Ardron et al., 1988; Sawicki et al., 1993). Fowler et al. (1989), who carried out their intervention amongst individuals with newly diagnosed diabetes, also did not report a significant effect. Furthermore, further analysis showed that the dropout rate was significantly higher (86% at the second visit) in the group approached without delay following diagnosis of diabetes (p<0.02) (Fowler et al., 1989).

Given these inconsistent findings, and in taking into consideration the high level of heterogeneity amongst the studies' interventions, a narrative component analysis followed.

4.5.5 Narrative component analysis

As recommended by Sutcliffe et al. (2015) (and outlined in section 4.4.5), first, the interventions' characteristics were derived inductively from the literature. The features of the interventions were mapped at the following levels: the framework/behavioural support method on which the intervention was based; its intensity, the length of each session and the number of sessions provided; the provision of additional information about tobacco associated diabetic complications, using visual or leaflets; the provision of pharmacotherapy; and the provision of general stop smoking information material. Given that in most studies (Albaroodi et al., 2021; Ardron et al., 1988; Fowler et al., 1989; Ng et al., 2010; Pérez-Tortosa et al., 2015; Thankappan et al., 2013b) more than one type of health professional was involved in delivering the intervention, the studies' interventions were not mapped at the provider level. However, the health professionals involved in providing the successful features of the studies' interventions were then identified. Table 4.3 maps out the characteristics of the studies' interventions based on these categories. This is followed by a brief analysis of each characteristic (component analysis).

Table 4.3: Main components of the smoking cessation interventions of the included studies

Study (studies with non-significant findings in italics)	**Length of session/s**		**No. of sessions provided**			**Additional information about tobacco associated diabetic complications**		**Provision of pharmaco-therapy**	**General stop smoking informational material**
	≤20 minutes	>20 minutes	1-2	3-4	5 or more	Visuals	Leaflets		
Intervention based on the 5As (and 5Rs) framework									
Albaroodi et al. (2021)	✓			✓					
Li et al. (2017)	✓			✓			✓		✓
Ng et al. (2010)[a,b]		✓	✓			✓	✓		
Thankappan et al. (2013)[a]		✓		✓		✓	✓		
Intervention based on motivational interviewing									
Hokanson et al. (2006)	✓			✓				✓	
Perez-Tortosa et al. (2015)		✓		✓				✓	
Intervention not based on a specific framework									
Ardron et al. (1988)[a]		✓	✓						✓
Canga et al. (2000)		✓		✓				✓	✓
Fowler et al. (1989)		✓		✓		✓			
Sawicki et al. (1993)		✓			✓			✓	

a: included brief smoking cessation advice prior to the intensive session/s
b: observed a significant decrease in the self-reported smoking prevalence in both groups

4.5.5.1 Interventions based on a specific framework

There is not enough evidence to suggest the use of a specific framework for smoking cessation amongst individuals with diabetes. While both Ng et al. (2010) and Thankappan et al. (2013b), who followed the 5As (and 5Rs) framework, reported a significant decrease in smoking prevalence in their studies, Albaroodi et al. (2021) and Li et al. (2017), who also followed the same framework, did not. Similarly, while Pérez-Tortosa et al. (2015) reported a significant smoking cessation outcome when providing a motivational interviewing based smoking

cessation intervention to their study participants, Hokanson et al. (2006), who utilised the same technique, did not. The use of the stages of change model also seems to be uncertain. Unlike Pérez-Tortosa et al. (2015), who structured their intervention according to the participants' stage of change, and Canga et al. (2000), who tailored their intervention based on the participants' readiness to change, Hokanson et al. (2006), whose frequency and number of additional telephone support sessions were based on the participants' readiness to quit, and Li et al. (2017), who provided stage-matched counselling, did not report any significant findings.

4.5.5.2 Interventions' intensity

The efficacy of a more intensive intervention, in terms of the sessions' length and the number of sessions provided, seems to be less uncertain (table 4.3). While in some studies, in which a non-significant smoking cessation outcome was reported, the experimental intervention was less intensive in nature, consisting of an initial session of 20 minutes duration and/or shorter sessions (Albaroodi et al., 2021; Hokanson et al., 2006), a 20-minute session and two 30-minutes telephone follow-up assessments which included brief booster sessions (Li et al., 2017), or one or two lengthier sessions (in addition to brief advice) in total (Ardron et al., 1988; Ng et al., 2010), in the studies by Thankappan et al. (2013b), who provided three 30-minute sessions, and Pérez-Tortosa et al. (2015), who provided a median of four sessions (with a median total cumulative time of 100 minutes; median time spent/visit - 22.1 minutes), more smokers in the intervention group quit smoking when compared to the those in the control group. Additionally, Canga et al. (2000), whose intervention was reported to be time demanding, which included a 40 minute initial counselling session, a telephone call, and two follow-up visits (no information on duration), also reported a significant smoking cessation outcome. It is however worth noting that while in Fowler et al.'s (1989) and Sawicki et al.'s (1993) studies, who also provided a more intensive intervention, the authors still reported a non-significant outcome, in both studies few participants adhered to the study protocol, thus possibly undermining the interventions' effectiveness. Trained nurses (Canga et al., 2000; Pérez-Tortosa et al., 2015), doctors (Pérez-Tortosa et al., 2015) and counsellors/non-physician diabetes educators (Thankappan et al., 2013b) provided the intensive sessions as part of the successful smoking cessation interventions.

Frequent smoking cessation support also seems to be beneficial as in both Canga et al.'s (2000) and Pérez-Tortosa et al.'s (2015) studies smokers who were ready to quit were provided with frequent smoking cessation support (one to two weeks follow-up appointments). Given that

the frequency of the sessions varied across the identified studies, it is however difficult to establish the ideal total duration of the studied interventions in terms of months.

4.5.5.3 Provision of pharmacotherapy

It is not clear whether the use of pharmacotherapy, such as NRT, provided in addition to behavioural support, helps to increase smoking cessation success. Pérez-Tortosa et al. (2015), who identified a significant difference between the study groups, provided pharmacotherapy for smoking cessation to the participants in the experimental group. However, they did not report the number of participants who utilised pharmacotherapy, comparing their smoking cessation rate to those who did not. Similarly, Canga et al. (2000), who offered NRT to 105 participants as part of the smoking cessation intervention, also reported an increased smoking cessation rate. While, it is worth noting that only 25 participants accepted to use NRT, Canga et al. (2000) also did not report the smoking cessation rate of those who utilised NRT, comparing it to those that did not.

It is even more difficult to ascertain the effect of the provision of pharmacotherapy on smoking cessation in Hokanson et al.'s (2006) and Sawicki et al.'s (1993) studies. This is because in both studies the participants in the intervention and control groups made use of such treatment.

4.5.5.4 Additional information about tobacco associated diabetic complications

The use of visuals of diabetes related complications, may have been useful in supporting smoking cessation. When considering that in Fowler et al.'s (1989) study few participants adhered to the study protocol, possibly undermining the intervention's effectiveness, in both Ng et al.'s (2010) and Thankappan et al.'s (2013b) studies, who also used visuals of diabetes related complications, a significant decrease in smoking prevalence was reported. Nonetheless, the use of diabetes-specific leaflets, in which information on diabetes related complications was also conveyed, is not clear, as unlike Ng et al. (2010) and Thankappan et al. (2013b), Li et al. (2017) did not report a significant smoking cessation outcome.

4.5.5.5 Use of general stop smoking informational material

There is not enough evidence to suggest the use of general stop smoking informational material as part of a smoking cessation intervention for individuals with diabetes. Unlike in Canga et al.'s (2000) study, in Ardron et al.'s (1988) study, the provision of a stop smoking leaflet did not augment the smoking cessation intervention provided. On the other hand it is difficult to ascertain the effect of having provided a stop smoking leaflet in Li et al.'s (2017) study as all participants (in both the intervention and control groups) were provided with the leaflet.

4.5.5.6 Analysis of informal evidence

Following the analysis of the identified components, as was explained in section 4.4.5, the researchers' reflections, and accounts of their experience in evaluating the intervention were coded to help understand the association between the intervention features and the success or failure of the intervention. Two major themes were identified: 'intensive smoking cessation support,' and 'strong warning messages on tobacco associated diabetic complications,' both of which were identified as being associated with smoking cessation success. These themes, examples of the underlying evidence, the number of studies contributing to these themes, and the correspondence between the themes and the study outcomes are outlined in table 4.4 followed by a brief analysis.

Table 4.4: Identified themes from the researchers' reflections and accounts of their experience

Theme	No. of studies contributing evidence to the theme	Informal evidence example	Correspondence between theme and study outcomes
Intensive smoking cessation support	6	"it is thus of paramount importance to design intensive and innovative interventions" (Li et al., 2017; p. 8) "an intensive intervention adapted to the individual stage of change delivered in primary care for diabetic smokers was feasible and effective" (Perez-Tortosa et al., 2015; p. 100) "This study found a dose response relationship between counseling and quit rate" (Thankappan et al., 2013b; p. 6)	Studies which provided intensive interventions (three or more sessions lasting more than 20 minutes each) were generally effective.
Strong warning messages on tobacco associated diabetic complications	3	"Our findings suggest that a brief disease-centred cessation message from the doctor, given in conjunction with use of disease-complication visual aids, has a significant impact on diabetes patients." (Ng et al., 2010; p. 133) "In our study both the doctor and the counselor used visual aids and diabetes specific smoking cessation materials ... to motivate patients to consider quitting to prevent complications from diabetes." (Thankappan et al., 2013b; p. 6)	Both Ng et al. (2010) and Thankappan et al. (2013b), who provided strong warning messages on tobacco associated diabetic complications (using visual aids, and by providing leaflets) were successful.

As seen in table 4.4, several authors commented on the need or the significance of intensive smoking cessation support. While Canga et al. (2000), Pérez-Tortosa et al. (2015), and Thankappan et al. (2013b), acknowledged the significance of an intensive smoking cessation intervention in achieving the outlined results, Albaroodi et al. (2021), Li et al. (2017) and Hokanson et al. (2006) whose intervention was less intensive in nature and unsuccessful, remarked on the need of a more intensive intervention. Thankappan et al. (2013b) and Ng et al. (2010) also remarked on the benefits of having conveyed strong messages on the harmful effects of smoking on diabetes for motivating smokers to quit. Conversely, Li et al. (2017), whose findings were not significant, recommended the use of stronger messages on tobacco associated diabetic complications to promote smoking cessation.

4.6 Discussion

Similar to the systematic review and meta-analysis by Nagrebetsky et al. (2014), this systematic review reported inconsistent findings across the identified studies. The relatively small number of trials identified, some of which were under powered, the significant diversity in the interventions utilised by the study authors (which limited comparability), and the incompletely reported outcomes/effect estimates in some of the identified studies, limited the ability to establish the effectiveness of stand-alone smoking cessation interventions for use amongst individuals with diabetes. Furthermore, as was outlined in section 4.5.3, several studies were judged to be possibly at risk-of-bias at several domains, as most trials provided incomplete information as regards to the randomization process, possible deviations from the intended interventions (effect of assignment to intervention), and the selection of the reported result.

Nonetheless, the addition of an ICA proved useful, as it helped to identify some of the critical features or 'active ingredients' of the identified diverse multi-component smoking cessation interventions, for informing the development of a smoking cessation intervention for individuals with diabetes. As was outlined in section 4.5.5.2, it appears that intensive smoking cessation interventions may help enhance smoking cessation success. The smoking cessation interventions which consisted of three to four sessions, lasting more than 20 minutes each, were generally more successful. Furthermore, the provision of frequent smoking cessation support also seems to have been beneficial. Such findings are in line with the current evidence on the effectiveness of smoking cessation interventions amongst the general population, as both

Cantera et al. (2015) and Lancaster & Stead (2017) highlighted the benefits of intensive interventions for smoking cessation in their systematic reviews (outlined in section 1.4.2).

The use of visual aids depicting diabetes related complications may also prove to be useful in supporting smoking cessation. Pictorial warnings of tobacco related complications have been found to elicit negative smoking attitudes and increase intentions to stop smoking (Noar et al., 2016). Furthermore, the need for more influential methods for communicating tobacco related harm, such as by depicting strong visual messages, was also one of the recommendations put forward in Li et al.'s (2017) study and in the scoping review (section 3.8).

On the other hand, there is not enough evidence to suggest the use of diabetes-specific or general stop smoking informational material. However, this is in line with current evidence, as in their systematic review and meta-analysis Livingstone-Banks et al. (2019) found that there is no evidence that self-help materials (such stop smoking informational material) increase the effectiveness of smoking cessation advice from a health professional or in using NRT in the general population (RR: 0.99, 95% CI [0.76-1.28]).

There is also limited evidence to suggest the use of a specific framework or behaviour change approach for smoking cessation amongst individuals with diabetes. As was also highlighted in the systematic review and meta-analysis by Lindson et al. (2019), there is not enough evidence to suggest the use of motivational interviewing based smoking cessation interventions amongst individuals with diabetes. It was also observed that in the study by Pérez-Tortosa et al. (2015) who reported a significant smoking cessation outcome on using MI, and its' study protocol (Roig et al., 2010), the authors provided almost no detail on the structure or components of the MI based intervention which was used. Given that MI based smoking cessation interventions have been found to vary substantially (Lindson et al., 2019), the poor reporting in Pérez-Tortosa et al. (2015)'s study limits further the ability to draw any conclusions on the use of MI based smoking cessation interventions amongst individuals with diabetes.

Similar to what was reported in the systematic review and meta-analysis by Cahill et al. (2010), who assessed the efficacy of stage-based smoking cessation intervention amongst the general population, there is also not enough evidence to suggest the use of stage-based smoking cessation interventions amongst individuals with diabetes. The applicability of the stages of changes outlined in the trans-theoretical model has in fact long been questioned. Etter and Sutton (2002) and West (2005) had already highlighted a number of theoretical and methodological problems, for which they discouraged use of this model.

While the 5As (and 5Rs) algorithm for smoking cessation have been featured in tobacco dependence treatment guidelines for the general population, given their easiness in use and their effectiveness (European Network for Smoking and Tobacco Prevention, 2020), and also suggested as a framework for the provision of both brief and intensive smoking interventions amongst individuals with diabetes (Lotrean, 2017), the underpinning evidence for recommending this practice was still found to be limited. In view of these recommendations and given that the use of MI or stage based smoking cessation interventions was not particularly recommendable, the use of the 5As framework for smoking cessation amongst individuals with diabetes was deemed to merit further investigation, as part of this doctoral research project.

Despite the observed promising use of pharmacotherapy for smoking cessation amongst individuals with diabetes in the scoping review (section 3.7.4), this review could not support its usefulness. Given that the effectiveness of the use of pharmacotherapy for smoking cessation amongst the general population has been highlighted in the literature (Cantera et al., 2015; Lancaster & Stead, 2017; Stead et al., 2016), the use of pharmacotherapy for smoking cessation, namely NRT as suggested in section 3.7.4, amongst individuals with diabetes also merits further investigation, as part of this doctoral research project.

In conclusion, the ICA helped to identify some of the critical features of the studies interventions which were missed in the narrative synthesis of the studies' findings and the systematic review and meta-analysis by Nagrebetsky et al. (2014) possibly due to the heterogeneity of the studies' interventions. In carrying out an ICA, intensive interventions, i.e. smoking cessation interventions which consist of three to four sessions, lasting more than 20 minutes each, were found to be more likely to be associated with smoking cessation success. The provision of frequent smoking cessation support and the use of visual aids depicting diabetes related complications were also found to be of possible significance. Given the promising use of the 5As (and 5Rs) framework for smoking cessation and the provision of pharmacotherapy for use amongst smokers with diabetes, their use was deemed to merit further investigation, as part of the doctoral research project.

4.6.1 Strengths and limitations of the systematic review

The strength of this review was that it was based on the recommendations drawn from the findings of a scoping review which mapped out the subject matter. While a meta-analysis of effect estimates was the preferred method of synthesis, given the incompletely reported

outcomes/effect estimates in some of the identified studies and the significant diversity in the interventions utilised by the study authors, this was not possible. Nonetheless, the addition of an ICA to the systematic review proved to be more useful, as in analysing the components of the identified interventions, some critical and promising features of the successful interventions were identified. This allowed the doctoral candidate to identify what works best within the specific context of smoking cessation interventions for individuals with diabetes, in line with the philosophy of pragmatism. Nevertheless, it is worth noting that the methods undertaken to carry out this systematic review were only conducted by the author. This falls short of the recommendation provided by Page et al. (2021) who recommend a minimum of two reviewers who work closely, but independently. Notwithstanding this limitation, a detailed study protocol was devised, which was reviewed by the supervisors. Furthermore, the methods undertaken, and the findings of this review were also reviewed by the supervisors.

Despite the utility of the ICA in identifying some of the critical and promising features of the successful interventions, this review is still limited in terms of its applicability to the development of a smoking cessation intervention as part of this doctoral research project. This is because it is important that the views and experiences of the recipients and providers of the identified features are explored for establishing the validity of this review's findings (Skivington et al., 2021), particularly given that some of the studies' findings were found to be possibly at risk-of-bias.

4.7 Implications for the doctoral research project/development of the intervention

Despite observing inconsistent findings across the identified studies, limiting the ability to establish the effectiveness of stand-alone smoking cessation interventions for use amongst individuals with diabetes, the addition of an ICA proved useful as it helped to identify some of the critical and promising features of the successful interventions, providing evidence-based practice recommendations.

Further to an ICA, Sutcliffe et al. (2015) also recommends carrying out further research to test the conclusions derived from this type of evidence synthesis. Consulting stakeholders (including patients) can not only help to maximise the potential of an intervention but also

identify the features that are more likely to be accepted and have a positive impact on the recipients' health, right at the development phase (Skivington et al., 2021). A qualitative descriptive study to explore the views of individuals with diabetes of the identified promising smoking cessation components was thus deemed to be required. The next chapter reports a study which was undertaken to explore the needs of individuals with diabetes to quit smoking, and their views of the identified promising smoking cessation components, for the development of a smoking cessation intervention for individuals with diabetes. Following this study, a tentative model of a smoking cessation intervention for individuals with diabetes was developed and presented to the diabetes practice nurses (the proposed providers).

4.8 Conclusion

This chapter aimed to assess the effectiveness of stand-alone smoking cessation interventions amongst individuals with diabetes, and to identify the critical features of the successful interventions. A systematic review of randomised controlled trials was carried out examining and comparing the effectiveness of stand-alone smoking cessation interventions to less intensive interventions, such as brief tobacco cessation advice or usual care. With the addition of an ICA, this systematic review also aimed to identify the components of the successful interventions for the development of a smoking cessation intervention for individuals with diabetes, as part of the developmental stage of this doctoral research project.

Despite observing inconsistent findings across the identified studies, limiting the ability to establish the effectiveness of stand-alone smoking cessation interventions for use amongst individuals with diabetes, the addition of an ICA proved useful as it helped to identify some of the critical and promising features of the studied successful interventions. Smoking cessation interventions which consist of three to four sessions, lasting more than 20 minutes each, were found to be more likely to be associated with smoking cessation success. The provision of frequent smoking cessation support and the use of visual aids depicting diabetes related complications were also found to be of possible significance. On the other hand, given that the use of the 5As (and 5Rs) framework for smoking cessation and the provision of pharmacotherapy look promising for use amongst smokers with diabetes, their use was deemed to merit further investigation, as part of the doctoral research project. To validate this review's

findings, and maximise the potential of the developing intervention, the use of qualitative explorative research amongst stakeholders was also recommended.

The next chapter presents a qualitative descriptive research study which explored the needs of individuals with diabetes to quit smoking, and their views of the identified promising smoking cessation components.

Chapter 5: Exploring the views of individuals living with diabetes of the identified promising smoking cessation components and their needs to quit smoking – a qualitative descriptive study

5.1 Introduction

This chapter reports a qualitative descriptive study which was carried out to explore the views of individuals with diabetes of the identified promising smoking cessation components (identified in the scoping and systematic reviews, chapters three and four, respectively), and their needs to quit smoking. This was done to maximise the potential of the developing intervention (as was recommended in section 4.7), for the development of a tentative model of a smoking cessation intervention for individuals with diabetes.

Section 5.2 provides the justification for conducting the qualitative study, followed by an outline of the guiding framework used to carry out this study (section 5.3). The aim and objectives are reported in section 5.4, while section 5.5 outlines the methods which were undertaken. The findings from this study are then reported in section 5.6, followed by a discussion in section 5.7. Section 5.8 outlines this study's implications for the development of the intervention. Section 5.9 is a conclusion to this chapter.

5.2 Involving individuals with diabetes in the development of the smoking cessation intervention

Given that health care interventions are very much dependent on patient involvement and their attitudes to them (Richards, 2015b), the need to explore the recipients' perspectives of the proposed intervention, as well as other needs, which may have not been identified in the literature, has been highlighted in recent guiding documents on developing complex interventions (Bleijenberg et al., 2018; Cathain et al., 2019; Skivington et al., 2021). In exploring patients' needs and views of the proposed intervention features, the researcher can

maximise the potential of an intervention, by taking note of their preferences, and by identifying the components of the proposed intervention that are more likely to be accepted and have a positive impact on the recipients' health, right at the development phase (Bleijenberg et al., 2018; Cathain et al., 2019; Skivington et al., 2021). Apart from expressing what matters most to them, recipients may also share some ideas about the content, format or delivery of the proposed intervention (Cathain et al., 2019). Both Bleijenberg et al. (2018) and Cathain et al. (2019) encourage the use of qualitative research to explore the recipients' needs and views of the proposed intervention.

As per these recommendations, a qualitative descriptive study was designed to explore the needs of individuals with diabetes to quit smoking, and their views of the identified promising smoking cessation components, i.e. the provision of intensive professional smoking cessation support, the use of pharmacotherapy for smoking cessation, and the provision of information on tobacco-associated diabetic complications, such as, by using visual images of tobacco-associated diabetic complications and by using video messages featuring former smokers who experienced tobacco-associated diabetic complications (as identified in the systematic review and recommended in section 3.8, respectively).

5.3 The use of the Information-Motivation-Behavioural Skills (IMB) model as a guiding framework

To explore the needs of individuals with diabetes to quit smoking to inform the development of the intervention, the Information-Motivation-Behavioural Skills (IMB) model (Fisher et al., 2006; Fisher et al., 2003) was chosen as the guiding framework. As explained below, the IMB model implies that behaviour change happens when individuals are well informed, highly motivated and possess the necessary skills to perform the required behaviour change (Fisher et al., 2006; Fisher et al., 2003). Consistent with this framework, the scoping and systematic reviews (sections 3.7 and 4.6, respectively) highlighted the need for more information on smoking and diabetes to enhance motivation among individuals with diabetes to quit smoking, alongside the development of behavioural skills for smoking cessation, especially in view of the diabetes-related challenges (discussed in sections 1.4.4, and 3.7.2). Furthermore, the IMB model has been suggested for the development of behaviour change complex interventions

(Abraham et al., 2015), and has been found to be a useful framework for identifying the unique needs of groups of individuals for the development of smoking cessation interventions (Cooperman et al., 2015; Georges et al., 2019; Shirley et al., 2018), resulting in feasible and acceptable interventions (Cooperman et al., 2018; Tseng et al., 2017). In addition, unlike other theoretical models, such as the Social Cognitive Theory (Bandura, 1997) and the Capability-Opportunity-Motivation-Behaviour (COM-B) model (Michie et al., 2011), the IMB model includes a specific elicitation research component (explained below), for assisting the design of an intervention based on the needs of the population (Fisher & Fisher, 2000).

According to the IMB model (figure 5.1, below), behaviour change requires individuals to be well informed, highly motivated and with the necessary skills to perform the required behaviour change (Fisher et al., 2006; Fisher et al., 2003). While the IMB model specifies that information and motivation work primarily through behavioural skills to result in a change in behaviour, it also asserts that information and motivation may also have direct effects on the behaviour (Fisher et al., 2006; Fisher et al., 2003). Furthermore, while Information and Motivation have been found to be correlated (Fisher et al., 2003), they are regarded as potentially independent constructs, as well-informed persons may not necessarily be highly motivated and vice versa (Fisher et al., 2006; Fisher et al., 2003).

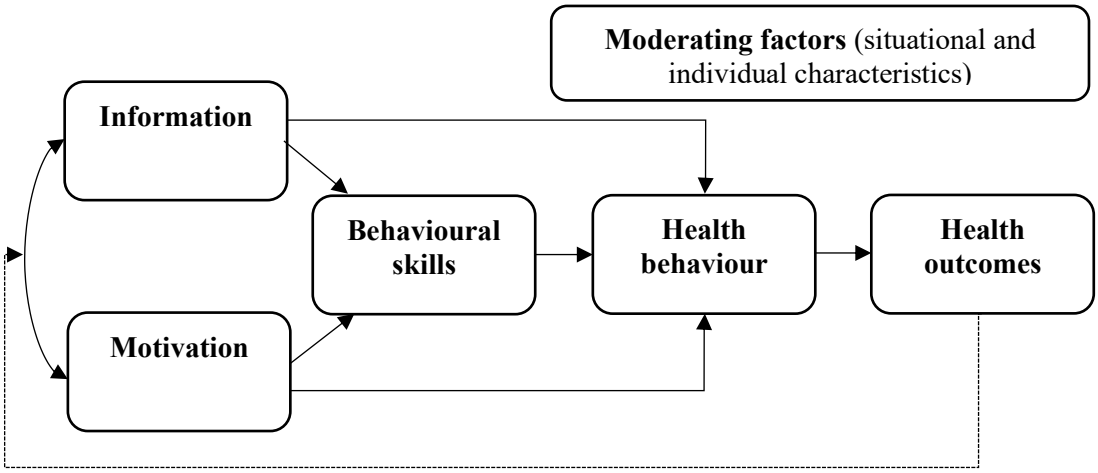
In addition to its core constructs, the IMB model also recognises the influence of moderating factors, such as situational and individual characteristics, which can positively or negatively influence the desired change in behaviour (Fisher et al., 2006; Fisher & Fisher, 2023; Fisher et al., 2011). Negative moderating factors can impact directly or indirectly on the behaviour by influencing the IMB model constructs or their relationships (Fisher et al., 2006). While lower levels of negative moderating factors may not alter the effects of the IMB model constructs, their relations and the desired behaviour change, moderators present at high or intense levels will impinge on the intervention's effectiveness, thus necessitating amelioration via the proposed intervention or an adjunct effort (Fisher et al., 2006).

The IMB model also asserts that individual objective and subjective health outcomes (e.g. poor glycaemic control on quitting) can also act as moderators, as they are directly linked to maintaining the desired behaviour (Fisher et al., 2006; Fisher & Fisher, 2023; Fisher et al., 2011). These, in turn, can influence behaviour change via a feedback loop that affects the IMB constructs, strengthening or weakening adherence (Fisher et al., 2006). Thus, positive health outcomes may strengthen an individual's confidence in his/her information about the desired

behaviour change, and strengthen his/her motivation, reinforcing the behavioural skills required for adhering to the new behaviour. Conversely, negative health outcomes will weaken the IMB constructs reducing adherence to the new behaviour.

In developing an IMB based intervention one is to first identify the specific IMB factors that are relevant to the particular health behaviour and target population through elicitation research (Fisher et al., 2006; Fisher et al., 2003). This helps to identify the population specific IMB strengths, which can be capitalised on, and any deficits, which need to be addressed when designing the population-specific intervention (Fisher et al., 2006; Fisher et al., 2003). Elicitation research may also help to identify any moderators that need to be accounted for and/or addressed via an intervention (Fisher et al., 2006). Figure 5.1 outlines the IMB model's constructs and their relationships.

Figure 5.1: The IMB model of behaviour change (After Fisher et al., 2006; Fisher et al., 2003)



Thus, to understand the unique needs of individuals with diabetes to quit smoking, this study aimed to explore the relevant information, motivational factors, and behavioural skills that could impact the ability of persons living with diabetes to quit smoking and their views of the identified promising smoking cessation components. This helped to identify the population specific IMB strengths, deficits, and the perceived moderators which were accounted for in the development of a tentative model of a smoking cessation intervention (reported in chapter six).

5.4 Aim and objectives of the qualitative research study

The aim of this study was to explore the needs of individuals with diabetes to quit smoking, and their views of the identified promising smoking cessation components, by:

- Exploring their views on
    - the relevant information,
    - motivational factors, and
    - behavioural skills

    that could impact the ability of individuals with diabetes to quit smoking
- And by exploring the views of individuals with diabetes on:
    - the use of pharmacotherapy for smoking cessation
    - tobacco-associated diabetic complications awareness raising efforts, such as, by using visual images of tobacco-associated diabetic complications and video messages featuring former smokers who experienced tobacco-associated diabetic complications
    - the role of health professional support to quit smoking.

5.5 Methods

5.5.1 Design

A qualitative descriptive design was adopted. The use of qualitative descriptive research has been recommended as part of the developmental process of complex interventions in health care for improving the proposed intervention prior to full-scale evaluation (Cathain et al., 2019). Qualitative descriptive research recognises the subjective nature of the phenomenon under investigation and so aims to explore and understand the perspectives and needs of relevant individuals with the intent to stay close to and describe participants' meanings (Bradshaw et al., 2017; Doyle et al., 2020), which is in line with the philosophy of pragmatism (Doyle et al., 2020). Qualitative description research thus takes a naturalistic approach aiming

to understand the phenomenon through the meanings the participants provide, relying entirely on the participants' subjective awareness of it (Bradshaw et al., 2017).

5.5.2 Data collection method

Focus group interviews were the initial preferred method of data collection. This was because in posing interview questions to a group, participants go beyond stating their views and opinions, but also interact with each other, agreeing or disagreeing, justifying themselves, yielding very rich data (Lune & Berg, 2017). Nonetheless, following the introduction of new COVID-19 restrictions just prior to the data collection period (March 2021), which limited public meetings to groups of two, another data collection method was resorted to. Individual interviews were the next preferred method of choice. Given the hesitancy by some participants to meet in person due to the pandemic situation at that time, these were held over the phone.

Individual interviews have been found to contribute to rich data, which is required in qualitative descriptive research (Bradshaw et al., 2017). Semi-structured interviews, in which the questions are asked in a systematic and consistent order, allowing freedom to the interviewer to probe further, were conducted (Lune & Berg, 2017). Interviews followed a question and probe guide which included questions on personal characteristics, and questions based on the IMB model of behaviour change, also addressing the views of the identified promising smoking cessation components. The question guide was examined by the supervisors and an advisor, facilitating the identification of poorly worded questions or blind spots. The instrument was also translated in Maltese and checked by a professional bilingual translator to ensure accuracy. In summary, participants were asked about:

- Personal characteristics – socio-demographic characteristics and the diabetes and smoking profile.
- Information – their knowledge about the harms and risks and interaction between smoking, smoking cessation and diabetes, also asking them about the required information to quit smoking. Participants were also asked about the perceived impact on smoking habits in raising awareness on tobacco-associated diabetic complications (such as by using visual images of tobacco-associated diabetic complications and video messages featuring former smokers who experienced tobacco-associated diabetic complications).

- Motivation – their motivational factors to quit smoking and avoid relapse.
- Behavioural Skills – their perceived facilitators to quit smoking, and their views on the use of pharmacotherapy for smoking cessation, and health professional support to quit smoking.
- Participants were also asked about their perceived barriers and challenges to quit smoking to help identify any situational and individual characteristics which could negatively impact on smoking cessation (negative moderators).

Interviews, lasting between 30 to 40 minutes, were held in Maltese or English, depending on the preference of the interviewee. The author moderated all interviews, posing the questions to the participants and stimulating further responses by using the structured prompts and other probes as necessary. The interviews were audio recorded with consent. The interview guide in English and Maltese is provided in Appendices 5.1 and 5.2, respectively.

5.5.3 Sampling method and sample

Purposive sampling, that is the sampling of participants with the desired attributes being researched (Lune & Berg, 2017), was adopted. Given the aim and the objectives set, participants had to have attempted quitting following a diabetes diagnosis. Thus, both former and current smokers of both genders with type 1 or type 2 diabetes, who had tried to quit following a diabetes diagnosis and who were able to converse in English or Maltese were eligible for this study. Given that sales of tobacco products is prohibited to those younger than 18 years, recruitment was restricted to those aged 18 years and older. To ensure wide coverage in recruitment, participants were recruited from the diabetes education units and the diabetic clinics at the two acute public hospitals, the primary health care department, from family doctors and a diabetes association. The health care professionals manning these clinics and the diabetes association were provided with recruitment flyers (Appendices 5.3 and 5.4) to distribute to help identify interested participants, forwarding their contact details to the researcher for recruitment. This helped establish the legitimacy of the participants as communication with participants was only done by phone (Lune & Berg, 2017).

In qualitative research, samples tend to be small because the emphasis is on the detail collected rather than generalisability (Bradshaw et al., 2017). Researchers thus base their sample size on the principle of 'data saturation' (Bradshaw et al., 2017; LoBiondo-Wood & Haber, 2014), seeing saturation when new data collected repeats what was expressed in the previously

collected data, with no necessary reference to the theory associated to these data (Saunders et al., 2018). Bradshaw et al. (2017) also suggests that researchers should also consider whether the data collected sufficiently answers the posed research objectives, taking also into consideration the research design and sampling procedure. In estimating the required sample size, reference was made to the seminal study by Guest, Bunce, & Johnson (2006) and a previous similar study by Georges et al. (2019) which explored the association between diabetes, smoking and gender, using questions based on the IMB model. In the study by Guest et al. (2006), data saturation was relatively achieved after only 12 interviews. In the study by Georges et al. (2019), saturation was achieved after 10 semi-structured individual interviews and five focus groups with former and current smokers (15 units of analysis; 21 participants in total). Thus, data saturation was estimated to be achieved after 15 interviews.

This study was carried out during the peak of the second wave of the COVID-19 pandemic, prior to the roll-out of vaccines to the public. Despite the controversy on the provision of incentives for participation, the use of incentives is appropriate and not unethical as long as these are reasonable and fair, appropriate to the study methods and population and do not present an excessive inducement to participants (Polacsek et al., 2016). Given that the study was initially designed as a focus group interview, where participants had to attend along with other participants for the interview (lasting around 90 minutes), a token of appreciation, a 10 Euro voucher was determined appropriate to acknowledge participants' time and inconvenience during such period and was thus mentioned in the participants' information and consent documents. Most participants, however, refused the voucher, citing altruistic reasons or benefits that can arise from this research.

Data was collected between April and June 2021. All participants were recruited from the two acute public hospitals as there were no referrals from the other entities. Participants were recruited with the aim to achieve data saturation but also with consideration to the sampling procedure, to ensure adequate representation by gender, age, type of diabetes, and smoking status. In total 20 interviews were held.

5.5.4 Data analysis

The participants' characteristics were analysed using descriptive statistics, i.e., using frequencies and percentages, and providing mean (and standard deviation) or median (and interquartile range) values for normally and non-normally distributed continuous data (tested

by using the Shapiro Wilk test). All audio recordings were transcribed verbatim and reviewed by listening again to ensure accuracy. This also helped in familiarising with the data for the search for themes and subthemes (Bradshaw et al., 2017). The transcripts in Maltese were not translated, in order to maintain the validity and reliability of the acquired data (Guest et al., 2014). Rather, as recommended by Chen & Boore (2010) and Squires (2009), analysis was conducted in the language of the participants (Maltese or English), generating categories in the source language, and then translating all identified themes (and matching phrases) into English. All transcripts were then imported into NVIVO (version 1.5.1).

Applied thematic analysis, described as a rigorous, primarily inductive method to identify and examine themes from textual data within an applied research context, in a way that is transparent and credible (Guest et al., 2014), was adopted. Applied thematic analysis has a descriptive and explorative orientation, aiming to present the meanings of the study participants as accurately and comprehensively as possible (Guest et al., 2014), making it applicable to qualitative descriptive research (Bradshaw et al., 2017). Guided by the applied thematic analysis approach by Guest et al. (2012), the following steps were taken: 1) familiarisation with the data by transcribing and re-reading transcripts several times; 2) reading through the text of four transcripts (two transcripts per language) observing things that were of interest to the research objectives, periodically stopping proposing themes (in both languages); 3) refining themes into codes, making notes about them - defining what they are, what they are not, providing examples (quotations), resulting in a draft coding scheme (an example code is provided in Appendix 5.5); 4) reviewing of codes and coding scheme by supervisors, with revisions; 5) coding and further development and refining of the coding scheme with periodic reviews of the themes to check accuracy. Given that the researcher was the sole data analyst, the researcher served as both the primary and secondary coder by reviewing again all the codes after some time, refining, and renaming themes/codes to reflect the meanings of the relevant datasets, enhancing reliability (Guest et al., 2014). Furthermore, given that the researcher was proficient in both languages and knowledgeable about the research and subject matter, the researcher translated and matched the Maltese themes to similar English ones, presenting all themes and sub-themes in the English language. In outlining themes/sub-themes in the findings section, the original participants' quotes are provided. The English translations of quotes in Maltese are also provided. Based on the IMB model, a summary of the findings is presented and illustrated in a figure format reflecting the latter model.

5.5.5 Trustworthiness

Based on the guide by Bradshaw et al. (2017), the following steps were taken to enhance rigor (in terms of credibility, confirmability, dependability, and transferability):

- As from recruitment the researcher aimed to establish rapport and a trusting relationship, encouraging participants to speak freely during the interviews. Furthermore, the researcher expressed compassion and empathy when participants disclosed any challenges experienced.
- Themes and sub-themes were based on participants' data and evidenced by direct quotations from participants available in the original language.
- The study's procedures and data analysis processes were documented.
- A rich description of the processes and the study details are presented so that this study can be recreated.

Furthermore, as outlined earlier, the coding and the coding scheme were reviewed by the supervisors (one of whom is bilingual) and by the researcher following a couple of weeks after the initial coding.

5.5.6 Ethical considerations

Before carrying out the study, permissions were sought from the recruiting stakeholders, while ethical clearance was sought from the Faculty of Health Sciences Research Ethics Committee on behalf of the University Research Ethics Committee (UREC FORM V_15062020 6327). All permissions are found in Appendices 5.6 – 5.18. No ethical issues were foreseen by the respective entities, and the study was approved.

On indicating their interest to participate in the study, prospective participants were verbally briefed on the purpose of the study and the data collecting procedure, answering any queries that they had. They were also provided with a detailed information letter and a consent form to sign (Appendices 5.19 – 5.22). This was sent by post or by email. Participants were reminded that participation was voluntary so that they could choose whether to participate or not, thus ensuring autonomy (Cohen, Manion, and Morrison, 2018). Participants were told that they were free to withdraw from the study at any time, without the need to provide a reason.

Participants were assured that refusing to participate or withdrawing from the study did not have any effect on their care whatsoever.

Before starting the phone interviews, the researcher reminded participants that discussions were confidential, and that the data was to be rendered anonymous. Participants were also assured that their identity and personal information were not to be revealed in any data/information arising from the research study. The audio-recordings were transcribed and pseudonymised. These were then erased, retaining data only in an anonymous format. Given the nature of the study, which may prompt the need to quit smoking, as suggested by Bradshaw et al. (2017), a referral system (to smoking cessation support) was established.

5.6 Study's findings

5.6.1 Participants' characteristics

The sample included ten former and ten current smokers. The participants' demographic characteristics, and their diabetes and smoking profiles are outlined in table 5.1 below.

Table 5.1: Participants' characteristics

Characteristics	Frequency	Percentage
Demographics		
Gender		
Male	14	70
Female	6	30
Mean age, years (SD)	50.0 (16.28)	
Education		
Primary level	2	10
Secondary level	8	40
Post-secondary level	3	15
Vocational training	2	10
Diploma	3	15
Degree	2	10
Employment		
Student	2	10
Employed	10	50
Unemployed (disability)	1	5
House duties	2	10
Retired	5	25
Diabetes profile		
Diabetes type		
Type 1	6	30
Type 2	14	70
Mean age at diagnosis, years (SD)	34.1 (17.45)	
Diabetes complications		
No	11	55
Yes	9	45
Smoking profile		
Mean age of starting smoking, years (SD)	15.2 (2.87)	
Median number of years since quitting amongst former smokers (IQR)	2.2 (0.5-15.0)	
Mean amount of cigarettes/day amongst current smokers (SD)*	17.2 (10.37)	
Motivation to quit amongst current smokers		
Yes, planning to quit in < 1 month	2	20
Yes, planning to quit in > 1 month	4	40
Not motivated to quit	4	40

* excluding one participant who smoked five cigarellos a day. SD – standard deviation, IQR – interquartile range.

As seen in table 4.1, most participants were male, middle aged, with type 2 diabetes. They were employed, holding at least a secondary level of education. Nine participants reported having a diabetic complication/s. Participants reported having experienced heart problems (n=5), peripheral vascular problems (n=2), blindness or partial blindness (n=2), renal failure (n=2) and stroke (n=1) associated with their diabetes status.

On average participants reported starting smoking at the age of 15 years. All smokers smoked daily; an average of 17 cigarettes per day. Six current smokers were motivated to quit smoking, however only two were planning to quit within the next month. All former smokers were previously daily smokers. Four former smokers were recent quitters, having quit smoking over the past year.

Themes and codes, that were extracted from the data collected, are organised according to the constructs of the IMB model of behaviour change (Information, Motivation, Behavioural skills and Moderators) and outlined in the sub-sections below. A summary of the findings, outlining the population specific IMB strengths and deficits and the identified moderators, is then presented in section 5.6.6.

5.6.2 Information

5.6.2.1 Knowledge on smoking, smoking cessation, and diabetes

All participants except one, were aware of the general health risks associated with smoking. Most participants referred to respiratory and cardiovascular health problems (table 5.2). Most participants (n=14) were also aware of the increased health risks for those who have diabetes and smoke (table 5.3). While four participants simply referred to increased health risks when smoking and having diabetes, nine participants specifically referred to increased cardiovascular health risks, most notably blockages in blood vessels (n=5).

Table 5.2: Participants' knowledge of the general health risks associated with smoking

Themes (and sub-themes)	Quote (translated quotes in italics)	Participants' code (number of participants)
Respiratory health problems		
Shortness of breath	"qtugħ ta' nifs." (*"shortness of breath."*) Male smoker 7, age 22	FS1, FS4, FS6, FS7, FS10, S2, S4, S5, S7, S9 (10)
Unspecified respiratory problems	"Any kind of respiratory issues" Male smoker 4, age 27	FS3, FS5, FS8, S3, S4, S6, S7 (7)
Lung cancer	"cancer fil-lungs" Male smoker 10, age 79	FS3, S9, S10 (3)
Complicated colds	"timrad b'xi riħ ikun iktar ikkomplikat hu" (*"when you catch a cold it can get more complicated"*) Female smoker 2, age 47	S2 (1)
Cardiovascular health problems		
Blockages in blood vessels	"jinstaddulek xi vini. Emm.. naħseb li l-iktar li jikkawża naħseb dawn, dawn l-arterji u l-vini u hekk." (*"your veins can get clogged. Emm.. I think the most it can cause, to these, to the arteries and veins and so on."*) Female smoker 5, age 28	FS2, FS5, FS7, S2, S3, S5, S6 (7)
Heart problems	"problemi fil-qalb" *("heart problems")* Male former smoker 9, age 29	FS1, FS7, FS9, FS10, S5, S10 (6)
High blood pressure	"I think high blood pressure" Male smoker 4, age 27	S4 (1)
Stroke	"u puplesija" (*"and stroke"*) Male smoker 10, age 79	S10 (1)
Unspecified cardiovascular problems	"cardiovascular problem will happen" Male smoker 1, age 36	S1 (1)
Cancer (not specified)	"Ehh, cancer hu!" Male former smoker 2, age 56	FS2, FS9, S4 (3)
Oral health problems	"gums, teeth" Male former smoker 5, age 51	FS5, FS7, S10 (3)
Loss of smell	"l-ewwel ma ġrali ma tantx nxomm u għadni sal-lum ma nxommx." *("the first thing that happened to me was that I couldn't smell well and I still don't today")* Female former smoker 6, age 66	FS6 (1)

Table 5.3: Participants' knowledge of the increased health risks for those who have diabetes and smoke

Themes (and sub-themes)	Quote (translated quotes in italics)	Participants' code (number of participants)
Increased cardiovascular health risks		
Blockages in blood vessels	"Ħeq! mhux għax jinstaddu l-vini." (*"Well! it's because the veins get clogged."*) Female former smoker 8, age 50	FS2, FS6, FS7, FS8, S6 (5)
Heart problems	"Naħseb l-iktar, l-iktar fuq il-qalb, għax it-tnejn speċi jikkawżaw problemi fil-qalb, allura t-tnejn f'daqqa, emm, jagħmlu ħafna agħar." (*"I think mostly on the heart, because both can cause heart problems, so both at once, emm, do a lot worse."*) Male former smoker 9, age 21	FS9, S1, S9 (3)
High blood pressure	"Hmm. In that case the only one thing I was told that would be a particular issue, would be the pressure, that I would need to keep an eye on the blood pressure." Male smoker 4, age 27	S4 (1)
Stroke	"Ħeq, jista' jtik stroke" *("Well, you can have a stroke")* Male smoker 9, age 42	S9 (1)
Increased health risks	"Emm… it-tipjip u d-dijabete.. ħeq.. Jiena naħseb li t-tipjip eee jikkaġuna iktar komplikazzjonijiet hu." (*"Emm… smoking and diabetes .. heqqe .. I think eee smoking causes more complications."*) Male former smoker 4, age 58	FS1, FS4, FS10, S2 (4)
Kidney problems	"Naħseb jiena, ħeq ifhima, tista' taffetwalek il-kliewi," (*"I think, well understand this, it could affect your kidneys."*) Male former smoker 7, age 68	FS7 (1)
Neuropathy	"and the nikotina will stock there. I mean it will make problem for your nerve system." Male former smoker 3, age 50	FS3 (1)

Only seven participants were aware of the positive effects of quitting on diabetes (table 5.4). Six participants just referred to having overall better health, while four and two participants understood that they would have better blood circulation, and controlled diabetes, respectively.

Table 5.4: Participants' knowledge on the positive effects of quitting on diabetes

Themes (and sub-themes)	Quote (translated quotes in italics)	Participants' code (number of participants)
Overall better health	"Emmm but I feel that I'm a lot more healthier... Ifhimni, just I feel it, which in itself is a major relevant." Male former smoker 5, age 51	FS5, FS6, FS8, FS10, S1, S9 (6)
Better blood circulation	"naħseb iżjed nkun qed ngħin lili nnifsi minħabba ċ-ċirkolazzjoni għax id-diabetic fiha, fiha eh, ċ-ċirkolazzjoni iżjed importanti hu." (*"I think I could be helping myself more, because of the blood circulation, because diabetes has, has eh, blood circulation is more important.")* Female former smoker 6, age 67	FS2, FS6, S1, S9 (4)
Controlled diabetes	"The diabetes will be more stable then." Male former smoker 2, age 56	FS2, S9 (2)

Despite the above reported knowledge, some participants lacked knowledge on the association and effect of smoking and smoking cessation on diabetes. One former smoker and five current smokers (FS5, S3, S5, S7, S8, S10) lacked knowledge on the additional harmful effects of smoking on diabetes, stating that they were not aware of any effects:

> "laqqas naf x'jistgħu jaffetwaw waħda lil oħra, ħa ngħid il-verita." (*"to tell you the truth I don't know how they affect one another.")* – Male smoker 10, age 79

Nine participants (FS1, FS4, FS8, S3, S5, S6, S7, S8, S10) also lacked knowledge on the effects of quitting smoking on diabetes, stating that they were unaware of the effects of quitting on diabetes:

> "Issa, eh x'jikkaġuna (quitting smoking) minħabba z-zokkor, id-dijabete, ma nafx hekk, dik ma nistax naf, nkun naf x'naqbad ngħid." (*"Now, eh, what's the effect (of quitting smoking) because of blood sugar, diabetes, I don't know, I can't know, I don't know what to say."*) – Male former smoker 4, age 58

Furthermore, several misconceptions on smoking and diabetes were reported by the participants (table 5.5). Seven participants, of whom two were former smokers, believed that smoking helps in diabetes management. Three smokers didn't believe that smoking effects diabetes management.

Table 5.5: Reported misconceptions on smoking and diabetes

Themes (and sub-themes)	Quote (translated quotes in italics)	Participants' code (number of participants)
Believing that smoking helps in diabetes management		
Believing that smoking helps in glucose control	"Meta tpejjep sigarett, iz-zokkor narah ma jitlax. Ngħidu aħna, k'niġi ġol-għalqa, jien, ma nkunx qed naħdem, qed nieħu kafe, u nieħu sigarett, u wara ftit, inħoss iz-zokkor jibda nieżel. Fl-għalqa nkun qiegħed relaxed eh, jiġifieri, u ma, ma jħabbtek ħadd u xejn. Eeee mbagħad jekk ma tieħux dak is-sigarett, qisu tarah tiela." (*"When I smoke a cigarette, my blood sugar doesn't go up. For example, if I go to the field, I wouldn't be working, I would be drinking a coffee and smoking a cigarette, and after some time, I would feel my blood sugar going down. In the field I would be relaxed, eh, and no one and nothing would bother you. Eeee and then if I don't smoke that cigarette, I would feel my blood sugar going up."*) Male smoker 3, age 58	FS9, S2, S3, S4, S6 (5)
Believing that smoking helps to control over eating	"Is-sigarett jżommni lura milli noqgħod innaqqar affarijiet oħrajn.. li mhux tajbin biex itella z-zokkor… Qisu jagħlaqni, daqshekk, (grinning) kilt, ħadt sigarett u daqshekk, waqaft." (*"The cigarette keeps me from picking up on other things ... which are not good for the blood sugar. It's as if it makes me feel full, (grinning) I have eaten, I took a cigarette and that's it, I stopped there."*) Female smoker 2, age 47	FS10, S2, S5 (3)
Don't believe that smoking effects diabetes management	"At first ... I was worried on how it (smoking) would affect me. But then I kept checking before and after to see how it would affect me, but I didn't see any particular issues, so.." Male smoker 4, age 27	S4, S8, S9 (3)

5.6.2.2 Perceived relevant information to support smoking cessation

When asked about the type of information required to support smokers with diabetes to quit, five participants (FS3, FS4, S7, S9, S10) claimed that they would not seek any particular information for quitting smoking:

> "Emm.. naħseb lanqas infittex informazzjoni ta' kieku." (*Hmmm.. I think I wouldn't even look for information, if so."*) – Male smoker 7, age 22

Nonetheless, as seen in table 5.6, most participants (n=10) identified the need for more awareness on the effects of smoking on diabetes, to encourage them to quit smoking, amongst others. Two participants perceived the need for guidance to quit smoking.

Table 5.6: Perceived relevant information to support smoking cessation

Themes (and sub-themes)	**Quote (translated quotes in italics)**	**Participants' code (number of participants)**
More awareness on the effects of smoking on diabetes		
Information on the effects of smoking on diabetes	"Iktar il-ħsara li jista' jagħmlu eh, speċi qisek, bħal teduka, tgħid, 'jagħmlu hekk, jagħmlu hekk, u jagħmlu hekk!' Tgħid 'Ara, hemm, hemm għalxiex nieqaf." (*"More about the damage that it can do, kind of like teaching, telling, 'they do that, do that, and do that!' You then say, 'Look, there is, there is a reason for which I should stop."*) Male smoker 3, age 58	FS1, FS2, FS5, FS7, FS8, FS9, FS10, S3, S4, S5 (10)
Raising awareness on the effects of smoking on diabetes using visual images	"Jiena naħseb li jekk ikun hemm iktar awareness ... Anke jekk hemm bżonn ritratti (of tobacco complications). Dak li jkun, forsi jibża, bħali. Qed tifhem?" (*"If there is more awareness, I think ... Even if there is a need for photos* (of tobacco complications). *Whoever it is, may get scared, like me. Do you understand?"*) Male former smoker 2, age 56	FS2, FS5 (2)
Guidance to quit smoking	"Maybe a guide." Male smoker 4, age 27	S4, S6 (2)
Tips from former smokers	"In-nies li kienu, li kienu fl-esperjenza, li kienu jpejpu u ma baqgħux ipejpu, u jagħtu, jagħtu, jgħinu lil ħaddieħor biex jagħtu l-esperjenzi tagħhom. Xi tips bħal meta nkun ħa nqabbad sigarett, jien naf, per eżempju ġo moħħi jiena ngħid, 'le mhux ħa nqabddu is-sigarett,' għax niftakar f'dak il-kliem." (*"The people who, who went through the experience, who smoked and stopped smoking, and they give, they give, they help others by telling their experiences. Some tips like for when I am about to light a cigarette, I don't know, for example in my mind I say, 'no, I won't light a cigarette,' because I remember those words."*) Female smoker 2, age 47	S2 (1)

5.6.2.3 Perceived impact on increasing awareness of tobacco associated diabetic complications on smoking

Eighteen participants perceived that an increase in awareness of tobacco associated diabetic complications would impact their smoking. Fifteen participants (FS1, FS2, FS4, FS5, FS6, FS7, FS8, FS9, FS10, S3, S4, S5, S7, S8, S9) stated that this would impact out of concern:

> "Għax, ifhem, forsi dawn affarijiet li ma nafhomx, eh. Jew forsi dawn affarijiet li ma nkunx naf bihom, qed tifhem, jew hekk. Jiġifieri, xi ħsara qiegħed nagħmel iktar għax għax diabetic." (*"Because, understand, maybe these are things which I don't know about, eh. Or maybe these are things that I wouldn't know about, are you understanding, or like that. That is, I am doing some harm because I am diabetic."*) – Male smoker 7, age 22

Another three participants (FS3, S1, S2) stated that it would impact their smoking out of fear:

> "Emmeee.. għax nibża mill-futur, qed tifhem … iktar ma tikber, ovjament, apparti li qegħdin nikbru u jista' jinqala kollox, għandi d-dijabete. Jiġifieri ma rridx inżid konsegwenzi" (*"Hmmm.. because I'm afraid of the future, are you understanding… the more I grow up, of course, apart from the fact that we are growing up and everything can happen, I have diabetes. I mean, I don't want to add to any consequences.")* – Female smoker 2, age 47

The remaining two participants did not perceive any impact. One participant (S10) stated that it would not influence him as he is not interested in quitting smoking, while the other participant (S6) stated that it would not support her to quit.

Impact of visual images of tobacco associated diabetic complications on smoking

Ten participants also perceived that seeing visual images of tobacco associated diabetic complications would impact their smoking. Five participants (FS2, FS5, FS7, S3, S8) stated that these would impact them out of concern:

> "Jien naħseb li jaffetwak, naħseb jaffetwak ħafna, meta tara dawk l-affarijiet naħseb, forsi, forsi jġibek f'sensik li qed tagħmel il-ħsara. Naħseb li jaffetwawk hu." (*"I think it affects you, I think it affects you a lot, when you see those things I think, maybe, maybe it makes you feel like you're harming yourself. I think it affects you."*) – Male former smoker 7, age 68

The other five participants (FS3, FS6, FS8, S1, S5) stated that these would impact on smoking out of fear:

> "Ħafna jaffetwani u nibża x'ħin narahom u iżjed jagħmluli kuraġġ biex naqtagħhom (chuckling)" (*"It bothers me a lot and I'm scared when I see them, and it gives me more courage to quit (chuckling)."*) – Female former smoker 6, age 67

In addition, three participants (S1, S3, S5) stated that the use of visuals is likely to bear effect as they were already affected from the warning images on tobacco products:

> "Dan anke tixtri ċertu sigaretti, jkun fihom l-istampa ta' nies bil bil-kanċer, ukoll idejquk." (*"Even when you buy certain cigarettes, they would have a picture of people with, with cancer, it also bothers you."*) – Male smoker 3, age 58)

Conversely the other ten participants did not perceive that seeing such images would impact their smoking (table 5.7). Four participants stated that they would avoid seeing such images, while another four participants stated that they were already not affected by the warning images of tobacco products. Another two participants had low perceived susceptibility to such diabetic complications.

Table 5.7: Reasons for which participants did not perceive that seeing visual images of tobacco associated diabetic complications would impact on smoking

Themes (and sub-themes)	**Quote (translated quotes in italics)**	**Participants' code (number of participants)**
Avoidance	"nipprova ma narahomx, ħa ngħidlek il-verita'." (*"To tell you the truth I would try not to see them."*) Female smoker 6, age 60	FS4, FS10, FS6, S7 (4)
Not affected by the warning images of tobacco products	"Qishom la ma affetwawnix dawk (warning images), ma naħsibx li jaffetwawni għal fuq mard iehor hu." (*"Since those* (warning images) *did not affect me, I don't think other illnesses would affect me"*) Male smoker 10, age 79	FS9, S2, S9, S10 (4)
Low perceived susceptibility	"Mostly because I see them as something that won't happen to me (laughing)." Male smoker 4, age 27	FS1, S4 (2)

Impact of a video clip featuring a person who had stopped smoking because of a tobacco associated diabetic complication on smoking

Most participants (n=17) perceived that watching a video clip featuring a person who had stopped smoking because of a tobacco-related diabetic complication would impact their smoking (table 5.8). Most participants stated that it would impact them out of concern (n=5) and because it would be a real story (n=5). Four participants stated that it would be effective in helping them stop smoking out of fear. Three participants said that it would impact their smoking as it would be easier to follow and understand while two participants said that it would be inspiring.

Table 5.8: Reasons for which participants perceived that watching a video clip featuring a person who had stopped smoking because of a tobacco associated diabetic complication would impact on smoking

Themes (and sub-themes)	**Quote (translated quotes in italics)**	**Participants' code (number of participants)**
Out of concern	"Jiġifieri ehe, jekk turu films awww, n-nies ehe ħa tinfluwenzawhom u forsi tinkoraġġixxi dawn il-persuni biex jaqtgħu s-sigaretti." (*"I mean, yes, if you show movies, the people, yes you will influence them and maybe you would encourage these people to quit smoking."*) Female former smoker 8, age 50	FS1, FS8, FS9, S1, S8 (5)
Real story	"Għax jekk qed tisma lil xi ħadd jgħidlek l-istorja tiegħu, qed jgħidlek minn xiex għadda hu eee once li qatagħhom għax kien jispiċċa hekk, jew għax spiċċa hekk!" (*"Because if you're going to hear someone telling you their story, they're going to tell you what they went through, once he/she quit because he/she was going to end up like that or ended up like that!"*) Female smoker 2, age 57	FS2, FS5, FS7, S2, S5 (5)
Out of fear	"Ħeq, filmat iktar ibeżżek." (*"Well, a video clip would be scarier."*) Male smoker 3, age 58	FS3, FS6, FS10, S3 (4)
Easier to follow and understand	"Ħeq għax int toqgħod tarah il-filmat ... heq bħal rumanz iżjed nieħu pjaċir nisimgħu milli naqrah, għax iżjed ndaħħlu f'moħħi noqgħod nisma u attenta." ("*Well, because you would watch the video clip ... well like a novel, I'd rather listen to it than read it, because I would understand it better, I would listen to it and pay attention."*) Female former smoker 6, age 67	FS4, FS6, S10 (3)
Inspiring	"Eh, it could work as an inspiration" Male smoker 4, age 27	S3, S4 (2)

Three participants did not perceive that such a strategy would impact their smoking habits, out of avoidance (S6), because it wouldn't support quitting (S9) and due to low perceived susceptibility (S7).

Preferred methods to relay visual images or video clips of tobacco associated diabetic complications

Table 5.9 outlines the participants' preferred methods to relay such tobacco associated diabetic complications. Most participants suggested showing visual images or video clips of tobacco associated diabetic complications during face-to-face sessions aimed at raising awareness on the effects of tobacco (n=7) or at the diabetic clinic (n=5), or on social media (n=4). The use of leaflets was mentioned by three participants.

Table 5.9: Participants' preferred methods to relay visual images or video clips of tobacco associated diabetic complications

Themes (and sub-themes)	Quote (translated quotes in italics)	Participants' code (number of participants)
Face-to-face sessions aimed at raising awareness on the effects of tobacco		
One-to-one sessions	"It would be much more ehh time consuming, but I believe a lot in a one-to-one sessions" Male former smoker 2, age 56	FS2, FS7, FS9, FS10 (4)
Group sessions	"Just make make a session, you know, a a big session for the people, I mean, eeeee invite eeee diabetic people" Male former smoker 3, age 50	FS3, FS8, S1 (3)
Diabetic clinic	"Jista, jista jkun id-dijabete, id-diabetic clinic stess ikun hemm xi talks, jew, xi taf kif. Naħseb id-diabetic clinic l-iktar" (*"Maybe, it could be at the diabetic, the diabetic clinic itself. Talks would be held, or, something, you know how. I think mostly the diabetic clinic."*) Female smoker 2, age 47	FS1, FS2, FS5, FS6, S2 (5)
Social media	"Eh meta nkun qed nqalleb facebook u nara per eżempju, xi stampa u hekk.. Ehh.. narahom.." (*"Oh when I would be scrolling on facebook and would see for example, a picture and so .. Ehh .. I would see them.."*) Female smoker 5, age 28	FS5, S2, S4, S5 (4)
Leaflets	"Leaflet qiegħed hemm, qiegħed hemm, u ħa tarah." (*"A leaflet is there, it's there and you would look at it."*) Male smoker 3, age 58	FS5, FS6, S3 (3)

Factors for consideration when relaying visual images or video clips of tobacco associated diabetic complications

The participants also highlighted several factors that need to be considered for better impact. As seen in table 5.10 seven participants highlighted the importance of the live presence of a health professional when conveying such information. Five participants highlighted the importance of accessibility. While three participants highlighted the ease in accessing information on social media, two participants remarked on the ease in accessing information on leaflets as individuals might not have an internet connection. Three participants suggested using a storytelling approach when conveying video messages.

Table 5.10: Factors for consideration when relaying visual images or video clips of tobacco associated diabetic complications

Themes (and sub-themes)	Quote (translated quotes in italics)	Participants' code (number of participants)
Live presence of a health professional		
Live presence of a health professional for impact	"When I am living alone, I am with a different ehhh.. mind setup, that time if I see them, the video clips, I think it will not impact. I think it will impact if you arrange a seminar in front of you ... that time that man will be like this mental setup, that it will impact very fast." Male smoker 1, age 36	FS2, FS9, FS10, S1 (4)
Health professional needs to be present and explain conveyed information	"Jien naħseb, fl-opinjoni tiegħi, jekk turihomlu u tkun qiegħed preżenti u tfehmu l-ħsara li qed jagħmel u tipprova ddaħalielu f'rasu li qed jagħmel, li ħa jġib dik l-estremita', naħseb li taffetwah iżjed jiena." (*"In my opinion, I think, if you show him and you are present and you explain the damage that he is doing and you try to make him understand what he's doing, that he will end up that way, I think it would be more effective."*) Male former smoker 7, age 68	FS7, FS8, S7 (3)
Accessibility		
Ease in accessing information on social media	"I would just picture it coming from YouTube. It would be more comfortable." Male smoker 4, age 27	S2, S4, S5 (3)
Ease in accessing information on leaflets for smokers without an internet connection	"għax jien niġi l-isptar kull ktieb li kien ikun hemm tad-diabetic u tas-sigaretti kollha kont niġborhom u noqgħod naqra fuqhom ... għax in-nies mhux kulħadd għandu l-internet" (*"Because when I used to go to the hospital I used to get all the leaflets that I could find on diabetes and on cigarettes and I would read them ... because not everyone has internet access"*) Female former smoker 6, age 67	FS6, S3 (2)
Storytelling approach	"Dak li jkun jarah, ikun isu bħala storja u mbaghad qisek tifhem." (*"Whoever it is would see it, it would be like a story, which you would understand."*) Male former smoker 4, age 58	FS2, FS4, FS6, (3)

5.6.3 Motivation

Participants reported various motivational factors which encouraged them to stop smoking or to avoid relapse (table 5.11). Sixteen participants mentioned health factors as motivators, in particular diabetic complications (n=13). All former smokers referred to their experienced

health problems as motivators. Ten participants mentioned family factors, i.e., encouragement from spouse and preserving health to enjoy children/grandchildren. Three and two participants referred to contextual factors and former smokers' success stories as motivators, respectively. Only eleven participants (FS3, FS4, FS5, FS6, FS7, FS8, FS9, FS10, S2, S3, S5) stated that having diabetes was a motivation to quit smoking.

Table 5.11: Reported motivational factors to quit smoking or to avoid relapsing

Themes (and sub-themes)	**Quote (translated quotes in italics)**	**Participants' code (number of participants)**
Health factors		
Diabetic complications		
Experiencing diabetic complications	"Iiii the main reason eeerrr the situation from my feet! That's what they make me stop." Male former smoker 3, age 50	FS2, FS3, FS4, FS5, FS7, FS8, FS10 (7)
Knowledge of possible diabetic complications	"Allura pruvajt nagħmel ħilti u, u waqqafthom, għax anke minħabba d-diabetic, ħa jaffetwaw ħafna affarijiet." (*"So I tried to do my best and, and I stopped them, because even because of diabetes, it would affect a lot of things."*) Female former smoker 6, age 67	FS6, FS9, S2, S3, S5, S6 (6)
Respiratory health factors		
Experiencing breathing problems	"għax l-ewwel nett bdejt inħoss in-nifs, qisni anke x'ħin norqod bil-lejl, is-sigarett beda jaffetwali n-nifs." (*"because at first I started to feel breathless, even when I slept at night, the cigarette started to affect my breathing."*) Female former smoker 6, age 67	FS1, FS6, S3, S4, S8 (5)
Fear of the increased impact of COVID-19 when smoking	"One of the major, major for me was the COVID effect ... I've heard of people who contracted the virus and were non non-smokers and had a very bad effect on their lungs, emm scared me a bit." Male former smoker 1, age 61	FS1 (1)
Family factors		
Encouragement from spouse	"My wife (laughing) … It's one of the most motivations I have, jiġifieri I am trying to be honest with you." Male smoker 9, age 42	FS1, FS10, S1, S2, S9 (5)
Preserving health to enjoy children/ grandchildren	"U għandi t-tifel … u ngħid, 'Nixtieq li almenu bid-diabetic ingawdih,' qed tifhimni?" (*"And I have a child ... and I say, 'despite having diabetes I wish I could at least enjoy him,' do you understand me?"*) Female smoker 5, age 28	FS4, FS5, FS8, S5, S7 (5)

Themes (and sub-themes)	Quote (translated quotes in italics)	Participants' code (number of participants)
Contextual factors		
Public smoking restrictions	"Dak kont se nsifer. Kont tiela' l-Liverpool u għidt, għidt, 'se tkun twila biex nagħmel tliet siegħat fuq ajruplan li ma nistax inpejjep." (*"I was going to go abroad. I was going up to Liverpool and I said, I said, 'It's going to take long to smoke having to spend three hours on a plane."*) Male smoker 10, age 79	S4, S10 (2)
Getting a home loan	"Dik tal-loan, taf int, dażż-żmien bla loan ma tixtrix dar allura emm, taf int." (*"For taking a loan, you know, nowadays you can't buy a house without taking a loan, so emm, you know."*) Male former smoker 9, age 21	FS9 (1)
Former smokers success stories	"Naħseb l-iktar ħaġa li kieku tinkoraġġini huma esperjenzi ta' ħaddieħor, emm.. li kienu jpejpu u rnexxielhom jaqtagħhom. Vera nħares lejhom bħala, bħala idoli, bħala heroes, tipo, Wow!" (*"I think the most encouraging thing is the experiences of others, emm.. those who used to smoke and managed to quit. I really look at them as, as idols, as heroes, like, Wow!"*) Female smoker 2, age 47	FS2, S2 (2)
Cost of tobacco	"Financially as well." Male former smoker 1, age 61	FS1 (1)

5.6.4 Behavioural skills

5.6.4.1 Smoking cessation facilitators

Various facilitators to quit smoking were reported by the study participants (table 5.12). The importance of motivational techniques was highlighted by 11 participants. Self-motivation and motivation from others were considered very helpful throughout the quitting process. Furthermore, several participants (n=7) highlighted the usefulness in using helpful distraction (action, mouth and thinking distractions). Three participants remarked the need to take a nicotine replacement to quit smoking.

Table 5.12: Reported facilitators to quit smoking

Themes (and sub-themes)	Quote (translated quotes in italics)	Participants' code (number of participants)
Motivational techniques		
Self-motivation		
Self-motivating talk	"Inżomm f'moħħi illi, 'ejja ħa nagħmilha ħalli r-raġel jkun emm proud illi għamilta,' … 'qeda t-tielet ġurnata bla sigaretti, ejja kompli naqra oħra!" (*"I keep in mind that,'come on let's do it so that my husband can be emm proud that I did it,' ... 'today is the third day without cigarettes, come on let's try further!"*) Female smoker 2, age 47	FS4, FS6, FS8, FS10, S2, S3 (6)
Thinking about experienced health complications	"I kept looking at my chest and picturing a eee a spring inside (chuckling)." Male former smoker 5, age 51	FS2 FS5, FS7, FS10 (4)
Motivation from others		
Motivation from family	"u t tfal jgħiduli, 'Kemm int brava ma,' … u kienu jgħiduli, 'u ejja ma agħmel kuraġġ, isa kemm inti brava u isa!" (*"And my children would say to me, 'How good you are mum,' ... and they used to tell me, 'come on mum be brave, come on, how good you are, come on!"*) Female former smoker 10, age 67	FS9, FS10, S9 (3)
Motivation from former smokers	"Bħal meta jkun hemm f'ta' l-alkoħolic, that you call the sponsor … Iċċempel lil dan il-persuna li jkun għadda minnha, fhimt, u jgħidlek, 'Ejja keep going!" (*"Like when you're in an alcoholic support group, that you call the sponsor ... You call this person who's been through it, do you understand, and he would say, 'Come on keep going!"*) Female smoker 2, age 47	S2 (1)
Helpful distraction		
Action distraction	"Not sitting down, you know. Making that one, making some DIY, go to the field, go for a walk. " Male smoker 9, age 42	S2, S7, S8, S9 (4)
Mouth distraction	"these nicotine inhalers that I bought, so I still have one without nicotine and anything and I just put it in my mouth and that's it." Male former smoker 1, age 61	FS1, FS7 (2)
Thinking distraction	"When I tried to quit smoking I made my mind busy in another thing." Male smoker 1, age 36	S1, S9 (2)

Themes (and sub-themes)	Quote (translated quotes in italics)	Participants' code (number of participants)
Taking nicotine replacement	"Naħseb substitute ta' xi ħaġa, li meta toħoda trid qisa tikkalma l-moħħ, għax hu dik li hemm, taqbdek ansjeta ġo moħħok, meta jtik għal sigarett." (*"I think a substitute for something, that when you take it you would want it as if it makes you feel calm, because that's what it is, you feel anxious when you crave a cigarette."*) Male smoker 3, age 58	FS2, FS9, S3 (3)
Planning ahead	"Allura rrid ngħid, 'mela jien jekk jien ħa jkolli n-nervi, irrid nwarrab minn fejn inkun, ħalli mhux jeħel ma' rasi xi ħadd ieħor." (*So I need to say, 'so, if I am going to be irritable, I need to leave, so that no one else suffers."*) Male smoker 3, age 58	S3 (1)
Not buying cigarettes	"Imma mbagħad iddeċidejt li ma nixtrix sigaretti ħalli żgur ma npejjipx. Dik is-soluzzjoni li waqafthom." (*"But then I decided not to buy cigarettes so I wouldn't smoke for sure. That's how I stopped."*) Female former smoker 6, age 67	FS6 (1)

5.6.4.2 Attitudes towards the use of pharmacotherapy for smoking cessation

On being asked about the use of pharmacotherapy for smoking cessation, only six participants reported positive attitudes towards the use of pharmacotherapy for smoking cessation (table 5.13). Three participants believed that pharmacotherapy is helpful if lacking willpower to quit smoking, while three participants perceived pharmacotherapy to be effective for smoking cessation out of their own personal experience, or of others.

Table 5.13: Positive attitudes towards the use of pharmacotherapy for smoking cessation

Themes (and sub-themes)	Quote (translated quotes in italics)	Participants' code (number of participants)
Helpful if lacking willpower	"Jiġifieri jekk inti ma jkollokx il-dik, li trid tieqaf mis-sigaretti, ħeq bilfors trid tieħu xi ħaġa biex tieqaf." (*"I mean, if you don't have that, the will to stop smoking, for sure you need to take something to stop."*) Female former smoker 6, age 67	FS6, FS10, S4 (3)
Perceived effective		
Perceived effective out of personal experience	"Imbagħad t-tieni darba ħassejt li kelli bżonn. Emm u ħadt nicotine gums u ħassejt li għinuni." (*"But at my second attempt I felt the need. Emm and I took nicotine gums and I felt they helped me. "*) Male former smoker 9, age 21	FS2, FS9 (2)
Perceived effective from the experience of others	"Naħseb. Naf min ippruvahom u vera waqaf" (*"I think so. I know who tried them and succeeded"*) Female smoker 5, age 28	S5 (1)

Conversely, 11 participants reported negative attitudes towards the use of pharmacotherapy for smoking cessation (table 5.14). Pharmacotherapy was perceived to be ineffective by nine participants, also out of personal experiences and of others, while four participants did not perceive its need, stating that having willpower is enough.

Table 5.14: Negative attitudes towards the use of pharmacotherapy for smoking cessation

Themes (and sub-themes)	Quote (translated quotes in italics)	Participants' code (number of participants)
Perceived ineffective		
Perceived ineffective out of personal experience	"Mmm ma tantx nemmen bihom, ta. Għax ippruvajt chewing gum kont, u ppruvajt sticker, maaaaa, ma rajthomx jaffetwawni." (*"Hmm I don't really believe they work. Because I tried the chewing gum, I tried the patch, it didn't seem they worked on me."*) Male smoker 3, age 58	FS5, FS7, S1, S3, S8, S9, S10 (7)
Perceived ineffective from the experiences of others	"Jien ma nemminx bihom. Jien ma nemminx bihom, għax naf min uża anke l-patches imma xorta ma ħadmux." (*"I don't believe in them. I don't believe in them, because I know who used the patches but they still didn't work."*) Female former smoker 8, age 50	FS8, S7 (2)
Unperceived need	"Jien, jiena qatt ma ħadthom dawn l-affarijiet. Jien waqqaft is-sigaretti bil-will tiegħi. Jiġifieri jien dawn l-affarijiet qatt ma ħadthom" (*"I, I never took these things. I quit smoking with my own will power. I mean, I have never had these things."*) Female former smoker 8, age 50	FS3, FS4, FS8, S3 (4)

In addition, two participants (FS1, S6) were uncertain on the effect of using pharmacotherapy for smoking cessation:

> "This time I've tried the nicotine inhalers. I bought them and tried them for about 15 days and since then I haven't used (smoked), so, emm I don't know if they helped or not." – Male former smoker 1, age 61.

Misconceptions were also reported, as three participants (FS1, S2 S6) were concerned about possible health consequences of using pharmacotherapy.

> "Għax per eżempju jiena kont smajt.. tgħidlix xi ħsara jagħmlu, imma smajt li l-patches jagħmlu l-ħsara." (*"Because for example I heard.. don't ask me what harm they cause, but I've heard that the patches are harmful."*) Female smoker 6, age 60

Nonetheless, 10 participants (FS1, FS2, FS9, FS10, S1, S2, S5, S6, S8, S9) stated that they would consider the use of pharmacotherapy for smoking cessation.

5.6.4.3 Attitudes towards health professional smoking cessation support

Seven participants (FS2, FS5, FS8, FS9, FS10, S3, S4) highlighted that there is lack of smoking cessation advice/support, particularly for those who have diabetes:

> "To be honest I had tried to enquire (about increased health risks) as I wasn't given much of eh a concrete response … whenever I used to ask someone like a doctor and they always gave me a generic response of 'Smoking is bad' which I just throw out of the window." – Male smoker 4, age 27)

Most participants (n=16) welcomed the provision of health professional support for smoking cessation. Seven participants (FS6, S3, S4, S5, S6, S9, S10) remarked that such support should provide guidance on how to quit:

> "Għax forsi jien hemm way kif dak li jkun tgħidlu, jgħidlek 'Isma eh biex tieqaf.. " *("Because maybe there's a way to tell someone, he would tell you, 'Listen, eh to quit..")* – Male smoker 3, age 58

Six former smokers (FS1, FS3, FS4, FS6, FS7, FS8) highlighted that in providing support, the health professional/s should inform participants about tobacco associated harm:

> "Naħseb eh, l-unika ħaġa li jipprovaw, ma nafx ta' jiġifieri, jipprovaw jispjegawlek hu, l-ħsara li qed tagħmel u l-ħsara li ħa tasal għaliha, li ma tkunx irreparabli imbagħad wara." (*"I think eh, at least they try, I don't know, but they try to explain to you, the harm that you are doing to yourself and the harm that you are going to get, so it won't be too late then.")* – Male former smoker 7, age 68

On the other hand, three participants claimed that they would not seek health professional support to quit smoking. One former smoker and a current smoker (FS2, S2) would prefer support from former smokers:

> "Naħseb iktar nies ta' esperjenza. Jiena dejjem ngħid illi minn jgħaddi minnha l-affari jaf x'jiġifieri." (*"I think, more people with experience. I always say that whoever goes through it knows what it means."*) – Female smoker 2, age 47

The other participant (S7) would prefer to attempt to quit on his own. Another former smoker (FS5) did not hold an opinion on the provision of health professional support for smoking cessation.

Preferences for smoking cessation support methods

As seen in table 5.15, most participants (n=10) would prefer one-to-one support, mainly face to face. Five participants (FS4, FS7, S1, S6, S8) remarked the need for one-to-one support for self-disclosure of confidential issues associated with smoking:

> "Dawn huma affarijiet one-to-one għax kif qed nitkellem miegħek jien u ngħidlek il-problemi li għandi eżempju, jekk jien ħa nkun ġo klassi miniex ħa ngħidhom ċerti affarijiet fuqi." (*"These are to be done one-to-one because as I am talking to you and for example, I tell you the problems I have, if I'm going to be in a class I won't say certain things about myself."*) – Female smoker 6, age 60

The other six participants preferred support in groups. Of these three participants (FS1, FS8, S3) also remarked the additional support that can be provided by the group members:

> "Il-group stess wkoll jista' jrabbi ċertu ħbiberija u ċerta relazzjoni u wieħed b'kuraġġ tal-ieħor jgħid, 'ara jien irnexxieli, jiena qtajt, jien irnexxieli.' U jekk l-ieħor ma setax, kulħadd jipprova jagħmillu kurraġġ." (*"The group itself can help to build a type of friendship and a type of relationship and one with encourage another, one would say, 'see, I succeeded, I quit, I succeeded.' And if the other couldn't, everyone tries to encourage him."*) – Male smoker 3, age 58

In discussing preferences, the added impact of the live presence of a health professional was highlighted by several participants (FS7, FS8, FS9, FS10, S1, S8, S10):

> "face to face għax forsi anke l-fatt li tħossok tgħid emm 'issa d-darba li jmiss x'ha ngħidlu lil dak li jkun? li erġajt qbadthom?' ... wiċċ b'imwiċċ ikollu mpatt iktar b'saħħtu l-intervent." (*"face to face because maybe even the fact that you feel like saying emm 'now what will I say to him next time? that I started smoking again?' ... the intervention will have a stronger impact if face to face")* – Male former smoker 9, age 21

Four participants (FS1, FS6, FS9, FS10) remarked having smoking cessation support at the diabetic clinic:

> "Probably diabetic clinic when I have an appointment or something like that." – Male former smoker 1, age 61

Table 5.15: Preferred methods of support

Themes (and sub-themes)	Quote (translated quotes in italics)	Participants' code (number of participants)
One-to-one support		
One-to-one face-to-face support	"So it will be very good if you manage the counsel, one by one, alone … infront of the specialist" Male smoker 1, age 36	FS4, FS6, FS7, FS10, S1, S6, S8, S10 (8)
One-to-one support via online chat	"Eh.. I would assume as an online chat" Male smoker 4, age 27	S4 (1)
One-to-one support via telephone	"Naħseb it-telefown ikun aħjar" (*"I think it's better on the phone"*) Male former smoker 9, age 21	FS9 (1)
Support in groups	"I think it's more better in a group than one to one. " Male smoker 9, age 42	FS1, FS3, FS8, S3, S5, S9 (6)

Preferred frequency and duration of health professional led smoking cessation support

When prompted, some participants provided more detail on their preferences for health professional support, discussing frequency and duration. The participants suggested that support should be provided frequently, either once every fortnight (FS4, S3), once every week (FS7, S1, S4), or twice a week (FS1, FS8, FS9, S5, S9, S10) at least on attempting quitting (FS9, S9). The participants also suggested that sessions should typically be between half an hour to one hour long. While the expected duration for the provision of smoking cessation support varied at large, the median number of weeks was found to be six (FS1, FS4, FS7, S1, S3, S4, S5). Nonetheless, three participants (FS8, S6, S9) remarked that the total duration of the provided smoking cessation support should be based on the individual's need:

> "I think it will be a good counsel, you know, counselling, counselling meeting until someone stops.. There is not a period, let's say some people, they stop after two weeks, some people stop after one month. Some people like me, I am talking about me again, they need more than two weeks, more maybe than one month." – Male smoker 9, age 42.

5.6.5 Moderators

The participants identified several barriers and challenges that could impact directly on achieving or maintaining the desired behaviour change or indirectly by influencing the IMB

model constructs or their relationships (table 5.16). Fourteen participants reported experiencing withdrawal symptoms on quitting smoking, particularly nervousness. Nine participants referred to the addiction or habit of smoking which makes it difficult for them to quit. For several participants (n=7), having diabetes was identified as a challenge or barrier to quit smoking, most notably in maintaining diabetes management on quitting. Six participants mentioned that smoking helps them to cope with stress/sadness, making it difficult to quit smoking. Other participants referred to unfavourable social factors (n=3) and having cigarettes available (n=2).

Table 5.16: Reported barriers and challenges to quit smoking

Themes (and sub-themes)	Quote (translated quotes in italics)	Participants' code (number of participants)
Withdrawal symptoms		
Nervousness	"emmm.. bdejt inħossni ħafna iktar nervuża. Uuu naħtaf! Tipo, taf kif, bla paċenzja." (*"emmm.. I started to feel a lot more nervous. And grouchy! Like, you know, impatient."*) Female smoker 2, age 47	FS3, FS7, FS8, S2, S3, S4, S5, S6, S7, S8, S9 (11)
Sadness	"Kont nibki. Jien bkejt. Fhimt u dwejjaq, kelli dwejjaq." (*"I used to cry. I cried. Do you understand, and sadness, I was sad."*) Female former smoker 10, age 67	FS10, S1, S2 (3)
Cravings	"Hmmm… The cravings number one." Male former smoker 5, age 51	FS5 (1)
Lack of concentration	"If I don't have a cigarette … I cannot take my mind on my work, on talking, like that." Male smoke 1, age 36	S1 (1)
Smoking addiction/habit		
Smoking addiction	I mean obviously there is also the addiction to the, to the nicotine as well." Former smoker 5, age 51	FS2, FS5, FS6, S5, S10 (5)
Smoking habit	"Jekk ħa noħroġ ħames darbiet bil-karozza biex immur nieħu xi measurements, dawk huma ħames sigaretti, għax jiena u nsuq, biss inhosshom." (*"If I go out five times by car to go get some measurements, those are five cigarettes, because I only need to smoke while driving."*) Male smoker 3, age 58	FS3, FS4, S1, S3 (4)
Having diabetes		
Maintaining diabetes management on quitting smoking		
Eating more on quitting which does not help diabetes management	"You start eating more. And in my position I can't start eating more, you know." Male smoker 9, age 42	FS7, FS8, FS9, S2, S9 (5)
Loosing glucose control on quitting	"Id-diffukultajiet kienu ... bdejt nitlef il-kontroll tal, taz-zokkor." (*"The difficulties were ... I started to lose sugar control."*) Female smoker 2, age 47	FS7, FS8, FS9, S2 (4)

Themes (and sub-themes)		Quote (translated quotes in italics)	Participants' code (number of participants)
	Smoking to cope with having diabetes	"dak iż-żmien kienet taboo li tkun dijabetku jiġifieri, qisni kont ninfexx fis-sigaretti" (*"At that time it was a taboo to be diabetic, that is, I used to smoke a lot of cigarettes to cope"*) Male former smoker 7, age 68	FS7, S5, S6 (3)
	Already feeling restricted because of diabetes	"Forsi li jiena ma nistax naqtgħu jew miniex interessata li naqta, emmmee minħabba li aħna għandna … noqogħdu lura minn minn wara l-ikel nieħdu deżertaaa, noqogħdu lura minn alcoħol għax itella z-zokkor.." (*"Maybe I can't quit or I'm not interested in quitting, emmmee because we have … to refrain from taking a dessert after eating, we refrain from alcohol because it raises the blood sugar."*) Female smoker 2, age 47	FS7, S2 (2)
Coping with sadness/stress			
	Coping with sadness	"Jien ngħid għalija nippreferi ngħid, 'pejjipt sigarett,' milli taqa f'dipressjoni jew hekk," (*"I'd rather say, 'I smoked a cigarette,' than fall into a depression or so,"*) Female smoker 5, age 28	FS3, S1, S5, S8 (4)
	Coping with stress	"Iva jitlali l-stress, u s-sigarett jien kien jikkalmani. Jien anke naqra ħsibijiet, ċlupp! Immur inqabbad sigarett." (*"Yes, the cigarette used to calm me down when in stress. Even just some thoughts, boom! I'm going to light a cigarette."*) Female former smoker 10, age 67	FS2, FS10 (2)
Unfavourable social factors			
	Family or friends who smoke	"Emmm.. mmm major one was obviously that I have, I had some friends that smoked as well … which made it a bit harder." Male former smoker 1, age 61	FS1, S6 (2)
	Lack of support	"Imma mbagħad il-ġlieda kienet nahseb għax kienet waħdi wkoll." (*"But then it was hard, I think, because I was on my own."*) Female smoker 2, age 47	S2 (1)
Having cigarettes available		"Ma tistax tixtri sigarett u tpejpu u daqshekk ma terġax tpejjep. Malli xtrajt pakett imbagħad … taf inti tqabbadhom, hekk." (*"You can't buy a cigarette and smoke, and that's it you don't smoke again. As soon as you buy a packet … you know you will eventually smoke them, so."*) Male former smoker 9 age 21	FS9, S3 (2)

In addition to these identified factors, it was also observed that some smokers attempted to minimise the harmful effects of smoking, which undervalued smoking cessation efforts. Three smokers (S2, S7, S8) downplayed the harmful effects of smoking, such as by referring to known persons who did not smoke and had cancer:

> "dan bħal meta jien naf, xi ħadd, per eżempju jgħidlek, 'Isma, ieqaf pejjep minħabba l-lungs u għaxx, għax, minħabba l-kanċer,' u hekk. Pero jien naf ħafna wkoll nies li mietu bil-cancer u kienu the healthiest ever, jiġifieri!" (*"it's like when, I don't know, someone, for example tells you, 'Listen, stop smoking for your lungs and because of cancer,' and so on. But I also know a lot of people who died of cancer and were the healthiest ever, that is!"*) – Female smoker 2, age 47

On the other hand, four former smokers remarked feeling better on quitting smoking, which encourages them to keep abstinent from smoking:

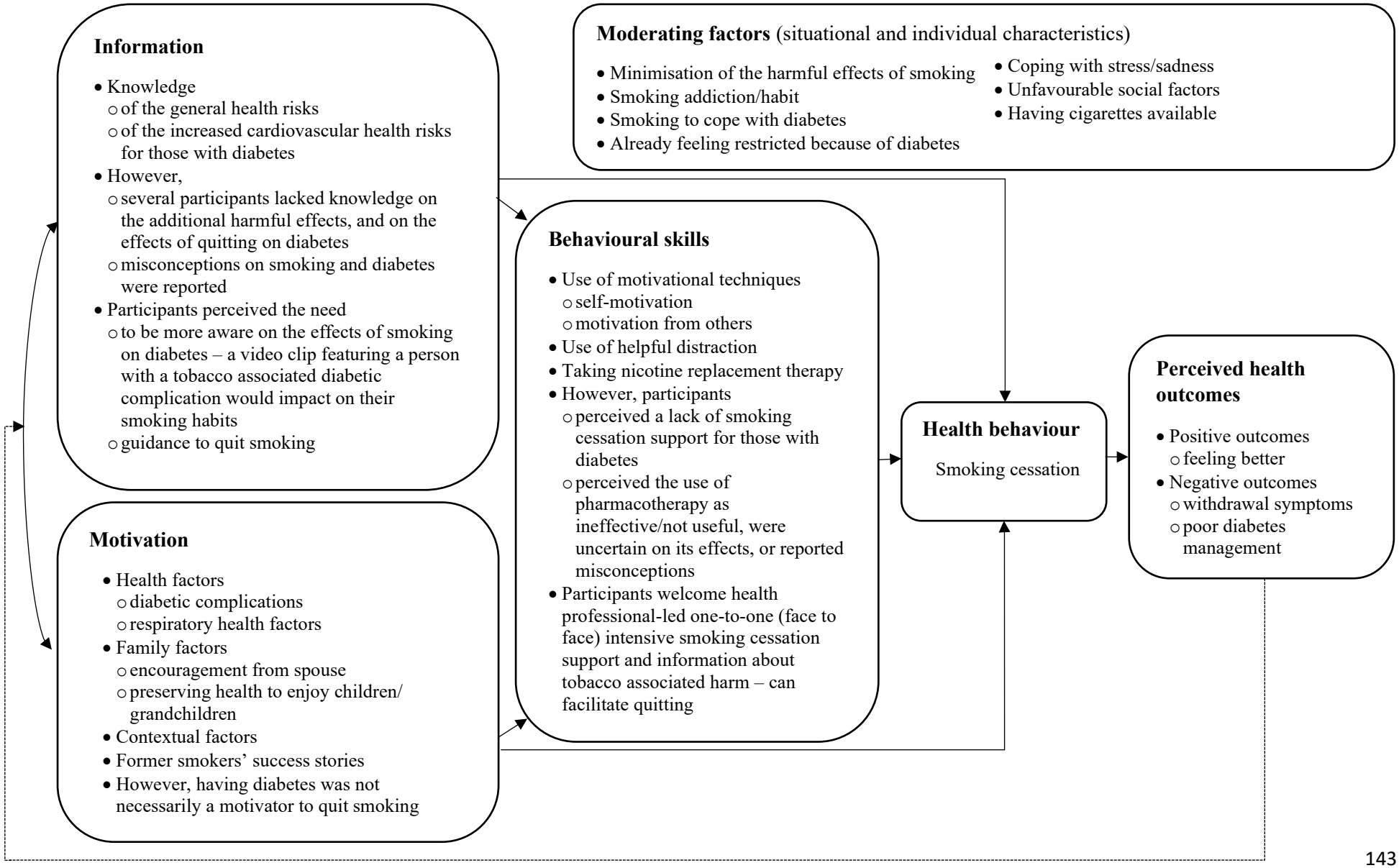
> "Jien inħossni tajba hu! Inħossni tajba. Xorta li għandi għadu hemm. Imma nħossni aħjar hu mingħajr is-sigaretti." (*"I feel good eh! I feel good. What I suffer from is still there. But I feel better without cigarettes"*) Female former smoker 8, age 50

5.6.6 Summary of findings – the population specific IMB strengths and deficits and moderating factors to behaviour change

The main findings from this study are summarised using the IMB model in figure 5.2 below. The IMB deficits identified include: a lack of knowledge on the additional harmful effects of tobacco on diabetes, and the effects of quitting on diabetes, and misconceptions on smoking and diabetes (information); the fact that having diabetes was not necessarily a motivator to quit smoking (motivation); and a perceived lack of smoking cessation support for those with diabetes, and negative perceptions/ uncertainty/ misconceptions on the use of pharmacotherapy for smoking cessation (behavioural skills). Furthermore, the following negative moderators were observed: the minimisation of the harmful effects of smoking; the smoking addiction/habit; smoking to cope with diabetes and feeling already restricted because of diabetes management; coping with stress/sadness; unfavourable social factors (e.g. family and friends who smoke); and having cigarettes available. Despite reporting feeling better on quitting smoking, which encouraged abstinence, participants also reported negative health outcomes, such as poor diabetes management and withdrawal symptoms, which discouraged

smoking cessation. Nonetheless, several IMB strengths were also identified which can be capitalized on in addressing the IMB deficits and moderators for encouraging smoking cessation. These include: knowledge of the general health risks and the increased cardiovascular health risks for those with diabetes; a perceived need for more awareness on the effects of smoking on diabetes (such as by featuring a person with a tobacco associated diabetic complication in a video clip) and guidance to quit smoking (information); various motivational factors (motivation); and use of motivational techniques; helpful distraction; taking nicotine replacement therapy; and health professional intensive smoking cessation support (behavioural skills).

Figure 5.2: Main findings based on the IMB model



5.7 Discussion

5.7.1 Information

Despite being aware of the general health risks caused by smoking and the additional health risks for those who have diabetes (including a certain degree of awareness of the benefits on quitting smoking) participants still lacked knowledge on the association and effect of smoking and smoking cessation on diabetes. Participants lacked accurate information, reporting misconceptions on smoking and diabetes, such as believing that smoking helps in diabetes management. This is consistent with previous literature; both in studies carried out amongst individuals with type 2 diabetes (Chau et al., 2015; Georges et al., 2019) and also amongst those with type 1 diabetes (Abu Ghazaleh et al., 2018; Haire-Joshu et al., 1994; Wakefield et al., 1997, 1998).

Nonetheless, as was found in Abu Ghazaleh et al.'s (2018) study, most participants in this study identified the need for more awareness on the effects of smoking on diabetes to support them in smoking cessation. This confirms the observed lack of awareness on the effects of smoking on diabetes and the need of more information for behaviour change, as postulated by the IMB model. Health professional advice on the effects of tobacco was in fact found to facilitate attempts to quit in Chau et al.'s (2015) study.

Unlike previous studies, this study explored further the need of having more awareness on the effects of smoking on diabetes, identifying a perceived impact on smoking habits mostly out of concern or fear. While the use of visual images of tobacco associated diabetic complications was identified as a possible effective method for relaying information on smoking and diabetes in the systematic review, this study suggests otherwise, as the participants portrayed mixed feelings about this. Noar et al. (2016), state that while the use of pictorial warnings, to which participants referred to, has been found to elicit negative attitudes towards smoking, effectively increasing intentions to quit, they recommend caution on using such methods as these can also increase aversiveness possibly leading to maladaptive responses, such as denial or avoidance. Given that some participants in this study stated that they would rather avoid such messages, the use of visual images of tobacco associated diabetic complications was thus not recommended to be part of the proposed smoking cessation intervention.

On the other hand, the use of video messages featuring former smokers' true stories of suffering from smoking related disease was identified as a promising tool to encourage smoking

cessation. This is because the participants in this study reported being more receptive to such messages, perceiving an impact on their smoking habits. It is likely that the participants were more likely to perceive such video clips as promoting self-efficacy as such an individual would have quit smoking. The perceived need of the live presence of a health professional when conveying such information reaffirms the need of a supporting role for promoting self-efficacy when depicting such threat eliciting messages.

5.7.2 Motivation

Similar to previous literature (Abu Ghazaleh et al., 2018; Albaroodi et al., 2018; Chau et al., 2015; Folan et al., 2014; Georges et al., 2019), most participants identified health as their primary motivator to quit smoking and stay off smoking. However, less participants stated that having diabetes was a motivation to quit smoking. This finding was also observed in Georges et al. (2019), where participants were less concerned about smoking when having diabetes as they did not perceive an impact of smoking on their diabetes management. It is likely that some of the participants in this study also held the same assumption, having not yet experienced any ill-health effects. Similar to the studies by Abu Ghazaleh et al. (2018), Albaroodi et al. (2018), Chau et al. (2015), Folan et al. (2014), and Georges et al. (2019), several participants mentioned family factors as a motivator to quit smoking and avoid relapse.

5.7.3 Behavioural skills

In this study several facilitators or skills for smoking cessation were identified. The need for ongoing motivation, stemming from self-talk, increased health awareness and family support, amongst others, was remarked by most participants. This is consistent with the literature, where participants also referred to increased health awareness (Abu Ghazaleh et al., 2018) and family support (Abu Ghazaleh et al., 2018; Chau et al., 2015; Haire-Joshu et al., 1994) as being facilitators for to quit smoking. Use of helpful distractions, which was remarked by several participants in this study, was also recommended by the participants in Abu Ghazaleh et al.'s (2018) study.

As in previous studies (Abu Ghazaleh et al., 2018; Chau et al., 2015), the participants in this study also stated that health professional support could facilitate smoking cessation. Health professionals can tackle the identified IMB deficits and negative moderators to behaviour

change by helping smokers overcome the identified smoking related barriers and challenges through the generation of problem-solving strategies as outlined in the 5As (and 5Rs) framework for smoking cessation (World Health Organization, 2014). This study also explored participants' preferences for health professional support to quit smoking. Despite the COVID-19 pandemic imposed social restrictions at the time of the study, most participants still expressed the need for face-to-face contact for more impact, preferring one-to-one support particularly for disclosing confidential issues. According to the study participants, sessions should not be brief in nature and should be provided frequently when attempting to quit smoking, which is in line with the systematic review's findings (chapter 4). Some participants also remarked that there is a lack of smoking cessation support for those with diabetes recommending support within diabetic clinics. This suggests further the need to integrate smoking cessation support within diabetes management.

While only half of the participants in this study were in favour of using pharmacotherapy for smoking cessation (as was similarly reported in previous literature; Abu Ghazaleh et al., 2018; Wakefield et al., 1997) the participants in this study may have not been well informed on the benefits and on the use of pharmacotherapy for smoking cessation. Furthermore, those who found it ineffective may have not been using it correctly. This warrants the need for providing more information on the benefits and on the use of pharmacotherapy for smoking cessation to target the identified negative attitudes, uncertainties, and misconceptions.

5.7.4 Moderators

This study identified several barriers and challenges, or negative moderators to behaviour change, which were also previously remarked in the literature. In previous studies, several participants also stated that they found it difficult to quit smoking because of withdrawal symptoms, such as nervousness (Georges et al., 2019) and cravings (Abu Ghazaleh et al., 2018; Ardron et al., 1988; Folan et al., 2014), and because of the smoking addiction/habit (Abu Ghazaleh et al., 2018; Albaroodi et al., 2018; Chau et al., 2015; Georges et al., 2019; Wakefield et al., 1997). Such challenges in quitting re-confirm the need of counselling strategies, as highlighted in the 5As (and 5Rs) framework (World Health Organization, 2014), for the identification of high-risk situations of smoking and the generation of problem-solving strategies and the use of Nicotine Replacement Therapy (NRT) for managing nicotine addiction and withdrawal symptoms.

Having diabetes was also remarked as a challenge in previous literature (Ardron et al., 1988; Chau et al., 2015; Georges et al., 2019; Haire-Joshu et al., 1994; Wakefield et al., 1997, 1998) in particular because of possible weight gain (Chau et al., 2015; Haire-Joshu et al., 1994; Wakefield et al., 1997, 1998) or glycaemic imbalance (Georges et al., 2019). This confirms the need for specific smoking cessation support for those who have diabetes. Consistent with previous literature (Albaroodi et al., 2018; Chau et al., 2015; Folan et al., 2014; Haire-Joshu et al., 1994; Wakefield et al., 1998), several participants in this study also remarked that quitting smoking was a challenge because smoking was identified as a way to cope with stress, warranting the need of counselling approaches for the identification of alternative healthier coping mechanisms.

Unlike in Wakefield et al.'s (1997) and Georges et al.'s (2019) studies, few participants minimised the harmful effects of tobacco in this study. It is however worth noting that when compared to these studies there were more participants who suffered from diabetic complications. Having experienced diabetic complications themselves, such participants may have been more likely to believe that tobacco can indeed result in such harm. Nonetheless, such false beliefs remark once again the need for more influential methods of conveying tobacco related harm such as by using video messages which depict the real personal experiences of tobacco harm of former smokers, for enhanced relatability, and receptivity of the conveyed messages.

5.7.5 Strengths and limitations

This is the first qualitative study guided by the IMB model which explored the specific needs of both individuals with type one and type two diabetes to quit smoking, and their views of the identified promising smoking cessation components. The use of the IMB model helped to identify the population specific IMB strengths and deficits, and the possible moderators that can impact on smoking cessation for the development of a targeted smoking cessation intervention for individuals with diabetes. While Georges et al.'s (2019) study was also guided by the IMB model, they only interviewed individuals with type 2 diabetes. Furthermore, they did not report the views and experiences of former smokers with type 2 diabetes in their study.

The use of purposive sampling ensured adequate representation by gender, age, educational and occupational levels, and different diabetes and smoking profiles. This ensured that the sample consisted of individuals with varying characteristics, including factors associated with

continued smoking amongst individuals with diabetes, such as heavy smoking habits, lower socio-economic and educational levels and absence of diabetic complications (Cho et al., 2018; Gariepy et al., 2011). Nonetheless, none of the identified participants smoked or used to smoke tobacco on an occasional (weekly) basis. Occasional smokers and former smokers who previously smoked on an occasional basis may have different needs and preferences than those identified in this study.

Another limitation of this study was that focus group interviews could not take place because of the COVID-19 pandemic social restrictions imposed at the time of the study. While individual phone interviews were more appropriate at that time, these resulted in loss of nonverbal information, which may have affected the contextual interpretation of responses. Nonetheless, the use of phone interviews still provided an in-depth understanding of the participants' needs and preferences resulting in rich data, successfully answering the aim and objectives of the study, thus demonstrating data saturation (Bradshaw et al., 2017)

5.8 Implications for the development of the smoking cessation intervention

This study helped to explore the views of individuals with diabetes of the identified promising smoking cessation components, validating the previously posed recommendations: raising awareness on the effects of smoking on diabetes, by showing video messages featuring former smokers' true stories of suffering from smoking related disease; and the provision of long and frequent smoking cessation counselling sessions, such as those based on 5As (and 5Rs) framework (World Health Organization, 2014). While several motivational factors and facilitators to quit smoking where identified, which can be capitalised on in the development of a smoking cessation intervention for individuals with diabetes, this study also helped to identify the needs of individuals with diabetes to quit smoking, based on the identified IMB deficits and negative moderators to smoking cessation. These re-confirmed the need for more awareness efforts on the effects of smoking on diabetes, the need for counselling strategies as outlined in the 5As (and 5Rs) framework (World Health Organization, 2014), the use (and explanation of the benefits) of NRT for smoking cessation, and the need for diabetes-specific

smoking cessation support, identifying an opportunity of introducing evidence-based smoking cessation support as part of local diabetes education efforts.

Based on this study's findings, a tentative model of a smoking cessation intervention was developed. This was presented to the diabetes nurse educators as potential intervention providers. The following chapter describes the proposed intervention and the training programme that was provided to the nurses so that they could deliver the intervention.

5.9 Conclusion

This chapter reported a qualitative descriptive study undertaken to explore the needs of individuals with diabetes to quit smoking, and their views of the identified promising smoking cessation components. Guided by the IMB model of behaviour change, this study found that individuals with diabetes need more information on the effects of smoking to diabetes to encourage smoking cessation. While several motivational factors and facilitators to quit smoking where identified, several challenges and barriers were remarked by the participants. Nonetheless, most participants welcomed and outlined preferences for the provision of health professional support for smoking cessation, identifying the need of smoking cessation support within diabetes clinics. The use of video messages featuring former smokers' true stories of suffering from smoking related disease was also identified as a promising tool to encourage smoking cessation. While only half of the participants in this study were in favour of using pharmacotherapy for smoking cessation, the participants in this study may have not been well informed on the benefits and on the use of pharmacotherapy for smoking cessation. Furthermore, those who found it ineffective may have not been using it correctly. Given the remarked benefits in using pharmacotherapy for smoking cessation, the use and provision of more information on the use pharmacotherapy for smoking cessation was recommended. The following chapter describes the proposed intervention, and the training programme that was provided to the nurses.

Chapter 6: The outline of the smoking cessation intervention developed, and the training programme provided

6.1 Introduction

The purpose of this chapter is to describe the proposed intervention and its programme theory, and the training programme, that was provided to help ensure that the intervention is delivered as intended. Hence, section 6.2 describes the proposed intervention (and the programme theory), while section 6.3 describes the training programme provided. Section 6.4 briefly outlines the next phase of the doctoral research project, while section 6.5 is a conclusion to this chapter.

6.2 The proposed intervention and its programme theory

As was discussed in sections 5.3 and 4.6, the mechanisms of the study intervention were theorised as per the IMB model for achieving and sustaining behaviour change (Fisher et al., 2006; Fisher et al., 2003), while the 5As (and 5Rs) algorithm (World Health Organization, 2014), was used as to structure the intervention pathway, linking activities to the desired outcomes. Collectively these elements explain the programme theory, i.e., how the intervention is expected to lead to its intended outcomes within its context (Skivington et al., 2021).

6.2.1 The theoretical foundation of the intervention

After identifying the needs of individuals living with diabetes to quit smoking (first step of the IMB approach for understanding and promoting behaviour change – reported in chapter five), the design of a population-specific intervention based on evidence (findings from chapters three, four and five) and theory, followed (Fisher et al., 2003). Guided by the IMB model as its theoretical foundation, the proposed intervention was designed to:

- inform the individuals with diabetes who smoke on the association between smoking, the complications of diabetes and the benefits of quitting smoking;
- motivate and encourage these individuals to quit smoking and/or remain abstinent; and
- support them in developing/using the appropriate behavioural skills to quit smoking and avoid relapse.

6.2.1.1 Information

In terms of the information, the intervention includes information on the increased health risks associated with smoking, such as the increased risk for poor glucose and lipid control, and the increased risk for cardiovascular diseases and mortality (as outlined in chapter one). Furthermore, as recommended in section 3.8 and 5.8, the intervention includes informational video clips which feature a person with tobacco associated diabetic complications (as depicted in the Tips from Former Smokers' campaign (Centers for Disease Control and Prevention (CDC), 2022). Thus, to raise awareness on the link between smoking and diabetes to encourage quitting, apart from providing prospective participants with information on the effects of smoking and smoking cessation on diabetes, these are also introduced to the story of Bill, featured in the 'Tips' campaign (CDC, 2022). Bill was an individual with type one diabetes who lived with and died of the tobacco associated complications of diabetes - kidney failure, poor circulation, heart disease and blindness (CDC, 2022). Prospective participants are then shown the three clips in which he explains the serious health problems he was experiencing and the importance of quitting smoking. Furthermore, they are also informed of the health benefits of quitting smoking, such as improved glycaemic and lipid control and decreased risk for cardiovascular diseases and mortality (as outlined in chapter one).

6.2.1.2 Motivation

As the IMB model asserts, the provision of such information can have a direct effect on motivating prospective participants and encouraging behaviour change (Fisher et al., 2006; Fisher et al., 2003). Nonetheless, in the case of unmotivated participants, defined as participants who are unsure or do not want to quit smoking in the next two weeks and/or not confident in doing so, other motivational strategies are to be employed to encourage smokers to quit (World Health Organization, 2014). Thus, the 5Rs (Relevance, Risks, Rewards, Roadblocks and Repetition) framework is followed for those who are not motivated, i.e., those who are unwilling to set a quit attempt (World Health Organization, 2014). Such participants are asked about how quitting is personally relevant to them, discussing risks and benefits

(rewards) and any identified challenges (roadblocks), reassessing commitment to change (repetition). These motivational techniques are not only used to help smokers quit but also used throughout the process to help sustain participants' intention to quit and remain abstinent.

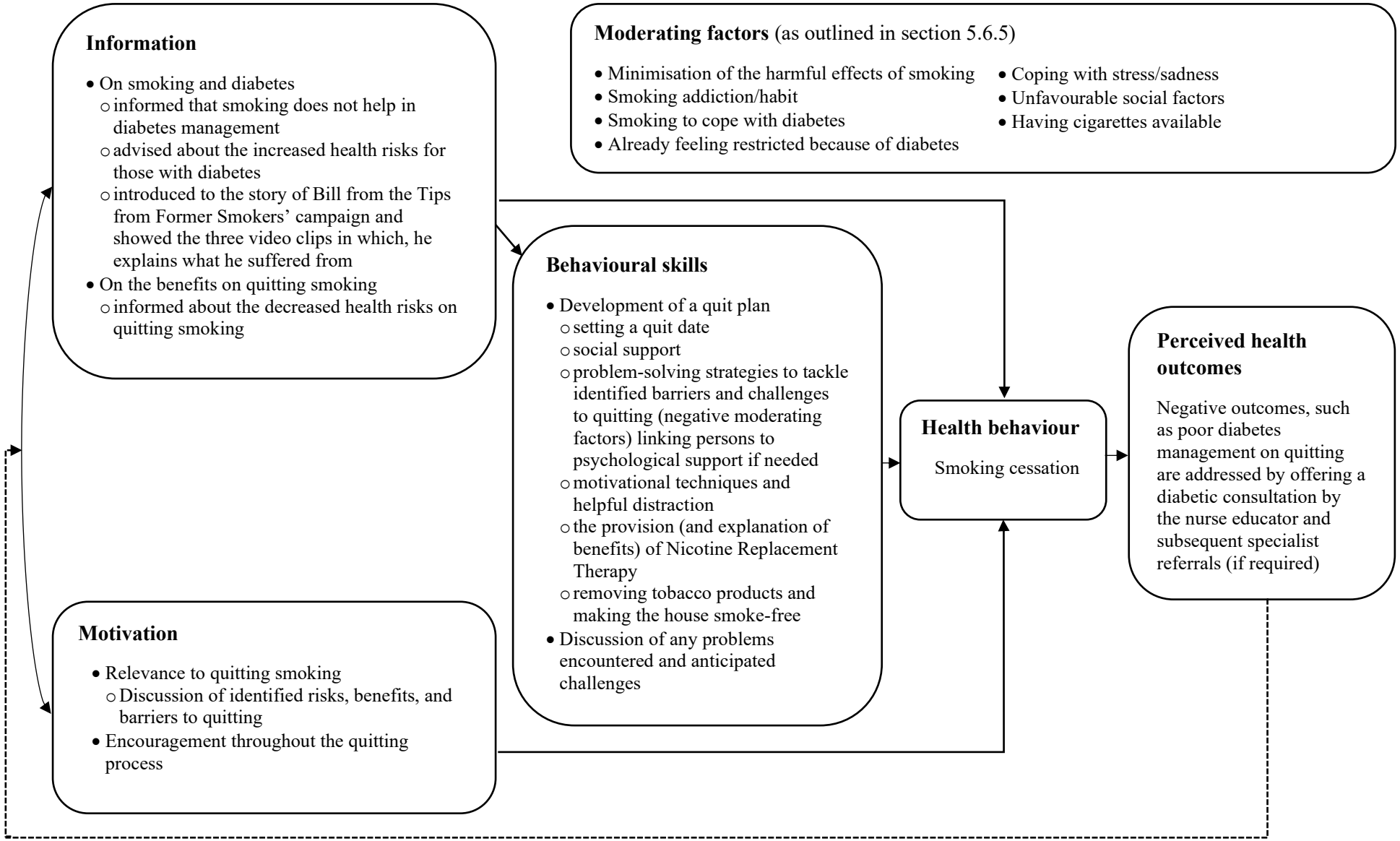
6.2.1.3 Behavioural skills

As part of the intervention, prospective participants are also supported in their quitting process through the development/recommendation of behavioural skills to quit smoking. As per the 5As framework and the findings reported in chapter five, prospective participants are helped to develop a quit plan, which includes the recommending (explaining the use and benefits) and provision of Nicotine Replacement Therapy (NRT; as was suggested in sections 3.7.4 and 4.6). Any situational and individual characteristics (moderators) which can negatively influence smoking cessation (such as those reported in chapter five) are also discussed. Given that negative health outcomes, such as poor diabetes management, can weaken the IMB constructs reducing adherence to the new behaviour (as outlined in section 5.6.6), participants are offered a diabetic consultation by the nurse educator (and subsequent specialist/s referrals, if required) if they experience poor glycaemic control, or are concerned about diabetes management following a change in diet or weight gain on quitting smoking.

Thus, to inform, motivate and support individuals with diabetes who smoke to develop/use the required behavioural skills to quit smoking, the developed intervention included three main components: smoking cessation behavioural support based on the 5As (and 5Rs) framework; informational video clips featuring Bill, an individual with diabetes who used to smoke from the 'Tips' campaign; and, the provision of NRT to support quitting. Further details on the support provided, to explain further how the intervention's activities are expected to lead to the intended outcomes (the programme theory), is described in the next sub-section.

Figure 6.1 is the theoretical model of the intervention based on the IMB model (Fisher et al., 2006; Fisher et al., 2003), outlining the strategies for addressing the IMB constructs (and any negative moderators and health outcomes) for achieving and sustaining smoking cessation among individuals with diabetes. A tentative model which outlines the process based on the 5As and (5Rs) framework (the intervention pathway) is presented and described in sub-section 6.2.2.

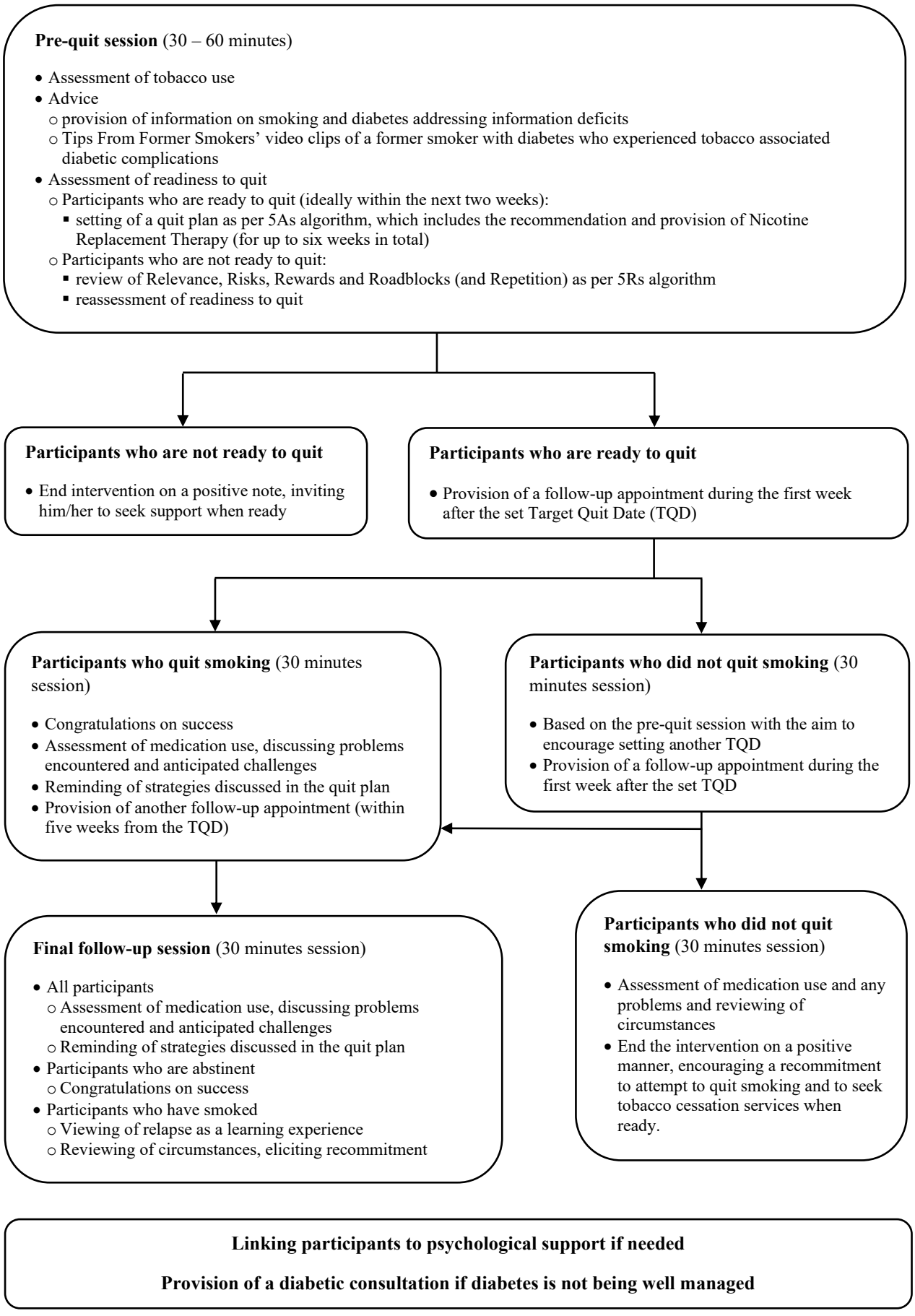
Figure 6.1: Strategies employed to address the IMB constructs for smoking cessation



6.2.2 The intervention pathway

To inform, motivate and support prospective participants to use the required behavioural skills to quit smoking (as described in the previous sub-section), the 5As (and 5Rs) algorithm (World Health Organization, 2014) was used as a guiding framework. Thus, after approaching the diabetes practice nurses to take part in this project (as outlined in sections 1.4.6 and 5.8), a tentative model for delivering the smoking cessation intervention based on the 5As (and 5Rs) framework, which draws on the recommendations reported in the previous chapters, was then developed. This is displayed in figure 6.2 below. A detailed explanation of the content of the sessions is described in the sub-sections below. Based on this content, a structured guide, which was followed in delivering the intervention, was developed and is presented in Appendix 6.1

Figure 6.2: Tentative model of the smoking cessation intervention



6.2.2.1 Session one – pre-quit session

In the first session, which lasts between 30 to 60 minutes, prospective participants are informed on the effects of tobacco on diabetes and encouraged and supported to quit smoking. Initially, tobacco use is assessed by asking or verifying (using the information provided in the baseline questionnaire) the number of cigarettes/tobacco products smoked every day (Ask). Prospective participants are informed on the effects of smoking on diabetes, and on the benefits of quitting as described in section 6.2.1.1 (Advise). They are also shown the three clips (with English subtitles) of Bill from the Tips from Former Smokers' campaign (CDC, 2022). In the first clip (31 seconds long), he briefly explains the health problems he developed, suggesting that smokers should make a list of everything they are willing to give up if they want to continue to smoke. In the second clip (one minute and 19 seconds long), Bill recounts on when he started smoking, ignoring his doctor's warning that smoking could make his diabetes worse. He also explains that life became more different and more challenging as he lost a leg, the functions of the kidneys, and the sight in one eye. In the last clip (one minute and 18 seconds), Bill emotionally recounts the problems he and his family faced because of smoking, encouraging others to quit smoking too. Following the video messages, and a brief reflection on the messages, prospective participants are advised to quit smoking in view of the health benefits, such as improved glycaemic and lipid control and decreased risk for cardiovascular diseases and mortality.

As per the 5As (and 5Rs) framework (World Health Organization, 2014), readiness to set a quit attempt within the next two weeks is assessed (Assess). The 5Rs algorithm (Relevance, Risks, Rewards, Roadblocks and Repetition) is followed for those who are unsure or not willing to quit smoking and/or not confident in attempting quitting (described in section 6.2.1.2). If a participant is not ready to attempt to quit, the intervention ends on a positive note, encouraging the participant to seek health care professional support when ready to quit smoking.

Conversely, those who are ready to quit are helped in developing a quit plan as per the 5As framework (Assist). This includes:

- setting a target quit date (TQD) in the next two weeks;
- telling family, friends and co-workers about their decision and asking them for support;
- the generation of problem-solving strategies to tackle identified barriers and challenges to quitting, such as those identified in the qualitative descriptive study (chapter five):

- the smoking habit and addiction,
- smoking as a coping mechanism, e.g. to cope with diabetes or cope with stress/sadness (linking individuals to psychological support if experiencing depression or anxiety, or on further discussion with participants who were identified as potential cases on the Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983), as explained in section 7.4.4.4,
- unfavourable social factors,
- false beliefs about smoking and managing diabetes (recommending the monitoring of blood glucose during the quitting process),
- and negative attitudes towards the use of pharmacotherapy;

- encouraging the use of motivational techniques and the use of helpful distraction as part of a guide to quit smoking (as suggested in chapter five), referring to what would be relevant for the participant if he/she quits smoking (to motivate him/her further);
- recommending, explaining the use and benefits of NRT (as recommended in section 5.8), and providing a supply of NRT for the quitting attempt up till the follow-up session (described in detail in section 6.2.2.3); and
- removing tobacco products and making the house smoke-free.

These participants are then provided with a follow-up appointment during their first week after their quit attempt (Arrange).

6.2.2.2 Sessions two and three (and four, if required)

The second session is usually held in the second or third week, depending on the set TQD. In this session, which takes about 30 minutes, participants are asked about their quit attempt. If the participant reports being abstinent from smoking (i.e. did not even have a puff for at least 24 hours before the follow-up session), the aim of the session is to help him/her avoid a relapse. Conversely, if the participant does not quit smoking, the aim of the session is to encourage him/her to set another TQD and support him/her in quitting smoking.

Those who do not manage to quit smoking are assessed about NRT use and any problems encountered, discussing experienced barriers and challenges. Participants are encouraged to attempt quitting again and thus helped in developing another quit plan (as described in section 6.2.2.1), providing a supply of NRT for the quitting attempt up till the follow-up session (if

required). If in their follow-up session (session number three) they fail to quit smoking, the intervention ends on a positive note, encouraging a recommitment to attempt to quit smoking and to seek tobacco cessation services when ready.

Conversely, for those who report being abstinent from smoking at their second session or at their third session (for those who attempt quitting smoking again) the aim of these sessions (and of the final follow-up session which is provided within five weeks from the successful TQD) is to encourage and support the participants in avoiding a relapse. At each session, the participants are congratulated on remaining abstinent. Any problems encountered and anticipated challenges are discussed. Strategies outlined in the quit plan are also reinforced. Participants are also assessed about NRT use and any problems encountered. They are also provided with a supply of NRT for use during the final follow-up period. If participants report smoking at their final follow-up session, the circumstances which lead to a slip or relapse are reviewed, encouraging recommitment.

Thus, for those who are willing to attempt to quit smoking the number of sessions provided ranges from three to four (in line with the recommendations of the systematic review; chapter four) over around six weeks (as was identified in the qualitative descriptive study; chapter five), up to a maximum of 10 weeks. So, the study period was set for 12 weeks.

Participants are also offered a diabetic consultation with the nurse educator (and subsequent specialist/s referrals, if required) if they experience poor glycaemic control, or are concerned about diabetes management following a change in diet or weight gain on quitting smoking.

6.2.2.3 Provision of Nicotine Replacement Therapy (NRT)

As was suggested in section 4.6, the study intervention includes the provision of NRT for supporting smoking cessation. As recommended by Papadakis (2021), prospective participants who report smoking 15 or more cigarettes a day are provided with combination NRT, i.e. the daily combination of the (16-hour) nicotine patch and a fast-acting nicotine product. Conversely, those who report smoking less than 15 cigarettes a day are only provided with a fast-acting nicotine product. Given that the systematic review and meta-analysis by Lindson et al. (2019) and the updated review by Theodoulou et al. (2023) reported no significant difference in quit rates between participant- versus clinician-selected NRT, all prospective participants are provided with the same type of fast-acting nicotine product – the nicotine mouth spray. The nicotine mouth spray was chosen as the nicotine that it delivers is absorbed considerably faster than the nicotine delivered via the other types of fast-acting nicotine

products, such as the gum or lozenge (Kraiczi et al., 2011), resulting in a faster relief of cravings (Hansson et al., 2012; McRobbie et al., 2010). While mild adverse effects, such as hiccups, local irritation (burning of throat/tongue), and nausea tend to be more frequent with the mouth spray than the nicotine lozenge (Hansson et al., 2012) or gum (Bolliger et al., 2007), this was still deemed the treatment of preference amongst participants who had used it (Bolliger et al., 2007; Tønnesen et al., 2012).

While Theodoulou et al. (2023) found that the duration of single/combination NRT use and/or length of provision of free NRT did not significantly increase quit rates, Siahpush et al. (2015) found that the use of NRT for at least five weeks was associated with an increased likelihood of successful smoking cessation. Hence, all prospective participants are provided with a six-week supply of NRT in total, which aligns well with the intervention's timeframe. As per tobacco dependence treatment recommendations (European Network for Smoking and Tobacco Prevention, 2020; Papadakis, 2021; Theodoulou et al., 2023), prospective participants are provided with the highest dose of the 16 hour-patch – 25 mgs, and/or the mouth spray (standard dose of 1mg/spray) for daily use if refraining from tobacco use. The latter is recommended for breakthrough urges and/or to reduce withdrawal symptoms further (every one to two hours or as required). Prospective participants are also advised to start using NRT prior to the TQD (one to two days before) if reducing smoking, as this can improve quit rates compared to using NRT from the TQD only (Theodoulou et al., 2023). The patch is tapered during the last two weeks (15mg and 10 mg, respectively). During this period the participants are also encouraged to reduce the use of the spray. This helps ensure that the participants are doing well without taking nicotine when seen in their final follow-up session. In total prospective participants are provided with up to six weekly packs of nicotine patches and/or four nicotine mouth sprays consisting of 150 sprays per bottle (based on the maximum application of 16 sprays a day for the first four weeks, and eight sprays a day for the last two weeks). Supplies are provided in a staggered manner; making sure that participants have enough products in between appointments.

6.2.3 Feedback from the study advisors

Following the development of the intervention, feedback from the study advisors was sought. Prof. Josanne Vassallo, and Prof. Noellie Brockdorff were independently asked to provide their advice on the draft outline of the planned content and the organisation of the proposed sessions.

No major concerns were expressed, and both study advisors found the proposed framework and the components useful for use amongst this target population.

6.3 Preparation for the delivery of the intervention: training of the health professionals

As was outlined in sections 1.4.6 and 5.8, the diabetes practice nurses, who provide formal diabetes education at Malta's acute public hospitals, were approached to take part in this project. The nurses who run these clinics had no basic training in providing smoking cessation interventions and so had to be trained prior to the initial testing of the intervention. Furthermore, a standardised training programme was also required as part of treatment fidelity, to help ensure that eventually the intervention is delivered as intended (Borrelli, 2011).

6.3.1 Development of the training programme

The training programme for this doctoral research project was based on a training programme on brief interventions for smoking cessation which was developed by the author (Grech, 2021), who was formerly in charge of the National Health Service's smoking cessation services. This face-to-face training programme, which followed the WHO toolkit for delivering the 5As (and 5Rs) for tobacco cessation (World Health Organization, 2014) and the recommendations drawn from the systematic review by Ye et al. (2018), was delivered in group format to interested health care professionals working in Maltese health care settings. Analysis was restricted to participants who had direct patient (adult) contact during a typical working day; n=133 (Grech, 2021). While response rate was notable low (47.4%), this study found that the training programme helped to improve the tobacco cessation practices of the respondents (n=63) at three months follow-up (Grech, 2021). Respondents were significantly more likely to report having frequently (always/usually), assisted patients with smoking cessation (69.8% vs. 37.1%), reviewed barriers to quitting among patients who were not ready to quit (66.7% vs. 42.6%), provided smoking cessation medication recommendations (54.0% vs. 34.4%), and arranged follow-ups (38.1% vs. 20.0%) when compared to baseline, i.e., prior to the training programme (Grech, 2021). Furthermore, this training programme also helped to address the participants' knowledge and skills gap, as at three months follow-up, participants were also

less likely to strongly agree/agree on the need for further training when compared to baseline (50.8% vs. 95.2%; Grech, 2021).

As was done in Grech's (2021) study and as is recommended by Borrelli (2011), the training programme for this study was designed to address the knowledge and skills deficit of the participants, and their attitudes for the effective provision of the tobacco cessation intervention. For the purpose of this study, the information provided was more focused on smoking and diabetes and on the use of the devised algorithm (presented in section 6.2.2). As recommended by Ye et al. (2018), this was achieved by focusing on the learner's ability to demonstrate competence in tobacco-nicotine knowledge, which is specific for diabetes, and in effectively intervening with clients according to the devised framework. As was also carried out in Grech's (2021) study, time was allocated so that the nurses could practice the delivery of the devised algorithm through role-play while being provided with feedback. Furthermore, the nurses were initially shadowed when piloting the intervention (section 7.3.3). An outline of the training program is presented in Appendix 6.2.

6.3.2 Delivery of the training programme

All four diabetes practice nurses who cared for adults living with diabetes at the two acute public hospitals were approached to take part in this project. One of the nurses did not want to participate in this study, and so only three diabetes practice nurses were trained. The training programme, which was described in section 6.3, was delivered on three occasions, twice at one hospital and once at the other hospital. The 3-hour training programme was delivered in November 2022.

The training sessions were delivered by the author, who used a PowerPoint® presentation (Appendix 6.3) and followed a prompt guide to maintain fidelity (Borrelli, 2011; Salloum et al., 2022). The nurses were also provided with printed resources as a reference: the guidelines by the National Health Service's general smoking cessation service on prescribing NRT; the model for delivering the smoking cessation intervention; and the structured guide that had to be followed for maintaining fidelity (Borrelli, 2011; Salloum et al., 2022).

6.4 The next phase of the doctoral research project

As was outlined in chapter two, following the development of the multi-component intervention, a feasibility study was required to reduce any key uncertainties such as those that relate to the evaluation design, e.g., uncertainties around recruitment and attrition, or the intervention itself, e.g., uncertainties regarding content, delivery, acceptability and likelihood of its effectiveness, prior to a definitive evaluation (Giangregorio & Thabane, 2015; Skivington et al., 2021). This is in line with the philosophy of pragmatism, which emphasises the understanding of the individuals' (participants) experiences and the outcomes of action to identify what works within a specific situation (section 2.2.2).

Guided by the MRC framework (Skivington et al., 2021), in the feasibility phase of this doctoral research project a randomised controlled feasibility study was undertaken; this was piloted beforehand. Chapter seven reports on the development of the research instruments required for the pilot and the feasibility studies, and on the pilot study that was carried out to test and refine the intervention, the feasibility study processes and the data collection methods. Chapter eight describes the work undertaken to evaluate the feasibility and acceptability of the multi-component smoking cessation intervention amongst the diabetes nurse educators, and the participants, the individuals with diabetes, and to assess its potential effectiveness in preparation for a future definitive trial.

6.5 Conclusion

This chapter described the intervention and its underlying theory, and the training programme that was provided to the diabetes practice nurses so that they could deliver the intervention. The next chapter reports on the development of the tools that were used in the pilot and the feasibility studies, and the piloting of the intervention with a small sample of individuals with diabetes.

Chapter 7: Testing the intervention, the feasibility study processes, and the data collection methods – a pilot study

7.1 Introduction

The purpose of this chapter is to present the preliminary work undertaken prior to conducting the randomised controlled feasibility study (reported in chapter eight). After developing tools (questionnaires) for use in the main feasibility study and assessing these for content validity (section 7.2), a pilot study was carried out to test and refine the methods to be used in the feasibility study with a small sample of individuals living with diabetes. Section 7.3 presents the aims and objectives of the pilot feasibility study, while section 7.4 details the methods that were followed. Section 7.5 reports the findings of the pilot feasibility study. These are then discussed in section 7.6. Section 7.7 outlines the pilot feasibility study's implications for the feasibility study as part of the doctoral research project. Section 7.8 is a conclusion to this chapter.

7.2 Development of the tools for use in the feasibility study

Given that the success of health care interventions is very much dependent on patient involvement and their attitudes to them, the assessment of patients' views of an intervention is crucial before implementing an intervention into practice (Giangregorio & Thabane, 2015). Prior to trialling out the study intervention, the identification of the appropriate methods for assessing the acceptability of the intervention, was thus necessary. Apart from utilising qualitative methods (such as by carrying out semi-structured interviews – discussed in sections 7.4.4.1 and 8.4.4.3), the use of quantitative methods, such as questionnaires, is also recommended (Feeley & Cossette, 2015; O'Cathain et al., 2015). In assessing acceptability (as is further explained in chapter eight), the use of quantitative tools such as questionnaires that assess participants' satisfaction with the intervention and their perceptions of its usefulness, can help fine-tune interventions to improve their uptake and success (Giangregorio & Thabane, 2015).

Despite the availability of valid client/patient satisfaction questionnaires, such as the widely used Client Satisfaction Questionnaire (CSQ-8) (Larsen et al., 1979), and the UK National Health Service Stop Smoking Service Client Satisfaction Survey (which also investigates perceived usefulness; May et al., 2009), these were deemed inadequate to help assess the satisfaction with and perceived usefulness of a smoking cessation intervention among individuals with diabetes. This is because such tools either measure satisfaction as a broad concept, without referring to smoking cessation (e.g., the CSQ-8), or are too specific, referring to a specific context/smoking cessation service (e.g., the UK National Health Service Stop Smoking Service Client Satisfaction Survey). Given that no quantitative tools on the feasibility of smoking cessation interventions amongst individuals with diabetes were identified in the scoping review, two instruments; one on the satisfaction with the smoking cessation provided and another on the perceived usefulness of the smoking cessation intervention, were developed.

7.2.1 Initial development of the tools

The satisfaction and perceived usefulness questionnaires were devised in the English language. Both questionnaires were devised to be appropriate for use amongst the participants who were assigned to the intervention (provision of the developed diabetes-specific smoking cessation intervention) and to the control group (provision of general smoking cessation support, as explained in chapter eight).

In the questionnaire on the satisfaction with the study's intervention, by means of a 5-point Likert scale (ranging from 'very unsatisfied' to 'very satisfied'), participants are asked to indicate their satisfaction to eight statements on the main elements of the smoking cessation interventions; on the support they received, the setting in which support was provided, the appointment times given, the waiting time for having the first session, the duration of each individual session, the frequency of the number of follow-up sessions, the number of sessions, and the method used to help the smoker quit. Two open-ended questions, asking participants to explain which aspects of the smoking cessation intervention they were most and least satisfied with complement this instrument.

In the questionnaire on the perceived usefulness of the smoking cessation intervention, by means of a 5-point Likert scale (ranging from 'strongly disagree' to 'strongly agree'), participants are asked to state their agreement with 14 statements. While the first two items are about the effectiveness of the smoking cessation intervention in meeting the participant's

expectations and his/her specific needs, respectively, the other 12 items are about the ability of the smoking cessation intervention in providing the necessary information, motivation and behavioural skills required to quit smoking as per the Information-Motivation-Behavioural Skills (IMB) model (Fisher et al., 2006; Fisher et al., 2003). These include: the provision of helpful information on quitting; raising awareness on the severe diabetic complications caused by smoking; raising concern on the severe diabetic complications caused by smoking; raising concern about smoking (information); provision of motives to quit; making one thinking that it is worthwhile to quit (motivation); helping one to consider a plan to quit; helping one to identify situations that increase the risk of smoking; helping one to identify factors to resist urges to smoke; helping one to respond effectively to urges to smoke; helping one to identify the most effective method to quit; helping one to be confident so that he/she can quit (behavioural skills). One open-ended question, asking participants for suggestions for improvement and a close-ended question ('yes' or 'no' answer) asking participants whether they would recommend the intervention, also complement this instrument. The initial version of these questionnaires is available in Appendix 7.1.

7.2.2 Assessment for content validity

Following the development of the questionnaires, these were assessed for face validity, i.e. the questionnaires were assessed for their appropriateness for the construct of interest (Devon et al., 2007). The study supervisors reviewed the questionnaires also looking at the grammar, syntax, and organization of the items. Only minor edits were required. Following revision, two individuals with diabetes (one male and one female) who were around 50 years of age and had attended the National Health Service's general smoking cessation services were asked to review the questionnaires for comprehension and appropriateness. However, no concerns were expressed.

As a minimum, Almanasreh, Moles, & Chen (2019) recommend that instrument developers should assess and establish the content validity of their instrument. Content validity, which is established if the items of the instrument sample the complete range of the construct of interest (Devon et al., 2007), was thus assessed for both questionnaires.

The content validation process entails inviting between five to ten experts (determined through selection criteria, such as clinical expertise), to determine (through quantification) the extent to which the items (and the instrument) measure a particular concept of interest (Almanasreh

et al., 2019). Basing expertise on clinical experience, the smoking cessation facilitators at the National Health Service's general smoking cessation service (n=7, excluding the author) and a former smoking cessation facilitator who still provided ad hoc smoking cessation support, were invited to participate in the content validation process. As recommended by Almanasreh et al. (2019), these were briefed about the assessment process, and an information kit containing the content validity assessment form (Appendix 7.2) and a copy of the developed instruments was sent to them via email. The smoking cessation facilitators were asked to assess each item for content relevance using the 4-point ordinal rating scale by Lynn (1986), i.e. 1 - 'not relevant', 2 - 'unable to assess relevance without item revision or item is in need of such revision that it would no longer be relevant', 3 - 'relevant but needs minor alteration', or 4 - 'very relevant and succinct.' As recommended by Almanasreh et al. (2019) and Lynn (1986), the facilitators were also invited to suggest additional items, deletion of any item, item rewording or provide any other comments.

Despite sending several reminders, three facilitators did not reply. The health care professional backgrounds of those who sent back their assessment forms were in podiatry, nursing, and occupational therapy. Three experts had five years or more experience in the provision of tobacco cessation services, while the remaining two had less than one year and three years, respectively. Two experts were also lecturers at the University of Malta. In order to establish the content validity for each item and for the whole instrument, the more conservative approach by Lynn (1986) was followed. Given that there were fewer than six experts in the panel, this required a 100% agreement by all experts in rating the items as three or four (Almanasreh et al., 2019; Lynn, 1986).

All experts rated all the items from both questionnaires as three - 'relevant but needs minor alteration' (suggesting minor edits), or four - 'very relevant and succinct.' However, Expert one suggested the deletion of the item 'Made you aware of severe diabetic complications caused by smoking' from the perceived usefulness questionnaire, remarking the following:

> *"I think that a client may not need or ask for this information as he/she may feel sufficiently informed. In this case would you still give the information? If not, I wonder whether this item should be retained."* Expert 1

Given that a 100% agreement was required for establishing content validity, this item was removed.

Another expert (Expert 2) suggested the addition of the following items for the same questionnaire: 'Provided you with options on how to quit smoking' and 'Helped you to set a specific date to quit.' Thus, as recommended by Almanasreh et al. (2019) and Lynn (1986), a second round of content validation was conducted. Once again, the experts rated almost all the items from both questionnaires as four - 'very relevant and succinct,' and a few items as three - 'relevant but needs minor alteration,' providing minor suggestions, however, Expert 1 suggested the deletion of the item, 'Helped you to set a specific date to quit,' stating the following:

> *"I know research states that having a quit date helps, but from experience I know that many (not to say most) individuals do not like to set a quit date..somehow this makes them anxious. Therefore, I would not include this statement."* Expert 1

Hence this was also removed. The final version of these instruments is available in Appendix 7.6. Following the establishment of the content validity of these questionnaires, a pilot feasibility study was carried out.

7.3 Aim and objectives

The aim of this pilot feasibility study was to test and refine the methods of the feasibility study with a small sample of individuals with diabetes.

The objectives were to:

- test and refine the intervention based on the feedback obtained; and
- test and refine the recruitment and implementation processes, and the data collection methods to be used in the feasibility study.

