

The relationship between health literacy and self-management in persons
living with type 2 diabetes mellitus: A cross-sectional survey study.

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Abstract

Background

Few studies have explored the relationship between health literacy and diabetes self-management in Europe. Individuals living with type 2 diabetes mellitus have a distinct self-management when compared to other classifications of diabetes. Moreover, each country may have different forms of support. Personal health literacy focuses on the individual rather than the organisation. The “Integrated Model of Healthy Literacy” was used as a theoretical framework in this present study. This addresses health literacy as a dynamic process and identifies health behaviours as influencing factors.

Objectives

The aim of this study was to explore the relationship between health literacy and diabetes self-management and glycaemic control amongst Maltese adults.

Design

A cross-sectional research design was used in this study.

Methods

Convenience sampling was used to recruit 381 participants from Diabetes Clinics in Malta. Data was collected by a questionnaire which included 16 items measuring health literacy from the ‘European Health Literacy Survey Questionnaire’ and 20 items from the ‘Diabetes self-management questionnaire-revised’. Recent laboratory test results for glycated haemoglobin levels were recorded as a measure of blood glucose control. Multiple regression was used to identify the predictors of health literacy. Spearman’s correlation was used to identify the relationships between health literacy and diabetes self-management and HbA1c.

Results

The results indicated that 47% (n= 179) of the participants had inadequate health literacy, 12.6% (n= 48) had limited health literacy whilst 40.4% (n= 154) had sufficient health literacy. The most significant predictors of health literacy were educational level, household monthly Net income and family history of diabetes. The results demonstrated medium-high diabetes self-management with medication taking being the strongest aspect of self-management. HbA1c values indicated that 27% of individuals had good glycaemic control, 47.5% had medium control and 25.5% had poor glycaemic control. Health literacy was significantly positively related to diabetes self-management and significantly negatively related to HbA1c levels.

Conclusions

Health literacy was poor amongst this cohort of persons living with type 2 diabetes. The results of this study indicating the importance of health literacy in encouraging self-management and in increasing the likelihood of good diabetes control highlight the importance of diabetes education. Diabetes nurse specialists are particularly placed to promote education and health literacy amongst persons with type 2 diabetes. Other health professionals however also have a role in assessing any areas in relation to diabetes care which need clarification. This should happen at every patient encounter.

Dedication

This dissertation is dedicated to my fiancé Johnross, my family and in-laws who wholeheartedly loved, supported and encouraged me throughout this journey. Thank you for bringing out the best in me.

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List of abbreviations

At the beginning of each chapter word abbreviations are defined these are:

ADA	American Diabetes Association
ADCES	Association of Diabetes Care and Education Specialists
BRIEF	Brief Health Literacy Screening Tool
CASP	Critical Appraisal Skill Programme
CINAHL	Cumulative Index to Nursing and Allied Health Literature
COREQ	Consolidated Criteria for Reporting Qualitative Studies
DCCT	Diabetes Control and Complications Trial units
DDSMB	Difficulty of diabetes self-management behaviour
DM	Diabetes mellitus
DSCS	Diabetes Self-Care Scale
DSME	Diabetes Self-Management and Education
DSMQ	Diabetes Self-Management Questionnaire
DSMQ-R	Diabetes Self-Management Questionnaire- revised
DPA	Data Protection Act
EHES	European Health Examination Survey
FCCHL	Functional, Communicative and Critical Health Literacy scale
FHL	Functional health literacy
FREC	Faculty Research Ethics Committee
FPG	Fasting plasma glucose
GDPR	General Data Protection Regulation
GGH	Gozo General Hospital
GPs	General practitioners
HbA1c/ A1C	Glycated haemoglobin
HCP	Healthcare professionals
HELIA	Health Literacy for Iranian Adults
HLS-EU-Q	European Health Literacy Survey Questionnaire
HLS-EU-Q-TR	Turkish version of the European Health Literacy Survey Questionnaire
IFCC	International Federation of Clinical Chemistry
IFCC	International Federation of Clinical Chemistry
IGT	Impaired glucose tolerance
IMHL	Integrated Model of Health Literacy
MesH	Medical subject heading
MDH	Mater dei hospital
MMAT	Mixed Methods Appraisal Tool
N/A	Not available
NGSP	National Glycohaemoglobin Standardization Programme
NSO	National Statistics Office
NVS	Newest Vital Sign
OGTT	Oral glucose tolerance test
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PubMed	Public/Publisher MEDLINE
RCT	Randomised controlled trial
REALM	Rapid Estimate of Adult Literacy in Medicine

SDSCA	Summary of Diabetes Self-Care Activities
SMI	Severe mental impairment
SR	Systematic review
sTOFHLA	Short Test of Functional Health Literacy in Adults
T1DM	Type 1 Diabetes Mellitus
T2DM	Type 2 Diabetes Mellitus
TOFHLA	Test of Functional Health Literacy in Adults
UM	University of Malta
UREC	University Research Ethics Committee
WHO	World Health Organisation

Statistical abbreviations:

I^2	Inconsistency levels
R^2	Coefficient of determination
χ^2	Chi-square test
%	Percentage
<	Smaller than
>	Greater than
\leq	Smaller than or equal to
\geq	Greater than or equal to
ANOVA	Analysis of covariance
CI	Confidence interval
df	Degrees of freedom
ICC	Intraclass correlation coefficient
M	Mean score
Mean \pm SD	Mean and/or standard deviation
mmol/mol	Millimoles per mole
N	Population size
n	Sample size
OR	Odds ratio
p	Population proportion
p -value	Level of statistical significance
Q test	Heterogeneity
r	Correlation coefficient
r_s	Spearman's correlation coefficient
SD	Standard deviation
SE	Standard error
U	Mann-Whitney U test
α	Alpha

Chapter 1- Introduction

1.1 Introduction

Chapter 1 underlines definitions and backgrounds of main concepts of diabetes self-management and health literacy, being the focus of this study. The problems of extensive diabetes self-management behaviours and inadequate health literacy are highlighted. The research question, aims and proposed methodology is then presented.

1.2 Definitions and background information

1.2.1 Type 2 Diabetes Mellitus

‘Diabetes mellitus’ is described by the World Health Organisation (WHO) as a metabolically disease which includes elevated blood glucose levels (WHO, 2021). The classification of DM is as follows; type 1 diabetes mellitus (T1DM) and type 2 diabetes mellitus (T2DM), being the core categories. One can also find maturity-onset diabetes of the young (MODY), gestational diabetes, neonatal diabetes, other triggers such as disease of the exocrine pancreas and secondary triggered drug-induced diabetes (‘American Diabetes Association’, 2020; Plows et al., 2018). T2DM is when the body has peripheral insulin resistance to use the insulin it produces. Also, in T2DM there might be a lack of insulin production however not absolute as with type 1 DM (T1DM) (Thota & Akbar, 2021). The ‘American Diabetes Association’ (ADA) differentiates T2DM by having distinct self-management, therefore, this is the population of interest (Holt et al., 2021). Presentation and pathophysiology also differs in T2DM (Sapra et al., 2021).

1.2.1.1 Pathophysiology and signs of T2DM

Clusters of cells known as islets of Langerhans within the pancreas control sugar levels via ‘insulin-producing beta (β) cells’ that secrete the insulin and ‘glucagon secreting alpha (α)

cells' that secrete glucagon (Sapra et al., 2021). The latter hormones manage the glucose level in the blood to maintain homeostasis (equilibrium) (Qaid & Abdelrahman, 2016). In T2DM there is an advanced reduction of adequate β -cell insulin secretion (American Diabetes Association, 2014). Therefore, when food is ingested, an elevated level of blood glucose results, body fats and proteins are broken down, generating ketones and having long-term weight loss. Consequently, the renal threshold ('limit') is exceeded hence, glucose is excreted in the urine resulting in osmotic diuresis (high urine output and thirst) which may be the first sign. When insulin is low, ketones accumulate, resulting in ketoacidosis. The latter is less common in T2DM due to the residual production of insulin (Hope et al., 2016; Puttanna & Padinjakara, 2014).

β -cell insulin secretion resistance leads to insulin secretion defects, inflammatory, metabolic stress and genetic effects, amongst others. Studies also found that obesity or increased abdominal fat leads to a degree of insulin resistance (American Diabetes Association guidelines, 2021). This mirrors the fact that the pathophysiology of DM is complex and still not well understood. DM can be more varied as individuals may be in remission where for example, due to rapid weight loss glucose level returns to normal. However, this can later go in progression (Captieux et al., 2020).

1.2.1.2 Risk factors and consequences of T2DM

The main risk factor for T2DM is age (U.S. Department of Health and Human Services, 2021). Moreover, smoking, unhealthy diet and lack of physical activity are considered as lifestyle risk factors. Furthermore, biological factors such as obesity, family history, hypertension (high blood pressure) and hyperlipidemia (high fats in the blood) are also risk factors (Wu et al., 2014). The combination of three or more aforementioned risk factors is known as the metabolic syndrome. Additionally, darker skinned individuals are more prone

in developing T2DM (Pham et al., 2019). The most common complications of diabetes are microvascular injury namely retinopathy (eye disease), nephropathy (kidney deterioration) and neuropathy (nerve damage) and/or macrovascular disease which enhances the risk of cardiovascular events and limb amputations (Goyal & Jialal, 2018). The mortality risk is increased when becoming severely ill by DM and in combination with COVID-19 infection (Gazzaz, 2021).