7.4 Methods

7.4.1 Design

A pilot study design was adopted. Prior to carrying out the randomised feasibility study (reported in chapter eight), which was primarily carried out to establish the feasibility and acceptability of the multi-component smoking cessation intervention amongst the providers and the participants, and the intervention's potential effectiveness, a pilot study, defined as a smaller replica of a study to test the proposed study methods (Bell et al., 2018; Giangregorio & Thabane, 2015), was required. A pilot study was suitable to identify 'what works' in line with the philosophy of pragmatism, as it provided the study participants with the study intervention, who then provided feedback to inform further development or refinement of the intervention prior to the feasibility trial. The pilot study was also required to assess the methods undertaken and the reliability of the developed tools which were used amongst the participants in the feasibility study. Thus the pilot study employed the same protocol as the feasibility study (Giangregorio & Thabane, 2015). The pilot study commenced in November 2022 and finished in July 2023.

7.4.2 Recruitment process and sampling

For recruiting individuals with diabetes who smoke to the pilot study, purposive sampling, a common strategy utilised in quantitative and qualitative research in which the researcher recruits individuals who are typical of the target population (LoBiondo-Wood & Haber, 2014), was adopted. As was stated in section 1.4.5., all adults with type 1 diabetes attend the diabetes outpatients' department at either one of the two acute public hospitals in Malta. Additionally, individuals with type 2 diabetes attend the respective diabetes outpatients' department when complications arise or at prescribed time intervals, at least once annually (Calleja et al., 2016). In this pilot study, the target population were adults living with diabetes who were cared for by the diabetes practice nurses (i.e. attend the diabetes education unit/the diabetic outpatients' department at these hospitals) who smoke. For providing feedback on the study questionnaires, which were devised in English but later translated in Maltese (section 7.4.4.4), participants had to be able to understand both English and Maltese. Current female and male smokers with type 1 or type 2 diabetes, who were 18 years or older and able to understand both English and Maltese were thus eligible for this study. The diabetes practice nurses together with the

diabetologists attending the diabetes outpatients' department helped identify interested eligible participants, forwarding their contact details to the researcher. Posters and flyers (Appendices 7.4 and 7.5) were also present at the diabetes outpatients' department so that participants could also self-refer to the study.

While sample size calculations are not generally required for pilot studies, Thabane et al. (2010) state that the sample size of a pilot study should be large enough to provide useful information as regards to the aims of the study. In the case of pilot studies which are then followed by more definitive studies, Julious (2005) recommends 12 participants per group. As discussed in section 5.5.3, a minimum of 12 participants was also required so that in analysing qualitative feedback, thematic saturation was relatively achieved (Guest et al., 2006). Nonetheless, the sample size also had to be sufficiently large to assess the internal consistency of the tools that were to be used. Given that the shortest instruments in the baseline and end of study questionnaires had five and eight items respectively (section 7.4.4.4), in assuming that the coefficient of Cronbach's alpha in the null hypothesis and alternative hypothesis to be equal to 0.0 and 0.7, respectively (based on the recommendations for pilot studies), based on alpha value fixed at 0.05, the minimum sample size requirement was of 16 and 15 participants (respectively) to achieve power of 80.0% (Bujang et al., 2018). Given that both the English and Maltese versions of the tools were assessed for internal consistency, the minimum sample size was therefore 32 participants at baseline and 30 participants at the end of the study. To account for drop out, the sample size was further increased to 34 participants.

The qualitative sample was smaller than the quantitative sample. As stated earlier and in chapter five, a minimum of 12 participants was required so that in analysing qualitative feedback thematic saturation was relatively achieved (Guest et al., 2006). This was increased to 15 to make sure that data saturation was relatively achieved in view of the aim of the study. Maximal variation sampling was adopted. The aim was to understand the views of different participants as regards to the study intervention (Feeley & Cossette, 2015), selecting individuals who:

- stopped or did not stop smoking;
- attended or stopped attending the support sessions provided; and
- used or did not use the NRT provided on attempting to quit smoking.

In selecting participants, due consideration was also made to sex, age, and the type of diabetes. All the three diabetes practice nurses who agreed to deliver the study intervention were included as study participants.

7.4.3 Implementation process

The participants were provided with the developed intervention, as described in section 6.2. To enhance adherence to the treatment components and the interactional style used, the author shadowed the nurses when delivering the intervention to their first two patients, providing prompt feedback (Borrelli, 2011).

7.4.4 Data collection methods

7.4.4.1 Semi-structured interviews

The use of qualitative research has been recommended for the testing and refinement of complex interventions in health care (O'Cathain et al., 2015). This is because qualitative research methods can help provide an in-depth understanding of the participants' perceptions of the intervention and their experience, providing the required information to fine-tune the intervention and the processes involved (Feeley & Cossette, 2015). While a range of qualitative methods are available, interviews tend to be the data collection method of choice. This is because interviews can be more informative than other qualitative methods as regards to each individual's impressions of the intervention (Feeley & Cossette, 2015). Semi-structured interviews, in which the questions are asked in a systematic and consistent order, allowing freedom to the interviewer to probe further (Lune & Berg, 2017), were conducted with both the nurses and the individuals with diabetes.

Interviews followed a question and probe guide. One guide was developed for use amongst individuals with diabetes and another for use amongst the diabetes practice nurses. Each interview guide included questions on personal (and professional) characteristics, questions about the diabetes and smoking profile and on the smoking cessation support received for the study intervention participants, and questions about the intervention participants' and nurses' impressions of the intervention features (i.e. the components, the number, duration and frequency of the sessions provided, and the mode of delivery) and the challenges encountered. The nurses were also asked about the recruitment method and were invited to identify any

facilitators which helped them in delivering the intervention. The question guides were reviewed by the supervisors. The question guide for use amongst individuals with diabetes was then translated in Maltese by a professional bilingual translator to ensure accuracy.

Both interviews lasted between 8 to 18 minutes. The interviews held with individuals with diabetes were held in Maltese or English, depending on the preference of the interviewee, while the interviews held with the nurses were carried out in English. The author moderated all interviews, posing the questions to the participants and stimulating further responses by using the structured prompts and other probes as necessary. The interviews were audio recorded with consent. The interview guide for individuals with diabetes in English and Maltese is provided in Appendices 7.6 and 7.7, respectively, while the guide used amongst nurses is provided in Appendix 7.8.

7.4.4.2 Audio-recording of the provision of the study intervention

In addition to carrying out interviews, the use of audio recordings of intervention delivery has been recommended to identify implementation constraints (O'Cathain et al., 2015). Furthermore, it also helps to assess fidelity, i.e., whether the intervention was delivered as intended, so that further training can be provided, if required (Borrelli, 2011; Moore et al., 2015). Thus, the nurses were asked to audio record the sessions provided with the patients' consent. As recommended by Borrelli (2011), a random sample (50%) from all the audio recordings (all different types of sessions provided by provider) was selected.

7.4.4.3 Intervention log

An intervention log, i.e., a document in which the intervention provider can log intervention details was also used (Feeley & Cossette, 2015). The following information was collected:

- the number (and duration) of the sessions provided (and the total time period [in weeks] during which the sessions were provided);
- provision of the 5Rs intervention at the first session;
- the amount of NRT provided (and returned);
- reported use of NRT (with reasons if a participant reports not using it); and
- any problems encountered (such as side effects on using NRT, identified mental health issues, issues with managing diabetes, and any referrals, including reasons for refusing support).

As recommended by Hollands et al. (2019), NRT adherence was assessed using a continuous outcome measure; total days of NRT use (and the average number of times the nicotine spray was used per day) during the first week following the Target Quit Date, TQD (and the subsequent TQD for those who agreed to reattempt quitting) which should coincide with the follow/up sessions/s and in the next four weeks (for those provided with a final follow-up session).

7.4.4.4 Questionnaires

Additionally, the baseline and end of study questionnaires, which were then used in the feasibility study, were also piloted to determine if any questions were not clear or misleading and to establish the reliability of the self-developed instruments prior to the main study (Portney, 2020).

Baseline questionnaire

The baseline questionnaire collected information on the variables that are known to be associated with smoking and smoking cessation. These included:

- sex (Caponnetto & Polosa, 2008; Holm et al., 2017);
- age (Caponnetto & Polosa, 2008; Cho et al., 2018; Gariepy et al., 2012; Holm et al., 2017; Morimoto et al., 2010);
- whether living alone or with others (Caponnetto & Polosa, 2008; Gariepy et al., 2012);
- whether living with someone who smokes or not (Caponnetto & Polosa, 2008; Morimoto et al., 2010);
- level of education (Cho et al., 2018; Gariepy et al., 2012; Holm et al., 2017; Morimoto et al., 2010);
- employment status (Cho et al., 2018; Gariepy et al., 2012; Morimoto et al., 2010);
- perceived health status and having chronic diseases (Cho et al., 2018; Gariepy et al., 2012; Holm et al., 2017);
- diabetes profile (Cho et al., 2018; Gariepy et al., 2012);
- smoking history (Caponnetto & Polosa, 2008; Cho et al., 2018; Gariepy et al., 2012; Holm et al., 2017; Morimoto et al., 2010), including cigarette dependence, previous

quit attempts and motivation to stop smoking (Caponnetto & Polosa, 2008; Morimoto et al., 2010);

- and anxiety and depression (Caponnetto & Polosa, 2008; Gariepy et al., 2012; Richards et al., 2013), which are well associated with having diabetes (Rotella & Mannucci, 2013; Smith et al., 2013).

The baseline questionnaire was structured into four sections. In the first section, the participants' main characteristics were collected. The second section was about the participants' perceived health status and diabetes profile, while the third section was about the participants' smoking profile. The last section of the baseline questionnaire assessed the anxiety and depression levels of the participants at baseline. Questions were developed by the author, based on the literature. These were then reviewed by the supervisors. Cigarette dependence, current motivation to stop smoking (which were part of the smoking profile) and anxiety and depression were however measured using established tools.

Cigarette dependence was measured using the Cigarette Dependence Scale-5, CDS-5 (Etter et al., 2003), the shorter version (five items) of the Cigarette Dependence Scale-12. In the first question, participants were to rate their addiction to cigarettes on a scale from 0 to 100. The second question was about the daily number of cigarettes smoked, while the third question was about the time taken from waking up to smoke the first cigarette. Participants were then asked whether quitting smoking would be impossible, very difficult, fairly difficult, fairly easy or very easy for them. The last question was about their urge to smoke after a few hours of not smoking, using a 5-point Likert scale (totally disagree, somewhat disagree, neither agree nor disagree, somewhat agree and fully agree). Participants' responses were coded using the original coding system by Etter et al. (2003); totals ranged from five to 25. The CDS-5 (Etter et al., 2003) was utilised for this study as it is a self-administered, quick and easy tool to measure cigarette dependence with minimal administration required. CDS-5 has similar measurement properties to CDS-12. Both scales have a high internal consistency (Cronbach's alpha ≥ 0.84) and test-retest reliability ($r \geq 0.83$), satisfying several criteria of content and construct validity (Etter et al., 2003). Furthermore, the CDS-5 had a higher internal consistency when compared to the well-known Fagerström Test for Cigarette Dependence (Heatherton et al., 1991): alpha=0.84 vs. 0.66 (Etter et al., 2003) and alpha=0.76 vs. 0.68 (Etter, 2008) and significantly higher test-retest correlation coefficients (Etter et al., 2003).

Motivation to stop smoking was measured using the Motivation To Stop Scale, MTSS (Hummel et al., 2016; Kotz et al., 2013). The MTSS consist of one item, asking participants to select one of the seven responses whose order reflects: no belief, desire or intention to quit smoking (1); belief only (2); moderate desire but no intention (3); strong desire but no intention (4); moderate desire and intention (5); strong desire and medium-term intention (6); and strong desire and short-term intention (7). The MTSS was utilised in this study as it is a single item measure which combines the key motivational constructs showing a strong ordinal association with subsequent quitting attempts (Hummel et al., 2016; Kotz et al., 2013). Furthermore, the discriminative accuracy of the MTSS was found to be marginally higher when compared to the well-known Stages of Change assessment by Prochaska et al. (1985) for assessing motivation and predicting quit attempts (Hummel et al., 2016).

The established Hospital Anxiety and Depression Scale, HADS (Zigmond & Snaith, 1983) was used for assessing the anxiety and depression levels of the participants at baseline. This scale consists of two subscales, consisting of seven items each, measuring anxiety and depression. Participants were to rate each item on a 4-point Likert scale ranging from the absence of a symptom or the presence of positive features (score 0) to maximal presentation of symptoms or the absence of positive features (score 3). A score of 0-7 on either subscale is regarded as being in the normal range, while a score of 8-10 or 11+ (on either subscale) suggests or indicates the probable presence of the mood disorder, respectively (Snaith, 2003; Zigmond & Snaith, 1983). The HADS was utilised in this study as it is relatively easy to be administered and takes only two to five minutes to complete. A review by Bjelland, Dahl, Haug, & Neckelmann (2002) on the validity of the HADS across the studies in which it was utilised, found that the tool was still valid when used in community and primary care settings. The internal consistency of the anxiety sub-scale varied from 0.68 to 0.93 (mean of 0.83), while that of the depression sub-scale varied from 0.67 to 0.90 (mean of 0.82). Furthermore, an optimal balance between sensitivity and specificity was achieved when the screening cut-off point for both anxiety and depression was defined by a score of eight or more (Bjelland et al., 2002), as was originally intended (Zigmond & Snaith, 1983). Additionally, Baldacchino, Bowman, & Buhagiar (2002) had already translated this scale, confirming its reliability amongst the Maltese population (Cronbach's alphas of the anxiety and of the depression sub-scales were 0.79 and 0.70, respectively).

Exhaled carbon monoxide (eCO), an indicator of recent (12-24 hours) smoke absorption from combustible tobacco products, was measured using the Bedfont piCO™ Smokerlyzer® and

reported on the baseline questionnaire. While an eCO level of ≥5ppm (parts per million) was used to confirm daily smoking (Benowitz et al., 2020), given that occasional smokers were still eligible to the study, this was not used for inclusion and exclusion purposes. However, clarifications were sought if participants remarked smoking daily but their eCO was found to be less than 5 ppm. The baseline questionnaire is outlined in Appendices 7.9.

End of study questionnaire

The end of study questionnaire was utilised to:

- assess for smoking abstinence;
- characterise the support utilised; and
- investigate the participants' satisfaction with the intervention and their perceptions of its usefulness.

Smoking abstinence was measured by following the recommendations by Piper et al. (2020). Participants were asked whether they intentionally spent the last seven days (seven-day point-prevalence abstinence) and/or at least seven consecutive days during the study period (seven-day floating abstinence) and/or at least one day/24 hours (quit episode) not smoking any combustible and non-combustible tobacco products or alternative products, and their current tobacco use if currently smoking. As recommended by Benowitz et al. (2020) for those who reported a seven-day point-prevalence abstinence, biochemical verification of tobacco abstinence was carried out by using the same carbon monoxide monitor and additionally by analysing a urine sample for cotinine (a derivative of nicotine) exposure using a multilevel lateral flow immunoassays urine test strip with a nominal 200 ng/mL cutoff. The latter helped to confirm abstinence from both combustible and non-combustible tobacco sources and use of alternative products, e.g. electronic cigarettes (Benowitz et al., 2020). Given that NRT also breaks down into cotinine and is detected in urine, participants were advised to stop using NRT prior to assessment, if possible.

To characterise the support utilised participants were asked whether they attended the scheduled smoking cessation sessions (and reasons if not), the number of smoking cessation sessions they received (and the time period), about the use of any NRT/medication to quit smoking, and whether they had any additional support that helped them in attempting to quit smoking.

To investigate the participants' satisfaction with the intervention and their perceptions of its usefulness, the instruments outlined in section 7.2 were used. The end of study questionnaire is displayed in Appendix 7.10.

Instrument translation

Except for HADS, which was already translated and validated into Maltese by Baldacchino et al. (2002), both the baseline and the end of study questionnaires were devised/available in the English language, and so required to be translated into Maltese for easy comprehension amongst the study participants. Thus, the questionnaires were translated in Maltese and back translated into English and compared to the original versions by bilingual translators who ensured their literal and syntactic equivalence and that the original denotation and connotation of the items still applied.

To ensure the content validity of the translated instruments, i.e. the two measures which were developed as part of this study (section 7.2) and the MTSS and CDS-5, conceptual equivalence, i.e. defined as a construct having the same meaning in both languages, had to be established for these instruments (Streinger et al., 2015; Tang & Dixon, 2002). This was carried out based on the process outlined by Tang & Dixon (2002).

The same panel of experts (n=5) was contacted again to help in assessing conceptual equivalence of the translated questionnaires to the original questionnaires. These were briefed about the assessment process, and then an information kit (Appendix 7.11), containing a translation validity assessment form (in which they were asked to assess each item of the Maltese questionnaires for conceptual equivalence using the 4-point ordinal rating scale by Tang & Dixon (2002), i.e. 1 - 'totally different,' 2 - 'needs major item modification to be equivalent,' 3 - 'equivalent but needs minor modification,' 4 - 'equivalent.'), and a copy of the developed instruments in English and Maltese was sent via email.

All experts sent back their assessment forms, rating all items from all questionnaires as three - 'equivalent but needs minor modification,' or four - 'equivalent.' This, i.e., a 100% agreement by all experts in rating the items as three or four, was deemed sufficient to establish conceptual equivalence (Tang & Dixon, 2002). When items were rated as 'three,' suggestions were provided. These were then discussed with the bilingual translators and revised accordingly. The translated baseline and end of study questionnaires are available in Appendices 7.12 and 7.13, respectively.

As recommended by Sousa & Rojjanasrirat (2011), in addition to establishing content equivalence of the instruments used, as a minimum, the translated instruments (except the MTSS, since it is a one item scale), and the self-produced instruments in English, also required internal reliability assessment. The data analysis procedure is described further in the sub-section below.

All participants were provided with the baseline questionnaire after consenting to the study (week 0), and with the end of study questionnaire at the end of the study period; at week 12. Participants were randomly given the English or Maltese versions, making sure that there was an equal distribution of the questionnaires in both languages in both groups. Questionnaires did not take more than 20 minutes to complete.

7.4.5 Data analysis

7.4.5.1 Semi-structured interviews

The professional and/or personal characteristics of the participants, i.e. the individuals with diabetes and the diabetes practice nurses were analysed and summarised using frequencies and percentages, and median and interquartile ranges (IQR) accordingly.

All audio recordings were transcribed verbatim and reviewed by listening again to ensure accuracy. As was done in the qualitative descriptive study (chapter five), the transcripts in Maltese and English were not translated, in order to maintain the validity and reliability of the acquired data (Guest et al., 2014). All transcripts were then imported into NVIVO.

The data analysis procedure was guided by the applied thematic analysis process by Guest et al. (2012), which was described in section 5.5.4. As was done in the qualitative descriptive study (chapter five), in outlining themes/sub-themes in the findings section, the original participants' quotes are provided. The English translations of quotes in Maltese are also provided. The steps outlined in section 5.5.5 were followed to enhance rigor.

7.4.5.2 Assessment of treatment fidelity

The audio-recordings of the sessions provided were analysed for treatment fidelity. The selected audio recorded sessions were listened to and by using a checklist, outlining the study algorithm components (Appendix 7.14), the occurrence or non-occurrence of the algorithm components were scored for calculating the level of adherence (Borrelli, 2011). As

recommended by Borrelli (2011), if adherence was found to be <80%, remedial training had to be given.

7.4.5.3 Recruitment and intervention log

The number of participants recruited, and the number of months required to recruit the required sample size were noted. Study uptake was examined by noting the participation rates and the reported use of NRT. Similar to Hollands et al.'s (2013) study, the median percentage of days (IQR) the nicotine patch and/or spray were used (and the average use of the nicotine spray/day) during the first week following the TQD (and the subsequent TQD for those who agreed to reattempt quitting), and in the next four weeks, were calculated. Reasons for not completing the intervention/not using NRT were noted. Any participants who opted not to see the informational video clips and/or did not want to set a TQD were noted (with reasons).

The average time period over which the intervention was provided was calculated, both for all the participants and for those who completed the intervention during the study period. The average time taken to deliver the sessions was also calculated. The number of participants who were provided with the 5Rs intervention was noted.

In addition, the average amount of NRT which were provided (taking note of any returned items) was calculated for all participants. Any problems, such as reported adverse events and referrals, were quantified. The number of participants who refused additional support was noted (with reasons).

7.4.5.4 Questionnaires

The data collected from the end of study questionnaire were also analysed using descriptive statistics; frequencies and percentages and mean (SD)/median (IQR) values for normally and non-normally distributed continuous data (tested by using the Shapiro Wilk test). In line with standard smoking cessation research practice (Li et al., 2017; Russo et al., 2022; Theodoulou et al., 2023), non-responders and participants whose abstinence could not be biochemically verified were considered non-quitters and non-reducers. Comments on the intervention and suggestions were summarised by following the ATA approach.

Additionally, the self-produced instruments, i.e. the satisfaction and perceived usefulness questionnaires (Maltese and English versions) and the translated CDS-5, were assessed for internal reliability using Cronbach's alpha scores. To identify any items which detracted from the overall reliability, Cronbach alpha (and scale mean) was also computed repeatedly, each time eliminating one item from the analysis. The correlation of each item with the sum of the

remaining items (item-to-total correlation), was also calculated. In distributing the questionnaires any comprehension problems were also taken note of.

7.4.6 Ethical considerations

Before carrying out the pilot study, permissions were sought from the authors of the tools used, from the recruiting stakeholders, and ethical clearance was sought from the Faculty of Health Sciences Research Ethics Committee on behalf of the University Research Ethics Committee (UREC FORM V_15062020 8618). All permissions are found in appendices 7.15 – 7.26. No ethical issues were foreseen, and the study was approved.

On indicating their interest to participate in the study, prospective participants were verbally briefed on the purpose of the study and the data collecting procedures, answering any queries that they had. All participants (including the nurses) were provided with a detailed information letter and a consent form to sign (Appendices 7.27 – 7.36). Participants were reminded that participation was voluntary so that they could choose whether to participate or not, thus ensuring autonomy (LoBiondo-Wood & Haber, 2014). Participants were told that they were free to withdraw from the study at any time, without the need to provide a reason. The individuals with diabetes were assured that refusing to participate or withdrawing from the study did not have any effect on their care whatsoever.

To provide a degree of anonymity, the questionnaires were linked to participants via unique codes known to the participants. The participants were encouraged to take the provided NRT on quitting smoking; however, they were also free to refuse to take it, thus supporting the participants' autonomy. In the very unlikely event of an adverse event, participants could inform the researcher who would ensure that they are seen by a doctor of their choice free of charge. The researcher reminded the participants that the audio-recorded sessions were only to be listened to by the researcher for quality assurance. The participants were assured that their identity and personal information were not to be revealed in any data/information arising from the research study. The audio-recorded interviews were pseudonymised on transcription. These (and the audio-recorded sessions) were then erased, retaining data only in an anonymous format. The participants who did not quit smoking by the end of the study were invited to attend to the National Health Service's smoking cessation services.

7.5 Study's findings

7.5.1 Recruitment

Thirty-four individuals living with type 1 or type 2 diabetes who reported having been smoking a tobacco product/s over the past week were recruited over a six-month period; between November 2022 to April 2023. From January onwards, no further participants were recruited from one of the hospitals as the sole diabetes practice nurse at this hospital had to stop working in late March due to planned long absence from work. The reason for this was unrelated to the pilot study. Most patients (n=22, 64.7%) were identified from the two diabetes education units.

7.5.2 Baseline characteristics of the individuals with diabetes who participated in the pilot study

The participants' demographic characteristics, their health status and diabetes and smoking profiles, and their anxiety and depression levels as measured by HADS, are outlined in Appendix 7.37. Most participants were male (n=27, 79.4%), with type 2 diabetes (n=28, 82.4%), and retired (n=19, 55.9%). All participants smoked daily; the median number of cigarettes smoked was 25 per day. The majority (n=21 61.8%) had not attempted to quit smoking in the past 12 months. Most participants (n=11, 32.4%) really wanted to stop smoking (strong desire) but didn't know when they would do so (no intention). Eight and six participants were found to be probably affected by depression and anxiety, respectively.

7.5.3 Findings from the analysis of the intervention logs

Of the 34 participants, only 19 (55.9%) attended all the scheduled sessions, i.e. 3 or 4 sessions. Fifteen participants discontinued the study intervention; 10 participants failed to turn up to the set appointment, while four participants called the researcher informing him that they intended to stop attending as they were not seeing any progress. One participant stopped attending as he was no longer interested. The average (median) session duration for the first, second, third (held for those who had reported not quitting smoking at the second session) and final follow-up sessions (held for those who reported quitting smoking at the second and third sessions) were of 45 minutes, IQR [40.0-45.0], 30 minutes, IQR [30.0-40.0], 25 minutes, IQR [20.0-30.0] and 25 minutes, IQR [20.0-40.0], respectively. The median number of weeks during

which the intervention was provided ranged from four weeks, IQR [3-7] for all participants, to seven weeks, IQR [4-8] for those who completed the intervention only. The median number of seven-day packs of nicotine patches and nicotine mouth sprays provided was 3.5, IQR [1-6] and two, IQR [1-4], respectively.

At the first session it was noted that four participants refused to watch the video clips which depicted the story of Bill. Two of these participants stated that they disliked watching health warning messages, while the other two stated that they can relate to them and so do not need to watch them. The 5Rs intervention was delivered to three participants. All participants except for one who dropped out of the study at the first session stating that he was no longer interested, agreed to set a TQD at their first session and at the second session (for continuing smokers).

During the provision of the intervention, it was noted that 15 participants were likely experiencing anxiety and/or depression and were thus advised to attend the psychotherapist service which was available at the outpatients' department (of both hospitals). However, most participants (n=12) refused the offer, as they believed that this was not required/they were coping well (n=5), they were not interested (n=3), or they were already being seen by a psychiatrist (n=4). Three participants agreed to attend the psychotherapy service; however, it is not known if they attended as they failed to attend to their follow-up session.

Table 7.1 displays the use of NRT as recorded during the second and third sessions (for continuing smokers) and final follow-up session (provided to those who had previously reported not smoking). Most participants reported using the patch and/or the spray almost every day during the first week from the first set TQD, however, the mouth spray was used less frequently during the first week from the second set TQD (for continuing smokers). On the other hand, at the final follow-up session, the participants reported not having used the patch on most days; they however used the spray more frequently (table 7.1). Eleven participants complained of minor adverse effects, such as mild throat/skin irritation when using NRT. These resolved on stopping/reducing the use of the mouth spray and changing skin sites, respectively.

Table 7.1: Reported use of Nicotine Replacement Therapy (NRT)

Use of Nicotine Replacement Therapy (NRT)	**All attending participants**	
Use of NRT during the first week from the TQD[a]	*Nicotine patch* (n=23)	*Nicotine mouth spray* (n=27)
Percentage of days of NRT use, median (IQR)	100 (100-100)	100 (71.4-100)
No. of sprays applied per day, median (IQR)		6 (3-10)
Use of NRT during the first week from the subsequent TQD (for continuing smokers)	*Nicotine patch* (n=8)	*Nicotine mouth spray* (n=10)
Percentage of days of NRT use, median (IQR)	100 (89.3-100)	64.3 (32.1-100)
No. of sprays applied per day, median (IQR)		5.5 (3-7.5)
Use of NRT during the subsequent four weeks following one week from the TQD	*Nicotine patch* (n=7)	*Nicotine mouth spray* (n=11)
Percentage of days of NRT use, median (IQR)	35.7 (14.3-85.7)	78.6 (0-100)
No. of sprays applied per day, median (IQR)		6 (0-14)

a - Target Quit Date. IQR – interquartile range

The nurses also reported that two participants were concerned about their glucose control, which was resolved following a diabetic consultation.

7.5.4 Assessment of treatment fidelity

Table 7.2 outlines the number of sessions (per type of session) which were assessed for treatment fidelity.

Table 7.2: Number of sessions which were assessed for treatment fidelity

Type of session	**Number of sessions**, n
Session one	17
Session two (for those who did not quit smoking)	6
Session two (for those who quit smoking), or session three (if reporting abstinence the first time)	9
Session three (for those who did not succeed to quit smoking)	4
Final follow-up session (for those who previously reported not smoking)	5

Tables 1-5 (Appendix 7.38) outline the treatment actions/components carried out by the intervention providers amongst the participants during these sessions and the average percentage adherence to the session protocol. In all cases the average percentage adherence to the protocol was ≥80.0%, except for session two (for those who quit smoking), or session three (if reporting abstinence the first time) where the average percentage adherence to the protocol was slightly less, at 79.8%. In these sessions, it was noted that when encouraging participants to remain abstinent, the nurses did not always refer to/identify what would be relevant for the patient if he/she quit smoking. Furthermore, the nurses did not always advise reducing the use of the spray over the coming weeks. Although the average percentage adherence to the first session and second session (for continuing smokers) protocol was ≥80.0%, it was noted that the appointments were not always given in a week from the set TQD but in two to three weeks' time.

7.5.5 Findings from the analysis of the end of study questionnaires

Thirty-one participants filled in the end of study questionnaire (91.2% response rate). The support utilised by the study participants has been reported in section 7.5.3. Among those who discontinued the intervention (n=12), four participants reported having stopped attending as

they did not find the patches and the spray effective, while three participants said that they did so because of personal/family issues. One participant stated that he/she forgot to attend. None of the participants claimed to have received additional support to attempt to quit smoking. Five participants (14.7%) had their seven-day point-prevalence abstinence biochemically verified.

Appendices 7.39 and 7.40 outline the participants responses to the satisfaction and perceived usefulness questionnaires, respectively. Most participants were satisfied with the intervention provided finding it useful. The satisfaction median total score was 34.0, IQR [32.0-38.0] (out of a total of 40), while the perceived usefulness median total score was 60.0, IQR [55.0-68.0] (out of a total of 70).

Some participants (n=6) remarked being most satisfied with the NRT; the patches (n=3), *"patches; ftit li xejn kienet telibni l-kilba,"* (*patches; I barely had cravings"* – translated from Maltese)," and the spray (n=2), "*spray helped a lot*," or both (n=1). Some participants (n=4) also reported being satisfied with everything, "*mill-bidu sal-aħħar sodisfatt ħafna b`kollox*," (*"very satisfied with everything, from start to finish"* – translated from Maltese). The other aspects which participants reported being most satisfied with included: the informative initial session (n=2), "*initial session was very informative*;" the intervention providers (n=2), "*she was very professional*;" the sessions (n=2), "*sessions*;" the personal achievements (n=2), "*with myself because finally I quit smoking*;" and the help provided (n=1), "*the help provided*."

Six participants identified an aspect of the smoking cessation intervention which they felt least satisfied with. Two participants, who did not manage to quit smoking and were thus provided with three sessions in total, remarked on the lack of further support, "*li ma kelliex iktar sapport wara li spiċċajt fuq sigarett wieħed*," ("*that I had no more support after I went down to one cigarette [a day]*" – translated from Maltese). A participant claimed that the patch was not that helpful, "*patches did not help much*", while another participant complained about the spray as he/she had gum pain "*spray: as I had gum pain*." Another participant, who reported quitting smoking, stated that he/she would have liked to be provided with NRT for more weeks, "*the assistance of nicotine replacement products are still needed; this is more expensive than the tobacco!"* The other participant referred to the "*videos*," but did not explain further.

Only five participants provided suggestions for improvement. Two participants who did not quit smoking and were provided with three sessions each, again remarked on the need of further sessions and support, "*aktar għajnuna u sessions*," ("*more help and sessions*" – translated from Maltese). The other three participants suggested the provision of: motivational support (n=1),

"*iżżid id-deċiżjoni tal-persuna sabiex tieqaf tpejjep*," ("*encourage the person to take the decision to quit smoking"* – translated from Maltese); more effective pharmacotherapy (n=1), "*nixtieq mediċina aktar qawwija u effettiva li nkun nista nieħu biex nieqaf*," ("*I would like a more powerful and effective drug that I can take so I can quit*" – translated from Maltese); and telephone calls to boost support (n=1) "*I think more telephone contact would be helpful, regarding boosting morale and confidence*." Nonetheless, all the participants would recommend the smoking cessation intervention provided.

7.5.6 Internal consistency assessment of the satisfaction and perceived usefulness questionnaires (Maltese and English versions) and the translated Cigarette Dependence Scale-5

Seventeen participants completed the Maltese version of the Cigarette Dependence Scale-5 (CDS-5) at baseline. Fifteen participants completed the Maltese versions of the satisfaction and perceived usefulness questionnaires, while 16 completed the English versions. Cronbach's alpha scores were high (≥0.80) for all instruments; CDS-5 (0.80), the English and Maltese versions of the satisfaction questionnaire (0.91 and 0.87, respectively) and the perceived usefulness questionnaire (0.96 and 0.94, respectively). On eliminating the items one at a time from the analysis, the Cronbach alpha (and scale mean) remained relatively stable (Tables 1-5, Appendix 7.41). All item-scale correlations were ≥0.4.

7.5.7 Findings from the interviews held with the study participants (individuals with diabetes)

7.5.7.1 Characteristics of the interviewees

All 15 participants, who were randomly chosen to sit for an interview based on the variables outlined in section 7.4.2, agreed to participate. Their characteristics are outlined in table 7.3.

Table 7.3: Characteristics of the interviewees (n=15)

Characteristics	Interviewees (n=15)
Sex, n (%)	
Male	13 (86.7)
Female	2 (13.3)
Age (years), median (IQR)	63.0 (45.0-68.0)
Diabetes type, n (%)	
Type 2	12 (80.0)
Type 1	3 (20.0)
Attended all scheduled sessions, n (%)	
Yes	10 (66.7)
No	5 (33.3)
Number of sessions attended, n (%)	
Three	9 (60.0)
Two	3 (20.0)
One	2 (13.3)
Four	1 (6.7)
Used the provided Nicotine Replacement Therapy on attempting to quit smoking, n (%)	
Yes	14 (93.3)
No	1 (6.7)
Reported smoking abstinence during the study period, n (%)	
Spent at least seven consecutive days not smoking, but currently smoking	6 (40.0)
Did not intentionally spend at least one day (≥24 hours) not smoking	5 (33.3)
Did not smoke any tobacco product over the past seven days	3 (20.0)
Intentionally spent at least one day (≥24 hours) not smoking but less than seven consecutive days	1 (6.7)
Cigarettes/day among continuing smokers, median (IQR)	10.5 (6.5-18.5)

IQR - Interquartile range

7.5.7.2 General impressions of the smoking cessation intervention provided

Most participants found that the intervention provided was helpful (n=9) and supportive (n=5) in attempting to/quitting smoking (table 7.4). Four participants stated that the intervention raised awareness on the effects of smoking on diabetes and that it acted as a motivator (n=2).

While one participant found the intervention surprising, he felt that the intervention was cut short.

Table 7.4: Individuals with diabetes' general impressions of the smoking cessation intervention provided

Themes	Quotes (translated quotes in italics)	Participants' code (number of participants)
Helpful	"I think it's very helpful" P2 (male, age 45 years; has not smoked any tobacco product over the past seven days)	P1, P2, P4, P5, P6, P7, P8, P11, P12 (9)
Supportive	"Le xejn, sapport kelli tajjeb hu. M'hemmx xi tgerger hu! Le, s-sapport kien tajjeb hu!" (*"No nothing, I had good support, eh. I cannot complain, eh! No, the support was good, eh!"*) P4 (male, age 63 years; did not intentionally spend at least one day (≥24 hours) not smoking)	P4, P7, P8, P9, P13 (5)
Raises awareness	"Emmmee, the knowledge that made me aware smoking while being on diabetes makes consequences." P6 (male, age 42 years; spent at least seven consecutive days not smoking, but currently smoking)	P3, P5, P6, 12 (4)
Motivator	"(Name of the nurse) made some very pertinent points that made me feel that yes, I do want to give up smoking, for me, not for somebody else." P1 (female, age 68 years; did not smoke any tobacco product over the past seven days)	P1, P8 (2)
Cut short	"Jiġifieri qisni rajtni jiena liiii, li qisu, meta bqajt b'dak is-sigarett wieħed qbadna u waqafna, fhimtni?" (*"I mean, it's like I saw it, it's like, when I remained smoking one cigarette we just stopped, do you understand me?"*) P14 (male, 55 years; intentionally spent at least one day (≥24 hours) not smoking but less than seven consecutive days)	P14 (1)
Surprising	"Jien għalija kienet sorpriża! ... (Name of the nurse) darba minnhom kelli niltaqa miegħu, magħha jiġifieri, fuq jiġifieri minħabba d-dijabete u hekk, u qaltli hekk, għedt, 'nipprova jien." (*"For me it was a surprise! ... (Name of the nurse) one time I had to meet him, with her that is, because of diabetes and that, and she told me that, and I said, 'I will try."*) P14	P14 (1)

7.5.7.3 Views on the video clips shown

Several participants commented on the video clips shown (table 7.5). Most participants found that these were impressive (n=6) and that these acted as a motivator (n=2). However, three participants disliked their use as part of the intervention.

Table 7.5: Individuals with diabetes' views on the video clips shown

Themes	Quotes (translated quotes in italics)	Participants' code (number of participants)
Impressive	"They do impress (grinning), they do impress, I mean. Some people may may not be aware of these things, I mean, I was a bit aware, but when you, when you, when you see, when you experience, when you, it's totally different." P2 (male, age 45 years; has not smoked any tobacco product over the past seven days)	P1, P2, P3, P4, P8, P9 (6)
Dislike	"Eh le, dawk m'għoġbunix hu. Uuu għax m'għoġbunix ... Dan il-mard ħadd ma jogħġbu hu!" (*"Eh no, I didn't like those. Uuu because I didn't like them ... Nobody likes diseases!"*) P7 (male, age 68 years; did not intentionally spend at least one day (≥24 hours) not smoking)	P7, P10, P14 (3)
Motivator	"Huma nkoraġġiment biex tieqaf tpejjep hu!" (*"They encourage you to quit smoking!"*) P12 (male, age 55 years; quit smoking for at least seven consecutive days, but currently smoking)	P12, P15 (2)

Two participants, P11, P13 (who did not intentionally spend at least one day (≥24 hours) not smoking) reported not having watched the videos as they believe that they would not be convinced to stop smoking by doing so:

> "ma nemminx biha jien li toqgħod tara stampiii u vidjows u.. Għax jien nemmen li l-bniedem huwa, ifhem. Mhux kulħadd xorta hu!" (*"I don't believe in watching pictures and videos and.. Because I believe that it has to come from the person, you understand. Not everyone is the same!"*) P11 (male, age 65 years)

7.5.7.4 Views on the Nicotine Replacement Therapy provided

Most participants (n=10) remarked that the NRT was helpful to reduce/quit smoking or to reduce withdrawal symptoms (table 7.6). However, two participants found these ineffective.

Additionally, three participants experienced adverse effects which discouraged their use. Two participants also reported finding it difficult to stop NRT.

Table 7.6: Individuals with diabetes' views on the Nicotine Replacement Therapy (NRT) provided

Themes (and sub-themes)	Quotes (translated quotes in italics)	Participants' code (number of participants)
Helpful		
To reduce/quit smoking	"I found, I found, I found the spray which was very good ... the spray was, was of good replacement." P2 (male, age 45 years; has not smoked any tobacco product over the past seven days)	P2, P4, P5, P10, P11, P12 (6)
To reduce withdrawal symptoms	"Emm, the giving of the emm, the patches and the spray, really helped as well ... When I have tried to stop smoking before I have been very, very agitated and depressed and tearful, but this time I wasn't." P1 (female, age 68 years; did not smoke any tobacco product over the past seven days)	P1, P8, P9, P14 (4)
As these are expensive	"Emm, the giving of the emm, the patches and the spray, really helped as well ... emm, they are expensive to buy," P1	P1 (1)
Adverse effects discouraged use	"L-ispray iġġiegħlni nisgħol. Il-patches għamilthom xi ħmistax żgur, imma mbagħad indunajt li għed jagħmluli l-ħakk u ma bqajtx hu." (*"The spray makes me cough. I must have used the patches for about a fortnight, but then I realised that they made me itch and I stopped."*) P7 (male, age 68 years; did not intentionally spend at least one day (≥24 hours) not smoking)	P7, P12, P14 (3)
Difficulty in stopping NRT	"It was very effective until I tried to eliminate them." P5 (male, age 41 years; spent at least seven consecutive days not smoking, but currently smoking)	P5, P14 (2)
Found ineffective	"Jiena dik rajta, ifhimni, rajta ma ma ħadmitx fuqi, qed tifhem? Għax nagħmilha uuu b'effett ta' xejn." (*"I found it, understand me, I found that it didn't work for me, do you understand? Because I would use it and it had no effect at all."*) P13 (male, age 64 years; did not intentionally spend at least one day (≥24 hours) not smoking)	P13, P15 (2)
Complementary to self-regulation	"dan inti trid tiġġieled, dan mhux se tibqa għomrok bil-patches inti! Daqqa kont nagħmilhom, daqqa kont le ... Tgħidli l-mara, 'insejthom il-patches,' ngħdiliha, 'U ħalliha (name of wife)!' Moħħok, moħħok!" (*"you have to fight it, you cannot keep on using the patches all your life! Sometimes I would use them, sometimes I wouldn't ... My wife used to tell me, 'You forgot the patches,' I used to tell her, 'Oh leave it (name of wife)!' It's your mind, your mind!"*) P3 (male, age 59 years; did not smoke any tobacco product over the past seven days)	P3 (1)

7.5.7.5 Views on the delivery method

Almost all participants (n=13) remarked that it was easy to attend the smoking cessation intervention, mainly as the location was easy to get to (table 7.7). Almost none of the participants (n=14) reported any challenges in attending to the intervention. One participant stated that he found it difficult to attend because of work commitments:

> "Minħabba x-xogħol żgur. Jiġifieri, biex biex nattendi ċerta ħinijiet. Minkejja li jien naħdem bix-xift, jiġifieri.." (*"Because of work for sure. I mean, to attend certain times. Despite working shifts, that is.."*) P14 (male, 55 years; intentionally spent at least one day (≥24 hours) not smoking but less than seven consecutive days).

Table 7.7: Individuals with diabetes' views on the delivery method

Themes	Quotes (translated quotes in italics)	Participants' code (number of participants)
Easy to attend to		
Good location	"Emm, well, it is a good thing because it is easy to get to." P1 (female, age 68 years; did not smoke any tobacco product over the past seven days)	P1, P2, P3, P4, P5, P6, P7, P10, P11, P12, P13 (11)
As wanted to quit smoking	"Jien għalija kienet faċli ħafna għax xtaqt nipprova nieqaf, ħa ngħid hekk." (*"For me it was very easy because I wanted to try to quit, let's say that."*) P15 (male, age 41 years; did not intentionally spend at least one day (≥24 hours) not smoking)	P14, P15 (2)
Face to face support works best	"Tajjeb ħafna eh. Għax titkellem wiċċ b'imwiċċ ikun aktar.. Jien għalija aħjar milli ċċempilli." (*"Very good eh. Because talking face to face is more.. For me it's better than calling me."*) P15	P15 (1)
Parking facilities	"There are good facilities here, parking and everything." P2 (male, age 45 years; has not smoked any tobacco product over the past seven days)	P2 (1)
Patient-centred	"Emm.. Well, it was ehh.. I was left to do it, my way. I mean, I was given, I was given options." P2	P2 (1)

7.5.7.6 Suggestions for improvement

Only three participants provided suggestions for improvement. These are outlined in table 7.8.

Table 7.8: Individuals with diabetes' suggestions for improvement

Themes	Quotes (translated quotes in italics)	Participants' code (number of participants)
Alternative pharmacotherapy	"Jien nixtieq.. jekk issibu xi ħaġa jew ikun hemm xi ħaġa biex nipprova jew nagħmel, dejjem ibqa' żommni dejjem ee attiv." (*"I would like to.. if you find something [a medicine] or there is something to try or do, always keep me always eh informed."*) P13 (male, age 64 years; did not intentionally spend at least one day (≥24 hours) not smoking)	P13 (1)
Further provision of NRTs	"Eeee what I would suggest, maybe they [nicotine replacement therapy] will be on more weeks, eemmee cause obviously addiction was, was still a bit hard on me once I finished the patches." P5 (male, age 41 years; spent at least seven consecutive days not smoking, but currently smoking)	P5 (1)
More contact	"I feel that it would have been nice to have more contact throughout those weeks … in terms of messages or telephone calls. Sessions are fine." P1 (female, age 68 years; did not smoke any tobacco product over the past seven days)	P1 (1)

7.5.8 Findings from the interviews held with the nurses

7.5.8.1 Characteristics of the interviewees

All three female diabetes practice nurses were interviewed. Their ages ranged from 40 to 58 years. The nurses reported having been in practice between 18 to 38 years and having been practicing as specialist nurses (in diabetes) between 4 to 14 years.

7.5.8.2 Views on the recruitment method

All nurses found this was good practice (table 7.9). However, two of the nurses highlighted that there could be potential issues with participant recruitment as a small number of patients attend their clinics, and not all who smoke want to quit.

Table 7.9: Nurses' views on the recruitment method

Themes	Quotes	Participants' code (number of participants)
Good practice	"As a recruitment, I contacted patients that came for education, to check, to see if they are smoking. I think it was good that I checked." N3	N1, N2, N3 (3)
Potential issues with participant recruitment	"We don't see a big number of patients a day … So, it's a small number, and eee, thank God most of them do not smoke, and not all those who smoke want to stop." N2	N2, N3 (2)

7.5.8.3 General impressions on the smoking cessation intervention provided

All nurses had a positive impression of the intervention (table 7.10), mostly stating that this was part of diabetes education. Two nurses also remarked that the intervention was supportive in nature.

Table 7.10: Nurses' general impressions on the smoking cessation intervention provided

Themes	Quotes	Participants' code (number of participants)
Part of diabetes education	"It is part of the education so it's good. I always encourage patients to stop smoking, when, if they smoke.." N3	N1, N2, N3 (3)
Supportive	"We discussed the plan, eh how they are going to quit and what they have to do like to remove the cigarettes, inform their relatives, their colleagues, what to do with their upcoming eh problems, I think they were good sessions." N2	N2, N3 (2)
Patient centred	"What I liked a lot was giving the the the patient, the client, sort of they had to choose, they were the ones to choose, if I am talking about the quit date, it's not me telling them, 'we are going to start from tomorrow and I am going to see you next week." N1	N1 (1)
Useful	"It was useful for patients to help them in stopping smoking." N3	N3 (1)

7.5.8.4 Views on the video clips shown

As outlined in table 7.11, all nurses thought that the videos portrayed had an impact on the participants' smoking behaviour.

Table 7.11: Nurses' views on the video clips shown

Themes	Quotes	Participants' code (number of participants)
Impactful	"when I showed this to certain patients, who we know have been successful in quitting smoking, I think it was was, the video had an impact on them. " N1	N1, N2, N3 (3)
Acceptable	"And I don't think it was like, graphic so it wouldn't, you know, influence the patients in a, you know, traumatic way" N3	N3 (1)

7.5.8.5 Views on the provision of Nicotine Replacement Therapy (NRT)

All nurses perceived the provision of the NRT as helpful for patients to quit smoking (table 7.12). Furthermore, two nurses also thought that this was helpful for those who could not afford them as these were provided for free.

Table 7.12: Nurses' views on the provision of Nicotine Replacement Therapy (NRT)

Themes	Quotes	Participants' code (number of participants)
Helpful to quit smoking	"I think it helped a lot especially with one of the patients who managed to stop smoking, emm helped a lot." N3	N1, N2, N3 (3)
Helpful for those who cannot afford them	"maybe they couldn't afford the NRTs.. with this method, at least if they had a problem in in their, financial problems, emm, this helped a lot hu, that the NRTs were provided for free." N2	N1, N2 (2)

7.5.8.6 Challenges experienced in delivering the intervention

Several challenges were perceived by the nurses (table 7.13). All nurses perceived a lack of experience/confidence in delivering the study intervention. Additionally, they remarked on

their limited availability. Two nurses also found it difficult when dealing with challenging patients.

Table 7.13: Nurses' perceived challenges in delivering the intervention

Themes	Quotes	Participants' code (number of participants)
Lack of experience/confidence	"Maybe I need to learn more, but the more we went along, I felt more confident every time." N2	N1, N2, N3 (3)
Limited availability	"We could have had more time, em, with the patients I suppose but unfortunately we can't because of resources." N1	N1, N2, N3 (3)
Challenging patients	"not all of them that tried to stop managed, because most of our patients are the uncontrolled ones." N2	N1, N2 (2)

7.5.8.7 Practice facilitators

On the other hand, all nurses identified practice facilitators (table 7.14). Knowing the patient and the use of the smoking cessation guide provided, facilitated the intervention delivery.

Table 7.14: Nurses' perceived facilitators in delivering the intervention

Themes	Quotes	Participants' code (number of participants)
Knowing the patient	"Knowing the patient, more than anything, you know. Knowing them, sort of, sort of, as I said before, having known them for many years, and em, I think having a relationship with the person, the patient, made it easier." N1	N1, N2 (2)
Smoking cessation guide	"The fact that I had a written protocol helped a lot, because you follow the protocol and emm, I didn't miss out on anything. So that helped a lot." N3	N2, N3 (2)
Practice	"the more I did, the more confident I felt" N2	N2 (1)

7.5.8.8 Suggestions for improvement

Two suggestions were made by two of the three nurses (table 7.15). Both nurses suggested following continuing smokers further, i.e. providing them with an additional session. Additionally, one of the nurses suggested planning follow-up sessions beforehand so as to make sure to follow up the patients in the stipulated time frame.

Table 7.15: Nurses' suggestions for improvement

Themes	Quotes	Participants' code (number of participants)
Following non-quitters further	"like we had some patients if they failed … maybe we give them another, another trial. We are saying that instead of three times, maybe, maybe we see them four times, giving them another trial, not more." N2	N1, N2 (2)
Planning follow-up sessions beforehand	" So there were times when we didn't have a one, a one week after appointment. So, what what I thought, maybe for the next time we have patients, when we give the first appointment, we make sure that the second appointment we have available one to two weeks after." N2	N2 (1)

7.6 Discussion

The main findings obtained are discussed in the following sub-sections in view of the pilot study's objectives.

7.6.1 Recruitment and implementation processes

7.6.1.1 Recruitment

This study took six months to recruit the required sample size from the two main hospitals. As was found in the systematic review and meta-regression analysis on the predictors of recruitment and retention in randomised controlled trials of behavioural smoking cessation interventions by Bricca et al. (2022), the active identification of potential participants by health care professionals (with whom patients might feel close with), such as the diabetes practice

nurses, helped to improve study uptake. However, it is worth noting that these nurses only see a small proportion of the individuals with diabetes (who smoke) who attend to the diabetes outpatients' departments. Conversely, fewer participants were recruited from the outpatients' departments. Considering the noted challenges in recruiting participants, it became apparent that additional recruitment efforts would be required to successfully recruit a larger number of participants for the feasibility study. Hence it was suggested to inform all health care professionals working at the diabetes outpatients' department about the study so that they can help identify potential patients for study recruitment during their practice. Considering that the provision of feedback on the recruitment process and the trial to the recruiters may also help improve recruitment rates (Briel et al., 2016; Treweek et al., 2018), it was also suggested to follow-up and keep the health professionals updated on the recruitment process and the feasibility study to encourage the identification of potential participants further.

7.6.1.2 Implementation

The study intervention was successfully delivered over a median number of 7 weeks. This allowed the intervention to be delivered by the end of the study period. The support sessions were also provided according to the estimated times (as displayed in figure 6.2).

All nurses had a positive impression of the intervention and in almost all instances treatment fidelity was high; 80-100% (Borrelli, 2011; Salloum et al., 2022). Given this finding, reviewing a random 20% of the audio recordings (all different types of sessions provided) in the feasibility was deemed optimal (Borrelli, 2011). It was however noted that the nurses did not always set the first (or second) follow-up appointment in a week from the Target Quit Date (TQD). This was found to be due to their limited availability. One of the nurses in fact suggested the planning of follow-up sessions beforehand to ensure that patients were followed up in the stipulated time frame. This strategy was recommended for when conducting the feasibility study. Given that the percentage adherence of treatment fidelity for delivering session two (for those who quit smoking), or session three (for those who reported abstinence the first time) was slightly less than 80.0%, remedial training (highlighting the omitted treatment actions/components) was recommended (Borrelli, 2011).

Despite having perceived a lack of experience/confidence when delivering the intervention to the patients, the nurses found that having the smoking cessation guide facilitated delivery. The use of a scripted guide or treatment manual is in fact one of the key recommendations for enhancing treatment fidelity (Borrelli, 2011). Given that the nurses also stated that having

known the patients helped them in delivering the intervention, the recruiting of participants from additional study locations to increase the number of participants for the feasibility study was avoided.

7.6.2 Intervention

As reported in the analysis of the findings obtained from the questionnaires and the interviews held, most participants were satisfied with the intervention provided, stating that it was helpful, supportive, and informative. They also remarked on its usefulness, particularly the provision of NRT, which was also perceived as helpful by the nurses. While a few participants disliked/did not want to watch the video messages, the remaining participants reported finding these as impressive and impactful, as did the nurses. Furthermore, most participants remarked that it was easy to attend to the smoking cessation intervention, suggesting that location and timing was also not an issue for the participants.

However, as reported in section 7.5.3, the participation rate was low (55.9%). Since some participants failed to attend a scheduled session and were subsequently not seen again, it was recommended to follow up with them to determine whether they are still interested in attending. Most respondents to the end of study questionnaire reported stopping attending as they did not find the NRT as effective, or because of personal/family issues. Treatment discontinuation was also found to be a common cause for attrition (approximately 30%) in the study on the efficacy and safety of varenicline among individuals with type 2 diabetes by Russo et al. (2022), which is further outlined in chapter nine. Given that few participants provided suggestions for improving participation or the support provided, it was recommended to explore further the views of participants on the usefulness of the intervention provided (including the use of pharmacotherapy) and any challenging contextual issues for improving participation when holding follow-up interviews in the feasibility study.

Unlike in Canga et al.'s (2000) study (referred to in chapter four), where only 23.8% accepted the NRT provided, almost all participants in this pilot study accepted and tried the NRT provided, reporting being mostly satisfied with it. The reported level of adherence (both the nicotine patch and the mouth spray) as recorded in the intervention logs was high during the first week following the first and second TQD. However, the rate of use of the nicotine patch during the subsequent four weeks was lower than that reported in the systematic review and meta-analysis on the level of adherence to NRT among participants of randomised controlled

trials by Mersha et al. (2021) (61%, 95% CI: 54-68%) and the previously referred study by Hollands et al. (2013) (median: 45%). Various factors could have played a role in this. Some participants might have reduced the use of the nicotine patch because of the minor adverse effects reported (e.g., skin irritation), which are commonly reported in the literature (Hartmann-Boyce et al., 2018), or because they were trying to tail them off. Conversely others might have stopped using them as they had restarted smoking. In fact, several participants returned some of the NRT supplies provided. While it was again suggested to explore further why participants might reduce/not use all the NRT provided when carrying out follow-up interviews in the feasibility study, it was also suggested to assess and compare the adherence to NRT among those who report being abstinent from tobacco smoking and those currently smoking at the final follow-up session.

As reported in the literature (Rotella & Mannucci, 2013; Smith et al., 2013), in this pilot study several participants were found to be potentially suffering from anxiety and/or depression. However, most refused the psychological support service offered, mostly because they felt that this was not required, or they were not interested. Thus, it was suggested to explore further the reluctance to try such services when carrying out follow-up interviews in the feasibility study.

Despite the reported satisfaction with the intervention provided and its perceived utility, a few participants who did not manage to quit smoking and were thus provided with three sessions in total, remarked on the lack of further support. The nurses also suggested following such patients further, by providing an additional session. Hence the addition of a follow-up session to those who report not quitting smoking, i.e. by still providing them with a fourth (final follow-up) session, was recommended. Additionally, given that the nurses did not always set the first (or second) follow-up appointment in a week from the Target Quit Date (TQD) due to limited availability, it was also recommended to extend the timeframe for these appointments for up to two weeks from the TQD.

7.6.3 Data collection methods

7.6.3.1 Questionnaires' response rate

The response rate at 12 weeks follow-up, i.e. the answering of the end of study questionnaire, which includes the assessment of tobacco use was high. This was also the case of most of the studies discussed in chapter four.

7.6.3.2 Internal consistency of the satisfaction and perceived usefulness questionnaires

Both the satisfaction and perceived usefulness questionnaires were found to have a high internal consistency, >0.8 (Field, 2017). Furthermore, all items correlated well with the total. These questionnaires provide a better alternative to the previously mentioned standard satisfaction questionnaire by Larsen et al. (1979), or the specific UK National Health Service Stop Smoking Service Client Satisfaction Survey by May et al. (2009). Furthermore, the addition of the perceived usefulness questionnaire can further help in assessing patient acceptability by investigating the participants' perceptions of the smoking cessation intervention in providing the necessary information, motivation and behavioural skills for stopping smoking as per the Information-Motivation-Behavioural Skills (IMB) model (Fisher et al., 2006; Fisher et al., 2003). These questionnaires were thus recommended for use in the feasibility study.

7.6.3.3 Amendments to the data collection methods

No amendments to the questionnaires, the intervention logs, or the audio-recording of the study intervention were deemed necessary. The interview guide for interviewing the study intervention participants was however revised, based on the above recommendations and the feasibility study's objectives which are different to those of this pilot study (outlined in section 8.3).

7.6.4 Strengths and limitations

This pilot study, which employed the same protocol as initially proposed for the feasibility study, helped to test, and provide recommendations for improving the recruitment and implementation processes, the study intervention and the data collection methods. The use of qualitative research with both the nurses and the individuals with diabetes, the logging of information on the provision of the intervention and the audio-recording of the intervention sessions, and the satisfaction and perceived usefulness questionnaires generated enough information to address this pilot study's objectives.

The satisfaction and perceived usefulness questionnaires were devised (and content validated) to be used in the feasibility study for those who were assigned to the intervention (provision of the developed diabetes-specific smoking cessation intervention) and to the control group (provision of general smoking cessation support by the National Health Service). However, the internal reliability assessment was only conducted with a small sample of participants who

attended the proposed study intervention. Furthermore, data was non-normally distributed. This can lead to over- or under-estimation of internal consistency reliability (Liu & Zumbo, 2007; Sheng & Sheng, 2012). Therefore, future research should involve a larger sample to better approximate a normal distribution. While it is also recommended to assess the external reliability of the questionnaires and validate the constructs using a larger sample, the results of this study support the use of these questionnaires for assessing and comparing the acceptability of smoking cessation interventions among individuals with diabetes in pilot/feasibility studies (Bujang et al., 2018). Additionally, as described earlier, in the feasibility study semi-structured interviews were also held to explore the participants' perceptions of the study intervention and their experience, providing further understanding of their satisfaction with and perceived usefulness of the intervention provided.

7.7 Implications for the refinement of the intervention, its delivery and the feasibility study

This study helped to test (for refining) the recruitment and implementation processes, the study intervention, and the data collection methods prior to the feasibility study which is reported in the next chapter. Considering the noted challenges in recruiting participants, it was decided to approach the other health care professionals working at the diabetes outpatients' department to help in the study recruitment. Therefore, in addition to the diabetes practice nurses and the diabetologists, the health care professionals working at the diabetes outpatients' department, namely the podiatrists and the nurses, were also informed about the study so that they could help identify potential patients for study recruitment. Furthermore, it was recommended to follow-up and keep the health professionals updated on the recruitment process and the feasibility study to encourage participant recruitment.

Most participants were satisfied with the intervention provided, perceiving it as useful. However, a few participants who did not manage to quit smoking and were thus provided with three sessions in total, remarked on the lack of further support. In agreement with the nurses, the study intervention was revised so that an additional follow-up session to those who report not quitting smoking, i.e. by still providing them with a fourth (final follow-up) session, was to be provided. Furthermore, in view of the nurses' limited availability, it was agreed that

sessions were to be planned beforehand to ensure adherence to the stipulated time frame. Additionally, the timeframe for setting the first and second follow-up appointments was extended (up to two weeks from the TQD), providing more flexibility to the nurses in setting these appointments. As noted earlier, some participants failed to attend a scheduled session and were not seen again. In agreement with the nurses, it was decided to follow up these patients to determine whether they were still interested in attending. If still interested, their follow-up session could be rescheduled accordingly.

While the mean percentage adherence of treatment fidelity was high in almost all instances (above 80.0%), when delivering session two (for those who quit smoking), or session three (for those who reported abstinence the first time) it was found to be slightly less than 80.0%. Hence, remedial training was advisable prior to carrying out the feasibility study. Given that the nurses did not always set the first (or second) follow-up appointment in a week from the set TQD, the planning of sessions beforehand to ensure that patients were followed up in the stipulated time frame was also agreed on for the feasibility study.

No amendments to the data collection methods were deemed necessary. The interview guide for the individuals with diabetes was however to be revised based on the posed recommendations for comprehensively investigating the satisfaction with and perceived usefulness of the studied smoking cessation intervention as per the feasibility study's objectives.

The following chapter provides a brief description of the remedial training which was provided to the nurses and the revised intervention. This is followed by a detailed report on the feasibility study which was undertaken.

7.8 Conclusion

This chapter described the development and validation of the satisfaction and perceived usefulness questionnaires and the piloting of the feasibility study with a small sample of smokers with diabetes recruited from the two main acute hospitals in Malta over a six-month period. Most participants were satisfied with the intervention provided, perceiving it as useful. The three diabetes practice nurses who agreed to participate in the doctoral research project as intervention providers had a positive impression of the intervention and in most instances

treatment fidelity was high, 80-100%. Both the English and the Maltese versions of the self-developed questionnaires were found to have a high internal consistency, >0.8.

This chapter ended by highlighting the required revisions for the feasibility study. Mainly it was decided to revise the recruitment strategy for the feasibility study by involving the other health care professionals working at the diabetes outpatients' department with the aim of increasing the number of recruited participants. Furthermore, given that treatment fidelity was not always high, remedial training was also advisable prior to carrying out the feasibility study. Based on the participants' feedback and in agreement with the nurses, the study intervention was also revised so that an additional follow-up session to those who report not quitting smoking, was to be provided.

The following chapter describes the revised intervention, and the training provided, and the feasibility study which was undertaken.

Chapter 8: Assessing the feasibility, acceptability and potential effectiveness of the multi-component smoking cessation intervention – a randomised feasibility study

8.1 Introduction

This chapter briefly describes the refined study intervention, and the remedial training provided, and reports on the feasibility trial which was then undertaken. Thus, while section 8.2 provides an outline of the finalised study intervention and of the remedial training given, the remainder of the chapter describes the randomised controlled study which was primarily undertaken to establish the feasibility and acceptability of the multi-component smoking cessation intervention amongst the providers and the participants, and the intervention's potential effectiveness in preparation for a future definitive evaluation. In section 8.3, the aims and objectives of the randomised controlled feasibility study are presented. Section 8.4 details the study methods, providing information on the study design, sampling, procedures, data collection methods used, data analysis, criteria for proceeding to a future trial, and ethical considerations. Section 8.5 then reports the findings from this study, which are then discussed in section 8.6. Section 8.7 is a conclusion to this chapter.

8.2 The refined study intervention and the remedial training provided

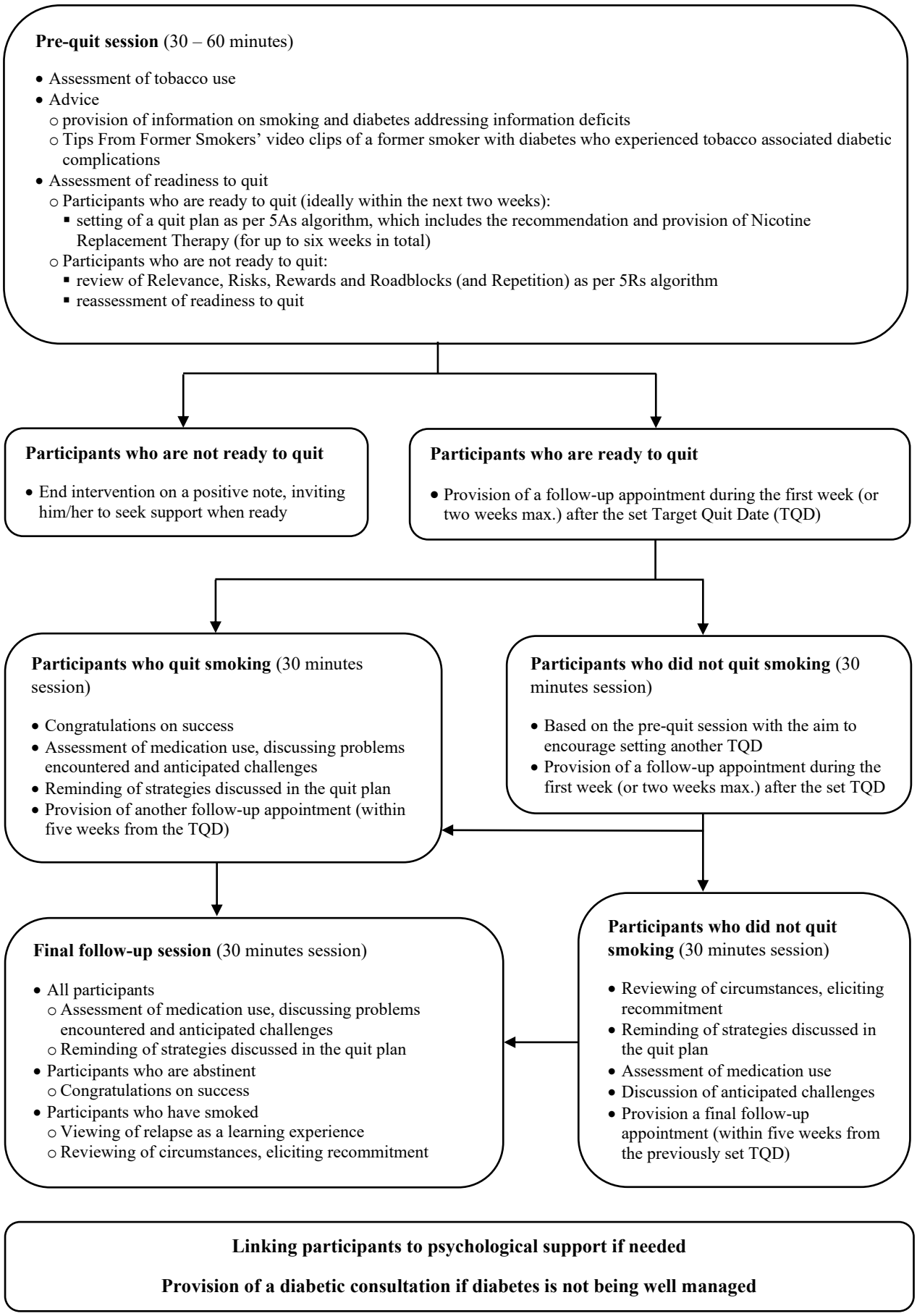
8.2.1 Study intervention

The revised model for delivering the smoking cessation intervention is displayed in figure 8.1 below. The process which was followed is the same as was described in sub-section 6.2.2, however, at the final follow-up session non-quitters were supported further.

As in the previous sessions, the barriers and challenges to quitting and any problems when using Nicotine Replacement Therapy (NRT) were discussed. Participants were also encouraged to attempt quitting again, reviewing the strategies outlined in the quit plan, and

discussing anticipated challenges. Participants were reminded that this was a learning experience and were encouraged to seek tobacco cessation services. The structured guide which was followed in delivering the intervention is presented in Appendix 8.1.

Figure 8.1: Intervention algorithm for the feasibility study



8.2.2 Remedial training

As pointed out in section 7.7, remedial training was advisable prior to carrying out the feasibility study. The training programme used for remedial training was similar to that outlined in section 6.3.1. The aim of the training session was to:

- reinforce previous learning;
- address any knowledge and skills gap by highlighting the omitted treatment actions/components (namely the importance to refer to/identify what would be relevant for the patient if he/she quit smoking); and
- outline and practice the revised study algorithm.

The training session was delivered once at an acute public hospital in Malta on the 31st of July 2023. The session lasted about 2 hours. The session was delivered by the author, who used a PowerPoint® presentation (Appendix 8.2) and followed a prompt guide to maintain fidelity (Borrelli, 2011; Salloum et al., 2022). The nurses were provided with the updated model for delivering the smoking cessation intervention and the structured guide that had to be followed for maintaining fidelity (Borrelli, 2011; Salloum et al., 2022). As recommended in section 7.7, they were reminded to plan sessions for participants' beforehand, to ensure that these were seen in the stipulated time frame. Participant recruitment for the feasibility study commenced on the following day.

8.3 Aim and objectives

The aim of this randomised controlled feasibility study was to establish the feasibility and acceptability of the multi-component smoking cessation intervention amongst patients and providers, and to assess its potential effectiveness prior to future evaluation and implementation.

The study's objectives were to:

- assess the feasibility of the intervention for a future definitive trial, by
    - analysing the recruitment and study uptake,
    - and the nurses' perceived challenges and facilitators to implementation;

- assess the acceptability of the intervention, by
    - analysing the participants' and the providers' satisfaction with the smoking cessation intervention provided,
    - analysing the participants' perceived usefulness of the intervention,
    - and by comparing the participants' satisfaction with and perceived usefulness of the smoking cessation intervention provided to standard care – the provision of general smoking cessation support;
- determine the preliminary evidence for the intervention's effectiveness, by comparing the smoking cessation and reduction outcomes achieved in both groups;
- and conduct a preliminary process evaluation, by exploring the intervention's functioning, i.e. the hypothesised mechanisms that are to lead to the intervention's outcome, and assessing whether the intervention was delivered as intended.

8.4 Methods

8.4.1 Design

An open-label, pragmatic, experimental design with a nested qualitative descriptive study was adopted. While an experimental design is not a requirement for undertaking a feasibility study, this helps to test the full version of a protocol prior to a definitive evaluation (Treweek, 2015). This allows assessment of the feasibility of undertaking a trial, by analysing the recruitment and study uptake and the successful delivery of the intervention, providing an indication of the resources required (Giangregorio & Thabane, 2015). A comparative analysis of an alternative standard course of action, i.e. the provision of general smoking cessation support by the National Health Service, in terms of the study outcomes (i.e., the smoking cessation rates, along with the opinions about the intervention, and satisfaction with the support provided), also provides preliminary evidence of the intervention's effectiveness for proceeding to a future trial (Hounsome & Shearer, 2022; Skivington et al., 2021).

A pragmatic approach was adopted as health care interventions cannot be assessed in silos being largely dependent on the real-world context in which they operate (Skivington et al.,

2021). Additionally, an open-label design was followed since blinding of participants, the intervention providers and the researcher was not possible. The participants, being aware of standard smoking cessation care, were able to distinguish between the assigned arms. Furthermore, the participants were adequately informed about the interventions offered so that informed consent was achieved (Portney, 2020). Due to the pragmatic nature of the study, blinding of the diabetes practice nurses was also not possible. Furthermore, given that the Ph.D. candidate had to be actively involved in recruiting participants and carrying out pre- and post-intervention assessments and data analyses, blinding of the outcome assessment was also not possible. Nonetheless, blinding in this study, being a feasibility study, was not required as there was no formal hypothesis testing (Giangregorio & Thabane, 2015).

In addition to the experimental design, this study included a qualitative strand for exploring intervention acceptability among patients and providers. The addition of a qualitative component can enhance the understanding of aspects of the study intervention which may not be apparent at first sight (Creswell & Plano Clark, 2018). In this case, it helped provide an in-depth exploration of the participants' perceived usefulness and satisfaction with the experimental intervention, complementing the basic quantitative measures used amongst the patients (Feeley & Cossette, 2015). The consideration of the participants' experience in quitting smoking, also helped to provide further understanding of the intervention's functioning, as part of a process evaluation (Moore et al., 2015). The addition of a qualitative strand to the experimental design ultimately helped ensure that the nature of the participants' experiences and the outcomes of action were comprehensively captured to identify what works within the diabetes outpatients setting, in line with the philosophy of pragmatism (section 2.2.2).

Given that the addition of the qualitative strand to the experimental design helped to complement the quantitative acceptability measures used, the procedure outlined in the convergent design (or convergent parallel design), initially conceptualised as a triangulation design (Borglin, 2015; Creswell & Plano Clark, 2018), were followed. These included: the separate collection of the quantitative and qualitative data about the subject of interest (roughly at the same time period), the separate analysis using quantitative and qualitative analytic procedures, and then the merging or comparison of the separate results, as an additional analysis, followed by an interpretation for a better understanding in response to the study's objectives (Borglin, 2015; Creswell & Plano Clark, 2018).

This study was prospectively registered on ClinicalTrials.gov (NCT05920096). The feasibility study commenced in August 2023 and finished in October 2024.

8.4.2 Recruitment process and sampling

8.4.2.1 Experimental study (quantitative research)

The recruitment process for this experimental study followed closely that described in the pilot study (section 7.3.2). However, as was remarked in section 7.4.1, participant recruitment and intervention implementation at one of the hospitals stopped in January 2023 as the diabetes practice nurse started her planned long leave. On planning the feasibility study the nurse was still on long leave and was not planning to go back to work any time soon. In view that she was thinking of being absent from work for a year or more and that the hospital administration was not considering replacing her role in full, it was decided to carry out the study at the other acute public hospital only.

Current smokers of both genders with type 1 or type 2 diabetes, who were 18 years or older and able to understand English or Maltese, provide informed consent and attend the research sessions were eligible for this study. The diabetologists working at the diabetes outpatients' department and the diabetes practice nurses screened new patients attending their clinics for tobacco use, forwarding the contact details of those interested in quitting to the researcher, with consent. Additionally, the health care professionals working at the diabetes outpatients' department (namely the nurses and the podiatrists) helped in recruitment by identifying interested smokers, referring them to the study. As suggested by Briel et al. (2016), to enhance recruitment, frequent onsite visits were held, at least every month, and email reminders were sent. The diabetologists and health care professionals were updated on the recruitment process and encouraged further to refer patients to the study. As in the pilot study, posters and flyers (Appendices 7.1 and 7.2) were also present at the diabetes outpatients' department to encourage self-referrals.

A power calculation to determine the sample size is not appropriate for a feasibility trial as the establishing efficacy of an intervention is not the goal (Treweek, 2015). There are no universally accepted recommendations for calculating samples size for feasibility trials, however the sample size should be sufficient enough to provide estimates for the feasibility

outcomes, such as the rate of consent to the study, the compliance to the study protocol and response-rate at follow-up, which are required for informing the progression to a future definitive trial (Giangregorio & Thabane, 2015; Lewis et al., 2021). In feasibility trials, both Lancaster, Dodd, & Williamson (2004) and Hertzog (2005) suggest 30 – 40 participants per group. Sim & Lewis (2012), however, suggest at least 50 participants, while Treweek (2015) and Teare et al. (2014) suggest around 60 participants. Guidance from the National Institute for Health Research suggests a sample size of 40 to 50 participants for feasibility studies (Hooper, 2019). Thus, this study aimed to recruit a minimum of 80 and a maximum of 100 participants in total, which was deemed justifiable in view of the resources required and time available (Teare et al., 2014).

In 2022, 1,786 new patients, most of whom were living with type 1 or type 2 diabetes, attended the main acute public hospital in Malta (of whom 473 attended the diabetes education unit) (Clinical Performance Unit, 2023). Based on the previous outlined analysis by the Directorate for Health Information and Research (2023) (chapter 1), 17.4% of these were likely to be smokers. Assuming a yearly population size of approximately 311 individuals who smoke, a sample size of 100 (or 80) participants (with a 95% Confidence Interval), would be sufficient to provide the previously feasibility estimates with an acceptable margin of error of 8% (or 10%) (Field, 2017). Based on a 66.4% (interquartile range, IQR: 42.7%-85.2%) consent rate for participating in smoking cessation rates (Bricca et al., 2022), it was anticipated that the required sample size would be achieved in a year.

8.4.2.2 Qualitative research

As recommended by Creswell & Plano Clark (2018) and Moore et al. (2015), the qualitative sample was much smaller than the quantitative sample, consisting only of the individuals in the experimental group to obtain a more rigorous in-depth qualitative understanding of the acceptability of the study and the perceived mechanisms of the study intervention. Maximal variation sampling, where individuals with different perspectives on the phenomenon are selected (Creswell & Plano Clark, 2018), was most appropriate for the qualitative strand for this study. This is because it was important to understand the views of different participants as regards to the acceptability of the study intervention and also to understand the hypothesised mechanisms for smoking cessation from different viewpoints (Feeley & Cossette, 2015). Thus, the aim was to adopt a stratified purposeful sample by selecting individuals who:

- stopped and did not stop smoking during the trial

- attended and stopped attending the study intervention
- utilised and did not utilise the Nicotine Replacement Therapy (NRT) provided.

In selecting participants, due consideration was also made to sex and age.

There is little guidance as to the estimated sample size required for qualitative research, as part of an experimental study. Creswell & Plano Clark (2018) state that number can range from one to two participants for a narrative study, and 20 to 30 in a grounded theory project. However, the aim of utilising qualitative research was not to generate theory but to determine the acceptability, and hence the feasibility of the study, and to explore the intervention's mechanisms, as part of the preliminary process evaluation. Another approach to ensure a sufficient sample size is to base the sample size on the principle of 'data saturation' (Borglin, 2015; Creswell & Plano Clark, 2018), as was explained in chapter five. Given that no previous studies, exploring the acceptability of a smoking cessation intervention for individuals with diabetes or its mechanisms amongst individuals with diabetes, were identified in the scoping review (chapter three), in estimating the required sample size, reference was made to the seminal study by Guest, Bunce, & Johnson (2006), in which thematic saturation, was relatively achieved after only 12 interviews. This was increased to 20 to make sure that data saturation would be relatively achieved.

To help explore intervention acceptability and the feasibility of introducing this intervention in practice, qualitative research was also conducted with the two diabetes practice nurses who agreed to deliver the study intervention.

8.4.3 Implementation process

As was done in the pilot feasibility study, all prospective participants were screened by telephone to assess eligibility. Eligible interested individuals attended a pre-intervention assessment session for providing informed consent. These were then randomly allocated to intervention or control on a 1:1 ratio using a computer-generated random block length (in blocks of two and four), using the random allocation software by Saghaei (2004). The sequence was prearranged before the commencement of the study, with assignments sealed in sequentially numbered opaque envelopes. The envelopes were assigned to the participants in the order they were met, prior to assessing their characteristics. Those assigned to the intervention group were provided with the developed intervention as described earlier.

Conversely, those assigned to the control group were actively referred to the National Health Service's one to one smoking cessation services which are provided within the primary care clinics around Malta. The smoking cessation support sessions were based on motivational interviewing and delivered by trained tobacco cessation facilitators. The sessions (lasting around 20 minutes each) were usually provided every fortnight, based on the clients' needs, during the 12-week study period. Occasionally, the facilitators also provided brief telephone calls (length not documented) to follow up on clients who had set a Target Quit Date (TQD).

8.4.4 Data collection methods

In addition to collecting data on the recruitment process (i.e., the number of referred smokers, per recruitment source, per month, taking note of any reasons for ineligibility, and for non-participation at consent stage), various data collection methods were utilised to achieve the set study objectives. The data collection methods used are outlined in the sub-sections below.

8.4.4.1 Baseline questionnaire

In the pre-intervention assessment session, the baseline questionnaire (outlined in detail in section 7.3.4.4) was used to collect information among all participants. Consisting of four sections, the questionnaire collected information on the participants' main characteristics, their perceived health status and diabetes profile, their smoking profile, and their anxiety and depression levels over the past week. The questionnaire is available in Appendices 8.3 and 8.4 (English and Maltese versions, respectively).

8.4.4.2 End of study questionnaire

At 12 weeks follow-up, all participants were invited to fill in the end of study questionnaire and to confirm self-reported abstinence. The end of study questionnaire was utilised to:

- assess for smoking abstinence;
- characterise the support utilised; and
- investigate the participants' satisfaction with the intervention and their perceptions of its usefulness.

More details on the content of the questionnaire and the process followed for biochemical verification of self-reported abstinence at follow-up (seven-day point-prevalence abstinence) is available in section 7.4.4.4. The questionnaire is available in Appendices 8.5 and 8.6

(English and Maltese versions, respectively). Participants were given the English or the Maltese versions of the baseline and end of study questionnaires, according to their preference.

8.4.4.3 Semi-structured interviews

As was explained in section 7.4.4.1, interviews were the best method for exploring acceptability amongst the study intervention participants. The use of interviews has also been recommended for understanding the functioning of the study intervention in practice (Creswell & Plano Clark, 2018; Moore et al., 2015), and for understanding the barriers and facilitators to implementation (Dogherty & Estabrooks, 2015). As was carried out in the pilot study, semi-structured interviews were carried out with the study intervention participants to obtain feedback on the study intervention (for assessing acceptability), and to explore their quit attempt (to explore the functioning of the study intervention). Semi-structured interviews were also carried out with the nurses to obtain feedback on the study intervention (for assessing acceptability) and to explore the facilitators and challenges to implementation (for assessing feasibility in implementation).

Interviews followed a question and probe guide. One guide was developed for use amongst individuals with diabetes and another for use amongst the diabetes practice nurses. Both interview guides included questions on personal (and professional) characteristics. Additionally, the interview guide for the study intervention participants included questions about their diabetes and smoking profile and on the smoking cessation support received.

To assess acceptability amongst the individuals with diabetes and the nurses, the participants were asked about their general impressions of the intervention features (including their opinions on the mode of delivery, and overall duration of the intervention), the facilitators and challenges encountered, and whether they would recommend the intervention to someone else who smokes (for the individuals with diabetes). Both the nurses and the individuals with diabetes were also asked to indicate whether they felt that the intervention was lacking in some aspect in supporting smoking cessation.

To explore the hypothesised mechanisms that lead to smoking cessation, the study intervention participants were asked about their quit attempt. As recommended by Atkins et al. (2015), theory guided the qualitative process evaluation, basing the questions/probes on the constructs of the Information-Motivation-Behavioural Skills (IMB) model for behaviour change (Fisher et al., 2006; Fisher et al., 2003), which was also used to frame the intervention. On the other

hand, to assess feasibility in implementation, the nurses were asked about the perceived facilitators and challenges towards implementing the intervention in practice.

Both question guides were reviewed by the supervisors. The question guide for use amongst individuals with diabetes was then translated in Maltese by a professional bilingual translator to ensure accuracy.

Both interviews lasted between 15 to 30 minutes. The interviews held with individuals with diabetes were held in Maltese or English, depending on the preference of the interviewee. The Ph.D. candidate moderated all interviews, posing the questions to the participants and stimulating further responses by using the structured prompts and other probes as necessary. The interviews were audio recorded with consent. The interview guide for individuals with diabetes in English and Maltese is provided in Appendices 8.7 and 8.8, respectively, while the guide used amongst nurses is provided in Appendix 8.9.

8.4.4.4 Audio-recording of the provision of the study intervention

As was done in the pilot feasibility study, to help capture fidelity, for assessing provider consistency and standardization across the nurses' practices (Borrelli, 2011; Moore et al., 2015), the nurses were asked to audio-record the sessions with consent.

8.4.4.5 Intervention log

Intervention providers also kept an intervention log, documenting the participants' compliance to the protocol, the resources utilised and any challenges encountered (Feeley & Cossette, 2015). The information collected was outlined in section 7.3.4.3. Additionally, any reasons reported by participants for discontinuing the study intervention were noted. The tobacco cessation officer at the National Health Service's smoking cessation services was also asked to take note of the number of sessions provided (including the number of weeks during which the sessions were provided) and any dropouts (with reasons).

8.4.5 Data analysis

Based on the recommendations for the analysis of pilot and feasibility studies, where a formal power calculation is not carried out, quantitative data analysis was descriptive in nature and no statistical comparison between the intervention and control groups were undertaken (Lee et al., 2014; Teresi et al., 2022; Thabane et al., 2010). Nonetheless, as recommended in the literature (Lee et al., 2014; Teresi et al., 2022; Thabane et al., 2010), the feasibility and acceptability

outcomes were reported with 95% Confidence Intervals (CI) to provide an estimated range of the said outcomes. Continuous data was summarised using means (and standard deviation, SD) and 95% CI or using medians (providing the interquartile range, IQR) for non-normal distributed data (tested by using the Shapiro Wilk test). Frequencies and proportions/percentages were used to report on categorical data. Proportions/rates were reported with 95% CI using the Clopper-Pearson 'exact' interval, which is deemed more conservative for estimating CIs when using binomial distributed data (Teresi et al., 2022; Wallis, 2013).

Qualitative data was summarised by following the Applied Thematic Analysis (ATA) approach by Guest et al. (2014), which was utilised and described in the qualitative descriptive study (chapter five). More detail on data analyses as per the data collection method used is provided in the sub-sections below.

8.4.5.1 Baseline questionnaire

The participants' baseline characteristics, as measured in the baseline questionnaire, were analysed per study group using descriptive statistics and described as outlined in section 7.4.5.4. In line with the Consolidated Standards of Reporting Trials (CONSORT) statement, no significance testing was conducted to assess the probability that these differences were due to chance, as randomisation already implies that these differences are due to chance (de Boer et al., 2015; Eldridge, Chan, et al., 2016; Moher et al., 2010). While analyses of outcomes adjusted for baseline imbalances may be useful in a definitive trial for providing additional information on the intervention's effectiveness, these are not appropriate in feasibility and pilot trials as these do not aim to determine treatment effects or differences in treatment effects across subgroups (Eldridge, Chan, et al., 2016). The baseline characteristics of those lost to follow-up/dropped out of the study and those followed up were compared descriptively. Additionally, the characteristics of those who did not attend to/discontinued the intervention during the study period and those who completed/continued the intervention during the study period were also compared descriptively.

8.4.5.2 End of study questionnaire

The data collected from the end of study questionnaire was also analysed per study group using descriptive statistics. Qualitative data was summarised by following the ATA approach (Guest et al., 2014). As was done in the pilot study, non-responders and participants whose abstinence could not be biochemically verified were considered non-quitters and non-reducers, in line with

standard smoking cessation research practice (Li et al., 2017; Russo et al., 2022; Theodoulou et al., 2023). There was no missing data in the responses to the sections on the perceived usefulness and satisfaction with the intervention provided, thus allowing the calculation of average scores without having to exclude cases, or impute data (e.g., single and multiple imputation) for missing data which meets the specification of missing completely at random (Mirzaei et al., 2022).

8.4.5.3 Semi-structured interviews

The characteristics of the interviewees, i.e. the individuals with diabetes in the intervention group and the diabetes practice nurses, were analysed and summarised descriptively. All audio recordings were transcribed verbatim and reviewed by listening again to ensure accuracy. As was done in the previous chapters (chapters five and seven) the transcripts in Maltese and English were not translated, in order to maintain the validity and reliability of the acquired data (Guest et al., 2014). All transcripts were then imported into NVIVO (version 1.5.1).

Given that qualitative research was used to enrich the experimental results in terms of providing an in-depth understanding of the acceptability of the study intervention and to understand the intervention's functioning, a manifest, or descriptive approach was utilised (Atkins et al., 2015). As recommended by Atkins et al. (2015), to explore how the intervention worked or how the participants responded to it, analysis was guided by the theory underpinning the study intervention (displayed in figure 6.1).

Qualitative data analysis was guided by the ATA approach (Guest et al., 2014), described in section 5.5.4. As was done in the qualitative descriptive study (chapter five), in outlining themes/sub-themes in the findings section, the original participants' quotes are provided. The English translations of quotes in Maltese are also provided. The steps outlined in section 5.5.5 were followed to enhance rigor.

8.4.5.4 Audio-recording of the provision of the study intervention

To assess for treatment fidelity (as part of the preliminary process evaluation), as was recommended in section 7.6.1.2, a random sample (20%) from all the audio recordings (all sessions provided) was selected. The audio recorded sessions were listened to, and by using a checklist outlining the study algorithm components (Appendix 8.10), the occurrence or non-occurrence of the algorithm components were scored for calculating the level of adherence (Borrelli, 2011). An 80-100% level of adherence constituted high fidelity, less than 80% medium fidelity, whereas ≤50% constituted low fidelity (Borrelli, 2011).

8.4.5.5 Recruitment and intervention log

The following feasibility outcomes were measured during the study recruitment period:

- The monthly recruitment rate of eligible smokers interested in quitting (recruitment rate);
- The proportion of eligible smokers identified from each source of recruitment; and,
- The proportion of participants who consent to the study (consent rate).

In addition, based on the information collected from the intervention logs, the following feasibility outcomes were measured:

- The proportion of participants who attended the scheduled sessions per group, along with reasons for not attending/discontinuing the intervention (participation rate);
- The reported use of NRT in the intervention group (as outlined in section 7.4.5.3);
- The average number of sessions provided per group, both for all participants and for those who completed/continued the intervention during the study period;
- The average duration (in weeks) of smoking cessation support provided per participant per group, both for all participants and for those who completed/continued the intervention during the study period;
- The average time (in minutes) taken to deliver the intervention sessions;
- The number of participants from the intervention group who were provided with the 5Rs intervention;
- The average number of NRT provided per participant (in the experimental group), both for all participants and for those who completed/continued the intervention during the study period; and
- The challenges to smoking cessation as identified by the nurses, i.e. the reported minor adverse events while using NRT, anxiety and/or depressive issues and glycaemic imbalances, and the number of referrals to additional support services, along with reasons for refusing support.

Additionally, as was recommended in section 7.6.2, a further analysis for assessing adherence to NRT among those who reported being abstinent from tobacco smoking at the final follow-up session and those who did not, was conducted.

Despite identifying the resources utilised in both groups, these were not costed and compared to the interventions' effect. This is because preliminary cost-effectiveness in feasibility studies, being based on small sample sizes and thus being under-powered, may inadvertently suggest that the intervention is cost-ineffective (Hounsome & Shearer, 2022). This would then jeopardise the progression to a full scale clinical trial of an intervention which could potentially be clinically effective or even cost-effective (Hounsome & Shearer, 2022).

8.4.5.6 Integrated data analysis

The end of study questionnaire, namely the satisfaction and perceived usefulness sub-sections, helped explore the intervention group participants' acceptability of the study intervention quantitatively, while the use of the open-ended questions complementing these measures (section 7.2) and the semi-structured interviews held with a sample of the intervention group participants provided an in-depth perspective on the matter.

To provide further understanding on the acceptability of the study intervention as experienced by the study participants (individuals with diabetes), the quantitative and qualitative data were analysed together. On identifying common concepts across both sets of the findings, these were compared to determine the ways they confirmed and expanded the evidence to ultimately enhance the understanding of the research objective, taking note of any disconfirming evidence (Creswell & Plano Clark, 2018). No data transformation integration procedures were carried out. Ultimately, all findings derived were integrated in a narrative discussion to understand what needs to be modified to enhance the feasibility and acceptability of the experimental intervention, prior to a future definitive study.

8.4.6 Criteria for proceeding to a future trial

Prior to carrying out the study, the following criteria were established so that a decision of whether to proceed to a future definitive trial could be made. The criteria set referred to the primary feasibility and acceptability outcomes, i.e., the recruitment and the study uptake, the acceptability of the intervention, and the providers' perceived challenges and facilitators to implementation.

As stated earlier, the required sample had to be recruited within a year. The study uptake criteria were based on the participation rates of two recent studies (Li et al., 2017; Russo et al., 2022). Li et al. (2017), who similarly provided individuals with type 2 diabetes with a counselling session at baseline, followed by a 1-week and 1-month follow-up session, reported participation rates of 90% and 86.2%, respectively (study discussed in chapter four). Conversely, Russo et al. (2022), who provided individuals with type 2 diabetes with weekly visits and varenicline for three months, reported an approximate 30% attrition (study is outlined in the next chapter). Based on these findings, the uptake for this study, including intervention participation rates, NRT usage (average percentage of days the nicotine patch and/or spray are used, at least during the first week after the TQD and the subsequent set TQD for continuing smokers) and response rate at the post-intervention assessment, had to be at least 70%. The participants from the intervention group had to rate the study intervention as satisfactory and useful, or above, with an average score of 32 and 56, respectively. The diabetes practice nurses had to be satisfied with the intervention, viewing it as feasible to introduce in practice for a definitive evaluation. Not reaching these criteria meant that modifications, informed from the qualitative findings, were required prior to a definitive evaluation.

8.4.7 Ethical considerations

As was described in chapter six, permissions were sought from the recruiting stakeholders, while ethical clearance was sought from the Faculty of Health Sciences Research Ethics Committee on behalf of the University Research Ethics Committee (UREC FORM V_15062020 8618). All permissions are found in Appendices 7.15-7.26. The same ethical considerations highlighted in section 7.4.6 were adopted. The information letters and consent forms used in the feasibility study are available in Appendices 8.11-8.20.

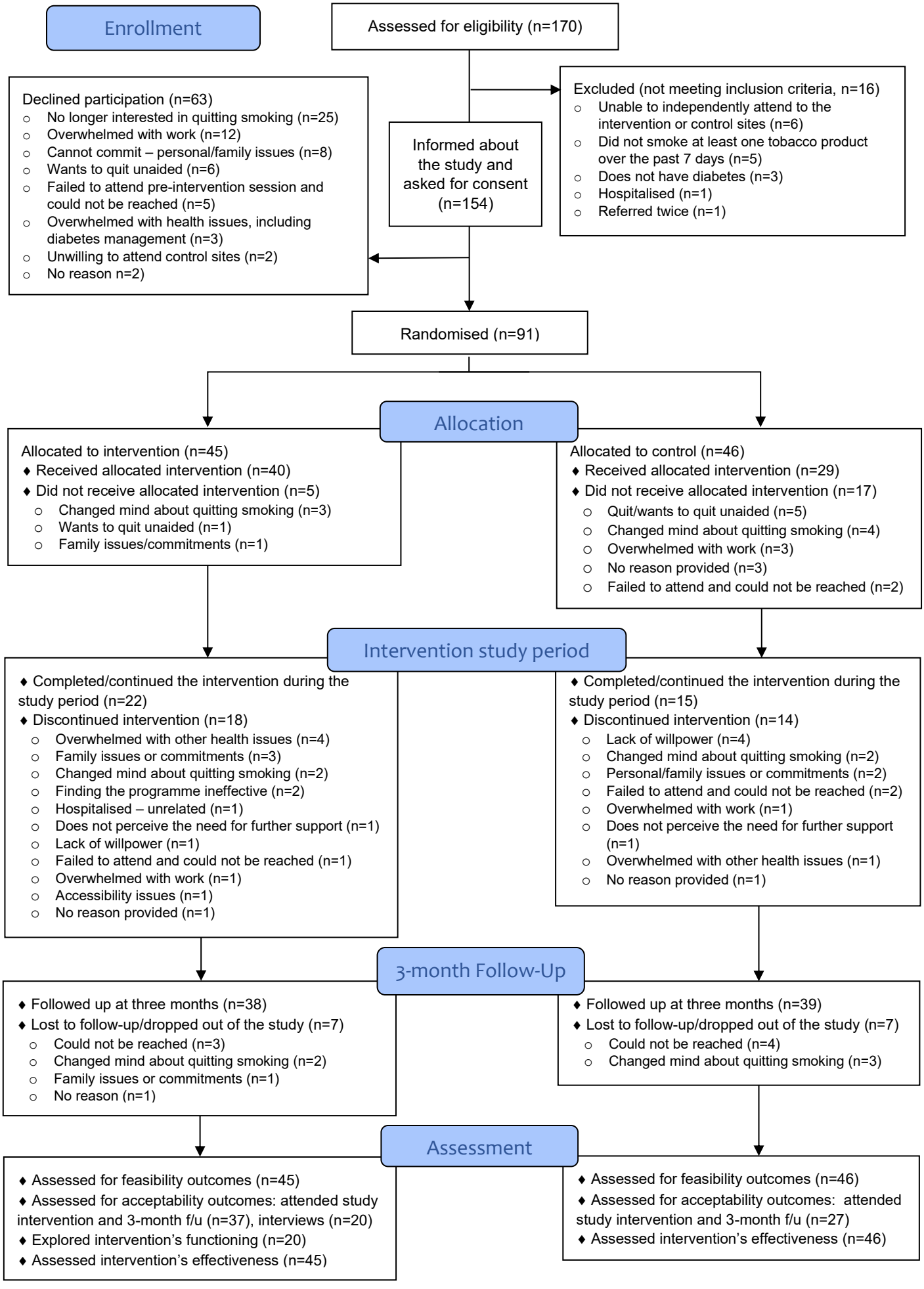
8.5 Study's findings

8.5.1 Recruitment parameters

One hundred and seventy individuals were referred to the study between August 2023 and July 2024. Of these, 16 individuals did not meet the inclusion criteria (see figure 8.2 below for full details). Eligible prospective participants were recruited to the study at a monthly rate of 13 participants (mean: 12.8, SD: 4.88). As displayed in Appendix 8.21, most participants (n=131,

85.1%) were recruited from the diabetes outpatients' department, mainly by nurses (40.9%). All prospective participants (n=154) were informed about the study and invited to consent; however, 63 individuals did not consent to the study (figure 8.2). Most of them stated that they were no longer interested in quitting smoking (n=25) or were overwhelmed with work (n=12) or could not commit because of personal/family issues (n=8). Thus, the consent rate stood at 59.1% (n=91). These were randomly assigned to the intervention (n=45) or to the control groups (n=46). Figure 8.2 shows the CONSORT flow diagram for randomised pilot and feasibility trials (Eldridge, Chan, et al., 2016).

Figure 8.2: The CONSORT flow diagram for this feasibility trial



8.5.2 Baseline characteristics of the individuals with diabetes who participated in the feasibility trial

The participants' demographic characteristics, their health status and diabetes and smoking profiles, and their anxiety and depression levels as measured by HADS, are outlined in table 8.1 below.

Table 8.1: Participants' characteristics at baseline per study group

Characteristics	**All participants** (n=91)	**Intervention group** (n=45)	**Control group** (n=46)
Demographics			
Sex, n (%)			
Male	65 (71.4)	35 (77.8)	30 (65.2)
Female	26 (28.6)	10 (22.2)	16 (34.8)
Age (years), median (IQR)	58.0 (50.0-63.0)	59.0 (50.5-63.0)	58.0 (49.0-64.3)
Education,[a] n (%)			
Upper secondary education	40 (44.0)	17 (37.8)	23 (50.0)
Post-secondary non-tertiary education	14 (15.4)	9 (20.0)	5 (10.9)
Lower secondary education	11 (12.1)	6 (13.3)	5 (10.9)
Primary education	10 (11.0)	5 (11.1)	5 (10.9)
Short cycle tertiary education	7 (7.7)	4 (8.9)	3 (6.5)
Bachelor's level	4 (4.4)	2 (4.4)	2 (4.3)
Master's level	3 (3.3)	2 (4.4)	1 (2.2)
Early childhood education	2 (2.2)	0 (0)	2 (4.3)
Employment status, n (%)			
Employed	58 (63.7)	30 (66.7)	28 (60.9)
Retired	18 (19.8)	9 (20.0)	9 (19.6)
Home duties	8 (8.8)	2 (4.4)	6 (13.0)
Unemployed	7 (7.7)	4 (8.9)	3 (6.5)
Living alone, n (%)			
No	72 (79.1)	35 (77.8)	37 (80.4)
Yes	19 (20.1)	10 (22.2)	9 (19.6)
Living with another smoker, n (%)			
No	51 (56.0)	29 (64.4)	22 (47.8)
Yes	40 (44.0)	16 (35.6)	24 (52.2)
Health status and diabetes profile			
Perceived health, n (%)			
Fair	51 (56.0)	27 (60.0)	24 (52.2)
Good	33 (36.3)	15 (33.3)	18 (39.1)
Bad	5 (5.5)	3 (6.7)	2 (4.3)
Very good	2 (2.2)	0 (0)	2 (4.3)
Very bad	0 (0)	0 (0)	0 (0)

Characteristics	All participants (n=91)	Intervention group (n=45)	Control group (n=46)
Diabetes type, n (%)			
Type 2	77 (84.6)	37 (82.2)	40 (87.0)
Type 1	14 (15.4)	8 (17.8)	6 (13.0)
Age at diagnosis (years), median (IQR)	46.0 (35.0-55.0)	49.0 (39.5-55.0)	43.0 (33.8-55.0)
Diabetic treatment, n (%)			
Antidiabetic pills	60 (65.9)	28 (62.2)	32 (69.6)
Insulin only	16 (17.6)	8 (17.8)	8 (17.4)
Antidiabetic pills and insulin	15 (16.5)	9 (20.0)	6 (13.0)
Diabetes complications, n (%)			
No	58 (63.7)	28 (62.2)	30 (65.2)
Yes	21 (23.1)	11 (24.4)	10 (21.7)
Don't know	12 (13.2)	6 (13.3)	6 (13.1)
Other chronic diseases, n (%)			
Yes	77 (84.6)	37 (82.2)	40 (87.0)
No	14 (15.4)	8 (17.8)	6 (13.0)
Smoking profile			
Age at initiation (years), median (IQR)	15.0 (13.0-16.0)	15.0 (13.0-16.5)	15.0 (13.0-16.0)
Cigarettes/day,[b,c] median (IQR)	20.0 (15.0-30.0)	20.0 (15.0-30.0)	23.0 (16.5-30.0)
CDS-5 score,[c,d] median (IQR)	20.0 (17.0-22.0)	20.0 (18.0-32.0)	20.0 (16.0-22.5)
Quit attempt/s in past 12 months, n (%)			
No	59 (64.8)	30 (66.7)	29 (63.0)
Yes	32 (35.2)	15 (33.3)	17 (37.0)
Ever quit smoking, n (%)			
Yes	60 (65.9)	30 (66.7)	30 (65.2)
No	27 (29.7)	12 (26.7)	15 (32.6)
Never attempted	4 (4.4)	3 (6.7)	1 (2.2)
MTTS,[e] n (%)			
I REALLY want to stop smoking but don’t know when I will. (4)	24 (26.4)	15 (33.3)	9 (19.6)
I want to stop smoking and hope to soon. (5)	23 (25.3)	13 (28.9)	10 (21.7)
I REALLY want to stop smoking and intend to in the next month. (7)	19 (20.9)	4 (8.9)	15 (32.6)
I REALLY want to stop smoking and intend to in the next 3 months. (6)	15 (16.5)	9 (20.0)	6 (13.0)
I want to stop smoking but haven’t thought about when. (3)	7 (7.7)	2 (4.4)	5 (10.9)
I think I should stop smoking but don’t really want to. (2)	3 (3.3)	2 (4.4)	1 (2.2)
I don’t want to stop smoking. (1)	0 (0)	0 (0)	0 (0)

Characteristics	All participants (n=91)	Intervention group (n=45)	Control group (n=46)
HADS[f]			
Anxiety subscale, n (%)			
Normal (0-7)	45 (49.5)	23 (51.1)	22 (47.8)
Probable presence (11+)	24 (26.4)	11 (24.4)	13 (28.3)
Suggestive presence (8-10)	22 (24.2)	11 (24.4)	11 (23.9)
Depression subscale, n (%)			
Normal (0-7)	63 (69.2)	29 (64.4)	34 (73.9)
Probable presence (11+)	14 (15.4)	6 (13.3)	8 (17.4)
Suggestive presence (8-10)	14 (15.4)	10 (22.2)	4 (8.7)
Probable presence of Anxiety and/or Depression			
No	62 (68.1)	32 (71.1)	30 (65.2)
Yes	29 (31.9)	13 (28.9)	16 (34.8)

IQR – interquartile range. a - As categorised in the International Standard Classification of Education (United Nations Educational Scientific and Cultural Organization, 2012). b - Includes six participants who smoked hand rolled cigarettes (four from the intervention group and two from the control group). One participant from the control group was a dual user, smoking also e-cigarettes. c - Excluding one participant (from the control group) who smoked 16 cigarillos a day. d - Cigarette Dependence Scale-5 (Etter et al., 2003). e - Motivation To Stop Scale Kotz et al. (2013). f - Hospital Anxiety and Depression Scale (Zigmond and Snaith, 1983).

As seen in table 8.1, most participants were male (n=65, 71.4%), in employment (n=58, 63.7%), holding an upper secondary level of education (n=40, 44.0%). Several participants did not live with another smoker (n=51, 56.0%). The majority had type 2 diabetes (n=77, 84.6%) and perceived their health as 'fair' (n=51, 56.0%). Twenty-one participants reported having diabetic complications. The reported diabetic complications in the intervention group included: peripheral vascular disease (n=6), neuropathy (n=3), retinopathy (n=3), non-alcoholic fatty liver disease (n=1) and erectile dysfunction (n=1). The reported diabetic complications in the control group included: peripheral vascular disease (n=6), neuropathy (n=5), retinopathy (n=1), coronary heart disease (n=1), nephropathy (n=1), chronic pancreatitis (n=1) and partial foot amputation (n=1). Several participants (n=77, 84.6%) also reported suffering from other chronic diseases. The most reported chronic diseases in the intervention group included: hypertension (n=23), hypercholesterolemia (n=22), coronary heart disease (n=7), anxiety (n=4), and depression (n=3). Similarly, the most reported chronic diseases in the control group included: hypercholesterolemia (n=29), hypertension (n=28), coronary heart disease (n=8), depression (n=6), anxiety (n=3) and asthma (n=3).

On average participants reported starting smoking at the age of 15 years. All smokers smoked daily; a pack (20 cigarettes) a day on average. The majority (n=59, 64.8%) had not attempted to quit smoking in the past 12 months, however most (n=60, 65.9%) did ever quit smoking in their life. Most participants (n=24, 26.4%) really wanted to stop smoking (strong desire) but didn't know when they will do so (no intention) or wanted to stop smoking and hoped to do so soon (n=23, 25.3%; moderate desire and intention). Several participants were found to be possibly (n=22, 24.2%) or probably (n=24, 26.4%) suffering from anxiety. Conversely, 28 participants were probable/suggestive cases of depression.

There was a good balance with respect to the age, employment status, health status and diabetes profile, presence of probable and possible anxiety and depression and smoking characteristics across the groups. However, there were slightly more females in the control group than in the intervention group. In addition, there were slightly more participants in the control group who had an upper secondary level of education, while there were slightly more participants in the intervention group who had a post-secondary non-tertiary level of education. While there were more participants in the control group who lived with a smoker, the participants in the control group were more likely to have a strong desire to quit smoking with an intention to quit in the short term than those in the intervention group.

8.5.3 Study uptake – findings from the analysis of the intervention logs

8.5.3.1 Smoking cessation support sessions provided

As displayed in figure 8.2, while 40 participants (88.9%) attended the experimental intervention, 29 (63.0%) attended the control intervention. Most of the participants from the intervention group who did not attend the experimental intervention stated that they had changed their mind about quitting smoking (n=3). Conversely, amongst those who did not attend the control intervention, most reported that they had quit or wanted to quit unaided (n=5) or that they had changed their mind about quitting smoking (n=4).

As displayed in figure 8.2, of the 40 and 29 participants who attended the experimental and control interventions, only 22 (55.0%; 95% CI: 38.5-70.7) and 15 (51.7%; 95% CI: 32.5-70.6) participants completed or continued attending the intervention during the study period (respectively). Figure 8.2 also outlines the reasons provided by the participants for discontinuing the intervention. Most participants in the intervention group discontinued the intervention as they were overwhelmed with other health issues (n=4), had family issues or

commitments (n=3), changed their mind about quitting smoking (n=2), or found the programme ineffective (n=2). Conversely, most participants in the control group discontinued the intervention because they lacked willpower (n=4), had changed their mind about quitting smoking (n=2), personal/family issues or commitments (n=2), or had failed to attend and could not be reached (n=2).

Table 8.2 displays the average number of support sessions provided per participant (and average intervention duration) per group, both for all the participants and for those who completed/continued the intervention during the study period. Most participants in the intervention group were provided with three or four sessions, while most participants in the control group were provided with just one or two sessions. Among the participants who completed/continued the intervention during the study period, most participants in the intervention group were provided with four sessions, while those in the control group were just provided with two sessions. This was because several participants in the control group (n=12) had either started the intervention late, postponed one or more sessions, or both. Three participants from the intervention group attended all the scheduled sessions during the study period but still had to attend another session (scheduled after the study period ended) because these had either started the intervention late, postponed one or more sessions, or both. As shown in table 8.2, the average number of weeks during which the experimental intervention was provided ranged from six (all participants) to nine weeks (those who completed/continued the intervention during the study period). The average number of weeks during which the control intervention was delivered ranged from one (all participants) to five weeks (those who completed/continued the intervention during the study period).

Table 8.2: Average number of support sessions provided per participant (and average intervention duration) per group

	Intervention group		Control group	
Smoking cessation support provided during the study period	All participants (n=45)	Participants who completed/ continued the intervention (n=22)[b]	All participants (n=46)	Participants who completed/ continued the intervention (n=15)[c]
Number of sessions, n (% [95% CI])				
No sessions[a]	5 (11.1 [3.7-24.1])		17 (37.0 [23.2-52.5])	
One session	9 (20.0 [9.6-34.6])		11 (23.9 [12.6-38.8])	3 (20.0 [4.3-48.1])
Two sessions	6 (13.3 [5.1-26.8])		12 (26.1 [14.3-41.1])	6 (40.0 [16.3-67.7])
Three sessions	13 (28.9 [16.4-44.3])	10 (45.5 [24.4-67.8])	4 (8.7 [2.4-20.8])	4 (26.7 [7.8-55.1])
Four sessions	12 (26.7 [14.6-41.9)	12 (54.5 [32.2-75.6])	2 (4.3 [0.5-14.8])	2 (13.3 [1.7-40.5])
Total time period during which the intervention was provided (weeks), median (IQR)	6.0 (1.0-9.0)	9.0 (7.8-10.0)	1.0 (0.0-3.0)	5.0 (3.0-7.0)

IQR – interquartile range; CI - Confidence Interval; a - These participants did not attend the smoking cessation intervention. b - Three participants attended all scheduled sessions during the study period but still had to attend another session (scheduled after the study period ended) because they had either started the intervention late, postponed one or more sessions, or both. Conversely, one participant missed one session as was hospitalised due to an ischaemic stroke (was advised by his General Practitioner to continue using the nicotine mouth spray to support smoking abstinence) but then attended his final follow-up session. c - Twelve participants were provided with only one, two, or three sessions during the study period, as they had either started the intervention late, postponed one or more sessions, or both.

The table in Appendix 8.22 displays the baseline characteristics of those who did not attend to/discontinued the intervention and those who completed/continued the intervention during the study period per assigned group.

Few differences were noted. It was observed that there were more participants from the control group who lived with another smoker who did not attend to/discontinued the study intervention (n=18), compared to those who did not (n=6). Additionally, it was noted that most participants from the control group who reported having never quit smoking (or ever attempted to) at baseline (n=13, 81.0%), discontinued or did not attend the control intervention. Most

participants in the control group who reported a moderate or no intention to quit smoking at baseline (n=22, 88.0%), were also more likely to discontinue (or not attend) the control intervention. Conversely, these patterns were not observed in the intervention group. Interestingly, most participants in the intervention group with a probable presence of anxiety and/or depression (n=9, 69.2%), were more likely to have completed/continued the intervention during the study period.

8.5.3.2 Participation rates

Tables 8.3 and 8.4 display the participation rates in the control and the intervention group (respectively) over the study period. Table 8.4 also outlines the average duration of the sessions held in the intervention group. In both study groups, participation rates dropped during the study period; with lower rates being reported in the control group. When taking into consideration all the participants who were assigned to the intervention and control groups (n=45 and n=46, respectively), the overall participation rates were of 48.9% (95% CI: 33.7-64.2) and 32.6% (95% CI: 19.5-48.0), respectively. The duration of the sessions of the experimental intervention were in line with the study protocol (table 8.5); the first session took slightly less than an hour, while the remaining sessions took about 30 minutes each.

Table 8.3: Participation rates (control group)

Participation rates during the study period[a]	**Control group,** n (% [95% CI])
Participation rate per session[a]	
First session (n=46)	29 (63.0 [47.5-76.8])
Second session (n=26)	18 (69.2 [48.2-85.7])
Third session (n=12)	6 (50.0 [21.1-78.9])
Fourth session (n=2)	2 (100)
Participants who attended and completed/continued the intervention during the study period (n=46)	15 (32.6 [19.5-48.0])

CI - Confidence Interval; a - Twelve participants were only provided with one, two, or three sessions during the study period, as they had either started the intervention late, postponed one or more sessions, or both.

Table 8.4: Participation rates and average duration of the sessions held (intervention group)

Participation rates during the study period[a]	**Intervention group,** n (% [95% CI])	**Average session duration** (minutes), median (IQR)
Participation rate per session		
First session (n=45)	40 (88.9 [75.9-96.5])	50.0 (45.0-60.0)
Second session (n=40)	31 (77.5 [61.5-89.2])	35.0 (30.0-45.0)
Third session (n=25)[b]	18 (72.0 [50.6-87.9])	30.0 (30.0-35.0)
Final follow-up session (n=22)[c]	19 (86.4 [65.1-97.1])	30.0 (25.0-30.0)
Participants who attended and completed/continued the intervention during the study period (n=45)	22 (48.9 [33.7-64.2])	

IQR – interquartile range; CI - Confidence Interval; a - Three participants attended all scheduled sessions during the study period but still had to attend their final follow-up session (scheduled after the end of study period) because they had either started the intervention late, postponed one or more sessions, or both. b - Held for those who did not report quitting smoking at second session. One participant missed this session as was hospitalised but then attended the final follow-up session. c - Excluding the three participants who had not attended their final follow-up session yet.

8.5.3.3 Provision and use of Nicotine Replacement Therapy, NRT (intervention group)

As shown in table 8.5, the average no. of seven-day packs of nicotine patches and nicotine mouth sprays provided was 5.5 and 2.0, respectively. As expected, more supplies were used by the average participant who completed/continued the intervention during the study period.

Table 8.5: Average amount of NRT provided per partcipant

Provision of NRT[a]	**All participants** (patch *n*=38) spray (*n*=45)	**Participants who completed/ continued the intervention** (patch *n*=19) spray (*n*=22)
Number of 7-day packs of nicotine patches, median (IQR)	5.5 (2.0-6.0)	6.0 (6.0-6.0)
Number of nicotine mouth sprays, median (IQR)	2.0 (2.0-4.0)	3.5 (2.0-4.0)

IQR - interquartile range; a - excluding returned unopened 7-day packs of nicotine patches and mouth sprays

The reported use of NRT as logged by the intervention providers is outlined in table 8.6 below. Most participants reported using the NRT provided during the first week from the TQD and the second week from the TQD (for continuing smokers). Three participants did not use the patch: two did not attempt to quit smoking, while no reason was provided by one participant. On the other hand, seven participants did not use the spray for the following reasons: did not attempt to quit smoking (n=2), minor adverse effects (n=2; see section 8.5.3.4 for details), no reason provided (n=2) and believed that NRT should only be used if not smoking (n=1). On average the participants reported utilising both the patch and the nicotine spray every day. The nicotine spray was applied 3-4 times a day, on average.

During the subsequent four weeks following one week from the last set TQD, 15 participants reported using the patch (88.2%) and the spray (78.9%); table 8.6. It was noted that two participants did not use patch: one participant remarked that supplies had finished, while no reason was provided for one participant. Four participants did not use the spray because of minor adverse effects (n=3), and because supplies had finished (n=1). During this four-week period, the participants used the patch and the spray less frequently (71.4% of the time). The nicotine spray was only applied two times a day, on average.

Table 8.6: Reported use of Nicotine Replacement Therapy (NRT) as logged by the intervention providers

Use of Nicotine Replacement Therapy (NRT)	**All attending participants**	
Use of NRT during the first week from the TQD	*Nicotine patch* (*n*=27)	*Nicotine mouth spray* (*n*=31)
Reported use of NRT, *n* (% [95% CI])	24 (88.9 [70.8-97.6])	26 (83.9 [66.3-94.5])
Percentage of days of NRT use, median (IQR)	100 (100-100)	100 (14.3-100)
No. of sprays applied per day, median (IQR)		3.0 (2.0-10.0)
Use of NRT during the first week from the subsequent TQD (for continuing smokers)	*Nicotine patch* (*n*=14)	*Nicotine mouth spray* (*n*=18)
Reported use of NRT, *n* (% [95% CI])	14 (100 [76.8-100])	16 (88.9 [65.3-98.6])
Percentage of days of NRT use, median (IQR)	100 (78.6-100)	100 (28.6-100)
No. of sprays applied per day, median (IQR)		4.0 (2.0-16.0)
Use of NRT during the subsequent four weeks following one week from the TQD	*Nicotine patch* (*n*=17)	*Nicotine mouth spray* (*n*=19)
Reported use of NRT, *n* (% [95% CI])	15 (88.2 [63.6-98.5])	15 (78.9 [54.4-93.9])
Percentage of days of NRT use, median (IQR)	71.4 (35.7-80.4)	71.4 (17.9-100)
No. of sprays applied per day, median (IQR)		2.0 (1.0-6.0)

TQD - Target Quit Date. IQR - interquartile range

The table in Appendix 8.23 displays the reported use of NRT during the subsequent four weeks following one week from the last set TQD per smoking status at the final follow-up session, i.e., abstinent from smoking or currently smoking. Almost all participants who reported being abstinent at final follow-up, reported using NRT. On average these participants reported utilising both the patch and the nicotine spray on most days of the week (≥75% of the period).

Conversely, the participants who did not report being abstinent from smoking used less NRT during this period (≤50% of the time, on average).

8.5.3.4 Problematic issues identified during the provision of the experimental intervention

Table 8.7 below, displays the problematic issues identified during the provision of the experimental intervention. During this period, it was noted that 19 participants were likely to be experiencing anxiety and/or depression and were thus advised to attend the psychotherapy service, which was available at the outpatients' department. While two participants reported already being seen by a psychotherapist/psychologist and so did not require a referral, only seven out of the remaining participants (n=17) accepted a referral to psychotherapy services. The remaining 10 participants declined the referral for the following documented reasons: not required/coping (n=3), not interested (n=3), being seen by a psychiatrist/on medication (n=3), focusing on a problem (smoking), one at a time (n=1). Of those who accepted the referral (n=7), four participants reported having attended. Two participants were lost to follow-up while the other participant stated that it was no longer required as he was coping.

As displayed in table 8.7, 12 participants reported minor adverse effects when using the NRT, which deterred them from using them. Most participants (n=8) reported mild mouth/throat irritation when using the nicotine mouth spray. Three participants reported a skin rash/irritation on using patch, while one participant reported heartburn when using the nicotine mouth spray.

During the study period (table 8.7), three participants reported experiencing hyperglycaemia while one participant reported hypoglycaemic events. These were invited to attend a diabetes education consultation, which they all attended. To resolve these issues, three participants were given lifestyle advice and had their insulin dosage revised, while one participant required lifestyle advice only.

Table 8.7: Identified problematic issues

Problematic issues to smoking cessation as identified by the intervention providers	**Intervention group,** n (% [95% CI])
Anxiety issues (n=40)[a]	17 (42.5 [27.0-59.1])
Depressive issues (n=40)[a]	11 (27.5 [14.6-43.9])
Anxiety and/or depressive issues (n=40)[a]	19 (47.5 [31.5-63.9])
Patient reported minor adverse events (n=31)[b]	12 (38.7 [21.8-57.8])
Patient reported glycaemic issues (n=31)[b]	4 (12.9 [3.6-29.8])

a - amongst those who at least attended their first session, b - amongst those who at least attended their second session

Unlike in the pilot study (section 7.4.3), the nurses did not report that any participants refused to watch the video clips featuring the story of Bill (part of the first session). Furthermore, all participants agreed on setting a TQD. The 5Rs intervention (as part of the first session) was delivered to two participants.

8.5.4 Acceptability of the study intervention – findings from the analysis of the end of study questionnaires

8.5.4.1 Response rate at the end of the study and respondents' characteristics

Seven participants from the intervention group and another seven participants from the control group were lost to follow-up/dropped out of the study (reasons displayed in figure 8.2). Thus, the response rate at the 3-month follow-up (post-intervention assessment) for the intervention group was 84.4% (95% CI: 70.5-93.5), while that of the control group was of 84.8% (95% CI: 71.1-93.7).

The table in Appendix 8.24 displays the baseline characteristics of those who were lost to follow-up and of the remaining participants per group. It was observed that the participants lost to follow-up were slightly younger than those who remained in the study (intervention group – 50 vs. 59 years; control group – 51 vs. 58 years).

8.5.4.2 Support utilised

The support utilised by the study participants has been reported in section 8.5.3. The table in Appendix 8.25 displays the reported smoking cessation support that was received or utilised during the study period for all the respondents (i.e. the participants who filled in the end of study questionnaire). Apart from 10 participants from the control group who used NRT, none of the participants reported receiving any additional support other than that provided in the assigned groups (described in section 8.5.3). The 10 respondents from the control group (25.6%) who reported using NRT, reported using the nicotine patch, spray or the gum for three to seven days.

8.5.4.3 Satisfaction with the smoking cessation intervention provided

Only the participants who attended the experimental and control interventions were asked about their satisfaction with and the perceived usefulness of the smoking cessation support provided; n=37 (intervention group), n=27 (control group). Tables 8.8 and 8.9 display the participants' ratings from the satisfaction questionnaire, per group. In general, the participants from both groups were satisfied or very satisfied with the respective intervention provided. However, on average, the participants from the control group remarked only being very satisfied with the 'Appointment times given.' Conversely, the participants from the intervention group reported being very satisfied with all the aspects of the intervention provided, except for, 'Number of sessions you had,' which was rated as satisfactory, on average. While the median total satisfaction score was high in both groups (>32), the intervention group had a notable higher score (37.0 vs. 33.0). This implies that the participants from the intervention group were more satisfied with the intervention provided, when compared to those assigned to the control group.

Table 8.8: Satisfaction with the smoking cessation intervention provided (Intervention group, n=37)

	Rating, n (%)					
How satisfied are you with the…	Very unsatisfied 1	Unsatisfied 2	Neutral 3	Satisfied 4	Very satisfied 5	Median (IQR)
Support you received to help you quit smoking.	0	0	0	10 (27.0)	27 (73.0)	5.0 (4.0-5.0)
Location where the smoking cessation intervention was provided.	0	1 (2.7)	2 (5.4)	10 (27.0)	24 (64.9)	5.0 (4.0-5.0)
Appointment times given.	0	0	3 (8.1)	10 (27.0)	24 (64.9)	5.0 (4.0-5.0)
Waiting period for having your first session.	0	0	0	12 (32.4)	25 (67.6)	5.0 (4.0-5.0)
Duration of each individual session.	0	0	0	13 (35.1)	24 (64.9)	5.0 (4.0-5.0)
Time interval between appointments.	0	0	1 (2.7)	13 (35.1)	23 (62.2)	5.0 (4.0-5.0)
Number of sessions you had.	0	1 (2.7)	2 (5.4)	16 (43.2)	18 (48.6)	4.0 (4.0-5.0)
Method used to help you quit.	0	0	5 (13.5)	10 (27.0)	22 (59.5)	5.0 (4.0-5.0)
Total median score (IQR)	37.0 (34.0-39.0)					

IQR - interquartile range

Table 8.9: Satisfaction with the smoking cessation intervention provided (Control group, n=27)

	Rating, *n* (%)					
How satisfied are you with the…	Very unsatisfied 1	Unsatisfied 2	Neutral 3	Satisfied 4	Very satisfied 5	Median (IQR)
Support you received to help you quit smoking.	1 (3.7)	1 (3.7)	5 (18.5)	7 (25.9)	13 (48.1)	4.0 (3.0-5.0)
Location where the smoking cessation intervention was provided.	0	0	5 (18.5)	11 (40.7)	11 (40.7)	4.0 (4.0-5.0)
Appointment times given.	0	0	3 (11.1)	9 (33.3)	15 (55.6)	5.0 (4.0-5.0)
Waiting period for having your first session.	0	2 (7.4)	4 (14.8)	10 (37.0)	11 (40.7)	4.0 (4.0-5.0)
Duration of each individual session.	0	0	1 (3.7)	13 (48.1)	13 (48.1)	4.0 (4.0-5.0)
Time interval between appointments.	0	3 (11.1)	5 (18.5)	7 (25.9)	12 (44.4)	4.0 (3.0-5.0)
Number of sessions you had.	0	1 (3.7)	5 (18.5)	12 (44.4)	9 (33.3)	4.0 (4.0-5.0)
Method used to help you quit.	2 (7.4)	3 (11.1)	7 (25.9)	7 (25.9)	8 (29.6)	4.0 (3.0-5.0)
Total median score (IQR)	33.0 (30.0-36.0)					

IQR - interquartile range

Thirty-six (97.3%) and 22 (81.5%) participants from the intervention and control groups (respectively), outlined what they were most satisfied with by answering the posed open-ended question. As shown in table 8.10, most participants from the intervention group were most satisfied with the NRT provided as this facilitated quitting (n=14), with the intervention which was informative (n=11) and supportive (n=9), with the intervention providers, who were socially skilled (n=7), and the encouragement given (n=4). Similarly, most participants from the control group highlighted the social skilled professionals (n=8), the supportive intervention (n=7), and the encouragement given (n=5) (Appendix 8.26).

Table 8.10: Aspects of the experimental intervention which the participants remarked being most satisfied with (n=36)

Themes	Quotes (translated quotes in italics)	Participants' code (number of participants)
Nicotine Replacement Therapy (NRT) facilitated quitting		
Helpful treatment provided	"plus the free patches and spray which helped me a lot." P12	P1, P2, P12, P13, P26, P34, P38, P50, P82 (9)
Nicotine mouth spray helped to relieve cravings	"Speċjalment l-ispray għax kif taqbadni l-leblieba tas-sigarett, nisprejja u jgħaddili." (*"The spray especially, because when I get a craving for a cigarette I spray and it goes away."*) P2	P2, P6, P9, P43, P75 (5)
NRT helped kickstart the quitting process	"It helped a lot that the sprays and patches ... It helped get me started." P1	P1, P18 (2)
Informative		
Explanations provided	"Bħala spjega. Spjegatli sewwa." (*"The explanation. She explained well to me."*) P48	P23, P45, P48, P53, P54, P66, P89 (7)
Informational videos on the consequences of smoking with diabetes	"Il-vidjow għoġobni ħafna għax fehmni fuq il-kumplikazzjonijiet." (*"I really liked the video because it made me understand the complications."*) P53	P53, P23, P61, P74, P77, P82 (6)
Supportive	"Is-sapport kien wieħed kontinwu" (*"The support was a continous one."*) P54	P6, P12, P22, P50, P53, P54, P59, P61, P89 (9)
Social skilled professionals	"Li tatni ċans nitkellem u niftaħ qalbi, u li qagħdet tismani wkoll." (*"That she gave me a chance to talk and open myself up, and that she listened to me too."*) P86	P9, P53, P58, P42, P70, P85, P86 (7)
Encouragement given	"Brought me forward to convince myself that I can work on it and do it." P69	P26, P64, P69, P86 (4)
Everything - nothing specific	"Kważi kollox għoġobni." (*"I liked almost everything."*) P29	P29 (1)
Having been suggested to attend psychotherapy as it is helpful	"Is-suġġeriment li nkellem terapista kien f'waqtu u qed tgħinni ħafna." (*"The suggestion to talk to a therapist was timely and it is helping me a lot."*)	P64 (1)

Nine (24.3%) and six (22.2%) respondents from the intervention and control groups respectively reported on an aspect of the smoking cessation intervention that they were least satisfied with. As seen in table 8.11, most participants in the intervention group referred to the minor adverse events on using NRT (n=2), the nicotine patches, which were perceived as ineffective (n=2), and being told to set a target quit date was not seen as helpful (n=2). Conversely, most participants from the control group highlighted that no pharmacotherapy was provided, n=3 (Appendix 8.27).

Table 8.11: Aspects of the experimental intervention which the participants remarked being least satisfied with (n=9)

Themes	Quotes (translated quotes in italics)	Participants' code (number of participants)
Minor adverse events on using Nicotine Replacement Therapy	"Il-patches qabduni l-ħakk u l-qris, l-ispray qisu jekk jinżillek ġol-istonku jaqbdek uġigħ ta' stonku." (*"The patches made me itch and pinch, the spray, it is as if, if it goes down into your stomach it will give you a stomachache."*) P48	P23, P48 (2)
Nicotine patches were perceived ineffective	"Bil-patches għax rajthom ma jagħmlux effett" (*"With the patches because I found them not having an effect."*) P75	P38, P75 (2)
Setting a Target Quit Date was not helpful	"Meta kien hemm il-pjan li trid tagħżel data biex tieqaf. Jien dik ma naqbilx magħha għax iżżidlek l-ansjeta'." (*"When there was the plan that you have to choose a date to stop. I don't agree with that because it increases your anxiety."*) P22	P12, P22 (2)
NRT was provided for a short period	"X'ħin spiċċawli l-ispray u l-patches." (*"When the spray and patches finished."*) P18	P18 (1)
Small crowdy clinic	"Iktar fejn konna niltaqgħu. Post żgħir, ġon-nies." (*"It was more where we used to meet. A small place, among people."*) P45	P45 (1)
Waiting time before being seen	"Waiting to be seen when having an appointment." P70	P70 (1)

8.5.4.4 Perceived usefulness of the smoking cessation intervention provided

While most participants in the control group agreed with the posed statements (table 8.13), most participants in the intervention group strongly agreed or agreed with the items posed (table 8.12). With the exception of the items, 'Met your expectations,' 'Applied to you specifically,' 'Helped you identify strategies to resist urges to smoke,' 'Helped you to respond

effectively to urges to smoke,' and 'Helped you identify the most effective method to quit smoking,' which most participants agreed with, the majority strongly agreed with the other helpful aspects of the experimental intervention. While the median total score was high in both groups (≥56.0), the intervention group had a notable higher score (63.0 vs. 56.0). This implies that the participants from the intervention group were more likely to find the provided intervention as useful, when compared to those assigned to the control group.

Table 8.12: Perceived usefulness of the smoking cessation intervention provided (Intervention group, n=37)

The smoking cessation intervention…	Rating, n (%)					Median (IQR)
	Strongly disagree 1	Disagree 2	Neutral 3	Agree 4	Strongly agree 5	
Met your expectations.	1 (2.7)	2 (5.4)	4 (10.8)	15 (40.5)	15 (40.5)	4.0 (4.0-5.0)
Applied to you specifically.	1 (2.7)	0	6 (16.2)	12 (32.4)	18 (48.6)	4.0 (4.0-5.0)
Provided you with helpful information about quitting.	0	0	0	15 (40.5)	22 (59.5)	5.0 (4.0-5.0)
Made you concerned on the severe diabetes complications caused by smoking.	0	0	2 (5.4)	11 (29.7)	24 (64.9)	5.0 (4.0-5.0)
Made you concerned about your smoking.	0	0	3 (8.1)	10 (27.0)	24 (64.9)	5.0 (4.0-5.0)
Provided you with the motives to quit.	0	1 (2.7)	2 (5.4)	11 (29.7)	23 (62.2)	5.0 (4.0-5.0)
Made you think that it is worthwhile to quit.	0	0	1 (2.7)	14 (37.8)	22 (59.5)	5.0 (4.0-5.0)
Helped you consider a plan to quit smoking.	0	0	0	17 (45.9)	20 (54.1)	5.0 (4.0-5.0)
Helped you identify situations that increase your risk of smoking.	0	1 (2.7)	1 (2.7)	16 (43.2)	19 (51.4)	5.0 (4.0-5.0)
Helped you identify strategies to resist urges to smoke.	0	0	5 (13.5)	15 (40.5)	17 (45.9)	4.0 (4.0-5.0)
Helped you to respond effectively to urges to smoke.	0	2 (5.4)	6 (16.2)	16 (43.2)	13 (35.1)	4.0 (4.0-5.0)
Provided you with options on how to quit smoking.	0	0	3 (8.1)	13 (35.1)	21 (56.8)	5.0 (4.0-5.0)
Helped you identify the most effective method to quit smoking.	0	0	7 (18.9)	12 (32.4)	18 (48.6)	4.0 (4.0-5.0)
Gave you the confidence so that you can quit.	0	2 (5.4)	7 (18.9)	8 (21.6)	20 (54.1)	5.0 (3.5-5.0)
Total median score (IQR)	63.0 (56.0-66.5)					

IQR - interquartile range

Table 8.13: Perceived usefulness of the smoking cessation intervention provided (Control group, n=27)

The smoking cessation intervention…	Rating, *n* (%)					Median (IQR)
	Strongly disagree 1	Disagree 2	Neutral 3	Agree 4	Strongly agree 5	
Met your expectations.	2 (7.4)	4 (14.8)	7 (25.9)	9 (33.3)	5 (18.5)	4.0 (3.0-4.0)
Applied to you specifically.	2 (7.4)	2 (7.4)	4 [14.8]	16 [59.3]	3 [11.1]	4.0 (3.0-4.0)
Provided you with helpful information about quitting.	1 (3.7)	0	4 (14.8)	17 (63.0)	5 (18.5)	4.0 (4.0-4.0)
Made you concerned on the severe diabetes complications caused by smoking.	0	2 (7.4)	1 (3.7)	13 (48.1)	11 (40.7)	4.0 (4.0-5.0)
Made you concerned about your smoking.	0	1 (3.7)	5 (18.5)	16 (59.3)	5 (18.5)	4.0 (4.0-4.0)
Provided you with the motives to quit.	1 (3.7)	0	5 (18.5)	15 (55.6)	6 (22.2)	4.0 (4.0-4.0)
Made you think that it is worthwhile to quit.	2 (7.4)	0	1 (3.7)	16 (59.3)	8 (29.6)	4.0 (4.0-5.0)
Helped you consider a plan to quit smoking.	1 (3.7)	3 (11.1)	3 (11.1)	12 (44.4)	8 (29.6)	4.0 (3.0-5.0)
Helped you identify situations that increase your risk of smoking.	1 (3.7)	1 (3.7)	2 (7.4)	18 (66.7)	5 (18.5)	4.0 (4.0-4.0)
Helped you identify strategies to resist urges to smoke.	1 (3.7)	3 (11.1)	3 (11.1)	14 (51.9)	6 (22.2)	4.0 (3.0-4.0)
Helped you to respond effectively to urges to smoke.	2 (7.4)	3 (11.1)	5 (18.5)	13 (48.1)	4 (14.8)	4.0 (3.0-4.0)
Provided you with options on how to quit smoking.	1 (3.7)	1 (3.7)	4 (14.8)	16 (59.3)	5 (18.5)	4.0 (4.0-4.0)
Helped you identify the most effective method to quit smoking.	1 (3.7)	1 (3.7)	5 (18.5)	17 (63.0)	3 (11.1)	4.0 (3.0-4.0)
Gave you the confidence so that you can quit.	1 (3.7)	2 (7.4)	4 9 (14.8)	10 (37.0)	10 (37.0)	4.0 (3.0-5.0)
Total median score (IQR)	56.0 (49.0-61.0)					

IQR - intequartile range

Thirteen (35.1%) and 14 (51.9%) participants from the intervention and control groups (respectively) provided suggestions for improving the smoking cessation intervention that was received. As seen in table 8.14, most participants in the intervention group (n=7) suggested increasing the support provided, mainly by extending the programme and the provision of NRT. Conversely, several participants in the control group (n=7) suggested the provision of NRT as part of the intervention (Appendix 8.28). Furthermore, three participants also suggested that the support should be focused on quitting smoking right from the start.

Table 8.14: Suggestions for improving the smoking cessation intervention that was received (intervention group, n=13)

Themes	**Quotes (translated quotes in italics)**	**Participants' code (number of participants)**
Increase the support provided		
Extend the programme	"Jien naħseb bħala kors huwa naqra fil-qosor. Kieku jkun naqra twil iktar naqra aħjar." (*"I think as a course it is a bit short. If it was longer it would be a bit better."*) P6	P6, P9, P12, P13 (4)
Extend the provision of NRT	"Jien naħseb li ttawlu t-trattament naqra oħra; l-patches u l-spray." (*"I think that you should prolong the treatment a bit more; the patches and the spray"*) P18	P12, P18 (2)
Ensure frequent support at the beginning	"Għal bidu is-sessions għandhom ikunu iktar frekwenti - kull ġimgħa" (*"At the beginning the sessions should be more frequent - every week"*) P61	P61 (1)
Provide longer sessions	"u aktar ħin" (*"and more time"*) P64	P64 (1)
Provide more information on smoking and diabetes	"Videos fuq il-ħsara li jistgħu jagħmlu" (*"Videos on the harm they can do"*) P86	P64, P86 (2)
Include group-based support	"make groups" P14	P14 (1)
Provide CO testing to highlight progress for encouragement	"Maybe more frequent CO testing to monitor progress as a way of further encouragement." P26	P26 (1)
Provide an alternative for the nicotine mouth spray	"Forsi xi ħaġa oħra flok l-ispray." (*"Maybe something else instead of the spray."*) P59	P59 (1)

All respondents from the intervention group (n=37) and all respondents except one from the control group (n=26) would recommend the smoking cessation intervention provided.

8.5.5 Acceptability of the study intervention – findings from the interviews held with the study participants (individuals with diabetes)

8.5.5.1 Characteristics of the interviewees

Out of 21 participants, who were randomly chosen to sit for an interview based on the variables outlined in section 8.4.4.2, 20 participants agreed to be interviewed. One participant (male, 33 years old, living with type 1 diabetes) declined the invitation to sit for an interview as he did not want to be audio-recorded. The characteristics of the interviewees are outlined in Appendix 8.29.

8.5.5.2 General impressions of the smoking cessation intervention provided

As seen in table 8.15 below, most participants found the intervention effective for smoking cessation/reduction (n=12), remarking on the NRT's facilitating role (n=10). The interviewees also stated that the intervention was supportive (n=8) and helped raise awareness on diabetic complications (n=7).