1.2.1.3 Diagnosis of T2DM

DM is diagnosed from plasma glucose either from 'fasting plasma glucose' (FPG), from an 'oral glucose tolerance test' (OGTT), and/or from 'glycated haemoglobin' (A1C) also known as HbA1c (American Diabetes Association, 2020). All aforementioned test irrelevant if symptomatic are also used to identify prediabetes meaning glucose is high however, does not meet the inclusion criteria for DM diagnosis (Alvarez et al., 2017).

HbA1c is an effective way to diagnose DM over 90 days (Eyth & Naik, 2021). This test has numerous benefits, such as, no fasting, contains enhanced pre-analytical stability, and trouble free when compared to the FPG and OGTT. However, it is not a direct measurement of blood glucose level as one must consider other interplaying factors such as age, race/ethnicity, pregnancy, genetics, HIV treatment and anaemia/haemoglobinopathies. Diagnosis of T2DM via HbA1c is usually by $\geq 48\text{mmol/mol}$ ($\geq 6.5\%$) for two repeated tests. However, if interfering factors to HbA1c are present, random plasma glucose $\geq 200\text{mg/dL}$ (11.1mmol/L) or FPG $\geq 126\text{mg/dL}$ is then recommended (Mayo Clinic, 2021).

1.2.1.4 Treatment of T2DM

People diagnosed with mild T2DM are initially suggested to follow a healthy lifestyle. T2DM do not need insulin to survive, unlike those with T1DM. However, at later stages they may be switched to insulin or insulin incorporated in their treatment; in fact, several people living with T2DM take a combination of oral hypoglycaemic (OHAs) medications coupled with insulin. It appears that T2DM when compared to T1DM has a stronger genetic history, although this is poorly understood (ADA, 2020).

1.2.2 Health literacy and diabetes literacy

In the 1970s the term health literacy was proposed (Simonds, 1974). It recognises the competency of an individual in this complex modern society, via promoting and maintaining health (Kickbusch & Maag., 2008). Complexity refers to: demands of health, simultaneous use of abilities, printed and spoken messages in the healthcare environment, comprehension of information, technology and the system altogether (Baker, 2006; Sørensen et al., 2012; Paasche-Orlow & Wolf, 2007). Health literacy was defined originally by WHO and was updated with the release of the ‘Health People 2023 initiative’, with a distinction made between ‘personal health literacy’ and ‘organisational health literacy.’ Personal health literacy is the focus of this study. The definition focuses on the individual and is as follows: “personal health literacy is the degree to which individuals have the ability to find, understand, and use information and services to inform health-related decisions and actions for themselves and others” (Centers for Disease Control and Prevention, 2021).

1.3 Reasons for selecting this topic

1.3.1 Self-management in T2DM

T2DM is prevalent worldwide with around 537 million individuals (aged 20-79 years) living with this condition in 2021, this is expected to increase by 246 million in 2045. Diabetes cause \$966 billion in health costs (International Diabetes Federation, 2021). Local cost of DM in Malta in 2017 was roughly estimated at €107,316,517.82 while the projected expenditure for 2045 was estimated to be €244,136,040 (Cuschieri, 2020). Furthermore, due to diabetes complications, in 2014, Malta had an average of 14.6 hospital admission days while EU average was 8.4 days (“A National Public Health Priority: A National Strategy for Diabetes 2016-2020”).

Therefore, individuals should be actively involved to routinely check their blood glucose levels at health centres, GP or by themselves to build a glycaemic status and address any issues from infancy. The diabetes self-management concept includes the following actions: “healthy coping, healthy eating, being active, taking medication, monitoring, reducing risk and problem-solving” (Association of Diabetes Care and Education Specialists, & Kolb, 2021; Adu et al., 2019). In the literature, self-management and self-care in diabetes are used interchangeably with the only factor being time (Funnell et al., 2011).

1.3.2 Health literacy in T2DM

Both health literacy and diabetes literacy are of interest. Health literacy is an important concept when incorporated to reduce non-communicable diseases (Košir & Sørensen, 2020). Ageing, low educational achievement, poor socioeconomic status and weak reading and language skills are limitations to health literacy (Haun et al., 2012). A local analysis found that educational attainment has increased in Malta since EU membership. In fact, the population completing tertiary education has almost tripled between 2005 and 2020, from

10.3%-28%. Age groups ranging between 25 and 34 years were highly educated, whilst those between 55 and 64 had only a basic level of education. However, this data may be misleading as Malta is experiencing an influx of mature students completing tertiary education (Gauci, 2021). In 2020 Malta, when compared to other EU countries, had the second-highest basic level of education corresponding to lower secondary education (40.3%) (Eurostat, 2020). However, few had upper secondary or post-secondary levels (31.7%) and fewer had tertiary levels of education (28%) (Eurostat, 2020). Refer to Appendix 1 for further explanation regarding the coding levels and graphical representation of educational attainment (Eurostat, 2020; ISCED, 2011). In Malta, high income is associated with a high level of education (Gauci, 2021).