Table 8.15: Individuals with diabetes' general impressions of the smoking cessation intervention provided (n=19)

Themes	Quotes (translated quotes in italics)	Participants' code (number of participants)
Effective for smoking cessation/reduction	"Ħeq, kien utli ħafna hu. Eh la kien ta' għajnuna; la waqaft inpejjep, naħseb kien utli hu." (*"Eh, it was very useful, ey. Eh, given that it helped; having stopped smoking, I think it was useful, ey."*) P1 (male, age 58 years; did not smoke any tobacco product over the past seven days - biochemically verified)	P1, P2, P3, P5, P6, P7, P8, P12, P16, P18, P19, P20 (12)
Nicotine Replacement Therapy (NRT) facilitated quitting		
NRT: a key component in smoking cessation	"I I think the the patches made a BIG difference (in quitting smoking).. but also, kind of you know, emm having access to theee, to the spray." P7 (male, age 44 years; did not smoke any tobacco product over the past seven days - biochemically verified)	P1, P2, P7, P8, P10, P18 (6)
Nicotine spray as a cigarette substitute	"L-ispray, qisni ħadt sigarett. Qisni ħadt sigarett (grinning).. (jiġifieri) ngħid, 'ħa nieħu puff, spray, flok sigarett," (*"The spray, it's like I took a cigarette. It's like a took a cigarette [grinning].. [I mean], I say, 'I will take a puff, a spray, instead of a cigarette."*) P3 (female, 63 years; intentionally spent at least one day not smoking but less than seven consecutive days)	P2, P3, P7, P8, P12 (5)
NRT helped kickstart the quitting process	"L-iktar li nkorraġġitni.. għax kemm bl-ispray u kemm bil-patches tibda tnaqqas bil-mod mal-ewwel qisek." (*"What encouraged me most.. it looks like with both the spray and the patches you start to reduce slowly at first."*) P8 (male, 46 years; intentionally spent at least one day not smoking but less than seven consecutive days)	P2, P8, P16, P17 (4)
Nicotine spray's pleasant taste as a deterrent to smoking	"Għax l-ispray anke iħallilek dik it-togħma ta xi ħaġa, ġo ħalqek. Ehhh hemm xi ħaġa li qed iżżommok, bħal speċi." (*"Because the spray even leaves you with that taste of something, in your mouth. Ehhh there's something holding you back, kind of."*) P12 (male, 53 years; did not intentionally spend at least one day not smoking)	P12 (1)
Supportive	"Għal min irid jaqtagħhom kuraġġ kbir hu! Eee, li hemm sapport hu mingħandkom." (*"It is very encouraging for those who want to quit! Eee, as support is available."*) P4 (female, 55 years; intentionally spent at least one day not smoking but less than seven consecutive days)	P4, P6, P7, P8, P9, P13, P18, P20 (8)

Themes	Quotes (translated quotes in italics)	Participants' code (number of participants)
Raises awareness on diabetic complications	"ħassejtu utli għax ġejt iktar aware ta' x' jista' jkunu l-problemi, jiġiferi awareness hemm." (*"I felt it was useful because I became more aware of what the problems could be, that is, there is awareness."*) P15 (female, 42 years; intentionally spent at least one day not smoking but less than seven consecutive days)	P2, P9, P14, P15, P17, P18, P20 (7)

While NRT was seen as a facilitator to quitting smoking by many (n=10), several participants (n=11) remarked on the unpleasant effects on using NRT, especially when using the nicotine mouth spray, which discouraged them from using it (table 8.16).

Table 8.16: Unpleasant effects experienced by individuals with diabetes on using Nicotine Replacement Therapy (n=11)

Themes	Quotes (translated quotes in italics)	Participants' code (number of participants)
Hot intense sensation on using spray	"ħaraqli ħafna ħalqi u tipo sprejjajt, naf żgur li sprejjajt tajjeb." (*"It burned my mouth a lot and I applied the spray, I know for sure that I applied the spray well."*) P15 (female, 42 years; intentionally spent at least one day not smoking but less than seven consecutive days)	P5, P8, P13, P15, P17 (5)
Stomach discomfort on using the spray	"u x'jismu hawn (the spray), beda iweġġaħuli l-istonku qisu, jekk nibilgħu naqra żgħira." (*"and what is it called eyy [the spray], it seemed to start to hurt my stomach, if I swallow a little."*) P11 (male, 52 years; did not intentionally spend at least one day not smoking)	P4, P5, P11, P14, P15 (5)
Skin irritation/ itchiness when applying the patch	"Eh, dawk l-istickers qishom bdew iqabbduni ħafna ħakk" ("Eh, those patches seemed to make me feel itchy" P11	P7, P11, P12, P13, P16 (5)

Three participants (P3, P4, P14) were also unsure about the effectiveness of the nicotine patch, as reflected in the following excerpt:

"L-istikk qisni bdejt naraha, li biha u mingħajra xorta, imma xorta kont nagħmilha." (*"It seemed that with or without the patch was the same, but I still applied it")* P3 (female, 63 years; intentionally spent at least one day not smoking but less than seven consecutive days)

Nonetheless, out of those who reported using the NRT to quit smoking (n=18), 15 participants stated that they would buy NRT to quit smoking. The other three participants would not buy NRT for the following reasons: perceived as ineffective (n=1), too expensive (n=1) and wanting to quit unaided (n=1).

8.5.5.3 Views on the delivery method

As seen in the table below (table 8.17), the majority found the duration of the programme adequate (n=15), that included frequent support (n=14) and was provided in a good location (n=7). The interviewees also remarked on the socially skilled professionals (n=8), the one-to-one level of support which facilitated self-disclosure (n=7) and the patient-centred approach of the intervention (n=4).

Table 8.17: Individuals with diabetes' views on the delivery method (n=19)

Themes	Quotes (translated quotes in italics)	Participants' code (number of participants)
Adequate programme duration	"Ħeq tul ta' żmien, ma tantx kien hemm xi tul ta' żmien eżaġerat hu. Naħseb, naħseb kien tajjeb." (*"Eh, duration of the programme, it was not that very long ey. I think, I think it was good."*) P1 (male, age 58 years; did not smoke any tobacco product over the past seven days - biochemically verified)	P1, P2, P3, P5, P7, P8, P10, P11, P12, P14, P16, P17, P18, P19, P20 (15)
Frequent support	"Now in terms of frequency … I think it was frequent enough … so that, that, I think it felt right, to be honest." P7 (male, age 44 years; did not smoke any tobacco product over the past seven days - biochemically verified)	P2, P3, P5, P6, P7, P8, P10, P14, P15, P16, P17, P18, P19, P20 (14)
Social skilled professionals	"Nies li jafu jmorru man-nies, għax dik importanti wkoll, tkun taf tmur ma' dak li jkun.." (*"People who know how to go about with people, because that's also important, knowing how to go with whoever."*) P5 (female, 72 years; did not intentionally spend at least one day not smoking)	P2, P5, P9, P10, P11, P12, P17, P18 (8)
Good location	"kind of it was on the way, right, for me." P7	P3, P5, P6, P7, P12, P17, P18 (7)
One-to-one support facilitated self-disclosure	"Il-fatt li persuna ma - one to one, it is it is very effective, naħseb, ħa ngħid hekk. Għax iktar tista' tgħid l-affarijiet - kif tħossok hu." (*"The fact that it is a person with - one to one, it is it is very effective, I think, let me say that. Because you can say more things - how you are feeling ey."*) P16 (male, age 61 years; did not smoke any tobacco product over the past seven days - biochemically verified)	P1, P6, P7, P10, P16, P17, P20 (7)
Patient-centred	"I never felt pressure to, to quit. It was more of, kind of you know, let us help you quit rather than being kind of almost obliged, you know, to quit?" P7	P4, P7, P15, P18 (4)

8.5.5.4 Views on the additional support offered

Seven interviewees were offered psychotherapy to help them manage their anxiety and/or depression better, however only two accepted the support. Table 8.18 outlines the various reasons for not taking up the additional support offered.

Table 8.18: Individuals with diabetes reported reasons for refusing psychotherapy for dealing with anxiety and/or depression (n=5)

Themes	Quotes (translated quotes in italics)	Participants' code (number of participants)
Did not perceive the need	"Ma ħassejtx li dan, tipo għandi bżonn daqshekk." (*"I didn't feel that, sort of I need that much."*) P15 (female, 42 years; intentionally spent at least one day not smoking but less than seven consecutive days)	P10, P15 (2)
Fear of mental health stigma	"Għax nibża nibża li, jien naf jekk, jien naf, forsi jien ... Allura ngħid ngħid, 'Jekk għandi xi ħaġa, mentalment,' ngħid, 'aħjar inżomma għalija milli.." (*"Because I'm afraid I'm afraid that, I don't know if, I don't know, maybe I ... So I say, 'If I have something wrong, mentally,' I say, 'it's better to keep it to myself than.."*) P20 (male, age 57 years; did not smoke any tobacco product over the past seven days - biochemically verified)	P20 (1)
Overwhelmed with other commitments	"Impenjat ħafna, impenjat ħafna u ma nixtieqx inżid iżjed." (*"I am very busy, very busy, and I don't want to add any further."*) P14 (male, 66 years; intentionally spent at least one day not smoking but less than seven consecutive days)	P14 (1)
Wanted to deal with issue alone	"Qisni għidt, 'iktar aħjar nipprova naħdem fuqha waħdi jiena,' hekk." (*"It's like I said, 'it is better to try to work on it on my own, myself,' like that."*) P8 (male, 46 years; intentionally spent at least one day not smoking but less than seven consecutive days)	P8 (1)

The two interviewees (P3, P6) who attended psychotherapy remarked that this helped to relieve anxiety as evidenced in the following excerpt:

> "Qabditni l-ansjeta', qed tifhimni? Panic attack, allura għedt, 'għandi bżonn l-għajnuna,' u (the psychotherapist) għenitni ħafna biex iktar jiena naqtagħhom. Dik, dik kienet għajnuna kbira." (*"I got anxious, do you understand me? A panic attack, so I said, 'I need help,' and [the psychotherapist] she helped me so that I can cut down even more. That, that was very helpful."*) P3 (female, 63 years; intentionally spent at least one day not smoking but less than seven consecutive days)

Two participants (P18, P20) were provided with a diabetic consultation due to hyperglycaemic episodes. They remarked that the support provided, to manage better their blood glucose, was an important part of the smoking cessation process:

"Jiġifieri importanti hu għax nkella tibqa sejra lura, jekk ma jieħdux ħsieb iz-zokkor wkoll." (*"That is, it is important because otherwise you will keep on getting worse, if they don't take care of the blood glucose too."*) P18 (female, age 62 years; did not smoke any tobacco product over the past seven days - biochemically verified)

8.5.5.5 Challenges to participation

Six participants reported having experienced challenges/barriers to participating in the smoking cessation intervention (table 8.19). Interviewees stated that they found it challenging to attend due to family issues/commitments (n=3), work commitments (n=2) and because they were unsuccessful in quitting (n=2).

Table 8.19: Individuals with diabetes reported challenges to participation (n=6)

Themes	Quotes (translated quotes in italics)	Participants' code (number of participants)
Family issues/commitments	"Għandi żewġt itfal autistic ... Qatt ma jkolli ċans ta' xejn. Xi ħaġa sabiħa liii kieku ssib naqra mument għalik. Imma jekk ma jkollokx, ma jkollokx!" (*"I have two autistic children ... I never have time for anything. It would be nice if you could find some time for yourself. But if you cannot, you cannot!"*) P4 (female, 55 years; intentionally spent at least one day not smoking but less than seven consecutive days)	P4, P10, P18 (3)
Being unsuccessful in quitting	"Jiena xtaqt niġi, imma qisu, la ma ħadimx qisu, rajtu, jien naf!" (*"I wanted to come, but it's like, since it sort of didn't work out, I found it, I don't know!"*) P11 (male, 52 years; did not intentionally spend at least one day not smoking)	P11, P13 (2)
Work commitments	"L-iktar, l-iktar minħabba x-xogħol hu jien." (*"No mostly, mostly because of my work."*) P1 (male, age 58 years; did not smoke any tobacco product over the past seven days - biochemically verified)	P1, P11 (2)

8.5.5.6 Factors which facilitated participation

Despite the challenges encountered, several participants reported on factors which facilitated/encouraged participation (table 8.20). Most participants remarked on their willingness to quit smoking as a strong factor for participation (n=8). The participants also

remarked on their concern for their health (n=4), experiencing success during the quitting process (n=4), and having been provided with suitable appointments (n=3).

Table 8.20: Factors which supported participation among individual with diabetes (n=16)

Themes	Quotes (translated quotes in italics)	Participants' code (number of participants)
Willingness to quit smoking	"għax irrid naqtagħhom. Ara, kieku ma rridx naqtagħhom, kont naqta', qed tifhem?" (*"because I want to quit smoking. Look, if I didn't want to quit, I would have stopped attending, do you understand?"*) P5 (female, 72 years; did not intentionally spend at least one day not smoking)	P1, P3, P5, P6, P11, P12, P13, P15 (8)
Concern for own health	"tbenġlet sieqi, voldieri l-pexxul tben, tbenġel. Għedt, 'imma dan biex tbenġel? Jiena ma lqattux!' Imbagħad rajt il-pakkett tas-sigaretti b'sieq imbenġla, u għedt, 'aħjar inkompli dan il-programm." (*"My leg got bruised, that is, my calf got bruised. I said, 'how did it get bruised? I didn't hit it!' Then I saw the pack of cigarettes with a bruised leg on it, and I said, 'I would better continue this program."*) P14 (male, 66 years; intentionally spent at least one day not smoking but less than seven consecutive days)	P14, P16, P17, P19 (4)
Feeling of success	"Għax ħassejt li qed jirnexxili, qed tifhem? Ħassejt li qed jirnexxili." (*"Because I felt that I was succeeding, do you understand? I felt that I was succeeding."*) P2 (female, age 63 years; spent at least seven consecutive days not smoking, but currently smoking)	P2, P7, P18, P20 (4)
Suitable appointments	"Setting up the appointment, the time for the appointment, right, for each session ... was actually arranged to be at the right time for me, so it was quite comfortable actually." P7 (male, age 44 years; did not smoke any tobacco product over the past seven days - biochemically verified)	P1, P7, P13 (3)

8.5.5.7 Recommendations and suggestions for improvement

Nineteen interviewees would recommend the programme to someone else as this was found to be supportive (n=12) and out of first-hand successful experience (n=8); table 8.21. One participant refrained from providing a clear answer, stating that it would be good if someone who would attend the programme would quit:

"Jekk jirnexxielu jieqaf, tajjeb." (*"If he manages to stop, it's good."*) P11 (male, 52 years; did not intentionally spend at least one day not smoking)

Table 8.21: Individuals with diabetes' reported reasons for recommending the study intervention (n=19)

Themes	Quotes (translated quotes in italics)	Participants' code (number of participants)
Supportive	"Bniedem ikollu sapport dejjem għajnuna hu!" (*"It is always helpful if someone is supported!"*) P4 (female, 55 years; intentionally spent at least one day not smoking but less than seven consecutive days)	P2, P4, P5, P7, P8, P9, P10, P13, P14, P15, P19, P20 (12)
First hand successful experience	"because so far it looks like it is working for me, so, ehh its kind of you know, if someone wants to quit, emm, I would, yes, recommend it." P7 (male, age 44 years; did not smoke any tobacco product over the past seven days - biochemically verified)	P1, P3, P6, P7, P12, P16, P17, P18 (8)

On the other hand, only four interviewees provided suggestions for improvement (table 8.22). Most participants (n=3) suggested extending the programme.

Table 8.22: Individuals with diabetes' suggestions for improvement (n=4)

Themes	Quotes (translated quotes in italics)	Participants' code (number of participants)
Extend the programme	"Le, mhix twil ħafna. Tajjeb, u jekk jiżdied xi naqra, naħseb aħjar." (*"No, it's not very long. It's good, and if it had to be longer, I think it would be better."*) P6 (male, 62 years; did not intentionally spend at least one day not smoking)	P6, P13, P15 (3)
Provide feedback on the physiological effect of smoking	"The test that you have done, the CO etc, it gives you a bit of, an actual metric ... I think having more of those ... hammers it home of how bad the situation really is (grinning)." P7 (male, age 44 years; did not smoke any tobacco product over the past seven days - biochemically verified)	P7 (1)

8.5.6 Integrated findings (quantitative and qualitative) on the acceptability of the study intervention as experienced by the individuals with diabetes

As was outlined in section 8.5.4.3 and 8.5.4.4, the median total satisfaction and perceived usefulness scores were high, implying that on average the participants were very satisfied/satisfied with the intervention, strongly agreeing/agreeing that the intervention was useful. The qualitative data collected, both from the questionnaires and the interviews held, also confirm that most participants were satisfied with the intervention, finding it useful to quit smoking. Almost all (97.3%) of the questionnaire respondents, and the interviewees (n=19) identified (at least) a useful aspect of the intervention they were most satisfied with. Several interviewees and questionnaire respondents remarked being satisfied with the intervention as this was found effective, informative and supportive, in line with the average scores for the relevant items in the satisfaction (items on the support and method used to help participants quit) and perceived usefulness questionnaires (items on informational factors and behaviour skills). Additionally, most interviewees remarked that the duration of the programme was adequate, that included frequent support, and was provided in a good location, in line with the participants' responses to the items on the characteristics of the programme as per the satisfaction questionnaire.

The use of the open-ended questions and the interviews held, helped to expand on the quantitative data collected, identifying the NRT provided as a crucial component of the intervention. Most respondents (n=14) and several interviewees (n=10), remarked on its facilitating role to quit smoking. Given that there were no items on the satisfaction/usefulness of the NRT provided in the questionnaires, such finding was not observed. Nonetheless, as was noted in section 8.5.4.3, most participants were very satisfied with the support provided and the method used to help them quit. Additionally, most participants strongly agreed that the intervention provided them with options on how to quit smoking and agreed that it helped them to identify the most effective method to quit smoking and to respond effectively to urges to smoke. (section 8.5.4.4).

Despite this positive finding, several interviewees (n=11) remarked on the unpleasant effects on using NRT, especially when using the nicotine mouth spray, which discouraged them from using it. However, only two questionnaire respondents referred to the minor adverse events on

using NRT (n=2), and the nicotine patches, which were perceived as ineffective (n=2), as an aspect of the intervention they were least satisfied with.

8.5.7 Feasibility and acceptability of the study intervention – findings from the interviews held with the nurses

8.5.7.1 Characteristics of the interviewees

Both diabetes practice nurses were interviewed. Their ages ranged between 55 to 59 years. The nurses reported having been into practice for 33 to 40 years and having been practicing as specialist nurses (in diabetes) between 11 to 15 years.

8.5.7.2 General impressions of the smoking cessation intervention provided

Both nurses had a positive impression of the intervention (table 8.23), finding it effective for smoking cessation, empowering, and comprehensive by providing additional support. Both nurses also found that the programme structure was adequate.

Table 8.23: Nurses' general impressions on the smoking cessation intervention provided

Themes	Quotes	Participants' code (number of participants)
Adequate programme structure	"We were able to see patients, the patients were given the opportunity not to be seen just once, twice, three times and even more than that, so I think it's good." N2	N1, N2 (2)
Comprehensive by providing additional support	"We also got to integrate the diabetes management, you know, and I think that was that was good." N2	N1, N2 (2)
Effective for smoking cessation	"I think it was very useful because we had patients who did quit smoking, so emmm, I believe it was useful!" N1	N1, N2 (2)
Empowering	"But when we come to the smoking cessation, we have more time again to discuss, emm to empower patients to make change." N2	N1, N2 (2)

8.5.7.3 Challenges experienced in delivering the intervention

Once again, as was reported in the pilot study, the nurses noted that they found it difficult when dealing with challenging patients. They also remarked on their limited availability to provide follow-up appointments.

Table 8.24: Nurses' perceived challenges in delivering the intervention

Themes	Quotes	Participants' code (number of participants)
Challenging patients	"we had some patients who weren't willing, either they didn't want to participate or they quit immediately." N1	N1, N2 (2)
Limited availability for providing early follow-up appointments	"As you as you saw with me and with (name of the nurse) emm, our appointment slots are not so free. I mean, there were times when we were supposed to get them after a week or two and we didn't have appointment slots." N1	N1, N2 (2)
Patient reluctance to attend to psychotherapy	"We offered the services (of a psychotherapist) by giving them a telephone number ... They were not readily accepting to meet her." N2	N2 (1)

8.5.7.4 Practice facilitators

As was reported in the pilot study, the nurses also found that the smoking cessation guide facilitated the intervention delivery (table 8.25).

Table 8.25: Nurses' perceived facilitators in delivering the intervention

Themes	Quotes	Participants' code (number of participants)
Smoking cessation guide	"The notes the notes you gave us, the programme, the step-by-step guide, that we would refer to all the time ... I could refer to the programme and know exactly you know, what's next." N2	N1, N2 (2)
Keeping patient notes	"if I didn't have those notes and for example the next patient I would have seen him after two or three weeks I would have forgotten or missed out something important, an important question or. So that helped a lot as well." N1	N1 (1)

8.5.7.5 Perceived challenges to intervention implementation

On being asked about the perceived challenges to implementing the intervention in practice, the nurses did not remark on the lack of human resources as some nurses were just transferred to their unit, as reflected below:

> "If we did this two weeks ago, I would have told you, '(name of the researcher), I am very sorry I don't have the staff to be able, the staff complement to be able to implement a programme dedicated for smoking cessation.' Today today, miraculously, we were given five new nurses, plus I can still use those nurses who have applied for the expression of interest ... we have been given these nurses, we don't have a problem with nurses." N2

Nonetheless, both nurses highlighted the issue of NRT affordability for patients if these were no longer to be provided for free (table 8.26).

Table 8.26: Nurses' perceived challenges in implementing the intervention in practice

Themes	Quotes	Participants' code (number of participants)
NRT affordability by patients if these are not provided for free	"Obviously I don't know if the NRTs would still be supplied for free because I think if the patient would need to buy them that would be a barrier for them." N1	N1, N2 (2)
Lack of consultant involvement	"Emm, but then our consultants have to be on board and working together. Sometimes I feel that they are not as involved as they.. should be. The thing is we need to act together as a team even for these programmes to, emm, to continue. If we want to implement this programme we need, emm, backing from our from our consultants." N2	N2 (1)

8.5.7.6 Perceived facilitators to intervention implementation

In view of the above-mentioned challenge, both nurses stated that the consideration and inclusion of NRT in the formulary list (supported by consultants) would facilitate the provision of the intervention in practice (table 8.27).

Table 8.27: Nurses' perceived facilitators to implementing the intervention in practice

Themes	Quotes	Participants' code (number of participants)
Consideration and inclusion of NRT in the formulary list, supported by consultants	"Issa (Now), should they (the NRT) be on the NHS, not the NHS, should they be on the formulary? Maybe maybe, we should, we should, obviously by a consultant, a consultant who is going to order on the schedule V application." N2	N1, N2 (2)
Active presence of the psychotherapist within the team	"We have seen, we had many, many of our participants who had issues, and we felt the need to refer them to psychotherapy. If the psychotherapist maybe was part of the team, it would have been, emm maybe easier … she may have been able to convince them to attend." N2	N2 (1)

8.5.7.7 Suggestions for improvement

Only one nurse provided a suggestion for improvement. She suggested following patients further to ensure continuity of care:

> "The number of sessions, we had three or four. Should there be more, emm, to get them as follow ups? Ehe, I think we should include a little bit of more sessions to ensure the continuity." N2

8.5.8 Preliminary evidence for the intervention's effectiveness

All participants from both groups (n=91) were included in the smoking cessation analysis. Initially, nine participants from the intervention group reported a seven-day point prevalence of abstinence at follow-up. However, after biochemical verification by using a carbon monoxide monitor, it was found that two participants were still smoking. Conversely, three participants from the control group, who had not attended the control intervention, stating that they had quit smoking on their own, reported a seven-day point prevalence of abstinence at follow-up. However, on being asked to provide biochemical verification, they admitted that they had reduced smoking rather than quit. Non-responders (n=14) and participants whose abstinence could not be biochemically verified (n=2) were considered non-quitters and non-reducers.

Table 8.28 reports the smoking cessation and reduction outcomes per group. Notably more participants from the intervention group (44.4%) compared to the control group (17.4%) reported a quitting episode during the study period. In addition, 24.4% vs. 6.5% participants reported a seven-day floating abstinence. Notably, there were more participants from the intervention group compared to the control group who had a biochemically verified seven-day point prevalence of abstinence at follow-up by using a carbon monoxide monitor (n=7, 15.6% [95% CI: 6.5-29.5] vs. n=1, 2.2% [95% CI: 0.1-11.5]). Two of the participants from the intervention group reported still using NRT and were indeed positive for the presence of cotinine in urine (table 8.28). The average reduction in the number of cigarettes smoked per day among continuing smokers from the intervention group (n=38) and the control group (n=44) were 7 and 2 cigarettes, respectively.

Table 8.28: Smoking cessation and reduction outcomes per group

Smoking cessation/reduction outcomes	Intervention group (*n*=45)	Control group (*n*=46)
Self-reported quit episode (≥24hrs smoking abstinence), *n* (%) [95% CI]	20 (44.4) [29.6-60.0]	8 (17.4) [7.8-31.4]
Self-reported floating abstinence (seven-day point prevalence abstinence at any during the study period), *n* (%) [95% CI]	11 (24.4) [12.9-39.5]	3 (6.5) [1.4-17.9]
Biochemically verified (eCO verified) seven-day point prevalence abstinence at follow-up, *n* (%) [95% CI]	7 (15.6) [6.5-29.5]	1 (2.2) [0.1-11.5]
Biochemically verified (eCO and UC verfied) seven-day point prevalence abstinence at follow-up,[a] *n* (%) [95% CI]	5 (11.1) [3.7-24.1]	1 (2.2) [0.1-11.5]
Average reduction in the number of cigarettes smoked per day, from baseline to the end of study period, among continuing smokers (*n*=38 intervention; *n*=44 control),[b] median (IQR)	7.0 (0-13.3)	2.0 (0-10.0)

IQR - interquartile range. CI - confidence interval. eCO - exhaled carbon monixide. UC - urinary cotinine. a - Two participants from the intervention group reported still using the nicotine mouth spray at follow-up. b - Excluding one participant (from the control group) who smoked 15 cigarellos a day. Three cigarette smokers from the control group were dual users, using electronic cigarettes as well.

In a future definitive study, the primary outcome on which the sample size will be calculated will be the smoking abstinence outcome measure. Appendix 8.30 outlines the method followed to calculate the sample size required for a future definitive trial.

In order to detect a minimum 12% difference in 6-month smoking abstinence rates between intervention arms (which was also observed in this study), with a control group rate of 6% (90% power, 5% significance level, two-sided test) 169 participants will be required per arm, 338 in total (Dean et al., 2013). Given that all randomised participants will be included in such an analysis including those lost to follow-up (assuming these as having not quit or reduced smoking), the sample size does not need to be adjusted for attrition. Based on the lower bound of the 95% CI for the achieved consent rate (taking a more prudent approach), which is 50.9%, 664 potentially eligible participants need to be approached to consent and randomise 338 participants. Based on the identified recruitment rate of 13 participants per month, recruitment can take an average of 51.9 months, unless the future definitive study is piloted and also conducted at another study site.

8.5.9 Process evaluation

8.5.9.1 Exploring the hypothesised mechanisms that lead to smoking cessation/reduction

As was explained in section 8.4.4.3, to explore the hypothesised mechanisms that lead to smoking cessation or reduction, the interviewees (individuals with diabetes, n=20) were asked about their quit attempt. This helped understand how the provided/known information, motivation and behavioural skills lead to smoking cessation or reduction.

Thirteen interviewees remarked on the influence of the provided/known information on smoking and diabetes on the quitting process. As seen in table 8.29, while two participants remarked being already aware of the harmful effects of smoking and diabetes, most participants (n=12) reported feeling concerned when learning about the possible diabetic complications caused by smoking. Most participants (n=11) reported feeling concerned after watching the informational video clips on the consequences of smoking with diabetes shown.

Table 8.29: The influence of the provided/known information on smoking and diabetes on the quitting process as reported by the individuals with diabetes (n=13)

Themes	Quotes (translated quotes in italics)	Participants' code (number of participants)
Concerns on diabetic complications caused by smoking		
Concern after watching the informational video clips on the consequences of smoking with diabetes	"Meta rajt dak il-video ukoll, ħa ngħid hekk, emm, affetwani, fis-sens li tiftaħ għajnejk iktar ehh, x'jista' jiġrilek, qed tifhem?" (*"When I saw that video too, let me say that, erm, it affected me, in the sense that you open your eyes more ehh, what can happen to you, do you understand?"*) P16 (male, age 61 years; did not smoke any tobacco product over the past seven days - biochemically verified)	P2, P6, P8, P12, P13, P14, P15, P16, P18, P19, P20 (11)
Verbal information on the effects of smoking on diabetes raised concern	"Emm, dak id-diskors li bdiet tgħidli n-ners, qed tifhimni, u mbagħad bdejt nikkalkulha fuq is-saħħa. Emm fuq is-saħħa taz-zokkor speċjalment, hemm għajnejk fin-nofs, saqajk, qed tifhimni?" (*"Emm, what the nurse started to tell me, are you understanding me, and then I started to think about health. Emm especially diabetes health; your eyes are at risk, your feet, do you understand me?"*) P2 (female, age 63 years; spent at least seven consecutive days not smoking, but currently smoking)	P2, P10, P12, P14, P15 (5)
Already aware of the harmful effects of smoking and diabetes	" I don't know the detail right … but I know that smoking and diabetes right, are not a great combination." P7 (male, age 44 years; did not smoke any tobacco product over the past seven days - biochemically verified)	P7, P18 (2)

As shown in table 8.30 below, while most participants (n=16) had several personal motives to quit smoking, several participants (n=10) remarked that during the programme their determination to quit smoking increased, mainly due to the awareness of the effects of smoking on diabetes (n=7), i.e. the information provided. The encouragement given during the quitting process also strengthened their determination (n=4).

Table 8.30: The influence of previous motivational factors and the motivation given on the quitting process as reported by the individuals with diabetes (n=19)

Themes	Quotes (translated quotes in italics)	Participants' code (number of participants)
Increased determination to quit smoking		
Awareness of the effects of smoking on diabetes increased the desire to quit	"rajtuni dak il-vidjow, ta' dak ir-raġel u hekk, u għidt, 'għandi bżonn nieqaf!" (*"you showed me that video, of that man and else, and I said, 'I need to stop!"*) P13 (male, 58 years; did not intentionally spend at least one day not smoking)	P5, P10, P12, P13, P17, P18, P20 (7)
Encouragement given strengthened determination	"Kemm bdejt niġi għand (name of the nurse) iktar ġejt determinata. Jiġifieri bil-kliem li kienet tgħidli, iktar bdejt niġġieled miegħi nnifsi biex naqtagħhom." (*"The more I attended to [name of the nurse] the more determined I became. I mean the words she used to tell me helped me more to fight myself to stop smoking."*) P3 (female, 63 years; intentionally spent at least one day not smoking but less than seven consecutive days)	P2, P3, P7, P13 (4)
Personal motives to quit smoking		
Health-related motivating factors		
General health-driven motivation	"So, so the reason for quitting smoking is that I felt that now I am at the age that I should be trying to take care of my health better." P7 (male, age 44 years; did not smoke any tobacco product over the past seven days - biochemically verified)	P3, P4, P7, P8, P9, P10, P11, P16, P20 (9)
Willingness to quit smoking because of existing diabetic complications	"Li għeni biex nipprova nieqaf ... diġa għandi l-komplikazzjonijiet jien, f'għajnejja u hekk." (*"What helped me to quit smoking ... I already have the complications myself, in my eyes and else."*) P18 (female, age 62 years; did not smoke any tobacco product over the past seven days - biochemically verified)	P12, P14, P18 (3)
Motivated to quit smoking due to existing health issues	"Jien inbati minn ħafna affarijiet, allura eee, ġejt immotivat mis-sitwazzjoni tiegħi wkoll hu." (*"I suffer from many things, so eee, I was motivated by my siutation as well."*) P1 (male, age 58 years; did not smoke any tobacco product over the past seven days - biochemically verified)	P1, P19, P20 (3)

Themes	Quotes (translated quotes in italics)	Participants' code (number of participants)
Motivated by respiratory health concerns	"Nifsi kont qed inħossu mhux tajjeb, I mean eh eh, ikollok nifsek mhux tajjeb, anke tiġi biex tagħmel xi ħaġa, qed tifhem? Allura dik xegħlitli eh eh ir-red light. Għedt, 'I have to do something." (*"I felt that my breathing was not good, I mean eh eh, having difficulty breathing, even when you have to do something, do you understand? So that turned on my eh eh red light. I said, 'I have to do something."*) P17 (female, 59 years; intentionally spent at least one day not smoking but less than seven consecutive days)	P6, P17, P19 (3)
Financial motivation for quitting	"Li nipprova nieqaf biex niffranka l-flus" (*"Trying to quit to save money"*) P4 (female, 55 years; intentionally spent at least one day not smoking but less than seven consecutive days)	P3, P4, P6, P10, P18 (5)
Wanting to quit smoking for safeguarding the family	"Il-motivation kien illi … il-ħsara li kont qed nagħmel lit-tfal għax jgħixu, kont inpejjep ġewwa." (*"My motivation was that ... the harm I was doing to my children because they live, I used to smoke inside."*) P18 (female, age 62 years; did not smoke any tobacco product over the past seven days - biochemically verified)	P4, P19 (2)

As reported in table 8.31 below, during the quitting process most participants (n=14), stated that they applied the NRT provided to help relieve smoking cravings. The use of distractions (mental, mouth and physical distractions) was also helpful in attempting to quit smoking (n=13). Ten participants also highlighted the importance of avoiding potential smoking triggers, mainly by not buying/ removing cigarettes. In addition, several participants (n=9) also remarked on having formulated a plan for quitting smoking. Nine participants also mentioned the importance of motivational techniques which were used during the quitting process.

Table 8.31: Behavioural skills utilised by the individuals with diabetes as part of the quitting process (n=17)

Themes (and sub-themes)	Quotes (translated quotes in italics)	Participants' code (number of participants)
Applying the NRT provided to help relieve smoking cravings		
Using the spray when craving for a cigarette	"L-ispray sibtu tajjeb għal fatt illi tiġi dik il-vera leblieba u tgħid, 'u ija ħa nieħu spray, puſjatura,' u tgħinek." (*"I found the spray good for the fact that when you get a strong craving, you would say, 'it's OK, I'll use the spray, take a puff,' and it helps you."*) P16 (male, age 61 years; did not smoke any tobacco product over the past seven days - biochemically verified)	P1, P2, P3, P6, P7, P8, P10, P12, P14, P16, P17, P18, P19, P20 (14)
Using the patch to decrease urges to smoke	"the patches did help! In the sense that the urges where not that bad." P7 (male, age 44 years; did not smoke any tobacco product over the past seven days - biochemically verified)	P2, P6, P7, P10, P14, P16, P17, P18, P19 (9)
Using helpful distractions		
Mental distraction	"Nipprova naljena rasi … nara t-televixin" (*"I try to distract my mind ... watching the television"*) P3 (female, 63 years; intentionally spent at least one day not smoking but less than seven consecutive days)	P2, P3, P7, P10, P12, P15, P17, P19 (8)
Mouth distraction	"..instead of going outside to smoke, either go and make a coffee." P7	P2, P4, P7, P8, P13, P17, P18 (7)
Physical distraction	"If it's bad I'll, I will leave, kind of you know, go out of the office and go for a walk." P7	P2, P4, P6, P7, P15 (5)
Avoiding potential smoking triggers		
Avoiding temptation by not buying/ removing cigarettes	"Għall-ewwel kienet triq iebsa ħafna ... l-ewwel ħaġa li għandek tagħmel ma tixtrix (cigarettes)." (*"At first it was very tough ... the first thing you should do is not buy [cigarettes]."*) P19 (female, age 60 years; did not smoke any tobacco product over the past seven days - biochemically verified)	P2, P3, P6, P7, P8, P12, P14, P18, P19 (9)
Removing smoking reminders to support quitting	"inneħħi l-affarijiet illi nara li jfakkruni fis-sigaretti. Nagħmlu mod għadt noqgħod naħsel is-sufan, il-cushions tas-sufan, biex ma nxommx rieħa ta' sigaretti" (*"I remove the things that remind me of cigarettes. For instance I washed the sofa, the sofa cushions, so that I don't smell cigarettes"*) P18 (female, age 62 years; did not smoke any tobacco product over the past seven days - biochemically verified)	P6, P17, P18 (3)

Themes (and sub-themes)	Quotes (translated quotes in italics)	Participants' code (number of participants)
Formulating a quit plan	"bdejna nitkellmu, tistaqsik x'tista' tagħmel, inti toħroġ bl-ideat u mbagħad qisa (name of the nurse) bdiet ittini ideat oħra ta' x'nista' nagħmel" (*"we started talking, she asks you what you can do, you come up with ideas and then it's like [name of the nurse] started giving me other ideas of what I can do"*) P15 (female, 42 years; intentionally spent at least one day not smoking but less than seven consecutive days)	P2, P6, P7, P12, P13, P15, P18, P19, P20 (9)
Making use of motivational techniques		
Thinking about the negative effects of smoking to keep motivated	"Jiena bdejt nimmaġina x'ħin immur għal sigarett, niftakar f'dak ir-ritratt, tal-pakett, u bdejt naqta' lura, bħal speċi." (*"When I would want to smoke a cigarette, I started to think about, to remember that photo, of the cigarette packet, and I stayed back from smoking, sort of."*) P14 (male, 66 years; intentionally spent at least one day not smoking but less than seven consecutive days)	P4, P6, P14, P18, P19 (5)
Self-motivating talk	"Kont nitkellem ħafna miegħi nnifsi, 'Issapporti għal ġid tieghek, issaporti għal ġid tiegħek." (*"I used to talk to myself a lot, 'hold on for your own sake, hold on for your own sake."*) P17 (female, 59 years; intentionally spent at least one day not smoking but less than seven consecutive days)	P15, P16, P17, P18 (4)
Motivation from friends/family	"Għax it-tifla qaltli, 'ma, la waqaft, isma' minni tmisshomx!' Għedtilha, 'le ħi, mhix ħa mmisshom. (*"Because my daughter told me, 'Mom, now that you stopped, listen to me don't go for them!' I told her, 'no, I will not smoke."*) P3 (female, 63 years; intentionally spent at least one day not smoking but less than seven consecutive days)	P3, P4, P18 (3)

Several moderators, mainly negative moderating factors, were identified by the interviewees as having hindered the quitting process. As displayed in table 8.32, stress and/or sadness triggered several participants to smoke (n=10). Seven participants also remarked that the adverse reactions to NRT hindered their smoking cessation efforts. Additionally, six participants remarked that they still lacked the willingness to stop smoking. The addiction to smoking and the associated withdrawal symptoms also challenged cessation efforts (n=4). On the other hand, two participants mentioned that an acute illness facilitated smoking cessation.

Table 8.32: Factors which moderated the quitting process as reported by the individuals with diabetes (n=17)

Themes (and sub-themes)	Quotes (translated quotes in italics)	Participants' code (number of participants)
Stress and/or sadness as triggers for smoking	"Ikun hemm naqra stress li, eee, jġgħalek tpejjep, għax forsi għalhekk għadni npejjep dan il-pakett. Jkolli ċerti stressijiet, tajjeb?" (*"There would be a little bit of stress that, eee, makes you smoke, because maybe that's why I still smoke a pack. I have certain stresses, okay?"*) P12 (male, 53 years; did not intentionally spend at least one day not smoking)	P2, P3, P4, P7, P8, P12, P13, P14, P17, P20 (10)
Adverse reactions to NRT hinder smoking cessation efforts	"Il-qtar (the spray) ma għinx, … Għax kif ħadtu, wara ftit, skużi, qlajtu." (*"The drops [the spray] didn't help … Because on taking it, after a while, excuse my language, I threw it up."*) P5 (female, 72 years; did not intentionally spend at least one day not smoking)	P4, P5, P11, P12, P13, P14, P15 (7)
Lack of willingness to stop smoking	"Jiena ppruvajt ħafna, eee, drabi biex naqta' s-sigaretti, pero naħseb din l-unika waħda illi, eeee, nista' ngħid għax ma rridx jiena għadni ma waqaftx għal kollox!" (*"I've tried many, eee, times to quit smoking, but I think this is the only time that, eee, I can say because I don't want to I still haven't stopped completely!"*) P12	P4, P5, P9, P12, P13, P17 (6)
Smoking addiction and withdrawal symptoms challenge cessation efforts	"Qed ngħidlek, bla sigaretti, ħassejt nuqqas kbir tagħhom. U nuqqas kbir. Sirt iktar, iktar nervuż u kollox … Xtaqt naqtagħhom, imma iebsa ħafna." (*"I'm telling you, without cigarettes, I felt a great loss. A great loss. I became more, more nervous and everything... I wanted to quit smoking, but it was very hard."*) P13 (male, 58 years; did not intentionally spend at least one day not smoking)	P6, P13, P14, P17 (4)
Acute illness experience as a facilitator of smoking cessation	"l-isptar (hospital admission due to an acute health event) naħseb agħmel l-effett wkoll hu tiegħu ... Għaddejt minn ħafna affarijiet hu. Għalhekk waħda mid-deċiżjonijiet li ħadt, li li li għentuni u rnnexxili nagħmilha.. ħeq, waħda mill-affarijiet minħabba minħabba dawn l-affarijiet (health issues) li ġrawli hu." (*"I think the hospital (hospital admission due to an acute health event) had its effect as well ... I went through a lot of things ey. That's why one of the decisions I took, where where where you helped me and I managed to do it.. right, one of the things because of these things (health issues) that happened to me, right.""*) P1 (male, age 58 years; did not smoke any tobacco product over the past seven days - biochemically verified)	P1, P8 (2)

Themes (and sub-themes)	Quotes (translated quotes in italics)	Participants' code (number of participants)
Lack of social support in the quitting process	"l-mara, flok jiġifieri sibt appoġġ, qaltli, 'mur aqbad u ixtri grossa,' u nsomma mbagħad jiena qbadt, qabżitli nsomma ... kieku sibt aktar appoġġ, emmm, minn naħħa tal-familja, kont, eee, forsi kont inżomma (not smoking), qed tifhem?" (*"my wife, instead of supporting me, told me, 'just go and buy a gross [of cigarette packs],' and in short, then I, in short I lost it ... if I had found more support, emmm, from my family's side, I could, eee, maybe I could keep up to it [not smoking], do you understand?"*) P10 (male, 46 years; intentionally spent at least one day not smoking but less than seven consecutive days)	P10 (1)

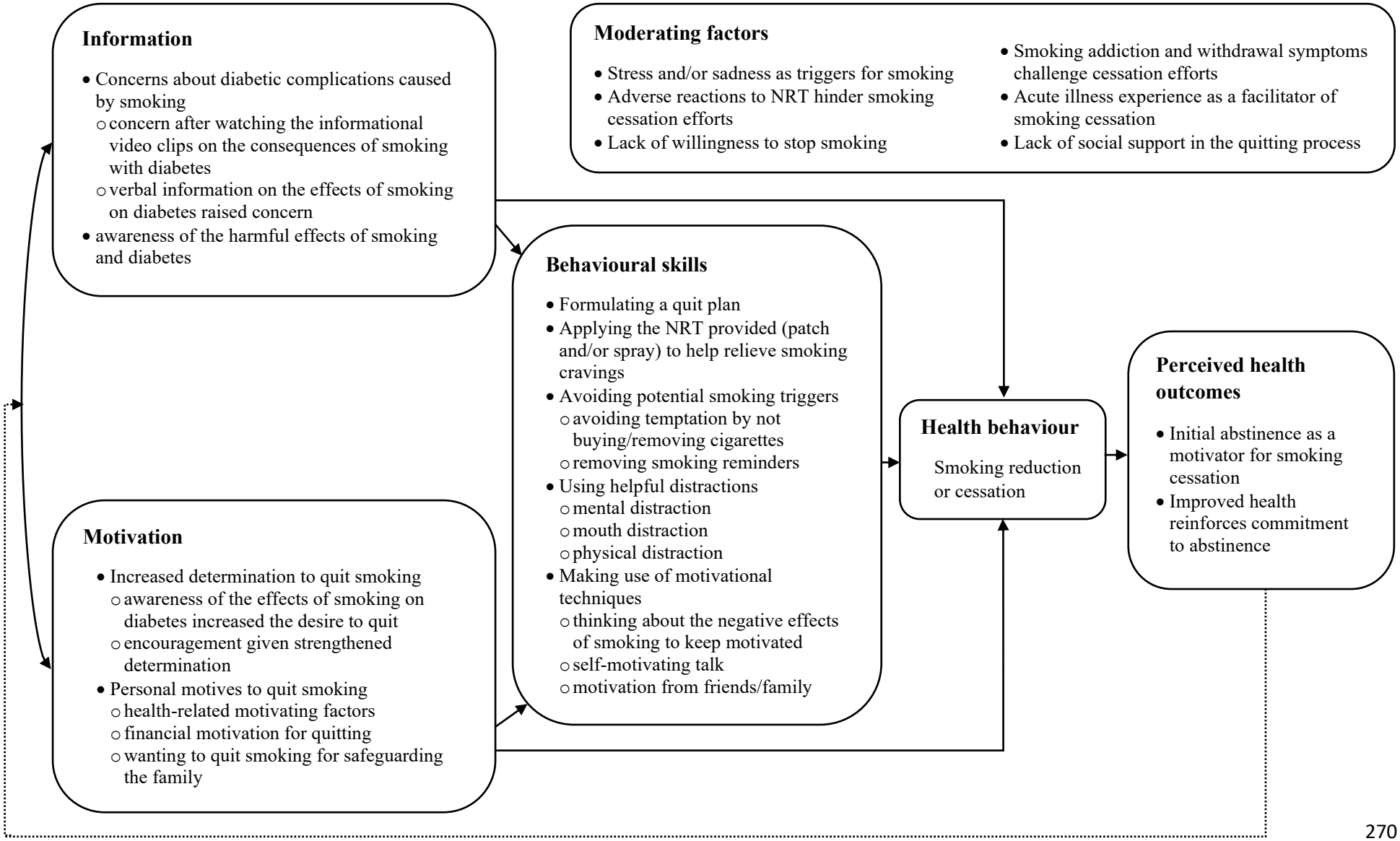
In addition to these moderating factors, five participants remarked on their perceived health on quitting/reducing smoking as a positive moderating factor to the quitting process, as outlined in the table below (table 8.33).

Table 8.33: Perceived health outcomes which moderated positively the quitting process as reported by the individuals with diabetes (n=5)

Themes (and sub-themes)	Quotes (translated quotes in italics)	Participants' code (number of participants)
Initial abstinence as a motivator for smoking cessation	"So, the fact that between the first time we met and, and, kind of you know, the second time, I did not smoke, that, that, that, kind of you know, encouraged me to actually, you know, make an effort." P7 (male, age 44 years; did not smoke any tobacco product over the past seven days - biochemically verified)	P7, P10, P18 (3)
Improved health reinforces commitment to abstinence	"Ħassejtni, aw la qeda nisgħol, la qeda nagħmel inhalers; dik għenitni ħafna wkoll." (*"I felt, aw I wasn't coughing, I wasn't using the inhalers; that helped me a lot too."*) P3 (female, 63 years; intentionally spent at least one day not smoking but less than seven consecutive days)	P3, P16 (2)

Figure 8.3 summarises this sub-section's findings, i.e., it provides an overview on how the mechanisms of the intervention, based on the IMB model's constructs (Fisher et al., 2006; Fisher et al., 2003), lead to the expected outcomes as described by the study recipients, the individuals with diabetes (n=20).

Figure 8.3: The intervention mechanisms (based on the IMB model's constructs) that lead to the expected outcome as described by the study recipients (n=20)



8.5.9.2 Assessment of treatment fidelity

Table 8.34 outlines the number of sessions (per type of session) which were assessed for treatment fidelity.

Table 8.34: Number of sessions which were assessed for treatment fidelity

Type of session	**Number of sessions**, n
Session one	8
Session two (for those who did not quit smoking)	5
Session two (for those who quit smoking), or session three (if reporting abstinence the first time)	3
Session three (for those who did not succeed to quit smoking)	4
Final follow-up session	4

Tables 1-5 (Appendix 8.31) outline the treatment actions/components carried out by the intervention providers with their patients during these sessions and the average percentage adherence to the session protocol. In all sessions the average percentage adherence to the protocol was ≥80%, except for session one, where the average was 74.0%. This is because the use of the 5Rs algorithm was required in two instances but not provided by the nurses. Furthermore, it was noted that at times at the first session and the second session (for continuing smokers), the nurses gave follow-up appointments within three weeks' time from the TQD.

8.6 Discussion

The main findings obtained are discussed in the following sub-sections in view of the feasibility study's objectives.

8.6.1 Feasibility of the intervention for a future definitive trial

8.6.1.1 Recruitment

In this study, despite having selected only one study site, the required sample size was achieved within a year, as planned (section 8.4.6). It is thus likely that the recommended actions for improving the recruitment process (outlined in section 7.7), helped to improve the recruitment process that was followed in the pilot study. Nonetheless, it is worth noting that the consent rate for this study was lower than that reported in the identified similar literature, i.e. studies where potential participants were identified from diabetic clinics and invited to participate in a smoking cessation randomised trial (Ardron et al., 1988; Ng et al., 2010; Pérez-Tortosa et al., 2015; Thankappan et al., 2013b). The only exception is the study by Li et al. (2017) who reported a consent rate of 62.6%. Despite these contrasting findings with previous literature, it is worth noting that the consent rate reported is still within the ranges expected in general smoking cessation trials, as reported in the previously mentioned comprehensive reviews on recruitment, consent and retention rates in trials by Bricca et al. (2022); 66.4% (IQR: 42.7-85.2), and Jacques et al. (2022); 72% (IQR: 50-88).

8.6.1.2 Study uptake

The experimental intervention was successfully delivered over an average of 9 weeks, however, there were three instances where the participants had not yet attended their final session at the end of the 12-week study period, as these had started the intervention late or postponed one or more sessions or both. While the primary intention was to assess the participants' acceptability of the experimental intervention as close as possible to the average end of treatment period, this limitation could have been avoided by slightly extending the study period. In a future randomised trial the study period should be longer, as the randomised trial should be able to detect differences in biochemically verified seven-day point prevalence of abstinence at a minimum of six months from treatment initiation (Piper et al., 2020). Having a longer study period would also allow those assigned to the control group to attend more sessions, as several participants were just provided with a session or two, due to the same reasons. It is worth noting that unlike the structured programme offered to the intervention group, the participants in the control group, as per standard care, were not restricted in the number of sessions they could receive during the study period. Consequently, the Ph.D. candidate was unable to identify a specific study period based on the control group treatment timeline. As outlined in section 8.5.3.2, the support sessions provided to the intervention group were provided according to the estimated times.

As reported in section 8.5.3.2, participation rates in both the intervention and control groups were low; 48.9% and 32.6%, respectively. Notably, there were more participants in the control group who did not attend the intervention at all, when compared to those assigned to the intervention group. This is unlikely to be related to the control group participants' characteristics, as minor differences were observed on comparing baseline characteristics among groups. Furthermore, it was found that the participants in the control group were more likely to have a strong desire to quit smoking with an intention to quit in the short term than those in the intervention group (section 8.5.2). Rather, it is more likely that most of them did not intend to attend the control intervention in the first place. While most of the participants who declined attending the control intervention stated that they had quit/wanted to quit unaided, none eventually confirmed having quit smoking at the end of the study period.

The participation rates recorded in the intervention group were lower to those reported in literature with similar follow-up periods (Li et al., 2017; Cristina Russo et al., 2022). Despite the lower than expected participation rates, it is worth noting that a low uptake of smoking cessation interventions has been previously reported in the literature (Lotrean, 2017). In this study, several participants reported discontinuing the study intervention because of various concerns, which they prioritised over smoking cessation – such as health and family issues. While discontinuing the intervention because of health issues may seem contradictory, this finding is also in line with previous literature, where smokers with diabetes were less likely to attend a cardiac rehabilitation programme and quit smoking after an acute coronary syndrome when compared to those who did not have diabetes (Clement et al., 2023). Smokers with diabetes may undervalue smoking cessation in view of other associated health priorities (Abu Ghazaleh et al., 2018). Despite having explored the challenges and facilitators to participation when conducting the interviews (as was recommended in the pilot study), none of the participants provided suggestions for improving the study intervention to encourage participation. Telephone counselling might be an alternative to such participants, i.e., those who can no longer attend because of personal commitments, thus helping them keep engaged. In fact, in the systematic review and meta-analysis on the effect of telephone counselling for smoking cessation, Matkin, Ordóñez-Mena, & Hartmann-Boyce (2019) found that the provision of proactive telephone counselling helped increase quit rates when compared to self-help material or brief support (Relative Risk: 1.25, 95% CI [1.15-1.35]). It is thus suggested that such participants should be offered a telephone-based follow-up session/s, which should also be based on the study protocol.

As was outlined in section 8.5.3.1, while most participants in the control group who did not attend to/discontinued the intervention were more likely to be living with another smoker, having never quit smoking, or having a moderate or no intention to quit smoking at baseline, which are known factors associated with continuing smoking (section 7.4.4.4), no similar patterns were observed across the intervention group. Rather the participants in the intervention group with a probable presence of anxiety and/or depression, which are also factors associated with continuing smoking (Caponnetto & Polosa, 2008; Gariepy et al., 2012; Richards et al., 2013), seem to have been more likely to have completed/continued the intervention during the study period. This suggests that the study intervention was helpful to all the intervention group participants, irrespective of their baseline characteristics. As was reported in section 8.5.4.1, the response rate at the 3-month follow-up (post-intervention assessment session) was more than 70% for both groups, thus reaching the established criterion for proceeding to a future definitive trial.

Almost all participants in this study accepted and tried the NRT provided, with most participants reporting using the patch and the spray on a daily basis during the first week following the first and second TQD. This contrasts with the findings of Canga et al.'s (2000) study, the only identified randomised controlled trial carried out amongst individuals with diabetes that reported on the use of NRT among the study participants (a usage rate of 23.8% and a completion rate of 9.5%; as reported in chapter four). However, it is worth noting that in Canga et al.'s (2000) study the provision of NRT was selective as they only offered nicotine patches to heavy smokers and those who did not succeed in quitting. In this study, a decrease in the rate of use of the nicotine patch and mouth spray during the subsequent four weeks from the first week from the last TQD was noted. However daily use of NRT was higher than that reported in the systematic review and meta-analysis on the level of adherence to NRT among participants of randomised controlled trials by Mersha et al. (2021) (61%, 95% CI: 54-68%) and the previously referred study by Hollands et al. (2013) (median: 45%). On analysing the use of NRT by self-reported abstinence at the final session (as was recommended in the pilot study), it was found that the average use of both the patch and the spray during the previous four weeks was higher among the abstinent group when compared to continuing smokers. While notably there were few participants in both groups, this finding suggests that the use of NRT was associated with self-reported smoking cessation at final follow-up. Such observation was noted in a previous study which was referred to in chapter three (Folan et al., 2014), and in another three studies which were conducted during the course of the doctoral research project

(Rojewski et al., 2024; Tønnesen et al., 2022). In the study by Folan et al. (2014), the use of one or combination NRT was associated with eCO verified smoking abstinence at 30 days post TQD among individuals with type 2 diabetes. Similarly, Rojewski et al. (2024) and Tønnesen et al. (2022), found that nicotine patches were effective for smokers with diabetes when compared to placebo. However, it is worth noting that these studies were based on analyses of data which limit the generalizability of their findings. The study by Folan et al. (2014) was based on analysis of data from a convenient sample of individuals with diabetes who participated in a general smoking cessation programme. Conversely, Rojewski et al. (2024) and Tønnesen et al. (2022) analysed data from patients with diabetes who participated in the EAGLES (Evaluating Adverse Events in a Global Smoking Cessation Study) clinical trial. Furthermore, to be eligible in the EAGLES trial, participants had to be motivated to stop smoking and to be clinically stable with no exacerbations in the past six months (Anthenelli et al., 2016). Hence, the generalisability of their findings to the broader population is limited. In this study, the nicotine spray was used sparingly during the study period. While some participants might have not required it frequently, given that they were also using the patch, some participants did not use it frequently because of the minor adverse effects experienced. This is discussed further in section 8.6.2.1.

As was previously reported in the literature (Rotella & Mannucci, 2013; Smith et al., 2013), several participants were found to be potentially suffering from anxiety and/or depression. Once again most refused the psychological support offered, because they did not perceive the need for it. In exploring further their reluctance to try such services (as was suggested in the pilot study), the interviewees also stated that they did not perceive the need, among other reasons, such as fear of mental health stigma and wanting to deal with the issue alone. Mental health help seeking behaviours are largely based on the individuals with diabetes' perceptions of need (Shin et al., 2017). Individuals with diabetes may also attempt to resolve their mental health problems on their own rather than seek professional support out of fear of shame (Wu et al., 2011). Apart from screening patients for mental health concerns, Shin et al. (2017) suggests raising awareness on mental health issues and treatment options. This may be facilitated if the psychotherapist is actively present in the outpatient's department, as one of the nurses suggested.

As was mentioned in section 8.5.3.4, while three participants experienced glycaemic imbalances during the study period, these were corrected by the diabetes practice nurses in a

timely manner, suggesting the utility of having the smoking cessation intervention in diabetes practice.

8.6.1.3 Perceived challenges and facilitators to implementation

On being asked on the feasibility to introduce the intervention in practice for a definitive evaluation, the nurses did not identify a lack of human resources as some nurses were recently transferred to the unit. However, both nurses highlighted the affordability of NRT by patients, if these were not provided. Given its possible contribution towards smoking cessation/reduction, the partial/full cost coverage or the consideration and possible inclusion of NRT in the formulary list, supported by consultants is suggested prior to intervention implementation.

8.6.2 Acceptability of the intervention

8.6.2.1 Participants' (individuals with diabetes) satisfaction with and perceived usefulness of the smoking cessation provided

The median total satisfaction and perceived usefulness scores were high among the intervention group, higher than the stipulated scores for proceeding with a future definitive trial, and higher than the scores reported in the control group. This suggests that the study intervention was comparable to standard care (and potentially superior) in terms of patient acceptability. The integration of the qualitative to the quantitative data helped to confirm these findings, as the participants, both the respondents and interviewees, remarked being satisfied with the intervention and its usefulness for quitting smoking. Furthermore, most participants remarked that the duration, frequency and location of the programme were appropriate, with a few participants suggesting extending the programme further.

As was reported in section 8.5.6, the use of qualitative data, reaffirmed the provision of NRT as a crucial component of the intervention, contributing to the limited literature base on the perceived effectiveness of NRT among individuals with diabetes. Participants were not asked about the use of NRT in the questionnaires. This is because both questionnaires were devised to be appropriate for use amongst both the participants who were assigned to the intervention group and those assigned to the control groups (section 7.2.1). Despite having been informed that standard care does not include the provision of any pharmacotherapy, some participants from the control group still remarked that they were not provided with such treatment. In fact, some participants recommended the provision of pharmacotherapy as part of the standard

smoking cessation treatment. This supports the previous suggestion, on the consideration and possible inclusion of NRT in the formulary list for individuals living with diabetes, and possibly for other smokers who use the National Health Service's smoking cessation services.

Despite the NRT's facilitating role in quitting smoking, several participants remarked on the unpleasant effects of using it, especially the nicotine mouth spray, which discouraged its use. As was remarked in section 6.2.2.3, the nicotine mouth spray was chosen over the other types of fast-acting nicotine products, as the nicotine that it delivers is absorbed considerably faster (Kraiczi et al., 2011), resulting in a faster relief of cravings (Hansson et al., 2012; McRobbie et al., 2010). In fact, the nicotine mouth spray was seen as a cigarette substitute by some interviewees. However, the mild adverse effects reported, which were also identified in the literature but tolerated by the participants in these studies (Bolliger et al., 2007; Hansson et al., 2012; Tønnesen et al., 2012), suggest the need to provide an alternative type of fast-acting NRT, such as the inhalator, gum or lozenge, in a future definitive trial. The provision of an alternative type of fast-acting NRT, may also encourage continuing participation (and further quit attempts) among those who stopped attending as they found the programme ineffective/felt unsuccessful in quitting, had changed their mind about quitting smoking, or lacked willpower, as was reported.

8.6.2.2 Providers' satisfaction with the smoking cessation provided

Despite encountering a few challenging patients, both nurses reaffirmed their positive feedback on the intervention, finding the intervention acceptable, effective and suitable to include in practice. A similar observation was also reported in the study by Özcan et al. (2023). In their study, on training diabetes nurse educators who lacked knowledge and skills to provide diabetes-specific smoking cessation education, they noted an improvement in practice, reporting that nurses were satisfied with the addition of this role in their practice, despite similar challenges (Özcan et al., 2023).

8.6.3 Preliminary evidence for the intervention's effectiveness

As was outlined in section 8.5.8, it appears that the study intervention was more effective than the control intervention in achieving smoking abstinence. Notably more participants from the intervention group compared to the control group reported a quitting episode during the study period. This is likely to be related to the 5As framework's more directive approach towards cessation, in which encouraging and setting a TQD is a crucial element (World Health

Organization, 2014), as well as the video clips portrayed, which have been associated with making a quitting attempt (Huang et al., 2015), as previously stated (section 3.7.3). This contrasts with motivational interviewing based interventions (as in the control intervention), where the focus is on encouraging participants to explore and resolve their ambivalence for behaviour change (Miller, 1983).

Despite these different approaches to smoking cessation, there were more participants in the intervention group who had a biochemically verified seven-day point prevalence of abstinence at follow-up when compared to the control group. This suggests that when compared to standard care, the multi-component smoking cessation intervention, which generally consisted of more and longer support sessions and that included informational video clips on the first-hand experience of smoking related diabetic complications and the provision of NRT (which has been identified as a key component of the intervention), is comparable and potentially more effective, as was hypothesised in this doctoral project. While initially it was found that two participants from the intervention group had falsely reported smoking abstinence, the confirmation rate (seven out of nine participants; 77.8%) is similar to that reported in Mini et al.'s (2015) study; 74% (referred to in chapter four). This reaffirms the utility of the CO monitor (for measuring eCO) to validate reported smoking abstinence from combustible sources of tobacco and the use of the multilevel lateral flow immunoassays urine test strips (for measuring cotinine levels in urine) to validate abstinence both from combustible sources of tobacco and non-combustible and alternative products, when participants are no longer on NRT.

The observed eCO biochemically verified smoking abstinence rate for the intervention group (15.6%, 95% CI: 6.5-29.5) was found to be lower to that reported by Pérez-Tortosa et al. (2015), whose intervention was based on motivational interviewing and included pharmacotherapy for smoking cessation (26.1% vs. 17.8% - a per protocol analysis). On the other hand, the abstinence rate reported in this study was higher to that reported by Hokanson et al. (2006), whose intervention was also based on motivational interviewing and included the provision of NRT or bupropion to those interested in quitting (7.0% vs. 3.5%). However, as was outlined in section 4.5.5, the intervention utilised by Hokanson et al. (2006) was less intensive, which may help explain the difference. Notwithstanding the contrasting difference between the smoking abstinence rate observed in this study and that reported by Pérez-Tortosa et al. (2015), this was found to be comparable to the rate reported by Canga et al. (2000). Canga et al. (2000), whose intervention was similar to that used in this study, being based on counselling, offering nicotine patches to heavy smokers and those who did not succeed in

quitting, found that the experimental intervention was more effective than usual care, reporting a biochemically verified (urine cotinine verified) smoking abstinence of 17% vs. 2.3% at six months follow-up.

Despite this observation, which may indicate further the potential of this study' intervention, it is important to note that the follow-up period in this study was only of three months. Relapse can occur at any time, as was also observed in this study; the floating abstinence rate was higher than the self-reported seven-day point prevalence abstinence at the end of the study period. As previously stated, in a future definitive study the study period will be a minimum of six months to assess for sustained smoking abstinence and for a better comparison to previous literature. In addition, the suggestion to provide an alternative type of fast-acting NRT to those who cannot tolerate the nicotine mouth spray (to support them further), should sustain and result in higher abstinence rates at final follow-up.

8.6.4 Preliminary process evaluation

8.6.4.1 Exploring the intervention's functioning

The findings reported in section 8.5.9.1, illustrate how the participants' recollections of their quitting process aligned with the hypothesised mechanisms of the study intervention, which were based on the IMB model (Fisher et al., 2006; Fisher et al., 2003). The information provided, especially the video clips on the smoking associated diabetic complications, the recall of which have been associated with taking smoking cessation action, such as making a quit attempt (Huang et al., 2015), created concern to most participants, and in turn increased the participants' motivation to quit smoking. This led the participants to act on their smoking behaviour as directed by the intervention providers, who helped them stay motivated during the process. Most participants highlighted the use of NRT which helped them to relieve their smoking cravings, as well as other skills, such as the use of helpful distractions, avoiding potential smoking triggers, formulating a quitting plan and the use of motivational techniques, which they were informed about during the sessions.

Nonetheless, some participants reported that stress and/or sadness and the smoking addiction (and associated withdrawal symptoms), challenged smoking cessation. These challenges were also identified in the qualitative descriptive study (chapter five), in previous literature (Abu Ghazaleh et al., 2018; Ardron et al., 1988; Chau et al., 2015; Folan et al., 2014; Georges et al., 2019; Ibrahim et al., 2023; Wakefield et al., 1997) and a recent study which explored the needs

and challenges to quit smoking among smokers (Noonan et al., 2024), which is outlined further in chapter nine. Furthermore, the participants in this study also remarked on the adverse reactions to NRT as an additional challenge to smoking cessation. This, however, should be mitigated in future research as previously explained (section 8.6.2.1), allowing participants to better control their withdrawal symptoms, without the reported inconveniences. Notably, some participants in this study also remarked on their lack of willingness to stop smoking as a barrier to quitting. As previously stated, individuals with diabetes are often reluctant to adopt and act on smoking cessation interventions (Clement et al., 2023; Lotrean, 2017). Continuous encouragement complemented with easily accessible mental health support for any anxiety and depression, common underlying issues among continuing smokers (Caponnetto & Polosa, 2008; Gariepy et al., 2012; Richards et al., 2013), may support such individuals further. Notably positive health outcomes on quitting/reducing smoking, encouraged the participants further in maintaining their new behaviour, as was remarked by the participants in the qualitative descriptive study (chapter five).

8.6.4.2 Intervention delivery fidelity

In most instances treatment fidelity was high; >80% (Borrelli, 2011; Salloum et al., 2022). Once again, it was noted that the nurses did not always set the first (or second) follow-up appointment within two weeks from the TQD, despite having suggested the planning of follow-up sessions beforehand. In fact, the nurses remarked on having had limited availability to provide early follow-up appointments. Hopefully, with the addition of the new staff at the unit, the nurses will have more availability for planning follow-up sessions, for when proceeding with a future definitive trial.

While the use of the smoking cessation guide, which is one of the key recommendations for enhancing treatment fidelity (Borrelli, 2011), was remarked as a practice facilitator, it is worth noting that in session one the use of the 5Rs algorithm, which is required to encourage those who are not motivated further (World Health Organization, 2014), was not always identified by the nurses. In this doctoral research project, the nurses were trained prior to the pilot study and then re-trained prior to the feasibility study. Given the longer period required for the feasibility study, the nurses might have benefitted if booster training sessions were provided, based on the concurrent assessment of treatment delivery fidelity (Borrelli, 2011). In a future definitive trial, it is thus recommended to assess for treatment delivery fidelity throughout the study, so that the intervention providers can be provided with tailored support, as required.

8.6.5 Strengths and limitations

This randomised controlled feasibility trial with a nested qualitative descriptive study comprehensively assessed the feasibility, acceptability and potential effectiveness of a unique multicomponent smoking cessation intervention, exploring its functioning. While two pilot randomised controlled trials were previously identified in the scoping review (chapter three), these focused on establishing the intervention's effectiveness, rather than comprehensively assessing the feasibility of the study intervention prior to further evaluation or implementation into practice (Ng et al., 2010; Thankappan et al., 2013).

In this study, attrition was high in both groups, however, the findings did not suggest that the participants who discontinued the experimental intervention did so for reasons related to the intervention's acceptability. Nonetheless, based on the observations made, recommendations were made to improve participation in future research. The study's findings suggest that a definitive trial is feasible and acceptable, and that the intervention may improve smoking quit rates when compared to standard care.

Despite the observed potential effectiveness of the intervention, it is worth noting that this study was not powered to establish the efficacy of the experimental intervention or its specific components, such as the provision of NRT, and hence it was not possible to look at any differences statistically. A power calculation to determine the study's sample size was not undertaken as feasibility studies should not establish the efficacy of the treatment being tested, but rather provide estimates on the recruitment and study uptake, amongst other outcomes, prior to further research (Treweek, 2015). Increasing the size of a feasibility trial to improve effect precision can be counterproductive, as it demands additional resources, time and costs, which may be unjustified if the trial ultimately proves unfeasible (Teare et al., 2014). Thus, the study outcomes were reported with 95% Confidence Intervals (CI) to provide an estimated range of the said outcomes as suggested in the literature (Lee et al., 2014; Teresi et al., 2022; Thabane et al., 2010).

In this study, the participants' self-reported data as collected by the intervention providers from both groups may have been subject to social desirability (LoBiondo-Wood & Haber, 2014). This was apparent when participants in the control group declined the control intervention stating that they had quit/wanted to quit unaided, however these eventually did not confirm having quit smoking at the end of the study period. To mitigate against this form of bias, participants were allowed to provide confidential feedback through the end of study

questionnaire where they could also list the reason for discontinuing the intervention, amongst other details. Despite the high attrition rate, a favourable (high) response rate at the final assessment session was observed in both groups, thus allowing the collection of data from most participants. While the participants in both groups may have completed the questionnaires in a socially desirable manner, this bias is unlikely to have affected the data collected from the groups unequally due to its systemic nature, (LoBiondo-Wood & Haber, 2014), thus allowing the Ph.D. candidate to compare the experimental intervention to standard care to draw conclusions on the acceptability of the developed intervention. The integration of the qualitative to the quantitative data collected also confirmed that most participants were satisfied with the experimental intervention, finding it useful to quit smoking. Furthermore, the use of qualitative data, reaffirmed the provision of NRT as a crucial component of the intervention, contributing to the limited literature base on the perceived effectiveness of NRT among individuals with diabetes. By additionally exploring the intervention's functioning as perceived by the participants, it was also found that their' recollections of their quitting process aligned with the hypothesised mechanisms of the study intervention, which were based on the IMB model (Fisher et al., 2006; Fisher et al., 2003), contributing to knowledge as per the philosophy of pragmatism.

However, a limitation to this study was the adoption of an open-label design, as described in section 8.4.1. While blinding in this study was not required as there was no formal hypothesis testing (Giangregorio & Thabane, 2015), steps were taken to reduce the risk of bias. All participants were informed that both interventions were helpful in supporting them to quit smoking. Furthermore, as explained in section 7.3.4.4, self-reported seven-day point prevalence of abstinence at follow-up were also objectively verified (Kahan et al., 2014). While it may not be possible to blind participants and providers, it is recommended for a future definitive trial that the outcome assessor/s are blind to treatment assignment to reduce the risk of bias.

An additional limitation was that this study was conducted at a single site and involved only two diabetes practice nurses. While the feasibility study's observations are expected to be generalisable to the other Maltese hospital, conducting a pilot study, such as an internal pilot study, is still recommended should a future definitive trial involve both hospitals or additional nurses. Conducting a pilot study prior to/as part of a future definitive trial would also allow for testing the proposed refinements to the study intervention, ensuring better study uptake.

8.7 Conclusion

This chapter outlined the refinements to the study's methods, i.e. the study intervention and the recruitment and implementation processes, and then reported on an open-label, pragmatic, experimental feasibility trial with a nested qualitative descriptive study. This study assessed the feasibility and acceptability of the revised multi-component smoking cessation intervention among the diabetes practice nurses and individuals with diabetes in preparation for a future definitive trial.

Ninety-one individuals living with type 1 or type 2 diabetes were successfully recruited from an acute public hospital in Malta over a 12-month period. These participants were randomly assigned to the experimental intervention, or to standard care – the provision of general smoking cessation support by the National Health Service, for a 12-week period. Feasibility outcomes included recruitment parameters, compliance with the protocol, resources used, problems identified, response rates at final follow-up and perceived challenges and facilitators to implementation. Acceptability outcomes included the participants and the nurses' satisfaction with the intervention and the participants' perceived usefulness of the intervention provided. The experimental intervention was compared to standard care in terms of its acceptability and effectiveness, and a preliminary process evaluation was conducted.

Almost all the established feasibility and acceptability criteria for proceeding to a future definitive trial were met. While study attrition was high in both groups, the findings did not suggest that the participants who discontinued the experimental intervention did so for reasons related to the intervention's acceptability. Nonetheless, recommendations were made to improve participation in a future study. These included offering a telephone-based follow-up session/s to future participants who might be finding it difficult to attend further, and the provision of an alternative type of fast-acting NRT to those who cannot tolerate the nicotine mouth spray.

The study findings suggest that the study intervention was comparable to standard care (and potentially superior) in terms of patient acceptability. Furthermore, it may improve smoking quit rates when compared to standard care. The integration of the qualitative to the quantitative data also confirmed that most participants were satisfied with the experimental intervention, finding it useful to quit smoking. Furthermore, the use of qualitative data, reaffirmed the provision of NRT as a crucial component of the intervention, contributing to the limited

literature base on the perceived effectiveness of NRT among individuals with diabetes. By additionally exploring the intervention's functioning as perceived by the participants, it was also found that their' recollections of their quitting process aligned with the hypothesised mechanisms of the study intervention, which were based on the IMB model (Fisher et al., 2006; Fisher et al., 2003). Despite encountering a few challenging patients, both nurses reaffirmed the positive feedback on the intervention, finding the intervention acceptable, effective and suitable to include in practice.

The study's findings suggest that a definitive trial is feasible and acceptable, and that the intervention may improve smoking quit rates when compared to standard care. The following chapter provides an overall discussion and conclusion to this doctoral research project.

Chapter 9: Overall Discussion and Conclusion

9.1 Introduction

This chapter outlines and discusses the main findings of the doctoral research project in the context of previous research as well as recent studies published following the development and feasibility assessment of the multi-component smoking cessation intervention. A summary of the research undertaken and the main findings are presented in section 9.2, while the research outputs and the project's contribution to knowledge are presented in section 9.3. Section 9.4 places the doctoral research project in the context of the literature on smoking cessation interventions for individuals living with diabetes, and their perceived challenges and barriers to quitting, which were published during the course of the project. Section 9.5 presents the main discussion points of the doctoral research project in view of the project's research question, along with a methodological critique of the overall research project. Section 9.6 presents recommendations for research and for policy and practice. The conclusion to the doctoral project is provided in section 9.7.

9.2 Summary of the research undertaken and the main findings

This section summarises the research undertaken as per the development and feasibility phases of the MRC framework (Skivington et al., 2021) and the main findings.

9.2.1 Developmental phase

9.2.1.1 Mapping the research on smoking cessation interventions in persons living with diabetes, and the faced challenges and barriers to cessation – a scoping review

Given the uncertainties with regards to evidence-based smoking cessation practice for individuals with diabetes (highlighted in section 1.4.3), a scoping review was carried out to

map out the literature on the smoking cessation interventions delivered to individuals living with diabetes, and on the challenges and barriers to smoking cessation amongst such individuals. A systematic search of 15 databases was undertaken with the key terms "diabetes mellitus" and "smoking cessation" and their synonyms using a scoping review framework (Arksey & O'Malley, 2005). Relevant publications published until May 2022 (n=59) were included. No restrictions were placed on the study design or quality.

Compared to the interventions which included smoking cessation as part of a broader intervention for improving diabetes management, stand-alone smoking cessation interventions, especially those which included pharmacotherapy, seem to have been more successful in helping smokers quit. These findings and the uncertainties as regard to the efficacy of the behavioural support approaches used, and the use of any additional smoking cessation components called for a more focused and rigorous review, a systematic review of effectiveness, which included an Intervention Component Analysis (ICA), for identifying the 'active ingredients' of the effective interventions. The scoping review also indicated the need for the use of more influential methods for communicating tobacco related harm, such as by drawing on the personal experiences (of tobacco related harm) of individuals with diabetes. Given the absence of randomised control trials on the impact of messages from former smokers who experienced smoking related disease (as depicted in the 'Tips' campaign), the use of such messages as an educational tool, part of a smoking cessation intervention for individuals with diabetes, was also recommended, as part of this doctoral research project.

9.2.1.2 Assessing the effectiveness of stand-alone smoking cessation intervention for individuals living with diabetes – a systematic review and intervention component analysis (ICA)

Based on the scoping review's recommendations, a systematic review which assessed the effectiveness of stand-alone smoking cessation interventions and identified the critical features of the successful interventions was conducted. Since this systematic review followed on the scoping review a new search of the literature was not required. Thus, this review included the 59 publications identified in the scoping review. Randomised controlled trials (n=10) which assessed the effectiveness of stand-alone smoking cessation interventions by comparing them to a less intensive intervention were included in this review. As outlined by Sutcliffe et al. (2015), the characteristics of the studies' interventions, taking into consideration the effectiveness of the interventions for establishing the components which appeared to be of significance, were then mapped out.

Despite observing inconsistent findings across the identified studies, limiting the ability to establish the effectiveness of stand-alone smoking cessation interventions for use amongst individuals with diabetes, the addition of an ICA proved useful as it helped to identify some of the critical and promising features of the studied successful interventions. Smoking cessation interventions which consist of three to four sessions, lasting more than 20 minutes each, were found to be more likely to be associated with smoking cessation success. The provision of frequent smoking cessation support and the use of visual aids depicting diabetes related complications were also found to be of possible significance. On the other hand, given that the use of the 5As (and 5Rs) framework for smoking cessation (World Health Organization, 2014), and the provision of pharmacotherapy look promising for use amongst smokers with diabetes, their use was deemed to merit further investigation, as part of the doctoral research project. To validate this review's findings, and maximise the potential of the developing intervention, the use of qualitative exploratory research amongst stakeholders (health care providers and patients) was recommended.

9.2.1.3 Exploring the views of individuals living with diabetes of the identified promising smoking cessation components and their needs to quit smoking – a qualitative descriptive study

A qualitative descriptive study was carried out between March and August 2021 to explore the needs of individuals with diabetes to quit smoking, and their views of the identified promising smoking cessation components, for the development of a smoking cessation intervention for individuals with diabetes. This study was guided by the Information, Motivation and Behavioural skills (IMB) model of behaviour change (Fisher et al., 2006; Fisher et al., 2003). Semi-structured interviews were carried out with 10 former and 10 current smokers of both genders (male or female) with type 1 or type 2 diabetes, who had tried to quit following their diabetes diagnosis.

This study helped to explore the views of individuals with diabetes of the identified promising smoking cessation components, validating the previously posed recommendations: raising awareness on the effects of smoking on diabetes, by showing video messages featuring former smokers' true stories of suffering from smoking related disease; and the provision of frequent and long (30 minutes or longer) smoking cessation counselling sessions, such as those based on 5As (and 5Rs) framework (World Health Organization, 2014). This study also helped to identify the needs of individuals with diabetes to quit smoking, necessitating the need for:

- more awareness efforts on the effects of smoking on diabetes;
- counselling strategies as outlined in the 5As framework (World Health Organization, 2014);
- the use of Nicotine Replacement Therapy (NRT) for smoking cessation;
- diabetes-specific smoking cessation support – identifying an opportunity of introducing evidence-based smoking cessation support as part of local diabetes education efforts.

9.2.1.4 The development of the study intervention

Based on the qualitative descriptive research study's findings and the strategies outlined in the 5As framework for smoking cessation (World Health Organization, 2014), an IMB model for smoking cessation for individuals with diabetes, was developed. This was done in consultation with the doctoral research project's advisors and the proposed providers, the diabetes practice nurses who run the local diabetes education clinics.

9.2.1.5 The development of the training programme for the nurses

A training programme was also developed. This was largely based on the training programme by the author (Grech, 2021), which followed the WHO toolkit for delivering the 5As (and 5Rs) for tobacco cessation (World Health Organization, 2014). The training programme for this study was designed to address the knowledge and skills deficit of the participants, and their attitudes for the effective provision of the developed smoking cessation intervention. After training three diabetes practice nurses who agreed to participate in the doctoral research project as intervention providers, the doctoral project progressed to the feasibility phase.

9.2.2 Feasibility phase

9.2.2.1 Testing the intervention, the feasibility study processes, and the data collection methods – a pilot study

After developing and validating the content of the satisfaction and perceived usefulness questionnaires for use in the main feasibility study, a pilot study was conducted to test the proposed intervention and the study methods and assess the internal consistency of the self-developed and translated tools, in preparation for the feasibility study. The pilot study employed the same protocol as the feasibility study. The study commenced in November 2022 and finished in July 2023.

Thirty-four individuals living with type 2 or type 1 diabetes were recruited from the two main acute hospitals in Malta over a six-month period and provided with the study intervention. Feedback was collected at three months follow-up by means of a questionnaire and by inviting 15 participants, who were selected based on their participation experience, to an interview. Feedback, to help refine the recruitment and implementation processes was also sought by asking the intervention providers to keep an intervention log and audio-record the provided sessions, and by conducting interviews with all the three nurses.

Most participants were satisfied with the intervention provided, perceiving it as useful. Additionally, all nurses had a positive impression of the intervention and in almost all instances treatment fidelity was high, 80-100%. Both the English and the Maltese versions of the self-developed questionnaires and the Maltese version of the CDS-5 (Etter et al., 2003), were found to have a high internal consistency, >0.8.

Given the long period to recruit the required sample size, it was decided to revise the recruitment strategy for the feasibility study by involving the other health care professionals working at the diabetes out-patients with the aim of increasing the number of recruited participants. Furthermore, given that treatment fidelity was not always high, remedial training was also advisable prior to carrying out the feasibility study. Based on the participants' feedback and in agreement with the nurses, the study intervention was also revised so that an additional follow-up session to those who report not quitting smoking, was to be provided.

9.2.2.2 Assessing the feasibility, acceptability and potential effectiveness of the multi-component smoking cessation intervention – a randomised feasibility study

Following the refinements carried out to the study intervention and the recruitment and implementation processes, a feasibility study was conducted to evaluate the feasibility and acceptability of the multi-component smoking cessation intervention amongst the diabetes nurse educators, and the participants, the individuals with diabetes, and to assess its potential effectiveness, in preparation for a future definitive trial. An open-label, pragmatic, experimental design with a nested qualitative descriptive study was adopted. The feasibility study commenced in August 2023 and finished in October 2024.

Ninety-one individuals living with type 1 or type 2 diabetes were recruited from an acute public hospital in Malta over a 12-month period. These participants were randomly assigned to the experimental intervention, or to standard care – the provision of general smoking cessation support by the National Health Service, for a 12-week period. The primary feasibility and

acceptability outcomes included the recruitment and participation rates, resources used, problems identified and the nurses' perceived challenges and facilitators to implementation, and the nurses' and participants' acceptability of the study intervention. A preliminary process evaluation was conducted, and the experimental intervention was compared to standard care in terms of its acceptability and effectiveness.

Almost all the established feasibility and acceptability criteria for proceeding to a future definitive trial were met. While study attrition was high in both groups, the findings did not suggest that the participants who discontinued the experimental intervention did so for reasons related to the intervention's acceptability. The study findings suggest that the study intervention was comparable to standard care (and potentially superior) in terms of patient acceptability. Furthermore, it may improve smoking quit rates when compared to standard care. The integration of the qualitative to the quantitative data also confirmed that most participants were satisfied with the experimental intervention, finding it useful to quit smoking. Furthermore, the use of qualitative data, reaffirmed the provision of NRT as a crucial component of the intervention. By additionally exploring the intervention's functioning as perceived by the participants, it was also found that their' recollections of their quitting process aligned with the hypothesised mechanisms of the study intervention, which were based on the IMB model (Fisher et al., 2006; Fisher et al., 2003). Despite encountering a few challenging patients, both nurses reaffirmed the positive feedback on the intervention, finding the intervention acceptable, effective and suitable to include in practice.

In conclusion, the study's findings suggest that a definitive trial is feasible and acceptable, and that the intervention may improve smoking quit rates when compared to standard care.

9.3 Research outputs and the project's contribution to knowledge

9.3.1 Research outputs

The doctoral research project delivered the following outputs and original contributions to the literature.

- A scoping review on the smoking cessation interventions carried out among individuals living with diabetes, and on their challenges and barriers to smoking cessation.

The scoping review was published (Grech et al., 2023b). A copy is available in Appendix 9.1.

- A systematic review of effectiveness of intensive stand-alone smoking cessation interventions for individuals with diabetes and an intervention component analysis (ICA).

The systematic review was also published (Grech et al., 2023a). A copy is available in Appendix 9.2.

- A qualitative descriptive study on the views of individuals with diabetes of the identified promising smoking cessation components and their needs to quit smoking.

This study was presented at the National Public Health Symposium, 2023 (Appendix 9.3), and published (Grech, Norman, & Sammut, 2024a). A copy is available in Appendix 9.4.

- The development and initial validation of acceptability measures for evaluating smoking cessation interventions among individuals with diabetes.

This study was presented at the European Conference for Tobacco Control, 2023 (Appendix 9.5) and published (Grech, Norman, & Sammut, 2024b). A copy is available in Appendix 9.6.

- A unique multicomponent smoking cessation intervention based on evidence, theory and the needs of individuals with diabetes which was piloted, and then assessed for its feasibility, acceptability and potential effectiveness.

The developmental process of the intervention was presented at the European Conference for Tobacco Control, 2023 (Appendix 9.7). Qualitative findings from the pilot study were presented at the University of Malta Research Expo, 2024 (Appendix 9.8). The finalised intervention was sufficiently described in the feasibility study protocol, which was published (Grech, Norman, Azzopardi, et al., 2024). A copy of the study protocol is available in Appendix 9.9. The study protocol has also been presented at the European Academy of Nursing Science Summer Conference, 2023 (Appendix 9.10).

9.3.2 Contribution to knowledge

This doctoral research project presents a unique, feasible, acceptable and potentially effective, multi-component smoking cessation intervention for individuals with diabetes, contributing to the limited literature base on the topic, especially that which favours the use of intensive interventions (pharmacological and/or non-pharmacological behavioural interventions for smoking cessation consisting of multiple and/or long support sessions) over less intensive interventions for this patient cohort. By taking a three-stepped research process – a scoping review, a systematic review (and ICA), and a qualitative descriptive study – this doctoral research project details the development of this unique intervention based on evidence and theory, and the needs of people living with diabetes locally. The mechanisms of the study intervention were theorised as per the IMB model for achieving and sustaining behaviour change (Fisher et al., 2006; Fisher et al., 2003), while the 5As (and 5Rs) algorithm (World Health Organization, 2014), was used as the guiding framework for the delivery of the intervention.

This thesis also reports on the findings from a randomised controlled feasibility trial with a nested qualitative descriptive study. The study's findings suggest that a definitive trial is feasible and acceptable, and that the intervention may improve smoking quit rates when compared to standard care. Furthermore, the use of qualitative data, reaffirmed the provision of NRT as a crucial component of a smoking cessation intervention, contributing to the limited literature base on the perceived effectiveness of NRT among individuals with diabetes. The feasibility study also validates the hypothesised mechanisms of the study intervention as per the IMB model's constructs based on the participants' quitting experiences, contributing to knowledge as per the philosophy of pragmatism. The intervention and its programme theory have been sufficiently described to allow its replication.

9.4 An overview and discussion of research related to the doctoral research project, published during the course of the project

Besides the above-mentioned published studies, i.e. the studies that were derived from this doctoral project, other similar studies were published during the course of the project, after the

scoping and systematic reviews searches were conducted. These include: two randomised controlled trials on smoking cessation interventions for individuals with diabetes (Huang et al., 2023; Russo et al., 2022); a multicentre retrospective cohort study in patients with type 2 diabetes who used tobacco (Wang et al., 2024); three reviews, one on behavioural therapy for individuals with diabetes who smoke (Sammut et al., 2024), one on nicotine-based interventions for smokers with diabetes (Haseen et al., 2024) and a systematic review and meta-analysis on smoking cessation pharmacological interventions for individuals with type 2 diabetes (Martin et al., 2025); and a qualitative descriptive study which explored the smoking cessation needs and challenges of individuals with type 2 diabetes who smoke (Noonan et al., 2024). In addition, a conference abstract which reports on a review on the smoking and smoking cessation experiences of individuals with diabetes was published (Martinez, 2024). Furthermore, during this period, the pre-print on the randomised controlled trial by Albaroodi et al. (2021), was also published (Ibrahim et al., 2023), however, this has already been discussed in the scoping and systematic review. The following sub-sections provide an overview and discussion of these recent studies.

9.4.1 Two randomised controlled trials on smoking cessation interventions for individuals with type 2 diabetes, published during the course of the doctoral project

Two randomised controlled trials which assessed the effectiveness of smoking cessation interventions for individuals with type 2 diabetes were identified. Huang et al. (2023) compared the effectiveness of a 6-month health coaching programme, based on various behavioural counselling theories and techniques, such as motivational interviewing, to usual care. Participants were also encouraged to take up Taiwan's National Health Insurance two-month varenicline treatment plan (Huang et al., 2023). Similarly, Russo et al. (2022) compared the effectiveness and safety of a 12-week provision of varenicline to placebo, providing both the intervention and control groups with weekly brief (up to 10 minutes) face to face/telephone counselling sessions.

Huang et al. (2023) did not observe any significant differences in self-reported abstinence rates between the groups, however, on conducting multivariate analysis to identify the predictors of smoking cessation by taking into consideration the whole sample, they found that varenicline use significantly predicted successful smoking cessation (Odds ratio, OR: 3.67, 95%

confidence interval, CI [1.27-10.60]). Similarly, Russo et al. (2022) found that biochemically verified continuous abstinence rates (by using a carbon monoxide monitor) were significantly higher for the varenicline group as compared to the placebo group at one year follow-up – 18.7% vs. 5.3% (OR: 4.07, 95% CI [1.79-9.27]).

Despite these promising findings, which highlight the contributing role of pharmacotherapy in supporting smoking cessation among individuals living with diabetes (as was also noted in this feasibility study), some observations are worth noting as these can limit the generalisability of these findings to the real-world clinical context. Unlike in the feasibility study, in both studies (Huang et al., 2023; Russo et al., 2022), patients with apparent and diagnosed depressive disorders (respectively), which are common among patients with diabetes (Rotella & Mannucci, 2013), were excluded from participation. This is likely due the concerns about the possible links between varenicline use and neuropsychiatric events, including depression (Cahill et al., 2013). Furthermore, in Russo et al.'s (2022) study, the participants were only deemed eligible for the study if they intended to quit smoking in the next month. While Russo et al. (2022) achieved the required sample size to detect a clinical meaningful difference in smoking abstinence between the groups, Huang et al. (2023) did not. Huang et al.'s (2023) study did not reach the target sample size as the study had to be discontinued because of the COVID-19 pandemic and following the recall of varenicline (due to the identified risk of a nitrosamine impurity in varenicline worldwide).

Nonetheless, these findings add to the conclusions by Tonstad & Lawrence (2017), which was referred to in section 3.7.4, and the two recent studies by Rojewski et al. (2024) and Tønnesen et al. (2022), which were referred to in section 8.6.1.2. These studies, who carried out secondary analyses of data of patients with diabetes in varenicline-based clinical trials, found that when compared to placebo, varenicline was more effective for smoking cessation (Rojewski et al., 2024; Tønnesen et al., 2022; Tonstad & Lawrence, 2017). In view of these positive findings and the observed limitations, future research should assess the feasibility of varenicline-based smoking cessation interventions among individuals with diabetes (along with the effectiveness and safety of the treatment) in real-world clinical settings, once varenicline is once again widely available, as was done in this doctoral research project.

During the course of the doctoral project, Clair et al. (2020) published a study protocol on a motivational interviewing-based smoking cessation intervention, that included a two week NRT starter kit, for individuals with type 2 diabetes. However, this trial, which was initiated

before the COVID-19 pandemic in 2018, did not reach the target sample size and was later terminated due to lack of funding (Claire, 2022). The reported low recruitment, uptake and challenges encountered in the studies by Clair et al. (2020) and Huang et al. (2023) emphasise further the importance of conducting feasibility studies before undertaking larger definitive smoking cessation trials among individuals with diabetes.

9.4.2 A multicentre retrospective cohort study in patients with type 2 diabetes who used tobacco

In addition to these two published randomised controlled trials, a cohort study was also identified. Wang et al. (2024) conducted a multicentre retrospective cohort study in patients with type 2 diabetes who used tobacco to determine whether the use of semaglutide, a glucagon-like peptide-1 receptor agonist (GLP-1RA), was associated with changes in health care use measures related to tobacco use. These measures included visits for tobacco use diagnosis, prescriptions for smoking cessation medications and counselling (Wang et al., 2024). The authors adopted an observational retrospective study by using a large electronic health record database, recruiting 222,942 new users of diabetic medications including 5,967 new users of semaglutide and 216,975 new users of other diabetic medications (Wang et al., 2024). Participants were followed up for 12 months.

While semaglutide was associated with a significantly lower risk for clinician visits for tobacco use diagnosis, reduced smoking cessation medication prescriptions, and counselling, the study fails to show the relationship between the use of semaglutide and smoking cessation (Wang et al., 2024). This is because Wang et al. (2024) did not assess quit rates or changes in smoking behaviour, which are required for evaluating the medication's effectiveness. So far, two trials have been published on the use of GLP-1RAs for smoking cessation (Lüthi et al., 2024; Yammine et al., 2021). While Yammine et al. (2021) found that exenatide demonstrated higher smoking abstinence rates at six weeks when compared to placebo in their pilot study, in a larger trial, Lüthi et al. (2024), who compared dulaglutide to placebo, reported no significant differences on smoking abstinence rates at 12 weeks. In view of these findings, and Wang et al.'s (2024) study limitations, further research on the use of GLP-1RAs for smoking cessation among individuals with diabetes is required to provide practice recommendations.

9.4.3 Three reviews on smoking cessation interventions for individuals with diabetes, published during the course of the doctoral project

In addition to these studies, three reviews which explored smoking cessation interventions carried out among individuals with diabetes were also published during the course of the doctoral project (Haseen et al., 2024; Martin et al., 2025; Sammut et al., 2024). Sammut and her colleagues (including the doctoral candidate) reviewed the literature on smoking cessation behavioural interventions (on the use of the 5As framework, motivational interviewing and counselling) which were carried out among individuals with diabetes by utilising a scoping review framework (Sammut et al., 2024). On the other hand, Haseen et al. (2024) carried out a systematic review of the literature that reported on the effectiveness of nicotine-based interventions for smoking cessation among individuals with diabetes. Martin et al. (2025) also conducted a systematic review investigating all types of pharmacotherapies for smoking cessation; namely, varenicline, bupropion and NRT, carrying out a meta-analysis. Unlike Sammut et al.'s (2024) review and the scoping review (chapter three), Haseen et al. (2024) included studies which targeted individuals with various chronic diseases that also included individuals with diabetes, as long as the smoking cessation or clinical outcomes for individuals with diabetes were reported separately. Martin et al. (2025) included reports on analysis of data (of individuals with diabetes) from studies which were not specific to individuals with diabetes.

Sammut et al. (2024) and Haseen et al. (2024) reached similar conclusions to those drawn in the scoping and systematic reviews of this doctoral project. Sammut et al. (2024) observed that interventions that were of a more intensive nature (consisting of multiple sessions lasting at least 30 minutes each) were more likely to report significant smoking cessation outcomes, similar to what was reported in the systematic review conducted as part of the doctoral research project. On the other hand, similar to what was observed in the scoping and the systematic reviews conducted as part of this doctoral project, Haseen et al. (2024) noted that in some of the identified studies, nicotine-based interventions in combination with behavioural support were successful in helping individuals with diabetes to quit smoking, suggesting the use of these interventions in future research. Additionally, Martin et al. (2025) found that when compared to placebo/usual care/counselling, the use of pharmacotherapy (NRT, bupropion, and varenicline) significantly increased continuous abstinence rates at 12 weeks (OR: 4.17, 95 % CI: [2.71-6.42]) and 24 weeks (OR: 3.80, 95 % CI [2.52-5.72]), providing further evidence on the contributing role of pharmacotherapy for smoking cessation for individuals with

diabetes. Varenicline was also significantly more effective at week 54 (no data were available on NRT or bupropion).

Despite having adopted a systematic and comprehensive approach to answer the research questions posed, the reviews by Sammut et al. (2024) and Haseen et al. (2024) were limited in providing specific recommendations for intervention development. While Sammut et al. (2024) observed that interventions were more successful when being of an intensive nature, they remarked that the complexity of the identified interventions limited the identification of the active components of the successful interventions. On the other hand, while Haseen et al. (2024) identified nicotine-based interventions as promising interventions for smoking cessation among individuals with diabetes, no recommendations on the type, dose or duration of such interventions were provided. Nonetheless, their observations and recommendations appear to be valid, as the developed multi-component smoking cessation intervention, which was of an intensive nature and included the provision of NRT, was comparable to, and potentially more effective than a less intensive approach, as hypothesised in this doctoral research project.

The acknowledged limitations by Martin et al. (2025) have also been referred to when discussing the included studies' limitations (Huang et al., 2023; Rojewski et al., 2024; Russo et al., 2022; Tønnesen et al., 2022; Tonstad & Lawrence, 2017) in sections 8.6.1.2 and 9.4.1. As stated in section 9.4.1, given the positive findings on using varenicline for smoking cessation among individuals with diabetes and the observed limitations, investigating the feasibility along with the effectiveness of varenicline-based smoking cessation interventions for individuals with diabetes in real-world clinical settings (as was done in this doctoral research project), is recommended, once varenicline is once again widely available.

In addition to these reviews, Martinez (2024) published a conference abstract which reports on a review on the experiences of smoking and smoking cessation in people with diabetes. While little detail is available, the presented findings resonate with those reported in the scoping review of this doctoral research project (section 3.6.5.2). As was reported in chapter three, Martinez (2024) found that individuals with diabetes underestimate the effects of smoking on diabetes. Furthermore, individuals with diabetes remarked that being advised to quit smoking or told about the additional health risks when smoking was not enough to help them quit smoking (Martinez, 2024). This review has not been fully published yet at the time of writing.

9.4.4 A qualitative descriptive study which explored the smoking cessation needs and challenges of individuals with type 2 diabetes who smoke

A qualitative descriptive study which explored the smoking cessation needs and challenges among individuals with type 2 diabetes who smoke, was also published during the course of the doctoral research project. Noonan et al. (2024) explored the needs and challenges to quit smoking among individuals with type 2 diabetes who smoke, along with their impressions of a text-based smoking cessation intervention, for the future development of an intervention. The authors recruited 10 participants from the UK and another 10 from the US by convenience sampling (Noonan et al., 2024). Semi structured interviews were held over the phone. Questions were based on the Capability, Opportunity, Motivation and Behaviour COM-B model by Michie, van Stralen, & West (2011).

While participants were generally aware of the health effects of smoking, participants still lacked knowledge on the association between smoking and diabetes (Noonan et al., 2024), as was observed in the qualitative descriptive study (chapter five). As was highlighted in chapter five, the participants in this study also highlighted health as a motivator (Noonan et al., 2024). They also acknowledged social reasons for smoking, the smoking habit and diabetes-related factors, such as concern about weight gain and management, which caused diabetes distress, as barriers to quitting (Noonan et al., 2024). Noonan et al. (2024) reported that the participants were generally supportive of a text-based smoking cessation intervention, however some participants remarked on the need of an intensive intervention, suggesting that text messages should be provided as an adjunct to smoking cessation support.

Despite being a small sample study which recruited participants from two different regions, this study validates the findings which were obtained in the qualitative descriptive study (chapter five), which include the perceived need of intensive smoking cessation support. At the time of writing, no studies (or protocols) on the evaluation of a text-based smoking cessation intervention for individuals with type 2 diabetes were published by Noonan and colleagues (Noonan et al., 2024).

9.5 Main discussion points of the doctoral research project

To inform the development and refinement of the smoking cessation intervention and the methods for assessing its feasibility and acceptability, the findings from the scoping and systematic reviews, the qualitative descriptive study, and the pilot study have already been reported and discussed in chapters three to six. Additionally, chapter eight presented and discussed in detail the findings obtained from the last research step of the doctoral research project. This section presents the main discussion points of the doctoral research project in view of the project's research question (section 1.5), along with the methodological critique of the project.

9.5.1 Is a multi-component smoking cessation intervention developed for persons living with diabetes who smoke feasible, acceptable to diabetes nurse educators and their patients, and potentially effective?

Despite the additional challenges faced by individuals with diabetes in quitting smoking (Campagna et al., 2019; Durlach et al., 2022), diabetes-specific evidence-based smoking cessation recommendations were limited at the start of the doctoral research project (Nagrebetsky et al., 2014; Zhan et al., 2016). In view of the identified gap in research, this research project commenced right from the developmental phase as per the MRC 2021 framework for the development and evaluation of complex interventions in health care (Skivington et al., 2021). The philosophy of pragmatism, which focuses on investigating knowledge based on individuals' experiences and the outcomes of action (Borglin, 2015; Morgan, 2014), served as the philosophical framework to this doctoral research project.

Following the development and refinement of a unique multi-component smoking cessation intervention for individuals with diabetes, a feasibility study was undertaken. In this randomised controlled feasibility trial with a nested qualitative descriptive study, the multi-component intervention, which consisted of intensive behavioural support sessions and NRT, was compared to standard care, which generally consisted of brief one to two sessions. Despite the noticeable higher attrition rate when compared to previous similar literature (Li et al., 2017; Russo et al., 2022), which was observed across both groups, the remaining feasibility criteria

for proceeding to a definitive trial were met, and the experimental intervention was perceived as acceptable among patients and providers. While previous literature had suggested that diabetes educators often prioritise other aspects of diabetes management over smoking cessation (Camilleri et al., 2021; Daly et al., 2014; Lotrean, 2017; Xu et al., 2016), the two providers who were recruited in the feasibility study took up this initiative identifying the possibility of including the programme into clinical practice.

Additionally, this study suggests that the study intervention was comparable to standard care (and potentially superior) in terms of both patient acceptability and effectiveness. This observation contributes to the limited literature base which favours the use of intensive interventions over less interventions (Nagrebetsky et al., 2014).

This doctoral project also adds on to the limited knowledge base on the use of NRT among smokers with diabetes. Unlike previous randomised controlled trials that provided NRT for smoking cessation among individuals with diabetes (Canga et al., 2000; Hokanson et al., 2006b; Pérez-Tortosa et al., 2015; Sawicki et al., 1993), all of which provided limited information on its use and/or its effect, this study measured treatment adherence and observed that the use of NRT might be associated with self-reported smoking cessation at final follow-up. The addition of qualitative research, reaffirmed the provision of NRT as a crucial component of the intervention, contributing to the limited literature base on the perceived effectiveness of NRT among individuals with diabetes.

In line with the philosophy of pragmatism, this doctoral project also illustrated how the participants' recollections of their quitting process aligned with the hypothesised mechanisms of the study intervention as per the IMB model's constructs. The intervention and its programme theory have been sufficiently described to allow its replication.

Despite the NRT's facilitating role in quitting smoking, several participants remarked on the unpleasant effects of using it, especially when using the nicotine mouth spray. While mild adverse effects have been reported in the literature, these were well tolerated, with users still preferring the mouth spray over other types of fast-acting NRT (Bolliger et al., 2007; Tønnesen et al., 2012). Nonetheless, in view of the feedback obtained, in a future study, the provision of an alternative type of fast-acting NRT to those who cannot tolerate the nicotine mouth spray is recommended. Additionally, in view of the high attrition rate, telephone-based follow-up session/s should be provided to those who might be finding it difficult to attend further.

In conclusion, this doctoral project, which was guided by the MRC framework (Skivington et al., 2021) and the pragmatism research paradigm, identified the developed multi-component intervention as feasible, acceptable among the diabetes nurse educators and the individuals with diabetes, and potentially effective for smoking cessation. This intervention provides an alternative to varenicline-based smoking cessation interventions for individuals with diabetes in real-world clinical practice, where not all patients may be suitable candidates for such treatment (section 9.4.1).

9.5.2 Methodological critique of the doctoral research project

While previous chapters have presented the strengths and weaknesses of each research step undertaken, the following sub-section provides a critique of the entire research project. It considers the methodological strengths of the doctoral research project as well as its limitations.

9.5.2.1 Strengths of project design and conduct of the research

Systematic development and testing of the intervention

A main strength of this doctoral research project was the use of the MRC framework to guide the development and feasibility assessment of this multi-component intervention. The MRC framework guided the researcher to develop an intervention in a systematic manner, testing it out prior to a future definitive evaluation (Craig et al., 2008, 2013; Skivington et al., 2021).

Given the lack of evidence-based smoking cessation practice recommendations for individuals with diabetes (Nagrebetsky et al., 2014; Zhan et al., 2016), a more comprehensive review (a scoping review) of the available literature on different types of smoking cessation interventions that have been utilised amongst individuals with diabetes, taking into consideration the challenges, and the barriers to smoking cessation that were identified amongst individuals with diabetes, was carried out to guide the conduct of a systematic review of effectiveness and intervention component analysis. After developing and pilot testing the intervention, a feasibility assessment of the finalised intervention was advisable prior to a definitive trial, particularly in view of the reported low recruitment, uptake and challenges encountered in two recent smoking cessation trials carried out among individuals with diabetes (Claire, 2022; Huang et al., 2023). This helped provide estimates on the recruitment and participation rates, identify perceived challenges and facilitators to implementation, and assure the intervention's acceptability among patients and providers, thus ensuring that the main trial targets can be met

before proceeding with a future larger sample size trial (Giangregorio & Thabane, 2015). Throughout the developmental and piloting phases, the research conducted identified key uncertainties which were addressed at a subsequent stage, ultimately resulting in a theoretically based, understandable (in terms of the active ingredients and their exerted effects), replicable complex intervention (Craig et al., 2008, 2013; Skivington et al., 2021).

Stakeholder involvement

Another strength of this doctoral research project was the involvement of stakeholders, persons with diabetes who smoke or used to smoke in particular, in the developmental phase of the project.

Despite identifying some of the critical and promising features of the reviewed successful smoking cessation interventions, the conducted reviews were still limited in terms of applicability of their findings to the development of the intervention as part of this doctoral thesis. Based on the recommendations from Skivington et al. (2021), the views of the recipients and potential providers of the identified features were explored for establishing the validity of the findings. Given that health care interventions are very much dependent on patient involvement and their attitudes to them (Richards, 2015b), a qualitative descriptive study was designed to explore the needs of individuals with diabetes to quit smoking, and their views of the identified promising smoking cessation components. Based on this study's findings and the identified literature, a tentative model of a smoking cessation intervention for individuals with diabetes, was developed. The proposed providers, the diabetes practice nurses who run the local diabetes education clinics, were consulted, as well as the doctoral research project's advisors.

Robust trial design

One of the strengths of the feasibility study was the adoption of a randomised controlled trial. While an experimental design is not a requirement for undertaking a feasibility study, this helped to test the full version of the protocol prior to a future definitive evaluation (Treweek, 2015). Furthermore, this allowed a direct comparison to current standard practice, i.e. the provision of general smoking cessation support by the National health Service, in terms of the study outcomes (i.e., participation rates, the smoking cessation rates, opinions about the intervention, and satisfaction with the support provided).

The addition of a qualitative strand to the feasibility study

In addition to the experimental design, the feasibility study included a qualitative strand for exploring intervention acceptability among patients and providers. The addition of a qualitative component to experimental research helped provide an in-depth exploration of the participants' perceived usefulness and satisfaction with the experimental intervention, complementing the basic quantitative measures used amongst the patients (Feeley & Cossette, 2015). The consideration of the participants' experience in quitting smoking, also helped to provide further understanding of the intervention's functioning, as part of a process evaluation (Moore et al., 2015). This is also in line with the philosophy of pragmatism where reality (how the intervention works) is shaped by the users' experience (Creswell & Plano Clark, 2018; Morgan, 2014).

Treatment fidelity

Another strength was the adoption of measures to enhance the fidelity of the intervention during the piloting/feasibility phase. Following the training sessions held, prior to the pilot and the feasibility studies, the nurses were provided with printed resources as a reference: the guidelines by the National Health Service's smoking cessation services on prescribing NRT; the model for delivering the smoking cessation intervention; and the structured guide that had to be followed by the providers for maintaining fidelity (Borrelli, 2011; Salloum et al., 2022). Additionally, during both the pilot and feasibility studies, the nurses were asked to audio-record the sessions (with consent) for fidelity assessment (Borrelli, 2011; Moore et al., 2015).

9.5.2.2 Limitations of the doctoral research project

Review methods conducted by one author

A main limitation of the scoping and the systematic reviews was that the methods were only undertaken by the author. This falls short of review recommendations (Page et al., 2021; Peters et al., 2020). Despite this limiting factor, the reviews by Haseen et al. (2024) and Sammut et al. (2024) have reached conclusions similar to those drawn in the scoping and systematic reviews, validating the main findings. While a meta-analysis of effect estimates is the preferred method of synthesis in a systematic review, given the incompletely reported outcomes/effect estimates in some of the identified studies and the significant diversity in the interventions utilised by the study authors, this was not possible (Cullum & Dumville, 2015; McKenzie & Brennan, 2022). Nonetheless, the addition of an ICA to the systematic review proved to be

more useful, as in analysing the components of the identified interventions, some critical and promising features of the successful interventions were identified.

Preliminary validation of the satisfaction and perceived usefulness questionnaires

The satisfaction and perceived usefulness questionnaires were developed to provide a better alternative to current standard satisfaction questionnaires for assessing intervention acceptability in the feasibility trial. However, the internal reliability assessment was only conducted among a small sample of participants who attended the proposed study intervention. Furthermore, data was non-normally distributed, which could have led to over-estimation of internal consistency reliability (Liu & Zumbo, 2007; Sheng & Sheng, 2012). Therefore, future research should involve a larger sample to better approximate a normal distribution and to assess the external reliability of the questionnaires and validate the constructs. Nonetheless, the results of this study supported the use of these questionnaires for assessing and comparing the acceptability of smoking cessation interventions among individuals with diabetes in pilot/feasibility studies (Bujang et al., 2018). Furthermore, the addition of a qualitative strand to the feasibility study enabled further understanding of the participants' satisfaction with and perceived usefulness of the intervention provided, complementing the use of these measures.

Open-label design

The main limiting factor of the feasibility trial was the adoption of an open-label design. This is because blinding of participants, the intervention providers and the researcher was not possible. While blinding in this study was not required as there was no formal hypothesis testing (Giangregorio & Thabane, 2015), steps were taken to reduce the risk of bias. All participants were informed that both interventions were helpful in supporting them to quit smoking. Furthermore, self-reported seven-day point prevalence of abstinence at follow-up were also objectively verified (Kahan et al., 2014). While it may not be possible to blind participants and providers, it is recommended for a future definitive trial that the outcome assessor/s are blind to treatment assignment to reduce the risk of bias.

Single site study

An additional limitation of the feasibility trial was that this study was conducted at a single site, involving only two diabetes practice nurses. The involvement of the doctoral candidate may have also influenced the nurses' views and feedback about the intervention, leading to positive opinions about the acceptability and possible implementation of the study intervention in practice. In future studies, data collection and analysis should be undertaken by another

researcher/s other than the principal investigator. Furthermore, a future definitive trial should also involve another study setting/s, and additional providers.

Social desirability

As explained in section 8.6.5, in the feasibility study, the participants' self-reported data as collected by the intervention providers from both groups may have been subject to social desirability (LoBiondo-Wood & Haber, 2014). To mitigate against this form of bias, participants were encouraged to provide feedback through the end of study questionnaire. While the participants in both groups may have completed the questionnaires in a socially desirable manner, this bias is unlikely to have affected the data collected from the groups unequally due to its systemic nature, (LoBiondo-Wood & Haber, 2014), thus allowing the Ph.D. candidate to compare the experimental intervention to standard care to draw conclusions on the acceptability of the developed intervention. The integration of the qualitative to the quantitative data collected also confirmed that most participants were satisfied with the experimental intervention, finding it useful to quit smoking.

9.6 Recommendations for research and for policy and practice

The following sub-section presents the recommendations drawn from the doctoral research project for research and for policy and practice.

9.6.1 Research recommendations

The findings of the feasibility study suggest that a definitive trial is feasible. Nonetheless, as was mentioned in the previous chapter, the study intervention should be refined to improve the study uptake in future research. This includes offering a telephone-based follow-up session/s based on the study protocol to participants who might be finding it difficult to attend further, and the provision of an alternative type of fast-acting NRT, such as the inhalator, gum or lozenge to those who cannot tolerate the nicotine mouth spray. As previously stated, in a future definitive study the study period will be a minimum of six months to assess for sustained smoking abstinence and for a better comparison to previous literature. Furthermore, as highlighted in the limitations section (section 9.5.2.2), in a future definitive trial the outcome assessor/s should be blind to treatment assignment to reduce risk of bias.

Based on the sample size calculation, recruitment of participants (n=338) for a future definitive study can take an average of 52 months. Including another study site is recommended as it will shorten the recruitment period and help assess the intervention's effectiveness in another study site. In view of the proposed refinements to the study intervention and the inclusion of another study site, conducting a pilot study is recommended prior to a definitive evaluation. The pilot study can be an internal pilot, allowing the data collected to be used in the final (definitive trial) analysis (Giangregorio & Thabane, 2015). As previously stated in section 8.6.4.1, given the longer study period, it is also recommended to assess for treatment delivery fidelity throughout the study so that the providers can be provided with tailored support, as required.

In the previous chapter, findings from the qualitative research highlighted the provision of NRT as a crucial component of the intervention. However, the nature of the study limits the ability to draw any conclusions about the effectiveness of NRT among individuals with diabetes. Given that the systematic review and component network meta-analysis by Hartmann-Boyce et al. (2021) found that the effects of intervention components were slightly weaker when all participants received pharmacotherapy for smoking cessation, it is recommended to analyse the specific effect of NRT as part of the multi-component smoking cessation intervention in future research. In line with Sammut et al.'s (2024) research recommendations, future studies should explore the added benefits of NRT as part of the smoking cessation programme by investigating its effectiveness compared to placebo in a three-arm randomised controlled trial.

In addition to conducting a definitive trial, as was recommended in section 9.5.2.2, future research should also consider evaluating the external reliability of the acceptability questionnaires and to validate the constructs using a larger sample of individuals with diabetes. Such analysis could also be part of a future definitive trial.

Having validated the hypothesised mechanisms of the study intervention as per the IMB model's constructs based on the participants' quitting experiences, and in view of the feasibility study's positive findings, future research initiatives should also include the testing of the study intervention in different contexts, such as within a local diabetes outpatients' clinic, part of a private health care setting, or in another country. Additionally, the study intervention can be adapted for use among the local diabetes association's smoking members. Such studies should also explore any contextual factors that might moderate how the intervention works, exploring any deviations from the theoretical mechanisms (Moore et al., 2015). The intervention and its programme theory have been sufficiently described allowing its replication in such settings.

As was highlighted earlier (section 9.5.2.1), the main strength of this doctoral research project was the use of the MRC framework to guide the systematic development and feasibility assessment of this multi-component intervention. The developmental and feasibility research processes, guided by the MRC framework, the IMB model, and stakeholder input, provide a structured approach that can be followed when conducting research in other clinical contexts.

9.6.2 Policy and practice recommendations

This doctoral research project suggests that when compared to standard care, the developed multi-component smoking cessation intervention is comparable and potentially effective, providing a promising alternative to varenicline-based smoking cessation interventions for individuals with diabetes in real-world clinical practice. The included two diabetes nurse educators did not identify any challenges from their end to implement this intervention in practice, however, both nurses highlighted the affordability of NRT by patients, if these were not provided.

Malta falls short in providing comprehensive cessation services. While a national quit line, and the National Health Service's smoking cessation services are cost-covered, NRT is not (World Health Organization, 2023). In 2012, NRT (nicotine patches) were made freely available to in-patients at one acute public hospital in Malta (Azzopardi-Muscat, 2012), however this practice had stopped. Given its possible contribution towards smoking cessation/reduction, partial/full cost coverage or the consideration and possible inclusion of NRT in the National Health Service's formulary list, at least for individuals with diabetes, who seem to suffer from an increased nicotine addiction when compared to other smokers (Keith et al., 2019; Yammine et al., 2019), is recommended.

While NRT's contributing role in smoking cessation has been emphasised, it is worth noting that the study participants still reported being satisfied with the other aspects (or components) of the intervention provided. In light of this and considering that providing cost coverage for NRT might take some time to implement, it is still recommended that the diabetologists and other health professionals attending the diabetes out-patients department continue to screen patients for tobacco use and direct them to diabetes education for smoking cessation support.

As noted in the feasibility study, several participants were identified to be potentially suffering from anxiety and/or depression. Apart from affecting the quality of life of the individual, these comorbidities hinder smoking cessation support efforts (Richards et al., 2013). While psychological support was offered, most refused it because they did not perceive the need for

it. As suggested in section 8.6.1.2, apart from screening patients for mental health concerns, raising awareness on mental health issues and treatment options at a departmental level is recommended. Furthermore, access to mental health care should be enhanced through streamlined referral routes, ideally via an integrated specialist diabetes mental health service (Sachar et al., 2023). Additionally, Sachar et al. (2023) suggest that health care professionals working in diabetes care should be trained to support the emotional well-being of their patients, particularly those not engaging with specialist services. Therefore, mental health training and upskilling initiatives should also be provided to the diabetes nurses educators and other health professionals. This includes any other professionals/providers involved when conducting other research initiatives in other settings (as suggested in the previous sub-section).

The current national diabetes strategy is outdated (Calleja et al., 2016). At the time of writing, the Ministry for Health and Active Ageing is writing an updated strategy. The doctoral candidate had informed the lead author on the feasibility study protocol so that this can be included as part of the work carried out on encouraging smoking cessation among individuals with diabetes locally. On publishing this thesis, these recommendations and underlying findings will be shared with the lead author of the diabetes strategy so that the practice and policy recommendations can be incorporated in the new strategy.

9.7 Conclusion

This doctoral research project aimed to answer the following research question:

Is a multi-component smoking cessation intervention developed for persons living with diabetes who smoke feasible, acceptable to diabetes nurse educators and their patients, and potentially effective?

Guided by the MRC framework (Skivington et al., 2021), a unique multicomponent smoking cessation intervention, based on the best evidence and theory and tailored for individuals living with diabetes who smoke was developed. This was pilot tested and then assessed for its feasibility and acceptability in the real-world context; in diabetes ambulatory care, where formal diabetes education is provided locally.

The study's findings suggest that a definitive trial is feasible and acceptable, and that the intervention may improve smoking quit rates when compared to standard care. Nonetheless,

in view of the feedback obtained, in a future study the provision of an alternative type of fast-acting NRT to those who cannot tolerate the nicotine mouth spray was recommended. Additionally, in view of the high attrition rate, telephone-based follow-up session/s should be provided to those who might be finding it difficult to attend further.

In view of NRT's contributing role to smoking cessation the partial/full cost coverage or the consideration and possible inclusion of NRT in the formulary list for individuals with diabetes was recommended. Nonetheless, given that the study participants still reported being satisfied with the other aspects of the intervention provided, it was recommended that the diabetologists and other health professionals attending the diabetes out-patients department continue to screen patients for tobacco use and direct them to diabetes education for smoking cessation support.

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Appendices

Appendix 3.1: Scoping review study protocol

Review title

Helping smokers with diabetes quit: a scoping review of the interventions utilised, and the challenges and barriers to smoking cessation

Main research question and secondary research questions

Main RQ

RQ 1: Which smoking cessation interventions are most promising in helping smokers with diabetes quit?

Secondary RQs

RQ 1.1: What type of smoking cessation interventions have been used amongst individuals with diabetes?

RQ 1.2: What challenges and barriers to smoking cessation were identified amongst individuals with diabetes?

RQ 1.3: What are the gaps in evidence?

Eligibility criteria (PCC framework)

PCC framework	Inclusion criteria	Exclusion criteria
Population	Individuals diagnosed with diabetes mellitus who smoke tobacco.	Individuals diagnosed with pre-diabetes. Studies in which only a proportion of the patients had diabetes.
Concept	Studies which assess the effect of smoking cessation interventions on achieving smoking abstinence and/or identify the challenges and barriers to smoking cessation.	Studies which focus exclusively on cessation and/or the challenges and barriers to smoking cessation of smokeless tobacco products, such as chewing tobacco.
Context	Any context (any geographical locations and healthcare settings).	No limiter
Type of studies	All types of research studies and reviews of the literature which report findings on the above concept amongst the specified population.	Opinion articles.

Searches

Sources

CINAHL Complete, Cochrane Central Register of Controlled Trials, Cochrane Clinical Answers, Cochrane Database of Systematic Reviews, Cochrane Methodology Register, MEDLINE Complete, APA PsycInfo (EBSCOhost)

Scopus (Elsevier)

Public Health Database (ProQuest)

PubMed (U.S. National Library of Medicine NLM)

Web of Science Core Collection (Web of Science)

Additional sources

Reference lists of eligible studies and review articles

Unpublished studies identified from the:

ProQuest Dissertations & Theses A&I (ProQuest)

System for Information on Grey Literature in Europe; OpenGrey (Exalead)

Search dates

No time limiters. From inception – February 2021 (updated May 2022)

Language

No language restrictions. The minimum requirement for non-English papers is that the title and/or abstract is to be translated into English in the bibliographic database.

Selection and data extraction

Identified records will be collated and uploaded into Mendeley and duplicates removed. The main researcher will apply the eligibility criteria and select studies for inclusion to the scoping review. A standardised form was developed and piloted for data extraction of the eligible studies. The following details will be extracted by the main researcher:

- Author/s and year of publication
- Study design
- Origin of study (country)
- Method
- Details on the smoking cessation intervention provided (if applicable):
    - Type of intervention and control intervention
    - Provider/s
    - Study setting
    - Follow-up period
- Sample characteristics:
    - Sample size
    - Type of diabetes
    - Gender
    - Age
- Relevant findings
    - Response at follow-up
    - Smoking cessation outcome (if applicable)

    - Challenges and barriers to smoking cessation (if applicable)
- Study limitations

Data synthesis

Extracted data will be presented in tabular form. A narrative summary will accompany the tabulated results and will describe how the results relate to RQs 1.1, 1.2, and 1.3

Appendix 3.2: Search strategies

Table 3.2.1: ProQuest Dissertations & Theses A&I search strategy

Search strings	Search terms	Hits
S1	su("tobacco cessation") OR su("tobacco use cessation") OR su("smoking cessation")	629
S2	su"diabetes mellitus"	855
S3	S1 AND S2	0
S4	ti(diabet* OR DM OR T1DM OR T2DM) OR ab(diabet* OR DM OR T1DM OR T2DM)	33,417
S5	ti(quit* OR stop* OR avoid* OR refrain* OR cessation OR abst* OR "give up" OR "gave up" OR cease* OR discontinu* OR termin* OR "break off" OR "broke off" OR "put an end to") OR ab(quit* OR stop* OR avoid* OR refrain* OR cessation OR abst* OR "give up" OR "gave up" OR cease* OR discontinu* OR termin* OR "break off" OR "broke off" OR "put an end to")	620,261
S6	ti(smok* OR tobacco) OR ab(smok* OR tobacco)	24,708
S7	S5 NEAR/5 S6	2,722
S8	S4 AND S7	95

Key: 'su' – subject headings; 'ti' – titles; 'ab' – abstracts; ' NEAR/5' – searching two or more words within a range of five words from each other

Table 3.2.2: Public Health Database search strategy

Search strings	Search terms	Search options	Hits
S1	su("tobacco cessation") OR su("tobacco use cessation") OR su("smoking cessation")	Limit to human	2,197
S2	su("diabetes mellitus")	Limit to human	18,734
S3	S1 AND S2		63
S4	ti(diabet* OR DM OR T1DM OR T2DM) OR ab(diabet* OR DM OR T1DM OR T2DM)	Limit to human	25,779
S5	ti(quit* OR stop* OR avoid* OR refrain* OR cessation OR abst* OR "give up" OR "gave up" OR cease* OR discontinu* OR termin* OR "break off" OR "broke off" OR "put an end to") OR ab(quit* OR stop* OR avoid* OR refrain* OR cessation OR abst* OR "give up" OR "gave up" OR cease* OR discontinu* OR termin* OR "break off" OR "broke off" OR "put an end to")	Limit to human	137,352
S6	ti(smok* OR tobacco) OR ab(smok* OR tobacco)	Limit to human	16,225
S7	S5 NEAR/5 S6		2,577
S8	S4 AND S7		131
S9	S3 OR S8		169

Key: 'su' – subject headings; 'ti' – titles; 'ab' – abstracts; NEAR/5' – searching two or more words within a range of five words from each other

Table 3.2.3: PubMed search strategy

Search strings	Search terms	Hits
S1	(("tobacco cessation"[MeSH Terms]) OR ("smoking cessation"[MeSH Terms])) OR ("tobacco use cessation"[MeSH Terms])	32,674
S2	"diabetes mellitus"[MeSH Terms]	479,856
S3	S1 AND S2	625
S4	diabet*[Title/Abstract] OR DM[Title/Abstract] OR T1DM[Title/Abstract] OR T2DM[Title/Abstract]	753,339
S5	smok*[Title/Abstract] OR tobacco[Title/Abstract]	371,193
S6	quit*[Title/Abstract] OR stop*[Title/Abstract] OR avoid*[Title/Abstract] OR refrain*[Title/Abstract] OR cessation[Title/Abstract] OR abst*[Title/Abstract] OR "give up"[Title/Abstract] OR "gave up"[Title/Abstract] OR cease*[Title/Abstract] OR discontinu*[Title/Abstract] OR termin*[Title/Abstract] OR "break off"[Title/Abstract] OR "broke off"[Title/Abstract] OR "put an end to"[Title/Abstract]	1,868,248
S7	S4 AND S5 AND S6	4,147
S8	S7 OR S3	4,477

Key: 'MeSH Terms' – medical subject headings

Table 3.2.4: Scopus search strategy

Search strings	Search terms	Hits
S1	TITLE-ABS-KEY (diabet* OR DM OR T1DM OR T2DM)	1,236,823
S2	TITLE-ABS-KEY (smok* OR tobacco)	661,738
S3	TITLE-ABS-KEY (quit* OR stop* OR avoid* OR refrain* OR cessation OR abst* OR "give up" OR "gave up" OR cease* OR discontinu* OR termin* OR "break off" OR "broke off" OR "put an end to")	5,637,839
S4	S3 W/5 S2	81,017
S5	S1 AND S4	6,377

Key: 'TITLE-ABS-KEY' – titles, abstracts and keywords; 'W/5' – searching two or more words within a range of five words from each other

Table 3.2.5: OpenGrey search strategy

Search string	Search terms	Hits
S1	Text search: (diabet* OR DM OR T1DM OR T2DM) AND (tobacco OR smok*)	48

Table 3.3.6: Web of Science search strategy

Search strings	Search terms	Hits
S1	AK=("smoking cessation" OR "tobacco cessation" OR "tobacco use cessation")	8,946
S2	AK=("diabetes mellitus")	71,622
S3	S1 AND S2	32
S4	TI=((diabet* OR DM OR T1DM OR T2DM)) OR AB=((diabet* OR DM OR T1DM OR T2DM))	827,686
S5	TI=(smok* OR tobacco) OR AB=(smok* OR tobacco)	386,624
S6	TI=(quit* OR stop* OR avoid* OR refrain* OR cessation OR abst* OR "give up" OR "gave up" OR cease* OR discontinu* OR termin* OR "break off" OR "broke off" OR "put an end to") OR AB=(quit* OR stop* OR avoid* OR refrain* OR cessation OR abst* OR "give up" OR "gave up" OR cease* OR discontinu* OR termin* OR "break off" OR "broke off" OR "put an end to")	3,238,787
S7	S6 NEAR/5 S5	44,364
S8	S4 AND S7	2,095
S9	S3 OR S8	2,103

Key: 'AK' – authors' keywords; 'TI' – titles; 'AB' – abstracts; NEAR/5' – searching two or more words within a range of five words from each other

Appendix 3.3: List of excluded studies with reasons from the scoping review

Author	Study title	Exclusion reason*
Andres, Gomez, and Saldana (2008)	Challenges and Applications of the Transtheoretical Model in Patients with Diabetes Mellitus	C
Aung et al. (2019)	Effectiveness of a new multi-component smoking cessation service package for patients with hypertension and diabetes in northern Thailand: a randomized controlled trial (ESCAPE study)	B
Barrera et al. (2011)	Multiple-behavior-change interventions for women with type 2 diabetes	A
Bastian et al. (2012)	Comparative effectiveness trial of family-supported smoking cessation intervention versus standard telephone counseling for chronically ill veterans using proactive recruitment	B
Camilleri et al. (2021)	Empowering patients living with diabetes mellitus to cease smoking will improve lower limb perfusion	A
Campagna et al. (2019)	Smoking and diabetes: dangerous liaisons and confusing relationships	C
Carpenter, DiChiacchio, and Barker (2019)	Interventions for self-management of type 2 diabetes: An integrative review	C
Celik et al. (2015)	Nationwide Smoking Cessation Treatment SupportProgram – Turkey project	B
Clark et al. (2001)	A systematic approach to risk stratification and intervention within a managed care environment improves diabetes outcomes and patient satisfaction	A
Clark et al. (2010)	Effects of a brief tailored intervention on the process and predictors of lifestyle behaviour change in patients with type 2 diabetes	A
Cole-Lewis and Kershaw (2010)	Text Messaging as a Tool for Behavior Change in Disease Prevention and Management	B
Crowley et al. (2013)	The Cholesterol, Hypertension, And Glucose Education (CHANGE) study: results from a randomized controlled trial in African Americans with diabetes	A

Den Ouden, Vos, Rutten (2017)	Effectiveness of shared goal setting and decision making to achieve treatment targets in type 2 diabetes patients: A cluster-randomized trial (OPTIMAL)	A
Durai et al. (2021)	Self-care practices and factors influencing self-care among type 2 diabetes mellitus patients in a rural health center in South India	A
Egede (2003)	Lifestyle modification to improve blood pressure control in individuals with diabetes: is physician advice effective?	A
Folan, Savrin, and McDonald (2014)	Characteristics of smokers with type 2 diabetes	D
Fredrix et al. (2018)	Goal-setting in diabetes self-management A systematic review and meta-analysis examining content and effectiveness of goal-setting interventions	C
Gaede et al. (2003)	Multifactorial Intervention and Cardiovascular Disease in Patients with Type 2 Diabetes	A
Gamble et al. (2012)	Patient-level evaluation of community-based, multifactorial intervention to prevent diabetic nephropathy in northern alberta, Canada	A
Gerber et al. (2005)	Implementation and evaluation of a low-literacy diabetes education computer multimedia application	A
Gil-Guillén (2015)	A cardiovascular educational intervention for primary care professionals in Spain: positive impact in a quasi-experimental study.	B
Gosadi (2021)	Lifestyle Counseling for Patients with Type 2 Diabetes in the Southwest of Saudi Arabia: An Example of Healthcare Delivery Inequality Between Different Healthcare Settings	A
Griffo et al. (2013)	Effective secondary prevention through cardiac rehabilitation after coronary revascularization and predictors of poor adherence to lifestyle modification and medication. Results of the ICAROS Survey	B
Gucciardi et al. (2019)	Emerging practices supporting diabetes self-management among food insecure adults and families: A scoping review.	C
Gürkan, Bahar, and Böber (2019)	Home-Based Intervention to the Diabetics	A
Haire-Joshu, Ziff, Houston (1995)	The Feasibility of Recruiting Hospitalized Patients With Diabetes for a Smoking Cessation Program	A

Halapy and MacCallum (2006)	A Pharmacist-run Smoking Cessation Program	B
Harbman (2014)	The development and testing of a nurse practitioner secondary prevention intervention for patients after acute myocardial infarction: a prospective cohort study	B
Heinrich, Schaper, de Vries (2010)	Self-management interventions for type 2 diabetes: a systematic review	C
Henson (2020)	Implementing a Smoking Cessation Protocol in Type 2 Diabetics in a Podiatry Clinic Using the Five A's Model	A
Huizinga et al. (2010)	Preventing glycaemic relapse in recently controlled type 2 diabetes patients: a randomised controlled trial	A
Hwong et al. (2021)	Smoking cessation treatment for individuals with comorbid diabetes and serious mental illness in an integrated health care delivery system	A
Ishani et al (2011)	Effect of Nurse Case Management Compared With Usual Care on Controlling Cardiovascular Risk Factors in Patients With Diabetes: A randomized controlled trial	A
Kardas, Lewandowski, and Bromuri (2016)	Type 2 Diabetes Patients Benefit from the COMODITY12 mHealth System: Results of a Randomised Trial	A
Katangwe, Bhattacharya, and Twigg (2019)	A systematic review exploring characteristics of lifestyle modification interventions in newly diagnosed type 2 diabetes for delivery in community pharmacy	C
Kim et al. (2016)	Community Health Workers Versus Nurses as Counselors or Case Managers in a Self-Help Diabetes Management Program.	A
Kiran et al. (2020)	Managing type 2 diabetes in primary care during COVID-19	A
Kumari et al. (2018)	Effectiveness of Lifestyle Modification Counseling on Glycemic Control in Type 2 Diabetes Mellitus Patients	A
Liu et al. (2018)	The impact of inpatient education on self-management for patients with acute coronary syndrome and type 2 diabetes mellitus: a cross-sectional study in China	A
Lu et al. (2019)	Effects of a Nurse-Led, Stage-Matched, Tailored Program for Smoking Cessation in Health Education Centers: A Prospective, Randomized, Controlled Trial	B

MacAller et al. (2011)	Collaborating With Diabetes Educators to Promote Smoking Cessation for People With Diabetes: The California Experience	A
Mays et al. (2012)	Cigarette smoking among adolescents with type 1 diabetes: Strategies for behavioral prevention and intervention	C
McMahon et al. (2005)	Web-based care management in patients with poorly controlled diabetes	A
Minet et al. (2011)	The effect of motivational interviewing on glycaemic control and perceived competence of diabetes self-management in patients with type 1 and type 2 diabetes mellitus after attending a group education programme: a randomised controlled trial	A
Mullimba and Byron-Daniel (2014)	Motivational interviewing-based interventions and diabetes mellitus	C
Nyein Aung et al. (2019)	Effectiveness of a new multi-component smoking cessation service package for patients with hypertension and diabetes in northern Thailand: a randomized controlled trial (ESCAPE study)	B
O'Donoghue et al. (2021)	Lifestyle Interventions to Improve Glycemic Control in Adults with Type 2 Diabetes Living in Low-and-Middle Income Countries: A Systematic Review and Meta-Analysis of Randomized Controlled Trials (RCTs)	C
Pagidipati et al. (2017)	Secondary Prevention of Cardiovascular Disease in Patients With Type 2 Diabetes Mellitus: International Insights From the TECOS Trial (Trial Evaluating Cardiovascular Outcomes With Sitagliptin)	A
Pai et al. (2007)	Cardiovascular risk reduction in HIV positive patients: Results from short-term medical intervention	B
Patil et al. (2018)	Effect of peer support interventions on cardiovascular disease risk factors in adults with diabetes: a systematic review and meta-analysis	C
Pedrol-Clotet (2006)	Bupropion use for smoking cessation in HIV-infected patients receiving antiretroviral therapy	B
Pi-Sunyer et al. (2007)	Reduction in weight and cardiovascular disease risk factors in individuals with type 2 diabetes: one-year results of the look AHEAD trial	A
Qin (2022)	Health Behavior Changes after a Diabetes Diagnosis: The Moderating Role of Social Support	D

Ragucci and Shrader (2009)	A Method for Educating Patients and Documenting Smoking Status in an Electronic Medical Record	B
Ramya et al. (2021)	Clinical audit on assessment of non-glycemic parameters in diabetic patients by physicians	A
Rashed et al. (2016)	Diabetes education program for people with type 2 diabetes: An international perspective	A
Rehman et al. (2017)	Using Mobile Health (mHealth) Technology in the Management of Diabetes Mellitus, Physical Inactivity, and Smoking.	B
Reid et al. (2018)	Prospective, Cluster-Randomized Trial to Implement the Ottawa Model for Smoking Cessation in Diabetes Education Programs in Ontario, Canada	B
Reilly and Cavanagh (2003)	The clinical and economic impact of a secondary heart disease prevention clinic jointly implemented by a practice nurse and pharmacist	B
Represas-Carrera et al. (2021)	Effectiveness of a Multicomponent Intervention in Primary Care That Addresses Patients with Diabetes Mellitus with Two or More Unhealthy Habits, Such as Diet, Physical Activity or Smoking: Multicenter Randomized Cluster Trial (EIRA Study)	D
Rigotti et al. (2011)	Offering population-based tobacco treatment in a healthcare setting: a randomized controlled trial	B
Román Santos, Cristauro Greco and Muñoz Cobos (1996)	Antitobacco intervention in chronic patients followed-up at a nursing consult	B
Ruffin et al. (2011)	Effect of preventive messages tailored to family history on health behaviors: the Family Healthware Impact Trial	B
Saxon et al. (2003)	Smoking cessation treatment among dually diagnosed individuals: Preliminary evaluation of different pharmacotherapies	B
Schellenberg et al. (2013)	Lifestyle Interventions for Patients With and at Risk for Type 2 Diabetes A Systematic Review and Meta-analysis	C
Scott et al. (2002)	A randomized controlled trial of an extensive lifestyle management intervention (ELMI) following cardiac rehabilitation: Study design and baseline data	B
Sease, Franklin, and Gerrald (2013)	Pharmacist management of patients with diabetes mellitus enrolled in a rural free clinic.	A
Seligman et al. (2011)	Facilitating behavior change with low-literacy patient education materials	A

Shah et al. (2015)	A Home-Based Educational Intervention Improves Patient Activation Measures and Diabetes Health Indicators among Zuni Indians	A
Smith et al. (2004)	The North Dublin randomized controlled trial of structured diabetes shared care	A
Sturt (2008)	One-to-one structured education using the Diabetes Manual: evidence of effectiveness.	A
Thomas, Weekes, and Thomas (2007)	The management of diabetes in indigenous Australians from primary care	A
Tonstad and Lawrence (2017)	Varenicline in smokers with diabetes: A pooled analysis of 15 randomized, placebo-controlled studies of varenicline	D
Toobert et al. (2003)	Biologic and quality-of-life outcomes from the Mediterranean Lifestyle Program: a randomized clinical trial	A
Trento et al. (2002)	Lifestyle intervention by group care prevents deterioration of Type II diabetes: a 4-year randomized controlled clinical trial	A
Tsiouda et al. (2014)	A Multifactoral Analysis of 1452 Patients for Smoking Sensation. An Outpatient Lab Experience	B
Tsuyuki et al. (2016)	The Effectiveness of Pharmacist Interventions on Cardiovascular Risk: The Multicenter Randomized Controlled RxEACH Trial	B
Vodopivec-Jamsek et al. (2012)	Mobile phone messaging for preventive health care	B
Wagner (2016)	A Nurse-Practitioner-Led Collaborative Care Model of Shared Medical Visits for Adult Patients with Diabetes Using the Centering ® Group Healthcare Model	A
Wan et al. (2016)	Effectiveness of a multidisciplinary risk assessment and management programme-diabetes mellitus (RAMP-DM) on patient-reported outcomes	A
Wilkinson (2015)	Promoting smoking cessation as an essential part of diabetes care	C
Yaman, Akdeniz, Katirci (2010)	Diabetes education in primary care and the 5 minute survival kit	A

Key: A - Primary studies which did not assess the effect of an intervention on smoking cessation or identify the challenges and barriers to quitting (n=41); B - Primary studies which were not exclusive to individuals with diabetes (n=24); C - Reviews which did not address the effectiveness of smoking cessation interventions (n=13); D - Reports on analysis of data from a study/ies which was/were not specific to individuals with diabetes (n=4)

Appendix 4.1 Systematic review study protocol

Review title

Effectiveness of stand-alone smoking cessation interventions for individuals with diabetes: a systematic review and intervention component analysis

Main research question and secondary research question

Main RQ

RQ 1: Compared to less intensive smoking cessation interventions such as brief tobacco cessation advice or usual care, are stand-alone smoking cessation interventions more effective in helping individuals with diabetes who smoke to quit?

Secondary RQ

RQ 1.1: What are the critical components of successful smoking cessation interventions?