In Canada, most individuals living with T2DM had inadequate/problematic health literacy (60%) (LeBrun et al., 2013). Almost half of EU adults living with T2DM had inadequate/problematic health literacy to manage their health and that of others (47%) (Cangussú et al., 2020; Sørensen et al., 2015). Locally, the latest available health literacy survey identified that individuals living with T2DM were prevalent in having inadequate/problematic health literacy (45.8%) (NSO, 2014; Attard, 2017). This survey classified Gozo and Comino population and those aged ≥ 76 as 'vulnerable' since $> 50\%$ had 'limited' or 'inadequate' health literacy levels. While, it was highlighted that high health literacy levels were found in those attending GPs and classified them as easy to afford to pay (NSO, 2014). When comparing means, Malta had a mean score of 34 on the 'General Health Literacy Index' that ranges from 0-50, whilst the EU average was 33.8. Therefore, Malta showed a slight increase in health literacy adequacy to the EU (NSO, 2014; Sørensen et al., 2015). The COVID-19 pandemic has initiated the fact that poor health literacy has been undervalued globally (Paakkari & Okan, 2020; Sentell et al., 2020; Spring, 2020).

1.3.3 The relationship between health literacy, diabetes self-management and glycaemic control

Diabetes involves extensive self-management behaviours that may differ and contribute to health outcomes discrepancies. It is questioned whether individuals having an inadequate health literacy levels can manage the disease. The first study to see the relationship between health literacy and diabetes self-management behaviours was published by the ADA in 2004. Inconsistency in results was found between the two variables, and no relationship resulted with HbA1c (Kim et al., 2004). Other studies highlighted that health literacy in T2DM is an independent factor associated with glycaemic control and lower medication adherence (Gazmararian et al., 2003; Norris et al., 2001; Schillinger et al., 2002).

Furthermore, it was concluded that more research is required to enhance self-management with the possibility of incorporating strategies (Protheroe et al., 2017). Self-management in T2DM is the key in controlling the disease burden on the healthcare system and on individuals themselves worldwide (Funnel et al., 2011; Ansari et al., 2019). Health literacy plays a vital part in self-management abilities (Yadav et al., 2019). Those with a high level of health literacy when compared to lower levels, tend to cope better with the resistance made through diabetes self-management diverse regimen (Powell et al., 2007; Niknami et al., 2018).

1.4 Purpose and focus

Following an extensive search, it was established that no study has been conducted in Malta exploring the relationship between health literacy/diabetes literacy, diabetes self-management in T2DM and diabetes control. Therefore, the search included tools that measure health literacy elements with diabetes self-management. Recent international studies, showing an increased interest in the subject area, exploring the relationship amongst health literacy and diabetes self-management were performed mainly outside

Europe. For example, three cross-sectional studies were carried out in Iran (Yarmohammadi et al., 2019; Niknami et al., 2018; RobotSarpooshi et al., 2020). Another two in Indonesia (Saleh et al., 2021; Rachmawati et al., 2019). One study in Saudi Arabia, one in Turkey and another in South Korea (Almigbal et al., 2020; Ilhan et al., 2021; Kim, 2021). Additionally, another cross-sectional study was held in the United States (Bains & Egede, 2011). Not all aforementioned studies' results agreed. Each country may have different forms of support that may increase their diabetes self-management for example, locally most people living with DM in Malta are entitled to a free glucose monitor. Additionally, demographic characteristics for example age and gender are also important to consider with health literacy (Protheroe et al., 2017).

Given gaps in knowledge, it is innovative to study a different country, having a distinct healthcare system management. Findings can improve the communication between the HCPs and the patient. DM is a complex disease as involves regular checks for detection of complications, medication and lifestyle adjustments that the individual may find difficult to follow (Chong et al., 2017; Mayo Clinic, 2021). It may be that T2DM individuals find following treatment regimens difficult until adequate health literacy levels are reached (Friis et al., 2016). Moreover, understanding the factors that lack diabetes self-management, strengthens and designs individualised interventions. This may reduce complications of diabetes, improve self-management, glycaemic control, healthcare costs and nurses overload through the capacity of the individual to self-manage their disease individually or collectively (Rachmawati et al., 2019).

1.5 The context of the study

This study was carried out in Malta and is a Southern European archipelago in the Mediterranean Sea, consisting of three islands; Malta, Gozo and Comino. This covers just over an area of 316km^2 , and the population in 2020 accounted for 516,100 individuals,

approximately a 0.3% increase from 2019 (NSO, 2021, p.1). According to the regional statistics, approximately, 35,0000 were from Gozo. Comino is mostly inhabited by tourists (NSO, 2021). An increase in non-Maltese residents over the past years has been seen. Maltese and English are the two official languages used (Britannica, 2021).

1.6 Research question, aims and proposed methodology

1.6.1 Research question

“What is the relationship between health literacy and self-management for persons living with type 2 diabetes mellitus?”

1.6.2 Research Aim

The study aimed to identify Maltese adults aged 18 and over living with T2DM; their health literacy, diabetes self-management and blood glucose control. This was done via scoring tools and statistically analysed their results. Glucose control was measured via HbA1c levels. Lastly, the identification of any sociodemographic variables of individual characteristics for differences in health literacy was performed.

1.6.3 Research design

A cross-sectional survey design via paper-based questionnaires explored the relationship amongst health literacy, diabetes self-management scores and HbA1c.

1.7 Conclusive summary

This initial chapter is a glimpse of the research study. A brief context of the study regarding Malta and Gozo was portrayed to engage foreign readers. Detailed research on T2DM self-management, health literacy and funnelling into the link between the two including

glycaemic control was performed. Information provided was linked to information gleaned from international studies, European and local studies when available. Figures related to health literacy levels, diabetes prevalence, costs and educational levels were carried out. However, no direct data was available for diabetes self-management locally and in other European countries. Therefore, this dissertation is the first to identify T2DM Maltese adult's rates of diabetes self-management. Unfortunately, poor health literacy has been underestimated globally. COVID-19 was highlighted to have an impact on the current research too. The proceeding chapter will give detail of the systematic search carried out, including hypotheses and objectives.

Chapter 2- Literature review

2.1 Overview

This chapter gives equal importance to both self-management and health literacy levels in type 2 diabetes mellitus (T2DM) individuals. The theoretical framework that supports this research is outlined. A systematic review (SR) involving search strategy in detail is presented. This mainly comprised sources, keywords, inclusion and exclusion criteria, key papers and the ‘Preferred Reporting Items for Systematic Reviews and Meta-Analyses’ (PRISMA) flow diagram. Appraisal tools applied in different literature designs are explained in section 2.5. Common scoring tools/ questionnaires that measure health literacy and diabetes self-management in T2DM population as applied in articles were identified. Main trends in the field are highlighted later on. Key debates and controversies about the relationship between health literacy and diabetes self-management in T2DM are presented. Lastly, gaps in the existing knowledge and hypotheses on the integration of this project are documented.

2.2. Main elements

2.2.1 Diabetes self-management in T2DM

As identified diabetes self-management behaviours in chapter 1 (section 1.3.1), these are individually explained here (Association of Diabetes Care and Education Specialists, & Kolb, 2021). Firstly, healthy coping with T2DM requires the individual to have a positive mind-set about diabetes and self-management together with a good relationship with others (Powers et al., 2017). Secondly, healthy eating includes the surrounding behaviour of what, when and how much one eats (Sauter et al., 2021). Thirdly being active, implies all types of durations and intense physical activity. Fourthly, taking medication is aimed at reaching therapeutic goals and reducing complications by ensuring the right timing, dosage and

frequency. Advances in the scientific field for different routes of diabetes medications have increased in dynamics, technology, demographics, environmental issues and access to healthcare (Miller et al., 2014; Stadler & Farooqi, 2017). All of these increase the need for a treatment approach and care plan at an individualised and/or grouping level (Fitipaldi et al., 2018). Monitoring does not only include blood glucose but also other self-care activities such as blood pressure and weight. Next reducing risk, is to identify and implement actions that reduce diabetes complications which were previously highlighted in chapter 1. Finally, problem-solving is a behaviour to identify the problem, acquiring substitutes to the solution, selecting, implementing and evaluating the situation (Hill-Briggs & Gemmell, 2007).

2.2.2 Health literacy in T2DM

Health literacy in T2DM is currently a public health problem (Rachmawati et al., 2019). The World Health Organisation (WHO) had listed health literacy as a main target of ‘Sustainable Development Goals’ (WHO, 2017). The impact of health literacy and its nature is understood as an important aspect of chronic disease; health promotion, prevention and treatment (Poureslam et al., 2017). Europe, England, Canada, USA, Australia and China classify health literacy a principal aspect of practices and regulations (Hernandez et al., 2017).