Eligibility criteria (PICO framework)

PICO framework	Inclusion criteria	Exclusion criteria
Population	Individuals diagnosed with diabetes mellitus who smoke tobacco.	Individuals diagnosed with pre-diabetes. Studies in which only a proportion of the patients had diabetes.
Interventions	Pharmacological or non-pharmacological (such as counselling/behavioural support or educational interventions) smoking cessation interventions.	Smoking cessation interventions which are part of a broader intervention for improving diabetes management.
Comparators	Usual care or a less intensive smoking cessation intervention.	No care.
Outcome	Smoking cessation (self-reported and/or biochemically verified smoking abstinence).	Cessation of smokeless tobacco products.
Study design	Randomised controlled trials.	Systematic reviews, non-randomised controlled trials and other types of studies.

Methods

Following the identification of the promising smoking cessation interventions (i.e., stand-alone smoking cessation interventions), published or unpublished reports of randomised controlled studies, which compare the smoking cessation rates of more intensive smoking cessation interventions to less intensive interventions, or usual care, will be retrieved from the scoping review. The additional following data will be extracted for the systematic review of effectiveness:

- Assessments of risk of bias domains guided by the Revised Cochrane risk-of-bias tool for randomized trials (RoB2) and/or RoB 2 for cluster-randomized trials:
    - bias arising from the randomisation process
    - bias arising from identification or recruitment of participants within clusters (cluster randomised controlled studies only)
    - bias due to deviations from intended interventions
    - bias due to missing outcome data

    - bias in the measurement of the relevant outcome
    - bias in selection of the reported result
- Detailed information on the interventions' nature, such as:
    - The intensity and duration of the smoking cessation intervention (e.g., number and length of sessions)
    - details on the intervention's characteristics
    - details on the use of additional components, such as, the use of pharmacological therapy, telephone support, educational materials etc.
    - the characteristics of the provider and setting.
- Time points of collection of smoking cessation outcome and reporting
- The author reflections and accounts of the experience of using the intervention (an inductive thematic analysis approach, part of the Intervention Component Analysis pragmatic approach for identifying the critical features of complex interventions, Sutcliffe et al., 2015).[1]

Risk of bias assessment

Assessments of risk of bias will be carried out by following the Revised Cochrane risk-of-bias tool for randomized trials (RoB2) and the RoB 2 for cluster-randomized trials.

Data synthesis

Study characteristics (including the point estimates for smoking abstinence between the intervention groups and control groups) will be presented in tabular form. While a meta-analysis of effect estimates (using the random effect analysis) is the preferred method of synthesis, in the case of incompletely reported outcomes/effect estimates, or clinical/methodological diversity, a narrative synthesis will be carried out. Analysis of the components of successful smoking cessation interventions will be carried out as reported by Sutcliffe et al. (2015). In the first stage of analysis, the effectiveness synthesis (as outlined above) and the identification of the interventions' characteristics will provide an

[1] Sutcliffe, K., Thomas, J., Stokes, G., Hinds, K., & Bangpan, M. (2015). Intervention Component Analysis (ICA): a pragmatic approach for identifying the critical features of complex interventions. *Systematic reviews*, 4, 140. https://doi.org/10.1186/s13643-015-0126-z

understanding of the differences between the interventions. In the second stage of the analysis, the identified informal evidence on the experience of using interventions will help explain the differences in outcomes. Both features of the successful smoking cessation interventions and the coded authors' reflections and accounts of the experience of using the intervention will be provided in tabular form. A narrative summary will follow.

Appendix 4.2: List of excluded studies with reasons from the systematic review

Author	Study title	Exclusion reason*
Abu Ghazaleh, Mulnier and Duaso (2018)	A qualitative approach exploring the experiences of smoking and quitting attempts in type 1 diabetes	C
Albareda et al. (2009)	Results of the application of the American Diabetes Association guidelines regarding tobacco dependency in subjects with diabetes mellitus	B
Albaroodi et al. (2018)	Smoking cessation intervention: Can diabetic patients' change their motivation to quit and nicotine dependence?	E
Bluml et al. (2014)	Improving outcomes for diverse populations disproportionately affected by diabetes: Final results of Project IMPACT: Diabetes	A
Bodmer et al. (1990)	How accurate is the smoking history in newly diagnosed diabetic patients?	B
Chau et al. (2015)	Misconceptions about smoking in patients with type 2 diabetes mellitus: a qualitative analysis	C
Daly et al. (2017)	Effect of nurse-led randomised control trials on cardiovascular risk factors and HbA1c in diabetes patients: A meta-analysis	D
Davies et al. (2008)	Effectiveness of the diabetes education and self management for ongoing and newly diagnosed (DESMOND) programme for people with newly diagnosed type 2 diabetes: cluster randomised controlled trial	A
Khunti et al. (2012)	Effectiveness of a diabetes education and self management programme (DESMOND) for people with newly diagnosed type 2 diabetes mellitus: three year follow-up of a cluster randomised controlled trial in primary care	A
Ekong and Kavookjian (2016)	Motivational interviewing and outcomes in adults with type 2 diabetes: A systematic review	D
Enxin et al. (2016)	心理干预对糖尿病吸烟者控烟效果影响的Ｍｅｔａ分析 (Meta analysis of influence of psychological interventions for smoking cessation effect in diabetic patient)	D

Georges, Galbiati and Clair (2019)	Smoking in men and women with type 2 diabetes: A qualitative gender-sensitive exploration of barriers to smoking cessation among people with type 2 diabetes	C
Griffin et al. (2014)	Multiple behaviour change intervention and outcomes in recently diagnosed type 2 diabetes: the ADDITION-Plus randomised controlled trial	A
Haire-Joshu et al. (1994)	Beliefs About Smoking and Diabetes Care	C
Ismail et al. (2000)	Failure to reduce nicotine addiction in young adults with diabetes	B
Javelot et al. (2009)	Report of a glycemic imbalance in a diabetic patient after-initiation of nicotine replacement therapy	B
Jones et al. (2003)	Changes in diabetes self-care behaviors make a difference in glycemic control the Diabetes Stages of Change (DiSC) study.	A
Katsaounou et al. (2019)	Smoking cessation in diabetic patients	B
Kirkman et al. (1994)	A Telephone-Delivered Intervention for Patients With NIPPM: Effect on coronary risk factors	A
Korkontzelou et al. (2020)	Smoking cessation in patients with Diabetes Mellitus	B
Kristensen, Pedersen-Bjergaard and Thorsteinsson (2008)	Varenicline may trigger severe hypoglycaemia in Type 1 diabetes	B
McDermott et al. (2015)	Community health workers improve diabetes care in remote Australian Indigenous communities: results of a pragmatic cluster randomized control trial	A
McGloin et al. (2015)	A case study approach to the examination of a telephone-based health coaching intervention in facilitating behaviour change for adults with Type 2 diabetes	A
Mishu et al. (2021)	Co-producing an intervention for tobacco cessation and improvement of oral health among diabetic patients in Bangladesh	C
Nagrebetsky et al. (2014)	Smoking cessation in adults with diabetes: a systematic review and meta-analysis of data from randomised controlled trials	D
Nkansah et al. (2008)	Clinical outcomes of patients with diabetes mellitus receiving medication management by pharmacists in an urban private physician practice	A

Onyinye, Ogochukwu and Victoria (2021)	Effect of a Pharmacist Intervention on Self Management Practices among Hypertensive-Diabetic Patients receiving care in a Nigerian Tertiary Hospital	A
Perrson and Hjalmarson (2006)	Smoking cessation in patients with diabetes mellitus: Results from a controlled study of an intervention programme in primary healthcare in Sweden	B
Persson, Lindstrom, and Lingfors (2000)	Quality improvement in primary health care using computerised journal, exemplified by a smoking cessation programme for diabetic patients	B
Ramallo-Fariña et al. (2021)	Patient-reported outcome measures for knowledge transfer and behaviour modification interventions in type 2 diabetes—the INDICA study: a multiarm cluster randomised controlled trial	A
Register et al. (2016)	Effectiveness of Non-Primary Care-Based Smoking Cessation Interventions for Adults with Diabetes: A Systematic Literature Review	D
Rubak et al. (2009)	General practitioners trained in motivational interviewing can positively affect the attitude to behaviour change in people with type 2 diabetes	A
Rubak et al. (2011)	Effect of motivational interviewing on quality of care measures in screen detected type 2 diabetes patients: A one-year follow-up of an RCT, ADDITION Denmark	A
Scemama et al. (2006)	Difficulties of smoking cessation in diabetic inpatients benefiting from a systematic consultation to help them to give up smoking	B
Smith et al. (2011)	Peer support for patients with type 2 diabetes: cluster randomised controlled trial	A
Taveira et al. (2010)	Pharmacist-Led Group Medical Appointment Model in Type 2 Diabetes	A
Cohen et al. (2011)	Pharmacist-Led Shared Medical Appointments for Multiple Cardiovascular Risk Reduction in Patients With Type 2 Diabetes	A
Tien and Tu (2016)	To increase smoking cessation rate among diabetic smokers who participate in smoking cessation clinics by means of effective health education	B
Toobert et al. (2011)	Outcomes from a Multiple Risk Factor Diabetes Self-Management Trial for Latinas: ¡Viva Bien!	A
Tranche et al. (2005)	Cardiovascular risk factors in type 2 diabetic patients: Multifactorial intervention in primary care	A

Tricco et al. (2012)	Effectiveness of quality improvement strategies on the management of diabetes: a systematic review and meta-analysis	D
Wakefield, Roberts and Rosenfeld (1997)	Smoking Cessation Among People with Diabetes: Beliefs and Barriers	C
Wakefield, Roberts and Rosenfeld (1998)	Prospects for smoking cessation among people with insulin dependent diabetes	C
Yasmin et al. (2020)	The influence of mobile phone-based health reminders on patient adherence to medications and healthy lifestyle recommendations for effective management of diabetes type 2: a randomized control trial in Dhaka, Bangladesh	A

Key: A - Studies which included smoking cessation as part of a broader intervention for diabetes management (n=19); B - Non-randomised controlled trials or other types of studies (n=11); C - Studies which did not evaluate a smoking cessation intervention (n=7); D - Systematic reviews of randomised controlled trials of different smoking cessation interventions (n=6); E - A report of a randomised controlled trial in which the authors did not report on the smoking cessation outcome (n=1).

Appendix 4.3: Risk-of-bias assessments of the identified individually-randomised parallel-group trials using RoB 2

Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)
TEMPLATE FOR COMPLETION

Edited by Julian PT Higgins, Jelena Savović, Matthew J Page, Jonathan AC Sterne
on behalf of the RoB2 Development Group

Version of 22 August 2019

The development of the RoB 2 tool was supported by the MRC Network of Hubs for Trials Methodology Research (MR/L004933/2- N61), with the support of the host MRC ConDuCT-II Hub (Collaboration and innovation for Difficult and Complex randomised controlled Trials In Invasive procedures - MR/K025643/1), by MRC research grant MR/M025209/1, and by a grant from The Cochrane Collaboration.

Study details

Reference	Albaroodi, K., Sulaiman, S., Awaisu, A., and Shafie, A. (2021). Impact of Brief Smoking Cessation Intervention on Abstinence Rate and Glycaemic Control in Patients with Diabetes Mellitus: A Randomised Controlled Trial. 10.21203/rs.3.rs-149819/v1. (preprint)

Study design

X Individually-randomized parallel-group trial

☐ Cluster-randomized parallel-group trial

☐ Individually randomized cross-over (or other matched) trial

For the purposes of this assessment, the interventions being compared are defined as

Experimental:	diabetes-specific tobacco cessation counselling (by following the 5A's algorithim) by physicians and nurses.	Comparator:	routine diabetes care counselling.

Specify which outcome is being assessed for risk of bias	Biochemically verified smoking cessation at six months
Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.	Four participants from each group quit smoking.

Is the review team's aim for this result…?

X to assess the effect of *assignment to intervention* (the 'intention-to-treat' effect)

☐ to assess the effect of *adhering to intervention* (the 'per-protocol' effect)

If the aim is to assess the effect of *adhering to intervention*, select the deviations from intended intervention that should be addressed (at least one must be checked):

☐ occurrence of non-protocol interventions
☐ failures in implementing the intervention that could have affected the outcome
☐ non-adherence to their assigned intervention by trial participants

Which of the following sources were <u>obtained</u> to help inform the risk-of-bias assessment? (tick as many as apply)

☐ Journal article(s) with results of the trial
☐ Trial protocol
☐ Statistical analysis plan (SAP)
☐ Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
☐ Company-owned trial registry record (e.g. GSK Clinical Study Register record)
X "Grey literature" (e.g. unpublished thesis)
☐ Conference abstract(s) about the trial
☐ Regulatory document (e.g. Clinical Study Report, Drug Approval Package)
☐ Research ethics application
☐ Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)
☐ Personal communication with trialist
☐ Personal communication with the sponsor

Risk of bias assessment

Responses underlined in green are potential markers for low risk of bias, and responses in red are potential markers for a risk of bias. Where questions relate only to sign posts to other questions, no formatting is used.

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Comments	Response options
1.1 Was the allocation sequence random?	"Participants were randomly assigned to intervention or control groups using a computer-generated allocation method." (Albaroodi et al., 2021; p. 4)	Yes (Y)
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?		No information (NI)
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	Not enough information is available in table 1 (Albaroodi et al., 2021; p. 6)	No information (NI)
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias arising from the randomization process?		Unpredictable

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of assignment to intervention*)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?	The people delivering the interventions were probably aware of the assignment of participants.	NI
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		Probably Yes (PY)
2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?		NI
2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?		Not Applicable (NA)
2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?		NA
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	Yes, the authors carried out modified intention-to-treat analysis (excluding participants with missing outcome data).	Y
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?		NA
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias due to deviations from intended interventions?		Unpredictable

Domain 3: Missing outcome data

Signalling questions	Comments	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?	Outcome was available for nearly all participants (126/140 participants)	PY
3.2 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?		NA
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?		NA
3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?		NA
Risk-of-bias judgement		Low
Optional: What is the predicted direction of bias due to missing outcome data?		NA

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Comments	Response options
4.1 Was the method of measuring the outcome inappropriate?	Smoking abstinence was confirmed by measuring exhaled carbon monoxide.	No (N)
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?	Objective measurements.	Probably No (PN)
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?		NI
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?	Smoking abstinence was confirmed objectively.	PN
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?		NA
Risk-of-bias judgement		Low
Optional: What is the predicted direction of bias in measurement of the outcome?		NA

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Comments	Response options
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?		NI
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	Probably no - smoking abstinence was biochemically verified at the end of the study (6 months).	PN
5.3 ... multiple eligible analyses of the data?	Probably no - smoking abstinence was analysed and biochemically confirmed per study group at the end of the study.	PN
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias due to selection of the reported result?		Unpredictable

Overall risk of bias

Risk-of-bias judgement	No information on concealment of allocation sequence and little detail on baseline characteristics. While there is no information on whether participants were aware of their assigned intervention during the trial, carers and people delivering the interventions were probably aware of participants' assigned intervention during the trial. The authors did not report whether deviations arose because of the trial context. No information on whether the result was analysed in accordance with a pre-specified analysis plan.	Some concerns
Optional: What is the overall predicted direction of bias for this outcome?		Unpredictable

Study details

Reference	Ardron, M., MacFarlane, I.A., Robinson, C., van Heyningen, C. and Calverley, P.M.A. (1988), Anti-smoking Advice for Young Diabetic Smokers: Is it a Waste of Breath?. *Diabetic Medicine*, 5: 667-670. https://doi.org/10.1111/j.1464-5491.1988.tb01077.x

Study design

X Individually-randomized parallel-group trial

☐ Cluster-randomized parallel-group trial

☐ Individually randomized cross-over (or other matched) trial

For the purposes of this assessment, the interventions being compared are defined as

Experimental:	same advice provided in comparator group and an intensive counselling session, a smoking cessation leaflet and a home visit by a diabetes health visitor.	Comparator:	routine brief diabetes-specific smoking cessation advice.

Specify which outcome is being assessed for risk of bias	Biochemically verified smoking cessation at six months
Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.	One person from the control group who quit smoking was confirmed by breath Carbon Monoxide (CO) and urinary cotinine: creatinine measurements.

Is the review team's aim for this result…?

X to assess the effect of *assignment to intervention* (the 'intention-to-treat' effect)
☐ to assess the effect of *adhering to intervention* (the 'per-protocol' effect)

If the aim is to assess the effect of *adhering to intervention*, select the deviations from intended intervention that should be addressed (at least one must be checked):

☐ occurrence of non-protocol interventions
☐ failures in implementing the intervention that could have affected the outcome
☐ non-adherence to their assigned intervention by trial participants

Which of the following sources were <u>obtained</u> to help inform the risk-of-bias assessment? (tick as many as apply)

X Journal article(s) with results of the trial
☐ Trial protocol
☐ Statistical analysis plan (SAP)
☐ Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
☐ Company-owned trial registry record (e.g. GSK Clinical Study Register record)
☐ "Grey literature" (e.g. unpublished thesis)
☐ Conference abstract(s) about the trial
☐ Regulatory document (e.g. Clinical Study Report, Drug Approval Package)
☐ Research ethics application
☐ Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)
☐ Personal communication with trialist
☐ Personal communication with the sponsor

Risk of bias assessment

Responses underlined in green are potential markers for low risk of bias, and responses in red are potential markers for a risk of bias. Where questions relate only to sign posts to other questions, no formatting is used.

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Comments	Response options
1.1 Was the allocation sequence random?	The only statement about randomisation is as follows: "They were randomized into two groups, half receiving 'routine advice' and half 'intensive advice'." (Ardron et al., 1988; p. 667)	NI
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?		NI
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	No imbalances are apparent - Table 2 (Ardron et al., 1988; p. 668)	N
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias arising from the randomization process?		Unpredictable

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of assignment to intervention*)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?	The people delivering the interventions were probably aware of the assignment of participants.	NI
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		PY
2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?		NI
2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?		NA
2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?		NA
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	Yes, all participants attended their final assessment.	Y
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?		NA
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias due to deviations from intended interventions?		Unpredictable

Domain 3: Missing outcome data

Signalling questions	Comments	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?	All participants attended their final assessment.	Y
3.2 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?		NA
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?		NA
3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?		NA
Risk-of-bias judgement		Low
Optional: What is the predicted direction of bias due to missing outcome data?		NA

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Comments	Response options
4.1 Was the method of measuring the outcome inappropriate?	Smoking abstinence was confirmed by measuring exhaled carbon monoxide and urinary cotinine.	N
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?	Probably no as abstinence was confirmed by objective measurements.	PN
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?	Probably yes. Participants' measurements were taken by the staff at the stop smoking clinic.	PY
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?	Probably no as abstinence was confirmed by objective measurements.	PN
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?		NA
Risk-of-bias judgement		Low
Optional: What is the predicted direction of bias in measurement of the outcome?		NA

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Comments	Response options
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?		NI
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	Probably no - smoking abstinence was biochemically verified at the end of the study (6 months).	PN
5.3 ... multiple eligible analyses of the data?	Probably no - smoking abstinence was analysed and biochemically confirmed per study group at the end of the study.	PN
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias due to selection of the reported result?		Unpredictable

Overall risk of bias

Risk-of-bias judgement	No information on randomisation methods and concealment of allocation sequence. While there is no information on whether participants were aware of their assigned intervention during the trial, carers and people delivering the interventions were probably aware of participants' assigned intervention during the trial. The authors did not report whether deviations arose because of the trial context. No information on whether the result was analysed in accordance with a pre-specified analysis plan.	Some concerns
Optional: What is the overall predicted direction of bias for this outcome?		Unpredictable

Study details

Reference	Canga, N., De Irala, J., Vara, E., Duaso, M. J., Ferrer, A., & Martínez-González, M. A. (2000). Intervention study for smoking cessation in diabetic patients: a randomized controlled trial in both clinical and primary care settings. *Diabetes care,* 23(10), 1455–1460. https://doi.org/10.2337/diacare.23.10.1455

Study design

X Individually-randomized parallel-group trial

☐ Cluster-randomized parallel-group trial

☐ Individually randomized cross-over (or other matched) trial

For the purposes of this assessment, the interventions being compared are defined as

Experimental:	an initial visit focused on diabetes-specific smoking cessation advice; self-help written material; optional transdermal NRT for heavy smokers and those who did not succeed in quitting; five follow up contacts (a letter, a telephone call or a visit) according to the set quit date.	Comparator:	usual care including advice to quit.

Specify which outcome is being assessed for risk of bias	Biochemically verified smoking cessation at six months
Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI	Twenty five (17.0%) vs. three smokers (2.3%) in the intervention and control groups, respectively, quit smoking (p<0.001). The

0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.	difference between the intervention and control groups was 14.8%, 95% CI (8.2–21.3).

Is the review team's aim for this result…?

X to assess the effect of *assignment to intervention* (the 'intention-to-treat' effect)

☐ to assess the effect of *adhering to intervention* (the 'per-protocol' effect)

If the aim is to assess the effect of *adhering to intervention*, select the deviations from intended intervention that should be addressed (at least one must be checked):

☐ occurrence of non-protocol interventions
☐ failures in implementing the intervention that could have affected the outcome
☐ non-adherence to their assigned intervention by trial participants

Which of the following sources were <u>obtained</u> to help inform the risk-of-bias assessment? (tick as many as apply)

X Journal article(s) with results of the trial
☐ Trial protocol
☐ Statistical analysis plan (SAP)
☐ Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
☐ Company-owned trial registry record (e.g. GSK Clinical Study Register record)
☐ "Grey literature" (e.g. unpublished thesis)
☐ Conference abstract(s) about the trial
☐ Regulatory document (e.g. Clinical Study Report, Drug Approval Package)
☐ Research ethics application
☐ Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)
☐ Personal communication with trialist
☐ Personal communication with the sponsor

Risk of bias assessment

Responses underlined in green are potential markers for low risk of bias, and responses in red are potential markers for a risk of bias. Where questions relate only to sign posts to other questions, no formatting is used.

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Comments	Response options
1.1 Was the allocation sequence random?	"Subjects were randomly assigned to experimental or control groups using a computer-generated allocation method. The randomized assignment was blinded." (Canga et al., 2000; p. 1455)	Y
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?		Y
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	Probably no. "At baseline, minimal differences were found between both groups (Table 1)." (Canga et al., 2000; p. 1457)	PN
Risk-of-bias judgement		Low
Optional: What is the predicted direction of bias arising from the randomization process?		NA

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of assignment to intervention*)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?	Probably no. "Special care was used in the masking process … To minimize the intervention effect of the research procedures, subjects randomized to the control group were not specifically informed that the trial focused on smoking behavior and were asked parallel questions on diet, exercise, and alcohol use." (Canga et al., 2000; p. 1456)	PN
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?	The nurse who provided the intervention was probably aware of the assignment of participants.	PY
2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?		NI
2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?		NA
2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?		NA
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	Intention-to-treat analysis. "The data were analyzed on an intention-to-treat basis assuming that the 2 subjects who did not complete the trial had not stopped smoking." (Canga et al., 2000; p. 1457)	Y
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?		NA
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias due to deviations from intended interventions?		Unpredictable

Domain 3: Missing outcome data

Signalling questions	Comments	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?	Yes - 99.3% response rate.	Y
3.2 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?		NA
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?		NA
3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?		NA
Risk-of-bias judgement		Low
Optional: What is the predicted direction of bias due to missing outcome data?		NA

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Comments	Response options
4.1 Was the method of measuring the outcome inappropriate?	No. "Biochemical validation was used to verify the smoking status of patients who stated that they had quit smoking." (Canga et al., 2000; p. 1457)	N
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?	Probably no – objective measurement.	PN
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?	The same nurse who provided the intervention carried out the measurements. "The same nurse conducted all interviews and follow-up examinations." (Canga et al., 2000; p. 1457).	Y
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?	Probably no – smoking abstinence was biochemically verified (objective measurement).	PN
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?		NA
Risk-of-bias judgement		Low
Optional: What is the predicted direction of bias in measurement of the outcome?		NA

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Comments	Response options
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?		NI
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	Probably no - smoking abstinence was biochemically verified at the end of the study (6 months).	PN
5.3 ... multiple eligible analyses of the data?	Probably no - smoking abstinence was analysed and biochemically confirmed per study group at the end of the study.	PN
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias due to selection of the reported result?		Unpredictable

Overall risk of bias

Risk-of-bias judgement	Carers and people delivering the interventions were probably aware of participants' assigned intervention during the trial, however the authors did not report whether deviations arose because of the trial context. No information on whether the result was analysed in accordance with a pre-specified analysis plan.	Some concerns
Optional: What is the overall predicted direction of bias for this outcome?		Unpredictable

Study details

Reference	Fowler, P., Hoskins, P., McGill, M., Dutton, S., Yue, D. and Turtle, J. (1989), Anti-smoking Programme for Diabetic Patients: The Agony and the Ecstasy. *Diabetic Medicine*, 6: 698-702. https://doi.org/10.1111/j.1464-5491.1989.tb01260.x

Study design

X Individually-randomized parallel-group trial

☐ Cluster-randomized parallel-group trial

☐ Individually randomized cross-over (or other matched) trial

For the purposes of this assessment, the interventions being compared are defined as

Experimental:	Intervention for Newly Diagnosed (ND) patients: the Smokescreen protocol (four educational visits with the use of visual coloured photographs delivered by health professionals). Intervention for patients with Pre-Existing (PE) diabetes: the Smokescreen protocol.	Comparator:	Comparator for ND patients: usual care with late access to the intervention. Comparator for patients with PE diabetes: counselling about the interaction between smoking and diabetic complications (same number of visits).

Specify which outcome is being assessed for risk of bias	Biochemically verified smoking cessation at six months
Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI	Only three patients quit smoking.

0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.	

Is the review team's aim for this result…?

X to assess the effect of *assignment to intervention* (the 'intention-to-treat' effect)

☐ to assess the effect of *adhering to intervention* (the 'per-protocol' effect)

If the aim is to assess the effect of *adhering to intervention*, select the deviations from intended intervention that should be addressed (at least one must be checked):

☐ occurrence of non-protocol interventions
☐ failures in implementing the intervention that could have affected the outcome
☐ non-adherence to their assigned intervention by trial participants

Which of the following sources were <u>obtained</u> to help inform the risk-of-bias assessment? (tick as many as apply)

X Journal article(s) with results of the trial
☐ Trial protocol
☐ Statistical analysis plan (SAP)
☐ Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
☐ Company-owned trial registry record (e.g. GSK Clinical Study Register record)
☐ "Grey literature" (e.g. unpublished thesis)
☐ Conference abstract(s) about the trial
☐ Regulatory document (e.g. Clinical Study Report, Drug Approval Package)
☐ Research ethics application
☐ Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)
☐ Personal communication with trialist
☐ Personal communication with the sponsor

Risk of bias assessment

Responses underlined in green are potential markers for low risk of bias, and responses in red are potential markers for a risk of bias. Where questions relate only to sign posts to other questions, no formatting is used.

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Comments	Response options
1.1 Was the allocation sequence random?	The only statements about randomisation are as follows: "Patients with newly diagnosed diabetes were further randomized to one of two treatment groups."	NI
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?	"Patients with preexisting diabetes who agreed to take part in the anti-smoking programme were further randomized to one of two treatment groups." (Fowler et al., 1989; p. 699)	NI
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	Baseline characteristics not provided.	NI
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias arising from the randomization process?		Unpredictable

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of assignment to intervention*)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?	The people delivering the interventions were probably aware of the assignment of participants.	NI
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		PY
2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?		NI
2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?		NA
2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?		NA
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	Modified intention-to-treat analysis (excluding participants with missing outcome data) was carried out.	Y
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?		NA
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias due to deviations from intended interventions?		Unpredictable

Domain 3: Missing outcome data

Signalling questions	Comments	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?	All participants were analysed. "Irrespective of whether all patients or only those who completed four visits were analysed, there was a reduction in the self-reported level of smoking at visit two which was not reflected by the mean plasma cotinine level." (Fowler et al., 1989; p. 700)	Y
3.2 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?		NA
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?		NA
3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?		NA
Risk-of-bias judgement		Low
Optional: What is the predicted direction of bias due to missing outcome data?		NA

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Comments	Response options
4.1 Was the method of measuring the outcome inappropriate?	Self-reported smoking abstinence was biochemically verified. "In only 3 patients was complete cessation of smoking verified by plasma cotinine level." (Fowler et al., 1989; p. 700)	N
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?	Probably no – objective measurement.	PN
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?		NI
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?	Probably no. Abstinence was verified objectively.	PN
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?		NA
Risk-of-bias judgement		Low
Optional: What is the predicted direction of bias in measurement of the outcome?		NA

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Comments	Response options
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?		NI
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	Probably no; smoking abstinence was biochemically verified at the end of the study (6 months).	PN
5.3 ... multiple eligible analyses of the data?	Analysis intentions are not available; however, the outcome measurement could have been analysed per study group.	NI
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias due to selection of the reported result?		Unpredictable

Overall risk of bias

Risk-of-bias judgement	No information on randomisation methods and concealment of allocation sequence. While there is no information on whether participants were aware of their assigned intervention during the trial, carers and people delivering the interventions were probably aware of participants' assigned intervention during the trial. The authors did not report whether deviations arose because of the trial context. No information on whether the result was analysed in accordance with a pre-specified analysis plan.	Some concerns
Optional: What is the overall predicted direction of bias for this outcome?		Unpredictable

Study details

Reference	Hokanson, J. M., Anderson, R. L., Hennrikus, D. J., Lando, H. A., & Kendall, D. M. (2006). Integrated Tobacco Cessation Counseling in a Diabetes Self-management Training Program. *The Diabetes Educator*, 32(4), 562–570. https://doi.org/10.1177/0145721706289914

Study design

- X Individually-randomized parallel-group trial
- ☐ Cluster-randomized parallel-group trial
- ☐ Individually randomized cross-over (or other matched) trial

For the purposes of this assessment, the interventions being compared are defined as

Experimental:	an individual smoking cessation counseling session and three to six telephone counselling sessions based on motivational interviewing and delivered by trained research nurses; and provision of NRT or bupropion to those were interested in quitting.	Comparator:	provision of information about local smoking cessation programmes

Specify which outcome is being assessed for risk of bias	Biochemically verified 7-day point prevalence of smoking at six months

Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.	83% and 84% of the participants in the control and intervention groups (respectively) were found to be smoking at six months follow-up (not significant).

Is the review team's aim for this result…?

X to assess the effect of *assignment to intervention* (the 'intention-to-treat' effect)

☐ to assess the effect of *adhering to intervention* (the 'per-protocol' effect)

If the aim is to assess the effect of *adhering to intervention*, select the deviations from intended intervention that should be addressed (at least one must be checked):

☐ occurrence of non-protocol interventions

☐ failures in implementing the intervention that could have affected the outcome

☐ non-adherence to their assigned intervention by trial participants

Which of the following sources were <u>obtained</u> to help inform the risk-of-bias assessment? (tick as many as apply)

X Journal article(s) with results of the trial

☐ Trial protocol

☐ Statistical analysis plan (SAP)

☐ Non-commercial trial registry record (e.g. ClinicalTrials.gov record)

☐ Company-owned trial registry record (e.g. GSK Clinical Study Register record)

☐ "Grey literature" (e.g. unpublished thesis)

☐ Conference abstract(s) about the trial

☐ Regulatory document (e.g. Clinical Study Report, Drug Approval Package)

☐ Research ethics application

☐ Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)

☐ Personal communication with trialist

☐ Personal communication with the sponsor

Risk of bias assessment

Responses underlined in green are potential markers for low risk of bias, and responses in red are potential markers for a risk of bias. Where questions relate only to sign posts to other questions, no formatting is used.

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Comments	Response options
1.1 Was the allocation sequence random?	"Subjects were randomized to either the intervention group or standard group using a computerized randomization scheme assigning subjects in blocks of 4." (Hokanson et al., 2006; p. 564)	Y
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?		NI
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	"Descriptive characteristics of the study population at baseline are outlined in Table 2. The intervention and standard care groups were not significantly different on any of the critical demographic measures reported." (Hokanson et al., 2006; p. 566)	N
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias arising from the randomization process?		Unpredictable

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of assignment to intervention*)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?	The research staff who provided counselling were probably aware of the assignment of participants.	NI
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		PY
2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?		NI
2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?		NA
2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?		NA
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	Both intention-to-treat and modified intention-to-treat analyses were carried out. "Comparisons between groups on 7-day point prevalence of smoking at each time point were conducted both for all patients (intent to treat) and for completers" (Hokanson et al., 2006; p. 566)	Y
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?		NA
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias due to deviations from intended interventions?		Unpredictable

Domain 3: Missing outcome data

Signalling questions	Comments	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?		N
3.2 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?	Yes: "Intent-to-treat analyses in which subjects not available for follow-up were considered smokers found a pattern of results similar to those performed with subjects available at each follow-up" (Hokanson et al., 2006; p. 567)	Y
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?		NA
3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?		NA
Risk-of-bias judgement		Low
Optional: What is the predicted direction of bias due to missing outcome data?		NA

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Comments	Response options
4.1 Was the method of measuring the outcome inappropriate?	No, biochemical verification was carried out. "At 6-month follow-up, participants who reported abstinence in the previous 7 days were asked for a saliva sample, and their self-report was confirmed by analysis for cotinine. (Hokanson et al., 2006; p. 565).	N
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?	Probably no – use of objective measurements.	PN
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?		NI
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?	Probably no as smoking abstinence was biochemically verified objectively.	PN
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?		NA
Risk-of-bias judgement		Low
Optional: What is the predicted direction of bias in measurement of the outcome?		NA

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Comments	Response options
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?		NI
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	Probably no - smoking abstinence was biochemically verified at the end of the study (6 months).	PN
5.3 ... multiple eligible analyses of the data?	Probably no - smoking abstinence was analysed and biochemically confirmed per study group at the end of the study.	PN
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias due to selection of the reported result?		Unpredictable

Overall risk of bias

Risk-of-bias judgement	No information on the concealment of allocation sequence. While there is no information on whether participants were aware of their assigned intervention during the trial, carers and people delivering the interventions were probably aware of participants' assigned intervention during the trial. The authors did not report whether deviations arose because of the trial context. No information on whether the result was analysed in accordance with a pre-specified analysis plan.	Some concerns
Optional: What is the overall predicted direction of bias for this outcome?		Unpredictable

Study details

Reference	Li, W. H., Wang, M. P., Lam, T. H., Cheung, Y. T., Cheung, D. Y., Suen, Y. N., Ho, K. Y., Tan, K. C., & Chan, S. S. (2017). Brief intervention to promote smoking cessation and improve glycemic control in smokers with type 2 diabetes: a randomized controlled trial. *Scientific reports*, 7, 45902. https://doi.org/10.1038/srep45902

Study design

X Individually-randomized parallel-group trial

☐ Cluster-randomized parallel-group trial

☐ Individually randomized cross-over (or other matched) trial

For the purposes of this assessment, the interventions being compared are defined as

Experimental:	an individualised counselling session based on the 5As (and 5Rs) framework and tailored to the participants' stage of change (TTM) delivered by a nurse counsellor, the self-help smoking cessation leaflet and a diabetes specific smoking cessation leaflet. Booster counselling sessions at one week and one month follow-up.	Comparator:	usual care, brief smoking cessation advice and a self-help smoking cessation leaflet.

Specify which outcome is being assessed for risk of bias	7-day point-prevalence smoking abstinence at 12 months (biochemically verified)

Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.	Nine (3.2%) vs.14 participants (5.1%) from the intervention and control groups, respectively quit smoking at 12 months follow-up.

Is the review team's aim for this result…?

X to assess the effect of *assignment to intervention* (the 'intention-to-treat' effect)

☐ to assess the effect of *adhering to intervention* (the 'per-protocol' effect)

If the aim is to assess the effect of *adhering to intervention*, select the deviations from intended intervention that should be addressed (at least one must be checked):

☐ occurrence of non-protocol interventions

☐ failures in implementing the intervention that could have affected the outcome

☐ non-adherence to their assigned intervention by trial participants

Which of the following sources were <u>obtained</u> to help inform the risk-of-bias assessment? (tick as many as apply)

X Journal article(s) with results of the trial

☐ Trial protocol

☐ Statistical analysis plan (SAP)

X Non-commercial trial registry record (e.g. ClinicalTrials.gov record)

☐ Company-owned trial registry record (e.g. GSK Clinical Study Register record)

☐ "Grey literature" (e.g. unpublished thesis)

X Conference abstract(s) about the trial

☐ Regulatory document (e.g. Clinical Study Report, Drug Approval Package)

☐ Research ethics application

☐ Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)

☐ Personal communication with trialist

☐ Personal communication with the sponsor

Risk of bias assessment

Responses underlined in green are potential markers for low risk of bias, and responses in red are potential markers for a risk of bias. Where questions relate only to sign posts to other questions, no formatting is used.

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Comments	Response options
1.1 Was the allocation sequence random?	"The nurse counselors assigned patients to the intervention or control group individually by simple randomization according to serially numbered sealed opaque envelopes containing a random number generated by the computer for each study site. The nurse counselors were unaware of the random sequence, which another researcher generated." (Li et al., 2017; p. 3)	Y
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?		Y
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	"Fewer patients in the intervention group (17.6%) reported having physician consultation in the past 30 days than in the control group (24.7%; $p < 0.05$). However, regression analysis showed that the higher rate of physician consultation did not predict smoking cessation at 6 and 12 months. Other demographic characteristics including smoking, DM, and health status were similar between groups." (Li et al., 2017; p.4)	PN
Risk-of-bias judgement		Low
Optional: What is the predicted direction of bias arising from the randomization process?		NA

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of assignment to intervention*)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?	The nurse counsellors were probably aware of the participants' assigned intervention during the trial.	NI
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		PY
2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?		NI
2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?		NA
2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?		NA
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	Yes, intention-to-treat analysis was carried out	Y
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?		NA
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias due to deviations from intended interventions?		Unpredictable

Domain 3: Missing outcome data

Signalling questions	Comments	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?		N
3.2 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?	Both intention-to-treat and per protocol analyses were carried out. "The smoking quit rate per protocol analysis for the intervention and control groups was 11.9% (22/185) and 17.3% (32/185), respectively, (rate ratio = 0.69, 95% CI 0.40–1.19, p = 0.17). By intention-to-treat analysis, the quit rate for the intervention and control groups were 9.4% and 13.7%, respectively." (Li et al., 2017; p. 4)	Y
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?		NA
3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?		NA
Risk-of-bias judgement		Low
Optional: What is the predicted direction of bias due to missing outcome data?		NA

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Comments	Response options
4.1 Was the method of measuring the outcome inappropriate?	Biochemical verification was carried out. "Patients who reported that they had successfully quit after 6 or 12 months … were invited to test on saliva cotinine (< 115 ng/mL NicAlert strips (www.nymox.com) and exhaled carbon monoxide." (Li et al., 2017; p.3-4)	N
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?	Probably no as abstinence was objectively verified.	PN
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?	"Three more follow-up telephone contacts at 3, 6, and 12 months were conducted by another nurse counselor who was blinded to the group assignment. The counselor collected information on smoking status…" (Li et al., 2017; p.3)	N
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?		NA
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?		NA
Risk-of-bias judgement		Low
Optional: What is the predicted direction of bias in measurement of the outcome?		NA

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Comments	Response options
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?	As per registered study protocol.	Y
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	Probably no - smoking abstinence was biochemically verified at the end of the study (12 months) (per study protocol).	N
5.3 ... multiple eligible analyses of the data?	Probably no - smoking abstinence was analysed and biochemically confirmed per study group at the end of the study (per study protocol).	N
Risk-of-bias judgement		Low
Optional: What is the predicted direction of bias due to selection of the reported result?		NA

Overall risk of bias

Risk-of-bias judgement	While there is no information on whether participants were aware of their assigned intervention during the trial, carers and people delivering the interventions were probably aware of participants' assigned intervention during the trial. The authors did not report whether deviations arose because of the trial context.	Some concerns
Optional: What is the overall predicted direction of bias for this outcome?		Unpredictable

Study details

Reference	Ng, N., Nichter, M., Siwi, R., Prabandari, Y. S., Muramoto, M., & Nichter, M. (2010). Bringing smoking cessation to diabetes clinics in Indonesia. *Chronic Illness*, 6(2), 125–135. https://doi.org/10.1177/1742395310364253

Study design

X Individually-randomized parallel-group trial

☐ Cluster-randomized parallel-group trial

☐ Individually randomized cross-over (or other matched) trial

For the purposes of this assessment, the interventions being compared are defined as

Experimental:	same intervention as provided to the control group and an active referral to a smoking cessation counselling session based on the 5As (and 5Rs) algorithm (with additional follow-ups as required).	Comparator:	brief smoking cessation advice, use of visual messages of smoking related diabetic complications and provision of educational materials on the harm of tobacco in diabetes by a doctor

Specify which outcome is being assessed for risk of bias	Self-reported 7-day point prevalence abstinence at 6 months follow-up
Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.	30.3% and 36.8% of the participants in the intervention and control groups (respectively) quit smoking.

Is the review team's aim for this result…?

X to assess the effect of *assignment to intervention* (the 'intention-to-treat' effect)

☐ to assess the effect of *adhering to intervention* (the 'per-protocol' effect)

If the aim is to assess the effect of *adhering to intervention*, select the deviations from intended intervention that should be addressed (at least one must be checked):

☐ occurrence of non-protocol interventions

☐ failures in implementing the intervention that could have affected the outcome

☐ non-adherence to their assigned intervention by trial participants

Which of the following sources were <u>obtained</u> to help inform the risk-of-bias assessment? (tick as many as apply)

X Journal article(s) with results of the trial

☐ Trial protocol

☐ Statistical analysis plan (SAP)

☐ Non-commercial trial registry record (e.g. ClinicalTrials.gov record)

☐ Company-owned trial registry record (e.g. GSK Clinical Study Register record)

☐ "Grey literature" (e.g. unpublished thesis)

☐ Conference abstract(s) about the trial

☐ Regulatory document (e.g. Clinical Study Report, Drug Approval Package)

☐ Research ethics application

☐ Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)

☐ Personal communication with trialist

☐ Personal communication with the sponsor

Risk of bias assessment

Responses underlined in green are potential markers for low risk of bias, and responses in red are potential markers for a risk of bias. Where questions relate only to sign posts to other questions, no formatting is used.

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Comments	Response options
1.1 Was the allocation sequence random?	The only statement about randomisation is as follows: "Immediately after completion of baseline data collection, patients were randomized into DA and CC groups and their medical records were flagged with different colour stickers to indicate group assignment." (Ng et al., 2010; p. 127)	NI
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?		NI
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	"There were no significant differences between the groups of DA and CC patients with respect to history of other chronic diseases, age at starting smoking, number of cigarettes smoked, smoking status in the last 6 months prior to the study and previous quitting attempts (p>0.1) (Table 1)." (Ng et al., 2010; p. 129)	N
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias arising from the randomization process?		Unpredictable

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of assignment to intervention*)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?	Yes. "patients were randomized into DA and CC groups and their medical records were flagged with different colour stickers to indicate group assignment." (Ng et al., 2010; p. 127)	NI
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		Y
2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?		NI
2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?		NA
2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?		NA
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	Intent-to-treat analysis was carried out. "In the intent to treat analysis, we adopted the most conservative approach for the primary outcomes, where patients for whom follow-up data were missing were treated as currently smoking." (Ng et al., 2010; p.129)	Y
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?		NA
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias due to deviations from intended interventions?		Unpredictable

Domain 3: Missing outcome data

Signalling questions	Comments	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?		N
3.2 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?	Intent-to-treat analysis was carried out. "In the intent to treat analysis, we adopted the most conservative approach for the primary outcomes, where patients for whom follow-up data were missing were treated as currently smoking." (Ng et al., 2010; p.129)	PY
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?		NA
3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?		NA
Risk-of-bias judgement		Low
Optional: What is the predicted direction of bias due to missing outcome data?		NA

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Comments	Response options
4.1 Was the method of measuring the outcome inappropriate?	Biochemical verification of smoking abstinence is important in clinical trials (Benowitz et al., 2020). The 7-day point prevalence abstinence, assessed at 1 week, 3 months and 6 months was not biochemically verified in both groups.	PY
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?		NI
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?	Probably yes as medical records were flagged (colour coded according to the intervention group).	PY
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?	Probably no, as there was a significant increase in smoking abstinence in both groups. "Repeated logistic regression analysis revealed a significant increase in abstinence prevalence in both groups over time, compared to baseline (p<0.001)." (Ng et al., 2010; p. 129)	PN
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?		NA
Risk-of-bias judgement		High
Optional: What is the predicted direction of bias in measurement of the outcome?		Unpredictable

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Comments	Response options
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?		NI
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	While analysis intentions are not available, the 7-day point prevalence smoking abstinence measured at the end of the study could have possibly been biochemically verified.	NI
5.3 ... multiple eligible analyses of the data?	Probably no – self-reported abstinence was analysed per study group at the end of the study.	PN
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias due to selection of the reported result?		Unpredictable

Overall risk of bias

Risk-of-bias judgement	No information on randomisation methods and concealment of allocation sequence. While there is no information on whether participants were aware of their assigned intervention during the trial, carers and people delivering the interventions were aware of participants' assigned intervention during the trial. The authors did not report whether deviations arose because of the trial context. Biochemical verification of smoking abstinence was not carried out, however a significant increase in self-reported abstinence was reported in both groups. No information on whether the result was analysed in accordance with a pre-specified analysis plan.	High
Optional: What is the overall predicted direction of bias for this outcome?		Unpredictable

Study details

Reference	Sawicki, P. T., Didjurgeit, U., Mühlhauser, I., & Berger, M. (1993). Behaviour therapy versus doctor's anti-smoking advice in diabetic patients. *Journal of internal medicine*, 234(4), 407–409. https://doi.org/10.1111/j.1365-2796.1993.tb00763.x

Study design

X Individually-randomized parallel-group trial

☐ Cluster-randomized parallel-group trial

☐ Individually randomized cross-over (or other matched) trial

For the purposes of this assessment, the interventions being compared are defined as

Experimental:	ten structured behavioural therapy smoking cessation sessions by a psychotherapist. Nicotine gum was offered to patients with 'severe' tobacco addiction	Comparator:	a 15 minutes unstructured smoking cessation advice session by a physician

Specify which outcome is being assessed for risk of bias	Biochemically verified smoking cessation at six months
Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.	Two (5%) and seven (16%) participants from the intervention and control group, respectively, quit smoking.

Is the review team's aim for this result…?

X to assess the effect of *assignment to intervention* (the 'intention-to-treat' effect)
☐ to assess the effect of *adhering to intervention* (the 'per-protocol' effect)

If the aim is to assess the effect of *adhering to intervention*, select the deviations from intended intervention that should be addressed (at least one must be checked):

☐ occurrence of non-protocol interventions
☐ failures in implementing the intervention that could have affected the outcome
☐ non-adherence to their assigned intervention by trial participants

Which of the following sources were <u>obtained</u> to help inform the risk-of-bias assessment? (tick as many as apply)

X Journal article(s) with results of the trial
☐ Trial protocol
☐ Statistical analysis plan (SAP)
☐ Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
☐ Company-owned trial registry record (e.g. GSK Clinical Study Register record)
☐ "Grey literature" (e.g. unpublished thesis)
☐ Conference abstract(s) about the trial
☐ Regulatory document (e.g. Clinical Study Report, Drug Approval Package)
☐ Research ethics application
☐ Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)
☐ Personal communication with trialist
☐ Personal communication with the sponsor

Risk of bias assessment

Responses underlined in green are potential markers for low risk of bias, and responses in red are potential markers for a risk of bias. Where questions relate only to sign posts to other questions, no formatting is used.

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Comments	Response options
1.1 Was the allocation sequence random?	The only information about randomisation methods is a statement that the study was randomised. "Out of this group 89 patients (1 1 %) agreed to participate and were randomized into an intervention group (n = 44) and a control group (n = 45)." (Sawicki et al., 1993; p. 407)	NI
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?		NI
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	No. Table 1 - "There was no significant difference concerning any parameter between the groups." (Sawicki et al., 1993; p. 408)	N
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias arising from the randomization process?		Unpredictable

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of assignment to intervention*)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?	The people delivering the interventions were probably aware of the assignment of participants.	NI
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		PY
2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?		NI
2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?		NA
2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?		NA
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	Intention-to-treat analysis was carried out.	Y
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?		NA
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias due to deviations from intended interventions?		Unpredictable

Domain 3: Missing outcome data

Signalling questions	Comments	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?	"All randomized patients were studied at baseline and re-investigated 6 months after intervention. No patients were excluded or lost to follow-up." (Sawicki et al., 1993; p. 408)	Y
3.2 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?		NA
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?		NA
3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?		NA
Risk-of-bias judgement		Low
Optional: What is the predicted direction of bias due to missing outcome data?		NA

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Comments	Response options
4.1 Was the method of measuring the outcome inappropriate?	Smoking status was biochemically verified. "Nonsmoking was assumed when at the 6-month visit a patient self-reported not smoking and not using nicotine replacements and serum cotinine was below 20 ng ml-I." (Sawicki et al., 1993; p. 408)	N
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?	Probably no – objective measurement.	PN
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?		NI
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?	Probably no – objective measurement.	PN
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?		NA
Risk-of-bias judgement		Low
Optional: What is the predicted direction of bias in measurement of the outcome?		NA

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Comments	Response options
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?		NI
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	Probably no - self-reported abstinence was biochemically verified at the end of the study (6 months).	PN
5.3 ... multiple eligible analyses of the data?	Probably no - smoking abstinence was analysed and biochemically confirmed per study group at the end of the study.	PN
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias due to selection of the reported result?		Unpredictable

Overall risk of bias

Risk-of-bias judgement	No information on randomisation methods and concealment of allocation sequence. While there is no information on whether participants were aware of their assigned intervention during the trial, carers and people delivering the interventions were probably aware of participants' assigned intervention during the trial. The authors did not report whether deviations arose because of the trial context. No information on whether the result was analysed in accordance with a pre-specified analysis plan.	Some concerns
Optional: What is the overall predicted direction of bias for this outcome?		Unpredictable

Study details

Reference	Thankappan, K. R., Mini, G. K., Daivadanam, M., Vijayakumar, G., Sarma, P. S., & Nichter, M. (2013b). Smoking cessation among diabetes patients: results of a pilot randomized controlled trial in Kerala, India. *BMC public health*, 13, 47. https://doi.org/10.1186/1471-2458-13-47

Study design

X Individually-randomized parallel-group trial

☐ Cluster-randomized parallel-group trial

☐ Individually randomized cross-over (or other matched) trial

For the purposes of this assessment, the interventions being compared are defined as

Experimental:	same intervention as provided to the control group with the addition of three counselling sessions based on the 5As (and 5Rs) algorithm by a counsellor over three months.	Comparator:	brief smoking cessation advice, use of visual messages of smoking related diabetic complications and provision of educational materials on the harm of tobacco in diabetes by a doctor.

Specify which outcome is being assessed for risk of bias	Self-reported 7-day point prevalence abstinence at 6 months follow-up
Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.	Fifty eight (51.8%) from the intervention group vs. 14 (12.5%) from the control group quit smoking (AOR: 8.4, 95% CI [(4.1-17.1]; p<0.001).

Is the review team's aim for this result…?

X to assess the effect of *assignment to intervention* (the 'intention-to-treat' effect)

☐ to assess the effect of *adhering to intervention* (the 'per-protocol' effect)

If the aim is to assess the effect of *adhering to intervention*, select the deviations from intended intervention that should be addressed (at least one must be checked):

☐ occurrence of non-protocol interventions

☐ failures in implementing the intervention that could have affected the outcome

☐ non-adherence to their assigned intervention by trial participants

Which of the following sources were <u>obtained</u> to help inform the risk-of-bias assessment? (tick as many as apply)

X Journal article(s) with results of the trial

☐ Trial protocol

☐ Statistical analysis plan (SAP)

X Non-commercial trial registry record (e.g. ClinicalTrials.gov record)

☐ Company-owned trial registry record (e.g. GSK Clinical Study Register record)

☐ "Grey literature" (e.g. unpublished thesis)

X Conference abstract(s) about the trial

☐ Regulatory document (e.g. Clinical Study Report, Drug Approval Package)

☐ Research ethics application

☐ Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)

☐ Personal communication with trialist

☐ Personal communication with the sponsor

Risk of bias assessment

Responses underlined in green are potential markers for low risk of bias, and responses in red are potential markers for a risk of bias. Where questions relate only to sign posts to other questions, no formatting is used.

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Comments	Response options
1.1 Was the allocation sequence random?	"Subsequently the counselor randomized the patients equally into two groups; intervention–1 and intervention– 2 groups, with block size four. Sequentially, every four patients enrolled were randomized into the two intervention groups using a computer generated random sequence to achieve a block size of four, to facilitate interim analysis." (Thankappan et al., 2013b; p. 4)	Y
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?		NI
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	"Baseline characteristics in both the intervention groups were comparable (Table 1)." (Thankappan et al., 2013b; p. 4)	N
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias arising from the randomization process?		Unpredictable

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of assignment to intervention*)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?	Yes. " Their medical records were then flagged with different colored stickers by the counselor in order to identify group assignment." (Thankappan et al., 2013b; p. 2)	NI
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		Y
2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?		NI
2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?		NA
2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?		NA
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	"A complete case analysis and intention to treat analysis were done." (Thankappan et al., 2013b; p. 4)	Y
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?		NA
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias due to deviations from intended interventions?		Unpredictable

Domain 3: Missing outcome data

Signalling questions	Comments	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?		N
3.2 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?	Yes. "Smoking status of the patients at the six-month followup based on complete case analysis is given in Table 2 and that based on intention to treat analysis in Table 3." (Thankappan et al., 2013b; p. 4)	Y
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?		NA
3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?		NA
Risk-of-bias judgement		Low
Optional: What is the predicted direction of bias due to missing outcome data?		NA

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Comments	Response options
4.1 Was the method of measuring the outcome inappropriate?	Biochemical verification of smoking abstinence is important in clinical trials (Benowitz et al., 2020). The 7-day point prevalence abstinence, assessed at 6 months was not biochemically verified in both groups.	PY
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?		NI
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?	Probably yes as medical records were flagged (colour coded according to the intervention group).	PY
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?		NI
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?		NI
Risk-of-bias judgement		High
Optional: What is the predicted direction of bias in measurement of the outcome?		Unpredictable

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Comments	Response options
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?	Trial registered retrospectively.	NI
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	While analysis intentions are not available, the 7-day point prevalence smoking abstinence measured at the end of the study could have possibly been biochemically verified.	NI
5.3 ... multiple eligible analyses of the data?	Probably no – self-reported abstinence was analysed per study group at the end of the study.	PN
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias due to selection of the reported result?		Unpredictable

Overall risk of bias

Risk-of-bias judgement	No information on concealment of the allocation sequence. While there is no information on whether participants were aware of their assigned intervention during the trial, carers and people delivering the interventions were aware of participants' assigned intervention during the trial. The authors did not report whether deviations arose because of the trial context. Biochemical verification of smoking abstinence was not carried out. No information on whether the result was analysed in accordance with a pre-specified analysis plan.	High
Optional: What is the overall predicted direction of bias for this outcome?		Unpredictable

Study details

Reference	Mini, G.K., Nichter, M., Nair, R.R., & Thankappan, K.R. (2015). Confirmation of self-reported non-smoking status by salivary cotinine among diabetes patients in Kerala, India. *Clinical Epidemiology and Global Health*, 3, 44-46. https://doi.org/10.1016/j.cegh.2014.05.003

Study design

X Individually-randomized parallel-group trial

☐ Cluster-randomized parallel-group trial

☐ Individually randomized cross-over (or other matched) trial

For the purposes of this assessment, the interventions being compared are defined as

Experimental:	same intervention as provided to the control group with the addition of three counselling sessions based on the 5As (and 5Rs) algorithm by a counsellor over three months	Comparator:	brief smoking cessation advice, use of visual messages of smoking related diabetic complications and provision of educational materials on the harm of tobacco in diabetes by a doctor

Specify which outcome is being assessed for risk of bias	Self-reported 30-days point prevalence abstinence (biochemically verified) at 1 year follow-up
Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.	Twenty six (74%) were verified as abstinent from smoking.

Is the review team's aim for this result…?

X to assess the effect of *assignment to intervention* (the 'intention-to-treat' effect)

☐ to assess the effect of *adhering to intervention* (the 'per-protocol' effect)

If the aim is to assess the effect of *adhering to intervention*, select the deviations from intended intervention that should be addressed (at least one must be checked):

☐ occurrence of non-protocol interventions

☐ failures in implementing the intervention that could have affected the outcome

☐ non-adherence to their assigned intervention by trial participants

Which of the following sources were <u>obtained</u> to help inform the risk-of-bias assessment? (tick as many as apply)

X Journal article(s) with results of the trial

☐ Trial protocol

☐ Statistical analysis plan (SAP)

X Non-commercial trial registry record (e.g. ClinicalTrials.gov record)

☐ Company-owned trial registry record (e.g. GSK Clinical Study Register record)

☐ "Grey literature" (e.g. unpublished thesis)

X Conference abstract(s) about the trial

☐ Regulatory document (e.g. Clinical Study Report, Drug Approval Package)

☐ Research ethics application

☐ Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)

☐ Personal communication with trialist

☐ Personal communication with the sponsor

Risk of bias assessment

Responses underlined in green are potential markers for low risk of bias, and responses in red are potential markers for a risk of bias. Where questions relate only to sign posts to other questions, no formatting is used.

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Comments	Response options
1.1 Was the allocation sequence random?	"Subsequently the counselor randomized the patients equally into two groups; intervention–1 and intervention– 2 groups, with block size four. Sequentially, every four patients enrolled were randomized into the two intervention groups using a computer generated random sequence to achieve a block size of four, to facilitate interim analysis." (Thankappan et al., 2013b; p. 4)	Y
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?		NI
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	"Baseline characteristics in both the intervention groups were comparable (Table 1)." (Thankappan et al., 2013b; p. 4)	N
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias arising from the randomization process?		Unpredictable

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of assignment to intervention*)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?	Yes. " Their medical records were then flagged with different colored stickers by the counselor in order to identify group assignment." (Thankappan et al., 2013b; p. 2)	NI
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		PY
2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?		NI
2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?		NA
2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?		NA
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	Modified intention-to-treat analysis (excluding participants with missing outcome data) was carried out.	Y
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?		NA
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias due to deviations from intended interventions?		Unpredictable

Domain 3: Missing outcome data

Signalling questions	Comments	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?	"All the 224 diabetic patients in the original randomized controlled trial were contacted ... We were able to contact 87.5% (n = 196) of them. Among this group there were 76 nonsmokers. We contacted 60 of them … Excluding patients who refused to consent (N = 8), who had moved out of the study area (n = 5), or could not be available at the time of our visit (N = 8), we collected saliva samples from 39 patients … Four patients self-reported some form of smokeless tobacco used in the last week during interviews, although not smoking, and were excluded from the cotinine validation study." (Mini et al., 2015; p. 45)	N
3.2 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?		PN
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?	All missing outcome data occurred for documented reasons that are unrelated to the outcome.	PN
3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?		NA
Risk-of-bias judgement		Low
Optional: What is the predicted direction of bias due to missing outcome data?		NA

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Comments	Response options
4.1 Was the method of measuring the outcome inappropriate?	Smoking status was biochemically verified. " we collected saliva samples from 39 patients who claimed to have not smoked even a single cigarette/bidi in the last 30 days for self report confirmation." (Mini et al., 2015; p. 45)	N
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?	Probably no as there was no distinction between study arms. Saliva samples were evaluated by an independent body. "Saliva samples were evaluated at an independent reference laboratory at the Laboratory Medicine and Molecular Diagnostics division of Rajiv Gandhi Centre for Biotechnology (RGCB), Trivandrum." (Mini et al., 2015; p. 45)	PN
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?		NI
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?	Probably no – objective measurement.	PN
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?		NI
Risk-of-bias judgement		Low
Optional: What is the predicted direction of bias in measurement of the outcome?		NA

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Comments	Response options
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?	Trial registered retrospectively	NI
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	Probably no - 30-day point prevalence abstinence smoking abstinence was measured at one year and biochemically confirmed	PN
5.3 ... multiple eligible analyses of the data?	Analysis intentions are not available; however, the outcome measurement could have been analysed per study group.	NI
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias due to selection of the reported result?		Unpredictable

Overall risk of bias

Risk-of-bias judgement	No information on concealment of the allocation sequence. While there is no information on whether participants were aware of their assigned intervention during the trial, carers and people delivering the interventions were aware of participants' assigned intervention during the trial. The authors did not report whether deviations arose because of the trial context. No information on whether the result was analysed in accordance with a pre-specified analysis plan. Nonetheless, the outcome measurement could have been analysed per study group.	Some concerns
Optional: What is the overall predicted direction of bias for this outcome?		Unpredictable

Study details

Reference	Thankappan, K. R., Mini, G. K., Hariharan, M., Vijayakumar, G., Sarma, P. S., & Nichter, M. (2014). Smoking cessation among diabetic patients in Kerala, India: 1-Year follow-up results from a pilot randomized controlled trial. *Diabetes care*, 37(12), e256-e257. https://doi.org/10.2337/dc14-1863

Study design

X Individually-randomized parallel-group trial

☐ Cluster-randomized parallel-group trial

☐ Individually randomized cross-over (or other matched) trial

For the purposes of this assessment, the interventions being compared are defined as

Experimental:	same intervention as provided to the control group with the addition of three counselling sessions based on the 5As (and 5Rs) algorithm by a counsellor over three months	Comparator:	brief smoking cessation advice, use of visual messages of smoking related diabetic complications and provision of educational materials on the harm of tobacco in diabetes by a doctor

Specify which outcome is being assessed for risk of bias	Self-reported 7-day point prevalence abstinence at 1 year follow-up
Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.	Quit rates were significantly higher in the intervention group (Adjusted Odds Ratio AOR: 3.35; 95% CI [1.82–6.18]).

Is the review team's aim for this result…?

X to assess the effect of *assignment to intervention* (the 'intention-to-treat' effect)

☐ to assess the effect of *adhering to intervention* (the 'per-protocol' effect)

If the aim is to assess the effect of *adhering to intervention*, select the deviations from intended intervention that should be addressed (at least one must be checked):

☐ occurrence of non-protocol interventions

☐ failures in implementing the intervention that could have affected the outcome

☐ non-adherence to their assigned intervention by trial participants

Which of the following sources were <u>obtained</u> to help inform the risk-of-bias assessment? (tick as many as apply)

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☐ Trial protocol

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☐ "Grey literature" (e.g. unpublished thesis)

X Conference abstract(s) about the trial

☐ Regulatory document (e.g. Clinical Study Report, Drug Approval Package)

☐ Research ethics application

☐ Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)

☐ Personal communication with trialist

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Risk of bias assessment

Responses underlined in green are potential markers for low risk of bias, and responses in red are potential markers for a risk of bias. Where questions relate only to sign posts to other questions, no formatting is used.

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Comments	Response options
1.1 Was the allocation sequence random?	"Subsequently the counselor randomized the patients equally into two groups; intervention–1 and intervention– 2 groups, with block size four. Sequentially, every four patients enrolled were randomized into the two intervention groups using a computer generated random sequence to achieve a block size of four, to facilitate interim analysis." (Thankappan et al., 2013b; p. 4)	Y
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?		NI
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	"Baseline characteristics in both the intervention groups were comparable (Table 1)." (Thankappan et al., 2013b; p. 4)	N
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias arising from the randomization process?		Unpredictable

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of assignment to intervention*)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?	Yes. " Their medical records were then flagged with different colored stickers by the counselor in order to identify group assignment." (Thankappan et al., 2013b; p. 2)	NI
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		PY
2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?		NI
2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?		NA
2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?		NA
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	Modified intention-to-treat analysis (excluding participants with missing outcome data) was carried out.	Y
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?		NA
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias due to deviations from intended interventions?		Unpredictable

Domain 3: Missing outcome data

Signalling questions	Comments	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?	86.6% of the participants were followed up.	PN
3.2 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?		PN
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?	Missing outcome data occurred for documented reasons. See Figure 1 – Patient flow diagram (Thankappan et al., 2014; p. e257)	PN
3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?		NA
Risk-of-bias judgement		Low
Optional: What is the predicted direction of bias due to missing outcome data?		NA

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Comments	Response options
4.1 Was the method of measuring the outcome inappropriate?	Biochemical verification of smoking abstinence is important in clinical trials (Benowitz et al., 2020). The 7-day point prevalence abstinence, assessed at 6 months was not biochemically verified in both groups.	PY
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?		NI
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?	Probably yes as medical records were flagged (colour coded according to the intervention group).	PY
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?		NI
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?		NI
Risk-of-bias judgement		High
Optional: What is the predicted direction of bias in measurement of the outcome?		Unpredictable

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Comments	Response options
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?	Trial registered retrospectively	NI
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	While analysis intentions are not available, the 7-day point prevalence smoking abstinence measured at the end of the study could have possibly been biochemically verified.	NI
5.3 ... multiple eligible analyses of the data?	Probably no – abstinence rate was analysed per study group at the end of the study.	PN
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias due to selection of the reported result?		Unpredictable

Overall risk of bias

Risk-of-bias judgement	No information on concealment of the allocation sequence. While there is no information on whether participants were aware of their assigned intervention during the trial, carers and people delivering the interventions were aware of participants' assigned intervention during the trial. The authors did not report whether deviations arose because of the trial context. Biochemical verification of smoking abstinence was not carried out. No information on whether the result was analysed in accordance with a pre-specified analysis plan.	High
Optional: What is the overall predicted direction of bias for this outcome?		Unpredictable

Study details

Reference	Nichter, M., Mini, G.K., & Thankappan, K.R. (2018). Low- level smoking among diabetes patients in India: a smoking cessation challenge. *Clinical Epidemiology and Global Health*, 6. https://doi.org/10.1016/j.cegh.2017.11.005.

Study design

X Individually-randomized parallel-group trial

☐ Cluster-randomized parallel-group trial

☐ Individually randomized cross-over (or other matched) trial

For the purposes of this assessment, the interventions being compared are defined as

Experimental:	same intervention as provided to the control group with the addition of three counselling sessions based on the 5As (and 5Rs) algorithm by a counsellor over three months	Comparator:	brief smoking cessation advice, use of visual messages of smoking related diabetic complications and provision of educational materials on the harm of tobacco in diabetes by a doctor

Specify which outcome is being assessed for risk of bias	Self-reported prolonged abstinence at 2 years follow-up
Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.	Five of the 72 individuals who quit smoking at six months remained smoke free.

Is the review team's aim for this result…?

X to assess the effect of *assignment to intervention* (the 'intention-to-treat' effect)

☐ to assess the effect of *adhering to intervention* (the 'per-protocol' effect)

If the aim is to assess the effect of *adhering to intervention*, select the deviations from intended intervention that should be addressed (at least one must be checked):

☐ occurrence of non-protocol interventions
☐ failures in implementing the intervention that could have affected the outcome
☐ non-adherence to their assigned intervention by trial participants

Which of the following sources were <u>obtained</u> to help inform the risk-of-bias assessment? (tick as many as apply)

X Journal article(s) with results of the trial
☐ Trial protocol
☐ Statistical analysis plan (SAP)
X Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
☐ Company-owned trial registry record (e.g. GSK Clinical Study Register record)
☐ "Grey literature" (e.g. unpublished thesis)
X Conference abstract(s) about the trial
☐ Regulatory document (e.g. Clinical Study Report, Drug Approval Package)
☐ Research ethics application
☐ Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)
☐ Personal communication with trialist
☐ Personal communication with the sponsor

Risk of bias assessment

Responses underlined in green are potential markers for low risk of bias, and responses in red are potential markers for a risk of bias. Where questions relate only to sign posts to other questions, no formatting is used.

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Comments	Response options
1.1 Was the allocation sequence random?	"Subsequently the counselor randomized the patients equally into two groups; intervention–1 and intervention– 2 groups, with block size four. Sequentially, every four patients enrolled were randomized into the two intervention groups using a computer generated random sequence to achieve a block size of four, to facilitate interim analysis." (Thankappan et al., 2013b; p. 4)	Y
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?		NI
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	"Baseline characteristics in both the intervention groups were comparable (Table 1)." (Thankappan et al., 2013b; p. 4)	N
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias arising from the randomization process?		Unpredictable

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of assignment to intervention*)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?	Yes. " Their medical records were then flagged with different colored stickers by the counselor in order to identify group assignment." (Thankappan et al., 2013b; p. 2)	NI
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		PY
2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?		NI
2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?		NA
2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?		NA
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	Intention-to-treat analysis was carried out.	Y
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?		NA
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias due to deviations from intended interventions?		Unpredictable

Domain 3: Missing outcome data

Signalling questions	Comments	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?	87% of all participants were followed up.	PN
3.2 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?	Probably yes. " Intention to treat analysis was used to find the change in level of smoking." (Nichter et al., 2018; p. 2)	PY
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?		NA
3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?		NA
Risk-of-bias judgement		Low
Optional: What is the predicted direction of bias due to missing outcome data?		NA

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Comments	Response options
4.1 Was the method of measuring the outcome inappropriate?	Biochemical verification of smoking abstinence is important in clinical trials (Benowitz et al., 2020). Prolonged abstinence, assessed at 24 months was not biochemically verified in both groups.	PY
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?		NI
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?		NI
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?		NI
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?		NI
Risk-of-bias judgement		High
Optional: What is the predicted direction of bias in measurement of the outcome?		Unpredictable

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Comments	Response options
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?	Trial registered retrospectively	NI
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	While analysis intentions are not available, smoking abstinence (measured at the end of the study) could have possibly been biochemically verified.	NI
5.3 ... multiple eligible analyses of the data?	Analysis intentions are not available; however, the outcome measurement could have been analysed per study group.	NI
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias due to selection of the reported result?		Unpredictable

Overall risk of bias

Risk-of-bias judgement	No information on concealment of the allocation sequence. While there is no information on whether participants were aware of their assigned intervention during the trial, carers and people delivering the interventions were aware of participants' assigned intervention during the trial. The authors did not report whether deviations arose because of the trial context. Biochemical verification of smoking abstinence was not carried out. No information on whether the result was analysed in accordance with a pre-specified analysis plan. Nonetheless, the outcome measurement could have been analysed per study group.	High
Optional: What is the overall predicted direction of bias for this outcome?		Unpredictable

Appendix 3.4: Risk-of-bias assessment of the identified cluster-randomised parallel-group trial using RoB 2

Revised Cochrane risk-of-bias tool for cluster-randomized trials (RoB 2 CRT)

TEMPLATE FOR COMPLETION

Version of 18 March 2021

The development of the RoB 2 tool was supported by the MRC Network of Hubs for Trials Methodology Research (MR/L004933/2- N61), with the support of the host MRC ConDuCT-II Hub (Collaboration and innovation for Difficult and Complex randomised controlled Trials In Invasive procedures - MR/K025643/1), by MRC research grant MR/M025209/1, and by a grant from The Cochrane Collaboration.

Study details

Reference	Pérez-Tortosa, S., Roig, L., Manresa, J. M., Martin-Cantera, C., Puigdomènech, E., Roura, P., Armengol, A., Advani, M., & ITADI Study Group (2015). Continued smoking abstinence in diabetic patients in primary care: a cluster randomized controlled multicenter study. *Diabetes research and clinical practice*, 107(1), 94–103. https://doi.org/10.1016/j.diabres.2014.09.009

Study design

- ☐ Individually-randomized parallel-group trial
- X Cluster-randomized parallel-group trial
- ☐ Individually randomized cross-over (or other matched) trial

For the purposes of this assessment, the interventions being compared are defined as

Experimental:	an intensive individual based intervention based on the participants' stage of change (TTM) using motivational interviewing, other therapies and medications according to the stage of change of the participant delivered by GPs and nurses	Comparator:	usual care

Specify which outcome is being assessed for risk of bias	Biochemically verified smoking cessation at six months
Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI	Sixty seven (17.8%) and 90 (26.1%) participants from the control and intervention groups quit (p=0.007).

0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.	

Is the review team's aim for this result…?

X to assess the effect of *assignment to intervention* (the 'intention-to-treat' effect)

☐ to assess the effect of *adhering to intervention* (the 'per-protocol' effect)

If the aim is to assess the effect of *adhering to intervention*, select the deviations from intended intervention that should be addressed (at least one must be checked):

☐ occurrence of non-protocol interventions
☐ failures in implementing the intervention that could have affected the outcome
☐ non-adherence to their assigned intervention by trial participants

Which of the following sources were <u>obtained</u> to help inform the risk-of-bias assessment? (tick as many as apply)

X Journal article(s) with results of the trial
X Trial protocol
☐ Statistical analysis plan (SAP)
☐ Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
☐ Company-owned trial registry record (e.g. GSK Clinical Study Register record)
☐ "Grey literature" (e.g. unpublished thesis)
☐ Conference abstract(s) about the trial
☐ Regulatory document (e.g. Clinical Study Report, Drug Approval Package)
☐ Research ethics application
☐ Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)
☐ Personal communication with trialist
☐ Personal communication with the sponsor

Risk of bias assessment

Responses underlined in green are potential markers for low risk of bias, and responses in red are potential markers for a risk of bias. Where questions relate only to sign posts to other questions, no formatting is used.

Domain 1a: Risk of bias arising from the randomization process

Signalling questions	Comments	Response options
1a.1 Was the allocation sequence random?	"Centres were then assigned to the intervention or the control (non-intervention, usual care) groups using a centralized, computerized randomization system (ratio 1:1). (Perez-Tortosa et al., 2015; p. 96)	Yes (Y)
1a.2 Was the allocation sequence concealed until clusters were enrolled and assigned to interventions?		Y
1a.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	No apparent baseline differences. "Table 2 compares characteristics among patients in intervention and control groups. Both groups showed similar characteristics regarding mean age at smoking initiation (17.6 [6.2] vs. 17.9 [6.0], p = 0.518), median (Q1–Q3) number of cigarettes smoked daily in the last 2 weeks (16.5 [8–20] vs. 15 [10–20], p = 0.531). Education level, comorbidities, diabetes- related complications, duration of diabetes, and previous attempts to quit smoking were similar in the two groups. Oral antidiabetic drugs were given to 66% of patients, oral antidiabetic agents combined with insulin in 12.4%, insulin in 11.8% and only diet in 9.8%. The distribution of treatment modalities among patients in the two study groups was also similar." (Perez-Tortosa et al., 2015; p. 97)	Probably No (PN)
Risk-of-bias judgement		Low
Optional: What is the predicted direction of bias arising from the randomization process?		Not Applicable (NA)

Domain 1b: Risk of bias arising from the timing of identification or recruitment of participants in a cluster-randomized trial

Signalling questions	Comments	Response options
1b.1 Were all the individual participants identified and recruited (if appropriate) before randomization of clusters?	Recruitment of the patients (phase 3 of the project) happened after recruitment (phase 1) (Roig et al., 2010).	No (N)
1b.2 If N/PN/NI to 1b.1: Is it likely that selection of individual participants was affected by knowledge of the intervention assigned to the cluster?		No Information (NI)
1b.3 Were there baseline imbalances that suggest differential identification or recruitment of individual participants between intervention groups?	No apparent baseline differences (see 1a.3)	PN
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias arising from the timing of identification and recruitment of participants?		Unpredictable

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of assignment to intervention*)

Signalling questions	Comments	Response options
2.1a Were participants aware that they were in a trial?		NI
2.1b. If Y/PY/NI to 2.1a: Were participants aware of their assigned intervention during the trial?	Probably Yes. "If a patient met the inclusion criteria, the doctor or nurse explained the study to the patient and solicited the patient's participation. If the subject agreed, he or she received information about the study and signed a consent form. If the subject did not wish to participate, the motives were documented." (Roig et al., 2010; p. 4) People delivering the interventions were aware of participants' assigned intervention. "The professionals in the intervention group received a full day specific training program that consisted of a motivational interview workshop and a pharmacological treatment workshop to quit smoking … Professionals in the control group attended a practical training session that covered the methodology of the study and the electronic data collection system. (Perez-Tortosa et al., 2015; p. 96)	Probably Yes (PY)
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		Y
2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?		NI
2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?		NA
2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?		NA
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	Yes. "A per-protocol analysis was used" (Perez-Tortosa et al., 2015; p. 96)	Y
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of		NA

the failure to analyse participants in the group to which they were randomized?		
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias due to deviations from intended interventions?		Unpredictable

Domain 3: Risk of bias due to missing outcome data

Signalling questions	Comments	Response options
3.1a Were data for this outcome available for all clusters that recruited participants?		NI
3.1b Were data for this outcome available for all, or nearly all, participants within clusters?	No, outcome data is available for 76.2% of the initial population. "However, 69 patients in the intervention group and 60 in the control group were excluded because no information on the initial TTM stage was available. Of the remaining 948 (88.0%) patients, in 226 (111 in the intervention group and 115 in the control group) it was not known if they continued to smoke or their motivation stage at the end of the study. Therefore, the analysis was restricted to 722 patients (345 in the intervention group and 377 in the control group) who completed the study." (Perez-Tortosa et al., 2015; p. 96)	N
3.2 If N/PN/NI to 3.1a or 3.1b: Is there evidence that the result was not biased by missing data?	Probably yes – differences were minimal. "Table 1 shows the comparison of baseline data of patients included in the study (n = 722) and those with missing data (n = 226). There were no significant differences in relation to age, number of male patients, age at smoking initiation, number of cigarettes consumed daily in the last 2 weeks, Richmond test and initial TTM stage. However, patients with missing data were significantly younger (mean [SD] age 57.7 [12.3] vs. 59.7 [11.3] years, p = 0.024) and showed a median (Q1–Q3) higher value in the Fagerstrom test for nicotine dependence (3 [1–4] vs. 2 [1–4], p = 0.030) as compared with patients included in the study. (Perez-Tortosa et al., 2015; p. 96-97)	PY
3.3 If N/PN to 3.2 Could missingness in the outcome depend on its true value?		NA
3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?		NA
Risk-of-bias judgement		Low
Optional: What is the predicted direction of bias due to missing outcome data?		NA

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Comments	Response options
4.1 Was the method of measuring the outcome inappropriate?	No – biochemical verification "continued abstinence was defined as at least 6 months without smoking and a carbon monoxide (CO) breath level of <6 ppm measured by a cooximeter in standard conditions." (Perez-Tortosa et al., 2015; p. 96)	N
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?	Probably no – objective measurement.	PN
4.3a If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware that a trial was taking place?	Yes, this was done by the professionals within the practices.	Y
4.3b If Y/PY/NI to 4.3a: Were outcome assessors aware of the intervention received by study participants?	Yes (as state earlier).	Y
4.4 If Y/PY/NI to 4.3b: Could assessment of the outcome have been influenced by knowledge of intervention received?	Probably no – objective measurement.	PN
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?		NA
Risk-of-bias judgement		Low
Optional: What is the predicted direction of bias in measurement of the outcome?		NA

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Comments	Response options
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?	Yes, per research protocol published in 2010.	Y
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	Probably no - smoking abstinence was biochemically verified at the end of the study (per research protocol).	PN
5.3 ... multiple eligible analyses of the data?	Probably no - smoking abstinence was analysed and biochemically confirmed per study group at the end of the study (per research protocol).	PN
Risk-of-bias judgement		Low
Optional: What is the predicted direction of bias due to selection of the reported result?		NA

Overall risk of bias

Risk-of-bias judgement	There is no information on whether the selection of individual participants (which were were identified/recruited after the randomisation selection) was affected by knowledge of the intervention assigned to the cluster. Participants were probably aware of their assigned intervention during the trial, while carers and people delivering the interventions were aware of participants' assigned intervention during the trial. Furthermore, the authors did not report whether deviations arose because of the trial context.	Some concerns
Optional: What is the overall predicted direction of bias for this outcome?		Unpredictable

Appendix 5.1: Interview guide in English (qualitative descriptive study)

Introduction

Thank you for sharing some of your time with me and for consenting to be interviewed. So I will be recording this interview with your permission. First, I have a few questions about your personal characteristics, and your diabetes and smoking profile. Then I will be asking you about your knowledge of smoking and diabetes and on quitting smoking. After that I will be asking you about the motivation to quit smoking. In the last part of this interview session I have some other questions about the behavioural skills required to quit smoking. The interview usually takes about 30-40 minutes.

At any time, please let me know if you need me to clarify any of the questions. Do you have any questions before we start? Are we okay to start?

So I will starting recording – is that okay?

Questions

Personal characteristics

In the first part of the session I will be asking you about your personal characteristics, and your diabetes and smoking profile.

1. Can you please tell me your age?
2. What is the highest level of education you have successfully completed?
3. What is your current occupation?
4. How old were you when you were first diagnosed with diabetes?
5. What type of diabetes were you diagnosed of?
6. Are you suffering from any health complications caused by diabetes?
   Probe: If yes, what are you suffering from?
7. How old were you when you first started smoking?

8. Do you currently smoke tobacco?
   If yes, ask questions no. 11, 12 and 13. If no, ask questions no. 9 and 10.
9. In the past have you smoked daily, or less than daily?
10. How long has it been since you quit smoking?
11. Do you smoke daily, or less than daily?
12. How much do you smoke?
13. Are you currently motivated to quit smoking?
    Probe: If yes, are you planning to quit within a month?

Information

I will now be asking you about your knowledge of smoking and diabetes and on quitting smoking.

14. What do you think are the harms and risks associated with by smoking?
    Probe: What are the effects of smoking on one's health?
15. What do you know about the interaction between smoking and diabetes?
    Probe: What are the additional negative effects of smoking on the health of those who have diabetes?
16. What do you know about the effects of quitting smoking on diabetes?
    Probe: How can quitting smoking impact on diabetes management?
17. What smoking cessation information would one need to quit?
    Probe: Which information could guide a smoker with diabetes to quit?
18. Would an increase in your awareness of the diabetic complications associated with smoking influence your smoking habit?
    Probe: Why would it (or wouldn't it) have an impact on your smoking habit?
19. Would visual images of diabetic complications associated with smoking influence your smoking habit?
    Probes: Why would it (or wouldn't it) have an impact on your smoking habit? How could this be relayed?
20. Would a video clip featuring a person who had stopped smoking because of a diabetic complication associated with smoking, influence your smoking habit?
    Probes: Why would it (or wouldn't it) have an impact on your smoking habit? How could this be relayed?

Motivation

Now I will be asking you some questions about the motivation required to quit smoking.

21. In your last quitting attempt, what was the main reason why you tried to quit?
    Probe: If you still smoke, what are the main reasons for which you decided to continue smoking or else to restart smoking after you had stopped?
22. If you still smoke, what would encourage you to stop smoking? If you have stopped smoking what encourages you to avoid starting again?
    Probes: Which health factors would encourage you to stop smoking/ encourage you to avoid starting again? Is having diabetes a motivational factor to quit smoking?

Behavioural skills

The following questions are about the barriers experienced in quitting smoking and the behavioural skills required to quit smoking.

23. What were the difficulties you encountered when trying to quit smoking?
    Probe: What factors prevented you from resisting the urge to smoke a cigarette?
24. How did you stay focused on quitting?
    Probes: How did you resist when you felt like having a cigarette? If you still smoke, which skills would help you resist triggers to stay off from smoking?
25. What do you think about the use of pharmacotherapy for smoking cessation?
    Probes: What do you think about using the Nicotine Gum/Patch/Spray/Inhalator or Varenicline for quitting smoking? Would you opt for pharmacotherapy to quit smoking?
26. What do you think of professional guidance/support to help one quit smoking?
    Probes: If you still smoke, what is your opinion of having a health care professional motivating you to quit and providing you with assistance in preparation for a quit? How can this service be provided? How frequent and for how long?

Any other issues

27. Is there anything else that could inform the development of a smoking cessation intervention for smokers with diabetes that we have not addressed and that you would like to mention?

Appendix 5.2: Interview guide in Maltese (qualitative descriptive study)

Introduzzjoni

Grazzi talli qsamt ftit mill-ħin tiegħek miegħi u talli tajtni l-kunsens sabiex tiġi intervistat/a. Bil-permess tiegħek jien se nkun qiegħed nirreġistra din l-intervista. L-ewwel għandi ftit mistoqsijiet dwar il-karatteristiċi personali tiegħek, u l-profil tad-dijabete u tat-tipjip tiegħek. Imbagħad se nkun qed nistaqsik dwar l-għarfien tiegħek fuq it-tipjip u d-dijabete u dwar meta tieqaf tpejjep. Wara dan se inkun qed nistaqsik dwar il-motivazzjoni biex tieqaf tpejjep. Fl-aħħar parti tal-intervista għandi xi mistoqsijiet oħra dwar il- ħiliet fl-imġiba meħtieġa biex tieqaf tpejjep. Ġeneralment l-intervista tieħu madwar 30-40 minuta.

Fi kwalunkwe ħin jekk jogħġbok għarrafni jekk għandekx bżonn li niċċara xi mistoqsija/ijiet. Għandek xi mistoqsijiet qabel ma nibdew? Aħna tajbin biex nibdew?

Allura se nibda nirreġistra - tajjeb?

Mistoqsijiet

Karatteristiċi personali

Fl-ewwel parti tas-sessjoni se nistaqsik dwar il-karatteristiċi personali tiegħek, u l-profil tad-dijabete u tat-tipjip tiegħek.

1. Tista' jekk jogħġbok tgħidli kemm għandek żmien?
2. X'inhu l-ogħla livell ta' edukazzjoni li temmejt b'suċċess?
3. X'inhi l-okkupazzjoni attwali tiegħek?
4. Kemm kellek żmien meta ġejt iddijanjostikat/a bid-dijabete għall-ewwel darba?
5. B'liema tip ta' dijabete ġejt iddijanjostikat/a?
6. Int qed tbati minn xi kumplikazzjonijiet tas-saħħa kkawżati mid-dijabete?
   Mistoqsija addizzjonali: Jekk iva, minn xiex qed tbati?
7. Kemm kellek żmien meta bdejt tpejjep għall-ewwel darba?
8. Bħalissa tpejjep it-tabakk?

Jekk iva, staqsi l-mistoqsijiet numru 11, 12 u 13. Jekk le, staqsi l-mistoqsijiet numru 9 u 10.

9. Fil-passat kont tpejjep kuljum, jew inqas minn kuljum?
10. Kemm ilu li waqaft mit-tipjip?
11. Tpejjep kuljum, jew inqas minn kuljum?
12. Kemm tpejjep?
13. Attwalment motivat biex tieqaf tpejjep?
    Mistoqsija addizzjonali: Jekk iva, qed tippjana li tieqaf fi żmien xahar?

Informazzjoni

Issa se nkun qed nistaqsik dwar l-għarfien tiegħek fuq it-tipjip u d-dijabete u dwar meta tieqaf tpejjep.

14. X'taħseb huma l-ħsarat u r-riskji assoċjati mat-tipjip?
    Mistoqsija addizzjonali: X'inhuma l-effetti tat-tipjip fuq is-saħħa?
15. X'taf dwar l-interazzjoni bejn it-tipjip u d-dijabete?
    Mistoqsija addizzjonali: X'inhuma l-effetti negattivi addizzjonali tat-tipjip fuq is-saħħa ta' dawk li għandhom id-dijabete?
16. X'taf dwar l-effetti fuq id-dijabete meta tieqaf tpejjep?
    Mistoqsija addizzjonali: B'liema mod jista' l-waqfien mit-tipjip jaffettwa l-immaniġġjar tad-dijabete?
17. Liema nformazzjoni dwar il-waqfien mit-tipjip tkun meħtieġa biex wieħed jieqaf jpejjep?
    Mistoqsija addizzjonali: Liema informazzjoni tista' tiggwida lil min għandu d-dijabete biex jieqaf?
18. Tista' żieda fl-għarfien tiegħek dwar il-kumplikazzjonijiet dijabetiċi assoċjati mat-tipjip tinfluwenza l-vizzju tat-tipjip tiegħek?
    Mistoqsija addizzjonali: Għaliex dan għandu jkollu (jew ma jkollux) impatt fuq il-vizzju tiegħek tat-tipjip?
19. Jistgħu immaġini viżwali ta' kumplikazzjonijiet dijabetiċi assoċjati mat-tipjip, jinfluwenzaw il-vizzju tat-tipjip tiegħek?
    Mistoqsijiet addizzjonali: Għaliex dan għandu jkollu (jew ma jkollux) impatt fuq il-vizzju tiegħek tat-tipjip? Dan kif jista' jiġi trasmess?

20. Jista' filmat li juri persuna li tkun waqfet mit-tipjip minħabba kumplikazzjoni dijabetika assoċjata mat-tipjip, jinfluwenza il-vizzju tat-tipjip tiegħek?
    Mistoqsijiet addizzjonali: Għaliex dan għandu jkollu (jew ma jkollux) impatt fuq il-vizzju tiegħek tat-tipjip? Dan kif jista' jiġi trasmess?

Motivazzjoni

Issa se nistaqsik xi mistoqsijiet dwar il-motivazzjoni meħtieġa biex tieqaf tpejjep.

21. Fl-aħħar tentattiv tiegħek biex tieqaf, x'kienet ir-raġuni ewlenija għaliex ippruvajt tieqaf?
    Mistoqsija addizjonali: Jekk għadek tpejjep, x'inhuma r-raġunijiet ewlenin li għalihom iddeċidejt li tkompli tpejjep jew inkella li terġa' tibda tpejjep wara li kont waqaft?
22. Jekk għadek tpejjep, x'jinkoraġġik sabiex tieqaf tpejjep? Jekk waqaft mit-tipjip, x'jinkoraġġik biex tevita li tibda tpejjep mill-ġdid?
    Mistoqsijiet addizzjonali: Liema fatturi tas-saħħa jistgħu jħeġġuk sabiex tieqaf tpejjep/ jħeġġuk biex tevita li tibda tpejjep mill-ġdid? Li jkollok id-dijabete huwa fattur motivazzjonali biex tieqaf tpejjep?

Ħiliet fl-imġiba

Il-mistoqsijiet li ġejjin huma dwar l-ostakli li esperjenzajt meta ppruvajt tieqaf mit-tipjip u dwar il-ħiliet fl-imġiba meħtieġa biex tieqaf tpejjep.

23. X'kienu d-diffikultajiet li ltqajt magħhom meta ppruvajt tieqaf tpejjep?
    Mistoqsija addizzjonali: Liema fatturi impeduk milli tirreżisti l-bżonn biex tpejjep sigarett?
24. Kif bqajt iffukat biex tieqaf?
    Mistoqsijiet addizzjonali: Kif irreżistejt meta ħassejt il-bżonn li tieħu sigarett? Jekk għadek tpejjep, liema ħiliet kieku jgħinuk tirreżisti l-kawżi biex tpejjep sabiex tibqa' 'l bogħod mit-tipjip?
25. X'taħseb dwar l-użu tal-farmakoterapija għall-waqfien mit-tipjip?
    Mistoqsijiet addizzjonali: X'taħseb dwar l-użu tan-Nicotine Gum/Patch/Spray/Inhalator jew Varenicline biex tieqaf tpejjep? Tagħżel kieku il-farmakoterapija biex tieqaf tpejjep?

26. X'taħseb dwar gwida/appoġġ professjonali biex jgħinu lil min ipejjep biex jieqaf?
    Mistoqsijiet addizzjonali: Jekk għadek tpejjep, x'inhi l-opinjoni tiegħek dwar li tkun imħeġġeġ minn professjonist tas-saħħa biex tieqaf u pprovdut b'għajnuna fit-tħejjija biex tipprova tieqaf? Kif jista' jiġi pprovdut dan is-servizz? Kemm spiss u għal kemm żmien?

Kwalunkwe kwistjoni oħra

27. Hemm xi ħaġa oħra li ma ndirizzajniex li tista' tinforma l-iżvilupp ta' intervent ta' waqfien mit-tipjip għal min għandu d-dijabete u jpejjep u li tixtieq issemmi?

Appendix 5.3: Recruitment flyer in English (qualitative descriptive study)

Are you 18 years old or older, a smoker or ex-smoker, and have diabetes?

Have you ever attempted to quit smoking while managing diabetes?

If you answered YES to both questions, I would like to seek your insight on tobacco use, tobacco use cessation and diabetes!
My name is Joseph Grech and I am exploring relevant information, motivational factors, and behavioural skills that could impact on the ability of individuals with diabetes to quit smoking. You will be provided with a token of appreciation for participating in this study.

Please contact me directly on 9[redacted] or on **joseph.grech.02@um.edu.mt** for more information or to participate in this study. Thank you in advance!

This study has been approved by the Research Ethics Committee of the Faculty of Health Sciences at the University of Malta.

Appendix 5.4: Recruitment flyer in Maltese (qualitative descriptive study)

Għandek 18-il sena jew aktar, tpejjep jew kont tpejjep, u għandek id-dijabete?

Qatt ippruvajt tieqaf tpejjep waqt li kont għed timmaniġġja d-dijabete?

Jekk weġibt IVA għaż-żewġ mistoqsijiet, nixtieq nsir naf aktar dwar l-għarfien tiegħek dwar l-użu tat-tabakk, il-waqfien mill-użu tat-tabakk u d-dijabete! Jisimni Joseph Grech u qed nesplora nformazzjoni rilevanti, fatturi motivazzjonali, u ħiliet fl-imġieba li jistgħu jħallu impatt fuq il-kapaċitá ta' individwi bid-dijabete biex jieqfu jpejpu. Se tingħata sinjal żgħir ta' apprezzament talli tipparteċipa f'dan l-istudju.

Jekk jogħġbok ikkuntattjani direttament fuq 9[redacted] jew fuq **joseph.grech.02@um.edu.mt** għal aktar informazzjoni jew biex tipparteċipa f'dan l-istudju. Grazzi bil-quddiem!

Dan l-istudju gie approvat mill-Kumitat għall-Etika fir-Riċerka fi ħdan il-Fakultà tax-Xjenzi tas-Saħħa fl-Università ta' Malta.

Appendix 5.5: Example code (qualitative descriptive study)

Code: Believing that smoking helps in glucose control

Definition: Expressing the belief that smoking helps in the management of glucose control when having diabetes.

When to use: Use this code when participants express the belief that smoking helps them manage their blood sugar.

When not to use: Do not use this code when participants refer to loosing blood sugar control on quitting smoking (see 'Loosing glucose control on quitting').

Example: "Meta tpejjep sigarett, iz-zokkor narah ma jitlax. Ngħidu aħna, k'niġi ġol-għalqa, jien, ma nkunx għed naħdem, għed nieħu kafe, u nieħu sigarett, u wara ftit, inħoss iz-zokkor jibda nieżel. Fl-għalqa nkun qiegħed relaxed eh, jiġifieri, u ma, ma jħabtek ħadd u xejn. Eeee mbagħad jekk ma tieħux dak is-sigarett, qisu tarah tiela." Male smoker 3, age 58

Appendix 5.6: Faculty Research Ethics Committee Approval (change in data collection method – qualitative descriptive study)

L-Università ta' Malta

Joseph Grech <joseph.grech.02@um.edu.mt>

UREC FORM V_15062020 6327 Joseph Grech

Rita Pace Parascandalo <rita.pace-parascandalo@um.edu.mt> 1 April 2021 at 16:34
To: Joseph Grech <joseph.grech.02@um.edu.mt>
Cc: Roberta Sammut <roberta.sammut@um.edu.mt>, Research Ethics HEALTHSCI <research-ethics.healthsci@um.edu.mt>

Dear Joseph,

your recently submitted changes to the previously approved REDP application and documents, have been reviewed and approval is granted obo FREC. However, please note that since you are also requesting a change in the title of your study, this also needs to be approved by Faculty Board. Kindly inform your departmental secretary so that your request to the change in the title is approved accordingly.

Good luck

Regards
Dr Rita PP

L-Università ta' Malta

Dr Rita Pace Parascandalo PhD (UClan)
BSc(Hons) (Melit.), MSc(Melit.), RM

Senior Lecturer, Department of Midwifery
Chairperson, Faculty Research Ethics Committee

Faculty of Health Sciences
Office No. 48
+356 2340 1176
rita.pace-parascandalo@um.edu.mt

[Quoted text hidden]

Appendix 5.7: Faculty Research Ethics Committee Approval (qualitative descriptive study)

L-Università ta' Malta

Joseph Grech <joseph.grech.02@um.edu.mt>

UREC FORM V_15062020 6327 Joseph Grech

Rita Pace Parascandalo <rita.pace-parascandalo@um.edu.mt> 14 February 2021 at 15:07
To: Joseph Grech <joseph.grech.02@um.edu.mt>
Cc: Roberta Sammut <roberta.sammut@um.edu.mt>, Research Ethics HEALTHSCI <research-ethics.healthsci@um.edu.mt>

Dear Joseph,

your recently submitted amendments as requested by UREC-DP have been reviewed and approval is granted obo FREC. You may now proceed with your study.

Good luck

Regards
Dr Rita PP

L-Università ta' Malta

Dr Rita Pace Parascandalo PhD (UCLan)
BSc(Hons) (Melit.), MSc (Melit.), RM.

Lecturer, Department of Midwifery
Chairperson, Faculty Research Ethics Committee

Faculty of Health Sciences

Office no 48
+356 2340 1176
rita.pace-parascandalo@um.edu.mt

[Quoted text hidden]

Appendix 5.8: Mater Dei Hospital Chief Executive Officer Approval (qualitative descriptive study)

L-Università ta' Malta

Joseph Grech <joseph.grech.02@um.edu.mt>

RE: [EXTERNAL] - Permission to carry out research study

CEO at Health-MDH <ceo.mdh@gov.mt> 2 November 2020 at 07:05
To: Joseph Grech <joseph.grech.02@um.edu.mt>

Dear Mr Grech,

Kindly be informed that Ms Celia Falzon has granted approval for you to conduct this study in line with applicable hospital protocols.

Regards

Carmen Farrugia
Personal Assistant To CEO

SPTAR MATER DEI

T +356 +356 25454102

E carmen.farrugia@gov.mt

Mater Dei Hospital, Triq id-Donaturi tad-Demm, l-Imsida, Malta MSD 2090 | Tel +356 2545 0000 | https://deputyprimeminister.gov.mt/en/MDH/Pages/Home.aspx | https://www.facebook.com/materdeihospital/

Appendix 5.9: Mater Dei Hospital Data Protection Officer Approval (qualitative descriptive study)

L-Università ta' Malta

Joseph Grech <joseph.grech.02@um.edu.mt>

RE: [EXTERNAL] - Re: Permission to carry out research study

Data Protection at MDH <datapro.mdh@gov.mt> 30 October 2020 at 10:53
To: Joseph Grech <joseph.grech.02@um.edu.mt>
Cc: Young Sharon at Health-MDH <sharon.young@gov.mt>, Data Protection Approval Form at Health-MDH <dpaform.mdh@gov.mt>, Roberta Sammut <roberta.sammut@um.edu.mt>, "Norman, Ian" <ian.j.norman@kcl.ac.uk>

Dear Mr Grech

On the basis of the documentation you submitted, from the MDH data protection point of view you have been cleared to proceed with your study titled ***Exploring smoking cessation related information, motivation, and behavioural skills among former and current smokers with diabetes: a focus group study*** provided that you obtain approval from MDH CEO (ceo.mdh@gov.mt - please provide the relevant documents including the Chair's approval and this email).

-

All data stored must be anonymized and in no way should you retain any personal details you obtain from your research and this should be destroyed at the end of your study and /or if any of your participants decides to withdraw. Remember that participants reserve the right to be forgotten.

Anonymisation and Data minimisation

Participant consent forms must be separated from the answered questionnaires and interview answers at source meaning that there will be no correlation between one and the other that will indicate how participants replied.

-

ALL data presented to your supervisors / tutors or examiners or any other personnel from UOM or anyone else must be already anonymized; meaning that you must not divulge to anyone the identity of your participants and / or how they replied. In exceptional circumstances where audio recordings are accessed by the declared undersigned supervisors (always following participant consent), ensure that the name of such participant is **omitted / not tagged** with the respective audio recording to adhere with the data minimisation principle; use coding for reference.

Consent Criteria

This clearance does not allow viewing of medical records nor access to Health Information Systems since you haven't declared so in the consent form.

Since you haven't declared otherwise, all your participants must be reached and approached (by your intermediaries) when physically at MDH grounds and NOT via postal services, email, telephone or any other means. You cannot be handed any contact details of potential participants, otherwise consent would be bypassed and breach GDPR.

Potential participants must only be approached by your declared intermediaries (the nurses working at the Diabetes Education Unit) for invitation and not directly by you. If potential participants decide to participate, they will approach you.

Your research assistant Ms Jessica Grech cannot be handed personal identifiable data since you did not declare her name in the information letter and consent form (in fact you stated: *I understand that the researcher is the only person who has access to this data. The academic supervisor/s and examiners will typically have access to coded data only. I am aware that there may be exceptional circumstances which allow the supervisors to the audio-recording too, for verification purposes*) hence participants are not aware that she is your research assistant therefore she may only be handed data such as statistics and which is not personal identifiable; this excludes signed consent forms, audio recordings and anything else which identifies the data subjects.

Audio recordings must be strictly accessed and listened only by you and by your declared (undersigned in the consent form) supervisors and not by any other personnel from UOM/ FHS or any other institution) and that all data (including transcripts) presented to UOM / FHS or any other institution must be completely anonymised. Such recordings are not to be sent via email, replicated and/or uploaded in any server, cloud storage, site or any other media. Audio recordings are to be destroyed once the study is completed as declared in the consent form or if the participant decides to withdraw from the study.

Clarifications

This clearance does not cover ethical approval.

All documents presented to your participants (including the questionnaires) must include UOM's logo.

Your submitted documentation must remain unchanged.

What was declared during this clearance process is what you will abide to.

You must abide with all the articles of the GDPR 2016 throughout the data collection process and thereafter.

You are requested to submit a copy of your findings to this office at the end of your study.

Please present this clearance email to your intermediaries.

To sign the data protection form, please contact us through dpaform.mdh@gov.mt *and provide the following:*

- *This clearance email*
- *A copy of the CEO's approval*
- *State the period of data collection*

- *Title of your research*

[Quoted text hidden]

Appendix 5.10: Mater Dei Hospital Chairperson Approval (qualitative descriptive study)

Tonna Lucy-Anne at Health-MDH

From: Joseph Grech <joseph.grech.02@um.edu.mt>
Sent: Monday, 26 October 2020 11:53
To: Tonna Lucy-Anne at Health-MDH
Subject: [EXTERNAL] - Fwd: Permission to carry out research study

Dear Ms. Tonna

Can you please ask Prof Fava to get back regarding the email below?

Thank you in advance,

Joseph grech

---------- Forwarded message ---------
From: **Joseph Grech** <joseph.grech.02@um.edu.mt>
Date: Wed, 21 Oct 2020 at 13:03
Subject: Permission to carry out research study
To: <stephen.fava@gov.mt>
Cc: Roberta Sammut <roberta.sammut@um.edu.mt>, Norman, Ian <ian.j.norman@kcl.ac.uk>

Dear Prof. Fava No objection

Prof. Stephen Fava
Chairman
Department of Medicine
Mater Dei Hospital

My name is Joseph Grech and I am currently reading for a Doctor of Philosophy (Ph.D.) in Nursing at the University of Malta. As part of my Ph.D. project, I will be conducting a research study entitled, **"Exploring smoking cessation related information, motivation, and behavioral skills among former and current smokers with diabetes: a focus group study"**. This study aims to explore relevant information, motivational factors, and behavioural skills that could impact the ability of individuals with diabetes to quit smoking, to inform the development of a smoking cessation intervention.

I would like to recruit around ten former and current smokers with type one or type two diabetes, of both genders, and above 18 years of age, from the Diabetes Education Unit at Mater Dei Hospital to participate in a focus group session. The nurses manning the Unit will be asked to identify suitable participants, providing these with a promotional leaflet (provided by myself) who can then contact me for more details about the study and participate.

The focus group should not take more than 1 hour and 30 minutes and will be held in a private and confidential setting at the University of Malta. Participants will be provided with an information letter to provide written informed consent, before the start of the study. Participants will also be reminded that they are free to withdraw from the study at any time, without the need to provide a reason. Before the focus group, the participants will be asked to fill in a short anonymous questionnaire on their personal characteristics, and their diabetes and smoking profile. While the focus group will be audio recorded, the recording will be transcribed and pseudonymised. The audio-recording and coded transcript will be stored on the researcher's personal computer that is password protected and in an encrypted format. The anonymous questionnaires and consent forms will be stored safely and separately to ensure

1

confidentiality. Once this research study is completed, the audio-recording will be erased, and data will be retained only in an anonymous form. Participants' identity and personal information will not feature within analysed data/information, direct participants' quotes, publications, reports, or presentations from this research. Consent forms will be destroyed after two years from the completion of the main study (Doctor of Philosophy in Nursing).

I am sending this email to seek your permission to carry out this study. I will also be seeking permission from the Chief Executive Officer, the Nursing and Midwifery Director, the Director of Nursing Management, and the Data Protection Officer). After being granted permission, I will be seeking ethical approval from the Research Ethics Committee of the Faculty of Health Sciences at the University of Malta.

Should you have any questions or concerns do not hesitate to contact me on 9[redacted]4 or by e-mail joseph.grech.02@um.edu.mt or my supervisor **Dr. Roberta Sammut** on **2340 1831** or roberta.sammut@um.edu.mt (in copy) or my co-supervisor **Prof. Ian James Norman** on **+44 (0)207 848 3020** or ian.j.norman@kcl.ac.uk (in copy).

Thank you in advance.

Yours Sincerely,

Joseph Grech

Appendix 5.11: Mater Dei Hospital Director Nursing Services Approval (qualitative descriptive study)

L-Università ta' Malta

Joseph Grech <joseph.grech.02@um.edu.mt>

Re: [EXTERNAL] - Re: Permission to carry out research study

Damato Carmela at Health-MDH <carmela.damato@gov.mt> 28 October 2020 at 12:23
To: Joseph Grech <joseph.grech.02@um.edu.mt>

dear joseph

you can poceed whilst i wish you the very best in your studies.

regards
carmen

Get Outlook for Android

Appendix 5.12: Mater Dei Hospital Chief Nursing Manager Approval (qualitative descriptive study)

L-Università ta' Malta

Joseph Grech <joseph.grech.02@um.edu.mt>

RE: [EXTERNAL] - Re: Permission to carry out research study

Buttigieg Paul at Health-MDH <paul.buttigieg@gov.mt> 22 October 2020 at 06:29
To: Joseph Grech <joseph.grech.02@um.edu.mt>
Cc: Roberta Sammut <roberta.sammut@um.edu.mt>, "Norman, Ian" <ian.j.norman@kcl.ac.uk>

Approved from my end.

Good luck for your studies and if I can be of any support pls don't hesitate to keep me posted

Paul Buttigieg
Chief Nursing Manager

SPTAR MATER DEI

T +356 +356 25454202

E paul.buttigieg@gov.mt

Mater Dei Hospital, Triq id-Donaturi tad-Demm, l-Imsida, Malta MSD 2090 | Tel +356 2545 0000 | https://deputyprimeminister.gov.mt/en/MDH/Pages/Home.aspx | https://www.facebook.com/materdeihospital/

Appendix 5.13: Gozo General Hospital Approval (qualitative descriptive study)

L-Università ta' Malta

Joseph Grech <joseph.grech.02@um.edu.mt>

RE: [EXTERNAL] - Re: Permission for research study

Georgene Xuereb <georgene.xuereb@stewardmalta.org> 1 November 2020 at 18:48
To: Joseph Grech <joseph.grech.02@um.edu.mt>
Cc: Joseph Fenech <joseph.fenech@stewardmalta.org>

Dear Mr Grech,

Kindly note that approval from both Mr Joseph Fenech, GGH Executive Director and Dr Luca Amato, Steward Legal Counsel has been provisionally granted. Study to commence only once we have the Ethics Committee confirmation in hand, please make sure that this is forwarded once available.

Kind Regards

Georgene Xuereb
Administration Manager
Gozo General Hospital, Steward Health Care Malta

Appendix 5.14: Gozo General Hospital Chief Executive Officer Approval (qualitative descriptive study)

L-Università ta' Malta

Joseph Grech <joseph.grech.02@um.edu.mt>

RE: [EXTERNAL] - Re: Permission for research study

Joseph Fenech <joseph.fenech@stewardmalta.org> 21 October 2020 at 14:13
To: Joseph Grech <joseph.grech.02@um.edu.mt>, Georgene Xuereb <georgene.xuereb@stewardmalta.org>
Cc: Roberta Sammut <roberta.sammut@um.edu.mt>, "Norman, Ian" <ian.j.norman@kcl.ac.uk>

Dear Mr. Grech,

Thanks for your correspondence – a very interesting one indeed!

You have my approval to conduct this study at GGH. I am looping in our DPO to assist you with the necessary paperwork.

Good luck with your study and will be looking forward for a copy!

Best regards,

J.

Steward Malta

Joseph Fenech
Executive Director, Gozo General Hospital
joseph.fenech@stewardmalta.org | https://www.stewardmalta.org/
Ghajn Qatet Street, Victoria, VCT2520, Malta

Appendix 5.15: Gozo General Hospital Director Nursing Services Approval (qualitative descriptive study)

L-Università ta' Malta

Joseph Grech <joseph.grech.02@um.edu.mt>

RE: [EXTERNAL] - Re: Permission for research study

Cini Simone A at GGH-Health <simone.a.cini@gov.mt> 21 October 2020 at 17:20
To: Joseph Grech <joseph.grech.02@um.edu.mt>

Dear Mr Grech

Pending approval from Mr. Fenech, Executive Director GGH, I find no issues with your collaboration with Ms Attard.

I wish you the best of luck throughout your studies, and would appreciate if you could present us with your findings and work when finalised.

Regards,

Simone

Simone Cini
Director Nursing Ser
Health-Gozo General Hospital

t +356 22106364 e simone.a.cini@gov.mt
https://health.gov.mt | www.publicservice.gov.mt

MINISTRY FOR HEALTH

GOZO GENERAL HOSPITAL, TA' L-IBRAGG STREET,
IR-RABAT, GOZO, MALTA

Appendix 5.16: Primary Health Care Department Approval (qualitative descriptive study)

Primary HealthCare
FRN 1940

PRIMARY HEALTHCARE

7 Harper Lane,
Floriana
FRN 1940

Website: http://www.health.gov.mt

Telephone: + 356 21239993
Telefax: + 356 21222856

22 March 2021

Joseph Grech
University of Malta

Re: Your request to carry out a study within the Primary Health Department

Dear Mr Grech,

I am pleased to inform you that your request to carry out the research within the department has been **fully approved.**
May I inform you that as we have to abide to the Data Protection Law, **we cannot provide you with a list of data subjects' (clients/patients/staff) personal contact details.*** The data subjects also have to sign an informed consent form that also includes a data protection statement (unless it is an anonymous questionnaire) prior to participating (see E below). Any modifications of this approach would have to be first discussed with the data protection officer. Where statistics are involved, only data in terms of age, sex etc can be forwarded to you but not names of individuals.

May I bring to your attention that the researcher is obliged to apply necessary safeguards as a condition for carrying out this research, namely -

A. The personal data (of data subjects) accessed or given are only to be used for that specific purpose to conduct the research and for no other purpose;
B. At the end of the research, all personal data should be destroyed;
C. All references to personal data should be omitted in the report unless an informed consent is specifically obtained from the person being identified in the research report;
D. Participation in the research being conducted should be at the discretion of the individual, and they can refuse any participation whatsoever if they so wish;
E. If data subjects (patients/staff) are going to be interviewed, video recorded or given a non-anonymous questionnaire to fill, an informed consent form should be signed by the participating data subject and a privacy policy statement read to them; Faces should be hidden or digitally modified as to conceal identity;
F. Any other measure deemed fit by the respective Head, depending on the research to be carried out.

I sincerely wish you every success in your studies.

Yours truly,

Dr Mario Vella, Data Protection Officer, Primary HealthCare
f/ CEO, Data Controller, Primary HealthCare

** May I suggest that you offer the invitation for participation through any officer in charge (e.g. Nursing officer/Senior GP/service provider)*

Appendix 5.17: Malta College of Family Doctors Approval (qualitative descriptive study)

L-Università ta' Malta

Joseph Grech <joseph.grech.02@um.edu.mt>

Permission for research study

president@mcfd.org.mt <president@mcfd.org.mt> 21 October 2020 at 14:28
To: Joseph Grech <joseph.grech.02@um.edu.mt>
Cc: Roberta Sammut <roberta.sammut@um.edu.mt>, "Norman, Ian" <ian.j.norman@kcl.ac.uk>

Dear Mr. Grech,

I thank you for this invitation. It is always a pleasure collaborating with other professionals, especially if it leads to valuable contributions to the health of our patients. On behalf of MCFD, I wholeheartedly accept your invitation.

Feel free to send the necessary information.

Regards,
Edward

Appendix 5.18: Malta Diabetes Association Approval (qualitative descriptive study)

11/13/2020 University of Malta Mail - Re: Permission for research study

L-Università ta' Malta

Joseph Grech <joseph.grech.02@um.edu.mt>

Re: Permission for research study

Chris Delicata <cjdelicata@hotmail.com> 9 November 2020 at 11:43
To: Joseph Grech <joseph.grech.02@um.edu.mt>
Cc: "Norman, Ian" <ian.j.norman@kcl.ac.uk>, Roberta Sammut <roberta.sammut@um.edu.mt>, "Moira.grixti@gov.mt" <Moira.grixti@gov.mt>

Dear Mr. Grech,

Apologies for the delay in replying.

As an association, we find no objection to you carrying out this study.

We suggest that the flyer is sent to us in jpg format and we will upload on our Facebook pages inviting any interested participants to contact you directly to participate in this study. Unfortunately, we cannot suggest names due to data protection reasons, but would be happy to assist by sharing your flyer and request on our Facebook pages.

Please let me know if this assists. We remain at your disposal for any further clarification or assistance you may require.

Best wishes
Chris

Chris J. Delicata
President | Maltese Diabetes Association

M - (00356) 9[redacted], E- cjd@diabetesmalta.org
W - www.diabetesmalta.org

Appendix 5.19: Information letter in English (qualitative descriptive study)

Participants` Information Sheet

Dear Participant,

My name is Joseph Grech and I am currently reading for a Doctor of Philosophy (Ph.D.) in Nursing at the University of Malta. As part of my Ph.D. project, I am conducting a research study entitled, **"Exploring smoking cessation related information, motivation, and behavioral skills among former and current smokers with diabetes"**. This study aims to explore relevant information, motivational factors, and behavioural skills that could impact the ability of individuals with diabetes to quit smoking, to inform the development of a smoking cessation intervention. Your participation in this study would help us gain a better understanding of the relevant smoking cessation components required by individuals with diabetes mellitus. All data collected from this research shall be used solely for this study.

You are being invited to participate in an interview exploring: information about smoking and diabetes, and smoking cessation; motivation – motives, and barriers to quitting; and behavioural skills – strengths, deficits and required skills/resources to quit. The interview should not take more than 40 minutes and will be held over the phone at a time and date most suitable for you. The consent form (which is attached to this letter) needs to be printed, signed, and sent back to the researcher by email (scanned or photographed), or by the post before holding the interview. Furthermore, you are also being asked to declare that you have read and understood this information letter and consent form, and that you give consent to participate in the study. Your declaration will be audio-recorded by the researcher before the interview and will be stored separately from the interview.

Unless you have any objections, the interview will also be audio-recorded. You are not obliged to answer all the questions and may withdraw from the study at any time without giving a reason. Withdrawal from the study will not have any negative repercussions on you or your care. Furthermore, any data collected from your end, unless this cannot be identified, e.g. has been already anonymised, will be erased. I can assure you that confidentiality will be maintained throughout the study and that your identity and personal information will not be revealed in the thesis and any publications, reports, and presentations arising from this research. All data collected will be pseudonymised meaning that the transcript of the audio recording will be protected by a code system and that this data will be stored securely and separately from any personal data (the audio-recorded interview and declaration, and consent form). This data may only be accessed by the researcher. The academic supervisors

and the examiners will typically have access to coded data only. There may be exceptional circumstances which allow the supervisors to have access to the audio-recording of the interview too, for verification purposes. The audio-recordings and transcript will be stored on the researcher`s personal computer that is password protected and in an encrypted format. Any material in hard-copy form, such as the consent form will be placed in a locked cupboard.

You are at no risk while participating in this interview. If you are interested in quitting smoking, the service of a smoking cessation advisor from the Health Promotion and Disease Prevention Directorate, is available at no financial cost on your part, by calling the National Quitline 8007 3333. You will be provided with a token of appreciation, a 10€ One4All voucher for participating in this study.

Participation in this study is completely voluntary and you are free to accept or refuse to take part without giving a reason. A copy of the information sheet and consent form will be provided for future reference. As a participant, you have the right, under the General Data Protection Regulation (GDPR) and national legislation that implements and further specifies the relevant provisions of said regulation, to access, rectify, and where applicable ask for the data concerning you to be erased. Once this research study is completed, the audio-recorded interview will be erased and data will be retained only in anonymous form. Anonymous results from this research study will be published in my Ph.D. thesis and may be published in academic journals or reported at conferences or to health service organisations. Some of the things you say may be used as direct quotes in publications or conferences, but your confidentiality and anonymity will be maintained, and it will not be possible to identify you. A summary of the results of this research study will be offered to all participants who show interest. Your consent form and audio-recorded declaration will be destroyed within two years from the completion of my Ph.D. project.

This study has been approved by the Research Ethics Committee of the Faculty of Health Sciences at the University of Malta.

Thank you for your time and consideration. Should you have any questions or concerns do not hesitate to contact me on **9*** ***4** or by e-mail joseph.grech.02@um.edu.mt or my supervisor **Dr. Roberta Sammut** on **2340 1831** or roberta.sammut@um.edu.mt or my co-supervisor **Prof. Ian James Norman** on **+44 (0)207 848 3020** or ian.j.norman@kcl.ac.uk.

Yours Sincerely,

Mr. Joseph Grech	**Dr. Roberta Sammut**	**Prof. Ian James Norman**
Researcher	Research Supervisor	Research Co-supervisor
Tel: 9* ***4**	**Tel. 2340 1831**	**Tel. +44 (0)207 848 3020**
joseph.grech.02@um.edu.mt	**roberta.sammut@um.edu.mt**	**ian.j.norman@kcl.ac.uk**

Appendix 5.20: Information letter in Maltese (qualitative descriptive study)

Formula ta' Informazzjoni għall-Parteċipanti

Għażiż/a Parteċipant/a,

Jiena Joseph Grech, u fil-mument preżenti qed insegwi Dottorat tal-Filosofija fl-istudju tal-Infermiera l-Università ta' Malta. Bħala parti mill-proġett tad-Dottorat, qiegħed immexxi studju ta' riċerka, li jismu, **"Esplorazzjoni ta' informazzjoni, motivazzjoni, u ħiliet fl-imġiba relatati mal-waqfien mit-tipjip, fost dawk li għandhom id-dijabete u fl-istess waqt ipejpju jew kienu jpejpu"**. L-għan ta' dan l-istudju hu li jinvestiga informazzjoni relevanti, fatturi motivazzjonali, u ħiliet fl-imġiba li jistgħu jħallu impatt fuq il-kapaċità ta' individwi bid-dijabete biex jieqfu jpejpu, biex jinfurmaw l-iżvilupp ta' intervent ta' waqfien mit-tipjip. Is-sehem tiegħek f'dan l-istudju jista' jgħin biex ikollna aktar għarfien dwar il-komponenti relevanti għall-waqfien mit-tipjip meħtieġa minn individwi bid-dijabete. Kull informazzjoni miġbura se tintuża biss għall-għan ta' dan l-istudju.

Int qed tiġi mistieden biex tipparteċipa f'intervista sabiex ninvestiga: informazzjoni dwar it-tipjip u d-dijabete, u l-waqfien mit-tipjip; motivazzjoni - motivi, u ostakli biex tieqaf; u ħiliet fl-imġiba - qawwiet, nuqqasijet u ħiliet/riżorsi meħtieġa biex tieqaf. Din il-intervista mhux se tieħu iktar minn 40 minuta u se ssir fuq it-telefown f'ġurnata u f'ħin l-aktar adattati għalik. Il-formola tal-kunsens (li hija mehmuża ma' din l-ittra) teħtieġ li tiġi stampata, ffirmata, u mibgħuta lura lir-riċerkatur b'imejl (skannjata jew fotografata), jew bil-posta, qabel ma ssir l-intervista. Barra minn hekk, se tintalab ukoll tiddikjara li qrajt u fhimt din l-ittra ta' informazzjoni u l-formola tal-kunsens, u li tagħti l-kunsens biex tipparteċipa fl-istudju. Id-dikjarazzjoni tiegħek se tiġi rrekordjata bl-awdjo mir-riċerkatur qabel l-intervista u se tiġi maħżuna separatament mill-intervista.

Sakemm m'għandek l-ebda oġġezzjoni, l-intervista se tiġi wkoll rrekordjata bl-awdjo. M'intix obbligat/a li twieġeb il-mistoqsijiet kollha u tista' twaqqaf l-istudju fi xħin trid mingħajr ma tagħti l-ebda raġuni. L-irtirar mill-istudju mhux se jkollu riperkussjonijiet negattivi fuqek jew fuq il-kura tiegħek. Barra minn hekk, kwalunkwe *data* miġbura mingħandek, sakemm din ma tistax tiġi identifikata, eż. hija diġà anonimizzata, se tigi mħassra. Nassigurak li se tinżamm il-kunfidenzjalità matul l-istudju kollu u l-identità tiegħek flimkien mal-informazzjoni personali miġbura, mhumiex se jiġu żvelati mkien fit-teżi, fir-rapporti, fil-preżentazzjonijiet u fil-pubblikazzjonijiet li jistgħu jirriżultaw minnha. Kull tagħrif miġbur se jiġi psewdonomizzat, jiġifieri it-traskrizzjoni tar-reġistrazzjoni tal-awdjo se tkun protetta permezz ta' sistema ta' kodiċi u miżmuma separatament mill-informazzjoni personali (ir-reġistrazzjoni tal-intervista u

tad-dikjarazzjoni bl-awdjo, u l-formola ta' kunsens). Din id-*data* tista' tkun aċċessata biss mir-riċerkatur. Is-Superviżuri akkademiċi u l-eżaminaturi se jkollhom biss aċċess għal *data* kkodifikata. Jista' jkun hemm ċirkostanzi eċċezzjonali li jippermettu lis-superviżuri akkademiċi jkollhom aċċess ukoll għar-reġistrazzjoni tal-intervista bl-awdjo, għal skop ta' verifikazzjoni. Ir-reġistrazzjoni tal-awdjo u d-*data* kollha se jinħażnu fuq il-kompjuter personali tar-riċerkatur permezz ta' kodifikazzjoni tad-*data* (*data encryption*) u li hi protetta b'password. Kwalunkwe materjal stampat, bħall- formoli tal-kunsens se jiġu ssiġillati f'armarju.

M'hemm l-ebda riskju waqt li tipparteċipa f'din l-intervista'. Jekk inti interessat li tieqaf tpejjep, is-servizz ta' konsulent dwar il-waqfien mit-tipjip mid-Direttorat għall-Promozzjoni tas-Saħħa u l-Prevenzjoni tal-Mard, huwa disponibbli mingħajr spejjeż finanzjarji min-naħa tiegħek, billi ċċempel lin-*National Quitline* 8007 3333. Se tingħata vawċer ta €10 tal-One4All bħala apprezzament għall-parteċipazzjoni tiegħek f'dan l-istudju.

Il-parteċipazzjoni tiegħek f'dan l-istudju hija għażla għal kollox volontarja u inti ħieles/ħielsa li taċċetta jew tirrifjuta li tieħu sehem mingħajr ma' tagħti ebda raġuni. Kopja tal-folja tal-informazzjoni u tal-formola ta' kunsens se jkunu pprovduti sabiex ikunu aċċessibbli fil-futur. Barra minn hekk, skont ir-Regolamenti Ġenerali dwar il-Protezzjoni tad-*Data* (GDPR) u l-leġiżlazzjoni nazzjonali li timplimenta u tispeċifika aktar il-provvedimenti relevanti tar-regolamenti msemmija, inti għandek id-dritt li taċċessa, tirretifika, u fejn japplika titlob sabiex titħassar id-*data* li tikkonċernak. Ladarba jitlesta dan l-istudju tar-riċerka, ir-reġistrazzjoni tal-intervista bl-awdjo se titħassar u d-*data* tinżamm biss f'forma anonima. Riżultati anonimi minn dan l-istudju ta' riċerka se jiġu ppubblikati fit-teżi tad-Dottorat tiegħi u jistgħu jiġu ppubblikati f'ġurnali akkademiċi jew irrappurtati f'konferenzi jew organizzazzjonijiet tas-servizzi tas-saħħa. Uħud mill-affarijiet li tgħid jistgħu jintużaw bħala kwotazzjonijiet diretti f'pubblikazzjonijiet jew konferenzi, iżda l-kunfidenzjalità u l-anonimità tiegħek se jinżammu, u mhux se jkun possibbli li tidentifikak. Sommarju tar-riżultati ta' dan l-istudju ta' riċerka se jkun offrut lill-parteċipanti kollha li juru interess. Il-formola tal-kunsens u d-dikjarazzjoni tiegħek rrekordjata bl-awdjo jinqerdu fi żmien sentejn mit-tlestija tal-proġett tad-Dottorat.

Dan l-istudju ġie approvat mill-Kumitat għall-Etika fir-Riċerka fi ħdan il-Fakultà tax-Xjenzi tas-Saħħa fl-Università ta' Malta.

Grazzi ħafna tal-ħin u s-sehem tiegħek f'dan l-istudju. F'każ li jkollok xi mistoqsijiet jew tixtieq tiċċara xi ħaġa, tista' ċċempilli fuq **9*** ***4** jew tibgħatli imejl fuq joseph.grech.02@um.edu.mt. Tista' wkoll tikkuntattja lis-Superviżura **Dr. Roberta Sammut** fuq **2340 1831** jew billi tibgħat imejl fuq roberta.sammut@um.edu.mt jew lil-Ko-Superviżur **Prof. Ian James Norman** fuq **+44 (0)207 848 3020** jew b'imejl fuq ian.j.norman@kcl.ac.uk.

Dejjem tiegħek,

Is-Sur Joseph Grech	**Dr. Roberta Sammut**	**Prof. Ian James Norman**
Isem ir-Riċerkatur	Isem is-Superviżura tar-riċerka	Isem il-Ko-Superviżur tar-riċerka
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Appendix 5.21: Consent form in English (qualitative descriptive study)

Participants` Consent Form

Exploring smoking cessation related information, motivation, and behavioral skills among former and current smokers with diabetes

I, the undersigned, give my consent to take part in the study conducted by Mr. Joseph Grech. The purpose of this document is to specify the terms of my participation in this research study.

1. I have been given written and verbal information about the purpose of the study and all questions have been answered.
2. I understand that I have been invited to participate in an interview, in which the researcher will ask questions to explore relevant information, motivational factors, and behavioural skills that could impact on the ability of individuals with diabetes to quit smoking, to inform the development of a smoking cessation intervention.
3. I am aware that the interview will not take longer than 40 minutes. I understand that the interview will be held over the phone at a date and time that is convenient for me.
4. I also understand that this consent form needs to be printed, signed, and sent back to the researcher by email (scanned or photographed), or by the post before holding the interview. I am aware that I will be asked to declare that I have read and understood the attached information letter and consent form, and that I give consent to participate in the study. I understand that my declaration will be audio-recorded by the researcher before the interview and will be stored separately from the interview.
5. I am aware that the interview will be audio-recorded and transcribed (written down as it has been spoken).
6. I am also aware that the transcript will be coded, and that this data will be stored securely and separately from any personal data (the audio-recorded interview and declaration, and consent form).
7. I understand that the researcher is the only person who has access to this data. The academic supervisors and examiners will typically have access to coded data only. I am aware that there may be exceptional circumstances which allow the supervisors to have access to the audio-recording of the interview too, for verification purposes.
8. I am also aware that the audio-recordings and the transcript will be stored on the researcher`s personal computer that is password protected and in an encrypted format. Any material in hard-copy form, such as the consent form will be placed in a locked cupboard.
9. I am also aware that my identity and personal information will not be revealed in the researcher's Ph.D. thesis and any publications, reports, and presentations arising from this research.

10. I understand that I am free to accept, refuse, or stop participation at any time without giving any reason. This will have no negative repercussions on myself or my care. Furthermore, I also understand that any data collected from my end, unless this cannot be identified, e.g. is anonymised, will be erased.
11. I also understand that my contribution will serve Mr. Joseph Grech to gain a better understanding of the relevant smoking cessation components required by individuals with diabetes mellitus.
12. I also understand that I am at no risk while participating in this interview. I am aware that if I become interested in quitting smoking, the service of a smoking cessation advisor from the Health Promotion and Disease Prevention Directorate is available at no financial cost on my part, by calling the National Quitline 8007 3333. I understand that I will be provided with a token of appreciation, a 10€ One4All voucher for participating in this study.
13. I am aware that under the General Data Protection Regulation (GDPR) and national legislation that implements and further specifies the relevant provisions of said regulation, I have the right to access, rectify, and where applicable ask for the data concerning me to be erased.
14. I understand that once the study is completed, the audio-recorded interview will be erased, and data will only be retained in anonymous form. I am aware that anonymous results from this research study will be published in the researcher's Ph.D. thesis and may be published in academic journals or reported at conferences or to health service organisations.
15. I understand that some of the things I say may be used as direct quotes in publications or conferences, but my confidentiality and anonymity will be maintained, and it will not be possible to identify me.
16. I am aware that a summary of the results of this research study will be offered if I show interest (see below).
17. I am also aware that any personal details, i.e. my consent form and audio-recorded declaration, will be destroyed within two years from completion of the Ph.D. project.
18. I am also aware that I will be provided with a copy of the information letter and consent form for future reference.
19. I have read and understood the points and statements of this form. I have had all the questions answered to my satisfaction, and I agree to participate in this study.

Participant: _____

Signature: _____

Date: _____

Mr. Joseph Grech	**Dr. Roberta Sammut**	**Prof. Ian James Norman**
Researcher	Research Supervisor	Research Co-supervisor
Tel: 9* ***4**	**Tel. 2340 1831**	**Tel. +44 (0)207 848 3020**
joseph.grech.02@um.edu.mt	**roberta.sammut@um.edu.mt**	**ian.j.norman@kcl.ac.uk**

Please note:
If you agree to be contacted again for future research resulting from this study and/or you agree to be contacted to be provided with a summary of the results of this research study please tick the following boxes accordingly while <u>providing your telephone/mobile number</u> here:

_____

I agree to be contacted for future research resulting from this study. ☐

I agree to be contacted to be provided with a summary of the results of this research study. ☐

Appendix 5.22: Consent form in Maltese (qualitative descriptive study)

Formola ta' Kunsens tal-Parteċipanti

Esplorazzjoni ta' informazzjoni, motivazzjoni, u ħiliet fl-imġiba relatati mal-waqfien mit-tipjip, fost dawk li għandhom id-dijabete u fl-istess waqt ipejpju jew kienu jpejpu

Jien, hawn taħt iffirmat, nagħti l-kunsens tiegħi biex nieħu sehem fl-istudju mmexxi mis-Sur Joseph Grech. L-għan ta' dan id-dokument hu li jiġu sspeċifikati t-termini tal-parteċipazzjoni tiegħi f'dan l-istudju ta' riċerka.

1. Jien ingħatajt informazzjoni miktuba u verbali dwar l-għan tal-istudju u l-mistoqsijiet kollha twieġbu.
2. Nifhem li ġejt mistieden sabiex nipparteċipa f' intervista, fejn ir-riċerkatur ħa jistaqsi mistoqsijiet sabiex jinvestiga informazzjoni rilevanti, fatturi motivazzjonali, u ħiliet fl-imġiba li jistgħu jħallu impatt fuq il-kapaċità ta' individwi bid-dijabete biex jieqfu jpejpu, biex jinfurmaw l-iżvilupp ta' intervent ta' waqfien mit-tipjip.
3. Naf li l-intervista mhux se tieħu aktar minn 40 minuta. Nifhem, li l-intervista se ssir fuq it-telefown f'ġurnata u f'ħin li jkun konvenjenti għalija.
4. Nifhem wkoll li din il-formola tal-kunsens teħtieġ li tiġi stampata, ffirmata, u mibgħuta lura lir-riċerkatur b'imejl (skannjata jew fotografata), jew bil-posta, qabel ma ssir l-intervista. Jien konxju/a li se niġi mitlub/a niddikjara li qrajt u fhimt l-ittra ta' informazzjoni mehmuża u l-formola tal-kunsens, u li nagħti l-kunsens biex nipparteċipa fl-istudju. Nifhem li d-dikjarazzjoni tiegħei se tiġi rrekordjata bl-awdjo mir-riċerkatur qabel l-intervista u se tiġi maħżuna separatament mill-intervista.
5. Jien konxju/a li l-intervista se tkun qed tiġi rrekordjata bl-awdjo u traskritta (miktuba kif ġie mitkellem).
6. Naf ukoll li t-traskrizzjoni tar-reġistrazzjoni tal-awdjo se tiġi kkodifikata, u li din id-*data* se tinħażen b'mod sigur u separat minn kwalunkwe *data* personali (ir-reġistrazzjoni tal-intervista u tad-dikjarazzjoni bl-awdjo, u l-formola ta' kunsens).
7. Nifhem li r-riċerkatur hu l-uniku persuna li se jkollu aċċess għal din l-informazzjoni, filwaqt li s-superviżuri akkademiċi u l-eżaminaturi se jkollhom aċċess għal *data* kkodifikata biss. Jiena konxju li jista' jkun hemm ċirkostanzi eċċezzjonali li jippermettu lis-superviżuri jkollhom aċċess għar-reġistrazzjoni tal-intervista bl-awdjo għal skop ta' verifika.
8. Jien konxju wkoll li r-reġistrazzjoni tal-awdjo u t-traskrizzjoni se jinħażnu fuq il-kompjuter personali tar-riċerkatur permezz ta' kodifikazzjoni tad-*data* (*data encryption*) u li hi protetta b'password. Barra minn hekk, naf li l-materjal stampat se jitqiegħed f'post sigur u se jinżamm sakemm joħorġu r-riżultati. Kwalunkwe materjal stampat, bħall- formola tal-kunsens se jiġu ssiġillati f'armarju.

9. Jien konxju wkoll li l-identità tiegħi u l-informazzjoni personali mhumiex se jinkixfu fit-teżi tad-Dottorat tar-riċerkatur, u fir-rapporti, fil-preżentazzjonijiet u fil-pubblikazzjonijiet li jistgħu jirriżultaw minn din ir-riċerka.
10. Nifhem li jien liberu/a li naċċetta, nirrifjuta jew inwaqqaf il-parteċipazzjoni tiegħi f'kull ħin bla ma nagħti raġuni. Dan mhu se jkollu ebda riperkussjonijiet negattivi fuqi nnifsi jew fuq il-kura tiegħi. Barra minn hekk, nifhem ukoll li kwalunkwe *data* miġbura mingħandi, sakemm din ma tistax tiġi identifikata, eż. hija anonimizzata, titħassar.
11. Nifhem ukoll li l-kontribuzzjoni tiegħi se sservi biex is-Sur Joseph Grech jikseb għarfien aħjar tal-komponenti rilevanti għall-waqfien mit-tipjip meħtieġa minn individwi bid-dijabete.
12. Nifhem ukoll li m'għandi l-ebda riskju waqt li nipparteċipa f'din l-intervista. Jiena konxju li jekk jien interessat/a li nieqaf mit-tipjip, is-servizz ta' konsulent dwar il-waqfien mit-tipjip mid-Direttorat għall-Promozzjoni tas-Saħħa u l-Prevenzjoni tal-Mard huwa disponibbli mingħajr spejjeż finanzjarji min-naħa tiegħi, billi ċċempel lin-*National Quitline* 8007 3333. Nifhem li se ningħata vawċer ta' €10 tal-One4All bħala apprezzament tal-parteċipazzjoni tiegħi f'dan l-istudju.
13. Jien konxju li skont ir-Regolamenti Ġenerali dwar il-Protezzjoni tad-*Data* (GDPR) u l-leġiżlazzjoni nazzjonali li timplimenta u tispeċifika aktar il-provedimenti relevanti tar-regolamenti msemmija, jiena għandi d-dritt li naċċessa, nirretifika, u fejn japplika, nitlob sabiex titħassar id-*data* li tikkonċernani.
14. Nifhem li ladarba jitlesta l-istudju, r-reġistrazzjoni tal-intervista bl-awdjo titħassar, u d-*data* tinżamm biss f'forma anonima. Jien konxju li r-riżultati anonimi minn dan l-istudju ta' riċerka se jiġu ppubblikati fit-teżi tad-Dottorat tar-riċerkatur u jistgħu jiġu ppubblikati f'ġurnali akkademiċi jew irrappurtati f'konferenzi jew lil organizzazzjonijiet tas-servizzi tas-saħħa.
15. Nifhem li wħud mill-affarijiet li ngħid jistgħu jintużaw bħala kwotazzjonijiet diretti f'pubblikazzjonijiet jew konferenzi, iżda l-kunfidenzjalità u l-anonimità tiegħi se jinżammu, u mhux se jkun possibbli li niġi identifikat/a.
16. Jiena konxju li se nkun offrut sommarju tar-riżultati ta' dan l-istudju ta' riċerka jekk nuri interess (ara hawn taħt).
17. Jiena konxju wkoll li kwalunkwe dettalji personali, jiġifieri l-formola tal-kunsens u d-dikjarazzjoni tiegħi rrekordjata bl-awdjo, se jinqerdu fi żmien sentejn mit-tlestija tal-proġett tad-Dottorat.
18. Jien naf ukoll li se ningħata kopja tal-folja ta' informazzjoni u tal-formola ta' kunsens sabiex inkun nista' naċċessahom fil-futur.
19. Jien qrajt u fhimt il-punti u d-dikjarazzjonijiet f'din il-formola. Inħossni sodisfatt/a bit-tweġibiet li ngħatajt għall-mistoqsijiet li kelli, u qed naċċetta minn jeddi li nipparteċipa f'dan l-istudju.

Parteċipant/a: _____

Firma: _____

Data: _____

_____	_____	_____
Is-Sur Joseph Grech	**Dr. Roberta Sammut**	**Prof. Ian James Norman**
Isem ir-riċerkatur	Isem is-superviżura	Isem il-ko-superviżur
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Jekk jogħġbok innota:

Jekk taqbel li terġa' tiġi kkuntattjat/a għal riċerka futura li tirriżulta minn dan l-istudju u/jew taqbel li tiġi kkuntattjat/a biex tingħata sommarju tar-riżultati ta' dan l-istudju ta' riċerka, jekk jogħġbok immarka l-kaxxi li ġejjin kif xieraq waqt li tipprovdi n-numru tat-telefown/mobajl tiegħek hawn:

_____

Naqbel li niġi kkuntattjat/a għal riċerka futura li tirriżulta minn dan l-istudju. ☐

Naqbel li niġi kkuntattjat/a biex ningħata sommarju tar-riżultati ta' dan l-istudju ta' riċerka. ☐

Appendix 6.1: Intervention guide (pilot study)

Session one – pre-quit session

The aim of this session is to inform the participant on the effects of tobacco on diabetes, and to encourage him/her to set a quit attempt and support him/her in quitting smoking. This session should take between 30-60 minutes long.

Take note/confirm the number of cigarettes/tobacco products smoked every day. Start by informing the participant on the effects of smoking on diabetes, as follows:

- *While you may know that tobacco smoking is a well-established risk factor associated with increased health risks and an increased risk of death, there is increasing evidence demonstrating that smoking is associated with increased complications for those who have diabetes.*
- *Filwaqt li jista' jkun li taf li t-tipjip huwa fattur ta' riskju stabbilit sew assoċjat ma' riskji akbar għas-saħħa u riskju akbar ta' mewt, hemm evidenza ċara li turi li t-tipjip huwa assoċjat ma' kumplikazzjonijiet akbar għal dawk li għandhom id-dijabete.*
- *In people with diabetes, smoking can make their insulin less effective, the cells that produce insulin function poorly, and release less insulin. It also contributes to other issues like high levels of sugar and fat in the blood. These all result in a higher risk of diabetic complications such as cardiovascular diseases, including coronary heart disease, stroke, myocardial infarction, heart failure, and poor circulation in the legs and even death from such diseases.*
- *F'individwi bid-dijabete, it-tipjip jista' jagħmel l-insulina tagħhom inqas effettiva, u ma jgħinx liċ-ċelloli li jipproduċu l-insulina jiffunzjonaw tajjeb, u b'hekk jirrilaxxaw inqas insulina. Jikkontribwixxi wkoll għal kwistjonijiet oħra bħal livelli għoljin taz-zokkor u xaħam fid-demm. Dawn kollha jirriżultaw f'riskju ogħla għal kumplikazzjonijiet dijabetiċi bħal mard kardjovaskulari, inkluż mard tal-qalb, puplesija, attakk tal-qalb, insuffiċenza tal-qalb, ċirkolazzjoni ħażina fir-riġlejn u anke mewt minn mard bħal dan.*

Following this information tell the participant that you would like to share with him/her the story of Bill as follows:

- *To remark on what I said, I would like to share with you the story of Bill, a real person with diabetes who used to smoke and only quit after experiencing some diabetic complications associated with smoking: kidney failure, blindness in one eye, heart disease and a leg amputation. I would like to show you the three short video clips that Bill made to encourage other people to quit smoking. The videos have subtitles in English.*

- *Biex nirrimarka fuq dak li għedt, nixtieq naqsam miegħek l-istorja ta' Bill, persuna reali bid-dijabete li kien ipejjep u waqaf biss wara li esperjenza xi kumplikazzjonijiet dijabetiċi assoċjati mat-tipjip: insuffiċjenza tal-kliewi, għama f'għajn waħda, mard tal-qalb u amputazzjoni tar-riġel. Nixtieq nurik it-tliet video clips qosra li għamel Bill biex iħeġġeġ nies oħra jieqfu jpejpu. Il-videos għandhom sottotitli bl-Ingliż.*

After showing the videos do allow some time for reflection or brief discussion, but do not dwell into lengthy conversations. Acknowledge any feelings or comments the participant may state. At this point simply advise <u>in a clear, strong and personalised manner</u> the participant to quit smoking in view of the health benefits:

- *There is clear evidence that quitting smoking provides clear benefits in terms of better blood sugar and cholesterol control and in reducing the risk of cardiovascular diseases and complications, and the risk of death in people with diabetes. It is important that you quit smoking so that you reduce the risk of having a diabetic complication. I can help you to quit smoking!*

- *Hemm evidenza ċara li l-waqfien mit-tipjip jipprovdi benefiċċji ċari f'termini ta' kontroll aħjar taz-zokkor fid-demm u tal-kolesterol u fit-tnaqqis tar-riskju ta' mard kardjovaskulari u kumplikazzjonijiet, u r-riskju ta' mewt f'persuni bid-dijabete. Huwa importanti li tieqaf tpejjep sabiex tnaqqas ir-riskju li jkollok xi kumplikazzjoni dijabetika. Jien nista' ngħinek tieqaf tpejjep!*

Following your advice, assess readiness in setting a quit attempt in the next two weeks by asking the following questions:

- *Would you like to attempt to quit smoking in the next two weeks?*

- *Tixtieq tipprova tieqaf tpejjep fil-ġimagħtejn li ġejjin?*

And

- *Do you think you have a chance of quitting successfully?*
- *Taħseb li għandek ċans li tieqaf b'suċċess?*

If the participant is ready to go ahead with a quit attempt, proceed to assist the participant with the setting of a quit plan. If the participant is unsure or doesn't want to quit smoking within the next two weeks and/or doesn't feel confident in attempting to quit, proceed to the 5Rs algorithm.

Please take note whether you have delivered the 5Rs or not.

The 5Rs algorithm (for participants who are unsure or do not want to quit smoking in the next two weeks and/or not confident in doing so)

While the information provided might have motivated the participant to consider quitting smoking, identifying, and discussing what is particularly relevant to the client (such as, the participant's disease status or risk, family or social situations, health concerns, age, sex, and other important characteristics) might encourage him/her further. Start by asking how quitting smoking would be relevant to the participant:

- *How would quitting smoking be particularly relevant to you?*
- *Kif inhu partikolarment rilevanti għalik li tieqaf mit-tipjip?*

Continue on what the participant has identified as being relevant (for e.g. health) by encouraging the participant to identify the potential negative consequences that are relevant to him/her if he/she continues to smoke, discussing further if required. For e.g. "Having mentioned that you are concerned about your health, what do you know about the risks of continuing smoking? What particularly worries you?"

Furthermore, ask the patient to identify potential benefits of stopping smoking which are relevant to him/her, discussing further if required. For e.g. "What do you know about the health benefits on stopping smoking?"

It is also important to help the participant identify any barriers or impediments to quitting smoking, discussing/providing realistic solutions (e.g. use of Nicotine Replacement Therapy, NRT to deal with cravings, dealing with anxiety/depression using better coping methods, avoiding or using distraction methods in situations which trigger smoking etc.):

- *So, what would be difficult in quitting for you?*
- *Allura, x'ikun diffiċli għalik sabiex tieqaf?*

Finally, after having motivated the participant to attempt to quit smoking and having increased his/her confidence by discussing possible solutions to the identified barriers, reassess readiness to quit smoking in the next two weeks, by asking again the following questions:

- *Now that we have had a little chat, would you like to attempt to quit smoking in the next two weeks?*
- *Issa li tkellimna ftit, tixtieq tipprova tieqaf tpejjep fil-ġimagħtejn li ġejjin?*

And

- *Do you think you have a chance of quitting successfully?*
- *Taħseb li għandek ċans li tieqaf b'suċċess?*

Encourage the participant to give it a try even if he/she is not 100% confident. If the participant is ready to go ahead with a quit attempt, proceed to *Assist* the participant with the setting of a quit plan. If the participant is still not ready to attempt to quit, end the intervention on a positive manner, inviting him/her to seek healthcare professional support/tobacco cessation services when ready. Inform the participant that he will be contacted to fill in the end of study questionnaire at 12 weeks follow-up.

Assist (for participants who intend to attempt quitting within the next two weeks)

After having successfully encouraged the participant to attempt to quit smoking in the next two weeks, proceed to help him/her develop a quit plan, providing practical counselling, and recommending (explaining the use and benefits) and providing a supply of NRT (25mgs nicotine patches, one per day, and nicotine mouth spray for breakthrough urges and/or to reduce withdrawal symptoms further for those who smoke at least 10-15 cigs/day, OR the nicotine mouth spray for those who smoke less than 10cigs/day) for use until the next session. Please note that participants are to receive up to a six-week supply of NRT during the study period.

In helping the participant to develop a quit plan, encourage him/her to talk about the quitting process, communicate caring and concern and encourage him/her further in the quit attempt by referring to/identifying what would be relevant for him/her if he quit smoking (*to motivate*

him/her further). The support given to the participant needs to be described positively but realistically.

Use the STAR method to help the participant develop a quit plan:

- Set a Target Quit Date (TQD) within the next two weeks.
- Tell the participant to inform his family, friends, and co-workers about his/her quitting attempt, and to ask for support.
- Anticipate the challenges or barriers to the upcoming quit attempt.
- Remove any tobacco products from the patient's environment (particularly closer to the quit date) and make the home smoke free.

Help the participant identify the challenges or barriers to the upcoming quit attempt, such as:

- smoking habits or the addiction
- any upcoming events that can trigger smoking
- smoking as a coping mechanism (e.g. to cope with diabetes or cope with stress/sadness)
- and activities or social circumstances that increase the risk of smoking or relapse

Help the participant generate problem-solving strategies to tackle the identified barriers and challenges to quitting, such as:

- the use of motivational techniques (e.g. self-motivation talk, thinking about health complications, reflecting on his/her personal reasons to quit smoking and seeking motivation from others [social support])
- use of helpful distraction (action distraction, thinking distraction, and mouth distraction)
- and taking nicotine replacement therapy (explaining their use and benefits), amongst others.

Advise monitoring of blood glucose. Link the participant to psychological support services if experiencing anxiety or depression (or on further discussion with participants who were identified as potential cases on the Hospital Anxiety and Depression Scale (HADS; Zigmond

and Snaith, 1983), i.e., those who obtained a score of eight or more on the Anxiety or Depression scale).

The participant should be provided with a follow-up appointment during their first week after their TQD. Inform the participant to call the diabetes education unit if he/she cannot make it.

Session two

In this session the participant is to be asked about his/her quit attempt. If the participant is abstinent from smoking (i.e. did not even have a puff for at least 24 hours before the follow-up session), the aim of the session is to help him/her avoid relapse. Conversely, if the participant did not quit smoking, the aim of the session should be to encourage him/her to set a quit attempt and support him/her in quitting smoking. In both cases the session should not take more than 30 minutes.

For those who did not quit smoking

Start off by reminding the participants that this is a learning experience. Take note of the number of cigarettes/tobacco products smoked every day. Take time to assess the use of NRT and any problems encountered (including over/under-dosing), providing recommendations, review experienced barriers and challenges (roadblocks), and elicit (encourage) a recommitment to quit smoking (refer to what is relevant to the participant – risks and rewards).

Encourage the participant to give it a try even if he/she is not 100% confident and proceed to *Assist* the participant with the setting of a quit plan. If the participant is not willing to attempt to quit, end the intervention on a positive manner, inviting him/her to seek healthcare professional support/tobacco cessation services when ready. Inform the participant that he will be contacted to fill in the end of study questionnaire at 12 weeks follow-up.

Assist (for participants who intend to attempt quitting within the next two weeks)

After having successfully encouraged the participant to attempt to quit smoking in the next two weeks, proceed to help him/her develop a quit plan, providing practical counselling, and recommending and topping up the supply of NRT (patch and/or spray) for use until the next session. In helping the participant to develop a quit plan, encourage him/her to talk about the quitting process, communicate caring and concern and encourage him/her further in the quit

attempt by referring to/identifying what would be relevant for him/her if he quit smoking (*to motivate him/her further* The support given to the participant needs to be described positively but realistically.

Use the STAR method to help the participant develop a quit plan:

- Set a TQD within the next two weeks.
- Tell the participant to inform his family, friends, and co-workers about his/her quitting attempt, and to ask for support.
- Anticipate the challenges or barriers to the upcoming quit attempt.
- Remove any tobacco products from the patient's environment (particularly close to the quit date) and make the home smoke free.

Help the participant identify the challenges or barriers to the upcoming quit attempt, such as:

- smoking habits or the addiction
- any upcoming events that can trigger smoking
- smoking as a coping mechanism (e.g. to cope with diabetes or cope with stress/sadness)
- and activities or social circumstances that increase the risk of smoking or relapse

Help the participant generate problem-solving strategies to tackle the identified barriers and challenges to quitting, such as:

- the use of motivational techniques (e.g. self-motivation talk, thinking about health complications, reflecting on his/her personal reasons to quit smoking and seeking motivation from others [social support])
- use of helpful distraction (action distraction, thinking distraction, and mouth distraction)
- and taking nicotine replacement therapy (explaining their use and benefits), amongst others.

Advise monitoring of blood glucose. Link the participant to psychological support services if experiencing anxiety or depression.

The participant should be provided with a follow-up appointment during their first week after their TQD.

For those who quit smoking

The aim of the session is to support the participants in avoiding a relapse.

The participant should be congratulated on stopping smoking. Any problems encountered (barriers and challenges [roadblocks] towards remaining abstinent from smoking), and anticipated challenges are to be discussed. Encourage the participant to remain abstinent (referring to what is relevant to the participant – risks and rewards). The strategies outlined in the quit plan should also be reinforced – remind the participant on the usefulness of social support (linking the participant to psychological support services if experiencing anxiety or depression). The participant is to be asked about the use of NRT and for any problems that were encountered (including over/under-dosing), providing recommendations.

Provide a supply of NRT for use between the session following the quit attempt and the final session. Provide a weekly supply of Step two and Step three patches for the last two weeks instead of Step one patches (for those who initially smoked at least 10-15 cigarettes a day), advising all participants to also reduce the use of the spray during these weeks.

Always advise monitoring of blood glucose. Participants are to be offered a diabetic consultation by the nurse educator (and subsequent specialist/s referrals, if required) if they experience poor glycaemic control, or are concerned about diabetes management following a change in diet or weight gain on quitting smoking.

The participant should be provided with a follow-up appointment within five weeks from their TQD. Inform the participant to call the diabetes education unit if he/she cannot make it.

Session three (for those who reported still smoking at session two)

As in the previous session, in this session the participant is to be asked about his/her quit attempt.

For those who quit smoking

If the participant is abstinent from smoking (i.e. did not even have a puff for at least 24 hours before the follow-up session), the aim of the session is to help him/her avoid relapse.

The participant should be congratulated on stopping smoking. Any problems encountered (barriers and challenges [roadblocks] towards remaining abstinent from smoking), and anticipated challenges are to be discussed. The participant is to be asked about the use of NRT and for any problems that were encountered (including over/under-dosing), providing recommendations. Encourage the participant to remain abstinent (referring to what is relevant to the participant – risks and rewards). The strategies outlined in the quit plan should also be reinforced – remind the participant on the usefulness of social support (linking the participant to psychological support services if experiencing anxiety or depression).

Provide the remaining assigned supply of NRT for use until the final session. Participants will have a supply of Step two and Step three patches for the last two weeks instead of Step one patches (for those who initially smoked at least 10-15 cigarettes a day). Advise all participants to reduce the use of the spray during these weeks.

Always advise monitoring of blood glucose. Participants are to be offered a diabetic consultation by the nurse educator (and subsequent specialist/s referrals, if required) if they experience poor glycaemic control, or are concerned about diabetes management following a change in diet or weight gain on quitting smoking.

The participant should be provided with a follow-up appointment within five weeks from their TQD. Inform the participant to call the diabetes education unit if he/she cannot make it.

For those who did not quit smoking

Conversely, if the participant did not quit smoking, no more sessions are to be provided. Nonetheless, do take some time to assess medication use and any problems and review circumstances (experienced barriers and challenges). End the intervention on a positive manner, encouraging a recommitment to attempt to quit smoking and to seek tobacco cessation services when ready. Inform the participant that he will be contacted to fill in the end of study questionnaire at 12 weeks follow-up.

Final follow-up session (session three or session four)

The aim of the session which is to be provided after five weeks following the TQD is to support the participants in avoiding a relapse.

The participant should be asked about tobacco use. If the participant is still abstinent from smoking, he/she should be congratulated. Conversely, if the participant has relapsed, take note of the number of cigarettes/tobacco products smoked every day, reminding him/her that this is a learning experience.

Either way, any problems encountered (barriers and challenges [roadblocks] towards remaining abstinent from smoking), and anticipated challenges are to be discussed. and anticipated challenges are to be discussed. The participant is to be asked about the use of NRT and for any problems that were encountered (including over/under-dosing), advising him/her to ideally reduce use if still on NRT (and abstinent from smoking). Encourage the participant to attempt quitting again if he/she relapsed or to remain abstinent (referring to what is relevant to the participant – risks and rewards). The strategies outlined in the quit plan should also be reinforced – remind the participant on the usefulness of social support (linking the participant to psychological support services if experiencing anxiety or depression).

Always advise monitoring of blood glucose. Participants are to be offered a diabetic consultation by the nurse educator (and subsequent specialist/s referrals, if required) if they experience poor glycaemic control, or are concerned about diabetes management following a change in diet or weight gain on quitting smoking.

End the intervention on a positive manner. Encourage the participant to seek tobacco cessation services if required. Inform the participant that he will be contacted to fill in the end of study questionnaire at 12 weeks follow-up.

Appendix 6.2: Outline of the training programme (pilot study)

Topics	Content
Basic science (an overview)	tobacco and the health, economic, and social impact the content of cigarette smoking nicotine dependence and withdrawal symptoms tobacco smoking and diabetes the epidemiology of tobacco smoking in people with diabetes - global and local situation the benefits and barriers to quitting smoking cessation and diabetes
Clinical science	a client-centred approach to smoking cessation the 5As and 5Rs algorithm for tobacco cessation interventions using video messages from a former smoker with diabetes to encourage smoking cessation Nicotine Replacement Therapy proposed algorithm for the smoking cessation intervention (including demonstration and role-play)

Appendix 6.3: PowerPoint® presentation of the training programme (pilot study)

Training programme on the diabetes practice nurse-led smoking cessation intervention

Joseph Grech

1

Introduction

- Tobacco kills more than half of those who regularly use it (Drope & Schluger, 2018; World Health Organization, 2014).
- Tobacco smoking has been associated with increased complications for those who have diabetes, negatively impacting on cardiometabolic markers (Kar et al., 2016), accelerating vascular damage (Campagna et al., 2019), thus impacting on diabetes management.

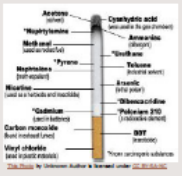
2

Aim

- To equip you with an evidence-based tobacco cessation intervention framework which aims to encourage and support individuals with diabetes to quit smoking.
- This course will help you to apply this framework among your patients/clients, by:
  - *Providing you with a current knowledge base on tobacco and diabetes, its health risks, and the challenges and benefits on quitting.*
  - *Teaching you on the use of the proposed algorithm for supporting smoking cessation.*
  - *And providing you with information on the use and prescription of Nicotine Replacement Therapy for smoking cessation and the other resources that are to be used.*

3

What is in a cigarette?



4

Nicotine

- Tobacco products contain nicotine which is addictive. Cigarettes and other forms of tobacco are addictive.
- Nicotine is highly addictive, as addictive as heroin and cocaine.
- Individuals with type 2 diabetes may metabolize nicotine faster, which in turn leads to a higher tendency to smoke more cigarettes over life, becoming more addicted than other individuals (Keith et al., 2019).

5

Harm from tobacco use

- Tobacco can damage nearly every organ system in the human body, causing many acute medical conditions as well as many chronic diseases including heart disease, strokes, cancer and chronic respiratory diseases.
- Even people who smoke **fewer than 5 cigarettes a day** can have early signs of cardiovascular disease.
- A regular life-long smoker **loses at least 10–11 years of life** to tobacco on average.

6

Smoking and diabetes

- An increased risk for **total cardiovascular disease**, (Relative Risk RR of 1.44, 95% CI[1.34-1.54]), **coronary heart disease** (RR of 1.51, 95% CI [1.41-1.62]), **stroke** (RR of 1.54, 95% CI [1.41-1.69]), **peripheral arterial disease** (RR of 2.15, 95% CI[1.62-2.85]), and **heart failure** (RR of 1.43, 95% CI [1.19-1.72]) compared to those with diabetes who do not smoke (Pan et al., 2015).
- A higher risk for **total mortality**, and for **cardiovascular mortality** has also been identified amongst smokers with diabetes (Qin et al., 2013).
- Tobacco use may also increase the risk of **microvascular diabetes complications**.
- Both individuals with type 1 and type 2 diabetes who smoke also seem to have **poorer cardiometabolic profiles**.

7

Economic and social impact

- 5 – 15% of a smoker's disposable incomes is spent on tobacco.
- The economic cost of tobacco attributed lung cancer (direct healthcare costs and indirect costs due to premature mortality) amounted to 17.7 million Euros in Malta in 2015 (Borg, 2021).
- Smoking affects social interaction and relationships negatively. There is a stigma attached to smoking.

8

Tobacco and diabetes – global and local situation

- The prevalence of smoking is still high amongst those with diabetes (Pan et al., 2015).
- On average 20% and 30% of individuals with type 2 and type 1 diabetes smoke, respectively (Durlach et al., 2022).
- Analysis of unpublished raw data from the European Health Interview Survey conducted in Malta in 2019/20 revealed that **17.4%** of those who reported having diabetes also reported to smoke (Directorate for Health Information and Research, 2023).

9

10

Quitting smoking and diabetes

- In the short-term quitting smoking may be associated with a negative impact on diabetes management.
- Despite the short-term potential negative impact on glycaemic control and weight management post-cessation, evidence still supports the position that quitting smoking provides clear benefits in terms of reducing the risk of cardiovascular morbidity, mortality, and overall mortality in people with diabetes as it does for the general population.

11

Challenges to quitting smoking

- Different people have different reasons why they smoke and why they don't quit.
- Reasons are typically classified into three categories:
  - *Psychological or Emotional connections*
  - *Behavioural and Social connections*
  - *And Physical addiction.*

12

Diabetes-specific challenges

- Factors such as depression (Abu Ghazaleh et al., 2018), or physical suffering (Georges et al., 2019), which are usually associated with diabetes and its complications.
- Smokers with diabetes in fact view smoking as a stress coping mechanism, which they remark as losing in trying to stop (Folan et al., 2014).
- Weight gain on cessation, which may lead may be lead to poor glycaemic control (Campagna et al., 2019), is also a common concern for patients with diabetes in attempting to quit smoking (Chau et al., 2015; Folan et al., 2014).
- Misconceptions about quitting have also been reported in the literature, making it harder for individuals to decide to quit smoking.

13

Withdrawal symptoms

- Craving for a cigarette
- Irritability
- Dizziness
- Chest tightness
- Constipation, stomach pain or gas
- Cough, dry throat and nasal drip
- Depressed mood
- Difficulty concentrating
- Fatigue
- Hunger
- Insomnia

14

Nicotine Replacement Therapy NRT

All smokers who attempt to quit smoking:

- should use NRT as from the quit date – they can also preload for increased effectiveness and for getting used to it (Lindson et al., 2019).
- should be advised to take combination NRT if smoking at least 10-15 cigs/day (Papadakis, 2021).
- should take NRT for as long as required (Lindson et al., 2019), however a minimum number of 5 weeks is suggested (Siahpush et al., 2015).

15

Video messages from a former smoker with diabetes

https://www.cdc.gov/tobacco/campaign/tips/stories/bill.html

16

Affecting change

- The client-centred approach is a non-directive behaviour change approach which enhances rapport building. This approach allows the client to accept responsibility for their own health and therefore to set their own goals. Core conditions of client-centred approach include:
- *Acceptance*
- *Empathy*
- *Genuineness*

20

Proposed algorithm for the smoking cessation intervention (based on the 5As and 5Rs framework)

21

First session

- Aim - to inform the participants on the effects of tobacco on diabetes, and to encourage and support them to quit smoking.
- Participants are informed that smoking does not help in diabetes management and are briefly told about the increased health risks, such as poor glucose and lipid control, and the increased risk for cardiovascular diseases and mortality.
- The participants are then briefly introduced to the story of Bill from the Tips from Former Smokers' campaign (Centers for Disease Control and Prevention (CDC), 2022), and showed the three video clips.
- Participants are advised to quit smoking in view of the health benefits, such as improved glycaemic and lipid control and decreased risk for cardiovascular diseases and mortality.

22

First session (cont.)

- Readiness to set a quit attempt within the next two weeks is then assessed (Assess).
- The 5R's algorithm (Relevance, Risks, Rewards, Roadblocks and Repetition) is followed for those who are unsure or not willing to quit smoking and/or not confident in attempting quitting.

23

First session (cont.)

- Conversely, those who are ready to quit are helped in developing a quit plan (Assist):
- *setting a Target Quit Date (TQD) in the next two weeks;*
- *telling family, friends and co-workers about their decision and asking them for support;*
- *the generation of problem-solving strategies to tackle identified barriers and challenges to quitting*
- *encouraging the use of motivational techniques and the use of helpful distraction as part of a guide to quit smoking;*
- *recommending the use (explaining use and benefits) of NRT, providing the patch and/or the spray for the quitting attempt up till the next follow-up appointment (participants are to receive a six-week supply of NRT in total);*
- *and removing tobacco products and making the house smoke-free.*
- These participants are then provided with a follow-up appointment during their first week after their set TQD (Arrange).

24

Sessions two and three (and four, if required)

- Aim – to assess the quit attempt, providing support accordingly. The second session is usually held in the second or third week, depending on the set TQD.
- For those who are found to have quit smoking, the aim of the session (and of the follow-up session which is provided after five weeks following the TQD) is to support the participants in avoiding a relapse.
- Conversely, those who do not manage to quit smoking are assessed about NRT use and any problems encountered (including over/under-dosing), providing recommendations, also discussing the experienced barriers and challenges. Participants are encouraged to set another TQD and provided with follow-up support (one or two follow-up sessions) accordingly.

25

26

27

Conclusion

- Quitting smoking provides clear benefits for those with diabetes, necessitating the provision of smoking cessation support as part of diabetes management.
- Being based on current evidence, the proposed diabetes practice nurse-led multi-component smoking cessation intervention should be of support and guidance for individuals with diabetes who smoke to quit smoking.

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Thank you!

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Appendix 7.1: Initial version of the questionnaires on the satisfaction with and perceived usefulness of the smoking cessation intervention provided

The following section, further divided in two sub-sections, is about your satisfaction with the smoking cessation intervention provided and your perceptions of its usefulness. Please do not answer this section **if you <u>have not</u>** attended any smoking cessation support sessions.

Satisfaction with the smoking cessation intervention provided

The following sub-section is about your satisfaction with the various elements of the smoking cessation intervention you have received. Please indicate your satisfaction for each statement.

	How satisfied are you with the…	**Very unsatisfied (1)**	**Unsatisfied (2)**	**Neutral (3)**	**Satisfied (4)**	**Very satisfied (5)**
1.	Support you received to stop smoking.	☐	☐	☐	☐	☐
2.	Location where the smoking cessation intervention was provided.	☐	☐	☐	☐	☐
3.	Appointment times given.	☐	☐	☐	☐	☐
4.	Waiting for having your first session.	☐	☐	☐	☐	☐
5.	Duration of each individual session.	☐	☐	☐	☐	☐
6.	Frequency of the follow-up appointments provided.	☐	☐	☐	☐	☐
7.	Number of sessions you had.	☐	☐	☐	☐	☐
8.	Method used to help you quit.	☐	☐	☐	☐	☐

9. **What aspect of the smoking cessation intervention were you most satisfied of? Please explain your answer.**

_____

_____

_____

10. **What aspect of the smoking cessation intervention were you least satisfied of? Please explain your answer.**

_____

_____

_____

Perceived usefulness of the smoking cessation intervention

The following sub-section is about your perceptions of the usefulness of the smoking cessation intervention provided. Please indicate your agreement for each statement.

	The smoking cessation intervention…	**Strongly disagree (1)**	**Disagree (2)**	**Neutral (3)**	**Agree (4)**	**Strongly agree (5)**
1.	Met your expectations.	☐	☐	☐	☐	☐
2.	Applied to you specifically.	☐	☐	☐	☐	☐
3.	Contained helpful information on quitting.	☐	☐	☐	☐	☐
4.	Made you aware of severe diabetic complications caused by smoking.	☐	☐	☐	☐	☐
5.	Made you concerned on the severe diabetes complications caused by smoking.	☐	☐	☐	☐	☐

	The smoking cessation intervention…	Strongly disagree (1)	Disagree (2)	Neutral (3)	Agree (4)	Strongly agree (5)
6.	Made you concerned about your smoking.	☐	☐	☐	☐	☐
7.	Provided you with the motives to quit.	☐	☐	☐	☐	☐
8.	Made you think that it is worthwhile to quit.	☐	☐	☐	☐	☐
9.	Helped you consider a plan to quit smoking.	☐	☐	☐	☐	☐
10.	Helped you identify situations that increase the risk of smoking.	☐	☐	☐	☐	☐
11.	Helped you identify factors to resist urges to smoke.	☐	☐	☐	☐	☐
12.	Helped you to respond effectively to urges to smoke.	☐	☐	☐	☐	☐
13.	Helped you identify the most effective method to quit smoking.	☐	☐	☐	☐	☐
14.	Gave you the confidence so that you can quit.	☐	☐	☐	☐	☐

15. Is there anything that we could do to make the intervention better to make it easier for you to quit smoking?

_____

_____

_____

16. Would you recommend this smoking cessation intervention to someone else?

No ☐ Yes ☐

Appendix 7.2: Content validity assessment form

Determination of content validity of the tools used in a feasibility study of a smoking cessation intervention for individuals with diabetes

Thank you for accepting to fill in this assessment form for content validity. As part of my Ph.D. studies, I will be conducting a randomised feasibility study, randomly assigning smokers with diabetes to a smoking cessation intervention (developed for use amongst individuals with diabetes) or to standard care – one-to-one smoking cessation support sessions by the Health Promotion and Disease Prevention Directorate. After providing participants with the smoking cessation intervention (the developed intervention or standard care), I will be asking participants about their satisfaction with the intervention and about their perceived usefulness of the smoking cessation intervention provided. To assess satisfaction with the intervention, participants will be asked about their satisfaction with the various elements of the smoking cessation intervention provided. To assess their perceptions of the usefulness of the intervention, participants will be asked for their opinion on whether the intervention provided them with the required information, motivation and behavioural skills to attempt to quit or quit smoking.

In filling in this assessment form, you are kindly asked to refer to the attached tools: a satisfaction questionnaire; and a questionnaire on the perceived usefulness of the smoking cessation intervention. Please rate each item of the attached tools as either 1 - 'not relevant', 2 - 'unable to assess relevance without item revision or item is in need of such revision that it would no longer be relevant', 3 - 'relevant but needs minor alteration', or 4 - 'very relevant and succinct'. You can also suggest item alterations, additional items or any other comments.

Rating of the satisfaction questionnaire

Rating key: 1 - 'not relevant', **2** - 'unable to assess relevance without item revision or item is in need of such revision that it would no longer be relevant', **3** - 'relevant but needs minor alteration', or **4** - 'very relevant and succinct'.

Item no.	Rating	Suggested alterations/comments (if any)
1		
2		
3		
4		
5		
6		
7		
8		

Additional items/other comments (if any):

Rating of the perceived usefulness questionnaire

Rating key: **1** - 'not relevant', **2** - 'unable to assess relevance without item revision or item is in need of such revision that it would no longer be relevant', **3** - 'relevant but needs minor alteration', or **4** - 'very relevant and succinct'.

Item no.	Rating	Suggested alterations/comments (if any)
1		
2		
3		
4		
5		
6		
7		
8		
9		

Item no.	Rating	Suggested alterations/comments (if any)
10		
11		
12		
13		
14		

Additional items/other comments (if any):

Appendix 7.3: Final version of the questionnaires on the satisfaction with and perceived usefulness of the smoking cessation intervention provided

The following section, further divided in two sub-sections, is about your satisfaction with the smoking cessation intervention provided and your perceptions of its usefulness. Please do not answer this section **if you <u>have not</u>** attended any smoking cessation support sessions.

Satisfaction with the smoking cessation intervention provided

The following sub-section is about your satisfaction with the various elements of the smoking cessation intervention you have received. Please indicate your satisfaction for each statement.

	How satisfied are you with the…	**Very unsatisfied (1)**	**Unsatisfied (2)**	**Neutral (3)**	**Satisfied (4)**	**Very satisfied (5)**
1.	Support you received to help you quit smoking.	☐	☐	☐	☐	☐
2.	Location where the smoking cessation intervention was provided.	☐	☐	☐	☐	☐
3.	Appointment times given.	☐	☐	☐	☐	☐
4.	Waiting period for having your first session.	☐	☐	☐	☐	☐
5.	Duration of each individual session.	☐	☐	☐	☐	☐
6.	Time interval between appointments.	☐	☐	☐	☐	☐
7.	Number of sessions you had.	☐	☐	☐	☐	☐
8.	Method used to help you quit.	☐	☐	☐	☐	☐

9. **What aspect of the smoking cessation intervention were you most satisfied with? Please explain your answer.**

_____

_____

_____

10. **What aspect of the smoking cessation intervention were you least satisfied with? Please explain your answer.**

_____

_____

_____

Perceived usefulness of the smoking cessation intervention

The following sub-section is about your perceptions of the usefulness of the smoking cessation intervention provided. Please indicate your agreement for each statement.

	The smoking cessation intervention…	**Strongly disagree (1)**	**Disagree (2)**	**Neutral (3)**	**Agree (4)**	**Strongly agree (5)**
1.	Met your expectations.	☐	☐	☐	☐	☐
2.	Applied to you specifically.	☐	☐	☐	☐	☐
3.	Provided you with helpful information about quitting.	☐	☐	☐	☐	☐
4.	Made you concerned on the severe diabetes complications caused by smoking.	☐	☐	☐	☐	☐
5.	Made you concerned about your smoking.	☐	☐	☐	☐	☐

	The smoking cessation intervention…	Strongly disagree (1)	Disagree (2)	Neutral (3)	Agree (4)	Strongly agree (5)
6.	Provided you with the motives to quit.	☐	☐	☐	☐	☐
7.	Made you think that it is worthwhile to quit.	☐	☐	☐	☐	☐
8.	Helped you consider a plan to quit smoking.	☐	☐	☐	☐	☐
9.	Helped you identify situations that increase your risk of smoking.	☐	☐	☐	☐	☐
10.	Helped you identify strategies to resist urges to smoke.	☐	☐	☐	☐	☐
11.	Helped you to respond effectively to urges to smoke.	☐	☐	☐	☐	☐
12.	Provided you with options on how to quit smoking.	☐	☐	☐	☐	☐
13.	Helped you identify the most effective method to quit smoking.	☐	☐	☐	☐	☐
14.	Gave you the confidence so that you can quit.	☐	☐	☐	☐	☐

15. Is there anything that we could do to make the intervention better to make it easier for you to quit smoking?

_____

_____

_____

16. Would you recommend this smoking cessation intervention to someone else?

No ☐ Yes ☐

Appendix 7.4 Recruitment flyer/poster in English (pilot and feasibility studies)

Are you 18 years old or older, a smoker, and have diabetes?

Would you consider changing your smoking habits?

If you answered **YES** to both questions, I am inviting you to participate in a study on smoking cessation. My name is Joseph Grech and I am evaluating the feasibility and acceptability of a smoking cessation intervention among individuals with diabetes.

Please contact me directly on 9[redacted]4 or on **joseph.grech.02@um.edu.mt** for more information or to participate in this study. Thank you in advance!

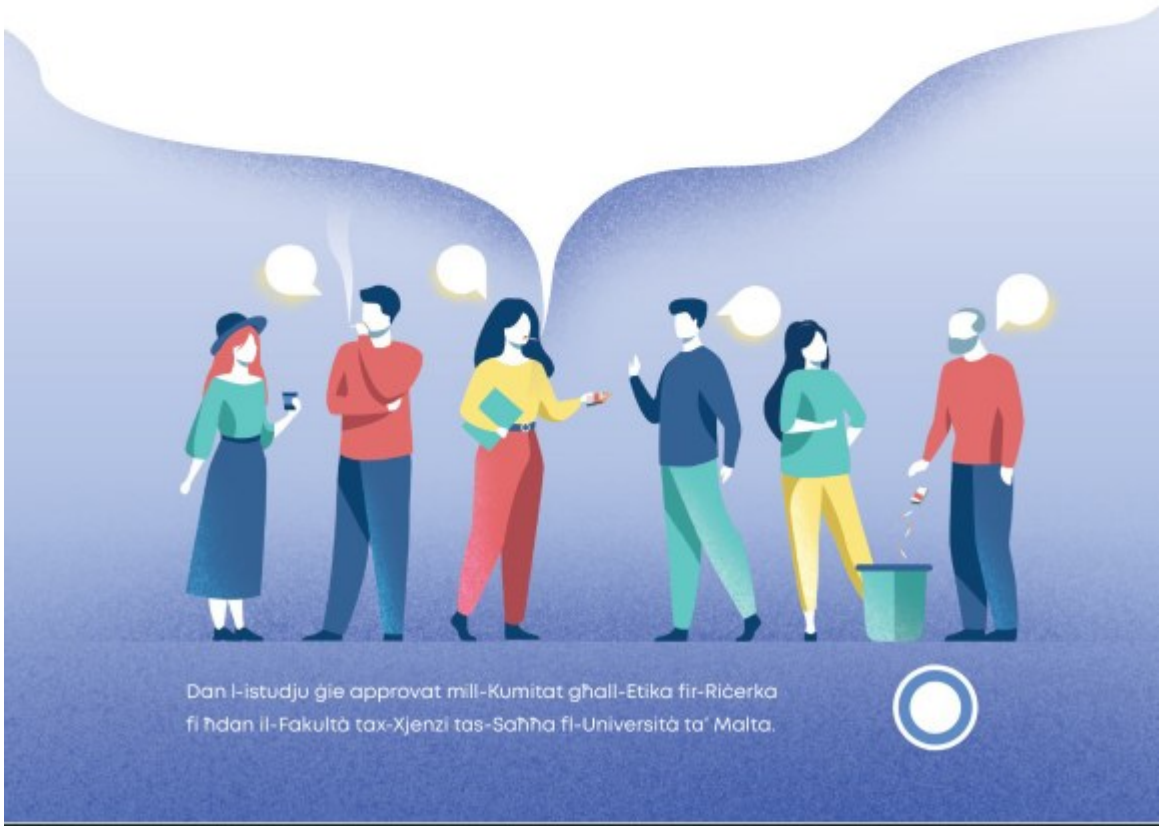
Appendix 7.5 Recruitment flyer/poster in Maltese (pilot and feasibility studies)

Għandek 18-il sena jew aktar, tpejjep, u għandek id-dijabete?

Tikkunsidra li tbiddel id-drawwiet tat-tipjip tiegħek?

Jekk weġibt **IVA** għaż-żewġ mistoqsijiet, qed nistiednek biex tipparteċipa fi studju dwar il-waqfien mit-tipjip. Jisimni Joseph Grech u qed nivvaluta l-fattibilità u l-aċċettabilità ta' intervent ta' waqfien mit-tipjip fost individwi bid-dijabete.

Jekk jogħġbok ikkuntattjani direttament fuq 9[redacted]4 jew fuq **joseph.grech.02@um.edu.mt** għal aktar informazzjoni jew biex tipparteċipa f'dan l-istudju. Grazzi bil-quddiem!



Appendix 7.6 Interview guide (for individuals with diabetes) in English (pilot study)

Introduction

Thank you for sharing some of your time with me and for consenting to be interviewed. So, I will be recording this interview with your permission. First, I have a few questions about your personal characteristics, and your diabetes and smoking profile. Then I will be asking you for your overall feedback on the smoking cessation intervention. The interview usually takes about 30-40 minutes.

At any time please let me know if you need me to clarify any of the questions. Do you have any questions before we start? Are we okay to start?

So I will starting recording – is that okay?

Questions

Personal characteristics and participants' diabetes and smoking profile

1. Can you please tell me your age?
2. What type of diabetes do you have?
3. How many smoking cessation support sessions did you attend? Did you complete the intervention, or did you stop attending?
4. Did you use the provided Nicotine Replacement Therapy on attempting to quit smoking?
5. Did you quit smoking at any point during the study? If you currently smoke, what type of tobacco and how much do you smoke?

Overall feedback

In this session, I will be asking you for your overall feedback on the smoking cessation intervention.

6. What are your general impressions of the smoking cessation intervention?
   Probes: What did you like about this intervention? What did you like least? What do you think about the shown video messages? What do you think about the sessions that were provided? What do you think about the provided Nicotine Replacement Therapy?
7. What do you think about the delivery method?
   Probes: How relevant was this to you? How easy was it to participate?
8. What do you think about the overall duration of the smoking cessation intervention?
   Probes: What do you think of the duration of each individual contact and the frequency of contacts provided?
9. What barriers did you experience in participating in this smoking cessation intervention?
   Probes: What difficulties did you encounter to fully participate in this smoking cessation intervention? What can we do to keep you engaged?

Any other issues

10. Is there anything else that we have not addressed that would be required to meet your preferences and needs for stopping smoking?
    Probe: Can you think of anything else that we could change or add to this smoking cessation intervention to make it better and more helpful for smokers with diabetes to quit?

Appendix 7.7 Interview guide (for individuals with diabetes) in Maltese (pilot study)

Introduzzjoni

Grazzi talli qsamt ftit mill-ħin tiegħek miegħi u talli tajtni l-kunsens sabiex tiġi intervistat/a. Bil-permess tiegħek jien se nkun qiegħed nirreġistra din l-intervista. L-ewwel għandi ftit mistoqsijiet dwar il-karatteristiċi personali tiegħek, u l-profil tad-dijabete u tat-tipjip tiegħek. Imbagħad se nkun qed nitolbok ir-rispons ġenerali tiegħek dwar l-intervent tal-waqfien mit-tipjip. Ġeneralment l-intervista tieħu madwar 30-40 minuta.

Fi kwalunkwe ħin jekk jogħġbok għarrafni jekk għandekx bżonn li niċċara xi mistoqsija/ijiet. Għandek xi mistoqsijiet qabel ma nibdew? Aħna tajbin biex nibdew?

Allura se nibda nirreġistra - tajjeb?

Mistoqsijiet

Karatteristiċi personali u l-profil tad-dijabete u tat-tipjip tal-parteċipanti

1. Tista' jekk jogħġbok tgħidli kemm għandek żmien?
2. Liema tip tad-dijabete għandek?
3. Kemm attendejt sessjonijiet ta' appoġġ għall-waqfien mit-tipjip? Lestejt l-intervent, jew waqaft tattendi?
4. Użajt is-sostituzzjoni terapewtika tan-nikotina pprovduta meta ppruvajt tieqaf tpejjep?
5. Waqaft mit-tipjip f'xi mument matul l-istudju? Jekk bħalissa qiegħed tpejjep, xi tpejjep tabakk u kemm tpejjep?

Rispons ġenerali

F' din is-sessjoni, se nkun qed nitolbok ir-rispons ġenerali tiegħek dwar l-intervent tal-waqfien mit-tipjip.

6. X’inhuma l-impressjonijiet ġenerali tiegħek dwar l-intervent tal-waqfien mit-tipjip?
   Mistoqsijiet addizzjonali: X’għoġbok minn dan l-intervent? X’inhu l-inqas li għoġbok? X'taħseb dwar il-messaġġi bil-vidjo murija? X'taħseb dwar is-sessjonijiet li ġew ipprovduti? X'taħseb dwar l-għoti tas-sostituzzjoni terapewtika tan-nikotina?
7. X’taħseb dwar il-metodu propost ta’ kif l-intervent ġie pprovdut?
   Mistoqsijiet addizjonali: Kemm kien relevanti għalik? Kemm kien faċli li tipparteċipa?
8. X’taħseb dwar it-tul ta’ żmien ġenerali tal-intervent tal-waqfien mit-tipjip?
   Mistoqsijiet addizzjonali: X’taħseb dwar it-tul ta’ kull kuntatt individwali u l-frekwenza tal-kuntatti li ġew ipprovduti?
9. Liema ostakli esperjenzajt meta pparteċipajt f’dan l-intervent għall-waqfien mit-tipjip?
   Mistoqsija addizzjonali: X’diffikultajiet sibt biex tipparteċipa bis-sħiħ f’dan l-intervent ta’ waqfien mit-tipjip? X’nistgħu nagħmlu biex ngħinuk tibqa nvolut?

Kwalunkwe kwistjoni oħra

10. Hemm xi ħaġa oħra li ma indirizzajniex li tkun meħtieġa biex tissodisfa l-preferenzi u l-bżonnijiet tiegħek biex tieqaf tpejjep?

    Mistoqsija addizzjonali: Tista’ taħseb f’xi ħaġa oħra li nistgħu nbiddlu jew inżidu ma' dan l-intervent ta’ waqfien mit-tipjip biex nagħmluh aħjar u ta’ aktar għajnuna għal dawk li għandhom id-dijabete u jpejpu biex jieqfu

Appendix 7.8 Interview guide (for nurses – pilot study)

Introduction

Thank you for sharing some of your time with me and for consenting to be interviewed. So, I will be recording this interview with your permission. First, I have a few questions about your personal and professional characteristics. Then I will be asking you for your overall feedback on the smoking cessation intervention. The interview usually takes about 30-40 minutes.

At any time, please let me know if you need me to clarify any of the questions. Do you have any questions before we start? Are we okay to start?

So, I will start recording – is that okay?

Questions

Personal and professional characteristics

1. Can you please tell me your age?
2. How long have you been practicing as a nurse?
3. How long have you been practicing as a diabetes practice nurse?

Overall feedback

In this session, I will be asking you for your overall feedback on the recruitment process and the smoking cessation intervention.

4. What do you think about the recruitment method of this study?
   Probes: How was it? Did you encounter any difficulties in identifying patients who smoke, inviting smokers to participate to the study?
5. What are your general impressions of the smoking cessation intervention?
   Probes: What did you like about this intervention? What did you like least? What do you think about the shown video messages? What do you think about the sessions that

were provided? What do you think about the provided Nicotine Replacement Therapy?

6. What do you think about the delivery method?
   Probes: How relevant was this to you?
7. What do you think about the overall duration of the smoking cessation intervention?
   Probes: What do you think of the duration of each individual contact and the frequency of contacts provided?
8. What barriers did you experience in delivering this smoking cessation intervention?
   Probe: What difficulties did you encounter in providing this smoking cessation intervention?
9. What facilitated the delivery of the smoking cessation intervention?
   Probe: What helped you to deliver the smoking cessation intervention as intended?

Any other issues

10. Is there anything else that we have not addressed that would be required to meet the preferences and needs of individuals with diabetes for stopping smoking?
    Probe: Can you think of anything else that we could change or add to this smoking cessation intervention to make it better and more helpful for smokers with diabetes to quit?

Appendix 7.9 Baseline questionnaire (pilot study – in English)

Thank you for accepting to participate in this study. As part of this study, please fill in this baseline questionnaire. The following questions are about your personal characteristics, your health status, your diabetes and smoking profiles, and your feelings in the past week. Where applicable please tick the chosen answer (✓). Please let me know if you require assistance in filling in this questionnaire, or if you have any questions.

Participant's code (please write down your unique participant code here) ☐

Exhaled carbon monoxide reading (for office use only) _____

Participants' characteristics

The first section of this questionnaire is about your personal characteristics.

1. **Are you male or female, or you prefer not to say?**

   Male ☐ Female ☐

   Prefer not to say ☐

2. **How old are you now?**

   _____years old

3. **Do you live on your own?**

   Yes ☐ No ☐

4. **Do you live with someone who smokes?**

   Yes ☐ No ☐

5. **What is the highest level of education you have successfully completed?**

   _____

6. **Which of the following best describes your current <u>main activities</u>?**

   Student ☐ Home duties ☐

   Employed ☐ Retired ☐

   Unemployed ☐

Health status and diabetes profile

The following six questions are about your health status and your diabetes profile.

7. **How is your health in general?**

   Very good ☐

   Good ☐

   Fair ☐

   Bad ☐

   Very bad ☐

8. **How old were you when you were first diagnosed with diabetes?**

   _____years old

9. **What type of diabetes were you diagnosed of?**

   Type 1 ☐ Type 2 ☐

10. **How do you treat diabetes?**

    By diet only ☐ Antidiabetic pills and insulin ☐

    Antidiabetic pills ☐ Insulin ☐

11. Are you suffering from any health problems/complications caused by diabetes? If yes, what are these conditions?

Yes ☐ Conditions: _____

No ☐ Don't know ☐

12. Are you suffering from any other chronic diseases?

Yes ☐ Conditions: _____

No ☐ Don't know ☐

Smoking profile

This section is about your smoking profile. This is further divided into three sub-sections: smoking history, dependence on cigarettes, and quitting smoking.

Smoking history

This section is about your smoking history and current smoking habit.

13. How old were you when you first started smoking?

_____years old

14. Do you currently smoke tobacco daily or less than daily?

Daily ☐ Less than daily ☐

15. **On average, how many of the following products do you currently smoke each day/week (<u>please indicate accordingly</u>)?** Strikethrough products which you do not use.

    Manufactured cigarettes _____ per day/week

    Hand-rolled cigarettes _____ per day/week

    Pipes full of tobacco _____ per day/week

    Cigars, cheroots, or cigarillos _____ per day/week

    Number of waterpipe (shisha) sessions _____ per day/week

    Others (including smokeless tobacco products and alternative products, e.g., electronic cigarettes): _____ per day/week

Dependence on cigarettes (The Cigarette Dependence Scale, CDS-5; Etter et al., 2003)

This section is about your addiction to cigarettes.

16. **Please rate your addiction to cigarettes on a scale of 0 – 100: _____**

    I am NOT addicted to cigarettes at all = 0

    I am extremely addicted to cigarettes = 100

17. **On average, how many cigarettes do you smoke per day?**

    _____ cigarette/day

18. **Usually, how soon after waking up do you smoke your first cigarette?**

    _____ minutes

19. **For you, quitting smoking for good would be:**

    Impossible ☐

    Very difficult ☐

    Fairly difficult ☐

    Fairly easy ☐

    Very easy ☐

20. Please indicate whether you agree with the following statement:

After a few hours without smoking, I feel an irresistible urge to smoke.

Totally disagree ☐

Somewhat disagree ☐

Neither agree nor disagree ☐

Somewhat agree ☐

Fully agree ☐

Quitting smoking

The following section is about your previous quit attempts and about your current intentions on quitting smoking.

21. Have you attempted to quit smoking in the past 12 months?

Yes ☐ No ☐

22. Have you ever been able to quit smoking? (i.e. not even a puff for at least seven consecutive days)

Never tried quitting ☐ Yes ☐

No ☐

23. Which of the following best describes you? (Motivation To Stop Scale; Kotz et al., 2013)

I don't want to stop smoking ☐

I think I should stop smoking but don't really want to ☐

I want to stop smoking but haven't thought about when ☐

I REALLY want to stop smoking but don't know when I will ☐

I want to stop smoking and hope to soon ☐

I REALLY want to stop smoking and intend to in the next 3 months ☐

I REALLY want to stop smoking and intend to in the next month ☐

Hospital Anxiety and Depression Scale (HADS; Zigmond and Snaith, 1983)

The final section assesses how you have been feeling in the past week. Read each item and please tick (✓) the box opposite the reply which comes closest to how you have been feeling in the past week.

Do not take too long over your replies: your immediate is best.

24. I feel tense or 'wound up':

Most of the time ☐

A lot of the time ☐

From time to time, occasionally ☐

Not at all ☐

25. I still enjoy the things I used to enjoy:

Definitely as much ☐

Not quite so much ☐

Only a little ☐

Hardly at all ☐

26. I get a sort of frightened feeling as if something awful is about to happen:

Very definitely and quite badly ☐

Yes, but not too badly ☐

A little, but it doesn't worry me ☐

Not at all ☐

27. I can laugh and see the funny side of things:

As much as I always could ☐

Not quite so much now ☐

Definitely not so much now ☐

Not at all ☐

28. Worrying thoughts go through my mind:

A great deal of the time ☐

A lot of the time ☐

From time to time but not too often ☐

Only occasionally ☐

29. I feel cheerful:

Not at all ☐

Not often ☐

Sometimes ☐

Most of the time ☐

30. I can sit at ease and feel relaxed:

Definitely ☐

Usually ☐

Not often ☐

Not at all ☐

31. 1 feel as if I am slowed down:

Nearly all the time ☐

Very often ☐

Sometimes ☐

Not at all ☐

32. I get a sort of frightened feeling like 'butterflies' in the stomach:

Not at all ☐

Occasionally ☐

Quite often ☐

Very often ☐

33. I have lost interest in my appearance:

Definitely ☐

I don't take so much care as I should ☐

I may not take quite as much care ☐

I take just as much care as ever ☐

34. I feel restless as if I have to be on the move:

Very much indeed ☐

Quite a lot ☐

Not very much ☐

Not at all ☐

35. I look forward with enjoyment to things:

As much as ever I did ☐

Rather less than I used to ☐

Definitely less than I used t o ☐

Hardly at all ☐

36. I get sudden feelings of panic:

Very often indeed ☐

Quite often ☐

Not very often ☐

Not at all ☐

37. I can enjoy a good book or radio or TV programme:

Often ☐

Sometimes ☐

Not often ☐

Very seldom ☐

Doctors are aware that emotions play an important part in most illnesses. If your doctor knows about these feelings she/he will be able to help you more. If you are concerned about your current feelings speak to your doctor for more support.

Thank you for completing this questionnaire!

Appendix 7.10 End of study questionnaire (pilot study – in English)

Thank you for accepting to fill in this questionnaire. The following questions are about your quitting attempt and your smoking status, about the support you have received during the study period, and about your satisfaction with the smoking cessation intervention provided and your perceptions of its usefulness. Where applicable please tick the chosen answer (✓). Please let me know if you require assistance in filling in this questionnaire, or if you have any questions.

Participant's code (please write down your unique participant code here) ☐

Exhaled carbon monoxide reading (for office use only) _____

Urine cotinine result (for office use only) _____

Smoking profile

The first section is about your quitting attempt during the intervention period, and your current smoking status if you still smoke.

1. **During the last 12 weeks have you intentionally spent at least one day (≥24 hours) not smoking any cigarettes or any tobacco products (i.e. you did not even take a puff), and not using any smokeless tobacco products or any alternative products such as electronic cigarettes?**

   No ☐ *Please go to question no. 4*

   Yes ☐ *Please go to question no. 2*

2. **During the last 12 weeks have you spent at least seven consecutive days not smoking any cigarettes or any tobacco products (i.e. you did not even take a puff), and not using any smokeless tobacco products or any alternative products such as electronic cigarettes?**

   No ☐ *Please go to question no. 4*

   Yes ☐ *Please go to question no. 3*

3. **In the last seven days have you smoked a cigarette or another tobacco product (even if you took a puff), or used a smokeless tobacco product or an alternative product such as an electronic cigarette?**

   Yes ☐ *Please go to question no. 4*

   No, I have not even had a puff for at least seven days ☐ *Please go to the next section*

4. **On average, how many of the following products do you currently smoke each day/week (<u>please indicate accordingly</u>)?** Strikethrough products which you do not use.

   Manufactured cigarettes _____ per day/week

   Hand-rolled cigarettes _____ per day/week

   Pipes full of tobacco _____ per day/week

   Cigars, cheroots, or cigarillos _____ per day/week

   Number of waterpipe (shisha) sessions _____ per day/week

   Others (including smokeless and alternative products, e.g., electronic cigarettes): _____ per day/week

Support received

The following section is about the smoking cessation support sessions that you have received and about any additional support that you may have received.

5. **Have you attended all the scheduled smoking cessation sessions? If no, please state why.**

   Yes ☐

   No ☐ _____

6. **How many smoking cessation support sessions did you attend?**

   None ☐ One session ☐

   Two sessions ☐ Three sessions ☐

   Four sessions ☐ Other:_____

7. **Over how many weeks did you attend these support sessions?**

   _____ weeks

8. **Did you take any nicotine replacement therapy/medication to help you quit smoking? If yes, please state what.**

   No ☐

   Yes ☐ _____

   How frequently and for how many days did you take this?

   _____

   _____

9. **Is there anything else which was not provided as part of the smoking cessation support provided which you found useful in attempting to quit smoking during the study period?**

   _____

   _____

   _____

Satisfaction with and perceived usefulness of the smoking cessation intervention provided

The following section, further divided in two sub-sections, is about your satisfaction with the smoking cessation intervention provided and your perceptions of its usefulness. Please do not answer this section **if you <u>have not</u>** attended any smoking cessation support sessions.

Satisfaction with the smoking cessation intervention provided

The following sub-section is about your satisfaction with the various elements of the smoking cessation intervention you have received. Please indicate your satisfaction for each statement.

	How satisfied are you with the…	Very unsatisfied (1)	Unsatisfied (2)	Neutral (3)	Satisfied (4)	Very satisfied (5)
10.	Support you received to help you quit smoking.	☐	☐	☐	☐	☐
11.	Location where the smoking cessation intervention was provided.	☐	☐	☐	☐	☐
12.	Appointment times given.	☐	☐	☐	☐	☐
13.	Waiting period for having your first session.	☐	☐	☐	☐	☐
14.	Duration of each individual session.	☐	☐	☐	☐	☐
15.	Time interval between appointments.	☐	☐	☐	☐	☐
16.	Number of sessions you had.	☐	☐	☐	☐	☐
17.	Method used to help you quit.	☐	☐	☐	☐	☐

18. What aspect of the smoking cessation intervention were you most satisfied with? Please explain your answer.

_____

_____

_____

19. What aspect of the smoking cessation intervention were you least satisfied with? Please explain your answer.

_____

_____

_____

Perceived usefulness of the smoking cessation intervention

The following sub-section is about your perceptions of the usefulness of the smoking cessation intervention provided. Please indicate your agreement for each statement.

	The smoking cessation intervention…	**Strongly disagree (1)**	**Disagree (2)**	**Neutral (3)**	**Agree (4)**	**Strongly agree (5)**
20.	Met your expectations.	☐	☐	☐	☐	☐
21.	Applied to you specifically.	☐	☐	☐	☐	☐
22.	Provided you with helpful information about quitting.	☐	☐	☐	☐	☐
23.	Made you concerned on the severe diabetes complications caused by smoking.	☐	☐	☐	☐	☐
24.	Made you concerned about your smoking.	☐	☐	☐	☐	☐
25.	Provided you with the motives to quit.	☐	☐	☐	☐	☐
26.	Made you think that it is worthwhile to quit.	☐	☐	☐	☐	☐
27.	Helped you consider a plan to quit smoking.	☐	☐	☐	☐	☐
28.	Helped you identify situations that increase your risk of smoking.	☐	☐	☐	☐	☐
29.	Helped you identify strategies to resist urges to smoke.	☐	☐	☐	☐	☐

	The smoking cessation intervention…	Strongly disagree (1)	Disagree (2)	Neutral (3)	Agree (4)	Strongly agree (5)
30.	Helped you to respond effectively to urges to smoke.	☐	☐	☐	☐	☐
31.	Provided you with options on how to quit smoking.	☐	☐	☐	☐	☐
32.	Helped you identify the most effective method to quit smoking.	☐	☐	☐	☐	☐
33.	Gave you the confidence so that you can quit.	☐	☐	☐	☐	☐

34. Is there anything that we could do to make the intervention better to make it easier for you to quit smoking?

_____

_____

_____

35. Would you recommend this smoking cessation intervention to someone else?

No ☐ Yes ☐

Thank you for completing this questionnaire!

Appendix 7.11 Translation validity assessment form

Determination of translation validity of the tools used in a feasibility study of a smoking cessation intervention for individuals with diabetes

Thank you for accepting to fill in this assessment form for translation validity. As part of my Ph.D. studies, I will be conducting a randomised feasibility study, randomly assigning smokers with diabetes to a smoking cessation intervention (developed for use amongst individuals with diabetes) or to standard care – one-to-one smoking cessation support sessions by the Health Promotion and Disease Prevention Directorate. Before providing participants with the smoking cessation intervention (the developed intervention or standard care), I will be asking participants about their tobacco dependence and motivation to quit smoking, using the validated Cigarette Dependence Scale and the Motivation to Stop Scale, respectively. Following the intervention, I will be asking the participants about their satisfaction with the intervention and about their perceptions of its usefulness using the questionnaires that you have previously assessed for content validity.

These four questionnaires have been translated into Maltese and back translated into English (and compared to the original versions) by bilingual translators who ensured their literal and syntactic equivalence and that the original denotation and connotation of the items still applied. I (together with my supervisor) overlooked this process to ensure that the same concept was being measured throughout for each item. I would now like to kindly ask you to evaluate the equivalence of the translated versions of these questionnaires to help ensure content validity. I would like you to compare the items of the translated questionnaires (Maltese version) to the original English ones to ensure that the original concept still applies, i.e. is being measured.

In filling in this assessment form, you are kindly asked to refer to the attached tools, the English and the translated versions (in Maltese) of the: Cigarette Dependence Scale-5 (CDS-5); Motivation to Stop Scale (MTSS); the satisfaction questionnaire; and the perceived usefulness questionnare. Please rate all the items in the questionnaires in Maltese as either: 1 = totally different; 2 = needs major item modification to be equivalent; 3 = equivalent but needs minor modification; 4 = equivalent.

Rating of MTSS (the Motivation to Stop Scale defines motivation in terms of its key elements: beliefs about what one should do, and desire and intention to act in a particular way).

Rating key: 1 = totally different; 2 = needs major item modification to be equivalent; 3 = equivalent but needs minor modification; 4 = equivalent.

Item no.	Rating	Suggested alterations/comments (if any)
1 (sentence 1 [absence of any belief, desire or intention)		
1 (sentence 2 [belief only])		
1 (sentence 3 [moderate desire but no intention])		
1 (sentence 4 [strong desire but no intention])		
1 (sentence 5 [moderate desire and intention])		
1 (sentence 6 [strong desire and medium-term intention])		
1 (sentence 7 [strong desire and short-term intention])		

Rating of CDS-5 (The Cigarette Dependence Scale is based on the dimensions of the DSM–IV and ICD-10 definitions of tobacco dependence)

Rating key: 1 = totally different; 2 = needs major item modification to be equivalent; 3 = equivalent but needs minor modification; 4 = equivalent.

Item no.	Rating	Suggested alterations/comments (if any)
1		
2		
3		
4		
5		

Rating of satisfaction questionnaire (measures satisfaction with the various elements of the smoking cessation intervention provided)

Rating key: 1 = totally different; 2 = needs major item modification to be equivalent; 3 = equivalent but needs minor modification; 4 = equivalent.

Item no.	Rating	Suggested alterations/comments (if any)
1		
2		
3		
4		
5		
6		
7		
8		

Rating of the perceived usefulness questionnaire (Assesses participants perceptions on whether the intervention provided them with the required information, motivation and behavioural skills to attempt to quit or quit smoking)

Rating key: 1 = totally different; 2 = needs major item modification to be equivalent; 3 = equivalent but needs minor modification; 4 = equivalent.

Item no.	Rating	Suggested alterations/comments (if any)
1		
2		
3		
4		
5		
6		
7		
8		
9		

Item no.	Rating	Suggested alterations/comments (if any)
10		
11		
12		
13		
14		

Appendix 7.12 Baseline questionnaire (pilot study – in Maltese)

Grazzi talli aċċettajt li tipparteċipa f'dan l-istudju. Bħala parti minn dan l-istudju, jekk jogħġbok imla dan il-kwestjonarju bażi. Il-mistoqsijiet li ġejjin huma dwar il-karatteristiċi personali tiegħek, l-istat ta' saħħtek, il-profil tad-dijabete u tat-tipjip tiegħek, u s-sentimenti tiegħek fil-ġimgħa li għaddiet. Fejn applikabbli jekk jogħġbok immarka t-tweġiba magħżula (✓). Jekk jogħġbok għarrafni jekk teħtiġx għajnuna biex timla dan il-kwestjonarju, jew jekk għandek xi mistoqsijiet.

Kodiċi tal-parteċipant (jekk jogħġbok ikteb il-kodiċi tal-parteċipant uniku tiegħek hawn) ☐

Qari tat-test tan-nifs tal-monossidu tal-karbonju (għall-użu tal-uffiċċju biss)

_____

Il-karatteristiċi tal-Parteċipanti

L-ewwel taqsima ta' dan il-kwestjonarju hija dwar il-karatteristiċi personali tiegħek.

1. **Int raġel jew mara, jew tippreferi li ma tgħidx?**

   Raġel ☐ Mara ☐

   Nippreferi li ma ngħidx ☐

2. **Kemm għandek żmien issa?**

   _____sena

3. **Tgħix waħdek?**

   Iva ☐ Le ☐

4. **Tgħix ma’ xi ħadd li jpejjep??**

   Iva ☐ Le ☐

5. **X'inhu l-ogħla livell ta’ edukazzjoni li temmejt b'suċċess?**

   _____

6. **Liema minn dawn li ġejjin l-aħjar li jiddeskrivu l-<u>attivitajiet ewlenin attwali tiegħek</u>?**

   Student ☐ Dmirijiet tad-dar ☐

   Impjegat ☐ Irtirat/a ☐

   Bla xogħol ☐

L-istat ta’ saħħtek u l-profil tad-dijabete

Is-sitt mistoqsijiet li ġejjin huma dwar l-istat ta’ saħħtek u l-profil dijabetiku tiegħek.

7. **Kif inhi saħħtek inġenerali?**

   Tajba ħafna ☐

   Tajba ☐

   Insomma ☐

   Ħażina ☐

   Ħażina ħafna ☐

8. **Kemm kellek żmien meta ġejt iddijanjostikat/a bid-dijabete għall-ewwel darba?**

   _____sena

9. **B’liema tip ta’ dijabete ġejt iddijanjostikat/a?**

   Tat-tip wieħed ☐ Tat-tip tnejn ☐

10. Kif tittratta d-dijabete?

Bid-dieta biss ☐ Pilloli kontra d-dijabete u insulina ☐

Pilloli kontra d-dijabete ☐ Insulina ☐

11. Int qiegħed/a tbati minn xi problemi/kumplikazzjonijiet tas-saħħa kkawżati mid-dijabete? Jekk iva, x'inhuma dawn il-kundizzjonijiet?

Iva ☐ Il-kundizzjonijiet: _____

Le ☐ Ma nafx ☐

12. Qed tbati minn xi mard kroniku ieħor?

Iva ☐ Il-kundizzjonijiet: _____

Le ☐ Ma nafx ☐

Profil tat-Tipjip

Din it-taqsima hija dwar il-profil tat-tipjip tiegħek. Din it-taqsima hija maqsuma fi tlitt subtaqsimiet: l-istorja tat-tipjip, id-dipendenza fuq is-sigaretti, u l-waqfien mit-tipjip.

L-istorja tat-tipjip

Din it-taqsima hija dwar l-istorja tat-tipjip tiegħek u l-vizzju kurrenti tiegħek tat-tipjip.

13. Kemm kellek żmien meta bdejt tpejjep għall-ewwel darba?

_____sena

14. Bħalissa tpejjep it-tabakk kuljum, jew inqas minn kuljum?

Kuljum ☐ Inqas minn kuljum ☐

15. Bejn wieħed u ieħor, kemm mill-prodotti li ġejjin tpejjep kull jum/ġimgħa (jekk jogħġbok indika kif sippost)? Ingassa l-prodotti li ma tużax.

Sigaretti manifatturati _____ kull jum/fil-ġimgħa

Sigaretti rrumblati bl-idejn _____ kull jum/fil-ġimgħa

Il-pipa mimlija bit-tabakk _____ kull jum/fil-ġimgħa

Sigarri, *cheroots*, jew *cigarillos* _____ kull jum/fil-ġimgħa

Numru ta' sessjonijiet ta' *waterpipe* (shisha) _____ kull jum/fil-ġimgħa

Oħrajn (inklużi prodotti tat-tabakk li ma jdaħnux u prodotti alternattivi, eż., sigaretti elettroniċi): _____ kull jum/fil-ġimgħa

Id-dipendenza fuq is-sigaretti (The Cigarette Dependence Scale, CDS-5; Etter et al., 2003)

Din it-taqsima hija dwar id-dipendenza tiegħek għas-sigaretti.

16. Jekk jogħġbok ikklassifika d-dipendenza tiegħek fuq is-sigaretti fuq skala bejn 0 u 100: _____

M'jien dippendenti XEJN fuq is-sigaretti = 0

Jien dipendenti ħafna fuq is-sigaretti = 100

17. Bħala medja, kemm-il sigarett tpejjep kuljum?

_____ sigarett / kuljum

18. Normalment, kemm iddum biex tqabbad l-ewwel sigarett tiegħek?

_____ minuti

19. Għalik, li tieqaf tpejjep għalkollox tkun:

Impossibbli ☐

Diffiċli ħafna ☐

Pjuttost diffiċli ☐

Pjuttost faċli ☐

Faċli ħafna ☐

20. Jekk jogħġbok indika jekk taqbilx mad-dikjarazzjoni li ġejja:

Wara ftit sigħat mingħajr tipjip, inħoss ħtieġa insaportabbli biex inpejjep.

Ma naqbilx totalment ☐

Pjuttost ma naqbilx ☐

Newtrali ☐

Pjuttost naqbel ☐

Naqbel ħafna ☐

Waqfien mit-Tipjip

It-taqsima li ġejja hija dwar l-attentati preċedenti tiegħek biex tieqaf u dwar l-intenzjonijiet attwali tiegħek biex tieqaf tpejjep.

21. Ippruvajt tieqaf tpejjep fl-aħħar 12-il xahar?

Iva ☐ Le ☐

22. Qatt irnexxielek tieqaf tpejjep? (jiġifieri lanqas ħadt nifs wieħed għal mill-inqas sebat ijiem konsekuttivi)

Qatt ma ppruvajt nieqaf ☐ Iva ☐

Le ☐

23. Liema stqarrija minn dawn li ġejjin tiddeskrivik l-aħjar? (Motivation To Stop Scale; Kotz et al., 2013)

Ma rridx nieqaf inpejjep ☐

Naħseb li għandi nieqaf inpejjep imma mhux verament irrid ☐

Irrid nieqaf inpejjep imma ma tajtx ħsieb għal meta ☐

Jien VERAMENT irrid nieqaf mit-tipjip imma ma nafx meta se nieqaf ☐

Irrid nieqaf inpejjep u nispera li jkun dalwaqt ☐

VERAMENT irrid nieqaf mit-tipjip u beħsiebni nieqaf fit-tliet xhur li ġejjin ☐

VERAMENT irrid nieqaf inpejjep u beħsiebni nieqaf fix-xahar li jmiss ☐

Skala ta'Ansjetà u Dipressjoni għall-Isptarijiet (HADS; Zigmond and Snaith 1983)

maqluba bil-Malti minn Baldacchino, Bowman and Buhagiar (2002)

L-aħħar taqsima tivvaluta kif kont tħossok fil-ġimgħa li għaddiet. Aqra kull stqarrija u jekk jogħġbok immarka (✓) il-kaxxa faċċata tat-tweġiba li toqrob l-eqreb ta' kif kont tħossok fil-ġimgħa li għaddiet.

Tieħux wisq ħin fit-tweġibiet tiegħek: ir-reazzjoni immedjata tiegħek hija l-aħjar.

24. Inħoss it-tensjoni u l-ansjeta':

Il-ħin kollu ☐

Ħafna mill-ħin ☐

Minn ħin għall-ieħor ☐

Qatt ☐

25. Għadni nieħu pjaċir nagħmel l-affarijiet li kont nagħmel qabel:

Żgur daqs qabel ☐

Ftit inqas minn qabel ☐

Ftit biss ☐

Kważi xejn ☐

26. Inħossni mbeżża' qisu ser jiġri xi ħaġa kerha:

Inħossu ħafna u ħażin ħafna ☐

Iva, imma mhux daqstant ☐

Ftit, iżda ma jinkwetanix ☐

Lanqas xejn ☐

27. Niccajta u nidħak u nara l-aspett inqas serju ta' l-affarijiet:

L-aktar li nista' possibli ☐

Mhux daqstant issa ☐

Żgur li le, issa ☐

Lanqas xejn ☐

28. Ħsibijiet ta' nkwiet jgħaddu minn moħħi:

Il-ħin kollu ☐

Parti kbira tal-ħin ☐

Minn ħin għall-ieħor, imma mhux spiss ☐

Xi kultant ☐

29. Inħossni kuntent/a:

Qatt ☐

Mhux dejjem ☐

Xi kultant ☐

Kważi l-ħin kollu ☐

30. Kapaċi noqgħod bilqegħda komdu u nħossni rilassat/a:

Dejjem ☐

Sikwit ☐

Mhux ta' spiss ☐

Qatt ☐

31. Inħossni qiegħed/a inċedi:

Il-ħin kollu ☐

Ta' spiss ☐

Xi kultant ☐

Qatt ☐

32. Inħoss sens ta' biżgħa u nħoss tferfir fl-istonku:

Lanqas xejn ☐

Xi kultant ☐

Ta' spiss ☐

Spissi ħafna ☐

33. Tlift kull interess ta' kif inżomm persunti:

Qatt ma nagħti kas ☐

Ma nagħtix kas daqskemm suppost ☐

Jista' jkun li ma tantx nagħti kas ☐

Nieħu ħsieb kemm nista' ☐

34. Inħossni bla kwiet, qisni għandi nibqa' sejjer il-ħin kollu:

Ħafna, ħafna ☐

Mhux ħażin ☐

Ftit li xejn ☐

Lanqas xejn ☐

35. Inħares bil-ferħ lejn l-affarijiet:

Ħafna bħal qabel ☐

Ftit inqas minn qabel ☐

Ħafna inqas minn qabel ☐

Ftit li xejn ☐

36. Kultant inħossni "ma nafx fejn se nagħti rasi":

Dejjem☐

Ta' spiss ☐

Mhux ta' spiss ☐

Qatt ☐

37. Nieħu gost naqra ktieb tajjeb jew nisma' r-radju jew nara programm tat-Televixin:

Spiss ☐

Xi kultant ☐

Mhux dejjem ☐

Rari ☐

It-tobba huma konxji li l-emozzjonijiet jilgħabu parti importanti fil-biċċa l-kbira tal-mard. Jekk it-tabib tiegħek ikun jaf dwar dawn is-sentimenti hu/hija jkun jista' jgħinek aktar. Jekk inti imħasseb dwar is-sentimenti attwali tiegħek kellem lit-tabib tiegħek għal aktar appoġġ.

Grazzi talli mlejt dan il-kwestjonarju!

Appendix 7.13 End of study questionnaire (pilot study – in Maltese)

Grazzi talli aċċettajt li timla dan il-kwestjonarju. Il-mistoqsijiet li ġejjin huma dwar it-tentattiv tal-waqfien mit-tipjip li għamilt u l-istatus tat-tipjip tiegħek, dwar l-appoġġ li rċevejt matul il-perjodu ta' dan l-istudju, u dwar is-sodisfazzjon tiegħek bl-intervent ipprovdut għall-waqfien mit-tipjip u il-perċezzjonijiet tiegħek dwar l-utilità tiegħu. Fejn applikabbli jekk jogħġbok immarka t-tweġiba magħżula (✓). Jekk jogħġbok għarrafni jekk teħtieġx għajnuna biex timla dan il-kwestjonarju, jew jekk għandek xi mistoqsijiet.

Kodiċi tal-parteċipant (jekk jogħġbok ikteb il-kodiċi tal-parteċipant uniku tiegħek hawn) ☐

Qari tat-test tan-nifs tal-monossidu tal-karbonju (għall-użu tal-uffiċċju biss)

_____

Riżultat tal-kotinina fl-awrina (għall-użu fl-uffiċċju biss) _____

Il-vizzju tat-tipjip

L-ewwel taqsima hija dwar it-tentattiv tal-waqfien mit-tipjip li għamilt matul il-perjodu ta' l-intervent, u l-istatus tiegħek tat-tabakk jekk għadek tpejjep.

1. **Matul l-aħħar 12-il ġimgħa qattajt intenzjonalment mill-inqas ġurnata waħda (≥24 siegħa) ma tpejjep l-ebda sigarett jew xi prodott tat-tabakk (jiġifieri lanqas biss ħadt nifs wieħed), u ma użajt l-ebda prodott tat-tabakk li ma jdaħħanx jew xi prodott alternattiv bħas-sigarett elettroniku?**

   Le ☐ *Jekk jogħġbok mur għall-mistoqsija numru 4*

   Iva ☐ *Jekk jogħġbok mur għall-mistoqsija numru 2*

2. **Matul l-aħħar 12-il ġimgħa qattajt mill-inqas sebat ijiem konsekuttivi ma tpejjep l-ebda sigarett jew xi prodott tat-tabakk (jiġifieri lanqas biss ħadt nifs wieħed), u ma użajt l-ebda prodott tat-tabakk li ma jdaħħanx jew xi prodott alternattiv bħas-sigarett elettroniku?**

   Le ☐ *Jekk jogħġbok mur għall-mistoqsija numru 4*

   Iva ☐ *Jekk jogħġbok mur għall-mistoqsija numru 3*

3. **Fl-aħħar sebat ijiem pejjipt sigarett jew prodott ieħor tat-tabakk (anki jekk ħadt nifs wieħed), jew użajt prodott tat-tabakk li ma jdaħħanx jew prodott alternattiv bħas-sigarett elettroniku?**

   Iva ☐ *Jekk jogħġbok mur għall-mistoqsija numru 4*

   Le, lanqas ħadt nifs wieħed għal mill-inqas sebat ijiem ☐ *Jekk jogħġbok mur fit-taqsima li jmiss*

4. **Bejn wieħed u ieħor, kemm mill-prodotti li ġejjin tpejjep kull jum/ġimgħa (jekk jogħġbok indika kif sippost)?** Ingassa l-prodotti li ma tużax.

   Sigaretti manifatturati _____ kull jum/fil-ġimgħa

   Sigaretti rrumblati bl-idejn _____ kull jum/fil-ġimgħa

   Il-pipa mimlija bit-tabakk _____ kull jum/fil-ġimgħa

   Sigarri, *cheroots*, jew *cigarillos* _____ kull jum/fil-ġimgħa

   Numru ta' sessjonijiet ta' *waterpipe* (shisha) _____ kull jum/fil-ġimgħa

   Oħrajn (inklużi prodotti tat-tabakk li ma jdaħnux u prodotti alternattivi, eż., sigaretti elettroniċi): _____ kull jum/fil-ġimgħa

Appoġġ riċevut

It-taqsima li ġejja hija dwar is-sessjonijiet ta' appoġġ għall-waqfien mit-tipjip li rċevejt u dwar kwalunkwe appoġġ addizzjonali li jista' jkun irċevejt.

5. **Attendejt is-sessjonijiet skedati kollha għall-waqfien mit-tipjip? Jekk le, jekk jogħġbok għid għaliex.**

   Iva ☐

   Le ☐ _____

6. **Kemm attendejt sessjonijiet ta' appoġġ għall-waqfien mit-tipjip?**

   Xejn ☐ Sessjoni waħda ☐

   Żewġ sessjonijiet ☐ Tliet sessjonijiet ☐

   Erba' sessjonijiet ☐ Oħrajn:_____

7. **Fuq kemm-il ġimgħa attendejt dawn is-sessjonijiet ta' appoġġ?**

   _____ -il ġimgħa

8. **Ħadt xi sostituzzjoni terapewtika tan-nikotina jew mediċina biex tgħinek tieqaf tpejjep? Jekk iva, jekk jogħġbok għid xiex.**

   Le ☐

   Iva ☐ _____

   Għal kemm ġranet għamilt dan, u kemm spiss?

   _____

   _____

9. **Hemm xi ħaġa oħra li ma ġietx ipprovduta bħala parti mill-appoġġ ipprovdut għall-waqfien mit-tipjip li sibtha utli biex tipprova tieqaf tpejjep matul il-perjodu ta' studju?**

   _____

   _____

   _____

Sodisfazzjon u utilità perċepita tal-intervent ipprovdut għall-waqfien mit-tipjip

It-taqsima li ġejja, li hija maqsuma f'żewġ subtaqsimiet, hija dwar is-sodisfazzjon tiegħek bl-intervent ipprovdut għall-waqfien mit-tipjip u l-perċezzjonijiet tiegħek dwar l-utilità tiegħu. Jekk jogħġbok tweġibx din it-taqsima **jekk ma attendejtx** xi sessjoni ta' appoġġ għall-waqfien mit-tipjip.

Sodisfazzjon bl-intervent ipprovdut għall-waqfien mit-tipjip

Is-subtaqsima li ġejja hija dwar is-sodisfazzjon tiegħek bid-diversi elementi tal-intervent tal-waqfien mit-tipjip li rċevejt. Jekk jogħġbok indika s-sodisfazzjon tiegħek għal kull dikjarazzjoni.

	Kemm int sodisfatt…	**M'jien sodisfatt xejn (1)**	**Mhux sodisfatt (2)**	**Newtrali (3)**	**Sodisfatt (4)**	**Sodisfatt ħafna (5)**
10.	Bis-sapport li rċevejt biex tieqaf tpejjep.	☐	☐	☐	☐	☐
11.	Bil-post fejn l-intervent għall-waqfien mit-tipjip ġie pprovdut.	☐	☐	☐	☐	☐
12.	Bil-ħinijiet mogħtija tal-appuntamenti	☐	☐	☐	☐	☐
13.	Biż-żmien ta' stennija għall-ewwel sessjoni tiegħek.	☐	☐	☐	☐	☐
14.	Bit-tul ta' ħin għal kull sessjoni individwali.	☐	☐	☐	☐	☐
15.	Bil-perjodu ta' żmien bejn appuntament u ieħor	☐	☐	☐	☐	☐
16.	Bin-numru ta' sessjonijiet li kellek.	☐	☐	☐	☐	☐
17.	Bil-metodu użat biex jgħinek tieqaf	☐	☐	☐	☐	☐

18. B'liema aspett tal-intervent tal-waqfien mit-tipjip kont l-iktar sodisfatt? Jekk jogħġbok spjega t-tweġiba tiegħek.

_____

_____

_____

19. B'liema aspett tal-intervent tal-waqfien mit-tipjip kont l-inqas sodisfatt? Jekk jogħġbok spjega t-tweġiba tiegħek.

_____

_____

_____

L-utilità perċepita tal-intervent tal-waqfien mit-tipjip

Is-subtaqsima li ġejja hija dwar il-perċezzjonijiet tiegħek dwar l-utilità tal-intervent ipprovdut għall-waqfien mit-tipjip. Jekk jogħġbok indika l-qbil tiegħek għal kull dikjarazzjoni.

	L-intervent għall-waqfien mit-tipjip…	**Ma naqbel xejn (1)**	**Ma naqbilx (2)**	**Newtrali (3)**	**Naqbel (4)**	**Naqbel ħafna (5)**
20.	Laħaq l-aspettattivi tiegħek.	☐	☐	☐	☐	☐
21.	Japplika għalik speċifikament.	☐	☐	☐	☐	☐
22.	Ipprovdielek informazzjoni utli dwar kif tieqaf.	☐	☐	☐	☐	☐
23.	Għamlek ikkonċernat fuq il-kumplikazzjonijiet severi tad-dijabete kkawżati mit-tipjip.	☐	☐	☐	☐	☐

	L-intervent għall-waqfien mit-tipjip…	Ma naqbel xejn (1)	Ma naqbilx (2)	Newtrali (3)	Naqbel (4)	Naqbel ħafna (5)
24.	Għamlek ikkonċernat dwar it-tipjip tiegħek.	☐	☐	☐	☐	☐
25.	Ipprovdielek il-motivi biex tieqaf.	☐	☐	☐	☐	☐
26.	Ġiegħlek taħseb li jaqbillek tieqaf.	☐	☐	☐	☐	☐
27.	Għenek tikkunsidra pjan biex tieqaf tpejjep.	☐	☐	☐	☐	☐
28.	Għenek tidentifika sitwazzjonijiet li jżidu r-riskju li tpejjep.	☐	☐	☐	☐	☐
29.	Għenek tidentifika strateġiji biex tirreżisti l-leblieba biex tpejjep.	☐	☐	☐	☐	☐
30.	Għenek tirrispondi effettivament għal-leblieba biex tpejjep.	☐	☐	☐	☐	☐
31.	Ipprovdilek għażliet dwar kif tieqaf tpejjep.	☐	☐	☐	☐	☐
32.	Għenek tidentifika l-iktar metodu effettiv biex tieqaf tpejjep.	☐	☐	☐	☐	☐
33.	Tak il-kunfidenza sabiex tkun tista' tieqaf.	☐	☐	☐	☐	☐

34. Hemm xi ħaġa li nistgħu nagħmlu biex intejbu l-intervent u nagħmluha aktar faċli għalik li tieqaf tpejjep?

_____

_____

_____

35. Tirrakkomanda dan l-intervent tal-waqfien mit-tipjip lil xi ħadd ieħor?

Le ☐ Iva ☐

Grazzi talli mlejt dan il-kwestjonarju!

Appendix 7.14: Treatment fidelity checklist (pilot study)

Session one – pre-quit session

Treatment action/component	Occurrence (✓)
Ask: Asked about/Confirmed the number of cigarettes/tobacco products smoked every day.	
Advise: Informed the participant on the effects of smoking on diabetes (as outlined in the intervention guideline).	
Advise: Gave an overview of the story of Bill to the participant (as outlined in the intervention protocol), showing him/her the three video clips.	
Advise: Allowed some time for reflection or brief discussion, acknowledging any feelings or comments the participant may state.	
Advise: Advised the participant to quit smoking in a clear, strong and personalised manner (as outlined in the intervention protocol).	
Assess: Assessed readiness in setting a quit attempt in the next two weeks, identifying the possible need of using the 5Rs algorithm (as outlined in the intervention protocol).	
5Rs: Helped the participant identify how quitting smoking would be relevant to him/her.	
5Rs: Encouraged the participant to identify the potential negative consequences (risks) that are relevant to him/her if he/she continues to smoke, discussing further if required.	
5Rs: Encouraged the patient to identify potential benefits of stopping smoking (rewards) which are relevant to him/her, discussing further if required.	
5Rs: Encouraged the participant to identify any barriers or impediments to quitting smoking (roadblocks), discussing/providing realistic solutions.	
5Rs: Reassessed readiness in setting a quit attempt in the next two weeks (repetition), encouraging the participant to give it a try.	
Assist: Helped the participant set a Target Quit Date (TQD) within the next two weeks.	
Assist: Told the participant to inform his family, friends, and co-workers about his/her quitting attempt, and to ask for support.	
Assist: Encouraged the participant to talk about the quitting process, anticipating the challenges or barriers to the upcoming quit attempt, (as outlined in the intervention protocol)	
Assist: Helped the participant generate problem-solving strategies to tackle the identified barriers and challenges to quitting (as outlined in the intervention protocol)	
Assist: Asked the participant to remove any tobacco products from the patient's environment (particularly closer to the quit date) and make the home smoke free.	
Assist: Recommended (explaining use and benefits) and provided a supply of NRT (patch and/or spray) for use until the next session.	

Assist: Encouraged the participant further in the quit attempt, by referring to/identifying what would be relevant for him/her if he quit smoking.	
Assist: Advised monitoring of blood glucose.	
Assist: Linked the participant to psychological support services if experiencing anxiety or depression.	
Arrange: Provided the participant with a follow-up appointment during the first week from their TQD.	
Total	/16 or /21
Treatment components added that were not specified by the protocol	

Session two – for those who did not quit smoking

Treatment action/component	**Occurrence (✓)**
Asked about tobacco use (no. of cigarettes/tobacco products smoked/day).	
Assessed the use of NRT and any problems encountered (including over/under-dosing), providing recommendations.	
Reviewed experienced barriers and challenges (roadblocks).	
Encouraged a recommitment to quit smoking (referring to what is relevant to the participant – risks and rewards).	
Encouraged the participant to give it a try even if not 100% confident.	
Assist: Helped the participant set a TQD within the next two weeks.	
Assist: Told the participant to inform his family, friends, and co-workers about his/her quitting attempt, and to ask for support.	
Assist: Encouraged the participant to talk about the quitting process, anticipating the challenges or barriers to the upcoming quit attempt, (as outlined in the intervention protocol)	
Assist: Helped the participant generate problem-solving strategies to tackle the identified barriers and challenges to quitting (as outlined in the intervention protocol)	
Assist: Asked the participant to remove any tobacco products from the patient's environment (particularly closer to the quit date) and make the home smoke free.	
Assist: Recommended (explaining use and benefits) and provided a supply of NRT (patch and/or spray) for use until the next session.	
Assist: Encouraged the participant further in the quit attempt, by referring to what would be relevant for him/her if he quit smoking.	
Assist: Advised monitoring of blood glucose.	
Assist: Linked the participant to psychological support services if experiencing anxiety or depression.	
Arrange: Provided the participant with a follow-up appointment during the first week from their TQD.	
Total	/15
Treatment components added that were not specified by the protocol	

Session two – for those who quit smoking (or session three, if reporting abstinence the first time)

Treatment action/component	**Occurrence (✓)**
Asked about tobacco use (no. of cigarettes/tobacco products smoked/day).	
Congratulated participant if he/she stopped smoking.	
Encouraged participant to remain abstinent (referring to what is relevant to the participant – risks and rewards).	
Assessed the use of NRT and any problems encountered (including over/under-dosing), providing recommendations.	
Reviewed experienced barriers and challenges (roadblocks) towards remaining abstinent from smoking.	
Discussed anticipated challenges.	
Reinforced strategies outlined in the quit plan – reminding the participant on the usefulness of social support.	
Linked the participant to psychological support services if experiencing anxiety or depression.	
Provided remaining assigned supply of NRT, advising all participants to reduce the use of the spray during these weeks.	
Advised monitoring of blood glucose and offered a diabetic consultation (and subsequent specialist/s referrals, if required) if the participant experienced poor glycaemic control, or is concerned about diabetes management following a change in diet or weight gain on quitting smoking.	
Provided the participant with a follow-up appointment within five weeks from their TQD.	
Total	/11
Treatment components added that were not specified by the protocol	

Session three – for those who did not succeed to quit smoking

Treatment action/component	**Occurrence (✓)**
Asked about tobacco use (no. of cigarettes/tobacco products smoked/day).	
Assessed the use of NRT and any problems encountered (including over/under-dosing), providing recommendations.	
Reviewed experienced barriers and challenges (roadblocks).	
Encouraged a recommitment to quit smoking (referring to what is relevant to the participant – risks and rewards).	
Ended the intervention on a positive manner, encouraging the participant to seek tobacco cessation services when ready.	
Total	/5
Treatment components added that were not specified by the protocol	

Final follow-up session (for those who previously reported not smoking)

Treatment action/component	**Occurrence (✓)**
Asked about tobacco use (no. of cigarettes/tobacco products smoked/day).	
Congratulated participant if he/she stopped smoking/remained abstinent from smoking or praised any other achievements (e.g. reduction in number of cigarettes smoked per day).	
Encouraged participant to attempt quitting again if he/she relapsed or to remain abstinent (referring to what is relevant to the participant – risks and rewards).	
Assessed the use of NRT and any problems encountered (including over/under-dosing), advising participants to ideally reduce use if still on NRT (and abstinent from smoking).	
Reviewed experienced barriers and challenges (roadblocks) towards remaining abstinent from smoking.	
Discussed anticipated challenges.	
Reinforced strategies outlined in the quit plan – reminding the participant on the usefulness of social support.	
Linked the participant to psychological support services if experiencing anxiety or depression.	
Advised monitoring of blood glucose and offered a diabetic consultation (and subsequent specialist/s referrals, if required) if the participant experienced poor glycaemic control, or is concerned about diabetes management following a change in diet or weight gain on quitting smoking.	
Ended the intervention on a positive manner, encouraging the participant to seek tobacco cessation services if required.	
Total	/10
Treatment components added that were not specified by the protocol	

Appendix 7.15: Permission to use the Motivation to Stop Scale

L-Università ta' Malta

Joseph Grech <joseph.grech.02@um.edu.mt>

AW: [Extern] - Permission to use the Motivation to Stop Scale

Joseph Grech <joseph.grech.02@um.edu.mt> 12 February 2021 at 14:43
To: Daniel.Kotz@med.uni-duesseldorf.de

Thank you very much.

Will do.

Joseph

On Fri, 12 Feb 2021 at 14:26, <Daniel.Kotz@med.uni-duesseldorf.de> wrote:

> Dear Joseph,
>
> Sure! It would be great if you could refer to our original publications when your report your findings.
>
> Kotz D, Brown J, West R. Predictive validity of the Motivation To Stop Scale (MTSS): A single-item measure of motivation to stop smoking. Drug and alcohol dependence. 2013;128(1–2):15-9.
>
> Hummel K, Brown J, Willemsen MC, West R, Kotz D. External validation of the Motivation To Stop Scale (MTSS): findings from the International Tobacco Control (ITC) Netherlands Survey. Eur J Public Health. 2017;27(1):129-34.
>
> Good luck with your research and best wishes
>
> Daniel

Appendix 7.16: Permission to use the Cigarette Dependence Scale-5

L-Università ta' Malta

Joseph Grech <joseph.grech.02@um.edu.mt>

Permission to use The Cigarette Dependence Scale CDS-5

Jean-François Etter <Jean-Francois.Etter@unige.ch> 21 April 2021 at 15:19
To: Joseph Grech <joseph.grech.02@um.edu.mt>

Hello,

of course you can use the CDS-5 scale, you do not need permission since the scale is published.

you can also translate it in Maltese, please send me the translation once it is done.

good luck with your study

JF Etter

De : Joseph Grech <joseph.grech.02@um.edu.mt>
Envoyé : mercredi, 21 avril 2021 12:58:27
À : Jean-François Etter
Objet : Permission to use The Cigarette Dependence Scale CDS-5

[Quoted text hidden]

Appendix 7.17: Permission to use the Hospital Anxiety and Depression Scale

Mapi Research Trust

HADS Work Order

Work order No. 2204962
Under Master User License Agreement

This Work Order is issued under the Master User License Agreement by and between Mapi Research Trust ("MRT") and University of Malta ("User"). Upon execution by both Parties, together with the **Master User License Agreement dated** 18 May 2020 ("MULA"), this Work Order identifies and governs the licensing by MRT of the COA referenced herein ("COA"), and is made a part of and is subject to the MULA.

This Work Order ("WO") is in addition to any and all previous Work Orders under the MULA.

This WO includes the terms and conditions of the MULA, which are hereby incorporated by this reference as though the same was set forth in its entirety and shall be effective as of the WO Effective Date set forth herein.

All capitalized terms which are not defined herein shall have the same meanings as set forth in the MULA.

This WO, including all attachments and the MULA contain the entire understanding of the Parties with respect to the subject matter herein and supersedes all previous agreements and undertakings with respect thereto. If the terms and conditions of this WO or any attachment conflict with the terms and conditions of the MULA, the terms and conditions of the MULA will control, unless this WO specifically acknowledges the conflict and expressly states that the conflicting term or provision found in this WO controls for this WO only. This WO may be modified only by written agreement signed by the Parties.

1. User information

MULA Reference	University of Malta_MT_283660_MULA_20200511_FE
User name	Joseph Grech
Category of User	Student
User address	Faculty of Health Sciences, Mater Dei Hospital, Msida, MSD2090, Malta
User VAT number	
User email	joseph.grech.02@um.edu.mt
User phone	
Billing information (if different from the above)	N/A

2. WO information

WO Number	2204962
WO Effective Date	Last date of signature of this WO by the Parties
WO Expiration Date ("Term")	• Fixed-term license: upon completion of the Stated Purpose, as defined in 4.1

DocUUID : c7a93fd4-7cbc-41c8-b68e-c58f90e035ba

HADS Work Order

Name of User's contact in charge of the WO	Joseph Grech

3. Identification of the COA

Name of the COA	HADS - Hospital Anxiety and Depression Scale
Author	Snaith RP; Zigmond AS;
Copyright Holder	GL Assessment Ltd
Copyright notice	HADS copyright © R.P. Snaith and A.S. Zigmond, 1983, 1992, 1994. Record form items originally published in Acta Psychiatrica Scandinavica 67, 361–70, copyright © Munksgaard International Publishers Ltd, Copenhagen, 1983.Published by GL Assessment Limited, 1st Floor Vantage London, Great West Road, London TW8 9AG, UK. All rights reserved. GL Assessment is part of the GL Education Group.
Bibliographic reference	Snaith RP. The Hospital Anxiety And Depression Scale. Health and Quality of Life Outcomes. 2003 Aug, 1:29 (Full text article) White D, Leach C, Sims R, Atkinson M, Cottrell D. Validation of the Hospital Anxiety and Depression Scale for use with adolescents. Br J Psychiatry. 1999 Nov;175:452-4 Herrmann C. International experiences with the Hospital Anxiety and Depression Scale - a review of validation data and clinical results. Journal of Psychosomatic Research 1997;42(1):17-41 Zigmond AS, Snaith RP. The Hospital Anxiety and Depression Scale. Acta Psychiatr Scand 1983;67:361-370
Module(s)/version(s) needed	• HADS

4. Context of use of the COA

The User undertakes to use the COA solely in the context of the Stated Purpose as defined hereafter.

4.1 Stated Purpose

Epidemiological Study

Title	Development and feasibility testing of a multi-component smoking cessation intervention for smokers living with diabetes mellitus
Study/protocol reference	N/A
Sponsor	Tertiary Education Scholarship Scheme TESS
Disease or condition	Diabetes mellitus
COA used as primary end point	No

Number of enrolled patients/subjects	150
Number of estimated failed patients/subjects	0
Number of submissions of the COA for each patient	1
Planned Term*	Start: 12/2022 End: 12/2024
Mode of Administration*	• Paper
If electronic administration, please indicate mode of data collection	
Use of IT Company (e-vendor)	No

4.2 Language Versions

4.2.1 Country and languages

MRT grants the License to use the COA on the following countries and in the languages indicated in the table below:

Language	For use in the following country	Availability
English	the UK	Yes
Maltese	Malta	Yes

5. Price and payment terms

In consideration for the License granted under this WO, the User is granted permission free of charge.

6. Specific requirements for the COA

- The Copyright Holder of the COA has granted ICON LS exclusive rights to translate the COA in the context of commercial studies or any project funded by for-profit entities. ICON LS is the only organization authorized to perform linguistic validation/translation work on the COA.
- In case the User wants to use an e-Version of the COA, the User shall send the Screenshots of the original version of the COA to MRT or ICON LS for review and approval. The Screenshots review may incur additional fees.
- In case the User wants to use an e-Version of the COA, ICON LS shall update (if needed) and populate the COA translations into the User's or IT Company's system and the User shall send the Screenshots of the translations of the COA to ICON LS for approval. The update (if needed), population of translations and the Screenshots review may incur additional fees.
- The User shall ensure that all persons administering the COA are qualified personnel or are working under the supervision of one or more appropriately qualified persons.
- Please include cost of the **HADS Manual** at **€62.95 per copy (plus shipping)** in any quote: Yes ☐

  No ☐X
- Please note that neither GL Assessment (GLA) nor the Mapi Research Trust (MRT) hold the rights to the following translated **HADS** questionnaires:
- **GERMAN** language translation of the HADS. If you require the German translation of the HADS, please contact Sylvia.Schlutius@hogrefe.ch at Hogrefe AG, Bern, Switzerland.
- Please **do not** include any number of **administrations** that are intended for the **German** HADS translation usage on this form as you may be charged twice.
- Permission to use the HADS from a user based in the United Kingdom/ Republic of Ireland/ Channel Islands are managed by GL Assessment. For other countries, permissions are managed by Mapi Research Trust.

EXECUTED, as of the WO Effective Date, by the duly authorized representatives as set forth below.

MAPI RESEARCH TRUST

Signature: _____

Laure-Lou Perrier

14 Apr 2022 15:20:041+0000

REASON: I approve this document

aa3a230b-fbee-40ae-9968-f17de634cb58

Title: _____

Date: _____

UNIVERSITY OF MALTA

Signature: _____

Name: JOSEPH GRECH

Title: STUDENT

Date: 20/4/2022

Appendix 7.18: Permission to use the CDC's Tips from Former Smoker advertisements

L-Università ta' Malta

Joseph Grech <joseph.grech.02@um.edu.mt>

Your request

Allen, Richard (CDC/DDNID/NCCDPHP/OSH) <gfq5@cdc.gov> 9 November 2021 at 19:48
To: "joseph.grech.02@um.edu.mt" <joseph.grech.02@um.edu.mt>

Dear Mr. Grech,

Thank you for contacting the Centers for Disease Control and Prevention (CDC). Your recent request regarding permission to use videos from CDC's *Tips From Former Smokers®* media campaign that are available on the YouTube website was forwarded by CDC-INFO to the Office on Smoking and Health. We appreciate your interest in using our ads to help smokers who are trying to quit.

It is fine for you to use the ads; however, the selected ads must be used as is, without other alterations.
The videos are part of a public domain website, which means you may link to them at no cost and without specific permission. Other campaign resources available on the *Tips From Former Smokers®* website (CDC.gov/tips) may also be helpful to those who visit your site. These include:

- Overviews of the health conditions featured in the campaign
- Real stories and videos of the people featured in the commercials
- Badges and buttons that you can place on your own site

Materials that can be downloaded from the *Tips®* website can also be used for free and without permission. Please understand, therefore, that the *Tips®* brand, logo, and associated images may not be modified, altered, or changed in any way.

Please visit https://dlc.plowsharegroup.com/cdc_tobacco_education.php. You will find all of the current content that we have available. Unfortunately, we may not have all the language translations you may need.

Again, thank you for contacting us. We appreciate your interest in our educational materials and your efforts to encourage smokers who want to quit and lead healthier lives.

Sincerely,

Office on Smoking and Health
National Center for Chronic Disease Prevention and Health Promotion
Centers for Disease Control and Prevention

Appendix 7.19: Faculty Research Ethics Committee Approval (pilot and feasibility studies)

L-Università ta' Malta

Joseph Grech <joseph.grech.02@um.edu.mt>

UREC FORM V_15062020 8618 Joseph Grech

Rita Pace Parascandalo <rita.pace-parascandalo@um.edu.mt> 5 October 2022 at 08:00
To: Joseph Grech <joseph.grech.02@um.edu.mt>
Cc: Research Ethics HEALTHSCI <research-ethics.healthsci@um.edu.mt>, Roberta Sammut <roberta.sammut@um.edu.mt>

Dear Joseph,

your proposed changes to your study have been reviewed. Approval is granted oBo FREC and you may proceed with your study accordingly. Kindly ensure that you update the REDP form through the link you had received. Additionally, send all documents (without track changes), including the revised REDP form, as attachments to this thread of emails, keeping FREC and your supervisors in copy. Kindly ensure that you include not only the revised/new documents but also any previously approved documents (which have not be revised) that you will still be using for your study.

Good luck

Regards
Dr Rita PP

L-Università ta' Malta

Dr Rita Pace Parascandalo PhD (UCLan)
BSc(Hons) (Melit.), MSc(Melit.), RM

Senior Lecturer, Department of Midwifery
Chairperson, Faculty Research Ethics Committee

Faculty of Health Sciences
Office No. 48
+356 2340 1176
rita.pace-parascandalo@um.edu.mt

[Quoted text hidden]

Appendix 7.20: Mater Dei Hospital Chief Executive Officer Approval (pilot and feasibility studies)

L-Università ta' Malta

Joseph Grech <joseph.grech.02@um.edu.mt>

Approval for study

Joseph Grech <joseph.grech.02@um.edu.mt> 30 April 2021 at 10:57
To: Portelli Marsette at Health-MDH <marsette.portelli@gov.mt>

Thank you very much.

Joseph

On Fri, 30 Apr 2021 at 10:50, Portelli Marsette at Health-MDH <marsette.portelli@gov.mt> wrote:

Good morning,

Approval from my end is being given.

Regards,

Marsette

From: Joseph Grech <joseph.grech.02@um.edu.mt>
Sent: Wednesday, April 28, 2021 11:54:06 AM
To: Portelli Marsette at Health-MDH <marsette.portelli@gov.mt>
Subject: Re: Approval for study

CAUTION: This email originated from OUTSIDE the Government Email Infrastructure. DO NOT CLICK LINKS or OPEN attachments unless you recognise the sender and know the content is safe.

Dear Ms. Portelli,

I will be recruiting patients with diabetes attending the out-patients department and diabetes education unit as study participants for my study " Development and feasibility testing of a multi-component smoking cessation intervention for smokers living with diabetes mellitus." I have obtained permission from Prof. Fava, the DPO, and the CEO, however, I have been advised to seek your approval as the data collected will be published in my thesis and any publications/reports/ presentations that might arise from it. Can you please approve/let me know what documentation is required for approval from your end?

Thank you

Joseph Grech

On Wed, 28 Apr 2021 at 09:08, CEO at Health-MDH <ceo.mdh@gov.mt> wrote:

Dear Mr Grech,

Yes you definitely need approval from Ms Marsette Portelli our Junior Legal Officer if the study will be published.

Her e-mail address is Marsette.portelli@gov.mt.

Regards

Carmen Farrugia
Personal Assistant To CEO

T +356 +356 25454102

E carmen.farrugia@gov.mt

Mater Dei Hospital, Triq id-Donaturi tad-Demm, l-Imsida, Malta MSD 2090 | Tel +356 2545 0000 | https://deputyprimeminister.gov.mt/en/MDH/Pages/Home.aspx | https://www.facebook.com/materdeihospital/

From: Joseph Grech <joseph.grech.02@um.edu.mt>
Sent: Tuesday, 27 April 2021 09:44
To: CEO at Health-MDH <ceo.mdh@gov.mt>
Subject: Re: Approval for study

Dear Ms. Farrugia

Thank you for your email. Can you kindly explain re: approval from Ms. Portelli? I will be recruiting participants for my studies from attending out-patients at MDH and other entities (e.g. GGH etc.). Hence I won't be collecting data on MDH per se (you can confirm by looking at the interview/focus group questions and questionnaires). Data will be shared with my supervisors, one of whom is foreign, while analysed data will be published in reports, presentations, publications, and my thesis. If you still think that I need her approval, can you please forward me her email address?

Thanks

Joseph

On Tue, 27 Apr 2021 at 06:59, CEO at Health-MDH <ceo.mdh@gov.mt> wrote:

> Dear Mr Grech,
>
> Kindly note that approval has been given by Ms Celia Falzon for you to conduct this study in line with applicable hospital protocols.
>
> Please also be reminded that Ms Marsette Portelli's approval on behalf of the CEO has to be

sought before any data being shared outside of hospital locally or abroad.

Regards

Carmen Farrugia
Personal Assistant To CEO

SPTAR MATER DEI

T +356 +356 25454102

E carmen.farrugia@gov.mt

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From: Joseph Grech <joseph.grech.02@um.edu.mt>
Sent: Friday, 23 April 2021 20:58
To: CEO at Health-MDH <ceo.mdh@gov.mt>
Cc: Farrugia Carmen at Health-MDH <carmen.farrugia@gov.mt>; Roberta Sammut <roberta.sammut@um.edu.mt>; Norman, Ian <ian.j.norman@kcl.ac.uk>
Subject: Approval for study

Dear Ms. Falzon,

Please find approval from Mr. Simon Caruana (DPO) and Profs. Fava, and the respective documents for your review and approval to carry out the study titled ***Development and feasibility testing of a multi-component smoking cessation intervention for smokers living with diabetes mellitus.***

Copied in this email are my research supervisors.

Thank you in advance,

Joseph Grech

Appendix 7.21: Mater Dei Hospital Data Protection Officer Approval (pilot and feasibility studies)

L-Università ta' Malta

Joseph Grech <joseph.grech.02@um.edu.mt>

Development and feasibility testing of a multi-component smoking cessation intervention for smokers living with diabetes mellitus

Joseph Grech <joseph.grech.02@um.edu.mt> 28 March 2022 at 12:10
To: Joseph Grech <joseph.grech.02@um.edu.mt>

---------- Forwarded message ---------
From: **Data Protection at Health-MDH** <datapro.mdh@gov.mt>
Date: Mon, 28 Mar 2022 at 04:47
Subject: RE: Development and feasibility testing of a multi-component smoking cessation intervention for smokers living with diabetes mellitus
To: Joseph Grech <joseph.grech.02@um.edu.mt>, Data Protection Approval Form at Health-MDH <dpaform.mdh@gov.mt>
Cc: Young Sharon at Health-MDH <sharon.young@gov.mt>

Dear Mr Grech

You may proceed as per conditions that were issued with the attached clearance letter but with the following amendments:

1. Video recordings will no longer take place

2. Study F1 (a focus group study) will no longer be held

3. Study D2 will be no longer be held

4. Study F2 will be held by the diabetes practice nurses' involvement, therefore the data protection form must also be signed before starting by:

- Ms Moria Grixti - moira.grixti@gov.mt

- Ms Catherine Azzopardi - catherine.c.azzopardi@gov.mt

The dp form will be sent through adobesign@adobesign.com to be signed electronically.

Dear Ms Aquilina

This study was cleared as per attached, however two persons were added to sign the form.

Details are as follows:

Recepients:

- Ms Moria Grixti - moira.grixti@gov.mt

- Ms Catherine Azzopardi - catherine.c.azzopardi@gov.mt

Name of approving Chair – *Prof Stephen Fava*

Title: *Development and feasibility testing of a multi-component smoking cessation intervention for smokers living with diabetes mellitus*

Data collection period - *December 2022 and December 2024*

Regards

Simon Caruana

Senior Manager (Compliance)

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Appendix 7.22: Mater Dei Hospital Chairperson Approval (pilot and feasibility studies)

L-Università ta' Malta

Joseph Grech <joseph.grech.02@um.edu.mt>

Development and feasibility testing of a multi-component smoking cessation intervention for smokers living with diabetes mellitus

Fava Stephen at Health-MDH <stephen.fava@gov.mt> 24 March 2022 at 10:17
To: Joseph Grech <joseph.grech.02@um.edu.mt>, Buhagiar Kelsy at Health-MDH <kelsy.buhagiar@gov.mt>
Cc: Grixti Moira at Health-MDH <moira.grixti@gov.mt>, Azzopardi Catherine C at Health-MDH <catherine.c.azzopardi@gov.mt>

Approved from my end.

From: Joseph Grech <joseph.grech.02@um.edu.mt>
Sent: 24 March 2022 10:11:49
To: Buhagiar Kelsy at Health-MDH
Cc: Grixti Moira at Health-MDH; Azzopardi Catherine C at Health-MDH; Fava Stephen at Health-MDH
Subject: Re: FW: FW: Development and feasibility testing of a multi-component smoking cessation intervention for smokers living with diabetes mellitus

Dear Kelsy

We spoke yesterday. I would appreciate if you could bring the email below to Prof Fava's attention.

Thank you in advance

Joseph

On Tue, 22 Mar 2022 at 18:35, Joseph Grech <joseph.grech.02@um.edu.mt> wrote:

> Dear Prof Fava
>
> A gentle reminder to the email below.
>
> Kind regards,
>
> Joseph Grech
>
> On Thu, 17 Mar 2022 at 12:10, Joseph Grech <joseph.grech.02@um.edu.mt> wrote:
>
> > Dear Prof Fava
> >
> > Hope this email finds you well. As you may recall I had asked for your permission in conducting a research study entitled, "**Development and feasibility testing of a multi-component smoking cessation intervention for smokers living with diabetes mellitus: a randomised feasibility study**" as part of my Ph.D. studies. This study aims to evaluate the feasibility and acceptability of a multi-component smoking cessation intervention among individuals with diabetes.
> >
> > While I had already planned to deliver the intervention myself, and thus sought ethical clearance (from yourself, from MDH, and the Faculty), following my initial studies (in which participants suggested that smoking cessation support could be provided within the diabetes clinic), I thought of the possibility of testing the intervention in practice by training the diabetes practice nurses and supporting them in providing the intervention to recruited patients as part of their practice (as a feasibility study). Both Moira and Catherine (and the diabetes practice nurse working in Gozo) agreed to try this out. In a nutshell, on enrollment to the study (probably over a year) participants will be randomised on a 1:1 basis to the intervention or to the control group for 12 weeks. Participants will be provided between three to eight 30 minutes sessions over this period during which the nurses will support the participants in quitting. Nicotine replacement therapy (nicotine patch and Spray for daily use for six weeks) will also be provided from my end. I am aiming to recruit around 100 participants (for both intervention and control) and an additional 30-40 participants (intervention and control) as a pilot study.
> >
> > I am sending this email thus to seek your approval so that I can submit the revisions to the Data Protection Officer at MDH and the CEO, and then to FREC and UREC.
> >
> > Thank you in advance
> >
> > Joseph Grech

Appendix 7.23: Mater Dei Hospital Chief Nursing Manager and Diabetes Practice Nurses Approvals (pilot and feasibility studies)

L-Università ta' Malta

Joseph Grech <joseph.grech.02@um.edu.mt>

Development and feasibility testing of a multi-component smoking cessation intervention for smokers living with diabetes mellitus

Azzopardi Catherine C at Health-MDH <catherine.c.azzopardi@gov.mt> 17 March 2022 at 13:35
To: Joseph Grech <joseph.grech.02@um.edu.mt>

Dear Joseph

I confirm that I will be helping out in this smoking cessation study.

Thanks and regards

Catherine Azzopardi
Practice Nurse
Diabetes Education Unit
Health-Mater Dei Hospital

T 2546 6119, +356 79701293 e catherine.c.azzopardi@gov.mt
https://health.gov.mt | www.publicservice.gov.mt | fb.com/servizzpubbliku

MINISTRY FOR HEALTH

MATER DEI HOSPITAL, TRIQ ID-DONATURI TAD-DEMM,
MSIDA, MALTA

Kindly consider your environmental responsibility before printing this e-mail

From: Joseph Grech <joseph.grech.02@um.edu.mt>
Sent: Thursday, 17 March 2022 10:03
To: Cini Rudolph at Health-MDH <rudolph.cini@gov.mt>
Cc: Grixti Moira at Health-MDH <moira.grixti@gov.mt>; Azzopardi Catherine C at Health-MDH <catherine.c.azzopardi@gov.mt>
Subject: Re: Development and feasibility testing of a multi-component smoking cessation intervention for smokers living with diabetes mellitus

Thank you very much.

Joseph

On Thu, 17 Mar 2022 at 06:52, Cini Rudolph at Health-MDH <rudolph.cini@gov.mt> wrote:

> Dear Joseph
>
> Thank you for informing me. I wish you success in your studies.
>
> If I can be of any help just let me know.

Rudolph

Rudolph Cini
Chief Nursing Manager

SPTAR MATER DEI

T +356 +356 25454261

E rudolph.cini@gov.mt

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From: Joseph Grech <joseph.grech.02@um.edu.mt>
Sent: Wednesday, 16 March 2022 20:59
To: Cini Rudolph at Health-MDH <rudolph.cini@gov.mt>
Cc: Azzopardi Catherine D at MTIP-PWD <catherine.d.azzopardi@gov.mt>; Grixti Moira at Health-MDH <moira.grixti@gov.mt>
Subject: Development and feasibility testing of a multi-component smoking cessation intervention for smokers living with diabetes mellitus

Dear Mr. Cini

My name is Joseph Grech and I am currently reading for a Doctor of Philosophy (Ph.D.) in Nursing at the University of Malta. As part of my Ph.D. project, I am conducting a research study entitled, "**Development and feasibility testing of a multi-component smoking cessation intervention for smokers living with diabetes mellitus: a randomised feasibility study**". This study aims to evaluate the feasibility and acceptability of a multi-component smoking cessation intervention among individuals with diabetes.

While I had already planned to deliver the intervention myself, and thus sought ethical clearance (from MDH and the Faculty), following my initial studies in which participants suggested that smoking cessation support could be provided within the diabetes clinic, I thought of the possibility of testing the intervention in practice by training the diabetes practice nurses and supporting them in providing the intervention to recruited patients as part of their practice (as a feasibility study). Both Moira and Catherine (and the diabetes practice nurse working in Gozo) agreed to try this out. In a nutshell, on enrollment to the study (probably over a year) participants will be randomised on a 1:1 basis to the intervention or to the control group for 12 weeks. Participants will be provided between three to eight 30 minutes sessions over this period during which the nurses will support the participants in quitting. Nicotine replacement therapy (nicotine patch and Spray for daily use for six weeks) will also be provided from my end. I am aiming to recruit around 100 participants (for both intervention and control) and an additional 30-40 participants (intervention and control) as a pilot study.

Kind regards,

Joseph

On Mon, 12 Apr 2021 at 13:44, Tonna Lucy-Anne at Health-MDH <lucy-anne.tonna@gov.mt> wrote:

From: Stephen Fava <stephen.fava@um.edu.mt>
Sent: Monday, 12 April 2021 13:40
To: Tonna Lucy-Anne at Health-MDH <lucy-anne.tonna@gov.mt>
Subject: Re: FW: Development and feasibility testing of a multi-component smoking cessation intervention for smokers living with diabetes mellitus

Approved from my end.

On Mon, 12 Apr 2021 at 06:53, Tonna Lucy-Anne at Health-MDH <lucy-anne.tonna@gov.mt> wrote:

For your approval please.

From: Joseph Grech <joseph.grech.02@um.edu.mt>
Sent: Saturday, 10 April 2021 21:20
To: Fava Stephen at Health-MDH <stephen.fava@gov.mt>
Cc: Tonna Lucy-Anne at Health-MDH <lucy-anne.tonna@gov.mt>; Roberta Sammut <roberta.sammut@um.edu.mt>; Norman, Ian <ian.j.norman@kcl.ac.uk>
Subject: Development and feasibility testing of a multi-component smoking cessation intervention for smokers living with diabetes mellitus

Dear Prof. Fava,

I hope you are doing well. I am Joseph Grech who had asked your permission to proceed with recruiting participants (patients attending at the diabetes education unit) for a study on smoking and diabetes. As you may recall I am currently studying for a Ph.D. where I will be eventually developing a smoking cessation intervention for individuals with diabetes and assessing this for its feasibility.

I am sending this email to seek approval from your end for the remaining studies, prior to applying to the University Research Ethics Committee. I will be needing the support of the staff at the diabetes education unit and also the diabetes out-patients department for recruiting patients as participants. I would appreciate it if these could identify potential participants, ask them if they would be interested in participating, and forward me their contact details (mobile phone number) with their permission and/or provide my details to them.

My Ph.D. project comprises several related research studies. The following are the studies for which I would need assistance in recruitment:

I am attaching the original permissions that I had acquired. I am sending this email thus to seek your approval so that I can submit the revisions to Prof Fava, the Data Protection Officer at MDH and the CEO, and then to FREC and UREC.

Thank you in advance

Joseph Grech

image001.jpg
24K

L-Università ta' Malta

Joseph Grech <joseph.grech.02@um.edu.mt>

Development and feasibility testing of a multi-component smoking cessation intervention for smokers living with diabetes mellitus

Grixti Moira at Health-MDH <moira.grixti@gov.mt> 17 March 2022 at 14:02
To: Cini Rudolph at Health-MDH <rudolph.cini@gov.mt>, Joseph Grech <joseph.grech.02@um.edu.mt>
Cc: Azzopardi Catherine C at Health-MDH <catherine.c.azzopardi@gov.mt>

Dear Joseph,

Good afternoon.

We are looking forward in participating in your study.

Thank you for the opportunity

Kind Regards

Moira

Moira Grixti
Senior Practice Nurse
Diabetes Education Unit
Health-Mater Dei Hospital

t +356 25455117/79847684 e moira.grixti@gov.mt
https://health.gov.mt | www.publicservice.gov.mt | fb.com/servizzpubbliku

MINISTRY FOR HEALTH

MATER DEI HOSPITAL, TRIQ ID-DONATURI TAD-DEMM,
MSIDA, MALTA

Appendix 7.24: Gozo General Hospital Approval (pilot study)

L-Università ta' Malta

Joseph Grech <joseph.grech.02@um.edu.mt>

RE: [External] - Development and feasibility testing of a multi-component smoking cessation intervention for smokers living with diabetes mellitus

Georgene Xuereb <georgene.xuereb@stewardmalta.org> 21 March 2022 at 12:02
To: Joseph Grech <joseph.grech.02@um.edu.mt>
Cc: Dorianne Attard <dorianne.d.attard@gov.mt>

Dear Mr Grech,

I would like to inform you that your request has been approved. You are kindly requested to forward a copy of Ethics Committee approval prior commencement of the mentioned sessions.

Kind Regards

Georgene Xuereb
Administration Manager
Gozo General Hospital, Steward Health Care Malta
+356 23446365

From: Joseph Grech <joseph.grech.02@um.edu.mt>
Sent: 18 March 2022 12:32
To: Georgene Xuereb <georgene.xuereb@stewardmalta.org>
Subject: Re: [External] - Development and feasibility testing of a multi-component smoking cessation intervention for smokers living with diabetes mellitus

[Quoted text hidden]

Appendix 7.25: Gozo General Hospital Diabetes Practice Nurse Approval (pilot study)

L-Università ta' Malta

Joseph Grech <joseph.grech.02@um.edu.mt>

Ph.D. on smoking and diabetes

Attard Dorianne at GGH-Health <dorianne.d.attard@gov.mt> 24 August 2021 at 12:52
To: Joseph Grech <joseph.grech.02@um.edu.mt>
Cc: Cini Simone A at GGH-Health <simone.a.cini@gov.mt>

Dear Joseph,

Thank you for your email and summary of our discussion. Helping patients living with diabetes to quit smoking is fundamental since this prevents several complications. Hence, I will be happy to help you in the study. I am copying Ms Simone Cini (Nursing Director GGH) to put her in the loop.

Regards,

Dorianne

Dorianne Attard
Practice Nurse
Nursing Administration Office
Health-Gozo General Hospital

t +356 23446311 e dorianne.d.attard@gov.mt
https://health.gov.mt | www.publicservice.gov.mt | fb.com/servizzpubbliku

MINISTRY FOR HEALTH
GOZO GENERAL HOSPITAL, TA' L-IBRAGG STREET,
IR-RABAT, GOZO, MALTA

Appendix 7.26: Health Promotion and Disease Prevention Directorate Director Approval (feasibility study)

L-Università ta' Malta

Joseph Grech <joseph.grech.02@um.edu.mt>

Development and feasibility testing of a multi-component smoking cessation intervention for smokers living with diabetes mellitus

Vassallo Pauline at Health Regulation <pauline.j.vassallo@gov.mt> 11 April 2021 at 22:54
To: Joseph Grech <joseph.grech.02@um.edu.mt>
Cc: Borg Buontempo Mariella at Health Regulation <mariella.borg-buontempo@gov.mt>, Roberta Sammut <roberta.sammut@um.edu.mt>, "Norman, Ian" <ian.j.norman@kcl.ac.uk>

proceed

Dr Paula Vassallo BChD, MSc, DDPH RCS, MBA, FFPH
Director
Health Promotion and Disease Prevention
Department for Health Regulation

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MINISTRY FOR HEALTH

HEALTH PROMOTION AND DISEASE PREVENTION, PJAZZA SAN LUQA,
PIETA, MALTA

Appendix 7.27: Pilot study information letter (in English)

Participants` Information Sheet

Dear Participant,

My name is Joseph Grech and I am currently reading for a Doctor of Philosophy (Ph.D.) in Nursing at the University of Malta. As part of my Ph.D. project, I am conducting a research study entitled, **"Development and feasibility testing of a multi-component smoking cessation intervention for smokers living with diabetes mellitus: a pilot study"**. The aim of this study is to test and refine the proposed smoking cessation intervention for individual with diabetes. While this study will help you to evaluate your smoking habits and assist you in quitting smoking, your insight will help us ensure the successfulness of this smoking cessation intervention for use amongst individuals with diabetes. You will only be asked to share data that is necessary for this research. All data collected from this research shall be used solely for this study.

You are being invited to participate in a pilot study lasting twelve weeks, where you will be provided with a multi-component smoking cessation intervention which includes the provision of nicotine replacement therapy – the nicotine patch and/or Spray for daily use for up to six weeks, helping you to re-consider your smoking habits and support you to quit smoking, free of charge. The multi-component smoking cessation intervention will be provided by nurses at the Diabetes Education Unit at Mater Dei Hospital or at the Diabetes Education Clinic at Gozo General Hospital. Each session should not take longer than one hour. You will be provided with a personal unique code, unknown to anyone else. You will have to refer to this code in filling in the study's baseline questionnaire (on your personal characteristics, your health status, your diabetes and smoking profiles, and your feelings in the past week), and the questionnaire at the end of the study period (on your smoking habit, about the support you have received during the study period, and your views and opinions of the provided intervention). Each questionnaire should not take you more than 20 minutes to fill in. You will also be asked to take a simple, easy, and non-invasive exhaled carbon monoxide test, to measure how much carbon monoxide is in your body at baseline. If you quit smoking, you will also be asked to take the carbon monoxide test again and to provide a urine sample which will be assessed for traces of nicotine to confirm smoking abstinence. Unless you have any objections, the provision of the multi-component smoking cessation intervention will be audio recorded. This will help ensure the integrity of the intervention provided. Following this study, you may be invited to participate to a follow-up interview.

Participation in this study does not expose you to any risks. If you fail to quit smoking, the service of a smoking cessation advisor from the Health Promotion and Disease Prevention

Directorate is available at no financial cost on your part, by calling the National Quitline 8007 3333. Participation in this study is completely voluntary and you are free to accept or refuse to take part without giving a reason. Refusing to participate will not have any impact or negative consequences on your care. While you are encouraged to take the provided nicotine replacement therapy on quitting smoking, you are also free to refuse without giving a reason. In the very unlikely event of an adverse event, you are to inform the researcher who will ensure that you are seen by a doctor of your choice free of charge. You may also withdraw from the study at any time without giving a reason and this will not bear any negative repercussions on you or your care. Any data collected by the researcher from your end, unless this cannot be identified, i.e. anonymized data, will hence be erased. All personal data collected by the researcher will only be accessed by the researcher. The audio-recordings (of the provision of the multi-component smoking cessation intervention) will be provided to the researcher on a password protected encrypted USB and stored on the researcher`s personal computer that is also password protected and in an encrypted format. A random selection of these audio-recordings will be listened to and assessed for treatment integrity by the researcher. I can assure you that confidentiality will be maintained throughout the study and that your identity and personal information will not be revealed in the thesis and any publications, reports, and presentations arising from this research. Any personal data in hard-copy form, such as the consent forms will be placed in a locked cupboard.

A copy of the information sheet and consent form will be provided for future reference. As a participant, you have the right, under the General Data Protection Regulation (GDPR) and national legislation that implements and further specifies the relevant provisions of said regulation, to access, rectify, and where applicable ask for the data concerning you to be erased. Anonymous results from this research study will be published in my Ph.D. thesis and may be published in academic journals or reported at conferences or to health service organisations. Some of the things you may write in the questionnaire may be used as direct quotes in publications or conferences, but your confidentiality and anonymity will be maintained, and it will not be possible to identify you. A summary of the results of this research study will be offered to all participants who show interest. Once this research study is completed, the audio-recordings will be erased. The consent forms will be destroyed within two years from the completion of my Ph.D. project.

This study has been approved by the Research Ethics Committee of the Faculty of Health Sciences at the University of Malta.

Thank you for your time and consideration. Should you have any questions or concerns do not hesitate to contact me on **9*** ***4** or by e-mail joseph.grech.02@um.edu.mt or my supervisor **Prof. Roberta Sammut** on **2340 1831** or roberta.sammut@um.edu.mt or my co-supervisor **Prof. Ian James Norman** on **+44 (0)207 848 3020** or ian.j.norman@kcl.ac.uk.

Yours Sincerely,

_____	_____	_____
Mr. Joseph Grech	**Prof. Roberta Sammut**	**Prof. Ian James Norman**
Researcher	Research Supervisor	Research Co-supervisor
Tel: 9* ***4**	**Tel. 2340 1831**	**Tel. +44 (0)207 848 3020**
joseph.grech.02@um.edu.mt	**roberta.sammut@um.edu.mt**	**ian.j.norman@kcl.ac.uk**

Appendix 7.28: Pilot study information letter (in Maltese)

Formula ta' Informazzjoni għall-Parteċipanti

Għażiż/a Parteċipant/a,

Jiena Joseph Grech, u fil-mument preżenti qed insegwi Dottorat tal-Filosofija fl-istudju tal-Infermiera fl-Università ta' Malta. Bħala parti mill-proġett tad-Dottorat, qiegħed immexxi studju ta' riċerka, li jismu, **"Żvilupp u ttestjar tal-fattibilità ta' intervent ta' waqfien mit-tipjip b'ħafna komponenti għal dawk li jpejpu u jgħixu bid-dijabete: studju pilota."** L-għan ta' dan l-istudju huwa li jittestja u jirfina l-intervent propost għall-waqfien mit-tipjip fost individwi bid-dijabete. Filwaqt li dan l-istudju se jgħinek tevalwa d-drawwiet tat-tipjip tiegħek u jgħinek biex tieqaf tpejjep, l-għarfien tiegħek se jgħinna niżguraw is-suċċess ta' dan l-intervent propost għall-waqfien mit-tipjip għall-użu fost individwi bid-dijabete. Int se tintalab biss taqsam informazzjoni li hija meħtieġa għal din ir-riċerka. Kull informazzjoni miġbura se tintuża biss għall-għan ta' dan l-istudju.

Int qed tiġi mistieden biex tipparteċipa fi studju pilota li jdum tnax -il ġimgħa, fejn tkun ipprovdut b'intervent għall-waqfien mit-tipjip b'ħafna komponenti li jinkludi l-għoti tas-sostituzzjoni terapewtika tan-nikotina - il-*patch* u/jew l-*ispray* tan-nikotina għall-użu ta' kuljum sa sitt ġimgħat, sabiex ngħinuk terġa' tikkunsidra d-drawwiet tat-tipjip tiegħek u se nappoġġjawk biex tieqaf tpejjep, mingħajr ħlas. L-intervent għall-waqfien mit-tipjip b'ħafna komponenti se jiġi pprovdut minn infermiera fit-Taqsima tal-Edukazzjoni tad-Dijabete fl-Isptar Mater Dei jew fil-Klinika tal-Edukazzjoni tad-Dijabete fl-Isptar Ġenerali ta' Għawdex. Kull sessjoni m'għandhiex tieħu aktar minn siegħa. Se tingħata kodiċi personali uniku mhux magħruf għal ħaddieħor. Int trid tirreferi għal dan il-kodiċi meta timla l-kwestjonarju bażi tal-istudju (dwar il-karatteristiċi personali tiegħek, l-istat ta' saħħtek, l-profil tad-dijabete u tat-tipjip tiegħek, u s-sentimenti tiegħek fil-ġimgħa li għaddiet), u l-kwestjonarju fi tmiem l-istudju (dwar il-vizzju tat-tipjip tiegħek, dwar l-appoġġ addizzjonali li rċevejt matul il-perjodu ta' dan l-istudju, u l-fehmiet u l-opinjonijiet tiegħek dwar l-intervent pprovdut). M'għandekx tieħu iktar minn 20 minuta biex timla kull kwestjonarju. Barra minn hekk, int se tintalab tieħu t-test tan-nifs tal-monossidu tal-karbonju li hu sempliċi, faċli u mhux invażiv, biex jkejjel kemm hemm monossidu tal-karbonju f'ġismek, fil-bidu tal-intervent. Jekk tieqaf tpejjep, tintalab ukoll biex terġa' tieħu t-test tal-monossidu tal-karbonju u tipprovdi kampjun tal-awrina li jiġi vvalutat għal traċċi tan-nikotina biex nikkonfermaw l-astinenza tat-tipjip. Sakemm m'għandek l-ebda oġġezzjoni, il-provvediment tal-intervent għall-waqfien mit-tipjip b'ħafna komponenti se jkun irrekordjat bl-awdjo. Dan jgħin biex tiġi żgurata l-integrità tal-intervent ipprovdut. Wara dan l-istudju tista' tkun mistieden biex tipparteċipa f'intervista li ssegwi fuq l-intervent.

Il-parteċipazzjoni tiegħek f'dan l-istudju ma tesponik għal ebda riskju. Jekk ma jirnexxilekx tieqaf mit-tipjip, is-servizz ta' konsulent dwar il-waqfien mit-tipjip mid-Direttorat għall-Promozzjoni tas-Saħħa u l-Prevenzjoni tal-Mard huwa disponibbli mingħajr spejjeż finanzjarji min-naħa tiegħek, billi ċċempel lin-*National Quitline* 8007 3333. Il-parteċipazzjoni tiegħek f'dan l-istudju hija għażla għal kollox volontarja u inti ħieles/ħielsa li taċċetta jew tirrifjuta li tieħu sehem mingħajr ma' tagħti ebda raġuni. Jekk tirrifjuta li tipparteċipa dan mhux ħa jkollu impatt jew konsegwenzi negattivi fuq il-kura tiegħek. Filwaqt li nħeġġuk sabiex tieħu s-sostituzzjoni terapewtika tan-nikotina pprovduta, int liberu wkoll li tirrifjuta mingħajr ma tagħti raġuni. Fil-każ improbabbli ħafna ta' avveniment avvers, inti għandek tinforma lir-riċerkatur li se jiżgura li tabib tal-għażla tiegħek jarak mingħajr ħlas. Tista' wkoll tirtira mill-istudju fi kwalunkwe ħin mingħajr ma tagħti raġuni u dan ma jkollu l-ebda riperkussjoni negattiva fuqek jew fuq il-kura tiegħek. Kwalunkwe *data* miġbura mir-riċerkatur minn tmiemek, sakemm din ma tistax tiġi identifikata, jiġifieri *data* anonimizzata, għalhekk titħassar. Id-*data* personali kollha miġbura mir-riċerkatur se tkun aċċessata biss mir-riċerkatur. Ir-reġistrazzjoniet bl-awdjo (tal-provvediment tal-intervent għall-waqfien mit-tipjip b'ħafna komponenti) se jiġu pprovduti lir-riċerkatur permezz ta' USB protetta b'*password* u b'*data encryption* u jinħażnu fuq il-kompjuter personali tar-riċerkatur li huwa wkoll protett b'*password* u b' *data encryption*. Għażla każwali ta' dawn ir-reġistrazzjonijiet bl-awdjo se tkun mismugħa u evalwata għall-integrità tat-trattament mir-riċerkatur. Nassigurak li se tinżamm il-kunfidenzjalità matul l-istudju kollu u l-identità tiegħek flimkien mal-informazzjoni personali miġbura, mhumiex se jiġu żvelati mkien fit-teżi, fir-rapporti, fil-preżentazzjonijiet u fil-pubblikazzjonijiet li jistgħu jirriżultaw minnha. Kwalunkwe *data* personali f'forma stampata, bħall-formoli tal-kunsens jitqegħdu f'armarju msakkra.

Kopja tal-folja tal-informazzjoni u tal-formola ta' kunsens se jkunu pprovduti sabiex ikunu aċċessibbli fil-futur. Barra minn hekk, skont ir-Regolamenti Ġenerali dwar il-Protezzjoni tad-*Data* (GDPR) u l-leġiżlazzjoni nazzjonali li timplimenta u tispeċifika aktar il-provvedimenti relevanti tar-regolamenti msemmija, inti għandek id-dritt li taċċessa, tirretifika, u fejn japplika titlob sabiex titħassar id-*data* li tikkonċernak. Riżultati anonimi minn dan l-istudju ta' riċerka se jiġu ppubblikati fit-teżi tad-Dottorat tiegħi u jistgħu jiġu ppubblikati f'ġurnali akkademiċi jew irrappurtati f'konferenzi jew organizzazzjonijiet tas-servizzi tas-saħħa. Uħud mill-affarijiet li tista' tikteb fil-kwestjonarji jistgħu jintużaw bħala kwotazzjonijiet diretti f'pubblikazzjonijiet jew konferenzi, iżda l-kunfidenzjalità u l-anonimità tiegħek se jinżammu, u mhux se jkun possibbli li tidentifikak. Sommarju tar-riżultati ta' dan l-istudju ta' riċerka se jkun offrut lill-parteċipanti kollha li juru interess. Ladarba jitlesta dan l-istudju tar-riċerka, ir-reġistrazzjoniet tal-awdjo se jitħasru. Il-formoli tal-kunsens jinqerdu fi żmien sentejn mit-tlestija tal-proġett tad-Dottorat.

Dan l-istudju ġie approvat mill-Kumitat għall-Etika fir-Riċerka fi ħdan il-Fakultà tax-Xjenzi tas-Saħħa fl-Università ta' Malta.

Grazzi ħafna tal-ħin u s-sehem tiegħek f'dan l-istudju. F'każ li jkollok xi mistoqsijiet jew tixtieq tiċċara xi ħaġa, tista' ċċempilli fuq **9*** ***4** jew tibgħatli imejl fuq joseph.grech.02@um.edu.mt. Tista' wkoll tikkuntattja lis-Superviżura **Prof. Roberta Sammut** fuq **2340 1831** jew billi tibgħat imejl fuq roberta.sammut@um.edu.mt jew lil-Ko-Superviżur **Prof. Ian James Norman** fuq **+44 (0)207 848 3020** jew b'imejl fuq ian.j.norman@kcl.ac.uk.

Dejjem tiegħek,

Mr. Joseph Grech	**Prof. Roberta Sammut**	**Prof. Ian James Norman**
Isem ir-Riċerkatur	Isem is-Superviżura tar-riċerka	Isem il-Ko-Superviżur tar-riċerka
Tel: 9* ***4**	**Tel. 2340 1831**	**Tel. +44 (0)207 848 3020**
joseph.grech.02@um.edu.mt	**roberta.sammut@um.edu.mt**	**ian.j.norman@kcl.ac.uk**

Appendix 7.29: Pilot study consent form (in English)

Participants` Consent Form

Development and feasibility testing of a multi-component smoking cessation intervention for smokers living with diabetes mellitus: a pilot study

I, the undersigned, give my consent to take part in the study conducted by Mr. Joseph Grech. The purpose of this document is to specify the terms of my participation in this research study.

1. I have been given written and verbal information about the purpose of the study and all questions have been answered.
2. I understand that I have been invited to participate in a pilot study lasting twelve weeks, which aims to test and refine the proposed smoking cessation intervention among individuals with diabetes. I am aware that I will be provided with the multi-component smoking cessation intervention which includes the provision of nicotine replacement therapy – the nicotine patch and/or spray for daily use for up to six weeks, helping me to re-consider my smoking habits and support me to quit smoking, free of charge.
3. I understand that the multi-component smoking cessation intervention will be provided by nurses at the Diabetes Education Unit at Mater Dei Hospital or at the Diabetes Education Clinic at Gozo General Hospital. I also understand that each session should not take longer than one hour.
4. I am also aware that I will be invited to fill in a questionnaire on my personal characteristics, my health status, my diabetes and smoking profiles, and my feelings in the past week on enrollment to the study, and another questionnaire on my smoking habit, about the support I have received during the study period, and my views and opinions of the provided intervention at the end of the study, as part of this research study. I understand that the questionnaires are anonymous; I will be aware of my personal identifier through the participant's code which I will refer to in filling in the questionnaires. I also understand that I should not take more than 20 minutes to fill in each questionnaire. I am aware that I will be invited to take a simple, easy, non-invasive exhaled carbon monoxide test at baseline. I am also aware that if I quit smoking, I will also be asked to take the carbon monoxide test and provide a urine sample which will be assessed for traces of nicotine to confirm smoking abstinence. I am also aware that the provision of the multi-component smoking cessation intervention will be audio recorded. I understand that following this study I may be invited to participate to a follow-up interview.
5. I also understand that the researcher is the only person who has access to any personal data collected from his end. I also understand that the audio-recordings (of

the provision of the multi-component smoking cessation intervention) will be provided to the researcher on a password protected encrypted USB and will be stored on the researcher`s personal computer that is also password protected and in an encrypted format. I am aware that a random selection of these audio-recordings will be listened to and assessed for treatment integrity by the researcher. I understand that any personal data in hard-copy form, such as the consent forms will be placed in a locked cupboard.