Low health literacy in T2DM is characterised by inadequate comprehension of information and limited disease knowledge, which consequently leads to an increase in mortality and medication errors. Additionally, it imposes health discrepancies and a financial burden (Berkman et al., 2011; Kindig et al., 2004; Sheridan et al., 2011).

Further studies below identify different subgroups of health literacy or tools including elements of interactivity, functionality and analytical health literacy in T2DM, these are all of interest (Almighal et al., 2020; Guo et al., 2020; Kim, 2021; Kim & Lee., 2016; Fransen et al., 2012; Rachmawati et al., 2019; Yarmohammadi et al., 2019). Furthermore, including both personal health literacy in general (as defined in chapter 1 section 1.2.2) and diabetes literacy are also of interest. Irrelevant to the vitality of health literacy and recent studies, a lack of agreement on the actual meaning of this concept with more than 250 definitions in the public academic literature is found (Malloy-Weir et al., 2016).

2.2.3 The relationship between health literacy and diabetes self-management in T2DM

Healthcare professionals (HCPs) find limited health literacy as a pervasive problem, especially in combination with T2DM self-management (Watts et al., 2017). Failure to study individuals with low health literacy may unintentionally worsen the issues related to the disease (Schillinger et al., 2002; Levin-Zamir et al., 2016).

An improved perspective of health status is achieved when the level of health literacy levels is linked to income, work, education or racial/ethnic group (Weiss, 2007). Health literacy in T2DM implies an increase in an individual's diabetes knowledge, self-efficacy, diabetes self-care behaviours and glucose management. Moreover, it might suggest ethnic differences in individuals living with diabetes mellitus (DM). Comprehending the role of health literacy may provide a way to enhance diabetes self-management via strategies such as using clear health communication for example; plain English, printing material, emphasising key elements and then assessing one's' understanding (Cavanaugh, 2011). This dissertation does not study diabetes knowledge or self-efficacy as they are distinct from self-management. In fact, diabetes knowledge and self-efficacy have distinct definitions to the previously defined self-management behaviours (section 2.2.1). However,

the significance of self-efficacy and diabetes knowledge are highlighted in the peer-reviewed studies and therefore their significance are mentioned later on. Understanding the cause, blood glucose management, diet, physical activity and consequences of the disease is defined as diabetes knowledge (Bukhsh et al., 2019). Furthermore, the beliefs about one's capability to perform a behavioural target is defined as self-efficacy (Bandura, 2004).

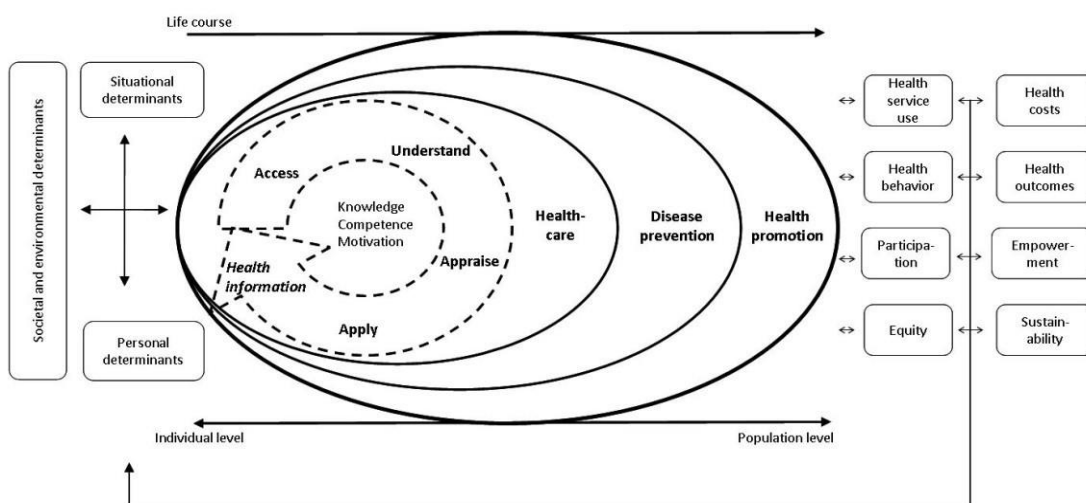
Health literacy influences and is influenced by health behaviours. However, this is not limited to health behaviours as the latter may be influenced by characteristics within the society and the healthcare system which enhances these decisions and increases the capacity to communicate (Sørensen et al., 2012; Freedman et al., 2009; Smith et al., 2013; Osborne et al., 2013).

2.3 Theoretical framework

According to the literature, no model is sufficient to keep up with the evolving definitions and competencies of health literacy (Sørensen et al., 2012; Liu et al., 2020). The “Integrated Model of Health Literacy” (IMHL) was used as a theoretical framework to aid in answering the research question in this present dissertation (Sørensen et al., 2012). The latter was used to guide the “European Health Literacy Survey” that will be mentioned later on in section 2.7.1 (Sørensen et al., 2013). The dynamic process of both population and individual levels were addressed by IMHL. Health literacy skills are developed individually, enabling navigation amongst health continuum domains of “healthcare”, “disease prevention”, and “health promotion”. Figure 1 below highlighted the model's core four competencies relating to the individual's development and process of promoting health hence, “accessing, understanding, appraising and applying health-related information” (Sørensen et al., 2012, p. 8). Proximal and distal variables influencing progress and implementation of these health literacy abilities. As portrayed in Figure 1 antecedents of health literacy (on the left) include “personal determinants” including age, gender, income,

education, race; “situational determinants” such as group support, relationships, media access and “societal and environmental determinants” such as culture, linguistic, societal and civil forces. The latter factors act as a framework for the development or deterioration in health literacy abilities. Also, in Figure 1 there are individual influencing and consequent factors (on the right) such as “health behaviour”, “health service use” and “participation”. Apart from all variables highlighted above, for the IMHL to develop and implement relevant treatments for enhancing health literacy at the individual and organisational levels, further research in different countries with varying health and health insurance systems is required (Baumeister et al., 2021).

Figure 1: Integrated Model of Healthy Literacy (IMHL) (Sørensen et al., 2012).



2.4 Search strategy

A SR exploring studies on the relationship between health literacy and diabetes self-management is presented. Here, one finds a detailed description of the search strategy used to conduct this SR including sources, keywords and inclusion and exclusion criteria.

2.4.1 Sources

An online search was systematically conducted for eligible studies. The literature review was carried out from April-December 2021. The database search included; 'CINAHL complete,' 'Medline complete', 'APA PsychInfo', 'Cochrane database for systematic reviews', 'Cochrane central register of controlled trials, 'AgeLine' and 'Academic search ultimate.' Additionally, 'PubMed' and 'Scopus' were also accessed through the University of Malta (UM) library. Later, 'Google Scholar' search was conducted. For non-published studies, research gate and the UM dissertation database named OAR@UM were also searched. The relevant papers reference list was screened for further eligible papers.

2.4.2 Keywords Search strategy

The free-text keywords were derived from the research question itself. Additionally, medical subject heading (MesH) terms were applied to increase the number of hits. Main keywords included "health literacy," "self-management" and "diabetes." 'Boolean Logistic Operators' i.e., "AND" to narrow the search and include relevant hits and "OR" to retrieve either-or of the search term were used. To enlarge the search, the following wildcards were included, for example, an asterisk "*" at the end of the phrase, and a question mark "?", where the latter replaces a sole character. The use of "*" is known as 'truncation', in fact, diabet* as found in Table 1 resulted in hits containing diabetes or diabetic or diabetics. Furthermore the "?" replaced a sole character, for example, "hyperglyc?emia" resulted in hits containing "hyperglycaemia" and "hyperglycemia", English and American terms respectively. Notably, "adult-onset diabetes" and "non-insulin-dependent DM" are no longer used.

Table 1: Keywords, MesH terms and Boolean logistic operators used.

<p>“Health literacy” OR “health education” OR “consumer health information” OR “information literacy” OR “health information” AND “self-?management” OR “self-?care” OR “self-?administration” OR “self-?medication” OR “self-?testing” OR “blood glucose self-?monitoring” AND "diabetes mellitus" OR "diabet*" OR "type 2 diabetes" OR “diabetes mellitus type 2” OR “Type II diabetes mellitus” OR “T2DM” OR “hyperglyc?emia” OR “glucose intolerance”</p>

2.4.3 Inclusion and exclusion criteria of studies

Studies chosen had to include the adult population meaning ≥ 18 -years-old therefore, excluding the younger population as shown in Table 2. The papers had to include or analyse separately T2DM individuals excluding; type 1 DM (T1DM) and other classifications of diabetes, as they are managed differently. The search was not limited to European countries but was wide open to other countries to see their relationship between health literacy and diabetes self-management. At this stage, both quantitative and qualitative studies were researched. Publication type comprised all types of papers i.e., both published and unpublished work meaning not only peer-reviewed articles/journals but also dissertations and conferences. Therefore, grey literature bias was minimised.