6. I am aware that my identity and personal information will not be revealed in the researcher's Ph.D. thesis and any publications, reports, and presentations arising from this research.
7. I understand that participation in this study does not expose me to any risks. I am aware that if I fail to quit smoking, the service of a smoking cessation advisor from the Health Promotion and Disease Prevention Directorate is available at no financial cost on my part, by calling the National Quitline 8007 3333. I am also aware that I will be encouraged to take the provided nicotine replacement therapy on quitting smoking, however, I am also free to refuse without giving a reason. I am also aware that in the very unlikely event of an adverse event, I am to inform the researcher who will ensure that I am seen by a doctor of my choice free of charge.
8. I understand that I am free to accept, refuse, or stop participation at any time without giving any reason. This will have no negative repercussions on myself or my care. Furthermore, I also understand that any data collected from my end, unless this cannot be identified, e.g. is anonymised, will be erased.
9. I also understand that my contribution will serve Mr. Joseph Grech to ensure the applicability of this smoking cessation intervention for use amongst individuals with diabetes.
10. I am aware that under the General Data Protection Regulation (GDPR) and national legislation that implements and further specifies the relevant provisions of said regulation, I have the right to access, rectify, and where applicable ask for the data concerning me to be erased.
11. I am also aware that anonymous results from this research study will be published in the researcher's Ph.D. thesis and may be published in academic journals or reported at conferences or to health service organisations.
12. I understand that some of the things I may write in the questionnaires may be used as direct quotes in publications or conferences, but my confidentiality and anonymity will be maintained, and it will not be possible to identify me.
13. I am aware that a summary of the results of this research study will be offered if I show interest (see below).
14. I understand that once the study is completed, the audio-recordings will be erased. I am aware that any personal details, i.e. the consent forms, will be destroyed within two years from completion of the Ph.D. project.

15. I am also aware that I will be provided with a copy of the information letter and consent form for future reference.
16. I have read and understood the points and statements of this form. I have had all the questions answered to my satisfaction, and I agree to participate in this study.

Participant: _____

Signature: _____

Date: _____

Mr. Joseph Grech	**Prof. Roberta Sammut**	**Prof. Ian James Norman**
Researcher	Research Supervisor	Research Co-supervisor
Tel: 9* ***4**	**Tel. 2340 1831**	**Tel. +44 (0)207 848 3020**
joseph.grech.02@um.edu.mt	**roberta.sammut@um.edu.mt**	**ian.j.norman@kcl.ac.uk**

Please note:

Please leave <u>your mobile phone number</u> so that we can contact you with the date, time, and place of your first smoking cessation session. At the end of the intervention, you may also be invited to participate in a follow-up interview:

_____

If you agree to be contacted to be provided with a summary of the results of this research study, please tick this box ☐

Appendix 7.30: Pilot study consent form (in Maltese)

Formola ta' Kunsens tal-Parteċipanti

Żvilupp u ttestjar tal-fattibilità ta' intervent ta' waqfien mit-tipjip b'ħafna komponenti għal dawk li jpejpu u jgħixu bid-dijabete: studju pilota

Jien, hawn taħt iffirmat, nagħti l-kunsens tiegħi biex nieħu sehem fl-istudju mmexxi mis-Sur Joseph Grech. L-għan ta' dan id-dokument hu li jiġu sspeċifikati t-termini tal-parteċipazzjoni tiegħi f'dan l-istudju ta' riċerka.

1. Jien ingħatajt informazzjoni miktuba u verbali dwar l-għan tal-istudju u l-mistoqsijiet kollha twieġbu.
2. Nifhem li ġejt mistieden biex nipparteċipa fi studju pilota li jdum tnax-il ġimgħa, li għandu l-għan li jittestja u jirfina l-intervent propost għall-waqfien mit-tipjip fost individwi bid-dijabete. Jiena konxju li se niġi pprovdut bl-intervent ta' waqfien mit-tipjip b'ħafna komponenti, li jinkludi l-għoti tas-sostituzzjoni terapewtika tan-nikotina - il-*patch* u/jew l-*ispray* tan-nikotina għall-użu ta' kuljum sa sitt ġimgħat, sabiex jgħinni nikkunsidra d-drawwiet tiegħi tat-tipjip u jappoġġjani biex nieqaf mit-tipjip, mingħajr ħlas.
3. Nifhem li l-intervent għall-waqfien mit-tipjip b'ħafna komponenti se jiġi pprovdut minn infermiera fit-Taqsima tal-Edukazzjoni tad-Dijabete fl-Isptar Mater Dei jew fil-Klinika tal-Edukazzjoni tad-Dijabete fl-Isptar Ġenerali ta' Għawdex. Nifhem ukoll li kull sessjoni m'għandhiex tieħu aktar minn siegħa.
4. Jiena konxju wkoll li se niġi mistieden biex nimla kwestjonarju dwar il-karatteristiċi personali tiegħi, l-istat ta' saħħti, l-profil tad-dijabete u tat-tipjip tiegħi, u s-sentimenti tiegħi fil-ġimgħa li għaddiet meta nirreġistra għall-istudju, u kwestjonarju ieħor dwar il-vizzju tat-tipjip tiegħi, dwar l-appoġġ li rċevejt matul il-perjodu ta' dan l-istudju, u dwar l-fehmiet u l-opinjonijiet tiegħi tal-intervent ipprovdut fi tmiem l-istudju, bħala parti minn dan l-istudju ta' riċerka. Nifhem li l-kwestjonarji huma anonimi; jien se nkun naf l-identifikatur personali tiegħi permezz ta' kodiċi tal-parteċipant li se nirreferi għalih biex nimla l-kwestjonarji. Nifhem ukoll li m'għandix nieħu aktar minn 20 minuta biex nimla kull kwestjonarju. Jiena konxju li se nkun mistieden biex nagħmel test tan-nifs tal-monossidu tal-karbonju li hu test sempliċi, faċli u mhux invażiv meta nirreġistra għall-istudju. Jiena konxju wkoll li jekk nieqaf mit-tipjip, nintalab ukoll biex nerġa' nieħu t-test tal-monossidu tal-karbonju u nipprovdi kampjun tal-awrina li jiġi vvalutat għal traċċi ta' nikotina biex tikkonfermaw l-astinenza tat-tipjip. Jiena konxju wkoll li l-provvediment tal-intervent għall-waqfien mit-tipjip b'ħafna komponenti se jkun irrekordjat bl-awdjo. Nifhem li wara dan l-istudju nista' nkun mistieden biex nipparteċipa f'intervista li ssegwi fuq l-intervent.

5. Nifhem ukoll li r-riċerkatur huwa l-unika persuna li għandha aċċess għal kwalunkwe *data* personali miġbura minn tmiemu. Nifhem ukoll li r-reġistrazzjoniet bl-awdjo (tal-provvediment tal-intervent għall-waqfien mit-tipjip b'ħafna komponenti) se jiġu pprovduti lir-riċerkatur permezz ta' USB protetta b'*password* u b'*data encryption* u jinħażnu fuq il-kompjuter personali tar-riċerkatur li huwa wkoll protett b'*password* u b' *data encryption*. Jiena konxju li l-għażla każwali ta' dawn ir-reġistrazzjonijiet tal-awdjo se tkun mismugħa u evalwata għall-integrità tat-trattament mir-riċerkatur. Nifhem li kwalunkwe *data* personali f'forma stampata, bħall-formoli tal-kunsens jitqegħdu f'armarju msakkar.
6. Jien konxju wkoll li l-identità tiegħi u l-informazzjoni personali mhumiex se jinkixfu fit-teżi tad-Dottorat tar-riċerkatur, u fir-rapporti, fil-preżentazzjonijiet u fil-pubblikazzjonijiet li jistgħu jirriżultaw minn din ir-riċerka.
7. Nifhem li l-parteċipazzjoni tiegħi f'dan l-istudju ma tesponini għal ebda riskju. Jiena konxju li jekk ma jirnexxilix nieqaf mit-tipjip, is-servizz ta' konsulent dwar il-waqfien mit-tipjip mid-Direttorat għall-Promozzjoni tas-Saħħa u l-Prevenzjoni tal-Mard huwa disponibbli mingħajr spejjeż finanzjarji min-naħa tiegħi, billi ċċempel lin-*National Quitline* 8007 3333. Jiena konxju wkoll li se nkun imħeġġeġ sabiex nieħu s-sostituzzjoni terapewtika tan-nikotina pprovduta meta nieqaf tpejjep, madankollu, jien liberu wkoll li nirrifjuta mingħajr ma nagħti raġuni. Jiena konxju wkoll li fil-każ improbabbli ħafna ta' avveniment avvers, jien għandi ninforma lir-riċerkatur li se jiżgura li tabib tal-għażla tiegħi jarani mingħajr ħlas.
8. Nifhem li jien liberu/a li naċċetta, nirrifjuta jew inwaqqaf il-parteċipazzjoni tiegħi f'kull ħin bla ma nagħti raġuni. Dan mhu se jkollu ebda riperkussjonijiet negattivi fuqi nnifsi jew fuq il-kura tiegħi. Barra minn hekk, nifhem ukoll li kwalunkwe *data* miġbura mingħandi, sakemm din ma tistax tiġi identifikata, eż. hija anonimizzata, titħassar.
9. Nifhem ukoll li l-kontribuzzjoni tiegħi se sservi lis-Sur Joseph Grech biex jiżgura s-siwi ta' dan l-intervent għall-waqfien mit-tipjip għall-użu fost individwi bid-dijabete.
10. Jien konxju li skont ir-Regolamenti Ġenerali dwar il-Protezzjoni tad-*Data* (GDPR) u l-leġiżlazzjoni nazzjonali li timplimenta u tispeċifika aktar il-provedimenti relevanti tar-regolamenti msemmija, jiena għandi d-dritt li naċċessa, nirretifika, u fejn japplika, nitlob sabiex titħassar id-*data* li tikkonċernani.
11. Jien konxju wkoll li r-riżultati anonimi minn dan l-istudju ta' riċerka se jiġu ppubblikati fit-teżi tad-Dottorat tar-riċerkatur u jistgħu jiġu ppubblikati f'ġurnali akkademiċi jew irrappurtati f'konferenzi jew lil organizzazzjonijiet tas-servizzi tas-saħħa.
12. Nifhem li wħud mill-affarijiet li ngħid jistgħu jintużaw bħala kwotazzjonijiet diretti f'pubblikazzjonijiet jew konferenzi, iżda l-kunfidenzjalità u l-anonimità tiegħi se jinżammu, u mhux se jkun possibbli li niġi identifikat/a.
13. Jiena konxju li se nkun offrut sommarju tar-riżultati ta' dan l-istudju ta' riċerka jekk nuri interess (ara hawn taħt).
14. Nifhem li ladarba jitlesta dan l-istudju tar-riċerka, ir-reġistrazzjoniet tal-awdjo se jitħasru. Jiena konxju li kwalunkwe dettalji personali, jiġifieri l-formoli tal-kunsens, se jinqerdu fi żmien sentejn mit-tlestija tal-proġett tad-Dottorat.

15. Jien naf ukoll li se ningħata kopja tal-folja ta’ informazzjoni u tal-formola ta’ kunsens sabiex inkun nista’ naċċessahom fil-futur.
16. Jien qrajt u fhimt il-punti u d-dikjarazzjonijiet f’din il-formola. Inħossni sodisfatt/a bit-tweġibiet li ngħatajt għall-mistoqsijiet li kelli, u qed naċċetta minn jeddi li nipparteċipa f’dan l-istudju.

Parteċipant/a: _____

Firma: _____

Data: _____

_____	_____	_____
Mr. Joseph Grech	**Prof. Roberta Sammut**	**Prof. Ian James Norman**
Isem ir-riċerkatur	Isem is-superviżura	Isem il-ko-superviżur
Tel: 9* ***4**	**Tel. 2340 1831**	**Tel. +44 (0)207 848 3020**
joseph.grech.02@um.edu.mt	**roberta.sammut@um.edu.mt**	**ian.j.norman@kcl.ac.uk**

Jekk jogħġbok innota:

Jekk jogħġbok ħalli n-numru tal-mowbajl tiegħek sabiex inkunu nistgħu nikkuntattjawk bil-ġurnata, l-ħin u l-post ta’ l-ewwel sessjoni tiegħek għall-waqfien mit-tipjip. Fl-aħħar tal-intervent, tista’ wkoll tkun mistieden biex tipparteċipa f’intervista ta’ segwitu:

_____

Jekk jogħġbok immarka din il-kaxxa jekk taqbel li tiġi kkuntattjat biex tingħata sommarju tar-riżultati ta’ dan l-istudju ta’ riċerka: ☐

Appendix 7.31: Pilot study follow-up interview information letter (in English)

Participants` Information Sheet

Dear Participant,

My name is Joseph Grech and I am currently reading for a Doctor of Philosophy (Ph.D.) in Nursing at the University of Malta. As part of my Ph.D. project, I am conducting a follow-up interview on the research study entitled, **"Development and feasibility testing of a multi-component smoking cessation intervention for smokers living with diabetes mellitus: a pilot study"**, to which you participated. This study aims to refine the proposed smoking cessation intervention for use amongst individuals with diabetes. Your insight will help us ensure the applicability of the multi-component smoking cessation intervention prior to further assessment. You will only be asked to share data that is necessary for this research. All data collected from this research shall be used solely for this study.

You are being invited to participate in an interview exploring your views, and suggestions on the smoking cessation intervention. The interview should not take more than 40 minutes and will be held at one of the Faculty of Health Science's approved and identified training sites at a time and date most suitable for you (Gozitan residents will be invited to attend at Gozo General Hospital). Unless you have any objections, the interview will be audio-recorded. You are not obliged to answer all the questions and may withdraw from the study at any time without giving a reason. Withdrawal from the study will not have any negative repercussions on you or your care. Furthermore, any data collected from your end, unless this cannot be identified, e.g. has been already anonymised, will be erased. I can assure you that confidentiality will be maintained throughout the study and that your identity and personal information will not be revealed in the thesis and any publications, reports, and presentations arising from this research. All data collected will be pseudonymised meaning that the transcript of the audio recording will be protected by a code system and that this data will be stored securely and separately from any personal data (audio-recording and consent forms). This data may only be accessed by the researcher. The academic supervisors and the examiners will typically have access to coded data only. There may be exceptional circumstances which allow the supervisors to have access to the audio-recording too, for verification purposes (if you would like to know who accessed your data, please contact me as per the details below). The audio-recording and transcript will be stored on the researcher`s personal computer that is password protected and in an encrypted format. Any material in hard-copy form, such as the consent forms will be placed in separate locked cupboards.

Participation in this study does not expose you to any risks. If you are still interested in quitting smoking, the service of a smoking cessation advisor from the Health Promotion and Disease Prevention Directorate, is available at no financial cost on your part, by calling the National Quitline 8007 3333.

Participation in this study is completely voluntary and you are free to accept or refuse to take part without giving a reason. Refusing to participate will not have any impact or negative consequences on your care. A copy of the information sheet and consent form will be provided for future reference. As a participant, you have the right, under the General Data Protection Regulation (GDPR) and national legislation that implements and further specifies the relevant provisions of said regulation, to access, rectify, and where applicable ask for the data concerning you to be erased. Once this research study is completed, the audio-recording will be erased and data will be retained only in anonymous form. Anonymous results from this research study will be published in my Ph.D. thesis and may be published in academic journals or reported at conferences or to health service organisations. Some of the things you say may be used as direct quotes in publications or conferences, but your confidentiality and anonymity will be maintained, and it will not be possible to identify you. A summary of the results of this research study will be offered to all participants who show interest. The consent forms will be destroyed within two years from the completion of my Ph.D. project.

This study has been approved by the Research Ethics Committee of the Faculty of Health Sciences at the University of Malta.

Thank you for your time and consideration. Should you have any questions or concerns do not hesitate to contact me on **9*** ***4** or by e-mail joseph.grech.02@um.edu.mt or my supervisor **Prof. Roberta Sammut** on **2340 1831** or roberta.sammut@um.edu.mt or my co-supervisor **Prof. Ian James Norman** on **+44 (0)207 848 3020** or ian.j.norman@kcl.ac.uk.

Yours Sincerely,

Mr. Joseph Grech	**Prof. Roberta Sammut**	**Prof. Ian James Norman**
Researcher	Research Supervisor	Research Co-supervisor
Tel: 9* ***4**	**Tel. 2340 1831**	**Tel. +44 (0)207 848 3020**
joseph.grech.02@um.edu.mt	**roberta.sammut@um.edu.mt**	**ian.j.norman@kcl.ac.uk**

Appendix 7.32: Pilot study follow-up interview information letter (in Maltese)

Formula ta' Informazzjoni għall-Parteċipanti

Għażiż/a Parteċipant/a,

Jiena Joseph Grech, u fil-mument preżenti qed insegwi Dottorat tal-Filosofija fl-istudju tal-Infermiera l-Università ta' Malta. Bħala parti mill-proġett tad-Dottorat, qed inwettaq intervista ta' segwitu fuq l-istudju ta' riċerka, li jismu, **"Żvilupp u ttestjar tal-fattibilità ta' intervent ta' waqfien mit-tipjip b'ħafna komponenti għal dawk li jpejpu u jgħixu bid-dijabete: studju pilota"**, li pparteċipajt fih. L-għan ta' dan l-istudju huwa li jirfina l-intervent propost għall-waqfien mit-tipjip għall-użu fost individwi bid-dijabete. L-għarfien tiegħek jgħinna niżguraw l-applikabilità ta' l-intervent ta' waqfien mit-tipjip b'ħafna komponenti qabel aktar valutazzjoni. Int se tintalab biss taqsam informazzjoni li hija meħtieġa għal din ir-riċerka. Kull informazzjoni miġbura se tintuża biss għall-għan ta' dan l-istudju.

Int qed tiġi mistieden biex tipparteċipa f'intervista li tesplora l-opinjonijiet, u s-suġġerimenti tiegħek dwar l-intervent għall-waqfien mit-tipjip,. Din il-intervista mhux se tieħu iktar minn 40 minuta u se ssir f'wieħed mis-siti ta' taħriġ approvati u identifikati mill-Fakultà tax-Xjenza tas-Saħħa f'ġurnata u f'ħin l-aktar adattati għalik (ir-residenti Għawdxin se jiġu mistiedna jattendu fl-Isptar Ġenerali ta' Għawdex). Sakemm m'għandek l-ebda oġġezzjoni, ir-risposti tiegħek se jiġu rrekordjati bl-awdjo. M'intix obbligat/a li twieġeb il-mistoqsijiet kollha u tista' twaqqaf l-istudju fi xħin trid mingħajr ma tagħti l-ebda raġuni. L-irtirar mill-istudju mhux se jkollu riperkussjonijiet negattivi fuqek jew fuq il-kura tiegħek. Barra minn hekk, kwalunkwe *data* miġbura mingħandek, sakemm din ma tistax tiġi identifikata, eż. hija diġà anonimizzata, se tigi mħassra. Nassigurak li se tinżamm il-kunfidenzjalità matul l-istudju kollu u l-identità tiegħek flimkien mal-informazzjoni personali miġbura, mhumiex se jiġu żvelati mkien fit-teżi, fir-rapporti, fil-preżentazzjonijiet u fil-pubblikazzjonijiet li jistgħu jirriżultaw minnha. Kull tagħrif miġbur se jiġi psewdonomizzat, jiġifieri it-traskrizzjoni tar-reġistrazzjoni tal-awdjo se tkun protetta permezz ta' sistema ta' kodiċi u miżmuma separatament mill-informazzjoni personali (reġistrazzjoni tal-awdjo u formoli ta' kunsens). Din id-*data* tista' tkun aċċessata biss mir-riċerkatur. Is-Superviżuri akkademiċi u l-eżaminaturi se jkollhom biss aċċess għal *data* kkodifikata. Jista' jkun hemm ċirkostanzi eċċezzjonali li jippermettu lis-superviżuri akkademiċi jkollhom aċċess ukoll għar-reġistrazzjoni tal-awdjo, għal skop ta' verifikazzjoni (jekk tkun tixtieq tkun taf min aċċessa d-*data* tiegħek, jekk jogħġbok ikkuntattjani skont id-dettalji ta' hawn taħt). Ir-reġistrazzjoni tal-awdjo u d-*data* kollha se jinħażnu fuq il-kompjuter personali tar-riċerkatur permezz ta' kodifikazzjoni tad-*data* (*data encryption*) u li hi protetta b'password. Il-formoli tal-kunsens jitqiegħdu f'armarju msakkar.

Il-parteċipazzjoni tiegħek f'dan l-istudju ma tesponik għal ebda riskju. Jekk inti interessat li tieqaf tpejjep, is-servizz ta' konsulent dwar il-waqfien mit-tipjip mid-Direttorat għall-Promozzjoni tas-Saħħa u l-Prevenzjoni tal-Mard, huwa disponibbli mingħajr spejjeż finanzjarji min-naħa tiegħek, billi ċċempel lin-*National Quitline* 8007 3333.

Il-parteċipazzjoni tiegħek f'dan l-istudju hija għażla għal kollox volontarja u inti ħieles/ħielsa li taċċetta jew tirrifjuta li tieħu sehem mingħajr ma' tagħti ebda raġuni. Kopja tal-folja tal-informazzjoni u tal-formola ta' kunsens se jkunu pprovduti sabiex ikunu aċċessibbli fil-futur. Barra minn hekk, skont ir-Regolamenti Ġenerali dwar il-Protezzjoni tad-Data (GDPR) u l-leġiżlazzjoni nazzjonali li timplimenta u tispeċifika aktar il-provvedimenti relevanti tar-regolamenti msemmija, inti għandek id-dritt li taċċessa, tirretifika, u fejn japplika titlob sabiex titħassar id-data li tikkonċernak. Ladarba jitlesta dan l-istudju tar-riċerka, ir-reġistrazzjoni tal-awdjo se titħassar u d-*data* tinżamm biss f'forma anonima. Riżultati anonimi minn dan l-istudju ta' riċerka se jiġu ppubblikati fit-teżi tad-Dottorat tiegħi u jistgħu jiġu ppubblikati f'ġurnali akkademiċi jew irrappurtati f'konferenzi jew organizzazzjonijiet tas-servizzi tas-saħħa. Uħud mill-affarijiet li tgħid jistgħu jintużaw bħala kwotazzjonijiet diretti f'pubblikazzjonijiet jew konferenzi, iżda l-kunfidenzjalità u l-anonimità tiegħek se jinżammu, u mhux se jkun possibbli li tidentifikak. Sommarju tar-riżultati ta' dan l-istudju ta' riċerka se jkun offrut lill-parteċipanti kollha li juru interess. Il-formoli tal-kunsens jinqerdu fi żmien sentejn mit-tlestija tal-proġett tad-Dottorat.

Dan l-istudju ġie approvat mill-Kumitat għall-Etika fir-Riċerka fi ħdan il-Fakultà tax-Xjenzi tas-Saħħa fl-Università ta' Malta.

Grazzi ħafna tal-ħin u s-sehem tiegħek f'dan l-istudju. F'każ li jkollok xi mistoqsijiet jew tixtieq tiċċara xi ħaġa, tista' ċċempilli fuq **9*** ***4** jew tibgħatli imejl fuq joseph.grech.02@um.edu.mt. Tista' wkoll tikkuntattja lis-Superviżura **Prof. Roberta Sammut** fuq **2340 1831** jew billi tibgħat imejl fuq roberta.sammut@um.edu.mt jew lil-Ko-Superviżur **Prof. Ian James Norman** fuq **+44 (0)207 848 3020** jew b'imejl fuq ian.j.norman@kcl.ac.uk.

Dejjem tiegħek,

Mr. Joseph Grech	**Prof. Roberta Sammut**	**Prof. Ian James Norman**
Isem ir-Riċerkatur	Isem is-Superviżura tar-riċerka	Isem il-Ko-Superviżur tar-riċerka
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Appendix 7.33: Pilot study follow-up interview consent form (in English)

Participants` Consent Form

Development and feasibility testing of a multi-component smoking cessation intervention for smokers living with diabetes mellitus: a pilot study (a follow-up interview)

I, the undersigned, give my consent to take part in the study conducted by Mr. Joseph Grech. The purpose of this document is to specify the terms of my participation in this research study.

1. I have been given written and verbal information about the purpose of the study and all questions have been answered.
2. I understand that I have been invited to participate in an interview, in which the researcher will ask questions to ensure the applicability of the multi-component smoking cessation intervention for use amongst individuals with diabetes.
3. I am aware that the interview will not take longer than 40 minutes. I understand that the interview is to be conducted at one of the Faculty of Health Science's approved and identified training sites at a day and time that is convenient for me (Gozitan residents will be invited to attend at Gozo General Hospital).
4. I am aware that the interview will be audio-recorded and transcribed (written down as it has been spoken).
5. I am also aware that the transcript will be coded, and that this data will be stored securely and separately from any personal data (audio-recording and consent forms).
6. I understand that the researcher is the only person who has access to this data. The academic supervisors and examiners will typically have access to coded data only. I am aware that there may be exceptional circumstances which allow the supervisors to have access to the audio-recording too, for verification purposes. I understand that if I would like to know who accessed my data, I can contact the researcher as per the details below.
7. I am also aware that the audio-recording and the transcript will be stored on the researcher`s personal computer that is password protected and in an encrypted format. Any material in hard-copy form, such as the consent forms will be placed in separate locked cupboards.
8. I am also aware that my identity and personal information will not be revealed in the researcher's Ph.D. thesis and any publications, reports, and presentations arising from this research.
9. I understand that I am free to accept, refuse, or stop participation at any time without giving any reason. This will have no negative repercussions on myself or my care. Furthermore, I also understand that any data collected from my end, unless this cannot be identified, e.g. is anonymised, will be erased.

10. I also understand that my contribution will help Mr. Joseph Grech refine the proposed smoking cessation intervention for use amongst individuals with diabetes.
11. I also understand that participating in this study does not expose me to any risks. I am aware that if I am still interested in quitting smoking, the service of a smoking cessation advisor from the Health Promotion and Disease Prevention Directorate is available at no financial cost on my part, by calling the National Quitline 8007 3333.
12. I am aware that under the General Data Protection Regulation (GDPR) and national legislation that implements and further specifies the relevant provisions of said regulation, I have the right to access, rectify, and where applicable ask for the data concerning me to be erased.
13. I understand that once the study is completed, the audio-recording will be erased, and data will only be retained in anonymous form. I am aware that anonymous results from this research study will be published in the researcher's Ph.D. thesis and may be published in academic journals or reported at conferences or to health service organisations.
14. I understand that some of the things I say may be used as direct quotes in publications or conferences, but my confidentiality and anonymity will be maintained, and it will not be possible to identify me.
15. I am aware that a summary of the results of this research study will be offered if I show interest (see below).
16. I am also aware that any personal details, i.e. the consent forms, will be destroyed within two years from completion of the Ph.D. project.
17. I am also aware that I will be provided with a copy of the information letter and consent form for future reference.
18. I have read and understood the points and statements of this form. I have had all the questions answered to my satisfaction, and I agree to participate in this study.

Participant: _____

Signature: _____

Date: _____

Mr. Joseph Grech	**Prof. Roberta Sammut**	**Prof. Ian James Norman**
Researcher	Research Supervisor	Research Co-supervisor
Tel: 9* ***4**	**Tel. 2340 1831**	**Tel. +44 (0)207 848 3020**
joseph.grech.02@um.edu.mt	**roberta.sammut@um.edu.mt**	**ian.j.norman@kcl.ac.uk**

Please note:
If you agree to be contacted to be provided with a summary of the results of this research study please provide your telephone/mobile number here:

_____

Appendix 7.34: Pilot study follow-up interview consent form (in Maltese)

Formola ta' Kunsens tal-Parteċipanti

Żvilupp u ttestjar tal-fattibilità ta' intervent ta' waqfien mit-tipjip b'ħafna komponenti għal dawk li jpejpu u jgħixu bid-dijabete: studju pilota (intervista ta' segwitu)

Jien, hawn taħt iffirmat, nagħti l-kunsens tiegħi biex nieħu sehem fl-istudju mmexxi mis-Sur Joseph Grech. L-għan ta' dan id-dokument hu li jiġu sspeċifikati t-termini tal-parteċipazzjoni tiegħi f'dan l-istudju ta' riċerka.

1. Jien ingħatajt informazzjoni miktuba u verbali dwar l-għan tal-istudju u l-mistoqsijiet kollha twieġbu.
2. Nifhem li ġejt mistieden sabiex nipparteċipa f'intervista, fejn ir-riċerkatur se jsaqsi mistoqsijiet sabiex jiżgura l-applikabbiltà tal-intervent tal-waqfien mit-tipjip għall-użu fost individwi bid-dijabete.
3. Naf li l-intervista mhux se tieħu aktar minn 40 minuta. Nifhem, li l-intervista se ssir f'wieħed mis-siti ta' taħriġ approvati u identifikati tal-Fakultà tax-Xjenza tas-Saħħa f'ġurnata u ħin li jkun konvenjenti għalija (ir-residenti Għawdxin se jiġu mistiedna jattendu fl-Isptar Ġenerali ta' Għawdex).
4. Jien konxju/a li r-risposti tiegħi se jkunu qed jiġu rrekordjati permezz ta' tagħmir awdjo u se jinkitbu r-risposti fuq formoli apposta.
5. Naf ukoll li t-traskrizzjoni tar-reġistrazzjoni tal-awdjo se tiġi kkodifikata, u li din id-*data* se tinħażen b'mod sigur u separat minn kwalunkwe *data* personali (reġistrazzjoni tal-awdjo u formoli ta' kunsens).
6. Nifhem li r-riċerkatur hu l-uniku persuna li se jkollu aċċess għal din l-informazzjoni, filwaqt li s-superviżuri akkademiċi u l-eżaminaturi se jkollhom aċċess għal *data* kkodifikata biss. Jiena konxju li jista' jkun hemm ċirkostanzi eċċezzjonali li jippermettu lis-superviżuri jkollhom aċċess għar-reġistrazzjoni tal-awdjo għal skop ta' verifika. Nifhem li jekk nixtieq inkun naf min aċċessa d-*data* tiegħi, nista' nikkuntattja lir-riċerkatur skont id-dettalji ta' hawn taħt.
7. Jien konxju wkoll li r-reġistrazzjoni tal-awdjo u t-traskrizzjoni se jinħażnu fuq il-kompjuter personali tar-riċerkatur permezz ta' kodifikazzjoni tad-*data* (*data encryption*) u li hi protetta b'password. Nifhem li il-formoli tal-kunsens jitqiegħdu f'armarju msakkar.
8. Jien konxju wkoll li l-identità tiegħi u l-informazzjoni personali mhumiex se jinkixfu fit-teżi tad-Dottorat tar-riċerkatur, u fir-rapporti, fil-preżentazzjonijiet u fil-pubblikazzjonijiet li jistgħu jirriżultaw minn din ir-riċerka.
9. Nifhem li jien liberu/a li naċċetta, nirrifjuta jew inwaqqaf il-parteċipazzjoni tiegħi f'kull ħin bla ma nagħti raġuni. Dan mhu se jkollu ebda riperkussjonijiet negattivi fuqi nnifsi

jew fuq il-kura tiegħi. Barra minn hekk, nifhem ukoll li kwalunkwe *data* miġbura mingħandi, sakemm din ma tistax tiġi identifikata, eż. hija anonimizzata, titħassar.

10. Nifhem ukoll li l-kontribuzzjoni tiegħi se sservi lis-Sur Joseph Grech sabiex jirfina l-intervent propost għall-waqfien mit-tipjip għall-użu fost individwi bid-dijabete.
11. Nifhem ukoll li l-parteċipazzjoni tiegħi f'dan l-istudju ma tesponini għall-ebda riskju. Jiena konxju li jekk jien interessat/a li nieqaf mit-tipjip, is-servizz ta' konsulent dwar il-waqfien mit-tipjip mid-Direttorat għall-Promozzjoni tas-Saħħa u l-Prevenzjoni tal-Mard huwa disponibbli mingħajr spejjeż finanzjarji min-naħa tiegħi, billi ċċempel lin-*National Quitline* 8007 3333.
12. Jien konxju wkoll li skont ir-Regolamenti Ġenerali dwar il-Protezzjoni tad-*Data* (GDPR) u l-leġiżlazzjoni nazzjonali li timplimenta u tispeċifika aktar il-provedimenti relevanti tar-regolamenti msemmija, jiena għandi d-dritt li naċċessa, nirretifika, u fejn japplika, nitlob sabiex titħassar id-*data* li tikkonċernani.
13. Nifhem li ladarba jitlesta l-istudju, r-reġistrazzjoni tal-awdjo u d-*data* tinżamm biss f'forma anonima. Jien konxju li r-riżultati anonimi minn dan l-istudju ta' riċerka se jiġu ppubblikati fit-teżi tad-Dottorat tar-riċerkatur u jistgħu jiġu ppubblikati f'ġurnali akkademiċi jew irrappurtati f'konferenzi jew lil organizzazzjonijiet tas-servizzi tas-saħħa.
14. Nifhem li wħud mill-affarijiet li ngħid jistgħu jintużaw bħala kwotazzjonijiet diretti f'pubblikazzjonijiet jew konferenzi, iżda l-kunfidenzjalità u l-anonimità tiegħi se jinżammu, u mhux se jkun possibbli li niġi identifikat/a.
15. Jiena konxju li se nkun offrut sommarju tar-riżultati ta' dan l-istudju ta' riċerka jekk nuri interess (ara hawn taħt).
16. Jiena konxju wkoll li kwalunkwe dettalji personali, jiġifieri l-formoli tal-kunsens, se jinqerdu fi żmien sentejn mit-tlestija tal-proġett tad-Dottorat.
17. Jien naf ukoll li se ningħata kopja tal-folja ta' informazzjoni u tal-formola ta' kunsens sabiex inkun nista' naċċessahom fil-futur.
18. Jien qrajt u fhimt il-punti u d-dikjarazzjonijiet f'din il-formola. Inħossni sodisfatt/a bit-tweġibiet li ngħatajt għall-mistoqsijiet li kelli, u qed naċċetta minn jeddi li nipparteċipa f'dan l-istudju.

Parteċipant/a: _____

Firma: _____

Data: _____

Mr. Joseph Grech	**Prof. Roberta Sammut**	**Prof. Ian James Norman**
Isem ir-riċerkatur	Isem is-superviżura	Isem il-ko-superviżur
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joseph.grech.02@um.edu.mt	**roberta.sammut@um.edu.mt**	**ian.j.norman@kcl.ac.uk**

Jekk jogħġbok innota:
Jekk taqbel li tiġi kkuntattjat/a biex tingħata sommarju tar-riżultati ta' dan l-istudju ta' riċerka jekk jogħġbok ipprovdi n-numru tat-telefon/mobajl tiegħek hawn:

_____

Appendix 7.35: Pilot study nurses' information letter

Participants` Information Sheet

Dear Nurse,

My name is Joseph Grech and I am currently reading for a Doctor of Philosophy (Ph.D.) in Nursing at the University of Malta. As part of my Ph.D. project, I am conducting a follow-up interview on the research study entitled, **"Development and feasibility testing of a multi-component smoking cessation intervention for smokers living with diabetes mellitus: a pilot study"**, to which you participated. This study aims to refine the proposed smoking cessation intervention for use amongst individuals with diabetes. Your insight will help us ensure the applicability of this diabetes practice nurse-led cessation intervention prior to further assessment. You will only be asked to share data that is necessary for this research. All data collected from this research shall be used solely for this study.

You are being invited to participate in an interview exploring your views, and suggestions on the smoking cessation intervention. The interview should not take more than 40 minutes and will be held at one of the Faculty of Health Science's approved and identified training sites at a time and date most suitable for you (Gozitans will be invited to attend at Gozo General Hospital). Unless you have any objections, the interview will be audio-recorded. You are not obliged to answer all the questions and may withdraw from the study at any time without giving a reason. Withdrawal from the study will not have any negative repercussions whatsoever. Furthermore, any data collected from your end, unless this cannot be identified, e.g. has been already anonymised, will be erased. I can assure you that confidentiality will be maintained throughout the study and that your identity and personal information will not be linked to your responses and revealed in the thesis and any publications, reports, and presentations arising from this research. All data collected will be pseudonymised meaning that the transcript of the audio recording will be protected by a code system and that this data will be stored securely and separately from any personal data (audio-recording and consent forms). This data may only be accessed by the researcher. The academic supervisors and the examiners will typically have access to coded data only. There may be exceptional circumstances which allow the supervisors to have access to the audio-recording too, for verification purposes (if you would like to know who accessed your data, please contact me as per the details below). The audio-recording and transcript will be stored on the researcher`s personal computer that is password protected and in an encrypted format. The consent forms will be placed in a locked cupboard.

Participation in this study does not expose you to any risks. Participation is completely voluntary and you are free to accept or refuse to take part without giving a reason. A copy of

the information sheet and consent form will be provided for future reference. As a participant, you have the right, under the General Data Protection Regulation (GDPR) and national legislation that implements and further specifies the relevant provisions of said regulation, to access, rectify, and where applicable ask for the data concerning you to be erased. Once this research study is completed, the audio-recording will be erased and data will be retained only in anonymous form. Anonymous results from this research study will be published in my Ph.D. thesis and may be published in academic journals or reported at conferences or to health service organisations. Some of the things you say may be used as direct quotes in publications or conferences, but your confidentiality and anonymity will be maintained, and it will not be possible to identify you. A summary of the results of this research study will be offered to all participants who show interest. The consent forms will be destroyed within two years from the completion of my Ph.D. project.

This study has been approved by the Research Ethics Committee of the Faculty of Health Sciences at the University of Malta.

Thank you for your time and consideration. Should you have any questions or concerns do not hesitate to contact me on **9*** ***4** or by e-mail joseph.grech.02@um.edu.mt or my supervisor **Prof. Roberta Sammut** on **2340 1831** or roberta.sammut@um.edu.mt or my co-supervisor **Prof. Ian James Norman** on **+44 (0)207 848 3020** or ian.j.norman@kcl.ac.uk.

Yours Sincerely,

Mr. Joseph Grech	**Prof. Roberta Sammut**	**Prof. Ian James Norman**
Researcher	Research Supervisor	Research Co-supervisor
Tel: 9980 2504	**Tel. 2340 1831**	**Tel. +44 (0)207 848 3020**
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Appendix 7.36: Pilot study nurses' consent form

Participants` Consent Form

Development and feasibility testing of a multi-component smoking cessation intervention for smokers living with diabetes mellitus: a pilot study (a follow-up interview)

I, the undersigned, give my consent to take part in the study conducted by Mr. Joseph Grech. The purpose of this document is to specify the terms of my participation in this research study.

1. I have been given written and verbal information about the purpose of the study and all questions have been answered.
2. I understand that I have been invited to participate in an interview, in which the researcher will ask questions to ensure the applicability of this diabetes practice nurse-led smoking cessation intervention for use amongst individuals with diabetes.
3. I am aware that the interview will not take longer than 40 minutes. I understand that the interview is to be conducted at one of the Faculty of Health Science's approved and identified training sites in a place and at a time that is convenient for me (Gozitans will be invited to attend at Gozo General Hospital).
4. I am aware that the interview will be audio-recorded and transcribed (written down as it has been spoken).
5. I am also aware that the transcript will be coded, and that this data will be stored securely and separately from any personal data (audio-recording and consent forms).
6. I understand that the researcher is the only person who has access to this data. The academic supervisors and examiners will typically have access to coded data only. I am aware that there may be exceptional circumstances which allow the supervisors to have access to the audio-recording too, for verification purposes. I understand that if I would like to know who accessed my data, I can contact the researcher as per the details below.
7. I am also aware that the audio-recording and the transcript will be stored on the researcher`s personal computer that is password protected and in an encrypted format. The consent forms will be placed in a locked cupboard.
8. I am also aware that my identity and personal information will not be linked to my responses and revealed in the researcher's Ph.D. thesis and any publications, reports, and presentations arising from this research.
9. I understand that I am free to accept, refuse, or stop participation at any time without giving any reason. This will have no negative repercussions on myself. Furthermore, I also understand that any data collected from my end, unless this cannot be identified, e.g. is anonymised, will be erased.

10. I also understand that my contribution will help Mr. Joseph Grech refine the proposed smoking cessation intervention for use amongst individuals with diabetes.
11. I also understand that participating in this study does not expose me to any risks.
12. I am aware that under the General Data Protection Regulation (GDPR) and national legislation that implements and further specifies the relevant provisions of said regulation, I have the right to access, rectify, and where applicable ask for the data concerning me to be erased.
13. I understand that once the study is completed, the audio-recording will be erased, and data will only be retained in anonymous form. I am aware that anonymous results from this research study will be published in the researcher's Ph.D. thesis and may be published in academic journals or reported at conferences or to health service organisations.
14. I understand that some of the things I say may be used as direct quotes in publications or conferences, but my confidentiality and anonymity will be maintained, and it will not be possible to identify me.
15. I am aware that a summary of the results of this research study will be offered if I show interest (see below).
16. I am also aware that any personal details, i.e. the consent forms, will be destroyed within two years from completion of the Ph.D. project.
17. I am also aware that I will be provided with a copy of the information letter and consent form for future reference.
18. I have read and understood the points and statements of this form. I have had all the questions answered to my satisfaction, and I agree to participate in this study.

Participant: _____

Signature: _____

Date: _____

Mr. Joseph Grech	**Prof. Roberta Sammut**	**Prof. Ian James Norman**
Researcher	Research Supervisor	Research Co-supervisor
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Please note:
If you agree to be contacted to be provided with a summary of the results of this research study please provide your telephone/mobile number here:

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Appendix 7.37: Participants' characteristics at baseline (pilot study)

Characteristics	All participants (n=34)	Respondents of the English questionnaire (n=17)	Respondents of the Maltese questionnaire (n=17)
Demographics			
Sex, *n* (%)			
Male	27 (79.4)	14 (82.4)	13 (76.5)
Female	7 (20.6)	3 (17.6)	4 (23.5)
Age (years), median (IQR)	62.5 (44.8-67.0)	55.0 (42.0-65.5)	64.0 (56.0-68.5)
Education,[a] *n* (%)			
Post-secondary non-tertiary education	11 (32.4)	4 (23.5)	7 (41.2)
Upper secondary education	9 (26.5)	6 (35.3)	3 (17.6)
Primary education	9 (26.5)	2 (11.8)	7 (41.2)
Short cycle tertiary education	3 (8.8)	3 (17.6)	0
Lower secondary education	2 (5.9)	2 (11.8)	0
Employment status, *n* (%)			
Retired	19 (55.9)	8 (47.1)	11 (64.7)
Employed	15 (44.1)	9 (52.9)	6 (35.3)
Living alone, *n* (%)			
No	29 (85.3)	15 (88.2)	14 (82.4)
Yes	5 (14.7)	2 (11.8)	3 (17.6)
Living with another smoker, *n* (%)			
Yes	21 (61.8)	11 (64.7)	10 (58.8)
No	13 (38.2)	6 (35.3)	7 (41.2)
Health status and diabetes profile			
Perceived health, *n* (%)			
Good	18 (52.9)	9 (52.9)	9 (52.9)
Fair	9 (26.5)	6 (35.3)	3 (17.6)
Very bad	3 (8.8)	0	3 917.6)
Very good	2 (5.9)	0	2 (11.8)
Bad	2 (5.9)	2 (11.8)	0
Diabetes type, *n* (%)			
Type 2	28 (82.4)	13 (76.5)	15 (88.2)
Type 1	6 (17.6)	4 (23.5)	2 (11.8)
Age at diagnosis (years), median (IQR)	46.0 (35.0-57.3)	42.0 (29.0-55.0)	53.0 (40.0-60.0)
Diabetic treatment, *n* (%)			
Antidiabetic pills	17 (50.0)	8 (47.1)	9 (52.9)
Insulin only	9 (26.5)	6 (35.3)	3 (17.6)
Antidiabetic pills and insulin	8 (23.5)	3 (17.6)	5 (29.4)

Characteristics	All participants (n=34)	Respondents of the English questionnaire (n=17)	Respondents of the Maltese questionnaire (n=17)
Diabetes complications, *n* (%)			
No	27 (79.4)	14 (82.4)	13 (76.5)
Yes	5 (14.7)	2 (11.8)	3 (17.6)
Don't know	2 (5.9)	1 (5.9)	1 (5.9)
Other chronic diseases, *n* (%)			
No	17 (50.0)	9 (52.9)	8 (47.1)
Yes	17 (50.0)	8 (47.1)	9 (52.9)
Smoking profile			
Age at initiation (years), median (IQR)	14.5 (12.0-16.0)	15.0 (13.0-16.5)	14.0 (11.5-15.0)
Cigarettes/day,[b] median (IQR)	25.0 (18.8-40.0)	30.0 (20.0-45.0)	20.0 (15.0-37.5)
CDS-5[c] score, mean (SD)	19.9 (4.22)	20.0 (5.01)	19.8 (3.40)
Quit attempt/s in past 12 months, n (%)			
No	21 (61.8)	12 (70.6)	9 (52.9)
Yes	13 (38.2)	5 (29.4)	8 (47.1)
Ever quit smoking, *n* (%)			
Yes	15 (44.1)	10 (58.8)	5 (29.4)
No	15 (44.1)	4 (23.5)	11 (64.7)
Never attempted	4 (11.8)	3 (17.6)	1 (5.9)
MTTS,[d] *n* (%)			
I REALLY want to stop smoking but don't know when I will. (4)	11 (32.4)	5 (29.4)	6 (35.3)
I want to stop smoking but haven't thought about when. (3)	9 (26.5)	5 (29.4)	4 923.5)
I want to stop smoking and hope to soon. (5)	7 (20.6)	4 (23.5)	3 (17.6)
I REALLY want to stop smoking and intend to in the next month. (7)	4 (11.8)	2 (11.8)	2 (11.8)
I REALLY want to stop smoking and intend to in the next 3 months. (6)	2 (5.9)	0	2 (11.8)
I think I should stop smoking but don't really want to. (2)	1 (2.9)	1 (5.9)	0
I don't want to stop smoking. (1)	0	0	0
HADS[e]			
Anxiety subscale, *n* (%)			
Suggestive presence (8-10)	15 (38.2)	8 (47.1)	7 (41.2)
Normal (0-7)	13 (38.2)	7 (41.2)	6 (35.3)
Probable presence (11+)	6 (17.6)	2 (11.8)	4 (23.5)

Characteristics	All participants (n=34)	Respondents of the English questionnaire (n=17)	Respondents of the Maltese questionnaire (n=17)
Depression subscale, *n* (%)			
Normal (0-7)	25 (73.5)	14 (82.4)	11 (64.7)
Probable presence (11+)	8 (23.5)	3 (17.6)	5 (29.4)
Suggestive presence (8-10)	1 (2.9)	0	1 (5.9)

IQR – interquartile range, SD – standard deviation. a - As categorised in the International Standard Classification of Education (2011). b - Includes three participants who smoked hand rolled cigarettes. Three participants were dual users, smoking e-cigarettes (n=2) and a heat-not-burn product (n=1). c - Cigarette Dependence Scale-5 (Etter et al., 2003). d - Motivation To Stop Scale Kotz et al. (2013). e - Hospital Anxiety and Depression Scale (Zigmond and Snaith, 1983).

Appendix 7.38: Treatment actions/components carried out by the intervention providers amongst the participants during the sessions and the average percentage adherence to the session protocol (pilot study)

Table 1: Treatment actions/components carried out by the providers amongst the participants as per session one protocol and the average percentage adherence to the protocol

Treatment action/component	**Number of participants provided with the treatment action/component** (n=17)
Ask: Asked about/Confirmed the number of cigarettes/tobacco products smoked every day.	17
Advise: Informed the participant on the effects of smoking on diabetes (as outlined in the intervention guideline).	17
Advise: Gave an overview of the story of Bill to the participant (as outlined in the intervention protocol), showing him/her the three video clips.	17
Advise: Allowed some time for reflection or brief discussion, acknowledging any feelings or comments the participant may state.	15
Advise: Advised the participant to quit smoking in a clear, strong and personalised manner (as outlined in the intervention protocol).	15
Assess: Assessed readiness in setting a quit attempt in the next two weeks, identifying the possible need of using the 5R's algorithm (as outlined in the intervention protocol).[a]	16
Assist: Helped the participant set a Target Quit Date (TQD) within the next two weeks.	17
Assist: Told the participant to inform his family, friends, and co-workers about his/her quitting attempt, and to ask for support.	13
Assist: Encouraged the participant to talk about the quitting process, anticipating the challenges or barriers to the upcoming quit attempt, (as outlined in the intervention protocol)	17
Assist: Helped the participant generate problem-solving strategies to tackle the identified barriers and challenges to quitting (as outlined in the intervention protocol)	17
Assist: Asked the participant to remove any tobacco products from the patient's environment (particularly closer to the quit date) and make the home smoke free.	11
Assist: Recommended (explaining use and benefits) and provided a supply of NRT (patch and/or spray) for use until the next session.	17
Assist: Encouraged the participant further in the quit attempt, by referring to/identifying what would be relevant for him/her if he quit smoking.	13
Assist: Advised monitoring of blood glucose.	12
Assist: Linked the participant to psychological support services if experiencing anxiety or depression.	14
Arrange: Provided the participant with a follow-up appointment during the first week from their TQD.	8
Average total per participant (out of 16)	14.8
Percentage adherence (%)	86.8

a - In all instances the use of the 5Rs algorithm was not required.

Table 2: Treatment actions/components carried out by the providers amongst the participants as per session two (for those who did not quit smoking) protocol and the average percentage adherence to the protocol

Treatment action/component	**Number of participants provided with the treatment action/component** (n=6)
Asked about tobacco use (no. of cigarettes/tobacco products smoked/day).	6
Assessed the use of NRT and any problems encountered (including over/under-dosing), providing recommendations.	6
Reviewed experienced barriers and challenges (roadblocks).	6
Encouraged a recommitment to quit smoking (referring to what is relevant to the participant – risks and rewards).	4
Encouraged the participant to give it a try even if not 100% confident.	6
Assist: Helped the participant set a TQD within the next two weeks.	6
Assist: Told the participant to inform his family, friends, and co-workers about his/her quitting attempt, and to ask for support.	6
Assist: Encouraged the participant to talk about the quitting process, anticipating the challenges or barriers to the upcoming quit attempt, (as outlined in the intervention protocol)	6
Assist: Helped the participant generate problem-solving strategies to tackle the identified barriers and challenges to quitting (as outlined in the intervention protocol)	5
Assist: Asked the participant to remove any tobacco products from the patient's environment (particularly closer to the quit date) and make the home smoke free.	3
Assist: Recommended (explaining use and benefits) and provided a supply of NRT (patch and/or spray) for use until the next session.	6
Assist: Encouraged the participant further in the quit attempt, by referring to what would be relevant for him/her if he quit smoking.	4
Assist: Advised monitoring of blood glucose.	4
Assist: Linked the participant to psychological support services if experiencing anxiety or depression.	4
Arrange: Provided the participant with a follow-up appointment during the first week from their TQD.	4
Average total per participant (out of 15)	12.7
Percentage adherence (%)	84.4

Table 3: Treatment actions/components carried out by the providers amongst the participants as per session two (for those who quit smoking), or session three (if reporting abstinence the first time) protocol and the average percentage adherence to the protocol

Treatment action/component	**Number of participants provided with the treatment action/component** (n=9)
Asked about tobacco use (no. of cigarettes/tobacco products smoked/day).	9
Congratulated participant if he/she stopped smoking.	9
Encouraged participant to remain abstinent (referring to what is relevant to the participant – risks and rewards).	4
Assessed the use of NRT and any problems encountered (including over/under-dosing), providing recommendations.	5
Reviewed experienced barriers and challenges (roadblocks) towards remaining abstinent from smoking.	9
Discussed anticipated challenges.	7
Reinforced strategies outlined in the quit plan – reminding the participant on the usefulness of social support.	5
Linked the participant to psychological support services if experiencing anxiety or depression.	9
Provided remaining assigned supply of NRT, advising all participants to reduce the use of the spray during these weeks.	4
Advised monitoring of blood glucose and offered a diabetic consultation (and subsequent specialist/s referrals, if required) if the participant experienced poor glycaemic control, or is concerned about diabetes management following a change in diet or weight gain on quitting smoking.	9
Provided the participant with a follow-up appointment within five weeks from their TQD.	9
Average total per participant (out of 11)	8.8
Percentage adherence (%)	79.8

Table 4: Treatment actions/components carried out by the providers amongst the participants as per the final follow-up session (for those who previously reported not smoking) protocol and the average percentage adherence to the protocol

Treatment action/component	**Number of participants provided with the treatment action/component** (n=4)
Asked about tobacco use (no. of cigarettes/tobacco products smoked/day).	4
Congratulated participant if he/she stopped smoking/remained abstinent from smoking or praised any other achievements (e.g. reduction in number of cigarettes smoked per day).	4
Encouraged participant to attempt quitting again if he/she relapsed or to remain abstinent (referring to what is relevant to the participant – risks and rewards).	4
Assessed the use of NRT and any problems encountered (including over/under-dosing), advising participants to ideally reduce use if still on NRT (and abstinent from smoking).	2
Reviewed experienced barriers and challenges (roadblocks) towards remaining abstinent from smoking.	4
Discussed anticipated challenges.	1
Reinforced strategies outlined in the quit plan – reminding the participant on the usefulness of social support.	3
Linked the participant to psychological support services if experiencing anxiety or depression.	4
Advised monitoring of blood glucose and offered a diabetic consultation (and subsequent specialist/s referrals, if required) if the participant experienced poor glycaemic control, or is concerned about diabetes management following a change in diet or weight gain on quitting smoking.	4
Ended the intervention on a positive manner, encouraging the participant to seek tobacco cessation services if required.	4
Average total per participant (out of 10)	8.5
Percentage adherence (%)	85.0

Table 5: Treatment actions/components carried out by the providers amongst the participants as per session three (for those who did not succeed to quit smoking) protocol and the average percentage adherence to the protocol

Treatment action/component	**Number of participants provided with the treatment action/component** (n=5)
Asked about tobacco use (no. of cigarettes/tobacco products smoked/day).	5
Assessed the use of NRT and any problems encountered (including over/under-dosing), providing recommendations.	4
Reviewed experienced barriers and challenges (roadblocks).	5
Encouraged a recommitment to quit smoking (referring to what is relevant to the participant – risks and rewards).	3
Ended the intervention on a positive manner, encouraging the participant to seek tobacco cessation services when ready.	5
Average total per participant (out of 5)	4.4
Percentage adherence (%)	88.0

Appendix 7.39: Satisfaction with the smoking cessation intervention provided (pilot study, n=31)

	Rating, n (%)					
How satisfied are you with the…	Very unsatisfied 1	Unsatisfied 2	Neutral 3	Satisfied 4	Very satisfied 5	Median score (IQR)
Support you received to help you quit smoking.	0	0	5 (16.1)	11 (35.5)	15 (48.4)	4 (4-5)
Location where the smoking cessation intervention was provided.	0	0	2 (6.5)	11 (35.5)	5 (58.1)	5 (4-5)
Appointment times given.	0	0	2 (6.5)	14 (45.2)	15 (48.4)	4 (4-5)
Waiting period for having your first session.	0	0	1 (3.2)	19 (61.3)	11 (35.5)	4 (4-5)
Duration of each individual session.	0	0	2 (6.5)	18 (58.1)	5 (35.5)	4 (4-5)
Time interval between appointments.	0	0	1 (3.2)	20 (64.5)	10 (32.3)	4 (4-5)
Number of sessions you had.	0	0	1 (3.2)	18 (58.1)	12 (38.7)	4 (4-5)
Method used to help you quit.	1 (3.2)	2 (6.5)	2 (6.5)	17 (54.8)	9 (29.0)	4 (4-5)
Total median score (IQR)	34 (32-38)					

IQR - interquartile range

Appendix 7.40: Perceived usefulness of the smoking cessation intervention provided (pilot study, n=31)

The smoking cessation intervention…	Rating, n (%)					Median score (IQR)
	Strongly disagree 1	Disagree 2	Neutral 3	Agree 4	Strongly agree 5	
Met your expectations.	1 (3.2)	5 (16.1)	0	12 (38.7)	13 (41.9)	4 (4-5)
Applied to you specifically.	1 (3.2)	3 (9.7)	2 (6.5)	13 (41.9)	12 (38.7)	4 (4-5)
Provided you with helpful information about quitting.	0	0	3 (9.7)	7 (22.6)	21 (67.7)	5 (4-5)
Made you concerned on the severe diabetes complications caused by smoking.	0	2 (6.5)	2 (6.5)	7 (22.6)	20 (64.5)	5 (4-5)
Made you concerned about your smoking.	0	4 (12.9)	0	11 (35.5)	16 (51.6)	5 (4-5)
Provided you with the motives to quit.	0	2 (6.5)	3 (9.7)	7 (22.6)	19 (61.3)	5 (4-5)
Made you think that it is worthwhile to quit.	0	0	2 (6.5)	13 (41.9)	16 (51.6)	5 (4-5)
Helped you consider a plan to quit smoking.	0	0	3 (9.7)	12 (38.7)	16 (51.6)	5 (4-5)
Helped you identify situations that increase your risk of smoking.	0	2 (6.5)	1 (3.2)	14 (45.2)	14 (45.2)	4 (4-5)
Helped you identify strategies to resist urges to smoke.	0	0	4 (12.9)	16 (51.6)	11 (35.5)	4 (4-5)
Helped you to respond effectively to urges to smoke.	0	0	8 (25.8)	11 (35.5)	12 (38.7)	4 (3-5)
Provided you with options on how to quit smoking.	0	2 (6.5)	0	13 (41.9)	16 (51.6)	5 (4-5)
Helped you identify the most effective method to quit smoking.	1 (3.2)	3 (9.7)	3 (9.7)	12 (38.7)	12 (38.7)	4 (4-5)
Gave you the confidence so that you can quit.	2 (6.5)	4 (12.9)	5 (16.1)	10 (32.3)	10 (32.3)	4 (3-5)
Total median score (IQR)	60 (55-68)					

IQR - interquartile range

Appendix 7.41: Internal consistency assessment of the satisfaction and perceived usefulness questionnaires (Maltese and English versions) and the translated Cigarette Dependence Scale-5

Table 1: Satisfaction questionnaire (English version) - Item-to-total statistics (n=16)

Satisfaction questionnaire items *How satisfied are you with the…*	**Scale mean if item deleted**	**Scale variance if item deleted**	**Corrected item-total correlation**	**Cronbach's alpha if item deleted**
Support you received to help you quit smoking.	31.4	9.20	0.42	0.92
Location where the smoking cessation intervention was provided.	31.4	9.05	0.63	0.90
Appointment times given.	31.3	9.40	0.58	0.90
Waiting period for having your first session.	31.6	8.40	0.86	0.88
Duration of each individual session.	31.5	8.67	0.75	0.89
Time interval between appointments.	31.5	8.53	0.80	0.88
Number of sessions you had.	31.6	7.86	0.83	0.88
Method used to help you quit.	31.8	8.43	0.78	0.88

Table 2: Satisfaction questionnaire (Maltese version) - Item-to-total statistics (n=15)

Satisfaction questionnaire items[a] *How satisfied are you with the…*	**Scale mean if item deleted**	**Scale variance if item deleted**	**Corrected item-total correlation**	**Cronbach's alpha if item deleted**
Support you received to help you quit smoking.	28.9	12.84	0.75	0.84
Location where the smoking cessation intervention was provided.	28.5	13.27	0.74	0.84
Appointment times given.	28.9	14.55	0.64	0.86
Waiting period for having your first session.	28.7	14.35	0.73	0.85
Duration of each individual session.	28.9	14.27	0.71	0.85
Time interval between appointments.	28.9	15.27	0.64	0.86
Number of sessions you had.	28.7	15.10	0.70	0.86
Method used to help you quit.	29.1	11.27	0.58	0.90

a - original items in Maltese

Table 3: Perceived usefulness questionnaire (English version) - Item-to-total statistics (n=16)

Perceived usefulness questionnaire items *The smoking cessation intervention…*	**Scale mean if item deleted**	**Scale variance if item deleted**	**Corrected item-total correlation**	**Cronbach's alpha if item deleted**
Met your expectations.	57.8	81.23	0.66	0.96
Applied to you specifically.	57.9	78.86	0.84	0.96
Provided you with helpful information about quitting.	57.5	84.80	0.65	0.96
Made you concerned on the severe diabetes complications caused by smoking.	57.6	78.25	0.90	0.95
Made you concerned about your smoking.	57.8	77.67	0.92	0.95
Provided you with the motives to quit.	57.8	78.60	0.77	0.96
Made you think that it is worthwhile to quit.	57.8	83.76	0.54	0.96
Helped you consider a plan to quit smoking.	57.7	81.16	0.90	0.96
Helped you identify situations that increase your risk of smoking.	57.9	77.32	0.95	0.95
Helped you identify strategies to resist urges to smoke.	57.8	80.96	0.90	0.96
Helped you to respond effectively to urges to smoke.	58.1	79.80	0.81	0.96
Provided you with options on how to quit smoking.	57.8	77.63	0.92	0.95
Helped you identify the most effective method to quit smoking.	58.0	77.33	0.88	0.95
Gave you the confidence so that you can quit.	58.6	71.32	0.71	0.97

Table 4: Perceived usefulness questionnaire (Maltese version) - Item-to-total statistics (n=15)

Perceived usefulness questionnaire items[a] *The smoking cessation intervention…*	**Scale mean if item deleted**	**Scale variance if item deleted**	**Corrected item-total correlation**	**Cronbach's alpha if item deleted**
Met your expectations.	52.7	76.67	0.74	0.93
Applied to you specifically.	52.5	80.27	0.61	0.94
Provided you with helpful information about quitting.	51.8	85.74	0.67	0.93
Made you concerned on the severe diabetes complications caused by smoking.	51.9	80.21	0.84	0.93
Made you concerned about your smoking.	52.2	76.17	0.93	0.93
Provided you with the motives to quit.	51.9	80.35	0.83	0.93
Made you think that it is worthwhile to quit.	51.7	89.64	0.56	0.94
Helped you consider a plan to quit smoking.	51.9	86.92	0.63	0.94
Helped you identify situations that increase your risk of smoking.	52.0	83.71	0.71	0.93
Helped you identify strategies to resist urges to smoke.	52.2	84.89	0.92	0.93
Helped you to respond effectively to urges to smoke.	52.1	83.12	0.74	0.93
Provided you with options on how to quit smoking.	51.9	84.27	0.71	0.93
Helped you identify the most effective method to quit smoking.	52.5	79.41	0.65	0.94
Gave you the confidence so that you can quit.	52.4	84.11	0.58	0.94

a - original items in Maltese

Table 5: Cigarette Dependence Scale-5 (Maltese version) - Item-to-total statistics (n=17)

Cigarette Dependence Scale-5 items[a]	Scale mean if item deleted	Scale variance if item deleted	Corrected item-total correlation	Cronbach's alpha if item deleted
Self-rated dependence, 0–100 score recoded to five categories	16.2	6.78	0.72	0.72
Cigarettes per day, five categories	16.0	7.50	0.40	0.85
Minutes to first cigarette, five categories	15.7	8.22	0.71	0.75
Quitting for good would be difficult.	15.9	8.43	0.65	0.76
An irresistible urge to smoke after a few hours.	15.5	7.76	0.63	0.76

a - original items in Maltese

Appendix 8.1: Intervention protocol (feasibility study)

Session one – pre-quit session

The aim of this session is to inform the participant on the effects of tobacco on diabetes, and to encourage him/her to set a quit attempt and support him/her in quitting smoking. This session should take between 30-60 minutes long.

Take note/confirm the number of cigarettes/tobacco products smoked every day. Start by informing the participant on the effects of smoking on diabetes, as follows:

- *While you may know that tobacco smoking is a well-established risk factor associated with increased health risks and an increased risk of death, there is increasing evidence demonstrating that smoking is associated with increased complications for those who have diabetes.*
- *Filwaqt li jista' jkun li taf li t-tipjip huwa fattur ta' riskju stabbilit sew assoċjat ma' riskji akbar għas-saħħa u riskju akbar ta' mewt, hemm evidenza ċara li turi li t-tipjip huwa assoċjat ma' kumplikazzjonijiet akbar għal dawk li għandhom id-dijabete.*
- *In people with diabetes, smoking can make their insulin less effective, the cells that produce insulin function poorly, and release less insulin. It also contributes to other issues like high levels of sugar and fat in the blood. These all result in a higher risk of diabetic complications such as cardiovascular diseases, including coronary heart disease, stroke, myocardial infarction, heart failure, and poor circulation in the legs and even death from such diseases.*
- *F'individwi bid-dijabete, it-tipjip jista' jagħmel l-insulina tagħhom inqas effettiva, u ma jgħinx liċ-ċelloli li jipproduċu l-insulina jiffunzjonaw tajjeb, u b'hekk jirrilaxxaw inqas insulina. Jikkontribwixxi wkoll għal kwistjonijiet oħra bħal livelli għoljin taz-zokkor u xaħam fid-demm. Dawn kollha jirriżultaw f'riskju ogħla għal kumplikazzjonijiet dijabetiċi bħal mard kardjovaskulari, inkluż mard tal-qalb, puplesija, attakk tal-qalb, insuffiċenza tal-qalb, ċirkolazzjoni ħażina fir-riġlejn u anke mewt minn mard bħal dan.*

Following this information tell the participant that you would like to share with him/her the story of Bill as follows:

- *To remark on what I said, I would like to share with you the story of Bill, a real person with diabetes who used to smoke and only quit after experiencing some diabetic complications associated with smoking: kidney failure, blindness in one eye, heart disease and a leg amputation. I would like to show you the three short video clips that Bill made to encourage other people to quit smoking. The videos have subtitles in English.*

- *Biex nirrimarka fuq dak li għedt, nixtieq naqsam miegħek l-istorja ta' Bill, persuna reali bid-dijabete li kien ipejjep u waqaf biss wara li esperjenza xi kumplikazzjonijiet dijabetiċi assoċjati mat-tipjip: insuffiċjenza tal-kliewi, għama f'għajn waħda, mard tal-qalb u amputazzjoni tar-riġel. Nixtieq nurik it-tliet video clips qosra li għamel Bill biex iħeġġeġ nies oħra jieqfu jpejpu. Il-videos għandhom sottotitli bl-Ingliż.*

After showing the videos do allow some time for reflection or brief discussion, but do not dwell into lengthy conversations. Acknowledge any feelings or comments the participant may state. At this point simply advise <u>in a clear, strong and personalised manner</u> the participant to quit smoking in view of the health benefits:

- *There is clear evidence that quitting smoking provides clear benefits in terms of better blood sugar and cholesterol control and in reducing the risk of cardiovascular diseases and complications, and the risk of death in people with diabetes. It is important that you quit smoking so that you reduce the risk of having a diabetic complication. I can help you to quit smoking!*

- *Hemm evidenza ċara li l-waqfien mit-tipjip jipprovdi benefiċċji ċari f'termini ta' kontroll aħjar taz-zokkor fid-demm u tal-kolesterol u fit-tnaqqis tar-riskju ta' mard kardjovaskulari u kumplikazzjonijiet, u r-riskju ta' mewt f'persuni bid-dijabete. Huwa importanti li tieqaf tpejjep sabiex tnaqqas ir-riskju li jkollok xi kumplikazzjoni dijabetika. Jien nista' ngħinek tieqaf tpejjep!*

Following your advice, assess readiness in setting a quit attempt in the next two weeks by asking the following questions:

- *Would you like to attempt to quit smoking in the next two weeks?*

- *Tixtieq tipprova tieqaf tpejjep fil-ġimagħtejn li ġejjin?*

And

- *Do you think you have a chance of quitting successfully?*
- *Taħseb li għandek ċans li tieqaf b'suċċess?*

If the participant is ready to go ahead with a quit attempt, proceed to assist the participant with the setting of a quit plan. If the participant is unsure or doesn't want to quit smoking within the next two weeks and/or doesn't feel confident in attempting to quit, proceed to the 5Rs algorithm.

Please take note whether you have delivered the 5Rs or not.

The 5Rs algorithm (for participants who are unsure or do not want to quit smoking in the next two weeks and/or not confident in doing so)

While the information provided might have motivated the participant to consider quitting smoking, identifying, and discussing what is particularly relevant to the client (such as, the participant's disease status or risk, family or social situations, health concerns, age, sex, and other important characteristics) might encourage him/her further. Start by asking how quitting smoking would be relevant to the participant:

- *How would quitting smoking be particularly relevant to you?*
- *Kif inhu partikolarment rilevanti għalik li tieqaf mit-tipjip?*

Continue on what the participant has identified as being relevant (for e.g. health) by encouraging the participant to identify the potential negative consequences that are relevant to him/her if he/she continues to smoke, discussing further if required. For e.g. "Having mentioned that you are concerned about your health, what do you know about the risks of continuing smoking? What particularly worries you?"

Furthermore, ask the patient to identify potential benefits of stopping smoking which are relevant to him/her, discussing further if required. For e.g. "What do you know about the health benefits on stopping smoking?"

It is also important to help the participant identify any barriers or impediments to quitting smoking, discussing/providing realistic solutions (e.g. use of Nicotine Replacement Therapy, NRT to deal with cravings, dealing with anxiety/depression using better coping methods, avoiding or using distraction methods in situations which trigger smoking etc.):

- *So, what would be difficult in quitting for you?*
- *Allura, x'ikun diffiċli għalik sabiex tieqaf?*

Finally, after having motivated the participant to attempt to quit smoking and having increased his/her confidence by discussing possible solutions to the identified barriers, reassess readiness to quit smoking in the next two weeks, by asking again the following questions:

- *Now that we have had a little chat, would you like to attempt to quit smoking in the next two weeks?*
- *Issa li tkellimna ftit, tixtieq tipprova tieqaf tpejjep fil-ġimagħtejn li ġejjin?*

And

- *Do you think you have a chance of quitting successfully?*
- *Taħseb li għandek ċans li tieqaf b'suċċess?*

Encourage the participant to give it a try even if he/she is not 100% confident. If the participant is ready to go ahead with a quit attempt, proceed to *Assist* the participant with the setting of a quit plan. If the participant is still not ready to attempt to quit, end the intervention on a positive manner, inviting him/her to seek healthcare professional support/tobacco cessation services when ready. Inform the participant that he will be contacted to fill in the end of study questionnaire at 12 weeks follow-up.

Assist (for participants who intend to attempt quitting within the next two weeks)

After having successfully encouraged the participant to attempt to quit smoking in the next two weeks, proceed to help him/her develop a quit plan, providing practical counselling, and recommending (explaining the use and benefits) and providing a supply of NRT (25mgs nicotine patches, one per day, and nicotine mouth spray for breakthrough urges and/or to reduce withdrawal symptoms further for those who smoke at least 10-15 cigs/day, OR the nicotine mouth spray for those who smoke less than 10cigs/day) for use until the next session. Please note that participants are to receive up to a six-week supply of NRT during the study period).

In helping the participant to develop a quit plan, encourage him/her to talk about the quitting process, communicate caring and concern and encourage him/her further in the quit attempt by referring to/identifying what would be relevant for him/her if he quit smoking (*to motivate*

him/her further). The support given to the participant needs to be described positively but realistically.

Use the STAR method to help the participant develop a quit plan:

- Set a Target Quit Date (TQD) within the next two weeks.
- Tell the participant to inform his family, friends, and co-workers about his/her quitting attempt, and to ask for support.
- Anticipate the challenges or barriers to the upcoming quit attempt.
- Remove any tobacco products from the patient's environment (particularly closer to the quit date) and make the home smoke free.

Help the participant identify the challenges or barriers to the upcoming quit attempt, such as:

- smoking habits or the addiction
- any upcoming events that can trigger smoking
- smoking as a coping mechanism (e.g. to cope with diabetes or cope with stress/sadness)
- and activities or social circumstances that increase the risk of smoking or relapse

Help the participant generate problem-solving strategies to tackle the identified barriers and challenges to quitting, such as:

- the use of motivational techniques (e.g. self-motivation talk, thinking about health complications, reflecting on his/her personal reasons to quit smoking and seeking motivation from others [social support])
- use of helpful distraction (action distraction, thinking distraction, and mouth distraction)
- and taking nicotine replacement therapy (explaining their use and benefits), amongst others.

Advise monitoring of blood glucose. Link the participant to psychological support services if experiencing anxiety or depression (or on further discussion with participants who were identified as potential cases on the Hospital Anxiety and Depression Scale (HADS; Zigmond

and Snaith, 1983), i.e., those who obtained a score of eight or more on the Anxiety or Depression scale).

The participant should be provided with a follow-up appointment during their first week (or two weeks maximum) after their quit attempt. Inform the participant to call the diabetes education unit if he/she cannot make it.

Session two

In this session the participant is to be asked about his/her quit attempt. If the participant is abstinent from smoking (i.e. did not even have a puff for at least 24 hours before the follow-up session), the aim of the session is to help him/her avoid relapse. Conversely, if the participant did not quit smoking, the aim of the session should be to encourage him/her to set a quit attempt and support him/her in quitting smoking. In both cases the session should not take more than 30 minutes.

For those who did not quit smoking

Start off by reminding the participants that this is a learning experience. Take note of the number of cigarettes/tobacco products smoked every day. Take time to assess the use of NRT and any problems encountered (including over/under-dosing), providing recommendations, review experienced barriers and challenges (roadblocks), and elicit (encourage) a recommitment to quit smoking (refer to what is relevant to the participant – risks and rewards).

Encourage the participant to give it a try even if he/she is not 100% confident and proceed to *Assist* the participant with the setting of a quit plan. If the participant is not willing to attempt to quit, end the intervention on a positive manner, inviting him/her to seek healthcare professional support/tobacco cessation services when ready. Inform the participant that he will be contacted to fill in the end of study questionnaire at 12 weeks follow-up.

Assist (for participants who intend to attempt quitting within the next two weeks)

After having successfully encouraged the participant to attempt to quit smoking in the next two weeks, proceed to help him/her develop a quit plan, providing practical counselling, and recommending and topping up the supply of NRT (patch and/or spray) for use until the next

session. In helping the participant to develop a quit plan, encourage him/her to talk about the quitting process, communicate caring and concern and encourage him/her further in the quit attempt by referring to/identifying what would be relevant for him/her if he quit smoking (*to motivate him/her further.* The support given to the participant needs to be described positively but realistically.

Use the STAR method to help the participant develop a quit plan:

- Set a TQD within the next two weeks.
- Tell the participant to inform his family, friends, and co-workers about his/her quitting attempt, and to ask for support.
- Anticipate the challenges or barriers to the upcoming quit attempt.
- Remove any tobacco products from the patient's environment (particularly close to the quit date) and make the home smoke free.

Help the participant identify the challenges or barriers to the upcoming quit attempt, such as:

- smoking habits or the addiction
- any upcoming events that can trigger smoking
- smoking as a coping mechanism (e.g. to cope with diabetes or cope with stress/sadness)
- and activities or social circumstances that increase the risk of smoking or relapse

Help the participant generate problem-solving strategies to tackle the identified barriers and challenges to quitting, such as:

- the use of motivational techniques (e.g. self-motivation talk, thinking about health complications, reflecting on his/her personal reasons to quit smoking and seeking motivation from others [social support])
- use of helpful distraction (action distraction, thinking distraction, and mouth distraction)
- and taking nicotine replacement therapy (explaining their use and benefits), amongst others.

Advise monitoring of blood glucose. Link the participant to psychological support services if experiencing anxiety or depression.

The participant should be provided with a follow-up appointment during their first week (or two weeks maximum) after their quit attempt. Inform the participant to call the diabetes education unit if he/she cannot make it.

For those who quit smoking

The aim of the session is to support the participants in avoiding a relapse.

The participant should be congratulated on stopping smoking. Any problems encountered (barriers and challenges [roadblocks] towards remaining abstinent from smoking), and anticipated challenges are to be discussed. Encourage the participant to remain abstinent (referring to what is relevant to the participant – risks and rewards). The strategies outlined in the quit plan should also be reinforced – remind the participant on the usefulness of social support (linking the participant to psychological support services if experiencing anxiety or depression). The participant is to be asked about the use of NRT and for any problems that were encountered (including over/under-dosing), providing recommendations.

Provide the remaining assigned supply of NRT for use until the final session. Participants will have a supply of Step two and Step three patches for the last two weeks instead of Step one patches (for those who initially smoked at least 10-15 cigarettes a day). Advise all participants to reduce the use of the spray during these weeks.

Always advise monitoring of blood glucose. Participants are to be offered a diabetic consultation by the nurse educator (and subsequent specialist/s referrals, if required) if they experience poor glycaemic control, or are concerned about diabetes management following a change in diet or weight gain on quitting smoking.

The participant should be provided with a follow-up appointment within five weeks from their TQD. Inform the participant to call the diabetes education unit if he/she cannot make it.

Session three (for those who reported still smoking at session two)

As in the previous session, in this session the participant is to be asked about his/her quit attempt.

For those who quit smoking

If the participant is abstinent from smoking (i.e. did not even have a puff for at least 24 hours before the follow-up session), the aim of the session is to help him/her avoid relapse.

The participant should be congratulated on stopping smoking. Any problems encountered (barriers and challenges [roadblocks] towards remaining abstinent from smoking), and anticipated challenges are to be discussed. Encourage the participant to remain abstinent (referring to what is relevant to the participant – risks and rewards). The strategies outlined in the quit plan should also be reinforced – remind the participant on the usefulness of social support (linking the participant to psychological support services if experiencing anxiety or depression). The participant is to be asked about the use of NRT and for any problems that were encountered (including over/under-dosing), providing recommendations.

Provide the remaining assigned supply of NRT for use until the final session. Participants will have a supply of Step two and Step three patches for the last two weeks instead of Step one patches (for those who initially smoked at least 10-15 cigarettes a day). Advise all participants to reduce the use of the spray during these weeks.

Always advise monitoring of blood glucose. Participants are to be offered a diabetic consultation by the nurse educator (and subsequent specialist/s referrals, if required) if they experience poor glycaemic control, or are concerned about diabetes management following a change in diet or weight gain on quitting smoking.

The participant should be provided with a follow-up appointment within five weeks from their TQD. Inform the participant to call the diabetes education unit if he/she cannot make it.

For those who did not quit smoking

If the participant did not quit smoking, the aim of the session should be to encourage him/her to quit again and to support him/her in doing so.

Start off by reminding the participants that this is a learning experience. Take note of the number of cigarettes/tobacco products smoked every day. Take time to assess the use of NRT and any problems encountered (including over/under-dosing), providing recommendations, review experienced barriers and challenges (roadblocks), and elicit (encourage) a recommitment to quit smoking (refer to what is relevant to the participant – risks and rewards), discussing anticipated challenges. The strategies outlined in the quit plan should also be reinforced – remind the participant on the usefulness of social support (linking the participant to psychological support services if experiencing anxiety or depression).

Provide the remaining assigned supply of NRT for use until the final session. Participants will have a supply of Step two and Step three patches for the last two weeks instead of Step one patches (for those who initially smoked at least 10-15 cigarettes a day). Advise all participants to reduce the use of the spray during these weeks.

Always advise monitoring of blood glucose. Participants are to be offered a diabetic consultation by the nurse educator (and subsequent specialist/s referrals, if required) if they experience poor glycaemic control, or are concerned about diabetes management following a change in diet or weight gain on attempting to quit smoking.

The participant should be provided with a follow-up appointment within five weeks from their previously set TQD (that agreed on in session two). Inform the participant to call the diabetes education unit if he/she cannot make it.

Final follow-up session (session three or session four)

The aim of the session which is to be provided after five weeks following the TQD is to support the participants in avoiding a relapse and support non-quitters further.

The participant should be asked about tobacco use. If the participant is still abstinent from smoking, he/she should be congratulated. Conversely, if the participant has relapsed or is still smoking, take note of the number of cigarettes/tobacco products smoked every day, reminding him/her that this is a learning experience. Do praise any achievements (e.g. reduction in number of cigarettes smoked per day).

Either way, any problems encountered (barriers and challenges [roadblocks] towards remaining abstinent from smoking/quitting), are to be discussed. The participant is to be asked about the use of NRT and for any problems that were encountered (including over/under-

dosing), advising him/her to ideally reduce use if still on NRT (and abstinent from smoking). Encourage the participant to attempt quitting again if he/she relapsed/is still smoking or to remain abstinent (referring to what is relevant to the participant – risks and rewards), discussing anticipated challenges. The strategies outlined in the quit plan should also be reinforced – remind the participant on the usefulness of social support (linking the participant to psychological support services if experiencing anxiety or depression).

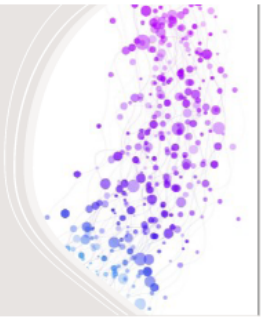
Always advise monitoring of blood glucose. Participants are to be offered a diabetic consultation by the nurse educator (and subsequent specialist/s referrals, if required) if they experience poor glycaemic control, or are concerned about diabetes management following a change in diet or weight gain on quitting/attempting to quit smoking.

End the intervention on a positive manner. Encourage the participant to seek tobacco cessation services if required. Inform the participant that he will be contacted to fill in the end of study questionnaire at 12 weeks follow-up.

Appendix 8.2: PowerPoint® presentation of the training programme (feasibility study)

Refresher training programme on the diabetes practice nurse-led smoking cessation intervention

Joseph Grech



1

Introduction

- Tobacco kills more than half of those who regularly use it (Drope & Schluger, 2018; World Health Organization, 2014).
- Tobacco smoking has been associated with increased complications for those who have diabetes, negatively impacting on cardiometabolic markers (Kar et al., 2016), accelerating vascular damage (Campagna et al., 2019), thus impacting on diabetes management.

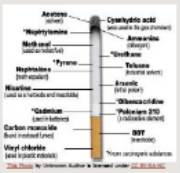
2

Aim

- To equip you with an evidence-based tobacco cessation intervention framework which aims to encourage and support individuals with diabetes to quit smoking.
- This course will help you to apply this framework among your patients/clients, by:
  - *Reinforcing previous learning on the current knowledge base on tobacco and diabetes, its health risks, and the challenges and benefits on quitting.*
  - *Teaching you on the use of the proposed algorithm for supporting smoking cessation.*
  - *And providing you with information on the use and prescription of Nicotine Replacement Therapy for smoking cessation and the other resources that are to be used.*

3

What is in a cigarette?



4

Nicotine

- Tobacco products contain nicotine which is addictive. Cigarettes and other forms of tobacco are addictive.
- Nicotine is highly addictive, as addictive as heroin and cocaine.
- Individuals with type 2 diabetes may metabolize nicotine faster, which in turn leads to a higher tendency to smoke more cigarettes over life, becoming more addicted than other individuals (Keith et al., 2019).

5

Harm from tobacco use

- Tobacco can damage nearly every organ system in the human body, causing many acute medical conditions as well as many chronic diseases including heart disease, strokes, cancer and chronic respiratory diseases.
- Even people who smoke **fewer than 5 cigarettes a day** can have early signs of cardiovascular disease.
- A regular life-long smoker **loses at least 10–11 years of life** to tobacco on average.

6

Smoking and diabetes

- An increased risk for **total cardiovascular disease,** (Relative Risk RR of 1.44, 95% CI[1.34-1.54]), **coronary heart disease** (RR of 1.51, 95% CI [1.41-1.62]), **stroke** (RR of 1.54, 95% CI [1.41-1.69]), **peripheral arterial disease** (RR of 2.15, 95% CI[1.62-2.85]), and **heart failure** (RR of 1.43, 95% CI [1.19-1.72]) compared to those with diabetes who do not smoke (Pan et al., 2015).
- A higher risk for **total mortality**, and for **cardiovascular mortality** has also been identified amongst smokers with diabetes (Qin et al., 2013).
- Tobacco use may also increase the risk of **microvascular diabetes complications**.
- Both individuals with type 1 and type 2 diabetes who smoke also seem to have **poorer cardiometabolic profiles.**

7

Economic and social impact

- 5 – 15% of a smoker's disposable incomes is spent on tobacco.
- The economic cost of tobacco attributed lung cancer (direct healthcare costs and indirect costs due to premature mortality) amounted to 17.7 million Euros in Malta in 2015 (Borg, 2021).
- Smoking affects social interaction and relationships negatively. There is a stigma attached to smoking.

8

Tobacco and diabetes – global and local situation

- The prevalence of smoking is still high amongst those with diabetes (Pan et al., 2015).
- On average 20% and 30% of individuals with type 2 and type 1 diabetes smoke, respectively (Durlach et al., 2022).
- Analysis of unpublished raw data from the European Health Interview Survey conducted in Malta in 2019/20 revealed that **17.4%** of those who reported having diabetes also reported to smoke (Directorate for Health Information and Research, 2023).

9

10

Quitting smoking and diabetes

- In the short-term quitting smoking may be associated with a negative impact on diabetes management.
- Despite the short-term potential negative impact on glycaemic control and weight management post-cessation, evidence still supports the position that quitting smoking provides clear benefits in terms of reducing the risk of cardiovascular morbidity, mortality, and overall mortality in people with diabetes as it does for the general population.

11

Challenges to quitting smoking

- Different people have different reasons why they smoke and why they don't quit.
- Reasons are typically classified into three categories:
  - *Psychological or Emotional connections*
  - *Behavioural and Social connections*
  - *And Physical addiction.*

12

Diabetes-specific challenges

- Factors such as depression (Abu Ghazaleh et al., 2018), or physical suffering (Georges et al., 2019), which are usually associated with diabetes and its complications.
- Smokers with diabetes in fact view smoking as a stress coping mechanism, which they remark as losing in trying to stop (Folan et al., 2014).
- Weight gain on cessation, which may lead may be lead to poor glycaemic control (Campagna et al., 2019), is also a common concern for patients with diabetes in attempting to quit smoking (Chau et al., 2015; Folan et al., 2014).
- Misconceptions about quitting have also been reported in the literature, making it harder for individuals to decide to quit smoking.

13

Withdrawal symptoms

- Craving for a cigarette
- Irritability
- Dizziness
- Chest tightness
- Constipation, stomach pain or gas
- Cough, dry throat and nasal drip
- Depressed mood
- Difficulty concentrating
- Fatigue
- Hunger
- Insomnia

14

Nicotine Replacement Therapy NRT

All smokers who attempt to quit smoking:

- should use NRT as from the quit date – they can also preload for increased effectiveness and for getting used to it (Lindson et al., 2019).
- should be advised to take combination NRT if smoking at least 10-15 cigs/day (Papadakis, 2021).
- should take NRT for as long as required (Lindson et al., 2019), however a minimum number of 5 weeks is suggested (Siahpush et al., 2015).

15

Video messages from a former smoker with diabetes

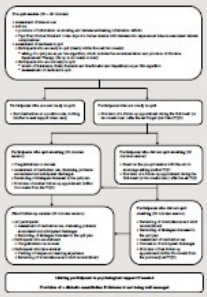
https://www.cdc.gov/tobacco/campaign/tips/stories/bill.html

16

Affecting change

- The client-centred approach is a non-directive behaviour change approach which enhances rapport building. This approach allows the client to accept responsibility for their own health and therefore to set their own goals. Core conditions of client-centred approach include:
- *Acceptance*
- *Empathy*
- *Genuineness*

20



Algorithm for the smoking cessation intervention (based on evidence and feedback collected in the pilot study)

21

First session

- Aim - to inform the participants on the effects of tobacco on diabetes, and to encourage and support them to quit smoking.
- Participants are informed that smoking does not help in diabetes management and are briefly told about the increased health risks, such as poor glucose and lipid control, and the increased risk for cardiovascular diseases and mortality.
- The participants are then briefly introduced to the story of Bill from the Tips from Former Smokers' campaign (Centers for Disease Control and Prevention (CDC), 2022), and showed the three video clips.
- Participants are advised to quit smoking in view of the health benefits, such as improved glycaemic and lipid control and decreased risk for cardiovascular diseases and mortality.

22

First session (cont.)

- Readiness to set a quit attempt within the next two weeks is then assessed (Assess).
- The 5R's algorithm (Relevance, Risks, Rewards, Roadblocks and Repetition) is followed for those who are unsure or not willing to quit smoking and/or not confident in attempting quitting.

23

First session (cont.)

- Conversely, those who are ready to quit are helped in developing a quit plan (Assist):
- *setting a Target Quit Date (TQD) in the next two weeks;*
- *telling family, friends and co-workers about their decision and asking them for support;*
- *the generation of problem-solving strategies to tackle identified barriers and challenges to quitting*
- *encouraging the use of motivational techniques and the use of helpful distraction as part of a guide to quit smoking;*
- *recommending the use (explaining use and benefits) of NRT, providing the patch and/or the spray for the quitting attempt up till the next follow-up appointment (participants are to receive a six-week supply of NRT in total);*
- *and removing tobacco products and making the house smoke-free.*
- These participants are then provided with a follow-up appointment during their first week (or two weeks maximum) after the set TQD (Arrange).

24

Sessions two and three (and four, if required)

- Aim – to assess the quit attempt, providing support accordingly. The second session is usually held in the second or third week, depending on the set TQD.
- For those who are found to have quit smoking, the aim of the session (and of the follow-up session which is provided after five weeks following the TQD) is to support the participants in avoiding a relapse.
- Conversely, those who do not manage to quit smoking are assessed about NRT use and any problems encountered (including over/under-dosing), providing recommendations, also discussing the experienced barriers and challenges. Participants are encouraged to set another TQD, providing a follow-up appointment in one (or two weeks max.) and five weeks from their new TQD (four sessions in total).

25

26

27

Conclusion

- Quitting smoking provides clear benefits for those with diabetes, necessitating the provision of smoking cessation support as part of diabetes management.
- Being based on current evidence and feedback from the pilot study, the proposed diabetes practice nurse-led multi-component smoking cessation intervention should be of support and guidance for individuals with diabetes who smoke to quit smoking.

28

Thank you!

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9[redacted]4

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Appendix 8.3: Baseline questionnaire (feasibility study – in English)

Thank you for accepting to participate in this study. As part of this study, please fill in this baseline questionnaire. The following questions are about your personal characteristics, your health status, your diabetes and smoking profiles, and your feelings in the past week. Where applicable please tick the chosen answer (✓). Please let me know if you require assistance in filling in this questionnaire, or if you have any questions.

Participant's code (please write down your unique participant code here) ☐

Exhaled carbon monoxide reading (for office use only) _____

Treatment allocation (for office use only) ☐

Participants' characteristics

The first section of this questionnaire is about your personal characteristics.

1. **Are you male or female, or you prefer not to say?**

   Male ☐ Female ☐

   Prefer not to say ☐

2. **How old are you now?**

   _____years old

3. **Do you live on your own?**

   Yes ☐ No ☐

4. **Do you live with someone who smokes?**

   Yes ☐ No ☐

5. **What is the highest level of education you have successfully completed?**

   _____

6. **Which of the following best describes your current <u>main activities</u>?**

   Student ☐ Home duties ☐

   Employed ☐ Retired ☐

   Unemployed ☐

Health status and diabetes profile

The following six questions are about your health status and your diabetes profile.

7. **How is your health in general?**

   Very good ☐

   Good ☐

   Fair ☐

   Bad ☐

   Very bad ☐

8. **How old were you when you were first diagnosed with diabetes?**

   _____years old

9. **What type of diabetes were you diagnosed of?**

   Type 1 ☐ Type 2 ☐

10. How do you treat diabetes?

By diet only ☐ Antidiabetic pills and insulin ☐

Antidiabetic pills ☐ Insulin ☐

11. Are you suffering from any health problems/complications caused by diabetes? If yes, what are these conditions?

Yes ☐ Conditions: _____

No ☐ Don't know ☐

12. Are you suffering from any other chronic diseases?

Yes ☐ Conditions: _____

No ☐ Don't know ☐

Smoking profile

This section is about your smoking profile. This is further divided into three sub-sections: smoking history, dependence on cigarettes, and quitting smoking.

Smoking history

This section is about your smoking history and current smoking habit.

13. How old were you when you first started smoking?

_____years old

14. Do you currently smoke tobacco daily or less than daily?

Daily ☐ Less than daily ☐

15. **On average, how many of the following products do you currently smoke each day/week (<u>please indicate accordingly</u>)?** Strikethrough products which you do not use.

Manufactured cigarettes _____ per day/week
Hand-rolled cigarettes _____ per day/week
Pipes full of tobacco _____ per day/week
Cigars, cheroots, or cigarillos _____ per day/week
Number of waterpipe (shisha) sessions _____ per day/week
Others (including smokeless and alternative products, e.g., electronic cigarettes):
_____ per day/week

Dependence on cigarettes (The Cigarette Dependence Scale, CDS-5; Etter et al., 2003)
This section is about your addiction to cigarettes.

16. **Please rate your addiction to cigarettes on a scale of 0 – 100: _____**
I am NOT addicted to cigarettes at all = 0
I am extremely addicted to cigarettes = 100

17. **On average, how many cigarettes do you smoke per day?**
_____ cigarette/day

18. **Usually, how soon after waking up do you smoke your first cigarette?**
_____ minutes

19. **For you, quitting smoking for good would be:**
Impossible ☐
Very difficult ☐
Fairly difficult ☐
Fairly easy ☐
Very easy ☐

20. Please indicate whether you agree with the following statement:

After a few hours without smoking, I feel an irresistible urge to smoke.

Totally disagree ☐

Somewhat disagree ☐

Neither agree nor disagree ☐

Somewhat agree ☐

Fully agree ☐

Quitting smoking

The following section is about your previous quit attempts and about your current intentions on quitting smoking.

21. Have you attempted to quit smoking in the past 12 months?

Yes ☐ No ☐

22. Have you ever been able to quit smoking? (i.e. not even a puff for at least seven consecutive days)

Never tried quitting ☐ Yes ☐

No ☐

23. Which of the following best describes you? (Motivation To Stop Scale; Kotz et al., 2013)

I don't want to stop smoking ☐

I think I should stop smoking but don't really want to ☐

I want to stop smoking but haven't thought about when ☐

I REALLY want to stop smoking but don't know when I will ☐

I want to stop smoking and hope to soon ☐

I REALLY want to stop smoking and intend to in the next 3 months ☐

I REALLY want to stop smoking and intend to in the next month ☐

Hospital Anxiety and Depression Scale (HADS; Zigmond and Snaith, 1983)

The final section assesses how you have been feeling in the past week. Read each item and please tick (✓) the box opposite the reply which comes closest to how you have been feeling in the past week.

Do not take too long over your replies: your immediate is best.

24. I feel tense or 'wound up':

Most of the time ☐

A lot of the time ☐

From time to time, occasionally ☐

Not at all ☐

25. I still enjoy the things I used to enjoy:

Definitely as much ☐

Not quite so much ☐

Only a little ☐

Hardly at all ☐

26. I get a sort of frightened feeling as if something awful is about to happen:

Very definitely and quite badly ☐

Yes, but not too badly ☐

A little, but it doesn't worry me ☐

Not at all ☐

27. I can laugh and see the funny side of things:

As much as I always could ☐

Not quite so much now ☐

Definitely not so much now ☐

Not at all ☐

28. Worrying thoughts go through my mind:

A great deal of the time ☐

A lot of the time ☐

From time to time but not too often ☐

Only occasionally ☐

29. I feel cheerful:

Not at all ☐

Not often ☐

Sometimes ☐

Most of the time ☐

30. I can sit at ease and feel relaxed:

Definitely ☐

Usually ☐

Not often ☐

Not at all ☐

31. 1 feel as if I am slowed down:

Nearly all the time ☐

Very often ☐

Sometimes ☐

Not at all ☐

32. I get a sort of frightened feeling like 'butterflies' in the stomach:

Not at all ☐

Occasionally ☐

Quite often ☐

Very often ☐

33. I have lost interest in my appearance:

Definitely ☐

I don't take so much care as I should ☐

I may not take quite as much care ☐

I take just as much care as ever ☐

34. I feel restless as if I have to be on the move:

Very much indeed ☐

Quite a lot ☐

Not very much ☐

Not at all ☐

35. I look forward with enjoyment to things:

As much as ever I did ☐

Rather less than I used to ☐

Definitely less than I used t o ☐

Hardly at all ☐

36. I get sudden feelings of panic:

Very often indeed ☐

Quite often ☐

Not very often ☐

Not at all ☐

37. I can enjoy a good book or radio or TV programme:

Often ☐

Sometimes ☐

Not often ☐

Very seldom ☐

Doctors are aware that emotions play an important part in most illnesses. If your doctor knows about these feelings she/he will be able to help you more. If you are concerned about your current feelings speak to your doctor for more support.

Thank you for completing this questionnaire!

Appendix 8.4: Baseline questionnaire (feasibility study – in Maltese)

Grazzi talli aċċettajt li tipparteċipa f'dan l-istudju. Bħala parti minn dan l-istudju, jekk jogħġbok imla dan il-kwestjonarju bażi. Il-mistoqsijiet li ġejjin huma dwar il-karatteristiċi personali tiegħek, l-istat ta' saħħtek, il-profil tad-dijabete u tat-tipjip tiegħek, u s-sentimenti tiegħek fil-ġimgħa li għaddiet. Fejn applikabbli jekk jogħġbok immarka t-tweġiba magħżula (✓). Jekk jogħġbok għarrafni jekk teħtiġx għajnuna biex timla dan il-kwestjonarju, jew jekk għandek xi mistoqsijiet.

Kodiċi tal-parteċipant (jekk jogħġbok ikteb il-kodiċi tal-parteċipant uniku tiegħek hawn) ☐

Qari tat-test tan-nifs tal-monossidu tal-karbonju (għall-użu tal-uffiċċju biss)

_____

Allokazzjoni tat-trattament (għall-użu tal-uffiċċju biss) ☐

Il-karatteristiċi tal-Parteċipanti

L-ewwel taqsima ta' dan il-kwestjonarju hija dwar il-karatteristiċi personali tiegħek.

1. **Int raġel jew mara, jew tippreferi li ma tgħidx?**

   Raġel ☐ Mara ☐

   Nippreferi li ma ngħidx ☐

2. **Kemm għandek żmien issa?**

   _____sena

3. **Tgħix waħdek?**

   Iva ☐ Le ☐

4. **Tgħix ma’ xi ħadd li jpejjep??**

   Iva ☐ Le ☐

5. **X'inhu l-ogħla livell ta’ edukazzjoni li temmejt b'suċċess?**

   _____

6. **Liema minn dawn li ġejjin l-aħjar li jiddeskrivu l-<u>attivitajiet ewlenin attwali tiegħek</u>?**

   Student ☐ Dmirijiet tad-dar ☐

   Impjegat ☐ Irtirat/a ☐

   Bla xogħol ☐

L-istat ta’ saħħtek u l-profil tad-dijabete

Is-sitt mistoqsijiet li ġejjin huma dwar l-istat ta’ saħħtek u l-profil dijabetiku tiegħek.

7. **Kif inhi saħħtek inġenerali?**

   Tajba ħafna ☐

   Tajba ☐

   Insomma ☐

   Ħażina ☐

   Ħażina ħafna ☐

8. **Kemm kellek żmien meta ġejt iddijanjostikat/a bid-dijabete għall-ewwel darba?**

   _____sena

9. **B'liema tip ta' dijabete ġejt iddijanjostikat/a?**

   Tat-tip wieħed ☐ Tat-tip tnejn ☐

10. **Kif tittratta d-dijabete?**

    Bid-dieta biss ☐ Pilloli kontra d-dijabete u insulina ☐

    Pilloli kontra d-dijabete ☐ Insulina ☐

11. **Int qiegħed/a tbati minn xi problemi/kumplikazzjonijiet tas-saħħa kkawżati mid-dijabete? Jekk iva, x'inhuma dawn il-kundizzjonijiet?**

    Iva ☐ Il-kundizzjonijiet: _____

    Le ☐ Ma nafx ☐

12. **Qed tbati minn xi mard kroniku ieħor?**

    Iva ☐ Il-kundizzjonijiet: _____

    Le ☐ Ma nafx ☐

Profil tat-Tipjip

Din it-taqsima hija dwar il-profil tat-tipjip tiegħek. Din it-taqsima hija maqsuma fi tlitt subtaqsimiet: l-istorja tat-tipjip, id-dipendenza fuq is-sigaretti, u l-waqfien mit-tipjip.

L-istorja tat-tipjip

Din it-taqsima hija dwar l-istorja tat-tipjip tiegħek u l-vizzju kurrenti tiegħek tat-tipjip.

13. **Kemm kellek żmien meta bdejt tpejjep għall-ewwel darba?**

    _____sena

14. **Bħalissa tpejjep it-tabakk kuljum, jew inqas minn kuljum?**

    Kuljum ☐ Inqas minn kuljum ☐

15. Bejn wieħed u ieħor, kemm mill-prodotti li ġejjin tpejjep kull jum/ġimgħa (jekk jogħġbok indika kif sippost)? Ingassa l-prodotti li ma tużax.

Sigaretti manifatturati _____ kull jum/fil-ġimgħa

Sigaretti rrumblati bl-idejn _____ kull jum/fil-ġimgħa

Il-pipa mimlija bit-tabakk _____ kull jum/fil-ġimgħa

Sigarri, *cheroots*, jew *cigarillos* _____ kull jum/fil-ġimgħa

Numru ta' sessjonijiet ta' *waterpipe* (shisha) _____ kull jum/fil-ġimgħa

Oħrajn (inkluż tabakk li ma jdaħħanx u prodotti alternattivi, eżempju, sigaretti elettroniċi): _____ kull jum/fil-ġimgħa

Id-dipendenza fuq is-sigaretti (The Cigarette Dependence Scale, CDS-5; Etter et al., 2003)

Din it-taqsima hija dwar id-dipendenza tiegħek għas-sigaretti.

16. Jekk jogħġbok ikklassifika d-dipendenza tiegħek fuq is-sigaretti fuq skala bejn 0 u 100: _____

M'jien dippendenti XEJN fuq is-sigaretti = 0

Jien dipendenti ħafna fuq is-sigaretti = 100

17. Bħala medja, kemm-il sigarett tpejjep kuljum?

_____ sigarett / kuljum

18. Normalment, kemm iddum biex tqabbad l-ewwel sigarett tiegħek?

_____ minuti

19. Għalik, li tieqaf tpejjep għalkollox tkun:

Impossibbli ☐

Diffiċli ħafna ☐

Pjuttost diffiċli ☐

Pjuttost faċli ☐

Faċli ħafna ☐

20. Jekk jogħġbok indika jekk taqbilx mad-dikjarazzjoni li ġejja:

Wara ftit sigħat mingħajr tipjip, inħoss ħtieġa insaportabbli biex inpejjep.

Ma naqbilx totalment ☐

Pjuttost ma naqbilx ☐

Newtrali ☐

Pjuttost naqbel ☐

Naqbel ħafna ☐

Waqfien mit-Tipjip

It-taqsima li ġejja hija dwar l-attentati preċedenti tiegħek biex tieqaf u dwar l-intenzjonijiet attwali tiegħek biex tieqaf tpejjep.

21. Ippruvajt tieqaf tpejjep fl-aħħar 12-il xahar?

Iva ☐ Le ☐

22. Qatt irnexxielek tieqaf tpejjep? (jiġifieri lanqas ħadt nifs wieħed għal mill-inqas sebat ijiem konsekuttivi)

Qatt ma ppruvajt nieqaf ☐ Iva ☐

Le ☐

23. Liema stqarrija minn dawn li ġejjin tiddeskrivik l-aħjar? (Motivation To Stop Scale; Kotz et al., 2013)

Ma rridx nieqaf inpejjep ☐

Naħseb li għandi nieqaf inpejjep imma mhux verament irrid ☐

Irrid nieqaf inpejjep imma ma tajtx ħsieb għal meta ☐

Jien VERAMENT irrid nieqaf mit-tipjip imma ma nafx meta se nieqaf ☐

Irrid nieqaf inpejjep u nispera li jkun dalwaqt ☐

VERAMENT irrid nieqaf mit-tipjip u beħsiebni nieqaf fit-tliet xhur li ġejjin ☐

VERAMENT irrid nieqaf inpejjep u beħsiebni nieqaf fix-xahar li jmiss ☐

Skala ta’Ansjetà u Dipressjoni għall-Isptarijiet (HADS; Zigmond and Snaith 1983)

maqluba bil-Malti minn Baldacchino, Bowman and Buhagiar (2002)

L-aħħar taqsima tivvaluta kif kont tħossok fil-ġimgħa li għaddiet. Aqra kull stqarrija u jekk jogħġbok immarka (✓) il-kaxxa faċċata tat-tweġiba li toqrob l-eqreb ta’ kif kont tħossok fil-ġimgħa li għaddiet.

Tieħux wisq ħin fit-tweġibiet tiegħek: ir-reazzjoni immedjata tiegħek hija l-aħjar.

24. Inħoss it-tensjoni u l-ansjeta':

Il-ħin kollu ☐

Ħafna mill-ħin ☐

Minn ħin għall-ieħor ☐

Qatt ☐

25. Għadni nieħu pjaċir nagħmel l-affarijiet li kont nagħmel qabel:

Żgur daqs qabel ☐

Ftit inqas minn qabel ☐

Ftit biss ☐

Kważi xejn ☐

26. Inħossni mbeżża' qisu ser jiġri xi ħaġa kerha:

Inħossu ħafna u ħażin ħafna ☐

Iva, imma mhux daqstant ☐

Ftit, iżda ma jinkwetanix ☐

Lanqas xejn ☐

27. Niccajta u nidħak u nara l-aspett inqas serju ta' l-affarijiet:

L-aktar li nista' possibli ☐

Mhux daqstant issa ☐

Żgur li le, issa ☐

Lanqas xejn ☐

28. Ħsibijiet ta' nkwiet jgħaddu minn moħħi:

Il-ħin kollu ☐

Parti kbira tal-ħin ☐

Minn ħin għall-ieħor, imma mhux spiss ☐

Xi kultant ☐

29. Inħossni kuntent/a:

Qatt ☐

Mhux dejjem ☐

Xi kultant ☐

Kważi l-ħin kollu ☐

30. Kapaċi noqgħod bilqegħda komdu u nħossni rilassat/a:

Dejjem ☐

Sikwit ☐

Mhux ta' spiss ☐

Qatt ☐

31. Inħossni qiegħed/a inċedi:

Il-ħin kollu ☐

Ta' spiss ☐

Xi kultant ☐

Qatt ☐

32. Inħoss sens ta' biżgħa u nħoss tferfir fl-istonku:

Lanqas xejn ☐

Xi kultant ☐

Ta' spiss ☐

Spissi ħafna ☐

33. Tlift kull interess ta' kif inżomm persunti:

Qatt ma nagħti kas ☐

Ma nagħtix kas daqskemm suppost ☐

Jista' jkun li ma tantx nagħti kas ☐

Nieħu ħsieb kemm nista' ☐

34. Inħossni bla kwiet, qisni għandi nibqa' sejjer il-ħin kollu:

Ħafna, ħafna ☐

Mhux ħażin ☐

Ftit li xejn ☐

Lanqas xejn ☐

35. Inħares bil-ferħ lejn l-affarijiet:

Ħafna bħal qabel ☐

Ftit inqas minn qabel ☐

Ħafna inqas minn qabel ☐

Ftit li xejn ☐

36. Kultant inħossni "ma nafx fejn se nagħti rasi":

Dejjem☐

Ta' spiss ☐

Mhux ta' spiss ☐

Qatt ☐

37. Nieħu gost naqra ktieb tajjeb jew nisma' r-radju jew nara programm tat-Televixin:

Spiss ☐

Xi kultant ☐

Mhux dejjem ☐

Rari ☐

It-tobba huma konxji li l-emozzjonijiet jilgħabu parti importanti fil-biċċa l-kbira tal-mard. Jekk it-tabib tiegħek ikun jaf dwar dawn is-sentimenti hu/hija jkun jista' jgħinek aktar. Jekk inti imħasseb dwar is-sentimenti attwali tiegħek kellem lit-tabib tiegħek għal aktar appoġġ.

Grazzi talli mlejt dan il-kwestjonarju!

Appendix 8.5: End of study questionnaire (feasibility study – in English)

Thank you for accepting to fill in this questionnaire. The following questions are about your quitting attempt and your smoking status, about the support you have received during the study period, and about your satisfaction with the smoking cessation intervention provided and your perceptions of its usefulness. Where applicable please tick the chosen answer (✓). Please let me know if you require assistance in filling in this questionnaire, or if you have any questions.

Participant's code (please write down your unique participant code here) ☐

Exhaled carbon monoxide reading (for office use only) _____

Urine cotinine result (for office use only) _____

Smoking profile

The first section is about your quitting attempt during the intervention period, and your current smoking status if you still smoke.

1. **During the last 12 weeks have you intentionally spent at least one day (≥24 hours) not smoking any cigarettes or any tobacco products (i.e. you did not even take a puff), and not using any smokeless tobacco products or any alternative products such as electronic cigarettes?**

   No ☐ *Please go to question no. 4*

   Yes ☐ *Please go to question no. 2*

2. **During the last 12 weeks have you spent at least seven consecutive days not smoking any cigarettes or any tobacco products (i.e. you did not even take a puff), and not using any smokeless tobacco products or any alternative products such as electronic cigarettes?**

   No ☐ *Please go to question no. 4*

   Yes ☐ *Please go to question no. 3*

3. **In the last seven days have you smoked a cigarette or another tobacco product (even if you took a puff), or used a smokeless tobacco product or an alternative product such as an electronic cigarette?**

   Yes ☐ *Please go to question no. 4*

   No, I have not even had a puff for at least seven days ☐ *Please go to the next section*

4. **On average, how many of the following products do you currently smoke each day/week (<u>please indicate accordingly</u>)?** Strikethrough products which you do not use.

   Manufactured cigarettes _____ per day/week
   Hand-rolled cigarettes _____ per day/week
   Pipes full of tobacco _____ per day/week
   Cigars, cheroots, or cigarillos _____ per day/week
   Number of waterpipe (shisha) sessions _____ per day/week
   Others (including smokeless tobacco products and alternative products, e.g., electronic cigarettes): _____ per day/week

Support received

The following section is about the smoking cessation support sessions that you have received and about any additional support that you may have received.

5. **Have you attended all the scheduled smoking cessation sessions? If no, please state why.**

   Yes ☐

   No ☐ _____

6. **How many smoking cessation support sessions did you attend?**

   None ☐ One session ☐

   Two sessions ☐ Three sessions ☐

   Four sessions ☐ Five sessions ☐

   Six sessions ☐ Other:_____

7. **Over how many weeks did you attend these support sessions?**

   _____ weeks

8. **Did you take any nicotine replacement therapy/medication to help you quit smoking? If yes, please state what.**

   No ☐

   Yes ☐ _____

   How frequently and for how many days did you take this?

   _____

   _____

9. **Is there anything else which was not provided as part of the smoking cessation support provided which you found useful in attempting to quit smoking during the study period?**

   _____

   _____

   _____

Satisfaction with and perceived usefulness of the smoking cessation intervention provided

The following section, further divided in two sub-sections, is about your satisfaction with the smoking cessation intervention provided and your perceptions of its usefulness. Please do not answer this section **if you <u>have not</u>** attended any smoking cessation support sessions.

Satisfaction with the smoking cessation intervention provided

The following sub-section is about your satisfaction with the various elements of the smoking cessation intervention you have received. Please indicate your satisfaction for each statement.

	How satisfied are you with the…	Very unsatisfied (1)	Unsatisfied (2)	Neutral (3)	Satisfied (4)	Very satisfied (5)
10.	Support you received to help you quit smoking.	☐	☐	☐	☐	☐
11.	Location where the smoking cessation intervention was provided.	☐	☐	☐	☐	☐
12.	Appointment times given.	☐	☐	☐	☐	☐
13.	Waiting period for having your first session.	☐	☐	☐	☐	☐
14.	Duration of each individual session.	☐	☐	☐	☐	☐
15.	Time interval between appointments.	☐	☐	☐	☐	☐
16.	Number of sessions you had.	☐	☐	☐	☐	☐
17.	Method used to help you quit.	☐	☐	☐	☐	☐

18. What aspect of the smoking cessation intervention were you most satisfied with? Please explain your answer.

_____

_____

_____

19. What aspect of the smoking cessation intervention were you least satisfied with? Please explain your answer.

_____

_____

_____

Perceived usefulness of the smoking cessation intervention

The following sub-section is about your perceptions of the usefulness of the smoking cessation intervention provided. Please indicate your agreement for each statement.

	The smoking cessation intervention…	**Strongly disagree (1)**	**Disagree (2)**	**Neutral (3)**	**Agree (4)**	**Strongly agree (5)**
20.	Met your expectations.	☐	☐	☐	☐	☐
21.	Applied to you specifically.	☐	☐	☐	☐	☐
22.	Provided you with helpful information about quitting.	☐	☐	☐	☐	☐
23.	Made you concerned on the severe diabetes complications caused by smoking.	☐	☐	☐	☐	☐
24.	Made you concerned about your smoking.	☐	☐	☐	☐	☐
25.	Provided you with the motives to quit.	☐	☐	☐	☐	☐

	The smoking cessation intervention…	Strongly disagree (1)	Disagree (2)	Neutral (3)	Agree (4)	Strongly agree (5)
26.	Made you think that it is worthwhile to quit.	☐	☐	☐	☐	☐
27.	Helped you consider a plan to quit smoking.	☐	☐	☐	☐	☐
28.	Helped you identify situations that increase your risk of smoking.	☐	☐	☐	☐	☐
29.	Helped you identify strategies to resist urges to smoke.	☐	☐	☐	☐	☐
30.	Helped you to respond effectively to urges to smoke.	☐	☐	☐	☐	☐
31.	Provided you with options on how to quit smoking.	☐	☐	☐	☐	☐
32.	Helped you identify the most effective method to quit smoking.	☐	☐	☐	☐	☐
33.	Gave you the confidence so that you can quit.	☐	☐	☐	☐	☐

34. Is there anything that we could do to make the intervention better to make it easier for you to quit smoking?

_____

_____

_____

35. Would you recommend this smoking cessation intervention to someone else?

No ☐ Yes ☐

Thank you for completing this questionnaire!

Appendix 8.6: End of study questionnaire (feasibility study – in Maltese)

Grazzi talli aċċettajt li timla dan il-kwestjonarju. Il-mistoqsijiet li ġejjin huma dwar it-tentattiv tal-waqfien mit-tipjip li għamilt u l-istatus tat-tipjip tiegħek, dwar l-appoġġ li rċevejt matul il-perjodu ta' dan l-istudju, u dwar is-sodisfazzjon tiegħek bl-intervent ipprovdut għall-waqfien mit-tipjip u il-perċezzjonijiet tiegħek dwar l-utilità tiegħu. Fejn applikabbli jekk jogħġbok immarka t-tweġiba magħżula (✓). Jekk jogħġbok għarrafni jekk teħtieġx għajnuna biex timla dan il-kwestjonarju, jew jekk għandek xi mistoqsijiet.

Kodiċi tal-parteċipant (jekk jogħġbok ikteb il-kodiċi tal-parteċipant uniku tiegħek hawn) ☐

Qari tat-test tan-nifs tal-monossidu tal-karbonju (għall-użu tal-uffiċċju biss)

_____

Riżultat tal-kotinina fl-awrina (għall-użu fl-uffiċċju biss) _____

Il-vizzju tat-tipjip

L-ewwel taqsima hija dwar it-tentattiv tal-waqfien mit-tipjip li għamilt matul il-perjodu ta' l-intervent, u l-istatus tiegħek tat-tabakk jekk għadek tpejjep.

7. **Matul l-aħħar 12-il ġimgħa qattajt intenzjonalment mill-inqas ġurnata waħda (≥24 siegħa) ma tpejjep l-ebda sigarett jew xi prodott tat-tabakk (jiġifieri lanqas biss ħadt nifs wieħed), u ma użajt l-ebda prodott tat-tabakk li ma jdaħħanx jew xi prodott alternattiv bħas-sigarett elettroniku?**

   Le ☐ *Jekk jogħġbok mur għall-mistoqsija numru 4*

   Iva ☐ *Jekk jogħġbok mur għall-mistoqsija numru 2*

8. **Matul l-aħħar 12-il ġimgħa qattajt mill-inqas sebat ijiem konsekuttivi ma tpejjep l-ebda sigarett jew xi prodott tat-tabakk (jiġifieri lanqas biss ħadt nifs wieħed), u ma użajt l-ebda prodott tat-tabakk li ma jdaħħanx jew xi prodott alternattiv bħas-sigarett elettroniku?**

   Le ☐ *Jekk jogħġbok mur għall-mistoqsija numru 4*

   Iva ☐ *Jekk jogħġbok mur għall-mistoqsija numru 3*

9. **Fl-aħħar sebat ijiem pejjipt sigarett jew prodott ieħor tat-tabakk (anki jekk ħadt nifs wieħed), jew użajt prodott tat-tabakk li ma jdaħħanx jew prodott alternattiv bħas-sigarett elettroniku?**

   Iva ☐ *Jekk jogħġbok mur għall-mistoqsija numru 4*

   Le, lanqas ħadt nifs wieħed għal mill-inqas sebat ijiem ☐ *Jekk jogħġbok mur fit-taqsima li jmiss*

10. **Bejn wieħed u ieħor, kemm mill-prodotti li ġejjin tpejjep kull jum/ġimgħa (jekk jogħġbok indika kif sippost)?** Ingassa l-prodotti li ma tużax.

    Sigaretti manifatturati _____ kull jum/fil-ġimgħa

    Sigaretti rrumblati bl-idejn _____ kull jum/fil-ġimgħa

    Il-pipa mimlija bit-tabakk _____ kull jum/fil-ġimgħa

    Sigarri, *cheroots*, jew *cigarillos* _____ kull jum/fil-ġimgħa

    Numru ta' sessjonijiet ta' *waterpipe* (shisha) _____ kull jum/fil-ġimgħa

    Oħrajn (inklużi prodotti tat-tabakk li ma jdaħnux u prodotti alternattivi, eż., sigaretti elettroniċi): _____ kull jum/fil-ġimgħa

Appoġġ riċevut

It-taqsima li ġejja hija dwar is-sessjonijiet ta' appoġġ għall-waqfien mit-tipjip li rċevejt u dwar kwalunkwe appoġġ addizzjonali li jista' jkun irċevejt.

11. **Attendejt is-sessjonijiet skedati kollha għall-waqfien mit-tipjip? Jekk le, jekk jogħġbok għid għaliex.**

    Iva ☐

    Le ☐ _____

12. Kemm attendejt sessjonijiet ta' appoġġ għall-waqfien mit-tipjip?

Xejn ☐ Sessjoni waħda ☐

Żewġ sessjonijiet ☐ Tliet sessjonijiet ☐

Erba' sessjonijiet ☐ Ħames sessjonijiet ☐

Sitt sessjonijiet ☐ Oħrajn:_____

9. Fuq kemm-il ġimgħa attendejt dawn is-sessjonijiet ta' appoġġ?

_____ -il ġimgħa

10. Ħadt xi sostituzzjoni terapewtika tan-nikotina jew mediċina biex tgħinek tieqaf tpejjep? Jekk iva, jekk jogħġbok għid xiex.

Le ☐

Iva ☐ _____

Għal kemm ġranet għamilt dan, u kemm spiss?

_____

_____

10. Hemm xi ħaġa oħra li ma ġietx ipprovduta bħala parti mill-appoġġ ipprovdut għall-waqfien mit-tipjip li sibtha utli biex tipprova tieqaf tpejjep matul il-perjodu ta' studju?

_____

_____

_____

Sodisfazzjon u utilità perċepita tal-intervent ipprovdut għall-waqfien mit-tipjip

It-taqsima li ġejja, li hija maqsuma f'żewġ subtaqsimiet, hija dwar is-sodisfazzjon tiegħek bl-intervent ipprovdut għall-waqfien mit-tipjip u l-perċezzjonijiet tiegħek dwar l-utilità tiegħu. Jekk jogħġbok tweġibx din it-taqsima **jekk ma attendejtx** xi sessjoni ta' appoġġ għall-waqfien mit-tipjip.

Sodisfazzjon bl-intervent ipprovdut għall-waqfien mit-tipjip

Is-subtaqsima li ġejja hija dwar is-sodisfazzjon tiegħek bid-diversi elementi tal-intervent tal-waqfien mit-tipjip li rċevejt. Jekk jogħġbok indika s-sodisfazzjon tiegħek għal kull dikjarazzjoni.

	Kemm int sodisfatt…	**M'jien sodisfatt xejn (1)**	**Mhux sodisfatt (2)**	**Newtrali (3)**	**Sodisfatt (4)**	**Sodisfatt ħafna (5)**
10.	Bis-sapport li rċevejt biex tieqaf tpejjep.	☐	☐	☐	☐	☐
11.	Bil-post fejn l-intervent għall-waqfien mit-tipjip ġie pprovdut.	☐	☐	☐	☐	☐
12.	Bil-ħinijiet mogħtija tal-appuntamenti	☐	☐	☐	☐	☐
13.	Biż-żmien ta' stennija għall-ewwel sessjoni tiegħek.	☐	☐	☐	☐	☐
14.	Bit-tul ta' ħin għal kull sessjoni individwali.	☐	☐	☐	☐	☐
15.	Bil-perjodu ta' żmien bejn appuntament u ieħor	☐	☐	☐	☐	☐
16.	Bin-numru ta' sessjonijiet li kellek.	☐	☐	☐	☐	☐
17.	Bil-metodu użat biex jgħinek tieqaf	☐	☐	☐	☐	☐

20. B'liema aspett tal-intervent tal-waqfien mit-tipjip kont l-iktar sodisfatt? Jekk jogħġbok spjega t-tweġiba tiegħek.

_____

_____

_____

21. B'liema aspett tal-intervent tal-waqfien mit-tipjip kont l-inqas sodisfatt? Jekk jogħġbok spjega t-tweġiba tiegħek.

_____

_____

_____

L-utilità perċepita tal-intervent tal-waqfien mit-tipjip

Is-subtaqsima li ġejja hija dwar il-perċezzjonijiet tiegħek dwar l-utilità tal-intervent ipprovdut għall-waqfien mit-tipjip. Jekk jogħġbok indika l-qbil tiegħek għal kull dikjarazzjoni

	L-intervent għall-waqfien mit-tipjip…	**Ma naqbel xejn (1)**	**Ma naqbilx (2)**	**Newtrali (3)**	**Naqbel (4)**	**Naqbel ħafna (5)**
20.	Laħaq l-aspettattivi tiegħek.	☐	☐	☐	☐	☐
21.	Japplika għalik speċifikament.	☐	☐	☐	☐	☐
22.	Ipprovdielek informazzjoni utli dwar kif tieqaf.	☐	☐	☐	☐	☐
23.	Għamlek ikkonċernat fuq il-kumplikazzjonijiet severi tad-dijabete kkawżati mit-tipjip.	☐	☐	☐	☐	☐
24.	Għamlek ikkonċernat dwar it-tipjip tiegħek.	☐	☐	☐	☐	☐

	L-intervent għall-waqfien mit-tipjip…	Ma naqbel xejn (1)	Ma naqbilx (2)	Newtrali (3)	Naqbel (4)	Naqbel ħafna (5)
25.	Ipprovdielek il-motivi biex tieqaf.	☐	☐	☐	☐	☐
26.	Ġiegħlek taħseb li jaqbillek tieqaf.	☐	☐	☐	☐	☐
27.	Għenek tikkunsidra pjan biex tieqaf tpejjep.	☐	☐	☐	☐	☐
28.	Għenek tidentifika sitwazzjonijiet li jżidu r-riskju li tpejjep.	☐	☐	☐	☐	☐
29.	Għenek tidentifika strateġiji biex tirreżisti l-leblieba biex tpejjep.	☐	☐	☐	☐	☐
30.	Għenek tirrispondi effettivament għal-leblieba biex tpejjep.	☐	☐	☐	☐	☐
31.	Ipprovdilek għażliet dwar kif tieqaf tpejjep.	☐	☐	☐	☐	☐
32.	Għenek tidentifika l-iktar metodu effettiv biex tieqaf tpejjep.	☐	☐	☐	☐	☐
33.	Tak il-kunfidenza sabiex tkun tista' tieqaf.	☐	☐	☐	☐	☐

35. Hemm xi ħaġa li nistgħu nagħmlu biex intejbu l-intervent u nagħmluha aktar faċli għalik li tieqaf tpejjep?

_____

_____

_____

36. Tirrakkomanda dan l-intervent tal-waqfien mit-tipjip lil xi ħadd ieħor?

Le ☐ Iva ☐

Grazzi talli mlejt dan il-kwestjonarju!

Appendix 8.7: Interview guide (for individuals with diabetes) in English (feasibility study)

Introduction

Thank you for sharing some of your time with me and for consenting to be interviewed. So, I will be recording this interview with your permission. First, I have a few questions about your personal characteristics, and your diabetes and smoking profile. Then I will be asking you for your overall feedback on the smoking cessation intervention. After that I will be asking you on your quit attempt. The interview usually takes about 30-40 minutes.

At any time please let me know if you need me to clarify any of the questions. Do you have any questions before we start? Are we okay to start?

So I will start recording – is that okay?

Personal characteristics and participants' diabetes and smoking profile

1. Can you please tell me your age?
2. What type of diabetes do you have?
3. How many smoking cessation support sessions did you attend? Did you complete the intervention, or did you stop attending? If you stopped attending, can you please tell me why?
4. Did you use the provided Nicotine Replacement Therapy on attempting to quit smoking? If not, can you please tell me why?
5. Did you quit smoking at any point during the study? If you currently smoke, what type of tobacco and how much do you smoke?

Overall feedback

In the first part of the session, I will be asking you for your overall feedback on the smoking cessation intervention.

6. Overall, what do you think of the smoking cessation intervention?
   Probes: What did you like about this intervention? What did you like least? What do you think about the usefulness of this smoking cessation intervention? Have you been offered any additional support services/sessions, such as psychological support to deal with anxiety and/or depression, or a diabetes consultation session for improving diabetes management? If yes, what do you think about the support services offered?
7. What do you think about the delivery method?
   Probe: How relevant was this to you?
8. What do you think about the overall duration of the smoking cessation intervention?
   Probe: What do you think of the duration of each individual contact and the frequency of contacts?
9. What helped you to stay engaged in this smoking cessation intervention?
   Probe: What helped you stay active and participate in this smoking cessation intervention?
10. What barriers did you experience in participating in this smoking cessation intervention?
    Probe: What difficulties did you encounter to fully participate in this smoking cessation intervention? What can we do to keep you engaged?
11. Would you recommend this smoking cessation intervention to someone else?
    Probe: Why would you recommend or not recommend this intervention?

Quit attempt

In the second part of the session, I will be asking you on your quit attempt.

12. What helped you to try to quit?
    Probes: Which information did you find useful? Which motivational factors motivated you to attempt to quit smoking? What helped you consider a plan to quit? What helped you to identify situations that increase the risk of smoking? What helped you to identify factors to help you resist urges to smoke? Which abilities did you find useful in attempting to quit? If you quit, what did you do to overcome your urge to smoke? Did you use the Nicotine Gum/Patch/Spray/Inhalator for quitting smoking? If

yes, how was it? Would you be willing to buy the nicotine replacement therapy for quitting smoking?

13. If you quit, how did you do that?
    Probes: What was the most effective method to quit smoking? How did you increase your confidence to quit?

Any other issues

14. Is there anything else that we have not addressed that would have helped in quitting smoking?
    Probe: Were there any expectations which were not met?

Appendix 8.8 Interview guide (for individuals with diabetes) in Maltese (feasibility study)

Introduzzjoni

Grazzi talli qsamt ftit mill-ħin tiegħek miegħi u talli tajtni l-kunsens sabiex tiġi intervistat/a. Bil-permess tiegħek jien se nkun qiegħed nirreġistra din l-intervista. L-ewwel għandi ftit mistoqsijiet dwar il-karatteristiċi personali tiegħek, u l-profil tad-dijabete u tat-tipjip tiegħek. Imbagħad se nkun qed nitolbok ir-rispons ġenerali tiegħek dwar l-intervent tal-waqfien mit-tipjip. Wara dan se nkun qed nitolbok dwar l-attentat tiegħek biex tieqaf. Ġeneralment l-intervista tieħu madwar 30-40 minuta.

Fi kwalunkwe ħin jekk jogħġbok għarrafni jekk għandekx bżonn li niċċara xi mistoqsija/ijiet. Għandek xi mistoqsijiet qabel ma nibdew? Aħna tajbin biex nibdew?

Allura se nibda nirreġistra - tajjeb?

Karatteristiċi personali u l-profil tad-dijabete u tat-tipjip tal-parteċipanti

1. Tista' jekk jogħġbok tgħidli kemm għandek żmien?
2. Liema tip tad-dijabete għandek?
3. Kemm attendejt sessjonijiet ta' appoġġ għall-waqfien mit-tipjip? Lestejt l-intervent, jew waqaft tattendi? Jekk waqaft tattendi tista' jekk jogħġbok tgħidli għaliex?
4. Użajt is-sostituzzjoni terapewtika tan-nikotina pprovduta meta ppruvajt tieqaf tpejjep? Jekk le tista' jekk jogħġbok tgħidli għaliex?
5. Waqaft mit-tipjip f'xi mument matul l-istudju? Jekk bħalissa qiegħed tpejjep, xi tpejjep tabakk u kemm tpejjep?

Rispons ġenerali

Fl-ewwel parti tas-sessjoni, se nkun qed nitolbok ir-rispons ġenerali tiegħek dwar l-intervent tal-waqfien mit-tipjip.

6. Kollox ma' kollox, x'taħseb dwar l-intervent tal-waqfien mit-tipjip?

Mistoqsijiet addizzjonali: X'għoġbok minn dan l-intervent? X'għoġbok l-inqas? X'taħseb dwar l-utilità ta' dan l-intervent għall-waqfien mit-tipjip? Ġejt offrut xi servizzi/sessjonijiet ta' appoġġ addizzjonali, bħal appoġġ psikoloġiku biex tittratta l-ansjetà u/jew id-dipressjoni, jew sessjoni ta' konsultazzjoni dwar id-dijabete għat-titjib tal-ġestjoni tad-dijabete? Jekk iva, x'taħseb dwar is-servizzi ta' appoġġ offruti?

7. X'taħseb dwar il-metodu kif ġie pprovdut?
   Mistoqsija addizzjonali: Kemm kien relevanti għalik?
8. X'taħseb dwar it-tul ta' żmien ġenerali tal-intervent tal-waqfien mit-tipjip?
   Mistoqsija addizzjonali: X'taħseb dwar it-tul ta' kull kuntatt individwali u l-frekwenza tal-kuntatti?
9. X'għenek tibqa' involut f'dan l-intervent tal-waqfien mit-tipjip?
   Mistoqsija addizzjonali: X'għenek tibqa' attiv u tipparteċipa f'dan l-intervent għall-waqfien mit-tipjip?
10. Liema ostakli esperjenzajt meta pparteċipajt f'dan l-intervent għall-waqfien mit-tipjip?
    Mistoqsija addizzjonali: X'diffikultajiet sibt biex tipparteċipa bis-sħiħ f'dan l-intervent ta' waqfien mit-tipjip? X'nistgħu nagħmlu biex ngħinuk tibqa nvolut?
11. Tirrakkomanda dan l-intervent għall-waqfien mit-tipjip lil xi ħadd ieħor?
    Mistoqsija addizzjonali: Għaliex tirrakkomanda jew ma tirrakkomandax dan l-intervent?

Attentat għal waqfien mit-tipjip

Fit-tieni parti tas-sessjoni, se nkun qed nitolbok dwar l-attentat tiegħek biex tieqaf.

12. X'għenek tipprova tieqaf?
    Mistoqsijiet addizzjonali: Liema informazzjoni sibt utli? Liema fatturi motivazzjonali wassluk biex tipprova tieqaf tpejjep? X'għenek tikkunsidra pjan biex tieqaf? X'għenek tidentifika sitwazzjonijiet li jżidu r-riskju tat-tipjip? X'għenek tidentifika fatturi biex jgħinuk tirreżisti l-leblieba biex tpejjep? Liema abbiltajiet sibt utli biex tipprova tieqaf? Jekk waqaft, x'għamilt biex għelibt il-leblieba biex tpejjep? Użajt in-Nicotine Gum/Patch/Spray/Inhalator jew Varenicline biex tieqaf tpejjep? Jekk iva, kif sibtu? Tkun lest li tixtri s-sostituzzjoni terapewtika tan-nikotina biex tieqaf tpejjep?
13. Jekk waqaft, kif irnexxielek?

Mistoqsijiet addizzjonali: Liema kien l-aktar metodu effettiv biex tieqaf tpejjep? Kif żidt il-kunfidenza tiegħek biex tieqaf?

Kwalunkwe kwistjoni oħra

14. Hemm xi ħaġa oħra li ma indirizzajniex li kienet tgħin biex tieqaf tpejjep?
    Mistoqsija addizzjonali: Kien hemm xi aspettattivi li ma ntlaħqux?

Appendix 8.9: Interview guide (for nurses – feasibility study)

Introduction

Thank you for sharing some of your time with me and for consenting to be interviewed. So, I will be recording this interview with your permission. First, I have a few questions about your personal and professional characteristics. Then I will be asking you for your overall feedback on the smoking cessation intervention. After that I will be asking you about your perceived challenges and facilitators to implementing this smoking cessation intervention in practice. The interview usually takes about 30-40 minutes.

At any time, please let me know if you need me to clarify any of the questions. Do you have any questions before we start? Are we okay to start?

So, I will start recording – is that okay?

Questions

Personal and professional characteristics

1. Can you please tell me your age?
2. How long have you been practicing as a nurse?
3. How long have you been practicing as a diabetes practice nurse?

Overall feedback

In the first part of the session, I will be asking you for your overall feedback on the recruitment process and the smoking cessation intervention.

4. What do you think about the recruitment method of this study?
   Probes: How was it? Did you encounter any difficulties in screening patients for tobacco use and inviting smokers to participate to the study?
5. Overall, what do you think of the smoking cessation intervention?

Probes: What did you like about this intervention? What did you like least? What do you think about the usefulness of this smoking cessation intervention?

6. What do you think about the delivery method?
   Probes: How relevant was this to you?
7. What do you think about the overall duration of the smoking cessation intervention?
   Probes: What do you think of the duration of each individual contact and the frequency of contacts provided?
8. What barriers did you experience in delivering this smoking cessation intervention?
   Probe: What difficulties did you encounter in providing this smoking cessation intervention?
9. What facilitated the delivery of the smoking cessation intervention?
   Probe: What helped you to deliver the smoking cessation intervention as intended?

Challenges and facilitators to implementation

In the second part of the session, I will be asking you about your perceived challenges and facilitators to implementing this smoking cessation intervention in practice.

10. What barriers would you anticipate if you had to implement this intervention in practice?
    Probe: What are the challenges in implementing this smoking cessation intervention in practice?
11. What could facilitate the implementation of this smoking cessation intervention in practice?
    Probe: What would make it easier to implement this intervention in practice?

Any other issues

12. Is there anything else that we have not addressed that would have helped your patients in quitting smoking?
    Probe: Were there any expectations which were not met?

Appendix 8.10: Treatment fidelity checklist (feasibility study)

Session one – pre-quit session

Treatment action/component	Occurrence (✓)
Ask: Asked about/Confirmed the number of cigarettes/tobacco products smoked every day.	
Advise: Informed the participant on the effects of smoking on diabetes (as outlined in the intervention guideline).	
Advise: Gave an overview of the story of Bill to the participant (as outlined in the intervention protocol), showing him/her the three video clips.	
Advise: Allowed some time for reflection or brief discussion, acknowledging any feelings or comments the participant may state.	
Advise: Advised the participant to quit smoking in a clear, strong and personalised manner (as outlined in the intervention protocol).	
Assess: Assessed readiness in setting a quit attempt in the next two weeks, identifying the possible need of using the 5Rs algorithm (as outlined in the intervention protocol).	
5Rs: Helped the participant identify how quitting smoking would be relevant to him/her.	
5Rs: Encouraged the participant to identify the potential negative consequences (risks) that are relevant to him/her if he/she continues to smoke, discussing further if required.	
5Rs: Encouraged the patient to identify potential benefits of stopping smoking (rewards) which are relevant to him/her, discussing further if required.	
5Rs: Encouraged the participant to identify any barriers or impediments to quitting smoking (roadblocks), discussing/providing realistic solutions.	
5Rs: Reassessed readiness in setting a quit attempt in the next two weeks (repetition), encouraging the participant to give it a try.	
Assist: Helped the participant set a Target Quit Date (TQD) within the next two weeks.	
Assist: Told the participant to inform his family, friends, and co-workers about his/her quitting attempt, and to ask for support.	
Assist: Encouraged the participant to talk about the quitting process, anticipating the challenges or barriers to the upcoming quit attempt, (as outlined in the intervention protocol)	
Assist: Helped the participant generate problem-solving strategies to tackle the identified barriers and challenges to quitting (as outlined in the intervention protocol)	
Assist: Asked the participant to remove any tobacco products from the patient's environment (particularly closer to the quit date) and make the home smoke free.	
Assist: Recommended (explaining use and benefits) and provided a supply of NRT (patch and/or spray) for use until the next session.	

Assist: Encouraged the participant further in the quit attempt, by referring to/identifying what would be relevant for him/her if he quit smoking.	
Assist: Advised monitoring of blood glucose.	
Assist: Linked the participant to psychological support services if experiencing anxiety or depression.	
Arrange: Provided the participant with a follow-up appointment during the first week (or two weeks maximum) from their TQD.	
Total	/16 or /21
Treatment components added that were not specified by the protocol	

Session two – for those who did not quit smoking

Treatment action/component	**Occurrence (✓)**
Asked about tobacco use (no. of cigarettes/tobacco products smoked/day).	
Assessed the use of NRT and any problems encountered (including over/under-dosing), providing recommendations.	
Reviewed experienced barriers and challenges (roadblocks).	
Encouraged a recommitment to quit smoking (referring to what is relevant to the participant – risks and rewards).	
Encouraged the participant to give it a try even if not 100% confident.	
Assist: Helped the participant set a TQD within the next two weeks.	
Assist: Told the participant to inform his family, friends, and co-workers about his/her quitting attempt, and to ask for support.	
Assist: Encouraged the participant to talk about the quitting process, anticipating the challenges or barriers to the upcoming quit attempt, (as outlined in the intervention protocol)	
Assist: Helped the participant generate problem-solving strategies to tackle the identified barriers and challenges to quitting (as outlined in the intervention protocol)	
Assist: Asked the participant to remove any tobacco products from the patient's environment (particularly closer to the quit date) and make the home smoke free.	
Assist: Recommended (explaining use and benefits) and provided a supply of NRT (patch and/or spray) for use until the next session.	
Assist: Encouraged the participant further in the quit attempt, by referring to/identifying what would be relevant for him/her if he quit smoking.	
Assist: Advised monitoring of blood glucose.	
Assist: Linked the participant to psychological support services if experiencing anxiety or depression.	
Arrange: Provided the participant with a follow-up appointment during the first week (or two weeks maximum) from their TQD.	
Total	/15
Treatment components added that were not specified by the protocol	

Session two – for those who quit smoking (or session three, if reporting abstinence the first time)

Treatment action/component	**Occurrence (✓)**
Asked about tobacco use (no. of cigarettes/tobacco products smoked/day).	
Congratulated participant if he/she stopped smoking.	
Encouraged participant to remain abstinent (referring to what is relevant to the participant – risks and rewards)	
Assessed the use of NRT and any problems encountered (including over/under-dosing), providing recommendations.	
Reviewed experienced barriers and challenges (roadblocks) towards remaining abstinent from smoking.	
Discussed anticipated challenges.	
Reinforced strategies outlined in the quit plan – reminding the participant on the usefulness of social support.	
Linked the participant to psychological support services if experiencing anxiety or depression.	
Provided remaining assigned supply of NRT for use until the final session, advising all participants to reduce the use of the spray during these weeks.	
Advised monitoring of blood glucose and offered a diabetic consultation (and subsequent specialist/s referrals, if required) if the participant experienced poor glycaemic control, or is concerned about diabetes management following a change in diet or weight gain on quitting smoking.	
Provided the participant with a follow-up appointment within five weeks from their TQD.	
Total	/11
Treatment components added that were not specified by the protocol	

Session three – for those who did not succeed to quit smoking

Treatment action/component	**Occurrence (✓)**
Asked about tobacco use (no. of cigarettes/tobacco products smoked/day).	
Assessed the use of NRT and any problems encountered (including over/under-dosing), providing recommendations.	
Reviewed experienced barriers and challenges (roadblocks).	
Encouraged a recommitment to quit smoking (referring to what is relevant to the participant – risks and rewards).	
Discuss anticipated challenges.	
Reinforced strategies outlined in the quit plan – reminding the participant on the usefulness of social support.	
Linked the participant to psychological support services if experiencing anxiety or depression.	
Provided remaining assigned supply of NRT for use until the final session, advising all participants to reduce the use of the spray during these weeks.	
Advised monitoring of blood glucose and offered a diabetic consultation (and subsequent specialist/s referrals, if required) if the participant experienced poor glycaemic control, or is concerned about diabetes management following a change in diet or weight gain on quitting smoking.	
Provided the participant with a follow-up appointment within five weeks from their TQD (that agreed on in session two).	
Total	/10
Treatment components added that were not specified by the protocol	

Final follow-up session

Treatment action/component	**Occurrence (✓)**
Asked about tobacco use (no. of cigarettes/tobacco products smoked/day).	
Congratulated participant if he/she stopped smoking/remained abstinent from smoking or praised any other achievements (e.g. reduction in number of cigarettes smoked per day)	
Reviewed experienced barriers and challenges (roadblocks) towards remaining abstinent from smoking/quitting.	
Assessed the use of NRT and any problems encountered (including over/under-dosing), advising participants to ideally reduce use if still on NRT (and abstinent from smoking).	
Encouraged participant to attempt quitting again if he/she relapsed/still smoking or to remain abstinent (referring to what is relevant to the participant – risks and rewards)	
Discussed anticipated challenges.	
Reinforced strategies outlined in the quit plan – reminding the participant on the usefulness of social support.	
Linked the participant to psychological support services if experiencing anxiety or depression.	
Advised monitoring of blood glucose and offered a diabetic consultation (and subsequent specialist/s referrals, if required) if the participant experienced poor glycaemic control or is concerned about diabetes management following a change in diet or weight gain on quitting/attempting to quit smoking.	
Ended the intervention on a positive manner, encouraging the participant to seek tobacco cessation services if required.	
Total	/10
Treatment components added that were not specified by the protocol	

Appendix 8.11: Feasibility study information letter (in English)

Participants` Information Sheet

Dear Participant,

My name is Joseph Grech and I am currently reading for a Doctor of Philosophy (Ph.D.) in Nursing at the University of Malta. As part of my Ph.D. project, I am conducting a research study entitled, **"Development and feasibility testing of a multi-component smoking cessation intervention for smokers living with diabetes mellitus: a randomised feasibility study"**. This study aims to evaluate the feasibility and acceptability of a multi-component smoking cessation intervention among individuals with diabetes. While this study will help you to evaluate your smoking habits and assist you in quitting smoking, your feedback will help me ensure the applicability of this smoking cessation intervention for use amongst individuals with diabetes. You will only be asked to share data that is necessary for this research. All data collected from this research shall be used solely for this study.

You are being invited to participate in a randomized feasibility study lasting twelve weeks, where you will be allocated at random either to the multi-component smoking cessation intervention and the provision of nicotine replacement therapy – the nicotine patch and/or spray for daily use for up to six weeks, or to standard care (referral to the Health Promotion and Disease Prevention Directorate's one to one smoking cessation counselling sessions), both of which will help you to re-consider your smoking habits and support you to quit smoking, free of charge. The multi-component smoking cessation intervention will be provided by nurses at the Diabetes Education Unit at Mater Dei Hospital. Each session should not take longer than one hour. The Health Promotion and Disease Prevention Directorate's one to one smoking cessation counselling sessions are usually provided within the Primary Health Care Department's health centres. Each session should not take longer than half an hour. Before being allocated to the smoking cessation interventions or standard care you will be provided with a personal unique code, unknown to anyone else. You will have to refer to this code in filling in the study's baseline questionnaire (on your personal characteristics, your health status, your diabetes and smoking profiles, and your feelings in the past week), and the questionnaire at the end of the study period (on your smoking habit, about the support you have received during the study period, and your views and opinions of the provided intervention). Each questionnaire should not take you more than 20 minutes to fill in. You will also be asked to take a simple, easy, and non-invasive exhaled carbon monoxide test, to measure how much carbon monoxide is in your body at baseline. If you quit smoking, you will also be asked to take the carbon monoxide test again and to provide a urine sample which will be assessed for traces of nicotine to confirm smoking abstinence. Unless you have any

objections, the provision of the multi-component smoking cessation intervention will be audio recorded. This will help ensure the integrity of the intervention provided. Following this study, you may be invited to participate to a follow-up interview.

Participation in this study does not expose you to any risks. If you fail to quit smoking, the service of a smoking cessation advisor from the Health Promotion and Disease Prevention Directorate is available at no financial cost on your part, by calling the National Quitline 8007 3333. Participation in this study is completely voluntary and you are free to accept or refuse to take part without giving a reason. Refusing to participate will not have any impact or negative consequences on your care. While if assigned to the group where you are provided with nicotine replacement therapy you are encouraged to take this on quitting smoking, you are also free to refuse without giving a reason. In the very unlikely event of an adverse event, you are to inform the researcher who will ensure that you are seen by a doctor of your choice free of charge. You may also withdraw from the study at any time without giving a reason and this will not bear any negative repercussions on you or your care. Any data collected by the researcher from your end, unless this cannot be identified, i.e. anonymized data, will hence be erased. In the case of having been allocated to standard care, you may also want to inform the Health Promotion and Disease Prevention Directorate about your decision so that they can erase any personal data that they may have collected on their behalf. All personal data collected by the researcher will only be accessed by the researcher. The audio-recordings (of the provision of the multi-component smoking cessation intervention) will be provided to the researcher on a password protected encrypted USB and stored on the researcher`s personal computer that is also password protected and in an encrypted format. A random selection of these audio-recordings will be listened to and assessed for treatment integrity by the researcher. I can assure you that confidentiality will be maintained throughout the study and that your identity and personal information will not be revealed in the thesis and any publications, reports, and presentations arising from this research. Any personal data in hard-copy form, such as the consent forms will be placed in a locked cupboard.

A copy of the information sheet and consent form will be provided for future reference. As a participant, you have the right, under the General Data Protection Regulation (GDPR) and national legislation that implements and further specifies the relevant provisions of said regulation, to access, rectify, and where applicable ask for the data concerning you to be erased. Anonymous results from this research study will be published in my Ph.D. thesis and may be published in academic journals or reported at conferences or to health service organisations. Some of the things you may write in the questionnaire may be used as direct quotes in publications or conferences, but your confidentiality and anonymity will be maintained, and it will not be possible to identify you. A summary of the results of this research study will be offered to all participants who show interest. Once this research study is completed, the audio-recordings will be erased. The consent forms will be destroyed within two years from the completion of my Ph.D. project.

This study has been approved by the Research Ethics Committee of the Faculty of Health Sciences at the University of Malta.

Thank you for your time and consideration. Should you have any questions or concerns do not hesitate to contact me on **9*** ***4** or by e-mail joseph.grech.02@um.edu.mt or my supervisor **Prof. Roberta Sammut** on **2340 1831** or roberta.sammut@um.edu.mt or my co-supervisor **Prof. Ian James Norman** on **+44 (0)207 848 3020** or ian.j.norman@kcl.ac.uk.

Yours Sincerely,

Mr. Joseph Grech	**Prof. Roberta Sammut**	**Prof. Ian James Norman**
Researcher	Research Supervisor	Research Co-supervisor
Tel: 9* ***4**	**Tel. 2340 1831**	**Tel. +44 (0)207 848 3020**
joseph.grech.02@um.edu.mt	**roberta.sammut@um.edu.mt**	**ian.j.norman@kcl.ac.uk**

Appendix 8.12: Feasibility study information letter (in Maltese)

Formula ta' Informazzjoni għall-Parteċipanti

Għażiż/a Parteċipant/a,

Jiena Joseph Grech, u fil-mument preżenti qed insegwi Dottorat tal-Filosofija fl-istudju tal-Infermiera l-Università ta' Malta. Bħala parti mill-proġett tad-Dottorat, qiegħed immexxi studju ta' riċerka, li jismu, **"Żvilupp u ttestjar tal-fattibilità ta' intervent ta' waqfien mit-tipjip b'ħafna komponenti għal dawk li jpejpu u jgħixu bid-dijabete: studju randomizzat dwar il-fattibilità."** L-għan ta' dan l-istudju hu li jevalwa l-fattibilità u l-aċċettabilità ta' intervent għall-waqfien mit-tipjip b'ħafna komponenti fost individwi bid-dijabete. Filwaqt li dan l-istudju se jgħinek tevalwa d-drawwiet tat-tipjip tiegħek u jgħinek biex tieqaf tpejjep, ir-rispons tiegħek se jgħinni niżgura l-applikabilità ta' dan l-intervent għall-waqfien mit-tipjip għall-użu fost individwi bid-dijabete. Int se tintalab biss taqsam informazzjoni li hija meħtieġa għal din ir-riċerka. Kull informazzjoni miġbura se tintuża biss għall-għan ta' dan l-istudju.

Int qed tiġi mistieden biex tipparteċipa fi studju randomizzat dwar il-fattibilità li jdum tnax -il ġimgħa, fejn tkun allokat b'mod każwali jew għall-intervent għall-waqfien mit-tipjip b'ħafna komponenti u l-għoti tas-sostituzzjoni terapewtika tan-nikotina - il-*patch* u/jew l-*ispray* tan-nikotina għall-użu ta' kuljum sa sitt ġimgħat, jew għal kura standardizzata (referenza għal sessjonijiet ta' pariri ghal waqfien mit-tipjip għand id-Direttorat tal-Promozzjoni tas-Saħħa u Prevenzjoni tal-Mard), li t-tnejn se jgħinuk terġa' tikkunsidra d-drawwiet tat-tipjip tiegħek u se jappoġġjawk biex tieqaf tpejjep, mingħajr ħlas. L-intervent għall-waqfien mit-tipjip b'ħafna komponenti se jiġi pprovdut minn infermiera fit-Taqsima tal-Edukazzjoni tad-Dijabete fl-Isptar Mater Dei. Kull sessjoni m'għandhiex tieħu aktar minn siegħa. Is-sessjonijiet ta' pariri għal waqfien mit-tipjip għand id-Direttorat tal-Promozzjoni tas-Saħħa u Prevenzjoni tal-Mard ġeneralment jingħataw fi ħdan iċ-ċentri tas-saħħa tad-Dipartiment tal-Kura tas-Saħħa Primarja. Kull sessjoni m'għandhiex tieħu aktar minn nofs siegħa. Qabel ma tkun allokat għall-interventi għall-waqfien mit-tipjip jew għall-kura standardizzata, int se tingħata kodiċi personali uniku mhux magħruf għal ħaddieħor. Int trid tirreferi għal dan il-kodiċi meta timla l-kwestjonarju bażi tal-istudju (dwar il-karatteristiċi personali tiegħek, l-istat ta' saħħtek, l-profil tad-dijabete u tat-tipjip tiegħek, u s-sentimenti tiegħek fil-ġimgħa li għaddiet), u l-kwestjonarju fi tmiem l-istudju (dwar il-vizzju tat-tipjip tiegħek, dwar l-appoġġ addizzjonali li rċevejt matul il-perjodu ta' dan l-istudju, u l-fehmiet u l-opinjonijiet tiegħek dwar l-intervent pprovdut). M'għandekx tieħu iktar minn 20 minuta biex timla kull kwestjonarju. Barra minn hekk, int se tintalab tieħu t-test tan-nifs tal-monossidu tal-karbonju li hu sempliċi, faċli u mhux invażiv, biex jkejjel kemm hemm monossidu tal-karbonju f'ġismek, fil-bidu tal-intervent. Jekk tieqaf tpejjep, tintalab ukoll biex terġa' tieħu t-test tal-monossidu tal-karbonju u tipprovdi

kampjun tal-awrina li jiġi vvalutat għal traċċi tan-nikotina biex nikkonfermaw l-astinenza tat-tipjip. Sakemm m'għandek l-ebda oġġezzjoni, il-provvediment tal-intervent għall-waqfien mit-tipjip b'ħafna komponenti se jkun irrekordjat bl-awdjo. Dan jgħin biex tiġi żgurata l-integrità tal-intervent ipprovdut. Wara dan l-istudju tista' tkun mistieden biex tipparteċipa f'intervista li ssegwi fuq l-intervent.

Il-parteċipazzjoni tiegħek f'dan l-istudju ma tesponik għal ebda riskju. Jekk ma jirnexxilekx tieqaf mit-tipjip, is-servizz ta' konsulent dwar il-waqfien mit-tipjip mid-Direttorat għall-Promozzjoni tas-Saħħa u l-Prevenzjoni tal-Mard huwa disponibbli mingħajr spejjeż finanzjarji min-naħa tiegħek, billi ċċempel lin-*National Quitline* 8007 3333. Il-parteċipazzjoni tiegħek f'dan l-istudju hija għażla għal kollox volontarja u inti ħieles/ħielsa li taċċetta jew tirrifjuta li tieħu sehem mingħajr ma' tagħti ebda raġuni. Jekk tirrifjuta li tipparteċipa dan mhux ħa jkollu impatt jew konsegwenzi negattivi fuq il-kura tiegħek. Filwaqt li jekk tiġi assenjat għall-grupp fejn se tiġi pprovdut b-sostituzzjoni terapewtika tan-nikotina inti mħeġġeġ tieħu dan meta tieqaf tpejjep, int liberu wkoll li tirrifjuta mingħajr ma tagħti raġuni. Fil-każ improbabbli ħafna ta' avveniment avvers, inti għandek tinforma lir-riċerkatur li se jiżgura li tabib tal-għażla tiegħek jarak mingħajr ħlas. Tista' wkoll tirtira mill-istudju fi kwalunkwe ħin mingħajr ma tagħti raġuni u dan ma jkollu l-ebda riperkussjoni negattiva fuqek jew fuq il-kura tiegħek. Kwalunkwe *data* miġbura mir-riċerkatur minn tmiemek, sakemm din ma tistax tiġi identifikata, jiġifieri *data* anonimizzata, għalhekk titħassar. Fil-każ li tkun allokat għal kura standardizzata, jaf ikollok għalfejn tavża lid-Direttorat tal-Promozzjoni tas-Saħħa u l-Prevenzjoni tal-Mard bid-deċiżjoni tiegħek sabiex ikunu jistgħu jħassru kwalunkwe *data* personali li setgħu ġabru f'isimhom. Id-*data* personali kollha miġbura mir-riċerkatur se tkun aċċessata biss mir-riċerkatur. Ir-reġistrazzjoniet bl-awdjo (tal-provvediment tal-intervent għall-waqfien mit-tipjip b'ħafna komponenti) se jiġu pprovduti lir-riċerkatur permezz ta' USB protetta b'*password* u b'*data encryption* u jinħażnu fuq il-kompjuter personali tar-riċerkatur li huwa wkoll protett b'*password* u b' *data encryption*. Għażla każwali ta' dawn ir-reġistrazzjonijiet bl-awdjo se tkun mismugħa u evalwata għall-integrità tat-trattament mir-riċerkatur. Nassigurak li se tinżamm il-kunfidenzjalità matul l-istudju kollu u l-identità tiegħek flimkien mal-informazzjoni personali miġbura, mhumiex se jiġu żvelati mkien fit-teżi, fir-rapporti, fil-preżentazzjonijiet u fil-pubblikazzjonijiet li jistgħu jirriżultaw minnha. Kwalunkwe *data* personali f'forma stampata, bħall-formoli tal-kunsens jitqegħdu f'armarju msakkra.

Kopja tal-folja tal-informazzjoni u tal-formola ta' kunsens se jkunu pprovduti sabiex ikunu aċċessibbli fil-futur. Barra minn hekk, skont ir-Regolamenti Ġenerali dwar il-Protezzjoni tad-*Data* (GDPR) u l-leġiżlazzjoni nazzjonali li timplimenta u tispeċifika aktar il-provvedimenti relevanti tar-regolamenti msemmija, inti għandek id-dritt li taċċessa, tirretifika, u fejn japplika titlob sabiex titħassar id-*data* li tikkonċernak. Riżultati anonimi minn dan l-istudju ta' riċerka se jiġu ppubblikati fit-teżi tad-Dottorat tiegħi u jistgħu jiġu ppubblikati f'ġurnali akkademiċi jew irrappurtati f'konferenzi jew organizzazzjonijiet tas-servizzi tas-saħħa. Uħud mill-affarijiet li tista' tikteb fil-kwestjonarji jistgħu jintużaw bħala kwotazzjonijiet diretti f'pubblikazzjonijiet

jew konferenzi, iżda l-kunfidenzjalità u l-anonimità tiegħek se jinżammu, u mhux se jkun possibbli li tidentifikak. Sommarju tar-riżultati ta' dan l-istudju ta' riċerka se jkun offrut lill-parteċipanti kollha li juru interess. Ladarba jitlesta dan l-istudju tar-riċerka, ir-reġistrazzjoniet tal-awdjo se jitħasru. Il-formoli tal-kunsens jinqerdu fi żmien sentejn mit-tlestija tal-proġett tad-Dottorat.

Dan l-istudju ġie approvat mill-Kumitat għall-Etika fir-Riċerka fi ħdan il-Fakultà tax-Xjenzi tas-Saħħa fl-Università ta' Malta.

Grazzi ħafna tal-ħin u s-sehem tiegħek f'dan l-istudju. F'każ li jkollok xi mistoqsijiet jew tixtieq tiċċara xi ħaġa, tista' ċċempilli fuq **9*** ***4** jew tibgħatli imejl fuq joseph.grech.02@um.edu.mt. Tista' wkoll tikkuntattja lis-Superviżura **Prof. Roberta Sammut** fuq **2340 1831** jew billi tibgħat imejl fuq roberta.sammut@um.edu.mt jew lil-Ko-Superviżur **Prof. Ian James Norman** fuq **+44 (0)207 848 3020** jew b'imejl fuq ian.j.norman@kcl.ac.uk.

Dejjem tiegħek,

_____	_____	_____
Mr. Joseph Grech	**Prof. Roberta Sammut**	**Prof. Ian James Norman**
Isem ir-Riċerkatur	Isem is-Superviżura tar-riċerka	Isem il-Ko-Superviżur tar-riċerka
Tel: 9* ***4**	**Tel. 2340 1831**	**Tel. +44 (0)207 848 3020**
joseph.grech.02@um.edu.mt	**roberta.sammut@um.edu.mt**	**ian.j.norman@kcl.ac.uk**

Appendix 8.13: Feasibility study consent form (in English)

Participants` Consent Form

Development and feasibility testing of a multi-component smoking cessation intervention for smokers living with diabetes mellitus: a randomised feasibility study

I, the undersigned, give my consent to take part in the study conducted by Mr. Joseph Grech. The purpose of this document is to specify the terms of my participation in this research study.

1. I have been given written and verbal information about the purpose of the study and all questions have been answered.
2. I understand that I have been invited to participate in a randomized feasibility study lasting twelve weeks, which evaluates the feasibility and acceptability of a multi-component smoking cessation intervention among individuals with diabetes. I am aware that I will be allocated at random either to the multi-component smoking cessation intervention and the provision of nicotine replacement therapy – the nicotine patch and/or spray for daily use for up to six weeks, or to standard care (referral to the Health Promotion and Disease Prevention Directorate's one to one smoking cessation counselling sessions), all of which will help me to re-consider my smoking habits and support me to quit smoking, free of charge.
3. I understand that the multi-component smoking cessation intervention will be provided by nurses at the Diabetes Education Unit at Mater Dei Hospital. I also understand that each session should not take longer than one hour. I am aware that the Health Promotion and Disease Prevention Directorate's one to one smoking cessation counselling sessions are usually provided every fortnight within the Primary Health Care Department's health centres. I am also aware that each session should not take longer than half an hour.
4. I am also aware that I will be invited to fill in a questionnaire on my personal characteristics, my health status, my diabetes and smoking profiles, and my feelings in the past week on enrollment to the study, and another questionnaire on my smoking habit, about the support I have received during the study period, and my views and opinions of the provided intervention at the end of the study, as part of this research study. I understand that the questionnaires are anonymous; I will be aware of my personal identifier through the participant's code which I will refer to in filling in the questionnaires. I also understand that I should not take more than 20 minutes to fill in each questionnaire. I am aware that I will be invited to take a simple, easy, non-invasive exhaled carbon monoxide test at baseline. I am also aware that if I quit smoking, I will also be asked to take the carbon monoxide test and provide a urine sample which will be assessed for traces of nicotine to confirm smoking abstinence. I

am also aware that the provision of the multi-component smoking cessation intervention will be audio recorded. I understand that following this study I may be invited to participate to a follow-up interview.

5. I also understand that the researcher is the only person who has access to any personal data collected from his end. I also understand that the audio-recordings (of the provision of the multi-component smoking cessation intervention) will be provided to the researcher on a password protected encrypted USB and will be stored on the researcher`s personal computer that is also password protected and in an encrypted format. I am aware that a random selection of these audio-recordings will be listened to and assessed for treatment integrity by the researcher. I understand that any personal data in hard-copy form, such as the consent forms will be placed in a locked cupboard.
6. I am aware that my identity and personal information will not be revealed in the researcher's Ph.D. thesis and any publications, reports, and presentations arising from this research.
7. I understand that participation in this study does not expose me to any risks. I am aware that if I fail to quit smoking, the service of a smoking cessation advisor from the Health Promotion and Disease Prevention Directorate is available at no financial cost on my part, by calling the National Quitline 8007 3333. I am also aware that if I am assigned to the group where I am provided with nicotine replacement therapy, I will be encouraged to take this on quitting smoking, however I am also free to refuse without giving a reason. I am also aware that in the very unlikely event of an adverse event, I am to inform the researcher who will ensure that I am seen by a doctor of my choice free of charge.
8. I understand that I am free to accept, refuse, or stop participation at any time without giving any reason. This will have no negative repercussions on myself or my care. Furthermore, I also understand that any data collected from my end, unless this cannot be identified, e.g. is anonymised, will be erased.
9. I am aware that in the case of having been allocated to standard care, I will have to inform the Health Promotion and Disease Prevention Directorate about my decision so that they can erase any personal data that they may have collected on their behalf.
10. I also understand that my contribution will serve Mr. Joseph Grech to ensure the applicability of this smoking cessation intervention for use amongst individuals with diabetes.
11. I am aware that under the General Data Protection Regulation (GDPR) and national legislation that implements and further specifies the relevant provisions of said regulation, I have the right to access, rectify, and where applicable ask for the data concerning me to be erased.
12. I am also aware that anonymous results from this research study will be published in the researcher's Ph.D. thesis and may be published in academic journals or reported at conferences or to health service organisations.

13. I understand that some of the things I may write in the questionnaires may be used as direct quotes in publications or conferences, but my confidentiality and anonymity will be maintained, and it will not be possible to identify me.
14. I am aware that a summary of the results of this research study will be offered if I show interest (see below).
15. I understand that once the study is completed, the audio-recordings will be erased. I am aware that any personal details, i.e. the consent forms, will be destroyed within two years from completion of the Ph.D. project.
16. I am also aware that I will be provided with a copy of the information letter and consent form for future reference.
17. I have read and understood the points and statements of this form. I have had all the questions answered to my satisfaction, and I agree to participate in this study.

Participant: _____

Signature: _____

Date: _____

Mr. Joseph Grech	**Prof. Roberta Sammut**	**Prof. Ian James Norman**
Researcher	Research Supervisor	Research Co-supervisor
Tel: 9* ***4**	**Tel. 2340 1831**	**Tel. +44 (0)207 848 3020**
joseph.grech.02@um.edu.mt	**roberta.sammut@um.edu.mt**	**ian.j.norman@kcl.ac.uk**

Please note:

Please leave your mobile phone number so that we can contact you with the date, time, and place of your first smoking cessation session. At the end of the intervention, you may also be invited to participate in a follow-up interview:

_____

If you agree to be contacted to be provided with a summary of the results of this research study, please tick this box ☐

Treatment allocation (for office use only) ☐

Appendix 8.14: Feasibility study consent form (in Maltese)

Formola ta' Kunsens tal-Parteċipanti

Żvilupp u ttestjar tal-fattibilità ta' intervent ta' waqfien mit-tipjip b'ħafna komponenti għal dawk li jpejpu u jgħixu bid-dijabete: studju randomizzat dwar il-fattibilità

Jien, hawn taħt iffirmat, nagħti l-kunsens tiegħi biex nieħu sehem fl-istudju mmexxi mis-Sur Joseph Grech. L-għan ta' dan id-dokument hu li jiġu sspeċifikati t-termini tal-parteċipazzjoni tiegħi f'dan l-istudju ta' riċerka.

1. Jien ingħatajt informazzjoni miktuba u verbali dwar l-għan tal-istudju u l-mistoqsijiet kollha twieġbu.
2. Nifhem li ġejt mistieden biex nipparteċipa fi studju ta' fattibilità randomizzat li jdum tnax-il ġimgħa, li jevalwa l-fattibilità u l-aċċettabilità ta' intervent ta' waqfien mit-tipjip b'ħafna komponenti fost individwi bid-dijabete. Jiena konxju li se nkun allokat b'mod każwali jew għall-intervent għall-waqfien mit-tipjip b'ħafna komponenti u l-għoti tas-sostituzzjoni terapewtika tan-nikotina - il-*patch* u/jew l-*ispray* tan-nikotina għall-użu ta' kuljum sa sitt ġimgħat, jew għal kura standardizzata (referenza għal sessjonijiet ta' pariri għal waqfien mit-tijpip għand id-Direttorat tal-Promozzjoni tas-Saħħa u Prevenzjoni tal-Mard), li lkoll se jgħinuni nikkunsidra d-drawwiet tiegħi tat-tipjip u jappoġġawni biex nieqaf mit-tipjip, mingħajr ħlas.
3. Nifhem li l-intervent għall-waqfien mit-tipjip b'ħafna komponenti se jiġi pprovdut minn infermiera fit-Taqsima tal-Edukazzjoni tad-Dijabete fl-Isptar Mater Dei. Nifhem ukoll li kull sessjoni m'għandhiex tieħu aktar minn siegħa. Jiena konxju li s-sessjonijiet ta' pariri għal waqfien mit-tipjip għand id-Direttorat tal-Promozzjoni tas-Saħħa u Prevenzjoni tal-Mard huma ġeneralment ipprovduti kull ħmistax fiċ-ċentri tas-saħħa tad-Dipartiment tal-Kura tas-Saħħa Primarja. Jiena konxju wkoll li kull sessjoni m'għandhiex tieħu aktar minn nofs siegħa.
4. Jiena konxju wkoll li se niġi mistieden biex nimla kwestjonarju dwar il-karatteristiċi personali tiegħi, l-istat ta' saħħti, l-profil tad-dijabete u tat-tipjip tiegħi, u s-sentimenti tiegħi fil-ġimgħa li għaddiet meta nirreġistra għall-istudju, u kwestjonarju ieħor dwar il-vizzju tat-tipjip tiegħi, dwar l-appoġġ li rċevejt matul il-perjodu ta' dan l-istudju, u dwar l-fehmiet u l-opinjonijiet tiegħi tal-intervent ipprovdut fi tmiem l-istudju, bħala parti minn dan l-istudju ta' riċerka. Nifhem li l-kwestjonarji huma anonimi; jien se inkun naf l-identifikatur personali tiegħi permezz ta' kodiċi tal-parteċipant li se nirreferi għalih biex nimla l-kwestjonarji. Nifhem ukoll li m'għandix nieħu aktar minn 20 minuta biex nimla kull kwestjonarju. Jiena konxju li se nkun mistieden biex nagħmel test tan-nifs tal-monossidu tal-karbonju li hu test sempliċi, faċli u mhux invażiv meta nirreġistra għall-istudju. Jiena konxju wkoll li jekk nieqaf mit-tipjip, nintalab ukoll biex

nerġa' nieħu t-test tal-monossidu tal-karbonju u nipprovdi kampjun tal-awrina li jiġi vvalutat għal traċċi ta' nikotina biex tikkonfermaw l-astinenza tat-tipjip. Jiena konxju wkoll li l-provvediment tal-intervent għall-waqfien mit-tipjip b'ħafna komponenti se jkun irrekordjat bl-awdjo. Nifhem li wara dan l-istudju nista' nkun mistieden biex nipparteċipa f'intervista li ssegwi fuq l-intervent.

5. Nifhem ukoll li r-riċerkatur huwa l-unika persuna li għandha aċċess għal kwalunkwe *data* personali miġbura minn tmiemu. Nifhem ukoll li r-reġistrazzjoniet bl-awdjo (tal-provvediment tal-intervent għall-waqfien mit-tipjip b'ħafna komponenti) se jiġu pprovduti lir-riċerkatur permezz ta' USB protetta b'*password* u b'*data encryption* u jinħażnu fuq il-kompjuter personali tar-riċerkatur li huwa wkoll protett b'*password* u b' *data encryption*. Jiena konxju li l-għażla każwali ta' dawn ir-reġistrazzjonijiet tal-awdjo se tkun mismugħa u evalwata għall-integrità tat-trattament mir-riċerkatur. Nifhem li kwalunkwe *data* personali f'forma stampata, bħall-formoli tal-kunsens jitqegħdu f'armarju msakkar.
6. Jien konxju wkoll li l-identità tiegħi u l-informazzjoni personali mhumiex se jinkixfu fit-teżi tad-Dottorat tar-riċerkatur, u fir-rapporti, fil-preżentazzjonijiet u fil-pubblikazzjonijiet li jistgħu jirriżultaw minn din ir-riċerka.
7. Nifhem li l-parteċipazzjoni tiegħi f'dan l-istudju ma tesponini għal ebda riskju. Jiena konxju li jekk ma jirnexxilix nieqaf mit-tipjip, is-servizz ta' konsulent dwar il-waqfien mit-tipjip mid-Direttorat għall-Promozzjoni tas-Saħħa u l-Prevenzjoni tal-Mard huwa disponibbli mingħajr spejjeż finanzjarji min-naħa tiegħi, billi ċċempel lin-*National Quitline* 8007 3333. Jiena konxju wkoll li jekk inkun assenjat għall-grupp fejn se nkun ipprovdut b-sostituzzjoni terapewtika tan-nikotina, se nkun imħeġġeġ nieħu dan meta nieqaf tpejjep, madankollu jien liberu wkoll li nirrifjuta mingħajr ma nagħti raġuni. Jiena konxju wkoll li fil-każ improbabbli ħafna ta' avveniment avvers, jien għandi ninforma lir-riċerkatur li se jiżgura li tabib tal-għażla tiegħi jarani mingħajr ħlas.
8. Nifhem li jien liberu/a li naċċetta, nirrifjuta jew inwaqqaf il-parteċipazzjoni tiegħi f'kull ħin bla ma nagħti raġuni. Dan mhu se jkollu ebda riperkussjonijiet negattivi fuqi nnifsi jew fuq il-kura tiegħi. Barra minn hekk, nifhem ukoll li kwalunkwe *data* miġbura mingħandi, sakemm din ma tistax tiġi identifikata, eż. hija anonimizzata, titħassar.
9. Jiena konxju li fil-każ li ġejt allokat għal kura standardizzata, ser ikolli ninforma lid-Direttorat għall-Promozzjoni tas-Saħħa u l-Prevenzjoni tal-Mard dwar id-deċiżjoni tiegħi sabiex ikunu jistgħu jħassru kwalunkwe *data* personali li setgħu ġabru min-naħħa tagħhom.
10. Nifhem ukoll li l-kontribuzzjoni tiegħi se sservi lis-Sur Joseph Grech biex jiżgura s-siwi ta' dan l-intervent għall-waqfien mit-tipjip għall-użu fost individwi bid-dijabete.
11. Jien konxju li skont ir-Regolamenti Ġenerali dwar il-Protezzjoni tad-*Data* (GDPR) u l-leġiżlazzjoni nazzjonali li timplimenta u tispeċifika aktar il-provedimenti relevanti tar-regolamenti msemmija, jiena għandi d-dritt li naċċessa, nirretifika, u fejn japplika, nitlob sabiex titħassar id-*data* li tikkonċernani.
12. Jien konxju wkoll li r-riżultati anonimi minn dan l-istudju ta' riċerka se jiġu ppubblikati fit-teżi tad-Dottorat tar-riċerkatur u jistgħu jiġu ppubblikati f'ġurnali akkademiċi jew irrappurtati f'konferenzi jew lil organizzazzjonijiet tas-servizzi tas-saħħa.

13. Nifhem li wħud mill-affarijiet li ngħid jistgħu jintużaw bħala kwotazzjonijiet diretti f'pubblikazzjonijiet jew konferenzi, iżda l-kunfidenzjalità u l-anonimità tiegħi se jinżammu, u mhux se jkun possibbli li niġi identifikat/a.
14. Jiena konxju li se nkun offrut sommarju tar-riżultati ta' dan l-istudju ta' riċerka jekk nuri interess (ara hawn taħt).
15. Nifhem li ladarba jitlesta dan l-istudju tar-riċerka, ir-reġistrazzjoniet tal-awdjo se jitħasru. Jiena konxju li kwalunkwe dettalji personali, jiġifieri l-formoli tal-kunsens, se jinqerdu fi żmien sentejn mit-tlestija tal-proġett tad-Dottorat.
16. Jien naf ukoll li se ningħata kopja tal-folja ta' informazzjoni u tal-formola ta' kunsens sabiex inkun nista' naċċessahom fil-futur.
17. Jien qrajt u fhimt il-punti u d-dikjarazzjonijiet f'din il-formola. Inħossni sodisfatt/a bit-tweġibiet li ngħatajt għall-mistoqsijiet li kelli, u qed naċċetta minn jeddi li nipparteċipa f'dan l-istudju.

Parteċipant/a: _____

Firma: _____

Data: _____

_____	_____	_____
Mr. Joseph Grech	**Prof. Roberta Sammut**	**Prof. Ian James Norman**
Isem ir-riċerkatur	Isem is-superviżura	Isem il-ko-superviżur
Tel: 9* ***4**	**Tel. 2340 1831**	**Tel. +44 (0)207 848 3020**
joseph.grech.02@um.edu.mt	**roberta.sammut@um.edu.mt**	**ian.j.norman@kcl.ac.uk**

Jekk jogħġbok innota:

Jekk jogħġbok ħalli n-numru tal-mowbajl tiegħek sabiex inkunu nistgħu nikkuntattjawk bil-ġurnata, l-ħin u l-post ta' l-ewwel sessjoni tiegħek għall-waqfien mit-tipjip. Fl-aħħar tal-intervent, tista' wkoll tkun mistieden biex tipparteċipa f'intervista ta' segwitu:

_____

Jekk jogħġbok immarka din il-kaxxa jekk taqbel li tiġi kkuntattjat biex tingħata sommarju tar-riżultati ta' dan l-istudju ta' riċerka: ☐

Allokazzjoni tat-trattament (għall-użu tal-uffiċċju biss) ☐

Appendix 8.15: Feasibility study follow-up interview information letter (in English)

Participants` Information Sheet

Dear Participant,

My name is Joseph Grech and I am currently reading for a Doctor of Philosophy (Ph.D.) in Nursing at the University of Malta. As part of my Ph.D. project, I am conducting a follow-up interview on the research study entitled, **"Development and feasibility testing of a multi-component smoking cessation intervention for smokers living with diabetes mellitus: a randomised feasibility study"**, to which you participated. This study aims to explore the feasibility and acceptability of this smoking cessation intervention amongst individuals with diabetes. Your insight will help us ensure the applicability of the multi-component smoking cessation intervention for use amongst individuals with diabetes. You will only be asked to share data that is necessary for this research. All data collected from this research shall be used solely for this study.

You are being invited to participate in an interview exploring your views, preferences, barriers and suggestions on the smoking cessation intervention and on your quitting attempt experience. The interview should not take more than 40 minutes and will be held at one of the Faculty of Health Science's approved and identified training sites at a time and date most suitable for you. Unless you have any objections, the interview will be audio-recorded. You are not obliged to answer all the questions and may withdraw from the study at any time without giving a reason. Withdrawal from the study will not have any negative repercussions on you or your care. Furthermore, any data collected from your end, unless this cannot be identified, e.g. has been already anonymised, will be erased. I can assure you that confidentiality will be maintained throughout the study and that your identity and personal information will not be revealed in the thesis and any publications, reports, and presentations arising from this research. All data collected will be pseudonymised meaning that the transcript of the audio recording will be protected by a code system and that this data will be stored securely and separately from any personal data (audio-recording and consent forms). This data may only be accessed by the researcher. The academic supervisors and the examiners will typically have access to coded data only. There may be exceptional circumstances which allow the supervisors to have access to the audio-recording too, for verification purposes (if you would like to know who accessed your data, please contact me as per the details below). The audio-recording and transcript will be stored on the researcher`s personal computer that is password protected and in an encrypted format. The consent forms, will be placed in a locked cupboard.

Participation in this study does not expose you to any risks. If you are still interested in quitting smoking, the service of a smoking cessation advisor from the Health Promotion and Disease Prevention Directorate, is available at no financial cost on your part, by calling the National Quitline 8007 3333.

Participation in this study is completely voluntary and you are free to accept or refuse to take part without giving a reason. A copy of the information sheet and consent form will be provided for future reference. As a participant, you have the right, under the General Data Protection Regulation (GDPR) and national legislation that implements and further specifies the relevant provisions of said regulation, to access, rectify, and where applicable ask for the data concerning you to be erased. Once this research study is completed, the audio-recording will be erased and data will be retained only in anonymous form. Anonymous results from this research study will be published in my Ph.D. thesis and may be published in academic journals or reported at conferences or to health service organisations. Some of the things you say may be used as direct quotes in publications or conferences, but your confidentiality and anonymity will be maintained, and it will not be possible to identify you. A summary of the results of this research study will be offered to all participants who show interest. The consent forms will be destroyed within two years from the completion of my Ph.D. project.

This study has been approved by the Research Ethics Committee of the Faculty of Health Sciences at the University of Malta.

Thank you for your time and consideration. Should you have any questions or concerns do not hesitate to contact me on **9*** ***4** or by e-mail joseph.grech.02@um.edu.mt or my supervisor **Prof. Roberta Sammut** on **2340 1831** or roberta.sammut@um.edu.mt or my co-supervisor **Prof. Ian James Norman** on **+44 (0)207 848 3020** or ian.j.norman@kcl.ac.uk.

Yours Sincerely,

_____	_____	_____
Mr. Joseph Grech	**Prof. Roberta Sammut**	**Prof. Ian James Norman**
Researcher	Research Supervisor	Research Co-supervisor
Tel: 9* ***4**	**Tel. 2340 1831**	**Tel. +44 (0)207 848 3020**
joseph.grech.02@um.edu.mt	**roberta.sammut@um.edu.mt**	**ian.j.norman@kcl.ac.uk**

Appendix 8.16: Feasibility study follow-up interview information letter (in Maltese)

Formula ta' Informazzjoni għall-Parteċipanti

Għażiż/a Parteċipant/a,

Jiena Joseph Grech, u fil-mument preżenti qed insegwi Dottorat tal-Filosofija fl-istudju tal-Infermiera l-Università ta' Malta. Bħala parti mill-proġett tad-Dottorat, qed inwettaq intervista ta' segwitu fuq l-istudju tar-riċerka intitolat, **"Żvilupp u ttestjar tal-fattibilità ta' intervent ta' waqfien mit-tipjip b'ħafna komponenti għal dawk li jpejpu u jgħixu bid-dijabete: studju randomizzat dwar il-fattibilità"**, li pparteċipajt fih. L-għan ta' dan l-istudju hu li jesplora l-fattibilità u s-siwi ta' dan l-intervent ta' waqfien mit-tipjip fost individwi bid-dijabete. L-għarfien tiegħek jgħinna niżguraw l-applikabilità ta' l-intervent ta' waqfien mit-tipjip b'ħafna komponenti għall-użu fost individwi bid-dijabete. Int se tintalab biss taqsam informazzjoni li hija meħtieġa għal din ir-riċerka. Kull informazzjoni miġbura se tintuża biss għall-għan ta' dan l-istudju.

Int qed tiġi mistieden biex tipparteċipa f'intervista li tesplora l-opinjonijiet, il-preferenzi, l-ostakli u s-suġġerimenti tiegħek dwar l-intervent għall-waqfien mit-tipjip u dwar l-esperjenza tiegħek tat-tentattiv biex tieqaf. Din il-intervista mhux se tieħu iktar minn 40 minuta u se ssir f'wieħed mis-siti ta' taħriġ approvati u identifikati mill-Fakultà tax-Xjenza tas-Saħħa f'ġurnata u f'ħin l-aktar adattati għalik. Sakemm m'għandek l-ebda oġġezzjoni, ir-risposti tiegħek se jiġu rrekordjati bl-awdjo. M'intix obbligat/a li twieġeb il-mistoqsijiet kollha u tista' twaqqaf l-istudju fi xħin trid mingħajr ma tagħti l-ebda raġuni. L-irtirar mill-istudju mhux se jkollu riperkussjonijiet negattivi fuqek jew fuq il-kura tiegħek. Barra minn hekk, kwalunkwe *data* miġbura mingħandek, sakemm din ma tistax tiġi identifikata, eż. hija diġà anonimizzata, se tigi mħassra. Nassigurak li se tinżamm il-kunfidenzjalità matul l-istudju kollu u l-identità tiegħek flimkien mal-informazzjoni personali miġbura, mhumiex se jiġu żvelati mkien fit-teżi, fir-rapporti, fil-preżentazzjonijiet u fil-pubblikazzjonijiet li jistgħu jirriżultaw minnha. Kull tagħrif miġbur se jiġi psewdonomizzat, jiġifieri it-traskrizzjoni tar-reġistrazzjoni tal-awdjo se tkun protetta permezz ta' sistema ta' kodiċi u miżmuma separatament mill-informazzjoni personali (reġistrazzjoni tal-awdjo u formoli ta' kunsens). Din id-*data* tista' tkun aċċessata biss mir-riċerkatur. Is-Superviżuri akkademiċi u l-eżaminaturi se jkollhom biss aċċess għal *data* kkodifikata. Jista' jkun hemm ċirkostanzi eċċezzjonali li jippermettu lis-superviżuri akkademiċi jkollhom aċċess ukoll għar-reġistrazzjoni tal-awdjo, għal skop ta' verifikazzjoni (jekk tkun tixtieq tkun taf min aċċessa d-*data* tiegħek, jekk jogħġbok ikkuntattjani skont id-dettalji ta' hawn taħt). Ir-reġistrazzjoni tal-awdjo u d-*data* kollha se jinħażnu fuq il-kompjuter personali

tar-riċerkatur permezz ta' kodifikazzjoni tad-*data* (*data encryption*) u li hi protetta b'password. Il-formoli tal-kunsens jitqiegħdu f'armarju msakkar.

Il-parteċipazzjoni tiegħek f'dan l-istudju ma tesponik għal ebda riskju. Jekk inti interessat li tieqaf tpejjep, is-servizz ta' konsulent dwar il-waqfien mit-tipjip mid-Direttorat għall-Promozzjoni tas-Saħħa u l-Prevenzjoni tal-Mard, huwa disponibbli mingħajr spejjeż finanzjarji min-naħa tiegħek, billi ċċempel lin-*National Quitline* 8007 3333.

Il-parteċipazzjoni tiegħek f'dan l-istudju hija għażla għal kollox volontarja u inti ħieles/ħielsa li taċċetta jew tirrifjuta li tieħu sehem mingħajr ma' tagħti ebda raġuni. Kopja tal-folja tal-informazzjoni u tal-formola ta' kunsens se jkunu pprovduti sabiex ikunu aċċessibbli fil-futur. Barra minn hekk, skont ir-Regolamenti Ġenerali dwar il-Protezzjoni tad-*Data* (GDPR) u l-leġiżlazzjoni nazzjonali li timplimenta u tispeċifika aktar il-provvedimenti relevanti tar-regolamenti msemmija, inti għandek id-dritt li taċċessa, tirretifika, u fejn japplika titlob sabiex titħassar id-*data* li tikkonċernak. Ladarba jitlesta dan l-istudju tar-riċerka, ir-reġistrazzjoni tal-awdjo se titħassar u d-*data* tinżamm biss f'forma anonima. Riżultati anonimi minn dan l-istudju ta' riċerka se jiġu ppubblikati fit-teżi tad-Dottorat tiegħi u jistgħu jiġu ppubblikati f'ġurnali akkademiċi jew irrappurtati f'konferenzi jew organizzazzjonijiet tas-servizzi tas-saħħa. Uħud mill-affarijiet li tgħid jistgħu jintużaw bħala kwotazzjonijiet diretti f'pubblikazzjonijiet jew konferenzi, iżda l-kunfidenzjalità u l-anonimità tiegħek se jinżammu, u mhux se jkun possibbli li tidentifikak. Sommarju tar-riżultati ta' dan l-istudju ta' riċerka se jkun offrut lill-parteċipanti kollha li juru interess. Il-formoli tal-kunsens jinqerdu fi żmien sentejn mit-tlestija tal-proġett tad-Dottorat.

Dan l-istudju ġie approvat mill-Kumitat għall-Etika fir-Riċerka fi ħdan il-Fakultà tax-Xjenzi tas-Saħħa fl-Università ta' Malta.

Grazzi ħafna tal-ħin u s-sehem tiegħek f'dan l-istudju. F'każ li jkollok xi mistoqsijiet jew tixtieq tiċċara xi ħaġa, tista' ċċempilli fuq **9*** ***4** jew tibgħatli imejl fuq joseph.grech.02@um.edu.mt. Tista' wkoll tikkuntattja lis-Superviżura **Prof. Roberta Sammut** fuq **2340 1831** jew billi tibgħat imejl fuq roberta.sammut@um.edu.mt jew lil-Ko-Superviżur **Prof. Ian James Norman** fuq **+44 (0)207 848 3020** jew b'imejl fuq ian.j.norman@kcl.ac.uk.

Dejjem tiegħek,

Mr. Joseph Grech	**Prof. Roberta Sammut**	**Prof. Ian James Norman**
Isem ir-Riċerkatur	Isem is-Superviżura tar-riċerka	Isem il-Ko-Superviżur tar-riċerka
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Appendix 8.17: Feasibility study follow-up interview consent letter (in English)

Participants` Consent Form

Development and feasibility testing of a multi-component smoking cessation intervention for smokers living with diabetes mellitus: a randomised feasibility study (a follow-up interview)

I, the undersigned, give my consent to take part in the study conducted by Mr. Joseph Grech. The purpose of this document is to specify the terms of my participation in this research study.

1. I have been given written and verbal information about the purpose of the study and all questions have been answered.
2. I understand that I have been invited to participate in an interview, in which the researcher will ask questions to explore the feasibility and acceptability of this smoking cessation intervention amongst individuals with diabetes.
3. I am aware that the interview will not take longer than 40 minutes. I understand that the interview is to be conducted at one of the Faculty of Health Science's approved and identified training sites in a place and at a time that is convenient for me.
4. I am aware that the interview will be audio-recorded and transcribed (written down as it has been spoken).
5. I am also aware that the transcript will be coded, and that this data will be stored securely and separately from any personal data (audio-recording and consent forms).
6. I understand that the researcher is the only person who has access to this data. The academic supervisors and examiners will typically have access to coded data only. I am aware that there may be exceptional circumstances which allow the supervisors to have access to the audio-recording too, for verification purposes. I understand that if I would like to know who accessed my data, I can contact the researcher as per the details below.
7. I am also aware that the audio-recording and the transcript will be stored on the researcher`s personal computer that is password protected and in an encrypted format. The consent forms will be placed in a locked cupboard.
8. I am also aware that my identity and personal information will not be revealed in the researcher's Ph.D. thesis and any publications, reports, and presentations arising from this research.
9. I understand that I am free to accept, refuse, or stop participation at any time without giving any reason. This will have no negative repercussions on myself or my care. Furthermore, I also understand that any data collected from my end, unless this cannot be identified, e.g. is anonymised, will be erased.

10. I also understand that my contribution will serve Mr. Joseph Grech ensure the applicability of this smoking cessation intervention for use amongst individuals with diabetes.
11. I also understand that participating in this study does not expose me to any risks. I am aware that if I am still interested in quitting smoking, the service of a smoking cessation advisor from the Health Promotion and Disease Prevention Directorate is available at no financial cost on my part, by calling the National Quitline 8007 3333.
12. I am aware that under the General Data Protection Regulation (GDPR) and national legislation that implements and further specifies the relevant provisions of said regulation, I have the right to access, rectify, and where applicable ask for the data concerning me to be erased.
13. I understand that once the study is completed, the audio-recording will be erased, and data will only be retained in anonymous form. I am aware that anonymous results from this research study will be published in the researcher's Ph.D. thesis and may be published in academic journals or reported at conferences or to health service organisations.
14. I understand that some of the things I say may be used as direct quotes in publications or conferences, but my confidentiality and anonymity will be maintained, and it will not be possible to identify me.
15. I am aware that a summary of the results of this research study will be offered if I show interest (see below).
16. I am also aware that any personal details, i.e. the consent forms, will be destroyed within two years from completion of the Ph.D. project.
17. I am also aware that I will be provided with a copy of the information letter and consent form for future reference.
18. I have read and understood the points and statements of this form. I have had all the questions answered to my satisfaction, and I agree to participate in this study.

Participant: _____

Signature: _____

Date: _____

Mr. Joseph Grech	**Prof. Roberta Sammut**	**Prof. Ian James Norman**
Researcher	Research Supervisor	Research Co-supervisor
Tel: 9* ***4**	**Tel. 2340 1831**	**Tel. +44 (0)207 848 3020**
joseph.grech.02@um.edu.mt	**roberta.sammut@um.edu.mt**	**ian.j.norman@kcl.ac.uk**

Please note:

If you agree to be contacted to be provided with a summary of the results of this research study please provide your telephone/mobile number here:

_____

Appendix 8.18: Feasibility study follow-up interview consent letter (in Maltese)

Formola ta' Kunsens tal-Parteċipanti

Żvilupp u ttestjar tal-fattibilità ta' intervent ta' waqfien mit-tipjip b'ħafna komponenti għal dawk li jpejpu u jgħixu bid-dijabete: studju randomizzat dwar il-fattibilità (intervista ta' segwitu)

Jien, hawn taħt iffirmat, nagħti l-kunsens tiegħi biex nieħu sehem fl-istudju mmexxi mis-Sur Joseph Grech. L-għan ta' dan id-dokument hu li jiġu sspeċifikati t-termini tal-parteċipazzjoni tiegħi f'dan l-istudju ta' riċerka.

1. Jien ingħatajt informazzjoni miktuba u verbali dwar l-għan tal-istudju u l-mistoqsijiet kollha twieġbu.
2. Nifhem li ġejt mistieden biex nipparteċipa f'intervista, li fiha r-riċerkatur se jistaqsi mistoqsijiet biex jesplora l-fattibilità u s-siwi ta' dan l-intervent għall-waqfien mit-tipjip fost individwi bid-dijabete.
3. Naf li l-intervista mhux se tieħu aktar minn 40 minuta. Nifhem, li l-intervista se ssir f'wieħed mis-siti ta' taħriġ approvati u identifikati tal-Fakultà tax-Xjenza tas-Saħħa f'post u f'ħin li jkun konvenjenti għalija.
4. Jien konxju/a li r-risposti tiegħi se jkunu qed jiġu rrekordjati permezz ta' tagħmir awdjo u r-risposti se jinkitbu fuq formoli apposta.
5. Naf ukoll li t-traskrizzjoni tar-reġistrazzjoni tal-awdjo se tiġi kkodifikata, u li din id-*data* se tinħażen b'mod sigur u separat minn kwalunkwe *data* personali (reġistrazzjoni tal-awdjo u formoli ta' kunsens).
6. Nifhem li r-riċerkatur hu l-uniku persuna li se jkollu aċċess għal din l-informazzjoni, filwaqt li s-superviżuri akkademiċi u l-eżaminaturi se jkollhom aċċess għal *data* kkodifikata biss. Jiena konxju li jista' jkun hemm ċirkostanzi eċċezzjonali li jippermettu lis-superviżuri jkollhom aċċess għar-reġistrazzjoni tal-awdjo għal skop ta' verifika. Nifhem li jekk nixtieq inkun naf min aċċessa d-*data* tiegħi, nista' nikkuntattja lir-riċerkatur skont id-dettalji ta' hawn taħt.
7. Jien konxju wkoll li r-reġistrazzjoni tal-awdjo u t-traskrizzjoni se jinħażnu fuq il-kompjuter personali tar-riċerkatur permezz ta' kodifikazzjoni tad-*data* (*data encryption*) u li hi protetta b'password. Il-formoli tal-kunsens jitqiegħdu f'armarju msakkar.
8. Jien konxju wkoll li l-identità tiegħi u l-informazzjoni personali mhumiex se jinkixfu fit-teżi tad-Dottorat tar-riċerkatur, u fir-rapporti, fil-preżentazzjonijiet u fil-pubblikazzjonijiet li jistgħu jirriżultaw minn din ir-riċerka.
9. Nifhem li jien liberu/a li naċċetta, nirrifjuta jew inwaqqaf il-parteċipazzjoni tiegħi f'kull ħin bla ma nagħti raġuni. Dan mhu se jkollu ebda riperkussjonijiet negattivi fuqi nnifsi

jew fuq il-kura tiegħi. Barra minn hekk, nifhem ukoll li kwalunkwe *data* miġbura mingħandi, sakemm din ma tistax tiġi identifikata, eż. hija anonimizzata, titħassar.

10. Nifhem ukoll li l-kontribuzzjoni tiegħi se sservi lis-Sur Joseph Grech biex jiżgura s-siwi ta' dan l-intervent għall-waqfien mit-tipjip għall-użu fost individwi bid-dijabete.
11. Nifhem ukoll li l-parteċipazzjoni tiegħi f'dan l-istudju ma tesponini għall-ebda riskju. Jiena konxju li jekk jien interessat/a li nieqaf mit-tipjip, is-servizz ta' konsulent dwar il-waqfien mit-tipjip mid-Direttorat għall-Promozzjoni tas-Saħħa u l-Prevenzjoni tal-Mard huwa disponibbli mingħajr spejjeż finanzjarji min-naħa tiegħi, billi ċċempel lin-*National Quitline* 8007 3333.
12. Jien konxju li skont ir-Regolamenti Ġenerali dwar il-Protezzjoni tad-*Data* (GDPR) u l-leġiżlazzjoni nazzjonali li timplimenta u tispeċifika aktar il-provedimenti relevanti tar-regolamenti msemmija, jiena għandi d-dritt li naċċessa, nirretifika, u fejn japplika, nitlob sabiex titħassar id-*data* li tikkonċernani.
13. Nifhem li ladarba jitlesta l-istudju, r-reġistrazzjoni tal-awdjo u d-*data* tinżamm biss f'forma anonima. Jien konxju li r-riżultati anonimi minn dan l-istudju ta' riċerka se jiġu ppubblikati fit-teżi tad-Dottorat tar-riċerkatur u jistgħu jiġu ppubblikati f'ġurnali akkademiċi jew irrappurtati f'konferenzi jew lil organizzazzjonijiet tas-servizzi tas-saħħa.
14. Nifhem li wħud mill-affarijiet li ngħid jistgħu jintużaw bħala kwotazzjonijiet diretti f'pubblikazzjonijiet jew konferenzi, iżda l-kunfidenzjalità u l-anonimità tiegħi se jinżammu, u mhux se jkun possibbli li niġi identifikat/a.
15. Jiena konxju li se nkun offrut sommarju tar-riżultati ta' dan l-istudju ta' riċerka jekk nuri interess (ara hawn taħt).
16. Jiena konxju wkoll li kwalunkwe dettalji personali, jiġifieri l-formoli tal-kunsens, se jinqerdu fi żmien sentejn mit-tlestija tal-proġett tad-Dottorat.
17. Jien naf ukoll li se ningħata kopja tal-folja ta' informazzjoni u tal-formola ta' kunsens sabiex inkun nista' naċċessahom fil-futur.
18. Jien qrajt u fhimt il-punti u d-dikjarazzjonijiet f'din il-formola. Inħossni sodisfatt/a bit-tweġibiet li ngħatajt għall-mistoqsijiet li kelli, u qed naċċetta minn jeddi li nipparteċipa f'dan l-istudju.

Parteċipant/a: _____

Firma: _____

Data: _____

Mr. Joseph Grech	**Prof. Roberta Sammut**	**Prof. Ian James Norman**
Isem ir-riċerkatur	Isem is-superviżura	Isem il-ko-superviżur
Tel: 9* ***4**	**Tel. 2340 1831**	**Tel. +44 (0)207 848 3020**
joseph.grech.02@um.edu.mt	**roberta.sammut@um.edu.mt**	**ian.j.norman@kcl.ac.uk**

Jekk jogħġbok innota:
Jekk taqbel li tiġi kkuntattjat/a biex tingħata sommarju tar-riżultati ta' dan l-istudju ta' riċerka jekk jogħġbok ipprovdi n-numru tat-telefon/mobajl tiegħek hawn:

_____

Appendix 8.19: Feasibility study nurses' information letter

Intervention Providers` Information Sheet

Dear Nurse,

My name is Joseph Grech and I am currently reading for a Doctor of Philosophy (Ph.D.) in Nursing at the University of Malta. As part of my Ph.D. project, I am conducting a follow-up interview on the research study entitled, **"Development and feasibility testing of a multi-component smoking cessation intervention for smokers living with diabetes mellitus: a randomised feasibility study"**, to which you participated. This study aims to explore the feasibility and acceptability of delivering this smoking cessation intervention amongst individuals with diabetes. Your insight will help us ensure the applicability of this diabetes practice nurse-led cessation intervention for use amongst individuals with diabetes in practice. You will only be asked to share data that is necessary for this research. All data collected from this research shall be used solely for this study.

You are being invited to participate in an interview exploring your views, and suggestions on the smoking cessation intervention and your perceived challenges and facilitators to implementing this smoking cessation intervention in practice. The interview should not take more than 40 minutes and will be held at one of the Faculty of Health Science's approved and identified training sites at a time and date most suitable for you. Unless you have any objections, the interview will be audio-recorded. You are not obliged to answer all the questions and may withdraw from the study at any time without giving a reason. Withdrawal from the study will not have any negative repercussions whatsoever. Furthermore, any data collected from your end, unless this cannot be identified, e.g. has been already anonymised, will be erased. I can assure you that confidentiality will be maintained throughout the study and that your identity and personal information will not be linked to your responses and revealed in the thesis and any publications, reports, and presentations arising from this research. All data collected will be pseudonymised meaning that the transcript of the audio recording will be protected by a code system and that this data will be stored securely and separately from any personal data (audio-recording and consent forms). This data may only be accessed by the researcher. The academic supervisors and the examiners will typically have access to coded data only. There may be exceptional circumstances which allow the supervisors to have access to the audio-recording too, for verification purposes (if you would like to know who accessed your data, please contact me as per the details below). The audio-recording and transcript will be stored on the researcher`s personal computer that is password protected and in an encrypted format. The consent forms, will be placed in a locked cupboard.

Participation in this study does not expose you to any risks. Participation is completely voluntary and you are free to accept or refuse to take part without giving a reason. A copy of the information sheet and consent form will be provided for future reference. As a participant, you have the right, under the General Data Protection Regulation (GDPR) and national legislation that implements and further specifies the relevant provisions of said regulation, to access, rectify, and where applicable ask for the data concerning you to be erased. Once this research study is completed, the audio-recording will be erased and data will be retained only in anonymous form. Anonymous results from this research study will be published in my Ph.D. thesis and may be published in academic journals or reported at conferences or to health service organisations. Some of the things you say may be used as direct quotes in publications or conferences, but your confidentiality and anonymity will be maintained, and it will not be possible to identify you. A summary of the results of this research study will be offered to all participants who show interest. The consent forms will be destroyed within two years from the completion of my Ph.D. project.

This study has been approved by the Research Ethics Committee of the Faculty of Health Sciences at the University of Malta.

Thank you for your time and consideration. Should you have any questions or concerns do not hesitate to contact me on **9*** ***4** or by e-mail joseph.grech.02@um.edu.mt or my supervisor **Prof. Roberta Sammut** on **2340 1831** or roberta.sammut@um.edu.mt or my co-supervisor **Prof. Ian James Norman** on **+44 (0)207 848 3020** or ian.j.norman@kcl.ac.uk.

Yours Sincerely,

Mr. Joseph Grech	**Prof. Roberta Sammut**	**Prof. Ian James Norman**
Researcher	Research Supervisor	Research Co-supervisor
Tel: 9980 2504	**Tel. 2340 1831**	**Tel. +44 (0)207 848 3020**
joseph.grech.02@um.edu.mt	**roberta.sammut@um.edu.mt**	**ian.j.norman@kcl.ac.uk**

Appendix 8.20: Feasibility study nurses' consent form

Intervention Providers` Consent Form

Development and feasibility testing of a multi-component smoking cessation intervention for smokers living with diabetes mellitus: a randomised feasibility study (a follow-up interview)

I, the undersigned, give my consent to take part in the study conducted by Mr. Joseph Grech. The purpose of this document is to specify the terms of my participation in this research study.

1. I have been given written and verbal information about the purpose of the study and all questions have been answered.
2. I understand that I have been invited to participate in an interview, in which the researcher will ask questions to explore the feasibility and acceptability of delivering this smoking cessation intervention amongst individuals with diabetes.
3. I am aware that the interview will not take longer than 40 minutes. I understand that the interview is to be conducted at one of the Faculty of Health Science's approved and identified training sites in a place and at a time that is convenient for me.
4. I am aware that the interview will be audio-recorded and transcribed (written down as it has been spoken).
5. I am also aware that the transcript will be coded, and that this data will be stored securely and separately from any personal data (audio-recording and consent forms).
6. I understand that the researcher is the only person who has access to this data. The academic supervisors and examiners will typically have access to coded data only. I am aware that there may be exceptional circumstances which allow the supervisors to have access to the audio-recording too, for verification purposes. I understand that if I would like to know who accessed my data, I can contact the researcher as per the details below.
7. I am also aware that the audio-recording and the transcript will be stored on the researcher`s personal computer that is password protected and in an encrypted format. The consent forms will be placed in a locked cupboard.
8. I am also aware that my identity and personal information will not be linked to my responses and revealed in the researcher's Ph.D. thesis and any publications, reports, and presentations arising from this research.
9. I understand that I am free to accept, refuse, or stop participation at any time without giving any reason. This will have no negative repercussions on myself. Furthermore, I also understand that any data collected from my end, unless this cannot be identified, e.g. is anonymised, will be erased.

10. I also understand that my contribution will help Mr. Joseph Grech ensure the applicability of this diabetes practice nurse-led smoking cessation intervention for use amongst individuals with diabetes in practice.
11. I also understand that participating in this study does not expose me to any risks.
12. I am aware that under the General Data Protection Regulation (GDPR) and national legislation that implements and further specifies the relevant provisions of said regulation, I have the right to access, rectify, and where applicable ask for the data concerning me to be erased.
13. I understand that once the study is completed, the audio-recording will be erased, and data will only be retained in anonymous form. I am aware that anonymous results from this research study will be published in the researcher's Ph.D. thesis and may be published in academic journals or reported at conferences or to health service organisations.
14. I understand that some of the things I say may be used as direct quotes in publications or conferences, but my confidentiality and anonymity will be maintained, and it will not be possible to identify me.
15. I am aware that a summary of the results of this research study will be offered if I show interest (see below).
16. I am also aware that any personal details, i.e. the consent forms, will be destroyed within two years from completion of the Ph.D. project.
17. I am also aware that I will be provided with a copy of the information letter and consent form for future reference.
18. I have read and understood the points and statements of this form. I have had all the questions answered to my satisfaction, and I agree to participate in this study.

Participant: _____

Signature: _____

Date: _____

Mr. Joseph Grech	**Prof. Roberta Sammut**	**Prof. Ian James Norman**
Researcher	Research Supervisor	Research Co-supervisor
Tel: 9* ***4**	**Tel. 2340 1831**	**Tel. +44 (0)207 848 3020**
joseph.grech.02@um.edu.mt	**roberta.sammut@um.edu.mt**	**ian.j.norman@kcl.ac.uk**

Please note:
If you agree to be contacted to be provided with a summary of the results of this research study please provide your telephone/mobile number here:

_____

Appendix 8.21: Recruitment parameters (feasibility study)

Recruitment parameters	**Eligible smokers interested in quitting smoking** (n=154)
Monthly recruitment rate over the 12-month study period (recruitment rate), mean (SD) [95% CI]	12.8 (4.88) [9.7-16.0]
Proportion of smokers identified from each source of recruitment, n (%) [95% CI]	
Diabetes and Endocrine Centre DEC (diabetes outpatients)	131 (85.1) [78.4-90.3]
Nurses working at the DEC	63 (40.9) [33.1-49.1]
Doctors working at the DEC	42 (27.3) [20.4-25.0]
Podiatrists working at the DEC	26 (16.9) [11.3-23.8]
Diabetes Education Unit	17 (11.0) [6.6-17.1]
Self-referral	6 (3.9) [1.4-8.3]
Rate of consent, n (%) [95% CI]	91 (59.1) [50.9-66.9]

CI - confidence interval

Appendix 8.22: Feasibility study participants' characteristics at baseline per study group by intervention continuation/completion status

Baseline variable	**Participants who did not attend to/discontinued the intervention during the study period** (n=54)		**Participants who completed/continued the intervention during the study period** (n=37)	
	Intervention group (n=23)	Control group (n=31)	Intervention group (n=22)	Control group (n=15)
Demographics				
Sex, n (%)				
Male	19 (82.6)	20 (64.5)	16 (72.7)	10 (66.7)
Female	4 (17.4)	11 (35.5)	6 (27.3)	5 (33.3)
Age (years), median (IQR)	58.0 (48.0-62.0)	58.0 (45.0-65.0)	60.0 (52.0-63.3)	58.0 (52.0-63.0)
Education,[a] n (%)				
Upper secondary education	9 (39.1)	15 (48.4)	8 (36.4)	8 (53.3)
Post-secondary non-tertiary education	4 (17.4)	3 (9.7)	5 (22.7)	2 (13.3)
Lower secondary education	4 (17.4)	5 (16.1)	2 (9.1)	0
Primary education	2 (8.7)	3 (9.7)	3 (13.6)	2 (13.3)
Short cycle tertiary education	2 (9.1)	1 (3.2)	2 (8.7)	2 (13.3)
Bachelor's level	1 (4.3)	2 (6.5)	1 (4.5)	0
Master's level	1 (4.3)	0	1 (4.5)	1 (6.7)
Early childhood education	0	2 (6.5)	0	0
Employment status, n (%)				
Employed	16 (69.6)	19 (61.3)	14 (63.6)	9 (60.0)
Retired	4 (18.2)	5 (16.1)	5 (21.7)	4 (26.7)
Home duties	1 (4.3)	4 (12.9)	1 (4.5)	2 (13.3)
Unemployed	1 (4.3)	3 (9.7)	3 (13.6)	0
Living alone, n (%)				
No	18 (78.3)	25 (80.6)	17 (77.3)	12 (80.0)
Yes	5 (21.7)	6 (19.4)	5 (22.7)	3 (20.0)
Living with another smoker, n (%)				
No	13 (56.5)	13 (41.9)	16 (72.7)	9 (60.0)
Yes	10 (43.5)	18 (58.1)	6 (27.3)	6 (40.0)
Health status and diabetes profile				
Perceived health, n (%)				
Fair	15 (65.2)	18 (58.1)	12 (54.5)	6 (40.0)
Good	7 (30.4)	10 (32.3)	8 (36.4)	8 (53.3)
Bad	1 (4.3)	1 (3.2)	2 (9.1)	1 (6.7)
Very good	0	2 (6.5)	0	0
Very bad	0	0	0	0

Baseline variable	**Participants who did not attend to/discontinued the intervention during the study period** (n=54)		**Participants who completed/continued the intervention during the study period** (n=37)	
	Intervention group (n=23)	Control group (n=31)	Intervention group (n=22)	Control group (n=15)
Diabetes type, n (%)				
Type 2	20 (87.0)	27 (87.1)	17 (77.3)	13 (86.7)
Type 1	3 (13.0)	4 (12.9)	5 (22.7)	2 (13.3)
Age at diagnosis (years), median (IQR)	49.0 (41.0-53.0)	42.0 (33.0-55.0)	47.0 (34.0-58.0)	46.0 (34.0-55.0)
Diabetic treatment, n (%)				
Antidiabetic pills	16 (69.6)	21 (67.7)	12 (54.5)	11 (73.3)
Insulin only	3 (13.0)	5 (16.1)	6 (27.3)	3 (20.0)
Antidiabetic pills and insulin	4 (17.4)	5 (16.1)	4 (18.2)	1 (6.7)
Diabetes complications, n (%)				
No	13 (56.5)	19 (61.3)	15 (68.2)	11 (73.3)
Yes	5 (22.7)	7 (22.6)	6 (26.1)	3 (20.0)
Don't know	4 (17.4)	5 (16.1)	2 (9.1)	1 (6.7)
Other chronic diseases, n (%)				
Yes	18 (78.3)	27 (87.1)	19 (86.4)	13 (86.7)
No	5 (21.7)	4 (12.9)	3 (13.6)	2 (13.3)
Smoking profile				
Age at initiation (years), median (IQR)	15.0 (13.0-16.0)	14.0 (13.0-16.0)	14.5 (12.0-18.5)	16.0 (13.0-16.0)
Cigarettes/day,[b,c] median (IQR)	20.0 (15.0-30.0)	20.0 (20.0-30.0)	20.0 (15.0-26.3)	24.0 (14.8-30.0)
CDS-5 score,[c,d] median (IQR)	20.0 (18.0-22.0)	21.0 (17.0-23.0)	20.0 (17.8-22.0)	19.5 (16.0-21.3)
Quit attempt/s in past 12 months, n (%)				
No	17 (73.9)	19 (61.3)	13 (59.1)	10 (66.7)
Yes	6 (26.1)	12 (38.7)	9 (40.9)	5 (33.3)
Ever quit smoking, n (%)				
Yes	15 (65.2)	18 (58.1)	15 (68.2)	12 (80.0)
No	6 (26.1)	12 (38.7)	6 (27.3)	3 (20.0)
Never attempted	2 (8.7)	1 (3.2)	1 (4.5)	0

Baseline variable	**Participants who did not attend to/discontinued the intervention during the study period** (n=54)		**Participants who completed/continued the intervention during the study period** (n=37)	
	Intervention group (n=23)	Control group (n=31)	Intervention group (n=22)	Control group (n=15)
MTTS,[e] n (%)				
I REALLY want to stop smoking but don't know when I will. (4)	8 (34.8)	9 (29.0)	7 (31.8)	0
I want to stop smoking and hope to soon. (5)	7 (30.4)	8 (25.8)	6 (27.3)	2 (13.3)
I REALLY want to stop smoking and intend to in the next month. (7)	3 (13.0)	7 (22.6)	1 (4.5)	8 (53.3)
I REALLY want to stop smoking and intend to in the next 3 months. (6)	4 (17.4)	2 (6.5)	5 (22.7)	4 (26.7)
I want to stop smoking but haven't thought about when. (3)	0	4 (12.9)	2 (9.1)	1 (6.7)
I think I should stop smoking but don't really want to. (2)	1 (4.3)	1 (3.2)	1 (4.5)	0
I don't want to stop smoking. (1)	0	0	0	0
HADS[f]				
Anxiety subscale, n (%)				
Normal (0-7)	13 (56.5)	15 (48.4)	10 (45.5)	7 (46.7)
Probable presence (11+)	3 (13.0)	9 (29.0)	8 (36.4)	4 (26.7)
Suggestive presence (8-10)	7 (30.4)	7 (22.6)	4 (18.2)	4 (26.7)
Depression subscale, n (%)				
Normal (0-7)	15 (65.2)	21 (67.7)	14 (63.6)	13 (86.7)
Probable presence (11+)	3 (13.0)	7 (22.6)	3 (13.6)	1 (6.7)
Suggestive presence (8-10)	5 (21.7)	3 (9.7)	5 (22.7)	1 (6.7)
Probable presence of Anxiety and/or Depression				
No	19 (82.6)	19 (61.3)	13 (59.1)	11 (73.3)
Yes	4 (17.4)	12 (38.7)	9 (40.9)	4 (26.7)

IQR – interquartile range. a - As categorised in the International Standard Classification of Education (United Nations Educational Scientific and Cultural Organization, 2012). b - Includes six participants who smoked hand rolled cigarettes (four from the intervention group and two from the control group). One participant from the control group was a dual user, smoking also e-cigarettes. c - Excluding one participant (from the control group) who smoked 16 cigarellos a day. d - Cigarette Dependence Scale-5 (Etter et al., 2003). e - Motivation To Stop Scale Kotz et al. (2013). f - Hospital Anxiety and Depression Scale (Zigmond and Snaith, 1983).

Appendix 8.23: Use of Nicotine Replacement Therapy (NRT) during the subsequent four weeks following one week from the TQD by smoking status (feasibility study)

	Participants who reported being abstinent from smoking at final follow-up		**Participants who did not report being abstinent from smoking at final follow-up**	
Use of NRT during the subsequent four weeks following one week from the TQD	Nicotine patch (n=9)	Nicotine mouth spray (n=9)	Nicotine patch (n=9)	Nicotine mouth spray (n=10)
Reported use of NRT, n (% [95% CI])	8 (88.9 [51.8-99.7])	9 (100 [66.4-100])	8 (88.9 [51.8-99.7])	6 (60.0 [26.2-87.8])
Percentage of days of NRT use, median (IQR)	80.4 (52.7-97.3)	75.0 (26.8-100.0)]	50.0 (17.9-75.0)	30.4 (0.0-78.6)
No. of sprays applied per day, median (IQR)		2.0 (2.0-8.0)		1.5 (0.0-5.5)

TQD - Target Quit Date. IQR - interquartile range

Appendix 8.24: Feasibility study participants' characteristics at baseline per study group by response rate at the 3-month follow-up (post-intervention assessment)

Baseline variable	**Participants lost to follow-up** (n=14)		**Remaining participants** (n=77)	
	Intervention group (n=7)	Control group (n=7)	Intervention group (n=38)	Control group (n=39)
Demographics				
Sex, n (%)				
Male	6 (85.7)	6 (85.7)	29 (76.3)	24 (61.5)
Female	1 (14.3)	1 (14.3)	9 (23.7)	15 (38.5)
Age (years), median (IQR)	50.0 (45.0-63.0)	51.0 (45.0-67.0)	59.0 (52.0-63.0)	58.0 (51.0-64.0)
Education,[a] n (%)				
Upper secondary education	2 (28.6)	6 (85.7)	15 (39.5)	17 (43.6)
Post-secondary non-tertiary education	0	0	9 (23.7)	5 (12.8)
Lower secondary education	2 (28.6)	0	4 (10.5)	5 (12.8)
Primary education	1 (14.3)	0	4 (10.5)	5 (12.8)
Short cycle tertiary education	1 (14.3)	0	3 (7.9)	3 (7.7)
Bachelor's level	0	0	2 (5.3)	2 (5.1)
Master's level	1 (14.3)	0	1 (2.6)	1 (2.6)
Early childhood education	0	1 (14.3)	0	1 (2.6)
Employment status, n (%)				
Employed	4 (57.1)	4 (57.1)	26 (68.4)	24 (61.5)
Retired	2 (28.6)	3 (42.9)	7 (18.4)	6 (7.7)
Home duties	1 (14.3)	0	1 (2.6)	6 (15.4)
Unemployed	0	0	4 (10.5)	3 (15.4)
Living alone, n (%)				
No	6 (85.7)	6 (85.7)	29 (76.3)	31 (79.5)
Yes	1 (14.3)	1 (14.3)	9 (23.7)	8 (20.5)
Living with another smoker, n (%)				
No	4 (57.1)	3 (57.1)	25 (65.8)	19 (48.7)
Yes	3 (42.9)	4 (42.9)	13 (34.2)	20 (51.3)
Health status and diabetes profile				
Perceived health, n (%)				
Fair	4 (57.1)	4 (57.1)	23 (60.5)	20 (51.3)
Good	2 (28.6)	2 (28.6)	13 (34.2)	16 (41.0)
Bad	1 (14.3)	0	2 (5.3)	2 (5.1)
Very good	0	1 (14.3)	0	1 (2.6)
Very bad	0	0	0	0

Baseline variable	**Participants lost to follow-up** (n=14)		**Remaining participants** (n=77)	
	Intervention group (n=7)	Control group (n=7)	Intervention group (n=38)	Control group (n=39)
Diabetes type, n (%)				
Type 2	6 (85.7)	6 (85.7)	31 (81.6)	34 (87.2)
Type 1	1 (14.3)	1 (14.3)	7 (18.4)	5 (12.8)
Age at diagnosis (years), median (IQR)	46.0 (44.0-57.0)	40.0 (33.0-47.0)	49.0 (39.0-55.0)	45.0 (34.0-55.0)
Diabetic treatment, n (%)				
Antidiabetic pills	4 (57.1)	6 (85.7)	24 (63.2)	26 (66.7)
Insulin only	2 (28.6)	1 (14.3)	6 (15.8)	7 (17.9)
Antidiabetic pills and insulin	1 (14.3)	0	8 (21.1)	6 (15.4)
Diabetes complications, n (%)				
No	6 (85.7)	3 (42.9)	22 (57.9)	27 (69.2)
Yes	1 (14.3)	3 (42.9)	10 (26.3)	7 (18.0)
Don't know	0	1 (14.2)	6 (15.8)	5 (12.8)
Other chronic diseases, n (%)				
Yes	4 (57.1)	5 (71.4)	33 (86.8)	35 (89.7)
No	3 (42.9)	2 (28.6)	5 (13.2)	4 (10.3)
Smoking profile				
Age at initiation (years), median (IQR)	14.0 (12.0-22.0)	13.0 (10.0-14.0)	15.0 (13.0-16.0)	15.0 (13.0-16.0)
Cigarettes/day,[b,c] median (IQR)	20.0 (10.0-20.0)	25.0 (10.0-40.0)	20.0 (15.8-30.0)	22.5 (17.3-30.0)
CDS-5 score,[c,d] median (IQR)	17.0 (13.0-18.0)	22.0 (18.0-23.0)	20.0 (18.8-22.0)	20.0 (16.0-22.0)
Quit attempt/s in past 12 months, n (%)				
No	5 (71.4)	5 (71.4)	25 (65.8)	24 (61.5)
Yes	2 (28.6)	2 (28.6)	13 (34.2)	15 (38.5)
Ever quit smoking, n (%)				
Yes	5 (71.4)	3 (42.9)	25 (65.8)	27 (69.2)
No	1 (14.3)	4 (57.1)	11 (28.9)	11 (28.2)
Never attempted	1 (14.3)	0	2 (5.3)	1 (2.6)
MTTS,[e] n (%)				
I REALLY want to stop smoking but don't know when I will. (4)	3 (42.9)	2 (28.6)	12 (31.6)	7 (17.9)
I want to stop smoking and hope to soon. (5)	1 (14.3)	1 (14.3)	12 (31.6)	9 (23.1)
I REALLY want to stop smoking and intend to in the next month. (7)	2 (28.6)	2 (28.6)	2 (5.3)	13 (33.3)
I REALLY want to stop smoking and intend to in the next 3 months. (6)	1 (14.3)	1 (14.3)	8 (21.1)	5 (12.8)
I want to stop smoking but haven't thought about when. (3)	0	1 (14.3)	2 (5.3)	4 (10.3)
I think I should stop smoking but don't really want to. (2)	0	0	2 (5.3)	1 (2.6)
I don't want to stop smoking. (1)	0	0	0	0

Baseline variable	**Participants lost to follow-up** (n=14)		**Remaining participants** (n=77)	
	Intervention group (n=7)	Control group (n=7)	Intervention group (n=38)	Control group (n=39)
HADS[f]				
Anxiety subscale, n (%)				
Normal (0-7)	5 (71.4)	5 (71.4)	18 (47.4)	17 (43.6)
Probable presence (11+)	1 (14.3)	0	10 (26.3)	11 (28.2)
Suggestive presence (8-10)	1 (14.3)	2 (28.6)	10 (26.3)	11 (28.2)
Depression subscale, n (%)				
Normal (0-7)	5 (71.4)	5 (71.4)	24 (63.2)	29 (74.4)
Probable presence (11+)	1 (14.3)	1 (14.3)	9 (23.7)	3 (7.7)
Suggestive presence (8-10)	1 (14.3)	1 (14.3)	5 (13.2)	7 (17.9)
Probable presence of Anxiety and/or Depression				
No	6 (85.7)	5 (71.4)	26 (68.4)	25 (64.1)
Yes	1 (14.3)	2 (28.6)	12 (31.6)	14 (35.9)

IQR – interquartile range. a - As categorised in the International Standard Classification of Education (United Nations Educational Scientific and Cultural Organization, 2012). b - Includes six participants who smoked hand rolled cigarettes (four from the intervention group and two from the control group). One participant from the control group was a dual user, smoking also e-cigarettes. c - Excluding one participant (from the control group) who smoked 16 cigarellos a day. d - Cigarette Dependence Scale-5 (Etter et al., 2003). e - Motivation To Stop Scale Kotz et al. (2013). f - Hospital Anxiety and Depression Scale (Zigmond and Snaith, 1983).

Appendix 8.25: Smoking cessation support received as reported in the end of study questionnaire (feasibility study)

Reported smoking cessation support received during the study period	**Intervention group** (n=38)	**Control group** (n=39)
Smoking cessation support sessions		
Number of sessions, n (%)		
No sessions	1 (2.6)	12 (30.8)
One session	7 (18.4)	11 (28.2)
Two sessions	6 (15.8)	11 (28.2)
Three sessions	12 (31.6)	3 (7.7)
Four sessions	12 (31.6)	2 (5.1)
Total time period during which the intervention was provided (weeks), median (IQR)	7.0 (3.8-9.0)	1.0 (0-3.0)
Use of Nicotine Replacement Therapy (NRT)		
Reported use of NRT, n (%)		
Yes	35 (92.1)	10 (25.6)
No	3 (7.9)	29 (74.4)
No. of days NRT was used, median (IQR)		
Nicotine patch, n=31(intervention), n=7 (control)	28 (11-42)	7 (3-18)
Nicotine mouth spray, n=34 (intervention), n=3 (control)	20.5 (5-50.8)	3 (2-14)
Nicotine gum, n=0 (intervention), n=4 (control)		4.5 (1.3-13)
No. of sprays applied per day, median (IQR)	3 (2-7)	3 (2-16)
No. of gums applied per day, median (IQR)		4 (3-7)

IQR - interquartile range

Appendix 8.26: Aspects of the control intervention which the participants remarked being most satisfied with (feasibility study, n=22)

Themes	Quotes (translated quotes in italics)	Participants' code (number of participants)
Social skilled professionals	"(Name of the tobacco cessation facilitator) is truly a professional in every sense! ... Her attitude encouraged me in so many ways. I felt free to share with her many times that the addiction to nicotine is way above me and my fear of not being able to stop completely. Never did she judge me nor tried to make me fear of not dealing without smoking not understood." P73	P8, P41, P46, P76, P73, P79, P84, P91 (8)
Supportive	"Is-sapport li tatni hi." (*"The support that she gave me.")* P52	P11, P30, P39, P52, P57, P60, P71 (7)
Encouragement given	"The amount of encouragement given." P4	P3, P4, P8, P73, P84 (5)
Patient-centred	"Li mhux dik il-ħaġa li trid tonqos daqshekk jew daqshekk. Li huma qegħdin hawn biex jissapportjawk bid-deċiżjoni tiegħek." (*"That it's not that thing that you have to cut down by that much or that much. That they are here to support you with your decision."*) P28	P28, P72, P73 (3)
Raises awareness	"The talk was convincing, in terms of the harm being done by smoking" P68	P39, P68 P73 (3)
Advice given	"Tajtuni pariri x'nagħmel" (*""You gave me advice on what to do"*) P3	P3, P90, P91 (3)
The sharing of the professional's own quitting experience provided guidance	"The fact that the person running the sessions was a former smoker and had gone through the process of quitting successfully. This gave me a better view on what to expect when quitting smoking." P63	P63 (1)

Appendix 8.27: Aspects of the control intervention which the participants remarked being least satisfied with (feasibility study, n=6)

Themes	Quotes (translated quotes in italics)	Participants' code (number of participants)
No pharmacotherapy provided	"No nicotine replacement therapy given." P4	P4, P72, P84 (3)
Lack of support	"No support." P20	P20 (1)
Long interval between sessions	"The interval between sessions. I think they could have been weekly at least bi-weekly." P63	P63(1)
Suggested Nicotine Replacement Therapy was not suitable nor effective	"L-affarijiet li tixtri xtrajthom għalxejn għax iċ-*chewing gum* ma stajtx nomogħdu, u l-patch ma ħassejt xejn." (*"The things you buy, I bought them for nothing because I couldn't chew the chewing gum, and I didn't feel anything with the patch."*) P28	P28 (1)

Appendix 8.28: Suggestions for improving the smoking cessation control intervention that was received (feasibility study, n=14)

Themes	Quotes (translated quotes in italics)	Participants' code (number of participants)
Provide Nicotine Replacement Therapy	"Provide nicotine replacement therapy." P4	P4, P8, P40, P46, P68, P72, P84 (7)
Support should be focused on quitting smoking right from the start	"Maybe I expected much harsher sessions, though they became more direct by each session." P63	P3, P63, P87 (3)
Add group-based support	"I think a mix of one to one sessions and a small number of groups sessions could possibly have been beneficial to me." P73	P57, P73 (2)
Provide frequent support	"Is-sessions iridu jkunu darba fil-ġimgħa." (*"The sessions must be once a week.""*) P60	P60 (1)

Appendix 8.29: Characteristics of the interviewees, n=20 (feasibility study follow-up interview)

Characteristics	Interviewees (*n*=20)
Sex, *n* (%)	
Male	12
Female	8
Age (years), mean (SD)	56.6 (7.82)
Diabetes type, *n* (%)	
Type 2	15 (75.0)
Type 1	5 (25.0)
Attended all scheduled sessions,[a] *n* (%)	
Yes	13 (65.0)
No	7 (35.0)
Number of sessions attended, *n* (%)	
Four	8 (40.0)
Three	5 (25.0)
One	4 (20.0)
Two	3 (15.0)
Used the provided Nicotine Replacement Therapy on attempting to quit smoking, *n* (%)	
Yes	18 (90.0)
No	2 (10.0)
Reported smoking abstinence during the study period, *n* (%)	
Did not intentionally spend at least one day (≥24 hours) not smoking	6 (30.0)
Intentionally spent at least one day (≥24 hours) not smoking but less than seven consecutive days	6 (30.0)
Did not smoke any tobacco product over the past seven days (biochemically verified)	6 (30.0)
Spent at least seven consecutive days not smoking, but currently smoking	2 (10.0)
Cigarettes/day among continuing smokers, mean (SD)	13.3 (10.82)

SD - Standard Deviation. a - One participant attended all scheduled sessions, but still had one more session to attend, which was scheduled after the end of the study period. Conversely, one participant missed one session as was hospitalised, but then attended his final follow-up session.

Appendix 8.30: Method for calculating sample size for a future definitive trial

In a future definitive study, the primary outcome on which the sample size will be calculated will be the smoking abstinence outcome measure. Based on the recommendations by Piper et al. (2020), this is defined as the biochemically verified seven day point prevalence at a minimum of six months from treatment initiation. The two smoking cessation trials (section 4.5.2) which carried out power calculations to inform their sample size (based on achieving a minimum clinically important difference in smoking abstinence between intervention groups at six months follow-up), both assumed a smoking abstinence rate of 6% for usual care and an abstinence rate of 18% for intensive smoking cessation support (Canga et al., 2000; Ibrahim et al., 2023). On the other hand, the recent smoking cessation trial by Russo et al. (2021) aimed to achieve a minimum clinically important difference of 18.7% at six months follow-up, assuming as well a smoking abstinence rate of 6% for usual care. Despite the latter observation, the minimum clinically important difference was set at 12%, as this results in a larger sample size and, therefore, reflects a more prudent approach. Open Epi, a software for epidemiological statistics by Dean et al. (2013), was used to calculate the sample size required for a future definitive trial at 90% power, 5% significance level, two-sided test, using the Fleiss with continuity correction method; a more conservative approach for when dealing with small sample sizes or low event rates. Based on the identified consent and recruitment rates for this study, the number of eligible individuals required for a future definitive study and the number of months needed were calculated.

Appendix 8.31: Treatment actions/components carried out by the intervention providers amongst the participants during the sessions and the average percentage adherence to the session protocol (feasibility study)

Table 1: Treatment actions/components carried out by the providers amongst the participants as per session one protocol and the average percentage adherence to the protocol

Treatment action/component	Number of participants provided with the treatment action/component (n=8)
Ask: Asked about/Confirmed the number of cigarettes/tobacco products smoked every day.	8
Advise: Informed the participant on the effects of smoking on diabetes (as outlined in the intervention guideline).	8
Advise: Gave an overview of the story of Bill to the participant (as outlined in the intervention protocol), showing him/her the three video clips.[a]	7
Advise: Allowed some time for reflection or brief discussion, acknowledging any feelings or comments the participant may state.[a]	7
Advise: Advised the participant to quit smoking in a clear, strong and personalised manner (as outlined in the intervention protocol).	8
Assess: Assessed readiness in setting a quit attempt in the next two weeks, identifying the possible need of using the 5R's algorithm (as outlined in the intervention protocol).[b]	4
5Rs: Helped the participant identify how quitting smoking would be relevant to him/her.[b]	1
5Rs: Encouraged the participant to identify the potential negative consequences (risks) that are relevant to him/her if he/she continues to smoke, discussing further if required.[b]	1
5Rs: Encouraged the patient to identify potential benefits of stopping smoking (rewards) which are relevant to him/her, discussing further if required.[b]	1
5Rs: Encouraged the participant to identify any barriers or impediments to quitting smoking (roadblocks), discussing/providing realistic solutions.[b]	1
5Rs: Reassessed readiness in setting a quit attempt in the next two weeks (repetition), encouraging the participant to give it a try.[b]	1
Assist: Helped the participant set a Target Quit Date (TQD) within the next two weeks.	8
Assist: Told the participant to inform his family, friends, and co-workers about his/her quitting attempt, and to ask for support.	7
Assist: Encouraged the participant to talk about the quitting process, anticipating the challenges or barriers to the upcoming quit attempt, (as outlined in the intervention protocol)	8
Assist: Helped the participant generate problem-solving strategies to tackle the identified barriers and challenges to quitting (as outlined in the intervention protocol)	8
Assist: Asked the participant to remove any tobacco products from the patient's environment (particularly closer to the quit date) and make the home smoke free.	7

Treatment action/component	**Number of participants provided with the treatment action/component** (n=8, excluding 5Rs algorithm)
Assist: Recommended (explaining use and benefits) and provided a supply of NRT (patch and/or spray) for use until the next session.	8
Assist: Encouraged the participant further in the quit attempt, by referring to/identifying what would be relevant for him/her if he quit smoking.	7
Assist: Advised monitoring of blood glucose.	5
Assist: Linked the participant to psychological support services if experiencing anxiety or depression.	6
Arrange: Provided the participant with a follow-up appointment during the first week (or two weeks maximum) from their TQD.	5
Average total per participant (out of 16 [excluding the 5Rs algorithm])	13.9
Percentage adherence (%)	86.7
Average total per participant (out of 21 [including the 5Rs algorithm])	15.5
Percentage adherence (%)	74.0

a - On one occasion the nurse could not play the videos but explained the story behind them b - Use of the 5Rs algorithm was required in three instances, but it was only done once. In three other instances the providers did not clearly assess readiness to quit (based on protocol).

Table 2: Treatment actions/components carried out by the providers amongst the participants as per session two (for those who did not quit smoking) protocol and the average percentage adherence to the protocol

Treatment action/component	**Number of participants provided with the treatment action/component** (n=5)
Asked about tobacco use (no. of cigarettes/tobacco products smoked/day).	5
Assessed the use of NRT and any problems encountered (including over/under-dosing), providing recommendations.	5
Reviewed experienced barriers and challenges (roadblocks).	5
Encouraged a recommitment to quit smoking (referring to what is relevant to the participant – risks and rewards).	4
Encouraged the participant to give it a try even if not 100% confident.	5
Assist: Helped the participant set a TQD within the next two weeks.	5
Assist: Told the participant to inform his family, friends, and co-workers about his/her quitting attempt, and to ask for support.	4
Assist: Encouraged the participant to talk about the quitting process, anticipating the challenges or barriers to the upcoming quit attempt, (as outlined in the intervention protocol)	5
Assist: Helped the participant generate problem-solving strategies to tackle the identified barriers and challenges to quitting (as outlined in the intervention protocol)	5
Assist: Asked the participant to remove any tobacco products from the patient's environment (particularly closer to the quit date) and make the home smoke free.	4
Assist: Recommended (explaining use and benefits) and provided a supply of NRT (patch and/or spray) for use until the next session.	5
Assist: Encouraged the participant further in the quit attempt, by referring to what would be relevant for him/her if he quit smoking.	4
Assist: Advised monitoring of blood glucose.	3
Assist: Linked the participant to psychological support services if experiencing anxiety or depression.	3
Arrange: Provided the participant with a follow-up appointment during the first week (or two weeks maximum) from their TQD.	2
Average total per participant (out of 15)	12.8
Percentage adherence (%)	85.3

Table 4: Treatment actions/components carried out by the providers amongst the participants as per session two (for those who quit smoking), or session three (if reporting abstinence the first time) protocol and the average percentage adherence to the protocol

Treatment action/component	**Number of participants provided with the treatment action/component** (n=3)
Asked about tobacco use (no. of cigarettes/tobacco products smoked/day).	3
Congratulated participant if he/she stopped smoking.	3
Encouraged participant to remain abstinent (referring to what is relevant to the participant – risks and rewards).	3
Assessed the use of NRT and any problems encountered (including over/under-dosing), providing recommendations.	3
Reviewed experienced barriers and challenges (roadblocks) towards remaining abstinent from smoking.	3
Discussed anticipated challenges.	3
Reinforced strategies outlined in the quit plan – reminding the participant on the usefulness of social support.	1
Linked the participant to psychological support services if experiencing anxiety or depression.	2
Provided remaining assigned supply of NRT, advising all participants to reduce the use of the spray during these weeks.	3
Advised monitoring of blood glucose and offered a diabetic consultation (and subsequent specialist/s referrals, if required) if the participant experienced poor glycaemic control, or is concerned about diabetes management following a change in diet or weight gain on quitting smoking.	3
Provided the participant with a follow-up appointment within five weeks from their TQD.	3
Average total per participant (out of 11)	10
Percentage adherence (%)	90.9

Table 4: Treatment actions/components carried out by the providers amongst the participants as per session three (for those who did not succeed to quit smoking) protocol and the average percentage adherence to the protocol

Treatment action/component	**Number of participants provided with the treatment action/component** (n=4)
Asked about tobacco use (no. of cigarettes/tobacco products smoked/day).	4
Assessed the use of NRT and any problems encountered (including over/under-dosing), providing recommendations.	4
Reviewed experienced barriers and challenges (roadblocks).	3
Encouraged a recommitment to quit smoking (referring to what is relevant to the participant – risks and rewards).	2
Discuss anticipated challenges.	4
Reinforced strategies outlined in the quit plan – reminding the participant on the usefulness of social support.	2
Linked the participant to psychological support services if experiencing anxiety or depression.	2
Provided remaining assigned supply of NRT for use until the final session, advising all participants to reduce the use of the spray during these weeks.	4
Advised monitoring of blood glucose and offered a diabetic consultation (and subsequent specialist/s referrals, if required) if the participant experienced poor glycaemic control, or is concerned about diabetes management following a change in diet or weight gain on quitting smoking.	4
Provided the participant with a follow-up appointment within five weeks from their TQD (that agreed on in session two).	4
Average total per participant (out of 10)	8.25
Percentage adherence (%)	82.5

Table 5: Treatment actions/components carried out by the providers amongst the participants as per the final follow-up session protocol and the average percentage adherence to the protocol

Treatment action/component	**Number of participants provided with the treatment action/component** (n=4)
Asked about tobacco use (no. of cigarettes/tobacco products smoked/day).	4
Congratulated participant if he/she stopped smoking/remained abstinent from smoking or praised any other achievements (e.g. reduction in number of cigarettes smoked per day).	4
Reviewed experienced barriers and challenges (roadblocks) towards remaining abstinent from smoking/quitting.	4
Assessed the use of NRT and any problems encountered (including over/under-dosing), advising participants to ideally reduce use if still on NRT (and abstinent from smoking).	4
Encouraged participant to attempt quitting again if he/she relapsed/still smoking or to remain abstinent (referring to what is relevant to the participant – risks and rewards)	3
Discussed anticipated challenges.	1
Reinforced strategies outlined in the quit plan – reminding the participant on the usefulness of social support.	1
Linked the participant to psychological support services if experiencing anxiety or depression.	4
Advised monitoring of blood glucose and offered a diabetic consultation (and subsequent specialist/s referrals, if required) if the participant experienced poor glycaemic control, or is concerned about diabetes management following a change in diet or weight gain on quitting smoking.	4
Ended the intervention on a positive manner, encouraging the participant to seek tobacco cessation services if required.	4
Average total per participant (out of 10)	8.25
Percentage adherence (%)	82.5

Appendix 9.1: The scoping review

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Helping smokers with diabetes quit: A scoping review of the interventions utilised, and the challenges and barriers to smoking cessation

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Smoking cessation

ABSTRACT

Tobacco smoking is recognised as a priority in diabetes management, yet many individuals with diabetes continue to smoke beyond diagnosis. This paper identifies the most promising smoking cessation strategies by reviewing the literature reporting interventions carried out amongst this study population, and the challenges and barriers to smoking cessation. Stand-alone smoking cessation interventions which included pharmacotherapy were found to be more successful in achieving abstinence than interventions which included smoking cessation as part of a broader intervention for improving diabetes management. Misconceptions about smoking and diabetes management were frequently reported, undervaluing smoking cessation. This emphasizes further the need to inform smokers with diabetes about the link between tobacco use and diabetes complications.

1. Introduction

Tobacco smoking, a well-established risk factor associated with a wide range of diseases and disorders [1], presents an unequivocal increased risk of complications for those who have diabetes. When compared to individuals with diabetes who do not smoke, both individuals with type 1 and type 2 diabetes who smoke have been found to be at increased risk of macrovascular complications; including coronary heart disease, stroke, and myocardial infarction [2]. Tobacco use may also increase the risk of microvascular diabetes complications [3]. While there is insufficient evidence to demonstrate the influence of tobacco use on the development of retinopathy and neuropathy [3], evidence has shown that smoking increases the risk of diabetic nephropathy amongst both individuals with type 1 and type 2 diabetes [4]. Both individuals with type 1 and type 2 diabetes who smoke also seem to have poorer cardiometabolic profiles, which in turn can lead to a worse cardiovascular outcome [5].

Given the increased risk of diabetes-related complications from tobacco use, smoking cessation has been recognised as a priority in diabetes management [3,6,7]. Nonetheless, worldwide, more than one in five individuals with diabetes continue to smoke beyond diagnosis [8]. Evidence suggests that when compared to other smokers, smokers with diabetes tend to be less motivated to stop smoking, possibly due to a number of diabetes-related barriers and challenges to quitting [3]. Concern about possible weight gain, a well-known side-effect following smoking cessation, and poor glycaemic control, which may occur on quitting, may deter individuals with diabetes from attempting to quit smoking [5]. Individuals with diabetes are also more likely to suffer from depression [9], which is known to hinder efforts in quitting smoking [10]. Evidence also suggests that individuals with diabetes metabolise nicotine faster, making them smoke more during their life, possibly increasing their nicotine addiction, making it harder for them to quit [11]. Given that these conditions may make it harder for individuals with diabetes to quit smoking, greater smoking cessation support efforts, tailored to this population, may be required [3].

Having been found to increase smoking cessation success in the general smoking population [12,13], intensive smoking cessation support, such as behavioural support (e.g. counselling), in combination with pharmacotherapy for smoking cessation, such as Nicotine Replacement Therapy (NRT), bupropion or varenicline, may also support individuals with diabetes in dealing with such diabetes-specific challenges. Nonetheless, convincing evidence to recommend this strategy amongst individuals with diabetes is still missing. Nagrebetsky et al. [14], who compared the effectiveness of intensive (pharmacological and/or non-pharmacological behavioural interventions) to less intensive smoking cessation interventions (such as usual care or brief advice to quit smoking) amongst individuals with diabetes, found that intensive interventions only resulted in a non-significant increase in

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biochemically verified smoking abstinence at six months follow-up. Conversely, Zhan et al. [15], who compared the effectiveness of psychological interventions for smoking cessation (i.e., behavioural-based support interventions focused on smoking cessation or interventions in which smoking cessation was a part of a broader intervention for improving diabetes management) to usual care, found that psychological interventions were more effective, however, the observed effect was no longer present beyond three months of follow-up.

Given the uncertainties, as regards the efficacy of smoking cessation interventions for individuals with diabetes, the identification of the most promising smoking cessation interventions for use amongst such individuals in view of the diabetes-specific barriers and challenges to quitting is a pressing need for clinical practice. However, there are no known reviews which have provided such evidence-based practice recommendations.

A comprehensive review was thus undertaken to identify the most promising smoking cessation methods for this study population by mapping out the literature on the smoking cessation interventions carried out amongst individuals with diabetes, and the challenges and barriers to smoking cessation that were identified amongst such individuals, taking note of any gaps in evidence. The following review question was formulated: Which smoking cessation interventions are most promising in helping individuals living with diabetes mellitus who smoke to quit?

2. Methods

2.1. Study design

A scoping review was best suited for this study as it takes a wider approach to the research problem in a transparent and rigorous manner, mapping out existing relevant literature for exploring and describing a concept and its research gaps [16]. The scoping review framework outlined by Arksey and O'Malley, which consists of six stages: identification of the research question; identification of relevant studies; selection of studies; charting of data; collation, and summarising and reporting of results [16], was selected.

2.2. Inclusion and exclusion criteria

The studies included in the review had to evaluate interventions in terms of their effect on smoking cessation and/or explore any challenges and barriers to quitting specifically amongst individuals diagnosed with diabetes. Thus, studies in which only a proportion of the participants had diabetes, or reports of studies which were not specific to individuals with diabetes were excluded. All published reports of research studies, including all research designs, were included. No language or time limiters were set. The minimum requirement for non-English papers was that the title and/or abstract had to be translated into English in the bibliographic database.

2.3. Search strategy

The search was undertaken on the 28th of May 2022 from inception on the following databases (via the following interfaces): APA PsycInfo, CINAHL Complete, Cochrane Central Register of Controlled Trials, Cochrane Clinical Answers, Cochrane Database of Systematic Reviews, Cochrane Methodology Register, MEDLINE Complete (EBSCOhost), ProQuest Dissertations & Theses A&I, Public Health Database (ProQuest), PubMed (U.S. National Library of Medicine), Scopus (Elsevier), System for Information on Grey Literature in Europe (Exalead), and all the databases on Web of Science. The keywords used included "diabetes mellitus" and "smoking cessation" and their synonyms (outlined in Supplementary document 1). The truncated terms were combined by using Boolean operators 'AND' and 'OR', and searched in titles, abstracts, and subject headings/medical subject headings accordingly. The search strategy used for searching in the EBSCOhost interface is outlined in Supplementary document 2. On the identification of the studies which were deemed relevant to this review, the reference lists of these studies were examined for the identification of other possible studies for inclusion in this review.

2.4. Study selection

Following the execution of the search strategy, the identified records were collated on Mendeley® for de-duplication. The remaining records were screened by reading titles and the whole abstracts. The retained articles were then assessed for eligibility basing decisions on the inclusion and exclusion criteria.

2.5. Data extraction, charting, and collation

The information extracted from the studies included: the author/s and year of publication; study design; location; method, including information on the smoking cessation intervention/s, if applicable; study sample; and relevant findings and observations. Data were collated, summarised, and reported using text and tables.

3. Results

3.1. Selection of studies

The Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) 2020 flow diagram [17] was utilised to outline the selection process (Fig. 1).

The number of records identified amounted to 15,442 of which 6007 were duplicates. After removing duplicates and screening the remaining records by reading titles and abstracts, 135 reports were found to be possibly relevant and eligible for full-text screening. On matching these publications to the inclusion criteria, 82 reports were found to be ineligible, while 53 reports were deemed eligible. An additional six, which were obtained from citation searching, were also included. This led to a final selection of 59 reports.

Some of the identified reports referred to the same study, resulting in a smaller number of studies being identified. Both Rubak et al. [18] and Rubak et al. [19] reported findings from the ADDITION study, while Albaroodi et al. [20] and Albaroodi et al. [21] reported findings from the same randomised control trial (RCT). Lam et al. [22] and Thankappan et al. [23] published the findings from the RCTs by Li et al. [24] and Thankappan et al. [25], respectively, in conference proceedings. Furthermore, in the publications by Thankappan et al. [26] and Nichter et al. [27], the authors followed up participants from Thankappan et al. [25]'s trial for a total of one and two years, respectively. Mini et al. [28] reported the cotinine measurements from the study by Thankappan et al. [25] in a separate publication. Similarly, in the publication by Khunti et al.'s study [29], the participants who had been enrolled in Davies et al. [30]'s trial were followed up for an additional two years. Thus, the total number of identified studies was 51.

3.2. General characteristics of the identified studies

Most of the identified papers reported on randomised control trials (n = 29) [18–26,28–48]. Studies were frequently conducted in the United Kingdom [30,31,36,47,49–51], or the United States [34,43–45,52–54]. Most reports (n = 25) focused on individuals with type 2 diabetes [18,19,22,24,29,30,34,36–39,42–48,55–61]), who were mostly men (n = 39) [19–30,32,34–36,38–44,46,47,49–51,54,56–59,61–66], and in their 50 s (n = 25) [22–28,30,32,34,35,38–40,45,47,51,52,57,59–62,67,68].

Most reports evaluated a smoking cessation intervention/s which was provided on its own (n = 25; Table 1) [14,21–28,31–34,38,40,41,50,51,59,61–63,69–71], or which was part of a broader intervention for

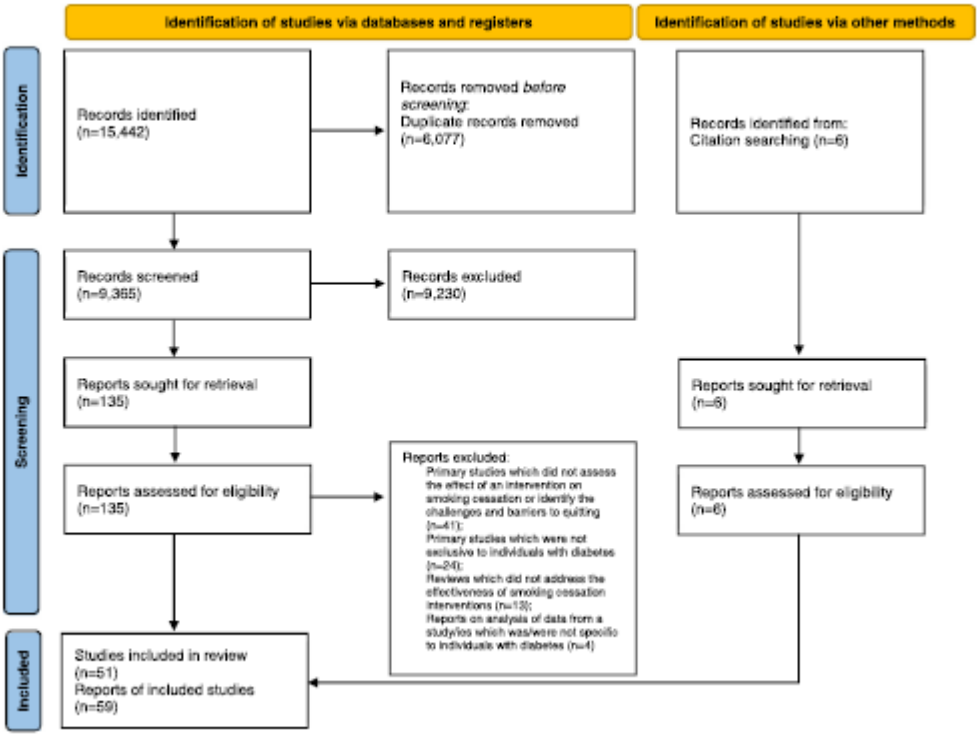

Fig. 1. PRISMA Flow diagram.

improving diabetes management (n = 20; Table 2) [18,19,29,30,35–37,39,42–48,52,54,60,67,72]. The reviews by Daly et al. [73], Ekong & Kavookjian [55], Zhan et al. [15], and Tricco et al. [64] included both types of studies (included in Table 2). Typically, the provided diabetes-specific smoking cessation support consisted of behavioural support, such as counselling (commonly based on the 5As algorithm, Ask, Advise, Assess, Assist and Arrange; n = 9 [14,15,21–25,38,71], or motivational interviewing; n = 9 [14,15,18,19,34,40,55,59,60]) or were education-based (n = 12) [14,15,30,33,39,43,45,47,48,52,54,72]. Pharmacotherapy for smoking cessation was also provided/recommended in some of the identified studies (n = 13) [14,15,32,34,41,55,59,61–63,69,70,73]. The identified interventions were mostly delivered by nurses (n = 14) [14,15,21,24,32,34,36,47,48,50,55,59,70,73], or doctors (n = 14) [14,15,18,19,21,25,31,38,48,50,55,63,67,71] at general practices/primary care settings (n = 17) [14,15,18,19,30,32,40,42,47,48,54,55,59,67,70,71,73] or at diabetic clinics (n = 12) [14,15,21,24,25,31,33,34,38,41,50,51].

In some of the identified studies (Table 3), the authors explored the barriers/challenges to smoking cessation as perceived by individuals living with diabetes [49,53,56,57,65,66,74], or as experienced by such individuals after attending a smoking cessation intervention [20,31,51,58,68]. Detailed descriptions of all these studies are available in Supplementary document 3. The key findings drawn from the identified studies are provided in the sub-sections below.

3.2.1. Studies whose intervention was focused on smoking cessation – key findings

Despite observing commonalities amongst the studied interventions, such as the use of counselling, the effect on smoking cessation was found to vary across the identified studies (Table 1). The efficacy of specific behavioural support approaches, such as the 5As algorithm, or motivational interviewing, and the tailoring of the study intervention according to the participants' stage of change, is also not clear. Nonetheless, it appears that the addition of pharmacotherapy to smoking cessation support was more likely to be associated with success. Except for the studies by Nagrebetsky et al. [14], which did not compare pharmacological to non-pharmacological interventions, Hokanson et al. [34], in which similar numbers in both groups utilised pharmacotherapy, and Sawicki et al. [41] and Scemama et al. [63], which both suffered from poor participation and response rate (respectively), in all the other studies in which the authors included pharmacotherapy as part of their intervention [14,32,40,59,61,62,69,70], a significant smoking cessation outcome was observed.

3.2.2. Studies whose smoking cessation intervention was part of a broader intervention for diabetes management – key findings

As outlined in Table 2, most of the studies included in the review were not successful in helping smokers quit. While Davies et al. [30], Ukoha-Kalu et al. [39], and Ramallo-Fariña et al. [48], who adopted an educational approach to smoking cessation, reported a significant smoking cessation outcome, the other study authors who took a similar approach [43,45,47,52,54], did not. Rubak et al. [18,19], and Tranche et al. [67], who integrated their interventions within routine clinical care, also found no significant increase in smoking cessation. None of the identified primary studies included pharmacotherapy as part of the smoking cessation support provided.

3.2.3. Studies which explored barriers and/or challenges to quitting – key findings

In most studies, participants remarked finding it difficult to quit because of the smoking habit and addiction [20,31,49,56,57,65,74], and stress and other troubles, such as depression, which were found to be relieved by smoking [20,49,53,65,66]. Many participants also tended to believe that smoking helped them manage diabetes (such as glycaemic

Table 1
Main characteristics and findings of the studies whose intervention was focused on smoking cessation.

Author/s (date)	Study design	Intervention's main characteristic/s	Control's main characteristic/s (if any)	Sample size, n	Follow-up period, months	Percentage followed up, %	Biochemically verified smoking cessation outcome at follow-up		Other key findings/ comments
							Intervention group, n (%)	Control group, n (%)	
[69] Albareda et al. (2009)	Prospective cohort study (PCS)	American Diabetes Association recommendations Tailored to the participants' stage of change Smoking cessation programme NRT accordingly.		156	12	90.4	65(46.1)*		19 participated in the programme
[21] Albaroodi et al. (2021)	Randomised controlled trial (RCT)	Counselling based on the 5 A's algorithm (Ask, Advise, Assess, Assist, Arrange)	Routine care	140	6	90	4	4	
[31] Ardron et al. (1988)	RCT	Brief advice Counselling	Brief advice	60	6	100	0	1	
[51] Bodmer et al. (1990)	PCS	Brief advice		43	3	84.2	6		
[32] Canga et al. (2000)	RCT	Counselling NRT accordingly	Usual care	280	6	99.3	25(17.0)	3(2.3)	25/105 accepted NRT
[33] Fowler et al. (1989)	RCT	Educational sessions using coloured photographs	Usual care	34	6	100			Three quit smoking. Drop-out rates (from the programme) were very high
[34] Hokanson et al. (2006)	RCT	Counselling based on motivational interviewing (MI) NRT or bupropion accordingly	Information about cessation programmes	114	6	63.2	6	6	Similar numbers in both groups utilised pharmacotherapy
[50] Ismail et al. (2000)	PCS	Brief advice		93	24	100	3		
[61] Katsaounou et al. (2019)	Pre-experimental study: one group, pre- and post-intervention (PES)	Smoking cessation programme Varenicline		17	3	100	12(70.5)		
[62] Korkontzelou et al. (2020)	PES	Smoking cessation programme Varenicline		41	3	100	25(61)		
[22,24] Lam et al./Li et al. (2017)	RCT	Counselling based on the 5 A's algorithm (and participants' stage of change)	Usual care	557	12	79.1	9(3.2)	14(5.1)	
[14] Nagrebetsky et al. (2014)	Systematic review and meta-analysis	Pharmacological or nonpharmacological intensive interventions	Less intensive interventions	872	6				Relative risk: 1.32, 95 % CI [0.23–7.43]; four trials
[38] NG et al. (2010)	Pilot RCT	Counselling session based on the 5As algorithm Control intervention	Brief advice using visuals of smoking-associated diabetic complications	71	6	78.9	14(36.8)*	10(30.3)*	A significant decrease in smoking prevalence in both groups
[40] Perez-Tortosa et al. (2015)	Cluster RCT	Counselling based on MI (and participants' stage of change) Pharmacotherapy	Usual care	948	12	76.2	67(17.8)	90(26.1)	
[59] Persson and Hjalmarson (2006)	Cluster non-randomised control trial	Group smoking cessation programme (group-based) based on MI Pharmacotherapy recommended	Letter	368	12	95.4	42(20)*	10(7)*	50/241 (patients within intervention centres) accepted to participate in the smoking cessation programme 29/211 (followed up participants from the intervention group) used pharmacotherapy but

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Table 1 (*continued*)

Author/s (date)	Study design	Intervention's main characteristic/s	Control's main characteristic/s (if any)	Sample size, n	Follow-up period, months	Percentage followed up, %	Biochemically verified smoking cessation outcome at follow-up		Other key findings/ comments
							Intervention group, n (%)	Control group, n (%)	
									use did not significantly affect abstinence.
[70] Persson et al. (2000)	PES	Smoking cessation programme (group-based) NRT		14	18		9(64)*		
[41] Sawicki et al. (1993)	RCT	Smoking cessation behavioural therapy programme NRT accordingly	Brief advice NRT accordingly	89	6	100	2	7	57 % participated in the programme
[63] Scemama et al. (2006)	PES	Counselling NRT prescription		38	9	7	1 *		16 (45.7 %) agreed to take NRT
[23,25,26] Thankappan et al. (2013) (2014)[28] Mini et al. (2015)[27] Nicther et al. (2017)	Pilot RCT with follow-up studies	Counselling based on the 5As algorithm Control intervention	Brief advice using visuals of smoking associated diabetic complications	224	6–24	87.5	58(51.8)*	14(12.5)*	Adjusted Odds Ratio: 3.35; 95 % CI [1.82–6.18] at 12 months (self-reported confirmed in 86 %) Five were abstinent from smoking at 24 months
[71] Tien and Tu (2016)	Cross-sectional study	Counselling based on the 5As algorithm		73	6		26(35.6)		

*self-reported data.

control, adherence to diet, or weight management) [53,56,57,65], thus making it difficult for them to stop. Attempts by participants to minimize the harmful effects of smoking by participants were also identified. Even though most participants knew that smoking was associated with health problems, they were not convinced that they were at a greater risk [31, 56,57,65]. Being advised by health professionals to quit smoking in view of the harmful effects of smoking when having diabetes failed to instil in some participants an urgency to decide to quit, undervaluing smoking cessation [31,56,65].

4. Discussion

As recommended in the literature [13], most research studies included in this review adopted an intensive approach for supporting smoking cessation, mainly by providing diabetes-specific stand-alone smoking cessation support, such as counselling, or diabetes management interventions, such as educational sessions which included smoking cessation. As was found in the systematic reviews by Nagrebetsky et al. [14], and Zhan et al. [15], the effect of these interventions on achieving smoking abstinence varied across the included studies. However, the present review found that stand-alone smoking cessation support, particularly behavioural support which included pharmacotherapy for smoking cessation, was more successful than interventions which included smoking cessation as part of a broader intervention for improving diabetes management.

Griffin et al.'s study [47], which assessed the impact of a broad intervention to address physical activity levels, dietary change, medication adherence and smoking cessation, found that having participants focus on various behaviours at once did not help them achieve the desired results. Furthermore, Rubak et al. [19], and Tranche et al. [67], found that when smoking cessation was included as part of routine clinical care, the smoking cessation intervention was not implemented systematically, thus undermining cessation efforts. Given the various behavioural changes required by most individuals with diabetes and the observed challenges and barriers to smoking cessation, it seems that having smoking cessation efforts as part of a broader approach to improve diabetes management may not be adequate to fully encourage and support smokers to quit smoking. It is however worth noting that several studies, which assessed such interventions, suffered from significant methodological limitations, such as few smokers within their sample, which could have affected statistical power. Hence, future research should carry out power calculations to ensure an adequate number of participating smokers for data analysis. This would provide a more valid picture of the effect of smoking cessation components, as part of broader interventions for diabetes management, such as diabetes management educational efforts.

While not all stand-alone smoking cessation interventions reported significant smoking cessation outcomes, the addition of pharmacotherapy to smoking cessation support was more likely to be associated with success. The use of pharmacotherapy for smoking cessation, which has been associated with increased smoking cessation success in the general smoking population [12], may be particularly useful for individuals with diabetes in light of the evidence which suggests that individuals with diabetes may have an increased nicotine addiction compared to other smokers [11], and in view of tobacco addiction being identified as a challenge by many of the participants of the included studies. Nonetheless, it is worth noting that in both Canga et al. [32] and Persson and Hjalmarson [59]'s studies, whose interventions were found to be effective, few participants utilised pharmacotherapy for smoking cessation. Furthermore, while acknowledging that the small number of participants who utilised pharmacotherapy may have limited the power to adequately compare the abstinence rates of those who used pharmacotherapy to those who did not, Persson and Hjalmarson [59] found that the smoking abstinence rates did not differ significantly between these groups. In view of these observations, further research is recommended to establish the significance of pharmacotherapy for smoking cessation amongst individuals with diabetes. Future research should also investigate the effect of pharmacotherapy (on smoking cessation) within diabetes management interventions, as none of the identified studies which included smoking cessation as part of a broader intervention for improving diabetes management included the use of pharmacotherapy.

Several challenges and barriers to quitting for individuals with diabetes were also identified in this review. While the commonly reported barriers, such as the smoking habit and addiction, and stress and other

Table 2
Main characteristics and findings of the studies whose smoking cessation intervention was part of a broader intervention for diabetes management.

Author/s (date)	Study design	Intervention's main characteristic/s	Control's main characteristic/s (if any)	Sample size, n (no. of smokers)	Follow-up period, months	Percentage followed up, %	Self-reported smoking cessation outcome at follow-up		Other key findings/ comments
							Intervention group, n (%)	Control group, n (%)	
[52] Bluml et al. (2014)	Pre-experimental study: one group, pre- and post-intervention	Educational consultations		1836 (270)	12	84.9	26(9.3)		
[44] Cohen et al. (2011)	Randomised controlled trial (RCT)	Group-based educational programme Education on tobacco cessation was based on the participants' stage of change	Standard care	99 (11)	6	97			Increase in smoking abstinence at follow-up was not significant
[73] Daly et al. (2017)	Systematic review (SR) and meta-analysis	Active nurse-led interventions	Usual care	(1890)	6				Relative Risk (RR): 6.65, 95 % CI [2.24–19.70]; two trials (biochemical verified)
[30] Davies et al. (2008),[29] Khunti et al. (2012)	Cluster RCT and follow-up study	Group-based educational programme	Usual care	824 (110)	12–36	68.2	25(43.9)	16(30.2)	Significant reduction in smoking prevalence not maintained at 36 months follow-up
[55] Ekong and Kavookjian (2016)	SR	Motivational Interviewing (MI) based interventions	Usual care (non-MI interventions)	(994)	6–16				No significant differences in smoking abstinence rates were observed (three trials)
[47] Griffin et al. (2014)	RCT	Behaviour change educational intervention Control intervention	Nurse-led intensive interventions in routine care	478 (65)	12	92.9	0	5*	
[35] Jones et al. (2003)	RCT	Health coaching (based on the participants' stage of change)	Physician visits and/or diabetes education	1029 (148)	12		39(23.3)	19(11.6)	Difference in smoking abstinence not significant
[36] Kirkman et al. (1994)	RCT	Health coaching	Usual care	275 (65)	12		4*	0	
[37] McDermott et al. (2015)	Cluster RCT	Home visits Out-of-clinic care	Waiting list	213 (72)	18	89.7	0	5	
[60] McGloin et al. (2015)	Longitudinal mixed-method case study design	Health coaching based on MI (based on the participants' stage of change)		10 (3)	12	80	1		
[54] Nkansah et al. (2008)	Retrospective time-series study	Educational consultations		77 (7)	6		0		
[48] Ramallo-Fariña et al. (2021)	Cluster RCT	Three arm: educational programme for patients (PTI), providers (PFI), or both (CBI)	Usual care	2334 (524)	24		PTI-47(41.5) CBI-46(42.3) PFI-37(23.4)	31(21.2)	Significant differences in smoking abstinence for PTI or CBI versus control ($p = 0.012$)
[72] Register et al. (2016)	SR	Pharmacists/ podiatrists/ optometrists/ dentists-led intensive smoking cessation	Usual care	(1124)	4–18				A significant decrease in smoking prevalence was only observed in one out of six studies
[18] Rubak et al. (2009)	Cluster RCT	MI in clinical practice	Usual care	265	12	88.3			Increase in abstinence at

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Table 2 (*continued*)

Author/s (date)	Study design	Intervention's main characteristic/s	Control's main characteristic/s (if any)	Sample size, n (no. of smokers)	Follow-up period, months	Percentage followed up, %	Self-reported smoking cessation outcome at follow-up		Other key findings/ comments
							Intervention group, n (%)	Control group, n (%)	
[19] Rubak et al. (2011)	Cluster RCT	MI in clinical practice	Usual care	628 (82)	12	88.6			follow-up was not significant Increase in abstinence at follow-up was not significant The intervention was not implemented systematically
[42] Smith et al. (2011)	Cluster RCT	Peer support group sessions Control intervention	Introduction of a diabetes care system	395 (71)	24	85	6(19.4)	11(28.0)	4/29 peer supporters were smokers
[43] Taveira et al. (2010)	RCT	Group-based educational programme Education on tobacco cessation was based on the participants' stage of change	Standard care	109 (27)	4	92.4	3	0	
[45] Toobert et al. (2011)	RCT	Group-based educational programme	Usual care	280 (30)	12	63.5	0	1	
[67] Tranche et al. (2005)	Prospective multicentre cohort study	Smoking cessation in clinical practice		3466 (596)	12	68.6	24(4)		The intervention was not implemented systematically
[64] Tricco et al. (2012)	SR and meta-analysis	Quality Improvement initiatives (e.g., counselling)	Usual care	(3231)	12				Non-significant reduction in smoking prevalence (RR:1.13, 95 % CI [0.99–1.29]; 13 trials)
[39] Ukoha-Kalu, et al. (2021)	RCT	Group-based educational programme	No intervention	284 (37)	9	72.9	11(69.0)	7(33.3)	
[46] Yasmin et al. (2020)	RCT	Health coaching	Usual care	319 (11)	12	85.3	2	4	
[15] Zhan et al. (2016)	SR and meta-analysis	Psychological smoking cessation interventions	Usual care	(2089)	1–12				At three months RR: 2.52, 95 % CI [1.32–4.80]; four trials Not significant at longer follow-up periods

*biochemically verified.

troubles, have also been identified in the literature carried out amongst the general smoking population [75], this review identified additional diabetes-specific challenges to quitting, calling once again for a focused approach for supporting individuals living with diabetes to quit smoking. Several misconceptions about smoking, smoking cessation, and diabetes management, and attempts to minimize the harmful effects of smoking were reported by the studies' participants. These findings emphasize the need to inform smokers with diabetes about the link between tobacco use and diabetes complications. However, given that being advised by health professionals to quit smoking failed to instil in some participants an urgency to quit, the use of more influential methods to communicate tobacco harm may be required. Given that in some studies participants were unconvinced about the risks of smoking on diabetes, the use of stronger warnings based on real experiences should be considered as a strategy to motivate further smokers with diabetes to quit smoking.

Unlike previous reviews [14,15], this review conducted a comprehensive search and analysis of the literature on the subject matter, for identifying the most promising smoking cessation interventions for individuals with diabetes. The literature on stand-alone smoking cessation interventions were compared to literature on diabetes management interventions which included a smoking cessation component. Furthermore, the most common barriers and challenges experienced by individuals with diabetes in quitting smoking were taken into consideration in identifying the most promising smoking cessation interventions.

This review is however not conclusive as the findings are based on a wide array of literature (including non-experimental studies), some of which suffered from significant methodological limitations. Therefore, more research is required, particularly on the effect of behavioural support smoking cessation interventions which utilise pharmacotherapy amongst individuals with diabetes.

Table 3
Main characteristics and findings of the studies which explored barriers and/or challenges to quitting.

Author/s (date)	Study design	Method	Sample size, n	Identified challenges/barriers
[49] Abu Ghazaleh et al. (2018)	Qualitative descriptive study	Interviews on experiences and beliefs about smoking and quitting	12	Smoking habit and addiction; lack of will-power and social support; smoking as a stress/emotional coping mechanism; adverse effects when using NRTs
[20] Albaroodi et al. (2018)	Randomised controlled trial (RCT)	Questionnaires on factors affecting smoking cessation pre- and post-intervention	140	Pre-intervention: Smoking habit (n = 82, 58.6 %); stress (n = 22, 15.7 %) Post-intervention: Smoking habit (n = 74, 58.7 %); stress (n = 24, 19.0 %)
[31] Ardron et al. (1988)	RCT	Reported reasons for continuing smoking following an intervention	60	Cravings (n = 31, 51.7 %); unconvinced by the health hazards (n = 13, 21.7 %); too restricted by the diabetic treatment regime (n = 10, 16.7 %)
[51] Bodmer et al. (1990)	Prospective cohort study	Reported reasons for continuing smoking following an intervention	25	Lack of will-power; like smoking too much
[56] Chau et al. (2015)	Qualitative descriptive study	Focus groups and interviews on perceptions about quitting	42 *	Lack of will-power; psychological addiction; weight gain after quitting; smoking peers; misconceptions about smoking and diabetes management; minimisation of the harmful effects of smoking
[57] Georges et al. (2019)	Qualitative descriptive study	Focus groups and interviews on needs and beliefs towards quitting	21	Smoking addiction and habit; peers/partners who smoke; misconceptions about smoking and diabetes management; minimisation of the harmful effects of smoking
[53] Haire-Joshu et al. (1994)	Cross-sectional study	Questionnaire on beliefs about smoking and diabetes	64	Weight gain after quitting (n = 31, 49 %); too restricted by the diabetic treatment regime (n = 27, 42 %); misconceptions about smoking and diabetes management
[58] Javelot et al. (2009)	Case report	Reported the glycaemic imbalance of a patient who took NRT	1	Hyper and hypoglycaemia on taking nicotine lozenges and patches
[68] Kristensen et al. (2008)	Case report	Reported the glycaemic imbalance of a patient who took varenicline	1	Hypoglycaemia on taking varenicline
[74] Mishu et al. (2021)	Cross-sectional study	Interviews on barriers to implementing a tobacco cessation intervention	15	Lack of knowledge on the effects of tobacco use; tobacco addiction; disinterest; lack of time
[65] Wakefield et al. (1997)	Qualitative descriptive study	Focus groups on beliefs about smoking and diabetes and barriers to quitting	18	Smoking to cope with stress/manage nicotine withdrawal; little social support; misconceptions about smoking and diabetes management
[66] Wakefield et al. (1998)	Cross-sectional study	Questionnaire on smoking and barriers to quitting	54	Having too many stressful things happening (n = 16, 30 %); gaining weight/glycaemic imbalance on quitting (n = 16, 30 %); having already given up on several things due to diabetes (n = 14, 26 %).

*included also former smokers

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Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Appendix A. Supporting information

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Appendix 9.2: The systematic review

Review Paper

Tobacco Induced Diseases

Effectiveness of intensive stand-alone smoking cessation interventions for individuals with diabetes: A systematic review and intervention component analysis

Joseph Grech[1], Ian J. Norman[2], Roberta Sammut[1]

ABSTRACT

INTRODUCTION Tobacco smoking poses a significant threat to the health of individuals living with diabetes. Intensive stand-alone smoking cessation interventions, such as multiple or long (>20 minutes) behavioral support sessions focused solely on smoking cessation, with or without the use of pharmacotherapy, increase abstinence when compared to brief advice or usual care in the general population. However, there is limited evidence so far for recommending the use of such interventions amongst individuals with diabetes. This study aimed to assess the effectiveness of intensive stand-alone smoking cessation interventions for individuals living with diabetes and to identify their critical features.

METHODS A systematic review design with the addition of a pragmatic intervention component analysis using narrative methods was adopted. The key terms 'diabetes mellitus' and 'smoking cessation' and their synonyms were searched in 15 databases in May 2022. Randomized controlled trials which assessed the effectiveness of intensive stand-alone smoking cessation interventions by comparing them to controls, specifically amongst individuals with diabetes, were included.

RESULTS A total of 15 articles met the inclusion criteria. Generally, the identified studies reported on the delivery of a multi-component behavioral support smoking cessation intervention for individuals with type I and type II diabetes, providing biochemically verified smoking abstinence rates at follow-up at six months. The overall risk-of-bias of most studies was judged to be of some concern. Despite observing inconsistent findings across the identified studies, interventions consisting of three to four sessions, lasting more than 20 min each, were found to be more likely to be associated with smoking cessation success. The additional use of visual aids depicting diabetes-related complications may also be useful.

CONCLUSIONS This review provides evidence-based smoking cessation recommendations for use by individuals with diabetes. Nonetheless, given that the findings of some studies were found to be possibly at risk-of-bias, further research to establish the validity of the provided recommendations is suggested.

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INTRODUCTION

Diabetes mellitus is a major public health concern. Diabetes mellitus, which is characterized by chronic high levels of blood glucose, can lead to the development of various macro- and micro-vascular complications, increasing the

risk of morbidity and even death[1]. It is estimated that diabetes affects 537 million adults aged 20–79 years worldwide[1]. Tobacco smoking is another major public health problem. While it is well known that tobacco smoking is associated with increased morbidity and mortality in the general population[2], leading to 8.7 million deaths each year[3], increasing evidence demonstrates the increased risk of complications and mortality for those who have diabetes and smoke. When compared to non-smokers living with diabetes, both individuals with type I and type II diabetes have been found to have an increased risk for coronary heart disease, myocardial infarction, and stroke, of 54%, 52% and 44%, respectively[4]. A higher risk for cardiovascular mortality and for total mortality for individuals with diabetes who smoke, has also been identified[4]. Tobacco use may also increase the risk of microvascular diabetes complications. While there is insufficient evidence to demonstrate the influence of tobacco use on the development of retinopathy and neuropathy[5], evidence has shown that smoking increases the risk of diabetic nephropathy amongst both individuals with type I and type II diabetes[6]. Both individuals with type I and type II diabetes who smoke also seem to have poorer cardiometabolic profiles. Non-smokers have been found to have a significant lower HbA1c (a mean difference in HbA1c of -0.61%) and a more favorable lipid profile (an HDL-cholesterol difference of 0.12 mmol/L and an LDL-cholesterol difference of -0.11mmol/L) when compared to smokers.[7]

Smoking cessation, being associated with a significant risk reduction for coronary heart disease[4,8], and for mortality from cardiovascular disease and total mortality[4], and better cardiometabolic profiles amongst individuals with diabetes[7], has been recommended as an essential component of diabetes management. Smoking cessation support, however, can range from a one-off episode of brief tobacco cessation advice or counselling session from a healthcare professional lasting ≤20 min, to more intensive approaches involving multiple and/or longer counselling sessions, with or without additional components, such as the use of pharmacotherapy for smoking cessation (e.g. nicotine replacement therapy NRT, varenicline or buproprion)[9]. Intensive smoking cessation interventions, such as, behavioral support (e.g. counselling) lasting more than >20 min[10], or interventions that combine behavioral support and pharmacotherapy[11], or interventions with two or more interacting components, such as multiple long (>20 min) counselling sessions with the addition of pharmacotherapy[12], have been found to increase smoking cessation success when compared to brief advice or usual care in the general population. Nonetheless, there is limited evidence so far for recommending the use of such intensive interventions amongst individuals with diabetes.

The systematic review and meta-analysis by Nagrebetsky et al.[13], which compared the effectiveness of intensive stand-alone smoking cessation interventions (i.e. pharmacological and/or non-pharmacological intensive behavioral interventions for smoking cessation which were not part of broader interventions for improving diabetes management) to less intensive interventions (such as usual care or brief smoking cessation advice) for individuals living with diabetes, found no evidence calling for the use of intensive smoking cessation interventions. When compared to less intensive interventions, intensive smoking cessation only resulted in a non-significant increase in biochemically verified smoking abstinence at follow-up at 6 months (RR=1.32; 95% CI: 0.23–7.43)[13]. On the other hand, Zhan et al.[14] who assessed the effectiveness of psychological interventions for smoking cessation (including both behavioral-based stand-alone smoking cessation interventions or interventions in which smoking cessation was part of a broader intervention for improving diabetes management in their review) comparing these to usual care, found that psychological interventions were more effective in achieving abstinence (RR=2.52; 95% CI: 1.32–4.80). However, the positive observed effect, which was based solely on self-reported data, lasted only up to the follow-up at 3 months[14]. Notwithstanding these inconsistencies, it is worth noting that both reviews suffered from substantial heterogeneity: I^2=76%[13] and I^2=69%[14], warranting caution in the interpretation of findings and application to clinical practice.

In view of uncertainty about the efficacy of smoking cessation interventions for individuals living with diabetes, a scoping review was recently undertaken to identify the most promising smoking cessation methods amongst such individuals, factoring in the diabetes challenges and barriers to quitting[15]. Grech

et al.[15] mapped the literature on the smoking cessation interventions carried out amongst individuals living with diabetes (including both stand-alone smoking cessation interventions and interventions in which smoking cessation was part of a broader intervention for improving diabetes management) and on the challenges and barriers to smoking cessation that were identified amongst such individuals. Stand-alone smoking cessation interventions were identified as more successful in achieving tobacco abstinence than interventions which included smoking cessation as part of a broader intervention for improving diabetes management[15]. However, given the nature of the review, no specific recommendations as regards the behavioral support methods to use, their intensity (the number of sessions and their duration), and on the use of additional components (apart from suggesting the use of pharmacotherapy for smoking cessation), could be provided[15], limiting application to clinical practice.

Given the potential of stand-alone smoking cessation interventions in achieving tobacco abstinence amongst individuals with diabetes, an update to the systematic review by Nagrebetsky et al.[13] was conducted. This review aimed to assess the effectiveness of intensive stand-alone smoking cessation interventions amongst individuals living with diabetes mellitus, and to identify the critical features of the successful interventions.

METHODS

Study design

A systematic review of effectiveness, being regarded as the gold standard for identifying evidence-based practice[16], was best suited for this review. Given that the review also aimed to identify the critical features of the successful interventions, it also included an intervention component-level analysis (ICA) as outlined by Sutcliffe et al.[17]. The ICA by Sutcliffe et al.[17] is a pragmatic but formal and rigorous approach for analyzing the characteristics of the studied interventions, which may be associated with successful outcomes. This method has been particularly recommended when the studies' interventions differ from one another, which limits the ability to explore meaningful numbers of mediators and moderators of intervention effect through other formal methods of analysis and synthesis[17]. In view of the significant diversity in the interventions utilized by the study authors (as remarked below), the ICA by Sutcliffe et al.[17] was found to best suited for this review to provide more information about the critical features of the successful interventions for providing practice recommendations. This review is presented in compliance with the Preferred Reporting Items for Systematic Reviews and Meta-Analysis PRISMA statement (Supplementary file Table 1).

Inclusion and exclusion criteria

The studies included in this review had to assess the effectiveness of intensive stand-alone smoking cessation interventions by comparing them to a less intensive intervention, such as brief tobacco cessation advice or usual care, specifically amongst individuals with diabetes. Intensive stand-alone interventions included pharmacological and/or non-pharmacological behavioral interventions for smoking cessation, which were not part of broader interventions for improving diabetes management, consisting of multiple and/or long (>20 min) smoking cessation support sessions). Studies in which the experimental smoking cessation intervention was part of a more extensive intervention for diabetes management, such as a lifestyle management intervention for improving diabetes, were thus considered ineligible. The studies included in this review had to include individuals living with (diagnosed) diabetes mellitus as their study population. Studies in which the participants had pre-diabetes or gestational diabetes were deemed ineligible. Furthermore, studies in which only a proportion of the participants had diabetes or reports of studies which were not specific to individuals with diabetes were also excluded. Only published articles, or unpublished reports, of randomized controlled trials were considered in this review. Non-randomized trials were deemed ineligible as these tend to produce higher effect estimates of the studied intervention when compared to randomized trials[18]. Systematic reviews were also not included. This is because none of the identified reviews[13-15] provided sufficient detail on the critical features of the successful interventions. No language or time limiters were set. The minimum requirement for non-English trials was that the title and/or abstract had to be available in English within the identified (below) bibliographic databases.

Search strategy

The search was carried out on the 28 May 2022 from inception using the following electronic literature databases: APA PsycInfo, CINAHL Complete, Cochrane Central Register of Controlled Trials, Cochrane Clinical Answers, Cochrane Database of Systematic Reviews, Cochrane Methodology Register, MEDLINE Complete, ProQuest Dissertations & Theses A&I, Public Health Database, PubMed, Scopus, System for Information on Grey Literature in Europe, and all the databases on Web of Science. Based on the review objective, the main keywords, 'diabetes mellitus' and 'smoking cessation' and their synonyms (Supplementary file Table 2), were combined using the Boolean operators 'AND' and 'OR', and searched in titles, abstracts, and subject headings/medical subject headings accordingly. The search strategy used for searching in Web of Science is outlined in Supplementary file Table 3.

Study selection

After carrying out the search, the identified records were collated on Mendeley® for de-duplication. The remaining records were screened by reading titles and abstracts. Potentially relevant articles were then read and assessed for eligibility basing decisions on the inclusion and exclusion criteria. The reference lists of these studies and those of the identified reviews[13-15] were also examined for the identification of other possible suitable studies for inclusion in this systematic review.

Data extraction

The following information was extracted from all the identified studies: authors; year of study; location; study duration; detailed information on the experimental smoking cessation intervention, its components and the control intervention; study sample; percentage followed up; smoking cessation outcome, time-points and reporting methods; information about the researchers' reflections and accounts of their experience in evaluating the intervention for conducting the ICA as per Sutcliffe et al.[17]; and other relevant observations. Furthermore, the information required to assess risk-of-bias (as outlined in the Cochrane risk-of-bias tool, RoB 2)[19] for each of the identified studies, was also extracted.

Quality assessment

In this review, the RoB 2 for randomized parallel-group trials and the RoB 2 tool specific to cluster-randomized trials were utilized. Studies found to be at high risk-of-bias were not excluded from the review or from the analysis. As recommended by Higgins et al.[20], the information obtained in carrying out the risk-of-bias assessment was presented as part of the review's findings and was also considered in the analysis and conclusions of the review. The *robvis* tool[21] was used to visualize the risk-of-bias assessments.

Synthesis of results

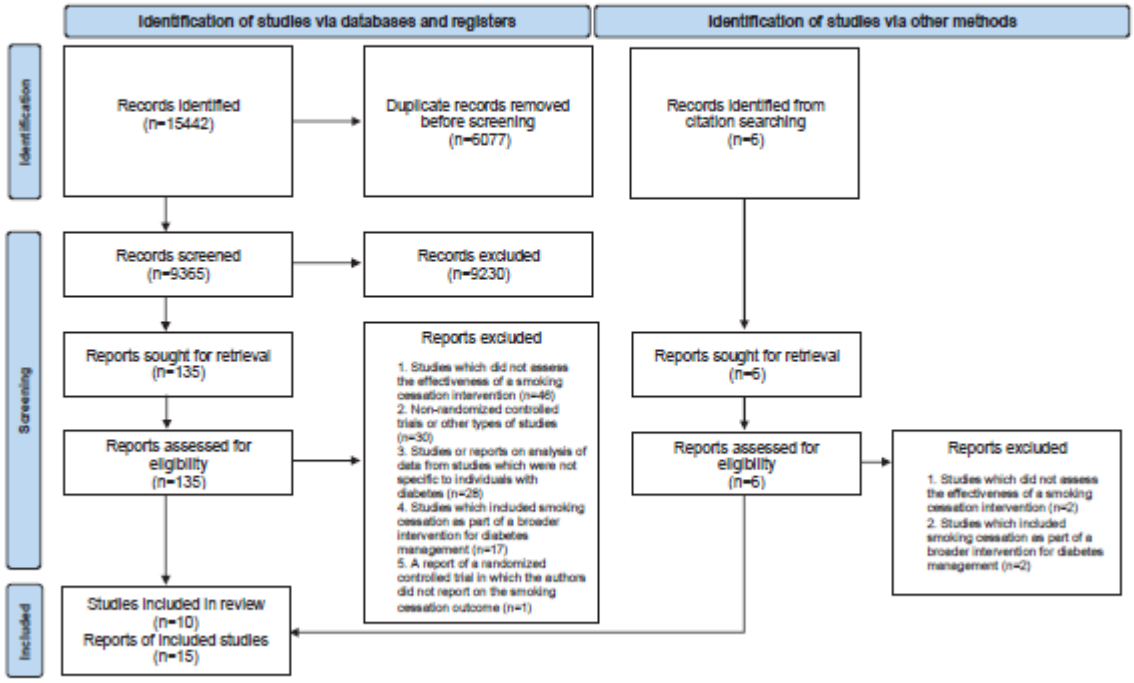
A meta-analysis of effect estimates was initially the preferred method of synthesis. However, given the significant diversity in the interventions (both experimental and control interventions) utilized by the study authors, and the incomplete reporting of outcomes/effect estimates in some of the identified studies[22-25], this was not recommended[18,26]. Thus, following data extraction and charting of data in table format, a narrative approach using vote counting based on the direction of effect[18], was adopted to analyze the results. In essence, the studies showing a statistically significant increase in smoking abstinence were compared to the studies which did not. Additionally, a narrative component analysis, in which the interventions' critical features were identified by following the method outlined by Sutcliffe et al.[17], followed. This included the mapping of the characteristics of the interventions, taking into consideration the effectiveness of the interventions for establishing the components which appeared to be of significance, and the coding of informal data on the researchers' reflections in evaluating the intervention (using inductive thematic analysis), to help understand the association between the identified characteristics and the studies outcomes.

RESULTS

Search results

The PRISMA 2020 flow diagram[27] was utilized to outline the selection process, providing details on the exclusion reasons at the full-text level of screening (Figure 1). A total of 15442 records were retrieved of which 6007 were found to be duplicates. After removing duplicates, 9365 were screened by reading titles and abstracts. A total of 135 reports

Figure 1. PRISMA flow diagram



were found to be possibly relevant and were screened at full-text level. On matching these publications to the inclusion criteria, 122 reports were found to be ineligible as they did not report on the effectiveness of stand-alone smoking cessation interventions for individuals with diabetes from randomized controlled trials. Conversely, 13 reports were deemed eligible. An additional six reports, which were obtained from citation searching, were assessed for eligibility. Two reports were found to be eligible and were included. This led to a final selection of 15 reports.

Some of the identified articles reported the same study, resulting in a smaller number of studies. Both Lam et al.[28] and Thankappan et al.[29] published the findings from the randomized control trials by Li et al.[30] and Thankappan et al.[31], respectively, in conference proceedings. Furthermore, in the publications by Thankappan et al.[25] and Nichter et al.[24], the authors followed up participants from the Thankappan et al.[31] trial for a total of one and two years, respectively, without providing any additional interventions. Additionally, Mini et al.[23] reported on the biochemical verification of a sample of non-smokers who participated in the Thankappan et al.[31] trail at follow-up at 1 year, in their publication. Thus, the total number of studies included was 10.

Characteristics of the selected studies and relevant findings

The characteristics and the relevant findings of the identified studies are outlined in Table 1. Except for the study by Pérez-Tortosa et al.[32], who reported the findings from a cluster randomized parallel-group trial, all the remaining publications reported the findings from individually randomized parallel-group trials. All studies were published in journals except for the study by Albaroodi et al.[33] which was available as a preprint.

Most studies included individuals with both type I and type II diabetes as study participants[33-36], who were mostly men[30-33,35-38], and in their fifties[30-32,35,37,38]. Sample sizes varied across the studies; from n=34[22] to n=948[32]; however, only three studies[30,32,35] reported *a priori* power calculations to detect a significance in smoking cessation outcome.

Most authors based their intervention on the 5As algorithm (Ask, Advise, Assess, Assist

Table 1. Characteristics of the identified trials and the reported smoking cessation outcome at six months and other relevant findings

Authors Date	Country	Sample characteristics[a]	Experimental intervention	Control intervention	Study setting Provider	Follow-up period (months)	Percentage followed up	Biochemically verified smoking abstinence at follow-up at 6 months		Other relevant findings/ comments
								Intervention n (%)	Control n (%)	
Albaroodi et al.[33] 2021	Malaysia	n=140 T1DM=13 T2DM=35 unknown=78 mean age: 47.6±13.6 years 95.2% male participants	Three (5-min) counselling sessions based on the 5As algorithm over three to four months	Routine care	Diabetes clinic Physicians and nurses	6	90	4	4	Preprint – not peer reviewed.
Ardron et al.[34] 1988	England	n=60 T1DM=50 T2DM=10 mean age: 29.1±7.4 years 48.3% male participants	Brief advice (5-min) Counselling (lengthier session) Smoking cessation leaflet Home visit within two weeks	Brief advice	Diabetes clinic Medical registrar and diabetes home visitor	6	100	0	1	
Canga et al.[35] 2000	Spain	n=280 T1DM=85 T2DM=195 mean age: 55±15.0 years 86.0% male participants	Counselling session (40-min) Self-help written material Five follow-up contacts (a letter, a phone call or a visit) NRT accordingly	Usual care	Primary care centers and hospitals Nurse	6	99.3	25 (17.0)	3 (2.3)	
Fowler et al.[22] 1989	England	n=34 T1DM=12 T2DM=22 mean age of newly diagnosed (ND) patients: 47±9.0 years Those with pre-existing (PE) diabetes: 53±13.0 years	Intervention for ND patients and those with PE diabetes: Four (30-min) educational visits over six months Use of visual aids of diabetic related complications	Intervention for ND patients: usual care with late access to the intervention. Intervention for patients with PE diabetes: counselling sessions	Diabetes clinic Health professionals	6	100			It is not known in which group the smokers who quit smoking (n=3) pertained. Drop-outs from the program were high.

Continued

Table 1. Continued

Authors Date	Country	Sample characteristics[a]	Experimental intervention	Control intervention	Study setting Provider	Follow-up period (months)	Percentage followed up	Biochemically verified smoking abstinence at follow-up at 6 months		Other relevant findings/ comments
								Intervention n (%)	Control n (%)	
Hokanson et al.[37] 2006	United States	n=114 (T2DM) mean age: 54±9.0 years 57.0% male participants	Counselling based on motivational interviewing (MI) – initial 20 minutes session and three to six 10-min telephone sessions NRT or bupropion accordingly	Information about cessation programs	Diabetes center Nurse	6	63.2	6 (16)	6 (17)	
Lam et al.[28] 2017 Li et al.[30] 2017	China	n=557 (T2DM) mean age: 56±11.4 years 88.3% male participants	A 20-min counselling session based on the 5As algorithm and tailored to the participants' stage of change Booster sessions at one week and one month Self-help smoking cessation leaflet Diabetes specific smoking cessation leaflet	Usual care Brief smoking cessation advice Self-help smoking cessation leaflet	Diabetic clinics Nurse counsellor	12	79.1	38 (13.4)[b]	39 (14.2)[b]	At follow-up at 12 months, 9 (3.2%) vs 14 (5.1%) participants from the intervention and control group, respectively, were abstinent from smoking (biochemically verified; p=0.25).
Ng et al.[38] 2010	Indonesia	n=71 (T2DM) mean age: 56±9.0 years 100% male participants	Counselling session (30-min) based on the 5As algorithm Control intervention	Brief advice using visual aids of smoking associated diabetic complications Educational materials on the smoking associated diabetic harm	Diabetic clinics and smoking cessation clinic Doctor and counsellor	6	78.9	14 (36.8)[b]	10 (30.3)[b]	A significant decrease in smoking prevalence in both groups.

Continued

Table 1. Continued

Authors Date	Country	Sample characteristics[a]	Experimental intervention	Control intervention	Study setting Provider	Follow-up period (months)	Percentage followed up	Biochemically verified smoking abstinence at follow-up at 6 months		Other relevant findings/ comments
								Intervention n (%)	Control n (%)	
Pérez-Tortosa et al.[32] 2015	Spain	n=948 (T1DM and T2DM) mean age: 59.7±11.3 years 75.7% male participants	Counselling sessions based on MI and participants' stage of change (median – four 22.1-min visits) Pharmacotherapy	Usual care	Primary care practices GPs and nurses	12	76.2			At follow-up at12 months, 67 (17.8%) vs 90 (26.1%) participants from the control and intervention group, respectively, were found to be abstinent from smoking (biochemically verified; p=0.007).
Sawicki et al.[36] 1993	Ireland	n=89 T1DM=72 T2DM=17 mean age: 38±12.0 years 61% male participants	Ten weekly (90-min) behavioral support sessions NRT accordingly	Brief advice NRT accordingly	Diabetes clinic Psychotherapist	6	100	2	7	Only 25 (57%) attended the support sessions.
Thankappan et al.[25,29,31] 2013, 2014 Mini et al.[23] 2015 Nichter et al.[24] 2018	India	n=224 mean age: 53 years 100% male participants	Three counselling sessions (30-min each) based on the 5As algorithm at baseline, at one month and at three months Control intervention	Brief advice using visual aids of smoking-associated diabetic complications Educational materials on the smoking-associated diabetic harm	Diabetic clinics Doctor and counsellor	6–24	87.5	58 (51.8)[b]	14 (12.5)[b]	Adjusted odds ratio at 6 months: (AOR=8.4; 95% CI: 4.1–17.1) at 12 months: (AOR=3.35; 95% CI:1.82–6.18) (self-reported data were confirmed in 86%) at 24 months: only five were abstinent.

a T1DM: type I diabetes. T2DM: type II diabetes. b Self-reported data. MI: motivational interviewing. GPs: general practitioners.

and Arrange)[30,31,33,38], followed by motivational interviewing[32,37]; however, the frequency and the number of sessions provided, and their duration greatly varied across the studies. In two studies[30,32], the authors also took into consideration the participants' current stage of behavior as per the trans-theoretical model of change[39] when delivering the intervention. Additionally in four of the identified studies[32,35-37], NRT or buproprion were provided depending on the set eligibility criteria. Information material, such as general or diabetes-specific smoking cessation leaflets were also provided in four studies[30,31,34,38], while in the studies of Fowler et al.[22], Ng et al.[38] and Thankappan et al.[31], visual aids of diabetes-related complications were also utilized. The identified interventions were mostly delivered by nurses[30,32,33,35,37], and doctors[31-34,38], and delivered in diabetes centers/clinics[22,30,31,33,36-38].

As seen in Table 2, in most studies the authors assessed the impact of the studied intervention on smoking cessation for up to 6 months. Smoking abstinence was usually defined as a 7-day point prevalence abstinence[25,30,31,37,38], and biochemically verified (at the end of the study) by measuring exhaled carbon monoxide[30,32-34], and/or cotinine in saliva, urine or blood plasma[22,30,34-37].

Assessment for risk-of-bias

A risk-of-bias assessment was carried out on the endpoint reported smoking cessation outcome of each publication. Risk-of-bias assessments were carried out by following the guide by Higgins et al.[20]. The assessments using RoB 2 are shown in Figure 2, while the risk-of-bias assessment using the RoB 2 tool for cluster-randomized trials is shown in Figure 3. Given that all studies were judged to be of concern of risk-of-bias in at least one domain, the overall risk-of-bias of most studies was also judged to be of some concern. Conversely, the overall risk-of-bias of the reports by Ng et al.[38], Thankappan et al.[25,31] and Nichter et al.[24] was judged 'high', as these were found to be at high risk-of-bias in the measurement of the smoking cessation outcome, being based on self-reported data.

Table 2. Main components of the smoking cessation interventions of the included studies

Study (studies with non-significant findings in italics)	*Length of session*		*Number of sessions provided*			*Additional information on tobacco-associated diabetic complications*		*Provision of pharmaco-therapy*	*General stop-smoking informational material*
	≤20 min	*>20 min*	*1–2*	*3–4*	*≥5*	*Visual aids*	*Leaflets*		
Intervention based on the 5As framework									
Albaroodi et al.[33] (2021)	√			√					
Li et al.[30] (2017)	√			√			√		√
Ng et al.[38] (2010)[a,b]		√	√			√	√		
Thankappan et al.[31] (2013)[a]		√		√		√	√		
Intervention based on motivational interviewing									
Hokanson et al.[37] (2006)	√			√				√	
Pérez-Tortosa et al.[32] (2015)		√		√				√	
Intervention not based on a specific framework									
Ardron et al.[34] (1988)[a]		√	√						√
Canga et al.[35] (2000)		√		√				√	√
Fowler et al.[22] (1989)		√		√		√			
Sawicki et al.[36] (1993)		√			√			√	

a Included brief smoking cessation advice prior to the intensive session(s). b Observed a significant decrease in the self-reported smoking prevalence in both groups.

Figure 2. Summary of risk-of-bias assessments performed using the RoB 2 for randomized parallel-group trials

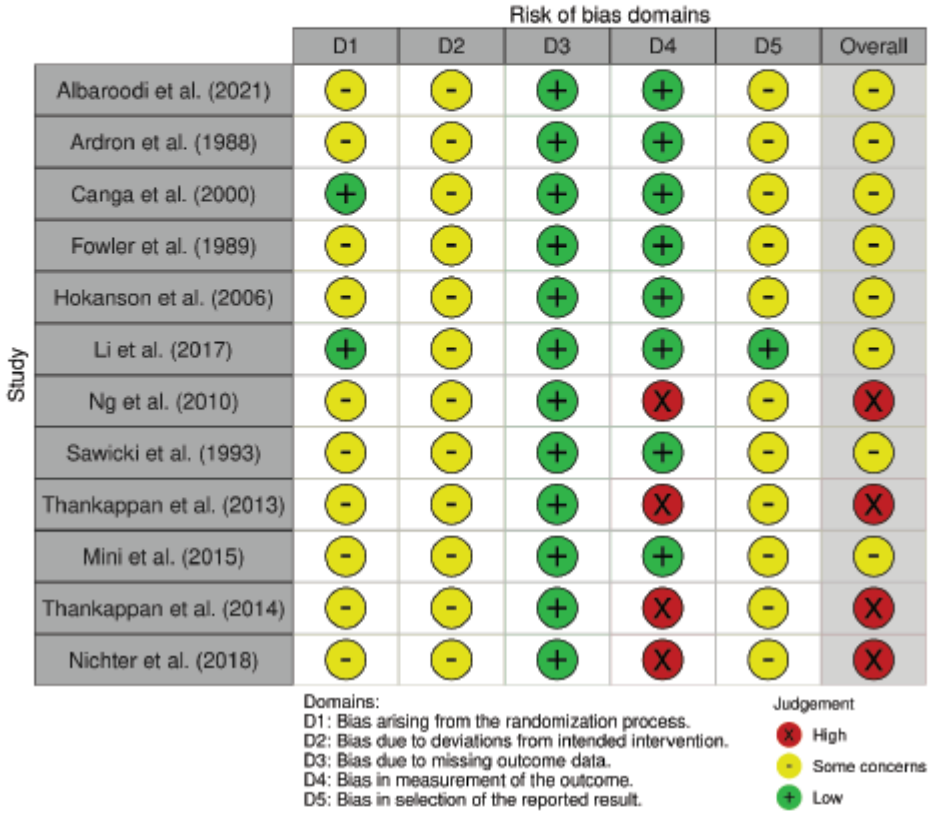
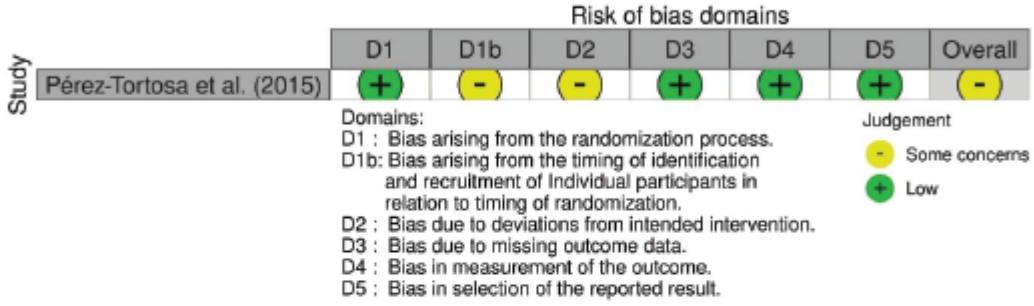


Figure 3. Summary of risk-of-bias assessment performed using the RoB 2 for cluster-randomized trials



Narrative analysis of the findings of the studies

As outlined in Table 1, significant differences in smoking cessation between the intervention and control group were only reported in the studies by Canga et al.[35] and Thankappan et al.[31] at follow-up at 6 months, and in the studies by Pérez-Tortosa et al.[32] and Thankappan et al.[25] at follow-up at 1 year. Conversely, the other study authors[22,24,30,33,34,36-38] did not report a significant improvement in the smoking cessation rate of the intervention group when compared to the control group; and although Ng et al.[38] reported a significant decrease in the self-reported smoking prevalence in both groups at follow-up at 6 months, in these studies the smoking abstinence rate

in both the intervention and control group was also deemed to be insignificant. Given these inconsistent findings, and taking into consideration the high level of heterogeneity amongst the interventions of the studies, a narrative component analysis was conducted.

Narrative component analysis

Guided by Sutcliffe et al.[17], the main features of the interventions were mapped out at the following levels: the framework/behavioral support method on which the intervention was based; its intensity, the length of each session and the number of sessions provided; the provision of additional information about tobacco associated diabetic complications, using visual aids or leaflets; the provision of pharmacotherapy; and the provision of general stop-smoking information material. Given that in most studies[22,31-34,38] two or more health professionals were involved in delivering the intervention, the interventions of the studies were not mapped at the provider level. However, the health professionals involved in providing the successful features of the interventions were then identified. Table 2 maps out the characteristics of the interventions of each study based on these categories.

It appears that intensive smoking cessation interventions may enhance smoking cessation success. Canga et al.[35], Thankappan et al.[31] and Pérez-Tortosa et al.[32], who provided 3–4 sessions of duration >20 min for their study participants, found that more smokers in the intervention group quit smoking when compared to those in the control group. Conversely, in the other studies, in which a non-significant smoking cessation outcome was reported, the experimental intervention was brief ≤20 min[30,33,37] or consisted of only one or two lengthier sessions in total[34,38]. While for the studies of Fowler et al.[22] and Sawicki et al.[36], whose experimental intervention was of an intensive nature, reported a non-significant outcome, it is worth noting that few participants adhered to the study protocol, possibly undermining the intervention's effectiveness. Trained nurses[32,35], doctors[32] and counsellors/diabetes educators[31] provided the lengthier sessions as part of the successful smoking cessation interventions.

The provision of frequent smoking cessation support also seems to have been beneficial. In the studies of Canga et al.[35] and Pérez-Tortosa et al.[32], smokers who were ready to quit were provided with frequent smoking cessation support (follow-up appointments at 1 to 2 weeks). Given that the frequency of the sessions varied across the identified studies, it is, however, difficult to establish the ideal total duration of the studied interventions in terms of months.

There is, however, not enough evidence to recommend the use of a specific framework/method for smoking cessation. While both Ng et al.[38] and Thankappan et al.[31], who based their intervention on the 5As framework, reported a significant decrease in smoking prevalence in their studies, Albaroodi et al.[33] and Li et al.[30], who also utilized the same framework, did not. Similarly, while Pérez-Tortosa et al.[32], whose intervention was based on motivational interviewing (MI), reported significant findings, Hokanson et al.[37], who utilized the same technique, did not. There is also not enough evidence to recommend the tailoring of interventions based on the participants' stage of change, as unlike Pérez-Tortosa et al.[32], Li et al.[30], who also based their intervention according to the participants' stage of change, did not report a significant smoking cessation outcome.

It is not clear whether the addition of pharmacotherapy to behavioral support helped increase smoking cessation success. While both Pérez-Tortosa et al.[32] and Canga et al.[35], who provided pharmacotherapy for smoking cessation to those assigned to the intervention group observed a significant smoking cessation outcome, they did not report the smoking cessation rate of those who used it. It is also worth noting that in the study of Canga et al.[35], only 25 out of 105 participants utilized the provided NRT. On the other hand, it is even more difficult to ascertain the effect of the provision of pharmacotherapy on smoking cessation in the Hokanson et al.[37] and Sawicki et al.[36] studies. This is because in both studies the participants in the intervention and control groups made use of such treatment.

On the other hand, the use of visual aids of diabetes-related complications, may have been useful in supporting smoking cessation. When considering that in the study of Fowler et al.[22] few participants adhered to the study protocol, possibly undermining the intervention's effectiveness, in both Ng et al.[38] and Thankappan et al.[31], who also used visual aids of

Table 3. Identified themes from the researchers' reflections and accounts of their experience

Theme	Number of studies contributing evidence to the theme	Informal evidence example	Correspondence between theme and study outcomes
Intensive smoking cessation support	6	'It is thus of paramount importance to design intensive ... interventions.' (Li et al.[30])	Canga et al.[35], Pérez-Tortosa et al.[32] and Thankappan et al.[31] acknowledged the significance of an intensive smoking cessation intervention in achieving the outlined results. On the other hand, Albaroodi et al.[33], Li et al.[30] and Hokanson et al.[37] whose interventions were less intensive in nature and unsuccessful, remarked on the need for a more intensive intervention.
		'An intensive intervention adapted to the individual stage of change delivered in primary care for diabetic smokers was feasible and effective.' (Pérez-Tortosa et al.[32])	
		'This study found a dose response relationship between counseling and quit rate.' (Thankappan et al.[31])	
Strong warning messages on tobacco associated diabetic complications	3	'Our findings suggest that a brief disease-centered cessation message from the doctor, given in conjunction with use of disease-complication visual aids, has a significant impact on diabetes patients.' (Ng et al.[38])	Both Ng et al.[38] and Thankappan et al.[31] whose interventions included strong warning messages on tobacco-associated diabetic complications (such as visual aids), reported a significant decrease in smoking prevalence. Conversely, Li et al.[30] whose findings were not significant, recommended the use of stronger messages on tobacco-associated diabetic complications to promote smoking cessation.
		'In our study both the doctor and the counselor used visual aids and diabetes specific smoking cessation materials ... to motivate patients to consider quitting to prevent complications from diabetes.' (Thankappan et al.[31])	

diabetes-related complications, a significant decrease in smoking prevalence was reported. Nonetheless, the use of diabetes-specific leaflets, in which information on diabetes-related complications was also conveyed, is not clear, as unlike Ng et al.[38] and Thankappan et al.[31], Li et al.[30] did not report a significant smoking cessation outcome.

There is not enough evidence to suggest the use of general stop-smoking leaflets. Unlike the Canga et al.[35] study, in both Ardron et al.[34] and Li et al.[30] (the latter of which provided leaflets to both the intervention and control group), non-significant findings were reported.

Analysis of informal evidence

As part of the ICA outlined by Sutcliffe et al.[17], the researchers' reflections, and accounts of their experience in evaluating the intervention, were coded to help understand the association between the identified intervention features and the success or failure of the interventions. Two major themes were identified: 'intensive smoking cessation support', and 'strong warning messages on tobacco associated diabetic complications', both of which were identified as being associated with smoking cessation success. Table 3 outlines these themes, providing examples of the underlying evidence, the number of studies contributing to these themes, and a brief explanation of the association between these themes and the studies' outcomes.

DISCUSSION

Similar to the systematic review and meta-analysis by Nagrebetsky et al.[13], this systematic review reports inconsistent findings across the identified studies. The relatively small number of trials identified, some of which were under powered, and the significant diversity in the interventions utilized by the study authors, limiting comparability, limited the ability to establish the effectiveness of stand-alone smoking cessation interventions for use amongst individuals with diabetes. Nonetheless, the addition of an ICA

provided more evidence-based recommendations for smoking cessation practice than the previous reviews[13,15], as it helped to identify some of the 'active ingredients' of the identified diverse multi-component smoking cessation interventions.

Intensive smoking cessation interventions may help enhance smoking cessation success. The smoking cessation interventions which consisted of three to four sessions, lasting >20 min each, were generally more successful. Additionally, the provision of frequent smoking cessation support also seems to be beneficial. These findings are in line with current evidence on the effectiveness of smoking cessation interventions amongst the general population[10,12].

The use of visual aids depicting diabetes-related complications, may also prove to be useful in supporting smoking cessation. Pictorial warnings of tobacco related complications have in fact been found to elicit negative smoking attitudes and increase intentions to stop smoking[40]. Given that the literature reports that some individuals with diabetes tend to be unconvinced about the additional risks posed by tobacco use on their health,[15] the use of such strong warnings as part of diabetes-specific intensive smoking cessation support efforts is further recommended.

Conversely, there is not enough evidence to suggest the use of diabetes-specific or general stop-smoking informational material. However, this is in line with current evidence, as in their systematic review and meta-analysis Livingstone-Banks et al.[41] also found that there is no evidence that informational material increases the effectiveness of smoking cessation advice from a health professional or in using NRT in the general population (RR=0.99; 95% CI: 0.76–1.28).

There is also limited evidence to suggest the use of a specific framework or behavior change method for smoking cessation amongst individuals with diabetes. As was highlighted in the systematic review and meta-analysis by Lindson et al.[42], who evaluated the efficacy of MI smoking cessation interventions amongst the general population, this review also reports inconsistent findings on the use of MI-based smoking cessation interventions amongst individuals with diabetes. It was also observed that in the study by Pérez-Tortosa et al.[32], who reported a significant smoking cessation outcome on using MI, and its study protocol[43], the authors provided almost no detail on the structure or components of the MI-based intervention which was used. Given that MI-based smoking cessation interventions have been found to vary at large[42], the poor reporting in the Pérez-Tortosa et al.[32] study limits further the ability to draw any conclusions on the use of MI-based smoking cessation interventions amongst individuals with diabetes.

Similar to what was reported in the systematic review and meta-analysis by Cahill et al.[44], who assessed the efficacy of stage-based smoking cessation intervention amongst the general population, there is also not enough evidence to suggest the use of stage-based smoking cessation interventions amongst individuals with diabetes. The classification of participants based on the stages of change as per the trans-theoretical model of change[39] for subsequent tailoring of smoking cessation support, has in fact been long questioned and also discouraged[45,46]. Furthermore, as was observed in the study of Pérez-Tortosa et al.[32], who tailored their intervention to the participants' stage of change, in taking the precontemplation stage as a reference point showed that being in the contemplation or preparation/action stage at baseline rather decreased the odds of quitting smoking, which should have not been the case. Unlike the smokers in the precontemplation stage, defined as having no intention to quit smoking in the next 6 months, the smokers in the contemplation or preparation/action stage indicated their intention to quit smoking in the next 6 months and next 30 days or were currently quitting, respectively[39]. Given that the provision of a comprehensive intensive smoking cessation intervention for those in the precontemplation stage, which first aimed to motivate and encourage them to quit smoking, and then supported them towards quitting, was more likely to increase smoking cessation success, the use of a rigid tailored approach based on the assumed participants' stage of change is rather not recommended for use amongst individuals with diabetes.

While the 5As algorithm for smoking cessation has been featured in guidelines for treating tobacco dependence in the general population[47], and suggested as a framework for the provision of both brief and intensive smoking interventions amongst individuals with diabetes[48], the underpinning evidence for recommending this practice was still found to be limited. Future research is thus required

to recommend the use of the 5As framework for smoking cessation amongst individuals with diabetes.

Despite the promising use of pharmacotherapy for smoking cessation amongst individuals with diabetes[15], this review could not establish its significance. Given that the effectiveness of the use of pharmacotherapy for smoking cessation amongst the general population has been highlighted in the literature[11,12], further research is also required amongst this specific population.

Strengths and limitations

This review builds on the findings of the scoping review by Grech et al.[15], assessing the effectiveness of intensive stand-alone smoking cessation interventions amongst individuals with diabetes. The strength of this review was that it comprised a systematic search of randomized trials of stand-alone smoking cessation interventions for individuals with diabetes, utilizing a wide range of databases. This review does not include trials in which smoking cessation was a part of a more extensive intervention for diabetes management. Furthermore, studies in which only a proportion of the participants had diabetes or reports of studies which were not specific to individuals with diabetes, were also excluded. While this limited the number of trials to be reviewed, it allowed us to specifically measure the effect of stand-alone smoking cessation interventions which were specifically designed for and delivered to individuals with diabetes.

While a meta-analysis of effect estimates was the initial preferred method of synthesis, given the significant diversity in the interventions utilized by the study authors, and the incomplete reporting of outcomes/effect estimates in some of the identified studies[22-25], this was not recommended. Nonetheless, the addition of an ICA to the systematic review proved insightful, as in analyzing the components of the identified diverse interventions some critical features of the successful interventions were identified. Furthermore, recommendations for further research were also provided.

Despite the utility of the ICA to this systematic review, it is worth noting that some of the findings of the studies were found to be possibly at risk-of-bias. Thus, further research to establish the validity of these findings is recommended. Sutcliffe et al.[17] suggest carrying out qualitative research to explore the views and experiences of recipients and providers of the identified features. Apart from establishing the validity of the obtained findings[17], in carrying out qualitative research with such stakeholders, the need for other smoking cessation intervention characteristics (specific to individuals with diabetes), may be identified. Given that healthcare interventions are very much dependent on patient involvement and their attitudes to them[49], the exploration of the views of individuals with diabetes on the identified promising smoking cessation components and their perceived needs to quit smoking, is thus recommended.

CONCLUSIONS

Tobacco smoking poses a significant threat to the health of those living with diabetes. Given the lack of evidence-based smoking cessation recommendations for use amongst individuals with diabetes, this systematic review aimed to assess the effectiveness of intensive stand-alone smoking cessation interventions amongst such individuals, and to identify the critical features of the successful interventions.

Despite observing inconsistent findings across the identified studies, limiting the ability to establish the effectiveness of intensive stand-alone smoking cessation interventions for use amongst individuals with diabetes, the addition of an ICA proved useful as it helped to identify some of the critical features of the successful interventions, providing evidence-based practice recommendations. Intensive smoking cessation interventions were generally more likely to be associated with smoking cessation success. Smoking cessation interventions which consisted of three to four sessions, lasting >20 min each, were generally more successful. The provision of frequent smoking cessation support was also found to be of possible significance. Additionally, the use of visual aids depicting diabetes-related complications may also have helped in supporting smoking cessation efforts. On the other hand, further research is required to recommend the use of the 5As framework for smoking cessation and to establish the significance of the use of pharmacotherapy for smoking cessation amongst individuals with diabetes. To establish the validity of this review's findings, the exploration of the views of individuals with diabetes on the identified promising smoking cessation components is also recommended.

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CONFLICTS OF INTEREST
The authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest and none was reported.

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ETHICAL APPROVAL AND INFORMED CONSENT
Ethical approval and informed consent were not required for this study.

DATA AVAILABILITY
The data supporting this research are available from the authors on reasonable request.

AUTHORS' CONTRIBUTIONS
Research concept and design: all authors. Collection and/or assembly of data, data analysis and interpretation, and writing of the article: JG. Critical revision of the article and final approval: all authors.

PROVENANCE AND PEER REVIEW
Not commissioned; externally peer reviewed.

Appendix 9.3: Certificate of abstract presentation (National Public Health Syposium)

Appendix 9.4: The qualitative descriptive study

Research Paper Tobacco Prevention & Cessation

Exploring the smoking cessation needs of individuals with diabetes using the Information-Motivation-Behavior Skills model

Joseph Grech[1], Ian J. Norman[2], Roberta Sammut[1]

ABSTRACT

INTRODUCTION Smoking cessation is an important aspect of diabetes management. Despite the increased risk for diabetes complications when smoking, evidence suggests that people living with type 1 and type 2 diabetes are less likely to quit smoking when compared to those without diabetes. Guided by the Information-Motivation-Behavioral Skills model, this study aimed to identify the needs of individuals living with type 1 and type 2 diabetes to quit smoking.

METHODS A qualitative descriptive design was adopted. Semi-structured telephone interviews were held between April and June 2021, with 20 former and current Maltese smokers living with type 1 or type 2 diabetes, recruited from the diabetic clinics within the two main acute public hospitals. The interview transcriptions were analyzed using applied thematic analysis.

RESULTS Individuals with diabetes need more information on the effects of smoking on diabetes to encourage cessation. Preventing diabetic complications was reported as a motivator to quit smoking. However, having diabetes was identified as a challenge to quitting. Participants welcomed the provision of health professional support for quitting smoking, identifying the need to provide smoking cessation support within diabetic clinics. The provision of information on tobacco-associated diabetic complications, by using video messages featuring former smokers' stories was also suggested.

CONCLUSIONS To promote smoking cessation among individuals with diabetes, they need to be informed about how smoking affects their condition. Utilizing video messages featuring real-life stories of former smokers with diabetes who experienced tobacco-associated diabetic complications may be influential. Additionally, providing diabetes-specific intensive smoking cessation support is crucial to help them quit.

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INTRODUCTION

Diabetes mellitus is a global epidemic affecting an estimated 537 million people worldwide[1]. Diabetes has also been recognized as a public health priority in Malta[2]. Although when compared to the other World regions, the European region has the second-lowest diabetes prevalence (9.2%; 95% CI: 7.1–10.4), Malta, a European country, has a high diabetes prevalence, estimated at 11.2% (95% CI: 8.7–13.8)[1].

People living with type 1 and type 2 diabetes require medical care, self-management education, and support that goes beyond glucose management[3]. Smoking cessation (and prevention) is an important aspect of diabetes

management[4,5]. Smoking worsens the cardiometabolic parameters of both individuals with type 1 and type 2 diabetes[6], increasing the risk of diabetes-related complications, such as coronary heart disease, stroke, heart failure, peripheral arterial disease, and even death[7]. Conversely, smoking cessation is associated with better cardiometabolic values[6] and reduced risks of cardiovascular morbidity and mortality[8]. Smoking cessation for individuals with diabetes is one of the key recommendations of Malta's national diabetes strategy[2].

Despite the benefits of quitting, evidence suggests that individuals living with diabetes are less likely to quit smoking when compared to those without diabetes[9,10]. Several diabetes-related factors may hinder the quitting process. Factors such as depression[11] or physical suffering[12] caused by diabetes, have been identified by individuals with diabetes as barriers to quitting. Weight gain on cessation, which may lead to poor glycemic control, is also a common concern for patients with diabetes in attempting to quit smoking[13]. Individuals with diabetes also tend to believe that smoking helps them manage diabetes, such as in glycemic control, adherence to diet, or weight management, making them reluctant to stop[12,13]. In view of these diabetes-specific barriers and challenges to quitting, the provision of tailored smoking cessation support has been recommended for individuals with diabetes[5,10].

Healthcare interventions, such as smoking cessation interventions, rely heavily on patient involvement and their attitudes toward the intervention[14]. Consequently, there is a need to explore recipients' perspectives on the proposed features of an intervention, as well as other needs that may not have been identified in the literature. This approach has been recommended in recent guidelines for the development of tailored healthcare interventions[15,16]. The Information-Motivation-Behavioral Skills (IMB) model by Fisher et al.[17] can help in identifying the unique needs of individuals with diabetes to quit smoking, and supporting the development of smoking cessation interventions[18]. The IMB model asserts that behavior change happens when individuals are well-informed, highly motivated, and possess the necessary skills to perform the required behavior change[17]. By understanding the specific IMB factors that are relevant to the particular health behavior and target population, researchers can promote behavior change through tailored interventions[17,18].

In developing an IMB-based intervention, one needs to first identify the specific IMB factors that are relevant to the particular health behavior and to the target population, through elicitation research[17]. This helps to identify the population-specific IMB strengths, which can be capitalized on, and any deficits that need to be addressed when designing the population-specific intervention[17,18]. Qualitative research may also help to identify challenges and barriers to behavior change, that is, any situational and individual characteristics that can negatively influence the desired behavior change; these may act as moderating factors[17]. Negative moderators, present at high or intense levels, may impinge on the intervention's effectiveness, thus necessitating change to the proposed intervention or an adjunct effort[17]. The IMB model also asserts that individual objective and subjective health outcomes (e.g. poor glycemic control on quitting) can also act as moderators, as they are directly linked with adherence to the desired behavior change[17]. These, in turn, can influence behavior change via a feedback loop that affects the IMB constructs, strengthening or weakening adherence[17].

The IMB model has been widely utilized to understand the behavior mechanisms that need to be altered to achieve and sustain behavior change[18]. In exploring diabetes self-care-related IMB factors, Osborn et al.[19] were able to tailor a diabetes self-care intervention for Puerto Ricans with type 2 diabetes, effectively improving food label reading, diet adherence, and glycemic control at three months follow-up. The IMB model has also been found to be a useful framework for identifying the unique needs of opiate-dependent smokers[20] and smokers living with HIV[21] for the development of feasible and acceptable smoking cessation interventions. Guided by the IMB model, Georges et al.[12] explored the association between diabetes, smoking, and gender, to develop a gender and diabetes-specific smoking cessation intervention[12]. However, they only included individuals with type 2 diabetes in their study and limited their analysis to the experiences of

current smokers[12]. Given that individuals with type 1 diabetes and former smokers with diabetes were not represented in the study of Georges et al.[12], and considering that none of the studies identified in a recent scoping review on smoking cessation and diabetes explored the perspectives of individuals with diabetes on evidence-based smoking cessation recommendations[22], further research was warranted.

This study aimed to identify the unique needs of individuals with type 1 and type 2 diabetes to quit smoking, for the future development of a tailored smoking cessation intervention. This study explored the smoking cessation-related IMB factors among Maltese individuals with diabetes and their views of the features of smoking cessation interventions, previously identified in a scoping and a systematic review as showing promise in use with persons with diabetes[22,23]. The features of the smoking cessation interventions identified included the provision of intensive professional smoking cessation support, the use of pharmacotherapy for smoking cessation, and the provision of information on tobacco-associated diabetic complications, by using visual images and/or video messages featuring former smokers who experienced tobacco-associated diabetic complications.

METHODS

Design

A qualitative descriptive design was utilized. The use of qualitative descriptive research has been recommended for exploring recipients' views of a proposed intervention or its features, and for identifying other needs as part of the developmental process of healthcare interventions[16].

The IMB model by Fisher et al.[17] was used as a guiding framework to identify the unique needs of individuals with type 1 and type 2 diabetes to quit smoking, for the future development of a tailored smoking cessation intervention. Thus, this research looked into identifying the diabetes-specific IMB strengths and any deficits, as well as the challenges and barriers to smoking cessation (negative moderating factors)[17]. Furthermore, considering that both specific objective and subjective health outcomes (e.g. poor glycemic control upon quitting) can function as moderators, either strengthening or weakening adherence to the new behavior (i.e. smoking abstinence)[17], these aspects were also explored.

Participants

Both former and current smokers with type 1 or type 2 diabetes who had tried to quit following a diabetes diagnosis and were able to converse in English or Maltese were eligible for inclusion in this study. Individuals with diabetes who had not attempted to quit smoking following their diabetes diagnosis were excluded. Healthcare professionals working within the Maltese diabetic out-patient clinics within community health centers and at the two main acute public hospitals, family doctors and the Malta Diabetes Association, were invited to help identify interested participants, forwarding their contact details to the research team for recruitment with the patient's consent.

The sample size was based on the principle of 'data saturation'[24], seeing saturation when new data collected repeats what was expressed in the previously collected data[25]. The aim was to ensure that the data collected was sufficient enough to answer the set objectives[24]. In estimating the required sample size, reference was made to the seminal study by Guest et al.[26], in which saturation was relatively achieved after 12 interviews, and the study by Georges et al.[12], who achieved saturation after ten individuals and five focus group interviews (15 units of analysis). Thus, it was estimated that data saturation would be achieved after 15 interviews.

Data collection

This study was carried out during the peak of the second wave of the COVID-19 pandemic. Initially, focus group interviews were the preferred method of data collection. However, following the introduction of new COVID-19 restrictions just prior to the data collection period, which limited public meetings to groups of two, this was changed to individual semi-structured interviews. Given the hesitancy of some participants to meet in-person due to the pandemic situation at that time, these were held over the phone.

Interviews followed a question-and-probe guide, which included questions on personal

characteristics and questions based on the IMB model, also addressing the participants' views of the identified promising smoking cessation components identified by Grech et al.[22,23]. The instrument was translated into Maltese by a professional bilingual translator and back-translated to English (by another bilingual translator) to ensure accuracy. Initially, participants were asked about their personal characteristics, i.e. their sociodemographic characteristics and diabetes and smoking profiles. Then, participants were asked about their knowledge about the harms, risks, and interactions between smoking, smoking cessation, and diabetes, and the information they believed they needed to quit smoking (Information). They were also asked for their views on the provision of information on tobacco-associated diabetic complications that influence smoking habits. This included the use of visual images of tobacco-associated diabetic complications and video messages featuring former smokers who experienced tobacco-associated diabetic complications. Furthermore, participants were asked about their motivational factors to quit smoking and avoid relapse (Motivation), their perceived facilitators to quit smoking, their views on the use of pharmacotherapy for smoking cessation, as well as their opinions on health professional smoking cessation support (Behavioral skills). Participants were also asked about their perceived barriers and challenges to quitting smoking to help identify any characteristics that could negatively impact smoking cessation.

Procedure

Data were collected between April and June 2021. On indicating their interest in participating in the study, prospective participants were verbally briefed on the purpose of the study and the data-collecting procedure, answering any queries that they had. They were also provided with a detailed information letter and a consent form to sign. Participants were reminded that participation was voluntary and that they were free to withdraw from the study at any time without the need to provide a reason. Participants were assured that refusing to participate or withdrawing from the study did not have any effect on their care whatsoever.

All participants were recruited from the diabetic clinics within the two main acute public hospitals in Malta. Participants were recruited with the aim of achieving data saturation. However, the research team also liaised with the recruitment intermediaries to ensure adequate representation by sex, age, type of diabetes, and smoking status. In total, 20 interviews were held. These took 30–40 minutes each and were held in Maltese or English, depending on the preference of the interviewee. All interviews were moderated by JG, who followed the interview guide.

Before starting the phone interviews, the researcher reminded participants that discussions were confidential and that the data would be rendered anonymous. Participants were also assured that their identity and personal information would not be revealed in any data/information arising from the research study. Interviews were audio recorded with consent using a password-protected and encrypted audio recorder. Once the audio recordings were transcribed (and pseudonymized), these were then erased, retaining data only in an anonymous format.

Given that initially focus group interviews, lasting 90 minutes each, were to be conducted, a token of appreciation, a €10 voucher, was determined appropriate to acknowledge the participants' time and inconvenience during such a period, and was thus mentioned in the participants' information and consent documents. As some participants were already recruited to the study (but not interviewed) before the change in data collection method, all participants were offered this token of appreciation on completion of their interview.

Data analysis

The participants' characteristics were reported using frequency percentages and median values. All audio recordings were transcribed verbatim with anonymization and imported into NVIVO (version 1.5.1). To maintain the validity and reliability of the acquired data, the transcripts in Maltese were not translated[27]. As recommended by Chen and Boore[28], analysis was conducted in the original language (Maltese or English), generating categories in the source language and then translating all identified themes (and matching phrases) into English.

All transcripts were analyzed by JG using applied thematic analysis, a rigorous, inductive method

for identifying themes from text with the aim of presenting the meanings of the study participants as accurately and comprehensively as possible[27]. The identified themes were then organized according to the different components of the IMB model[17] and also illustrated in a figure format.

Several strategies were adopted to enhance rigor. A draft coding scheme was developed by JG based on the initial four transcripts analyzed. The coding scheme and the codes were reviewed by the other authors and revised accordingly. The coding scheme was also reviewed after a couple of weeks of analysis, refining, and renaming themes/codes to reflect the meanings of the relevant datasets, enhancing reliability[27]. Generated themes and sub-themes were supported by excerpts from the original participant data; English translations of quotes in Maltese were provided. Additionally, the methods undertaken and data analysis processes were documented and presented so that this study can be replicated[27].

RESULTS

Participant characteristics

The sample included ten former and ten current smokers. The participants' characteristics, including their diabetes and smoking profiles, are outlined in Table 1. Most participants were middle-aged males with type 2 diabetes. They had at least a secondary level of education and were in employment. Nine participants reported having diabetic complication(s), with five having ischemic heart problems associated with their diabetes status. All smokers smoked daily, smoking on average 16 cigarettes per day. Six current smokers were motivated to quit smoking. However, only two were planning to quit within the next month. All former smokers were previously daily smokers.

Main findings based on the IMB model

The main findings of this study are organized according to the IMB model[17]. Figure 1 outlines the identified diabetes-specific IMB strengths and deficits, and the identified moderators.

Information

Knowledge of smoking, smoking cessation, and diabetes

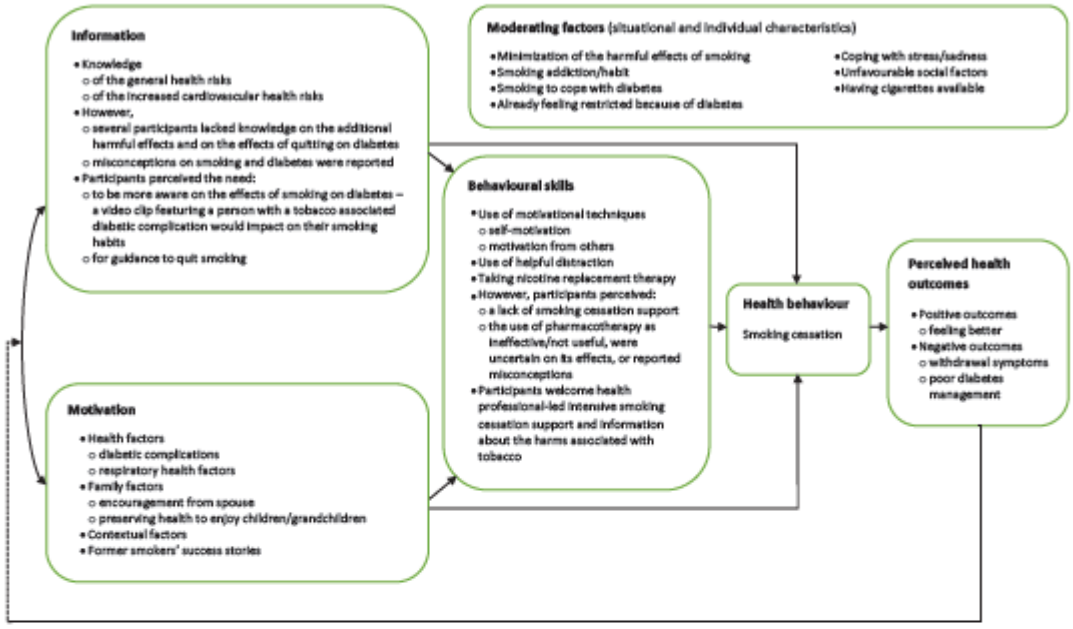
All participants, except one, were aware of the general health risks associated with smoking, mostly referring to respiratory and cardiovascular health problems. The majority (n=14) were also aware of

Table 1. Characteristics of the interviewees recruited from the diabetes care clinics within the two main acute public hospitals in Malta in 2021 (N=20)

Characteristics	n	%
Demographics		
Gender		
Male	14	70
Female	6	30
Median age (years)	51	
Education level		
Primary level	2	10
Secondary level	8	40
Post-secondary level	3	15
Vocational training	2	10
Diploma	3	15
Degree	2	10
Employment status		
Student	2	10
Employed	10	50
Unemployed (disability)	1	5
House duties	2	10
Retired	5	25
Diabetes profile		
Diabetes type		
Type 1	6	30
Type 2	14	70
Median age at diagnosis (years)	32.50	
Diabetes complications		
No	11	55
Yes	9	45
Smoking profile		
Smoking status		
Median age starting smoking (years)	15	
Median number of years since quitting amongst former smokers	2.21	
Median number of cigarettes/day amongst smokers[a]	16	
Motivation to quit amongst smokers		
Planning to quit in <1 month	2	20
Planning to quit in ≥1 month	4	40
Not motivated to quit	4	40

a Excluding one participant who smoked five cigarillos per day.

Figure 1. Main findings based on the IMB model, insights from interviews with participants recruited from diabetes care clinics in Malta in 2021 (N=20)



the increased health risks for those who have diabetes, highlighting the increased cardiovascular health risks (n=9). Conversely, one former smoker and five current smokers stated that they were not aware of any additional health risks.

Few participants (n=7) were aware of the positive effects of quitting on diabetes. Six participants just referred to having overall better health, while four and two participants understood that they would have better blood circulation and controlled diabetes, respectively. On the other hand, three former smokers and six current smokers were unaware of the effects of quitting on diabetes. Furthermore, five current smokers (CSs) and two former smokers (FCs) believed that smoking helps in diabetes management, such as in glucose control (n=5):

'When I smoke a cigarette, my blood sugar doesn't go up … and then if I don't smoke that cigarette, I would feel my blood sugar going up.' (CS 3, male, translated quote)

and to control overeating (n=3):

'The cigarette keeps me from picking up on other things … It's as if it makes me feel full, (grinning) I have eaten, I took a cigarette, and that's it!' (CS2, female, translated quote).

Three current smokers did not believe that smoking affects diabetes management:

'At first, I was worried about how it would affect me. But then I kept checking (blood glucose) before and after to see how it would affect me, but I didn't see any particular issues, so.' (CS4, male)

Perceived relevant information to support smoking cessation

Most participants (n=10) perceived the need for more awareness of the effects of smoking on diabetes to encourage smoking cessation. In addition, two participants perceived the need for guidance to quit smoking. Conversely, five participants stated that they would not seek any information.

Views on the provision of information on tobacco-associated diabetic complications to influence smoking habits

Eighteen participants perceived that an increase in

awareness of tobacco-associated diabetic complications would impact their smoking, out of concern (n=15):

'Maybe these are things which I don't know about ... That is, I am doing some harm because I am diabetic.' (CS7, male, translated quote)

and out of fear (n=3):

'Because I'm afraid of the future ... I have diabetes, I mean, I don't want to add to any consequences.' (CS2, female, translated quote)

Ten participants also perceived that the use of visual images of tobacco-associated diabetic complications would be effective out of concern or fear. However, the remaining participants (five current and five former smokers) did not agree because they were not affected by the warning images on tobacco products (n=4):

'Since those did not affect me, I don't think other illnesses would affect me.' (CS10, male, translated quote)

or because they had low perceived susceptibility to such complications (n=2):

'Mostly because I see them as something that won't happen to me (laughing).' (CS4, male)

Another four participants would simply avoid such messages:

'To tell you the truth, I would try not to see them.' (CS6, female, translated quote)

Conversely, more participants (n=17) perceived that watching a video clip featuring a person who had stopped smoking because of a tobacco-related diabetic complication would impact their smoking, mainly out of concern (n=5), fear (n=4), or because it is a real story (n=5):

'They're going to tell you what they went through.' (CS2, female, translated quote)

Three participants added that it would be easier to follow and understand, and two participants stated that it would be inspiring.

Motivation

Various motivational factors to stop smoking or avoid a relapse were reported (Table 2). Most participants (n=16) mentioned health factors as motivators, in particular, prevention of diabetic complications (n=13). Other participants referred to family factors (n=10), contextual factors (n=4), and former smokers' success stories (n=2) (Table 2). On being prompted, only eight former and three current smokers stated that having diabetes was a motivator to quit smoking.

Table 2. Reported motivational factors to quit smoking or to avoid relapsing, interview findings (N=20)

Themes and sub-themes	Quotes	n
Health factors		16
Diabetic complications		13
Experiencing diabetic complications	*'The situation from my feet! That's what they make me stop.'* (FS3, male)	7
Knowledge of possible diabetic complications	*'Because even because of diabetes, it would affect a lot of things.'* (FS6, female, translated quote)	6
Respiratory health factors	*'The cigarette started to affect my breathing.'* (FS6, female, translated quote)	5
Family factors		10
Encouragement from spouse	*'My wife (laughing) ... every second "Stop stop stop" ... It's one of the most motivations I have.'* (CS9, male)	5
Preserving health to enjoy children and grandchildren	*'I have a child ... despite having diabetes I wish I could at least enjoy him'* (CS5, female, translated quote)	5
Contextual factors		4
Public smoking restrictions	*'I was going to go abroad ... I said, "It's going to take long to smoke having to spend three hours on a plane."'* (CS10, male, translated quote)	2
Getting a home loan	*'For taking a loan, you know, nowadays you can't buy a house without taking a loan, so emm, you know.'* (CS9, male, translated quote)	2
Former smokers' success stories	*'I think the most encouraging thing is the experiences of others, emm ... those who used to smoke and managed to quit'* (CS2, female, translated quote)	2

FS: former smoker. CS: current smoker.

Behavioral skills

Smoking cessation facilitators

Various facilitators for smoking cessation were reported (Table 3). The majority (n=11) highlighted the importance of motivational techniques and the usefulness of using helpful distractions (n=7). Three participants remarked on the need to make use of nicotine replacement to quit smoking.

Attitudes towards the use of pharmacotherapy for smoking cessation

Six participants reported positive attitudes towards the use of pharmacotherapy, perceiving it as effective out of the personal experience or of others (n=3), and helpful if lacking willpower (n=3). Conversely, the use of pharmacotherapy was perceived as ineffective by nine participants:

'I don't really believe they work ... didn't seem they worked on me.' (CS3, male, translated quote)

Furthermore, four participants did not perceive its need, stating that having willpower is enough:

'I never took these things. I quit smoking with my own willpower.' (FS8, female, translated quote)

In addition, two participants were uncertain about the effect of using pharmacotherapy:

'I've tried the nicotine inhalers ... I don't know if they helped or not.' (FS1, male)

Three participants were concerned about the possible health consequences of using pharmacotherapy:

'Because, for example, I heard ... that the patches are harmful.' (CS6, female, translated quote)

Nonetheless, six current and four former smokers stated that they would consider the use of pharmacotherapy for smoking cessation.

Attitudes towards health professional smoking cessation support

Several participants (n=7) highlighted that there is a lack of smoking cessation advice/support for those who have diabetes:

'Whenever I used to ask someone (about the health risks) ... they always gave me a generic response of "Smoking is bad" which I just throw out of the window.' (CS4, male)

Most participants (n=16) welcomed the provision of health professional support for smoking cessation, mainly for providing guidance on how to quit (n=7) and informing them about tobacco-associated harm (n=6). The participants suggested that smoking cessation support should be of an intensive nature, consisting of sessions of half an hour to one hour (n=12), and provided frequently, such as once or twice a week (n=9), over a median value of six weeks.

Table 3. Reported facilitators to quit smoking, interview findings (N=20)

Themes and sub-themes	Quotes	n
Motivational techniques		11
Self-motivation		9
Self-motivating talk	'I keep in mind that ... "tomorrow is the third day without cigarettes, come on let's try further!"' (CS2, female, translated quote)	6
Thinking about experienced health complications	'I kept looking at my chest and picturing a spring inside (chuckling).' (FS5, male)	4
Motivation from others	'My children ... used to tell me, "come on be brave, come on, how good you are, come on!"' (FS10, female, translated quote)	4
Helpful distraction		7
Action distraction	'Not sitting down, you know. Making that one, making some DIY, go to the field, go for a walk.' (CS9, male)	4
Mouth distraction	'emm you know I told you these Nicotine inhalers that I bought, so I still have one without nicotine and anything and I just put it in my mouth and that's it.' (FS1, male)	2
Thinking distraction	'When I tried to quit smoking, I made my mind busy in another thing.' (CS1, male)	2
Taking nicotine replacement	'I think a substitute for something, that when you take it you would want this to make you feel calm, because that's what it is, you feel anxious when you crave a cigarette.' (CS3, male, translated quote)	3

FS: former smoker. CS: current smoker.

On the other hand, three participants claimed that they would not seek health professional support to quit smoking, while one participant (FS5) did not hold an opinion on the provision of smoking cessation support.

Moderators

Several barriers and challenges that could impact directly on achieving or maintaining abstinence or indirectly by influencing the IMB model constructs or their relationships, were identified (Table 4). Fourteen participants reported experiencing withdrawal symptoms on quitting smoking, particularly nervousness. Nine participants highlighted the smoking habit/addiction. Having diabetes was remarked as a challenge (n=7), mostly in maintaining diabetes management or quitting. Smoking was also found to help participants cope with stress/sadness (n=6).

In addition, three current smokers attempted to downplay the harmful effects of smoking, undervaluing smoking cessation:

'It's like when someone, for example, tells you, "Listen, stop smoking for your lungs and because of cancer", but I also know a lot of people who died of cancer and were the healthiest ever.' (CS2, female, translated quote)

Conversely, four former smokers remarked feeling better about quitting smoking, which encouraged them to remain abstinent.

Table 4. Reported barriers and challenges to quit smoking, interview findings (N=20)

Themes and sub-themes	*Quotes*	*n*
Withdrawal symptoms		14
Nervousness	*'I started to feel a lot more nervous.'* (CS2, female, translated quote)	11
Sadness	*'I used to cry. I cried. Do you understand, and sadness, I was sad.'* (FS10, female, translated quote)	3
Smoking addiction/habit		9
Smoking addiction	*'I mean obviously there is also the addiction to the, to the nicotine as well.'* (FS5, male)	5
Smoking habit	*'Now, if I go out five times by car ... those are five cigarettes, because I only need to smoke while driving.'* (CS3, male, translated quote)	4
Having diabetes		7
Maintaining diabetes management on quitting smoking		5
Eating more on quitting which does not help diabetes management	*'You start eating more. And in my position, I can't start eating more, you know.'* (CS9, male)	5
Loosing glucose control on quitting	*'The difficulties were ... I started to lose sugar control.'* (FS2, female, translated quote)	4
Smoking to cope with having diabetes	*'At that time it was as if it was a taboo to be diabetic, that is, I used to smoke a lot of cigarettes to cope, so to speak.'* (FS7, male, translated quote)	3
Already feeling restricted because of diabetes	*'Maybe I can't quit or I'm not interested in quitting, emm because we are restricted in a lot of things, that is, we refrain from taking a dessert after eating, we refrain from alcohol because it raises the blood sugar.'* (CS2, female, translated quote)	2
Coping with sadness/stress		6
Coping with sadness	*'I'd rather say, "I smoked a cigarette", than fall into a depression or so, I would say, "a cigarette is enough, I don't need anything else!"'* (CS5, female, translated quote)	4
Coping with stress	*'Yes, yes, stress, stress. Yes, the cigarette used to calm me down when in stress.'* (FS10, female, translated quote)	2
Unfavorable social factors		4
Family members or friends who smoke	*'I had some friends that smoked as well ... which made it a bit harder.'* (FS1, male)	2
Lack of support	*'But then it was hard, I think, because I was on my own.'* (FS2, female, translated quote)	2
Having cigarettes available	*'As soon as you buy a packet ... you know you will eventually smoke them, so.'* (FS9, male, translated quote)	2

FS: former smoker. CS: current smoker.

DISCUSSION

Despite being aware of the general smoking health risks and the additional risks for individuals with diabetes, the participants still lacked knowledge of the association between smoking, smoking cessation, and diabetes. As in previous studies carried out amongst individuals with type 2[12,13], and type 1 diabetes[11], this study's participants also lacked accurate information, reporting misconceptions about smoking and diabetes.

Nonetheless, as was found in the study of Abu Ghazaleh et al.[11], the need for more awareness of the effects of smoking on diabetes to support smoking cessation, was expressed by the study participants. While the use of visual images of tobacco-associated diabetic complications has been recommended to raise awareness of such complications for encouraging cessation[23], this study suggests otherwise, as the participants had mixed feelings about this. Noar et al.[29], in fact, suggest caution in using tobacco pictorial warnings, as these can also encourage denial or avoidance of such messages. Conversely, the participants were more receptive to the use of video messages featuring former smokers who experienced tobacco-associated diabetic complications to convey such information. The use of such video messages as part of a mass media campaign has been found to increase awareness of tobacco-related harm, quit attempts, and smoking cessation efforts amongst the general population[30,31]. Given these positive findings, future research should investigate the use of such video messages as an educational tool, part of a smoking cessation intervention for individuals with diabetes.

Similar to previous literature[11-13], most participants identified health as their primary motivator to quit smoking and remain abstinent. As was observed in the study of Georges et al.[12], only half of the participants stated that having diabetes was a motivator to quit smoking. This suggests further that some participants did not believe that smoking impacted their diabetes management.

Most of the mentioned facilitators or skills for smoking cessation (such as increased health awareness, family support, and helpful distractions) were also identified in previous studies[11,13]. As was found in the literature[11,13], the participants in this study also identified the need for health professional support to quit smoking. These suggested that this should be intensive, in line with Grech et al.[23] recommendations. Given the identified lack of smoking cessation support for those with diabetes, the provision of intensive smoking cessation support as part of diabetes management is thus recommended.

Despite the promising use of pharmacotherapy for smoking cessation among individuals with diabetes[22,32], only half of the participants in this study were in favor of using it. In addition, some participants held negative attitudes or had misconceptions about using pharmacotherapy. This warrants the need to provide more information on the benefits and use of pharmacotherapy for smoking cessation to target any negative attitudes and misconceptions.

As in previous literature[11-13], several barriers and challenges to quitting or negative moderators to behavior change, such as the smoking habit/addiction or experiencing withdrawal symptoms on quitting, were identified by the study participants. Such challenges in quitting re-confirm the need for health professional support for the identification of high-risk situations of smoking and the generation of problem-solving strategies and the use of nicotine replacement therapy for managing nicotine addiction and withdrawal symptoms. Having diabetes was also reported as a challenge in previous literature[11-13], in particular, because of possible weight gain or glycemic imbalance. This confirms the need for tailored smoking cessation support for those who have diabetes, presenting an opportunity to introduce smoking cessation support as part of local diabetes education efforts.

Strengths and limitations

Guided by the IMB model, this study helped to identify the unique needs of individuals with type 1 and type 2 diabetes to quit smoking, for the future development of a tailored smoking cessation intervention. As shown in Figure 1, this research identified the diabetes-specific IMB strengths that can be capitalized on, and any deficits that need to be addressed, when designing a smoking cessation intervention[17]. Furthermore, as suggested by Fisher et al.[17], this study also explored any moderating factors that can influence smoking cessation and

abstinence.

Healthcare interventions are very much dependent on patient involvement and their attitudes to them[14]. Hence, this study also explored the participants' views of the features of smoking cessation interventions, previously identified in a scoping and a systematic review, as showing promise in use with persons with diabetes[22,23]. This study validated the following recommendations: raising awareness of the effects of smoking on diabetes by showing video messages featuring former smokers' true stories of suffering from smoking-related diseases, and the provision of intensive smoking cessation support.

In this study, the use of purposive sampling ensured adequate representation by gender, age, education level and employment status, and different diabetes and smoking profiles. However, none of the identified participants smoked or used to smoke on an occasional (weekly) basis. Occasional smokers may have different needs and preferences than those identified in this study. Another limitation of this study was that focus group interviews could not take place as previously explained. Nonetheless, the use of phone interviews still provided an in-depth understanding of the participant's needs and preferences, successfully achieving the aim of the study.

CONCLUSIONS

Guided by the IMB model, this study helped to identify the unique needs of individuals with type 1 and type 2 diabetes to quit smoking, presenting practice and research recommendations. The study's findings emphasize the need for more awareness efforts on the effects of smoking on diabetes to encourage cessation. Using video messages that showcase the true stories of former smokers with diabetes who have experienced smoking-related health issues, may have an impact on smoking cessation. Hence, future research should investigate the use of such video messages as an educational tool and as a part of a smoking cessation intervention for individuals with diabetes. Considering the perceived lack of tailored smoking cessation support for those with diabetes and the reported diabetes-specific challenges and barriers to quitting smoking, the provision of intensive smoking cessation support as an integral part of diabetes management is also recommended.

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CONFLICTS OF INTEREST
The authors have each completed and submitted an ICMJE form for Disclosure of Potential Conflicts of Interest. The authors declare that they have no competing interests, financial or otherwise, related to the current work. R. Sammut reports that she has received funds for attending conferences from University of Malta, and had an unpaid role on the Board of Directors (Id-Dar tal-Providenza).

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ETHICAL APPROVAL AND INFORMED CONSENT
Ethical approval was obtained from the Research Ethics Committee of the University of Malta (Approval number: UREC FORM V_15062020 6327; Date: 1 April 2021). Participants provided informed consent.

DATA AVAILABILITY
The data supporting this research are available from the authors upon reasonable request.

AUTHORS' CONTRIBUTIONS
JG: collection and assembly of data, data analysis and interpretation, and writing of the manuscript. All authors: research concept and design, critical revision and final approval of the manuscript.

PROVENANCE AND PEER REVIEW
Not commissioned; externally peer reviewed.

Appendix 9.5: Abstract presentation (European Conference on Tobacco Control – abstract no. 1)

The guideline included 9 clinical questions, 4 of which related to behavioral interventions (including brief advice, counselling and digital interventions), 4 related to pharmacological interventions (including pharmacological interventions alone or in association with behavioral support), and one related to the training of healthcare professionals. The results of the systematic reviews conducted for each question were discussed with the multidisciplinary panel and, by using the GRADE Evidence to Decision (EtD) framework, 29 recommendations for clinical practice, 1 recommendation for further studies and 8 Good Practice Statements, were issued.

Conclusions

To our knowledge, this is the first CPG that includes the treatment of nicotine dependence as well as the treatment of conventional tobacco dependence following a standardized and internationally recognized methodology.

Conflicts of interest

The authors have no conflicts of interest to disclose.

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Teachers against tobacco summarize their project on attitudes to tobacco and nicotine at fairs and political parties' municipal days

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Background and Purpose

Teachers against Tobacco works with influence at fairs and where politicians gather. Since 2019, questionnaires have been distributed in connection with a prize competition with some questions about attitudes to tobacco and nicotine products. The purpose of the questionnaires is to start a conversation about tobacco issues, to arouse the respondents' interest in the issues and to obtain figures on the attitudes in the various contexts.

Method

We handed out the survey on an A5 paper. The results were then compiled in an Excel file.

Results

A majority of respondents want a more restrictive tobacco policy. However, Liberals and Center Party members are less negative to a more restrictive tobacco policy.

Conclusions

The respondents request a more restrictive tobacco policy. The respondents in the political parties are also in favor of a more restrictive tobacco policy, significantly more than what is expressed in the parties' policies in the Riksdag.

Implications

There is every reason to highlight that the political parties do not represent the views of their members on the tobacco issue.

Limitations and Future Research

The sample is limited to those who are willing to answer the survey. On some occasions there are few respondents but the answers do not differ significantly. More information can be obtained from materials such as e.g. about men or Women have different attitudes as well as the attitudes of those who use tobacco and those who do not.

Conflicts of interest

The author has no conflicts of interest to disclose.

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Initial validation of the satisfaction and perceived usefulness questionnaires for evaluating smoking cessation interventions among individuals with diabetes

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Background

Evidence suggest that individuals with diabetes do not easily adopt smoking cessation interventions. Assessing the acceptability of such interventions is crucial before implementation, yet there are no quantitative measures which evaluate satisfaction and perceived usefulness of smoking cessation interventions among individuals with diabetes.

Objectives

Validate and assess the internal consistency of two self-developed instruments measuring satisfaction and perceived usefulness of a smoking cessation intervention among individuals with diabetes.

Methods

The instruments were developed and validated in English, then translated into Maltese. The satisfaction questionnaire contained eight statements while the perceived usefulness questionnaire had fourteen; both rated on a 5-point Likert scale. Content validation involved five tobacco cessation facilitators rating item relevance using a 4-point ordinal rating scale, suggesting improvements, and later assessing the conceptual equivalence of the translated questionnaires using a similar scale. Unanimous agreement among experts was required for item relevance and equivalence. Thirty-four individuals with type 1 or type 2 diabetes, attending a diabetes-specific smoking cessation intervention, received either the Maltese or English versions of the questionnaires. Internal consistency was measured using Cronbach's alpha scores.

Results

Two rounds of content validation resulted in minor changes to the questionnaires, including removing one item and adding another to the perceived usefulness questionnaire. Experts unanimously agreed on item relevance and conceptual equivalence. Fifteen participants completed the Maltese versions of the questionnaires, while sixteen completed the English versions. Cronbach's alpha scores were 0.87 and 0.91 for the Maltese and English versions of the satisfaction questionnaire, and 0.94 and 0.96 for the Maltese and English versions of the perceived usefulness questionnaire. All item-scale correlations were >0.4.

Conclusions

These findings provide initial validation for utilizing the developed instruments to assess satisfaction and perceived usefulness of smoking cessation interventions among individuals with diabetes. Further validation with a larger sample and factor analyses is recommended.

Conflicts of interest

The authors have no conflicts of interest to disclose.

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Appendix 9.6: Validity study

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Acceptability measures for evaluating smoking cessation interventions among individuals with diabetes

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ABSTRACT

Background: The literature indicates that individuals with diabetes do not easily adopt smoking cessation interventions. Given that the success of such interventions depends on patient involvement and attitudes, assessing intervention acceptability, including patient satisfaction and perceived usefulness, is crucial before implementing a smoking cessation intervention. This paper reports the preliminary validation of the satisfaction and perceived usefulness questionnaires for evaluating smoking cessation interventions among individuals with diabetes.
Study design: Validity study.
Methods: The satisfaction questionnaire contained eight statements while the perceived usefulness questionnaire had fourteen; both rated on a 5-point Likert scale. Content validation involved five tobacco cessation facilitators rating item relevance using a 4-point ordinal rating scale, suggesting improvements. The questionnaires were also translated into Maltese for local use and assessed for translation validity using a similar scale. Unanimous agreement among experts was required for item relevance and equivalence. Thirty-four individuals with type 1 or type 2 diabetes, attending a diabetes-specific smoking cessation intervention, received either the Maltese or English versions of the questionnaires. Internal consistency was measured using Cronbach's alpha.
Results: After two rounds of content validation, the experts unanimously agreed on item relevance and conceptual equivalence. Fifteen and sixteen participants completed the Maltese and English versions of the questionnaires, respectively. Both questionnaires' versions were found to have a high internal consistency (>0.8).
Conclusions: These findings provide the initial validation of these instruments for assessing the acceptability of smoking cessation interventions among individuals with diabetes. Further validation in different settings using a larger sample is suggested.

1. What this study adds

This study reports on the initial validation of the satisfaction and perceived usefulness questionnaires for evaluating smoking cessation interventions among individuals with diabetes.

2. Implications for policy and practice

The use of these measures is recommended to assess the acceptability of a smoking cessation intervention amongst individuals with diabetes.

3. Introduction

Diabetes mellitus (DM), characterised by chronic hyperglycaemia which can lead to the development of various macro- and micro-vascular complications, is estimated to affect 537 million people worldwide [1]. While glycaemic control is key in diabetes management, to prevent the associated diabetic complications people living with DM require medical care and education that also go beyond glucose management. The cessation (and prevention) of tobacco smoking, is a crucial aspect of diabetes management. In addition to causing endothelial dysfunction and altering plasma viscosity, tobacco smoking has been found to increase insulin resistance and worsen glycaemic and lipid control in individuals with DM [2]. This increases the risk for both macro- and microvascular complications of DM. Compared to non-smokers with diabetes, both individuals with type 1 and type 2 DM who smoke are at approximately 50% higher risk of developing cardiovascular events such as coronary heart disease and stroke [3]. Additionally, a higher risk for

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cardiovascular mortality and for total mortality among smokers with type 1 and type 2 DM has been identified [3]. Tobacco use may also increase the likelihood of microvascular complications associated with diabetes, such as diabetic nephropathy, neuropathy and retinopathy, particularly amongst individuals with type 1 DM [2]. However, despite these risks, many individuals with diabetes continue to smoke even after diagnosis. Durlach et al. estimated that on average 20% of individuals with type 2 DM and 30% of individuals with type 1 DM smoke [2].

The provision of tailored smoking cessation interventions for individuals with diabetes has been recommended at large [2,4]. However, the literature suggests that individuals living with diabetes do not easily adopt smoking cessation interventions, and often smoking cessation success rates are low [4]. Given that the success of healthcare interventions is very much dependent on patient involvement and their attitudes to them, the assessment of patients' views of an intervention is crucial before implementing an intervention into practice [5]. Assessing the acceptability of any smoking cessation intervention to patients, in terms of their satisfaction with the intervention and their perceptions of its usefulness, can help fine-tune interventions to improve uptake and success [5]. While the use of qualitative research, being flexible and explorative in nature, has been widely used to improve interventions before further evaluation and implementation, the additional use of quantitative methods, such as questionnaires, has also been recommended [6].

Despite the availability of valid satisfaction questionnaires, such as the widely used Client Satisfaction Questionnaire (CSQ-8) [7], and the UK National Health Service (NHS) Stop Smoking Service Client Satisfaction Survey (which also investigates perceived usefulness) [8], these were deemed inadequate to help assess the satisfaction with and perceived usefulness of a smoking cessation intervention among individuals with diabetes. This is because such tools either measure satisfaction as a broad concept, without referring to smoking cessation (e.g., the CSQ-8) [7], or are too specific, referring to a specific context/smoking cessation service (e.g., the UK National Health Service Stop Smoking Service Client Satisfaction Survey) [8]. Since no quantitative measures which evaluate satisfaction and perceived usefulness of smoking cessation interventions among individuals with diabetes have been identified [4], this study aimed to validate the content of two self-developed instruments. These instruments were designed to measure satisfaction and perceived usefulness of a smoking cessation intervention among individuals with diabetes. Additionally, this study aimed to establish the conceptual equivalence of these measures after translation into Maltese for local use. It also sought to assess the internal consistency of both versions of the instruments.

4. Methods

4.1. Questionnaires

Prior to the development of the satisfaction and perceived usefulness questionnaires, the literature, including the ePROVIDE™ platform (a centralised platform for Patient-Centered Outcomes, particularly for Clinical Outcome Assessments) [9], was screened to identify existing valid and reliable acceptability measures for evaluating smoking cessation interventions/programmes. However, only the UK NHS Smoking Service Client Satisfaction Survey [8] was identified. Both instruments were initially developed in English by JG, after consideration of the literature and the satisfaction questionnaires identified [7,8,10,11], and were reviewed by the other authors. The questionnaires were devised to evaluate diabetes-specific or general smoking cessation face-to-face interventions which may not include the provision of pharmacotherapy for smoking cessation.

The satisfaction questionnaire consisted of eight statements covering the main elements of smoking cessation interventions [8], i.e., the support received, the setting, the appointment times given, the waiting time for having the first session, the duration of each session, the frequency and the number of follow-up sessions, and the method used to help the smoker quit. Conversely, the perceived usefulness questionnaire consisted of 14 items. While the first two items were about the ability of the smoking cessation intervention in meeting the participant's expectations and his/her needs, the other 12 items were about the ability of the intervention in providing the necessary information, motivation, and behavioural skills required to quit smoking as per the Information-Motivation-Behavioural Skills (IMB) model of behaviour change [10]. Both instruments were rated by a 5-point Likert scale, ranging from (1) 'very unsatisfied' to (5) 'very satisfied' or 'strongly disagree' to 'strongly agree,' respectively. Three open-ended questions, asking participants to explain which aspects of the smoking cessation intervention they were most and least satisfied with, and for suggestions for improvement, complemented these instruments. A close-ended question ('yes' or 'no' answer) asking participants whether they would recommend the intervention to others, was also added.

Following the development of the questionnaires, two individuals with diabetes, who had attended general stop-smoking services, were asked to review the questionnaires for comprehension and appropriateness. However, no concerns were expressed.

4.2. Content validity

Basing expertise on clinical experience, all the smoking cessation facilitators within the Maltese National Health (NHS) Stop Smoking Services (n = 7, excluding JG) and a former smoking cessation facilitator who still provided ad hoc smoking cessation support services, were invited to participate in the content validation process. Using the 4-point ordinal rating scale by Lynn [12], ranging from (1) 'not relevant' to (4) 'very relevant and succinct,' they were asked to independently rate the extent to which the items and the instruments measure the concepts of interest. They were also invited to suggest additional items, item rewording/deletion, or provide comments [12]. Despite sending several reminders three facilitators did not reply. All the facilitators who replied held a Master of Science degree in a healthcare-related subject, with professional backgrounds in podiatry, nursing, and occupational therapy. One facilitator also held a Doctor of Philosophy degree. Three experts had over five years of experience in tobacco cessation services, while the other two had less than one year and three years, respectively. Two experts were also lecturers, teaching public health and research methods, and tobacco cessation and control modules, respectively, at the University of Malta. Given that there were less than six experts in the panel, a 100% agreement by all experts in rating the items as (3) 'relevant but needs minor alteration' or (4) 'very relevant and succinct' was required [12].

4.3. Translation validity

Once validated, the questionnaires were translated into Maltese and back-translated into English and compared to the original versions by bilingual translators who ensured their literal and syntactic equivalence. Minor edits were required.

To ensure that the original concepts were still being measured, the same panel of experts was asked to assess each item of the Maltese questionnaires for conceptual equivalence using the 4-point ordinal rating scale by Tang and Dixon [13], ranging from (1) 'totally different to (4) 'equivalent.' Again unanimous agreement by all experts in rating the items as (3) 'equivalent but needs minor modification,' or (4) 'equivalent' was required [13].

4.4. Internal consistency

In addition to establishing content validity and equivalence of the questionnaires, both sets of questionnaires required at least the assessment of internal reliability as part of this initial validation process [14]. Given that the shorter instrument had eight items, in assuming that the

coefficient of Cronbach's alpha in the null hypothesis and alternative hypothesis be equal to 0.0 and 0.7, respectively, based on an alpha value fixed at 0.05, a minimum sample size of 15 was required to achieve a power of 80.0% [15]. Therefore, a minimum of 30 participants were required for assessing the internal consistency of both versions of the questionnaires.

Between November 2022 and July 2023, a pilot study was conducted to test and refine a diabetes-specific smoking cessation intervention [16], which included the provision of Nicotine Replacement Therapy (NRT). The pilot study involved a small sample of individuals with type 1 or type 2 DM (n = 34), recruited from the diabetic clinics within the two main acute public hospitals in Malta. All the participants filled out a questionnaire on their general characteristics, and their diabetes and smoking profiles on recruitment. These were then invited to complete the satisfaction and perceived usefulness questionnaires at the end of their study period (at 12 weeks). Participants were randomly given the English or Maltese versions of these questionnaires, ensuring an equal distribution.

The mean scores (SD) and Cronbach alpha values for both sets of questionnaires were calculated. To identify any items which detracted from the overall reliability, Cronbach alpha (and scale mean) was also computed repeatedly, each time eliminating one item from the analysis. The correlation of each item with the sum of the remaining items (item-to-total correlation), was also calculated. The findings from the open-ended questions and the additional close-ended question are not reported in this paper.

5. Results

5.1. Content validity

All experts rated almost all the items from both questionnaires as relevant (3–4 ratings), suggesting minor edits. However, one expert (Expert 1) suggested the deletion of the item 'Made you aware of severe diabetic complications caused by smoking' in the perceived usefulness questionnaire, remarking that such information may not be needed if the client is sufficiently informed. Given that a 100% agreement was required for establishing content validity, this item was removed. Conversely, another expert suggested the addition of the following items for the same questionnaire, 'provided you with options on how to quit smoking,' and 'helped you to set a specific date to quit.' Thus, a second round of content validation was conducted. All experts found almost all items relevant, however, Expert 1 suggested the deletion of the recently added item, 'Helped you to set a specific date to quit,' stating that from experience most individuals do not like to set a quit date and so might not perceive its utility. Hence, this was removed. The final version of the questionnaires is available in the Supplementary file.

5.2. Translation validity

All experts unanimously agreed that the items were equivalent, providing three or four ratings. When items were rated as 'three,' suggestions were provided. These were then discussed with the bilingual translators and revised accordingly.

5.3. Internal consistency

Fifteen participants completed the Maltese versions of the questionnaires, while sixteen completed the English versions. Descriptive statistics of the respondents, including the demographics, diabetes, and smoking profiles (at baseline and end-of-study period) and the number of smoking cessation support sessions provided are available in the Supplementary file. The mean scores of the satisfaction and perceived usefulness questionnaires (both versions) were high, denoting that most participants were satisfied/agreed with the posed statements (Table 1). Cronbach's alpha scores were 0.87 and 0.91 for the Maltese and English versions of the satisfaction questionnaire, and 0.94 and 0.96 for the Maltese and English versions of the perceived usefulness questionnaire. On eliminating the items one at a time from the analysis, the Cronbach alpha (and scale mean) remained relatively stable (Supplementary file, Tables 2–5). All item-scale correlations were >0.4.

Table 1
Questionnaires' scores and internal consistency assessment.

Instrument	No. of items	Total score range	n	Mean (SD)	Cronbach's alpha
Satisfaction questionnaire - English version	8	8–40	16	36.0 (3.35)	0.91
Satisfaction questionnaire - Maltese version			15	32.9 (4.22)	0.87
Perceived usefulness questionnaire - English version	14	14–70	16	62.3 (9.57)	0.96
Perceived usefulness questionnaire - Maltese version			15	56.1 (9.76)	0.94

6. Discussion

This paper reports on the initial validation of the satisfaction and perceived usefulness questionnaires for evaluating smoking cessation interventions among individuals with diabetes. Following content validation of the English questionnaire, the conceptual equivalence of the translated Maltese questionnaires was established. Both versions of the questionnaires were found to have a high internal consistency (>0.8). Furthermore, all items correlated well with the total.

These questionnaires present a better alternative to current standard satisfaction questionnaires for assessing the acceptability of smoking cessation interventions among individuals with diabetes. This satisfaction questionnaire is more specific than a general satisfaction questionnaire, e.g., the CSQ-8 [7]. Conversely, it is not as specific as the UK NHS Smoking Service Client Satisfaction Survey [8], thus allowing its use in different face-to-face settings for comparative purposes. The perceived usefulness questionnaire adds to the use of the satisfaction questionnaire. The use of the perceived usefulness questionnaire can help researchers assess acceptability further by investigating participants' perceptions of a smoking cessation intervention in providing the necessary information, motivation and behavioural skills, which are required to quit smoking as per the Information-Motivation-Behavioural Skills (IMB) model of behaviour change [10]. The use of both questionnaires, with or without use of additional methods, such as semi-structured interviews, is thus recommended to help researchers investigate the acceptability of a smoking cessation intervention amongst individuals with diabetes to improve its uptake and success.

In this study, participants were satisfied with the intervention provided, perceiving it as useful. While the evaluation of the tested diabetes-specific smoking cessation intervention was beyond the scope of this study, the findings obtained appear promising for its potential use. Thus, further research is required to assess the feasibility of implementing this smoking cessation intervention in practice.

7. Strengths and limitations

This study's findings provide the initial validation of the satisfaction and perceived usefulness questionnaires for assessing the acceptability of diabetes-specific or general smoking cessation interventions among individuals with diabetes. However, internal reliability assessment was only conducted among a small sample of participants, the majority of whom were males with type 2 diabetes, as expected (see supplementary file) [2], who attended a diabetes-specific smoking cessation

intervention. Hence, further validation, which may include assessing the questionnaires' stability over time and factor analyses, in different settings using a larger sample is suggested.

Ethical approval

Ethical approval was obtained from the Faculty of Health Sciences Research Ethics Committee on behalf of the University Research Ethics Committee of the University of Malta (UREC FORM V_15062020 8618, Date: October 5, 2022). Participants provided informed consent.

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Consent

Informed consent was obtained from all individual participants included in the study.

Data availability

The data supporting this research are available from the authors on reasonable request.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.puhip.2024.100487.

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Appendix 9.7: Abstract presentation (European Conference on Tobacco Control – abstract no. 2)

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Development of a multi-component smoking cessation intervention for individuals living with diabetes

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Background
Smoking cessation is an integral aspect of diabetes management. Given the diabetes-specific challenges faced by individuals with diabetes in attempting to quit smoking, the provision of tailored smoking cessation support has been recommended. However, there has been limited research on the development of tailored smoking cessation interventions for this cohort.
Objectives
Develop a diabetes-specific smoking cessation intervention, based on evidence and the needs of individuals with diabetes.
Methods
A scoping review of the literature on smoking cessation interventions for individuals with diabetes, and on the challenges and barriers to quitting was carried out to identify the most promising smoking cessation methods for this cohort. This was followed by a systematic review and intervention component analysis of the identified smoking cessation methods, for identifying the most effective smoking cessation elements. Additionally, a qualitative descriptive study was held amongst 20 Maltese former and current smokers with diabetes to explore their needs to quit smoking and views on the identified intervention components.
Results
Based on the reviews and the qualitative descriptive study's findings, a multi-component smoking cessation was developed. This consists of three to four behavioural support sessions (about 30 minutes each) and a six-week provision of Nicotine Replacement Therapy. To address the documented need for more impactful communication about tobacco-related harm, the intervention includes three brief video clips featuring a person with diabetes who experienced tobacco-associated diabetic complications. Participants from the qualitative descriptive study also expressed the need for smoking cessation support in local diabetes practice, presenting an opportunity to integrate the smoking cessation intervention into local diabetes education initiatives.
Conclusions
This study reports on the development of a unique multi-component smoking cessation intervention based on evidence and the needs of individuals with diabetes. The intervention will now be piloted as part of local diabetes education efforts.
Conflicts of interest
The authors have no conflicts of interest to disclose.

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The history of smoking cessation support in Hungary

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Background
Tobacco use remains the greatest preventable cause of death in Hungary, with a smoking-related death rate (2019: 360/100 000 age-standardized death rate) among the highest in the WHO European Region. Despite WHO FCTC-defined tobacco control measures in place, smoking prevalence is high (2019: 27%) and has not decreased since 2014.
Objectives
This study attempts to summarize the progress of smoking cessation support in Hungary aiming to identify strengths and areas for improvement to lessen the toll caused by smoking.
Methods
A literature search was conducted using the Hungarian Digital Archives Database. After 2012, the data has been derived from the National Methodology Center for Cessation Support (Center) reports.
Results
The National Korányi Institute of Pulmonology (NKIP) established the first organized network of cessation counseling services in 1987 at outpatient pulmonary clinics (OPCs) sponsored by a State Insurance tender. By 1999, individual behavior counseling with medication was accessible at 130 healthcare providers thanks to pharmaceutical company support. Since 2005, the National Health Insurance Fund has supported, albeit at a low value, behavior counseling at OPCs. The Center at NKIP was established in 2012 and entrusted with the following: education of healthcare workers in cessation support (2430 persons between 2012-2023), operation of the national quitline (on average 1000 persons counseled per year), formulation of relevant guidelines, and coordination of cessation support programs. Having recognized that OPCs are overburdened by the organizational tasks of cessation support and funding was intermittent, from 2020 counseling service has steadily transferred to the existing network of health promotion offices, although without specific funding for cessation programs and communication.
Conclusions
To achieve tobacco control advances, adequate and regular funding for established counseling services and nicotine withdrawal treatment is essential. Furthermore, the role of healthcare professionals in reducing the tobacco epidemic toll is outstanding, therefore individual responsibilities should be recognized.
Conflicts of interest
The authors have no conflicts of interest to disclose.

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Quitting smoking without gaining weight: short- and long-term results from a study of individuals with overweight and obesity

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Appendix 9.8: Abstract presentation (University of Malta Research Expo)

L-Università ta' Malta

UM RESEARCH EXPO 2024

Certificate of Participation

This is to certify that

Joseph Grech
392884M

has participated in the

University of Malta Research Expo 2024

with a poster presentation

Exploring Participants' and Providers' Views of a Nurse-Led Smoking Cessation Intervention for Individuals with Diabetes

29 May 2024

Director
Doctoral School

Pro-Rector Research &
Knowledge Transfer

Academic Registrar

Appendix 9.9: Feasibility study protocol

Open access Protocol

BMJ Open

Assessing the feasibility and acceptability of a diabetes-specific nurse-led multicomponent smoking cessation intervention in diabetes education: study protocol for an open-label pragmatic randomised controlled trial

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ABSTRACT

Introduction Smoking cessation is an essential, but often overlooked aspect of diabetes management. Despite the need for tailored smoking cessation support for individuals with diabetes, evidence of effective interventions for this cohort is limited. Additionally, individuals with diabetes do not easily adopt such interventions, resulting in low uptake and abstinence rates. This protocol describes a study that aims to assess the feasibility and acceptability of a unique smoking cessation intervention, based on the best evidence, theory and the needs of individuals with diabetes, among patients and service providers, the diabetes nurse educators.

Methods and analysis This is an open-label pragmatic randomised controlled trial. Between 80 and 100 individuals with type 1 or type 2 diabetes who smoke will be recruited from the diabetes outpatients at the main acute public hospital in Malta, starting in August 2023. Participants will be randomly assigned (1:1 ratio) to the intervention or control arm for 12 weeks. The experimental intervention will consist of three to four smoking cessation behavioural support sessions based on the 5As (Ask, Advise, Assess, Assist and Arrange) algorithm, and a 6-week supply of nicotine replacement therapy. The control intervention will consist of an active referral to the Maltese National Health Service's one-to-one smoking cessation support service, which is based on motivational interviewing. The primary feasibility and acceptability outcomes include the recruitment and participation rates, resources used, problems identified by the nurses, the nurses' perceived challenges and facilitators to implementation and the nurses' and patients' acceptability of the study intervention. Data analyses will be descriptive, with quantitative feasibility and acceptability outcomes reported with 95% confidence intervals.

Ethics and dissemination Ethical clearance was obtained from the Faculty of Health Sciences Research Ethics Committee, University of Malta. The study results will be disseminated through conference presentations and a publication in a peer-reviewed journal.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This paper outlines the study protocol of a feasibility trial, an overlooked, but critical step in the development and evaluation of smoking cessation interventions among individuals with diabetes, in preparation for a future definitive evaluation.
⇒ Since healthcare interventions are highly context-dependent, this study will adopt a pragmatic approach, assessing the feasibility of the intervention in the real-world context of diabetes ambulatory care, where formal diabetes education is provided locally.
⇒ A unique multicomponent smoking cessation intervention based on evidence, theory and the needs of individuals living with diabetes is described to allow its replication.
⇒ This is a feasibility trial and is not powered to determine the effectiveness of the intervention.

Trial registration number NCT05920096.

INTRODUCTION

Diabetes mellitus (DM) is a major public health concern both worldwide and in the Maltese context. DM, characterised by chronically elevated blood glucose levels that lead to the development of various macrovascular and microvascular complications, thus increasing the risk of morbidity and death, is estimated to affect approximately 1 in every 10 adults aged 20–79 years worldwide.[1] While the European region has the second-lowest diabetes prevalence (at 9.2%; 95% CI 7.1 to 10.4), Malta, a European country, has a high

diabetes prevalence, estimated at 11.2% (95% CI 8.7 to 13.8).[1]

Individuals living with DM require medical care, self-management education and support that goes beyond glucose management. Tobacco cessation is an essential, but often overlooked aspect of diabetes management.[2] In persons with DM, tobacco smoking, likely mediated by the effects of nicotine, appears to contribute to greater insulin resistance,[5–6] worsened beta-cell function and impaired insulin secretion,[3 4] glucolipotoxicity and dyslipidaemia.[5–6] This exacerbates both macrovascular and microvascular complications of DM. Both individuals with type 1 and type 2 DM who smoke are at approximately 50% higher risk of adverse cardiovascular events, such as coronary heart disease and stroke, compared with non-smokers with diabetes.[7 8] Similarly, a higher risk for cardiovascular mortality and total mortality has also been identified among smokers with type 1 and type 2 DM.[7 8] Tobacco smoking may also increase the risk of microvascular diabetes complications, such as diabetic nephropathy, neuropathy and retinopathy, particularly among individuals with type 1 DM.[4 9] Furthermore, individuals with DM who smoke experience a 1.65-fold increase in the risk of diabetic foot amputations.[10] Conversely, smoking cessation is associated with significant health benefits, including improved cardiometabolic profiles,[3] and a notable reduction in the risk for cardiovascular disease, cardiovascular mortality and overall mortality among this population.[7 8] Smoking cessation for individuals with diabetes is one of the key recommendations of Malta's national diabetes strategy.[11]

Despite the importance of quitting smoking, having diabetes does not appear to motivate individuals to quit.[12 13] Durlach *et al* estimated that on average 20% of individuals with type 2 DM and 30% of individuals with type 1 DM smoke.[4] Analysis of unpublished raw data from the Malta National Health Interview survey revealed that 17.4% of those who reported having diabetes also reported being a smoker (unpublished data on smoking and diabetes; Directorate for Health Information and Research, 2023). Smokers with diabetes may be less motivated to stop smoking due to several diabetes-related barriers and challenges to quitting. These include: concern about possible weight gain and poor glycaemic control, which may occur on quitting smoking[3]; comorbid anxiety and depression,[14 15] which can hinder efforts in quitting smoking[16] and possibly increased nicotine metabolism associated with having diabetes, which increases nicotine addiction, making it harder for them to quit.[17 18]

While the need for providing tailored smoking cessation support to tackle these diabetes-related barriers and challenges to quitting has been emphasised,[4 9 13] evidence-based smoking cessation recommendations for individuals living with DM are still lacking. The systematic review and meta-analysis by Nagrebetsky *et al* aimed to assess the effectiveness of intensive smoking cessation interventions, such as intensive behavioural support (eg, intensive counselling) or interventions that combine behavioural support and pharmacotherapy, such as nicotine replacement therapy (NRT), bupropion or varenicline, among individuals with DM.[19] However, the limited number of reviewed studies and the significant heterogeneity in the intervention tested and comparator group limited the authors' conclusions regarding the efficacy of diabetes-specific smoking cessation interventions, and from providing practice recommendations.

Grech *et al*, who recently updated the systematic review by Nagrebetsky *et al* and included an intervention component analysis, found that intensive smoking cessation interventions, comprising three to four sessions, each lasting >20 min, were more likely to be associated with smoking cessation compared with brief interventions or those consisting of fewer sessions.[20] However, inconsistent findings limited their ability to make comprehensive recommendations for practice, particularly concerning the use of specific behavioural interventions and smoking cessation pharmacotherapy.[20] Given the identified gap in evidence, further research on the development and evaluation of tailored smoking cessation interventions for individuals with diabetes has been recommended.[19 20]

Notwithstanding the limited evidence-based smoking cessation recommendations for individuals with DM, evidence suggests that health professionals who care for individuals with diabetes are less likely to advise their patients against smoking and support them towards quitting, compared with health professionals who treat individuals without diabetes.[21 22] International and local literature suggest that diabetes clinicians and educators often prioritise other aspects of diabetes management over smoking cessation.[2 23–25] Diabetes educators have reported feeling inadequately prepared to discuss smoking cessation with individuals with diabetes, lacking motivation and time to do so.[2 26]

Given that the success of a proposed healthcare intervention, such as a smoking cessation intervention, is very much dependent on stakeholder engagement, patients and providers alike, investigating the feasibility and acceptability of a proposed intervention is crucial prior to further evaluation and implementation.[27] The feasibility and acceptability assessment of a proposed diabetes-specific smoking cessation intervention for undertaking a future large-scale randomised controlled trial is particularly advisable in view of the reported low recruitment, uptake and challenges encountered in two recent smoking cessation trials carried out among individuals with DM.[28 29] These trials, which were initiated before the COVID-19 pandemic, in 2018,[28] and after the declaration of the pandemic, in August 2020,[29] did not reach the target sample size and were later terminated due to lack of funding,[28] and following the recall of varenicline which was one element of the study intervention,[29] respectively. Conducting a feasibility study will help estimate the recruitment rate and study uptake, identify potential challenges (along with mitigating factors) and assure the intervention's acceptability among patients and providers a priori, thus ensuring that the main trial

targets can be met before proceeding with a larger, definitive trial.[30]

In summary, following the development of a unique multicomponent smoking cessation intervention, based on best evidence and theory, and tailored for people living with DM who smoke,[20 31 32] a feasibility study was proposed prior to a definitive evaluation. This study aims to assess the feasibility of a definitive randomised controlled trial, by analysing the recruitment and study uptake, the perceived challenges and facilitators to implementation among service providers and the acceptability of the intervention. This will involve analysing participants' and providers' satisfaction with the smoking cessation support provided, as well as participants' perceived usefulness of the intervention. The feasibility study also aims to compare the participants' satisfaction with and perceived usefulness of the smoking cessation support provided to standard care (the provision of general smoking cessation support); undertake a preliminary process evaluation, by assessing whether the intervention was delivered as intended and exploring the intervention's functioning and determine the preliminary evidence of the intervention's effectiveness, by comparing the smoking cessation rates achieved in the intervention group with the control group (standard care).

METHODS AND ANALYSIS

This feasibility study is part of a research project titled, 'Development and feasibility testing of a multicomponent smoking cessation intervention for smokers living with diabetes mellitus', which is guided by the Medical Research Council (MRC) 2021 framework for the development and evaluation of complex interventions in healthcare.[27] The methods and analysis reported in this paper match the trial registration details available on ClinicalTrials.gov (NCT05920096). This protocol follows the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) reporting guidelines (online supplemental file 1).[33]

Design

An open-label, pragmatic, experimental design will be adopted. While a feasibility study may not need to be a randomised trial,[30] a comparative analysis of an alternative standard course of action (ie, the provision of general smoking cessation support by the Health Promotion and Disease Prevention Directorate, within the Maltese National Health Service), in terms of the outcomes (ie, smoking cessation rates, and satisfaction with and perceived usefulness of the intervention provided), will provide sufficient information to make decisions about progressing to the evaluation stage of the MRC framework.[27] Furthermore, adopting the same design and protocol as would be used in a larger scale randomised controlled trial will help assess the feasibility of undertaking the trial. This involves analysing the recruitment and study uptake as well as the successful delivery of the intervention, while also taking note of the resources used.[34] Given that healthcare interventions are highly dependent on the context in which they are tested, this study will adopt a pragmatic approach, assessing the feasibility of the intervention in the real-world context,[27] specifically in diabetes ambulatory care where formal diabetes education is provided locally.[11] An open-label design will be adopted. The participants, who are likely to be aware of the Maltese National Health System's smoking cessation services, may be able to distinguish between the assigned arms and hence will not be blind to treatment. On the other hand, due to the pragmatic nature of the study, blinding the intervention providers will also not be possible. The Principal Investigator (PI), JG, who will be actively involved in recruiting and carrying out pre-intervention and post-intervention assessments and data analyses, also cannot be blinded to treatment assignment. However, being a feasibility study, blinding is not strictly required as there is no formal hypothesis testing.[30] Nonetheless, as explained below, the 7-day point prevalence abstinence at follow-up will be objectively measured to minimise bias.[35] Furthermore, the questionnaires used during the pre-intervention and post-intervention assessments will be coded to avoid participant identification.

Study population

In Malta, all adults with type 1 DM are under the care of the diabetologists attending the diabetes outpatients/the Diabetes and Endocrine Centre (DEC) at the main acute public hospital in Malta, Mater Dei Hospital.[11] While individuals with type 2 DM may be seen in primary care, they also attend the DEC when complications arise, or at prescribed time intervals, at least once annually.[11] In this study, participants will be recruited from the DEC, and the adjacent Diabetes Education Unit (DEU), where formal diabetes education is provided.

Inclusion criteria

- Documented diagnosis of type 1 or type 2 diabetes (meeting the diagnostic criteria of the American Diabetes Association (ADA))[36] and attending the DEU or the DEC at Mater Dei Hospital on an outpatient basis.
- Having smoked at least 100 cigarettes in one's lifetime and currently smoking.
- Being ≥18 years of age.
- Speaking and understanding English or Maltese.
- Able to provide written informed consent.

Exclusion criteria

- Not being able to provide informed consent (due to dementia, a learning disability, or a psychological disorder).
- Being pregnant or breastfeeding.
- Unable to independently attend to the DEU and any of the health centres in which the Health Promotion and Disease Prevention Directorate provide smoking cessation support during the study period.

- Currently enrolled in another smoking cessation study/programme or multi-behavioural programme which also focuses on smoking cessation.
- Enrolment of the investigator or the research collaborators, and their family members.

Sample size

A power calculation to determine the sample size is not appropriate for a feasibility trial, as the purpose of a feasibility trial is not to establish efficacy.[37] However, the sample should be large enough to provide estimates of the parameters that are used to calculate the sample size for definitive trials. For estimating the CIs for feasibility outcomes, such as the recruitment rate and rate of consent to the study, and the compliance to the study protocol, Hertzog[38] suggests having 30–40 participants per group, while Teare *et al*[39] recommend having 60 participants per group. However, ultimately the sample size decision must also take into consideration the resources required and time available.[39] Thus, this study aims to recruit a minimum of 80 and a maximum of 100 participants.

Recruitment and randomisation

At the DEC, all new patients with type 1 or type 2 DM are screened for tobacco use by diabetologists and advised to quit smoking. As part of the study's pragmatic approach to assess the feasibility of providing smoking cessation support in diabetes practice, the diabetologists working at the diabetes outpatients will be asked to identify smokers who are interested in quitting and to refer them to the PI for study recruitment. Additionally, the healthcare professionals working at the diabetic clinics at the DEC, such as the nurses and the podiatrists, and the diabetes specialist nurses (diabetes nurse educators) at the DEU, will also be asked to identify any interested smokers during their practice and to refer them to the study. Posters and flyers will also be present at the DEC so that participants can also self-refer to the study. To enhance recruitment, onsite visits will be held during which feedback on the recruitment process will be provided to all healthcare professionals.[40] No additional strategies, such as offering patient incentives, will be employed, as they would limit the feasibility study's capacity to truly assess the need for smoking cessation support within diabetes practice.

In 2022, there were 1786 new patients (most of whom are individuals with type 1 or type 2 DM) who attended the diabetes outpatients (of whom 473 attended the DEU) at Mater Dei Hospital.[41] Of these, 17.4% were likely to be smokers (unpublished data on smoking and diabetes; Directorate for Health Information and Research, 2023). Assuming a yearly population size of approximately 311 individuals, a sample size of 100 (or 80) participants, with a 95% CI, would be sufficient to provide the aforementioned feasibility estimates with an acceptable margin of error of 8% (or 10%).[42] Given that the consent rate for participating in smoking cessation trials was found to be 66.4% (IQR 42.7%–85.2%),[43] it is anticipated that the target sample size of 80 or 100 participants will be achieved within 1 year.

The PI will screen all recruited patients by telephone to assess eligibility, inviting them to participate in the study. Eligible interested individuals will attend a pre-intervention assessment session for informed consent, during which the PI will randomly assign them to the intervention or control group and assess baseline characteristics. Participants will be randomly allocated to the intervention or control arm on a 1:1 ratio using a computer-generated random block length (in blocks of two and four), using the random allocation software by Saghaei.[44] The sequence will be prearranged before the study begins, with group assignments sealed in sequentially numbered opaque envelopes. The PI will assign the sequentially numbered opaque envelopes in the order they are met. The participants' characteristics will not be known before the assignment of the envelopes.

Participants are to receive the respective intervention within 2 weeks from the assignment. Post-intervention evaluation will take place 12 weeks after the pre-intervention assessment session. Figure 1 displays the participant timeline for this study, based on the SPIRIT participant timeline figure.[33]

Pre-intervention assessment

In the pre-intervention assessment session, a baseline questionnaire will be used to collect information on the participants. This questionnaire will collect demographic data, perceived health status, diabetes and smoking profiles and anxiety and depression levels. Questions are based on the literature. Cigarette dependence, current motivation to stop smoking, which are part of the smoking profile and anxiety and depression will be measured using well-established validated questionnaire scales. Cigarette dependence will be measured using the Cigarette Dependence Scale-5 (CDS-5),[45] while motivation to stop smoking will be measured using the Motivation To Stop Scale (MTSS).[46 47] Conversely, the Hospital Anxiety and Depression Scale (HADS)[48] will be used for screening for anxiety and depression. As part of the smoking profile section, exhaled carbon monoxide will also be measured using the Bedfont piCO Smokerlyzer to confirm smoking status.[49]

The baseline questionnaire will be made available to participants in English and Maltese. Except for HADS,[48] which was already translated and validated into Maltese by Baldacchino *et al*,[50] the CDS-5[45] and the MTSS[46 47] required translation and validity assessment. To ensure the content validity of the translated instruments, conceptual equivalence was established for these instruments by following the process outlined by Tang and Dixon.[51] Additionally, the CDS-5[45] was assessed for internal reliability using Cronbach's alpha. Based on the minimum sample size required,[52] 17 individuals living with type 1 or type 2 diabetes were invited to complete the Maltese version of the CDS-5 prior to participating in a smoking cessation programme. The Cronbach's alpha score was high; 0.80.

	STUDY PERIOD				
	Enrolment	Pre-intervention assessment	Post-allocation	Post-intervention assessment	End of study
TIMEPOINT	0	$week_0$	$week_1$ to $week_{12}$	$week_{12}$	
ENROLMENT:					
Eligibility screen	X	X			
Informed consent	X	X			
Random allocation		X			
INTERVENTIONS:					
Experimental: Multi-component smoking cessation intervention			⟷		
Control: Health Promotion and Disease Prevention Directorate's one-to-one smoking cessation service			⟷		
ASSESSMENTS:					
Baseline characteristics		X			
Feasibility outcomes:					
Recruitment parameters	X	X			
Compliance with the protocol, resources utilised and problems identified			X		
Response rate at 12 weeks follow-up				X	
Perceived challenges and facilitators to implementation					X
Acceptability outcomes:					
Participants' satisfaction with and perceived usefulness of the intervention				X	
Nurses' satisfaction with the intervention					X
Treatment fidelity of the experimental intervention					X
Exploration of the experimental intervention's functioning				X	
Preliminary evidence of effectiveness				X	

Figure 1 Participant timeline for this feasibility trial (based on the Standard Protocol Items: Recommendations for Interventional Trials figure).

On eliminating the items one at a time from the analysis, the Cronbach's alpha (and scale mean) remained relatively stable (online supplemental file 2). All item-scale correlations were ≥0.4.

Interventions

Experimental intervention

Intervention development

The development of the intervention followed a three-stepped research process. Initially, a scoping review was undertaken to identify the most promising smoking cessation methods for persons living with diabetes, identifying any gaps in evidence.[51] This was followed by a systematic review and intervention component analysis of the identified most promising smoking cessation methods to identify their critical components.[20] Then a qualitative descriptive study was conducted to explore the needs of individuals with diabetes to quit smoking, and their views of the identified promising smoking cessation components.[52] Based on the reviews and the qualitative descriptive study's findings and recommendations, a

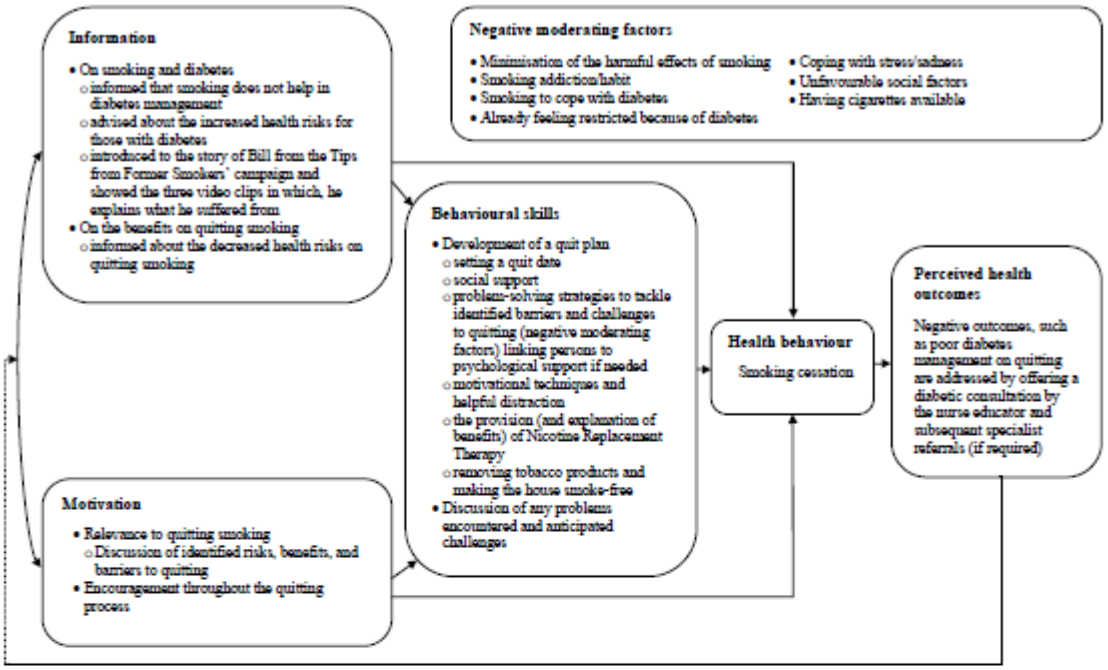

Figure 2 The theoretical model of this intervention, outlining the strategies for addressing the information-motivation-behavioural constructs for achieving and sustaining abstinence among individuals with diabetes mellitus.

multicomponent smoking cessation was developed and proposed to the diabetes specialist nurses working at the DEU.

Theoretical framework

The intervention is based on information-motivation-behavioural skills (IMB) model for achieving behaviour change,[53] and thus aims to:

- inform individuals with diabetes who smoke on the association between smoking and diabetic complications and the benefits of quitting;
- motivate and encourage individuals to quit smoking and/or remain abstinent;
- support them in developing/using the appropriate behavioural skills to quit smoking and avoid relapse;
- tackle any situational and individual characteristics (moderating factors) that can negatively influence smoking cessation, and negative health outcomes on quitting smoking, which can weaken adherence to the new behaviour via a feedback loop affecting the IMB constructs.

Figure 2 presents the theoretical framework of this intervention, outlining the strategies for addressing the IMB constructs (and any negative moderators and health outcomes)[53] for achieving and sustaining abstinence among individuals with DM.

Components of the intervention

The main components of this intervention include:

- Three to four (30–60 min) smoking cessation behavioural support sessions based on the 5As (Ask, Advise, Assess, Assist and Arrange) and 5Rs (Relevance, Risks, Rewards, Roadblocks and Repetition) algorithm,[54] which will be provided by two diabetes specialist nurses at the DEU (figure 3).
- Three brief video clips (with English subtitles) featuring Bill from the Tips from Former Smokers' campaign, to raise awareness on the link between smoking and diabetes drawing on first-hand experience.[55] Bill was an individual with type 1 diabetes who suffered and died from tobacco-associated diabetic complications (kidney failure, poor circulation, heart disease and blindness).[55]
- A 6-week supply of NRT based on the recommendations of Siahpush *et al*.[56]Despite the increasing evidence demonstrating the effectiveness of nicotine electronic cigarettes (e-cigarettes) for smoking cessation compared with NRT,[57 58] participants in this study will not be provided with e-cigarettes to address their nicotine dependence. This is because in Malta, in line with WHO's recommendations,[59] and that of other organisations, including the ADA,[60 61] the use of e-cigarettes is not recommended for smoking cessation in clinical practice. The decision to provide NRT instead of e-cigarettes is also based on the observation that individuals who quit smoking using e-cigarettes tend to continue using them, unlike those who use

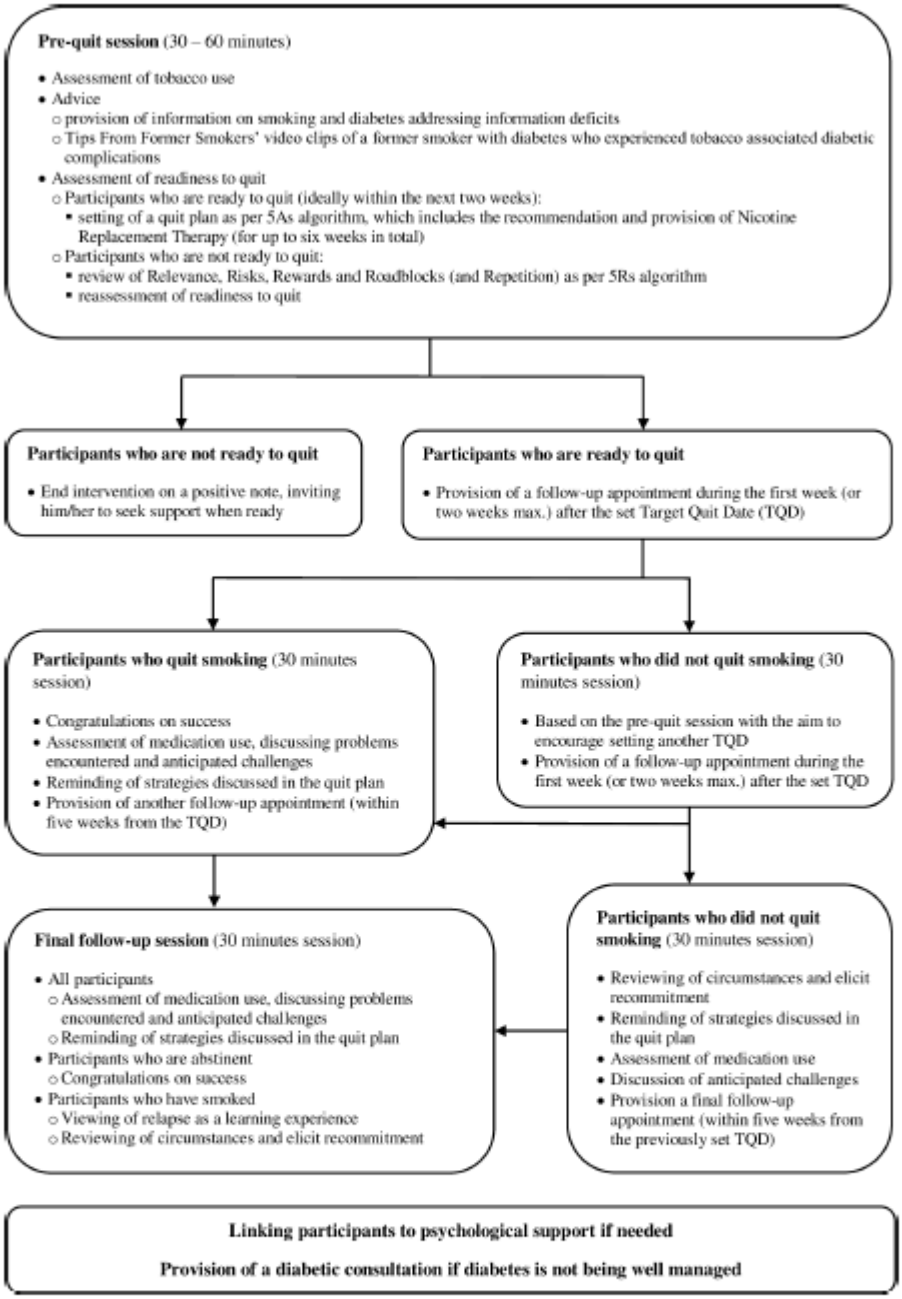

Figure 3 Study intervention algorithm based on the 5As (Ask, Advise, Assess, Assist and Arrange) (and 5Rs (Relevance, Risks, Rewards, Roadblocks and Repetition)) framework for smoking cessation.

NRT,[5 57 62 65] possibly leading to permanent nicotine dependence,[62] and the associated ill-health effects previously mentioned. Consistent with the literature, combination NRT, that is, the daily combination of the (16-hour) nicotine patch and a fast-acting nicotine product will be provided to individuals who smoke ≥10 cigarettes per day, while a fast-acting nicotine product will be provided to those who smoke fewer.[60 64 65] The nicotine mouth spray was selected as the preferred fast-acting nicotine product due to its

faster absorption rate compared with other options like gum or lozenges, resulting in quicker relief of cravings.[66 67] While mild adverse effects, such as hiccups and burning of the throat/tongue, tend to be more common when using the mouth spray, this was still deemed the treatment of preference among those who had used it.[68 69] Additionally, in the systematic review and meta-analysis by Theodoulou *et al*,[65] no significant difference in quit rates was identified between participant-selected and clinician-selected NRT. Participants will be provided with 6 weekly packs of 25 mg 16-hour nicotine patch (tapered during the last 2 weeks; 15 mg and 10 mg, respectively) and/or four nicotine mouth sprays (1 mg/spray; 150 sprays per bottle) for daily use if refraining from tobacco use, recommending the latter for breakthrough urges and/or to reduce withdrawal symptoms further.[60 64 65]

Additionally, participants will be referred for psychological support if reporting experiencing depression or anxiety, or on further discussion with those identified as potential cases; a score of ≥11 on the anxiety/depression subscale on the HADS.[48 70 71] Participants will also be offered a diabetic consultation by the nurse educator if reporting poor glycaemic control, or if they are concerned about diabetes management following a change in diet or weight gain on quitting smoking. Subsequent referrals to specialists, such as dietitians and diabetologists at the DEC, will be provided as needed.

Nurses' training

The two diabetes specialist nurses have been trained in smoking cessation prior to the study. A training programme, based on the successful training programme by Grech[72] (the PI), which followed the WHO toolkit for delivering the 5As and 5Rs for tobacco cessation,[54] was developed and delivered by the PI to the nurses prior to the initial testing of the intervention in November 2022 and to the commencement of the feasibility study (July 2023). To help assess fidelity, all the sessions provided by the two nurses will be audio-recorded with consent.[73 74]

Intervention log

Additionally, the nurses will be asked to keep an intervention log to document the following information per participant for measuring compliance to the protocol, the resources used and any challenges encountered[75]:

- the number, and duration of the sessions provided (and the number of weeks during which the sessions are provided) and non-attendance, along with reasons;
- provision of the 5Rs intervention at the first session;
- whether the participant opts not to see the informational video clips, along with reasons;
- whether the participant agrees to attempt to quit smoking (by setting a Target Quit Date (TQD)) at their first session, and subsequent session, if still smoking), along with reasons for not wanting to;
- the amount of NRT provided, and returned;
- reported use of NRT, along with reasons if a participant reports not using it;
- any problems encountered, such as side effects on using NRT, identified mental health issues, issues with managing diabetes and any referrals, including reasons for refusing support.

As recommended by Hollands *et al*,[76] NRT adherence will be assessed using a continuous outcome measure: the total days of NRT use, and the average number of times the nicotine spray is used per day. This assessment will cover the first week following the TQD (and the subsequent TQD for those who agree to reattempt quitting), which should coincide with the follow-up session/s, as well as the next 4 weeks, coinciding with the final follow-up session.

Control intervention

The participants who are assigned to the control group will be actively referred to the Health Promotion and Disease Prevention Directorate's one-to-one smoking cessation service, which is provided within community health centres around Malta. The smoking cessation support provided is based on motivational interviewing and is delivered by trained tobacco cessation facilitators. The counselling sessions, lasting around 20 min each, are usually provided every fortnight, based on the individuals' needs.

The smoking cessation services coordinator will be asked to take note of the number of sessions provided (including the number of weeks during which the sessions are provided) and any dropouts (with reasons).

Post-intervention evaluation

End-of-study questionnaire

All participants will be invited to a post-intervention assessment session, held at 12 weeks follow-up in which they will be invited to fill in the end-of-study questionnaire, available in English or Maltese. In the questionnaire, participants will be asked about their quitting attempt and smoking status, about the support they received during the study period and to rate their satisfaction with the smoking cessation intervention provided and their perceptions of its usefulness.

Smoking abstinence will be measured by following the recommendations by Piper *et al*.[77] Participants will be asked if, in the past 7 days, they intentionally refrained from smoking any combustible or non-combustible tobacco products and alternative products (7-day point-prevalence abstinence). They will also be asked if they abstained from smoking for seven consecutive days (or more) during the study period (7-day floating abstinence) or for at least 1 day or 24 hours (quit episode). Continuing smokers will be asked about their current tobacco use.

Biochemical verification of tobacco abstinence will be conducted for those reporting 7-day point-prevalence abstinence, based on the recommendations of Benowitz *et al*.[49] This will be carried out by using the same carbon

monoxide monitor and additionally by analysing a urine sample for cotinine exposure using a multilevel lateral flow immunoassays urine test strip with a nominal 200 ng/mL cut-off. The latter will help to confirm abstinence from both combustible and non-combustible tobacco sources and the use of alternative products, for example, e-cigarettes. Participants will be advised to discontinue the use of NRT prior to assessment, if possible, as cotinine can also be detected in urine because of NRT use.

To investigate the participants' satisfaction with the intervention and their perceptions of its usefulness, the measures by Grech *et al* for assessing the satisfaction and perceived usefulness of smoking cessation interventions among individuals with diabetes, will be used.[78] The satisfaction questionnaire consists of eight statements covering the main elements of smoking cessation interventions. It is rated by a 5-point Likert scale, ranging from (1) 'very unsatisfied' to (5) 'very satisfied'. The total score ranges from 8 to 40. Conversely, the perceived usefulness questionnaire consists of 14 items, based on the IMB model of behaviour change. It is also rated by a 5-point Likert scale, ranging from (1) 'strongly disagree' to (5) 'strongly agree'. The total score ranges from 14 to 70. Four additional questions, asking participants to explain which aspects of the smoking cessation intervention they were most and least satisfied with, suggestions for improvement and whether they would recommend the intervention to others ('yes' or 'no' option), complement these instruments. Both questionnaires (in English and Maltese) were found to have a high internal consistency (>0.8).[78]

Semi-structured interviews

Additionally, the participants who are assigned the experimental intervention will be interviewed to obtain feedback on the study intervention and to explore their quit attempt. The qualitative sample will consist of a purposeful sample, for obtaining an in-depth understanding of the acceptability of the study and the mechanisms of the study intervention from different viewpoints,[73 75] selecting individuals who stop or do not stop smoking, attend or stop attending the study intervention and use or do not use the NRT provided on attempting to quit smoking. In selecting participants, due consideration will also be made to sex, age and the type of diabetes. The sample size will be determined based on the principle of 'data saturation',[79] which occurs when newly collected data begin to repeat what was expressed in the previously collected data.[80] Given that no previous studies have explored the acceptability of a smoking cessation intervention among individuals with diabetes,[31] in estimating the required sample size, reference is made to the seminal study by Guest *et al*,[81] in which saturation was relatively achieved after only 12 interviews. The estimated sample size was increased to 20 participants.

Semi-structured interviews will also be carried out with both nurses to obtain feedback on the study intervention and to explore the facilitators and challenges to implementation.

Patient and public involvement

Individuals living with DM were involved during both the development and in planning feasibility testing of the intervention. During the developmental phase, a qualitative descriptive study was conducted to explore the needs of individuals with DM to quit smoking, and their views of the identified promising smoking cessation components,[20 31 32] to guide the development of the study intervention. Additionally, in November 2022, a pilot study was conducted to test and refine the intervention with a small sample of individuals with diabetes.[78] Based on the feedback received from both patients and providers, the study intervention was revised to include an additional follow-up session for those who report not quitting smoking, bringing the total to four sessions. Patients/Public were not involved in the design or the conducting of this study. A summary of the study findings, presented in a simple factsheet with pictograms, will be offered to all participants.

Outcome measures

Primary feasibility and acceptability outcomes

Feasibility: recruitment parameters

The following outcomes will be measured during the study recruitment period:

- The monthly recruitment rate of eligible smokers interested in quitting (recruitment rate).
- The proportion of eligible smokers identified from each source of recruitment (DEU, DEC and self-referral).
- The proportion of participants who consent to the study out of the total number of recruited eligible smokers, along with reasons for non-participation (consent rate).
- The recruitment duration in months.

Feasibility: compliance with the protocol, resources used and problems identified

These feasibility outcomes will be measured based on the information documented by the intervention providers during the intervention period:

- The proportion of participants who attend the scheduled sessions per group, along with reasons for not attending (participation rate).
- The proportion/number of participants in the intervention group who choose not to watch the informational video clips, along with their reasons.
- The proportion/number of participants in the intervention group who choose not to set a TQD at their first session (or subsequent session if still smoking), along with their reasons.
- The proportion of participants in the intervention group who use the nicotine patch and/or spray on their TQD, during the subsequent TQD for continuing

smokers, and in their final follow-up period, along with reasons for not using it.
- The average percentage of days the nicotine patch and/or spray are used by participants in the intervention group during the first week after the TQD, the subsequent TQD for continuing smokers and during the subsequent 4 weeks following 1 week from the TQD.
- The average daily usage of nicotine spray by participants in the intervention group during the first week after the TQD, the subsequent TQD for continuing smokers and during the subsequent 4 weeks following 1 week from the TQD.
- The average number of sessions provided per participant per group.
- The average duration (in weeks) of smoking cessation support provided per participant per group.
- The average time (in minutes) taken to deliver the experimental intervention sessions.
- The proportion/number of participants from the intervention group who were provided with the 5Rs intervention.
- The average amount of NRT provided per participant (taking note of any returned items).
- The number of problematic issues identified by the diabetes specialist nurses, such as reported adverse events while using NRT, and the number of referrals to additional support services (eg, psychotherapists). Participants who decline additional support will be documented, along with their reasons for refusal.

Feasibility: response rate at 12 weeks follow-up

- The proportion of participants attending their 12-week postintervention evaluation session in both groups, with reasons for dropouts.

Feasibility: perceived challenges and facilitators to implementation

- The perceived challenges and facilitators to implementation as identified when conducting interviews with the diabetes specialist nurses at the end of the study.

Acceptability outcomes

The following acceptability outcomes will be measured based on information collected from participants in the intervention group during their post-intervention evaluation sessions (questionnaires and interviews), as well as interviews with diabetes specialist nurses at the end of the study.
- Participants' satisfaction with the intervention provided.
- Participants' perceived usefulness of the intervention provided.
- Nurses' satisfaction with the intervention.

Secondary outcomes

Secondary acceptability outcomes

The following outcomes will be measured based on the data collected from the end-of-study questionnaires.
- Group comparison of the participants' satisfaction with the smoking cessation support provided.
- Group comparison of the participants' perceived usefulness of the smoking cessation support provided.

Preliminary process evaluation

- Treatment fidelity of the experimental intervention. A random sample (20%) from all the audio recordings (all sessions provided) from both nurses will be selected, listened to and cross-checked against a list outlining the intervention's action components (for each type of session) for calculating the level of adherence.[74] Any deviations from the study protocol will also be taken note of. An 80%–100% level of adherence constitutes high fidelity, <80% medium fidelity, whereas ≤50% constitutes low fidelity.[74]
- Exploring the experimental intervention's functioning when conducting interviews with the participants.

Preliminary evidence of effectiveness

The following outcomes will also be measured, based on the data collected from the end-of-study questionnaires:
- Proportion of participants per group reporting a quit episode during their study period.
- Proportion of participants per group reporting a 7-day point prevalence abstinence at any time during the study period (floating abstinence).
- Proportion of participants per group reporting a 7-day point prevalence abstinence at follow-up, biochemically verified.
- The change in the average number of cigarettes smoked per day (among continuing smokers) per group at follow-up.

Data analysis plan

Quantitative data

Based on the recommendations for the analysis of pilot and feasibility studies, where a formal power calculation is not carried out, the data analyses will be descriptive in nature, and no statistical comparisons between the intervention and control groups will be undertaken.[82–84] Nonetheless, the feasibility and acceptability outcomes will be reported with 95% CIs to provide an estimated range of the said outcomes.[82–84]

Continuous data will be summarised using means (and SD) and 95% CIs, and medians (and IQR) for normally and non-normally distributed variables, respectively. For categorical data, frequencies and proportions/percentages will be used. Proportions/Rates will also be reported with 95% CIs using the Clopper-Pearson 'exact' interval, which is more conservative for estimating CIs when using binomial distributed data.[83 85]

Missing data

In line with standard smoking cessation research practice,[65 80 87] intention-to-treat analysis will be used for assessing effectiveness. Participants with missing smoking outcome data, that is, those who drop out of the study or who are lost to follow-up, and participants whose

abstinence cannot be biochemically verified, will be considered as continuing smokers or to have resumed smoking.[65 86 87] The baseline characteristics of those followed up and those lost to follow-up will be compared descriptively.

To calculate the satisfaction and perceived usefulness questionnaires' average scores, any missing data will be handled in accordance with the recommendations of Mirzaei *et al*.[88] In case of a missing data percentage of up to 10% (eg, one item in the perceived usefulness questionnaire), the single imputation method will be conducted.[88] In the case of 10%–40% missing data per questionnaire, missing data may be imputed if the Little's test of missingness determines that the missing values meet the specification of missing completely at random.[88] In such a case, the recommended imputation method is multiple imputation.[88 89] Given that it is not possible to confirm if the missing data are missing at random or missing not at random, no imputation will be carried out in such cases and these will be excluded from analyses.[88 89] However, qualitative investigation (by inviting such participants to an interview) will be recommended.[88] The same principle applies to >40% of missing data.[88]

Missing data in the intervention logs will not be imputed. The intervention logs will be frequently checked by the PI for their completeness and to ensure that they are being filled up in a timely manner.

Qualitative data

Qualitative data will be summarised by following the Applied Thematic Analysis (ATA) approach.[90] ATA has been described as a rigorous, primarily inductive method for describing and exploring the experiences of participants as accurately and comprehensively as possible.

To provide a further understanding of the acceptability of the study intervention and its functioning as experienced by the study participants, the quantitative and qualitative data will be compared to confirm, disconfirm or expand each other. Ultimately, all findings derived from all sources will be synthesised to understand what needs to be modified to enhance the feasibility and acceptability of the study intervention, prior to a full-scale randomised trial.[75]

Criteria for proceeding to a future trial

The decision of whether to proceed to a future definitive trial will be based on the feasibility and acceptability data, that is, the data on the recruitment and study uptake, and the acceptability of the intervention. As stated earlier, the required sample should be recruited within a year. Based on two previous studies, which similarly provided individuals with type 2 DM with a counselling session at baseline followed by a 1-week and 1-month follow-up (participation rates of 90% and 86.2%, respectively),[87] and another study which provided individuals with type 2 DM with weekly visits and varenicline for 3 months (reporting an approximate 30% attrition),[86] the uptake for this study, including participation rates, NRT usage (average percentage of days the nicotine patch and/or spray are used, at least during the first week after the TQD and the subsequent set TQD for continuing smokers) and follow-up response rates, should be not <70%. The participants from the intervention group should also rate the study intervention as satisfactory and useful, or above, with an average score of 32 and 56, respectively. The intervention providers should also be satisfied with the intervention, finding it feasible to introduce it in practice for a definitive assessment. Not reaching these criteria does not necessarily indicate that a future definitive trial is unfeasible, however, modifications, informed from the qualitative findings, will be required before further testing and a definitive evaluation.

ETHICS AND DISSEMINATION

Before carrying out the study, permissions were sought from the authors of the tools that will be used, the recruiting stakeholders, the clinical chairperson and the hospital administration. Ethical clearance was sought from the Faculty of Health Sciences Research Ethics Committee on behalf of the University Research Ethics Committee (UREC FORM V_15062020 8618). No ethical issues were foreseen, and the study was approved. The study started in August 2023 and is ongoing.

On indicating their interest to participate in the study, prospective participants will be verbally briefed on the study by the PI and provided with a detailed information letter and consent form to sign (online supplemental files 3 and 4). The participants and the nurses (intervention providers) who participate in the interviews at the end of the study will also receive an information letter and consent form to sign (online supplemental files 5–8). Participants will be informed that participation is voluntary and that they are free to withdraw from the study at any time, without the need to provide a reason. They will also be assured that refusing to participate or withdrawing from the study will not have any effect on their care whatsoever.

The participants in the intervention group will be encouraged to take the provided NRT in attempting to quit smoking, however, they are also free to refuse to take it. Often NRT may cause minor adverse reactions (eg, irritation of the site of use, the skin), however, such adverse events can usually be minimised or avoided by applying the treatment correctly and so should not warrant treatment discontinuation.[91] On the other hand, on rare occasions, NRT may also cause non-ischaemic chest pain and palpitations but there is no evidence of an excess of serious cardiac problems, even in people with established cardiac disease.[91] In the unlikely event of such a serious adverse event, NRT will be discontinued and participants will be seen by a doctor of their choice, free of charge.

Data will be securely stored in an encrypted computer, with access restricted to the PI. While the questionnaires used will be coded, to allow the comparison of the baseline characteristics of those followed up and those lost

to follow-up, only the participants will be aware of their unique code, thus ensuring anonymity. The audio-recorded interviews will also be pseudonymised by the PI on transcription. These, and the audio-recorded experimental intervention sessions, which will only be listened to by the PI for quality assurance, will then be erased. The participants who do not quit smoking by the end of the study will be invited to attend the Health Promotion and Disease Prevention Directorate's smoking cessation services.

The data supporting this research will be available from the corresponding author on reasonable request. The study results will be communicated and disseminated through conference presentations at national and international conferences on general medicine, diabetes, public health, nursing and/or tobacco control. A publication is planned in a high-impact peer-reviewed journal. The study reporting will follow the Consolidated Standards of Reporting Trials statement for the reporting of randomised pilot and feasibility trials.[92] Depending on the results, modifications to the study methods followed by further testing, or a definitive evaluation, will be proposed.

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Appendix 9.10: Poster presentation (European Academy of Nursing Science)

A diabetes specialist nurse-led smoking cessation intervention for individuals living with diabetes: study protocol for a randomized controlled feasibility study

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Introduction

Smoking cessation is an important aspect of diabetes management. While the need for tailored smoking cessation support for those who have diabetes has been emphasized, evidence-based smoking cessation recommendations for this cohort are still lacking.[1] Additionally, there has been limited research on the development and evaluation of tailored smoking cessation interventions for individuals with diabetes.[1]

Following the development of a diabetes specialist nurse-led smoking cessation intervention, based on evidence and theory, and the needs of people living with diabetes,[2-4] a feasibility study has been proposed prior to a definitive evaluation. Primarily this feasibility study aims to assess the feasibility of a large-scale randomized controlled trial and the acceptability of the intervention.

This study protocol reports the methods and analyses that will be undertaken.

Methods and Analysis

Design
A two-arm randomized controlled trial.

Participants
This study aims to recruit 80-100 individuals with diabetes who smoke from the Diabetes Education Unit and the Diabetes Out-patients at Mater Dei Hospital in Malta over a 12-month period starting in August 2023. Participants will be randomly assigned (1:1 ratio) to either the intervention or control group for 12 weeks.

Intervention
Based on the Information-Motivation-Behavioral skills model[5] and guided by the 5A's (Ask, Advise, Assess, Assist, and Arrange) framework for smoking cessation.[6] It will be delivered by two diabetes specialist nurses at the Diabetes Education Unit. Participants will also receive a six-week supply of Nicotine Replacement Therapy.

Control
Active referral to standard care - community-based smoking cessation services.

Primary outcome measures
Recruitment and participation rates; resources utilized; identified problems and referrals; nurses' satisfaction, perceived challenges and facilitators to implementation; participants' satisfaction and perceived usefulness of the intervention (both arms).

Data collection methods
Intervention logs; participant questionnaires; interviews with the nurses and the intervention group participants.

Data analyses
Per feasibility study guidelines, data analyses will be descriptive and no statistical comparisons between the randomized groups will be conducted. Feasibility and acceptability outcome measures (proportions/ rates and means and standard deviations) will be reported with 95% Confidence Intervals. Qualitative data will be thematically analyzed.

Conclusion

This study protocol outlines methods to investigate the feasibility and acceptability of a nurse-led smoking cessation support for individuals with diabetes, before definitive evaluation. Participant recruitment starts in August 2023.

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