The English language was used as an inclusion criterion, excluding other languages for the fact that the researcher is most fluent in this language and most of the available papers were written in this language. Studies for this literature review were open to 2021 and not restricted to particular years. Moreover, the initial search resulted in studies having psychometric properties i.e., a valid and reliable tool implying validity due to high values of internal and external consistency (Asunta et al., 2019). Topics of interest had to include the relationship between health literacy and diabetes self-management, excluding other

variables relating to health literacy such as; psychological aspects, eHealth, social media interventions and quality of life. The topic of interest included health literacy whilst excluded numeracy literacy although it may also be associated with diabetes self-management. However, another testing tool exists, and it would have been too complicated and extensive to also carry out (Klinovszky et al., 2021). The setting of studies was not limited to outpatients departments but also primary care, excluding private general practitioners (GPs). This is because the definitions of outpatients and primary care relate; where person-centred and team-based care are reassured. However, due to hospital costs and large countries (not Malta) around the world, outpatients have shifted more to primary care (van Hoof et al., 2016)

Table 2: Inclusion and exclusion criteria of studies

Type	Inclusion	Exclusion
Age	≥18 i.e., adults	<18 years
Papers population	Include or analyse separately Type 2 diabetes mellitus	Type 1 diabetes mellitus and other classifications of diabetes
Nationality	All types	N/A
Studies	Quantitative and qualitative studies	N/A
Publication	All types i.e., both published and unpublished work (peer-reviewed articles/journals, dissertations and conferences)	N/A
Language	English	Others
Date of search	No limiters in terms of date	N/A
Topic	Relationship between health literacy and diabetes self-management	Relationship between health literacy and other variables
Literacy	Health literacy	Numeracy literacy
Setting	Outpatients and/or primary care	Private general practitioners (GPs)

2.4.4 Detailed electronic search

A detailed electronic search held in August 2021 using 'all fields' is presented in Table 3 below. It is noted that no hits resulted for 'Cochrane database for SR.' In the 'AgeLine' database, the number of hits pre-and post-limiters remained the same. This suggests the fact that papers posted in English have a higher probability of getting published (Di Bitetti & Ferreras, 2017). Shorter keywords, hence, "health literacy" AND "diabetes self-management" were used for the following entitled databases. Specifically, for 'PubMed' a 'syntax error' (mistakes in used language) resulted when inputting all; keywords, Mesh terms and Boolean operators and for 'Scopus' when all the keywords were inputted, only one irrelevant hit resulted. Moreover, these short keywords were also used for 'ScienceDirect' as this only supports a limited number of Boolean operators, with no limiters applied as it mainly accesses British Elsevier (Harnegie, 2013). Besides, for the search engine 'Google Scholar' the shorter keywords listed above had to also be used due to an enormous number of hits (18,000+). The latter search engine does not allow language as a limiter which was narrowed down for studies in the past two years (2019-2021) due to a further abundant number of hits (8,350 before limiter application).

Table 3: Detailed electronic search

Database or source	Keywords, Mesh terms and Boolean operators	Initial number of hits	Limiters used	Hits post limiters
CINAHL complete	<p>“Health literacy” OR “health education” OR “consumer health information” OR “information literacy” OR “health information”</p> <p>AND</p> <p>“self-?management” OR “self-?care” OR “self-?administration” OR “self-?medication” OR “self-?testing” OR “blood glucose self-?monitoring”</p> <p>AND</p> <p>"diabetes mellitus" OR "diabet*" OR "type 2 diabetes" OR “diabetes mellitus type 2” OR “Type II diabetes mellitus” OR “T2DM” OR “hyperglyc?emia” OR “glucose intolerance”</p>	805	English language	720
Medline complete	<p>“Health literacy” OR “health education” OR “consumer health information” OR “information literacy” OR “health information”</p> <p>AND</p> <p>“self-?management” OR “self-?care” OR “self-?administration” OR “self-?medication” OR “self-?testing” OR “blood glucose self-?monitoring”</p> <p>AND</p> <p>"diabetes mellitus" OR "diabet*" OR "type 2 diabetes" OR “diabetes mellitus type 2” OR “Type II diabetes mellitus” OR “T2DM” OR “hyperglyc?emia” OR “glucose intolerance”</p>	1,259	English language	1,209
Apa PsychInfo	<p>“Health literacy” OR “health education” OR “consumer health information” OR “information literacy” OR “health information”</p> <p>AND</p> <p>“self-?management” OR “self-?care” OR “self-?administration” OR “self-?medication” OR “self-?testing” OR “blood glucose self-?monitoring”</p> <p>AND</p> <p>"diabetes mellitus" OR "diabet*" OR "type 2 diabetes" OR “diabetes mellitus type 2” OR “Type II diabetes mellitus” OR “T2DM” OR “hyperglyc?emia” OR “glucose intolerance”</p>	649	English language	645
Cochrane database for	<p>“Health literacy” OR “health education” OR “consumer health information” OR “information literacy” OR “health information”</p>	0	N/a	0

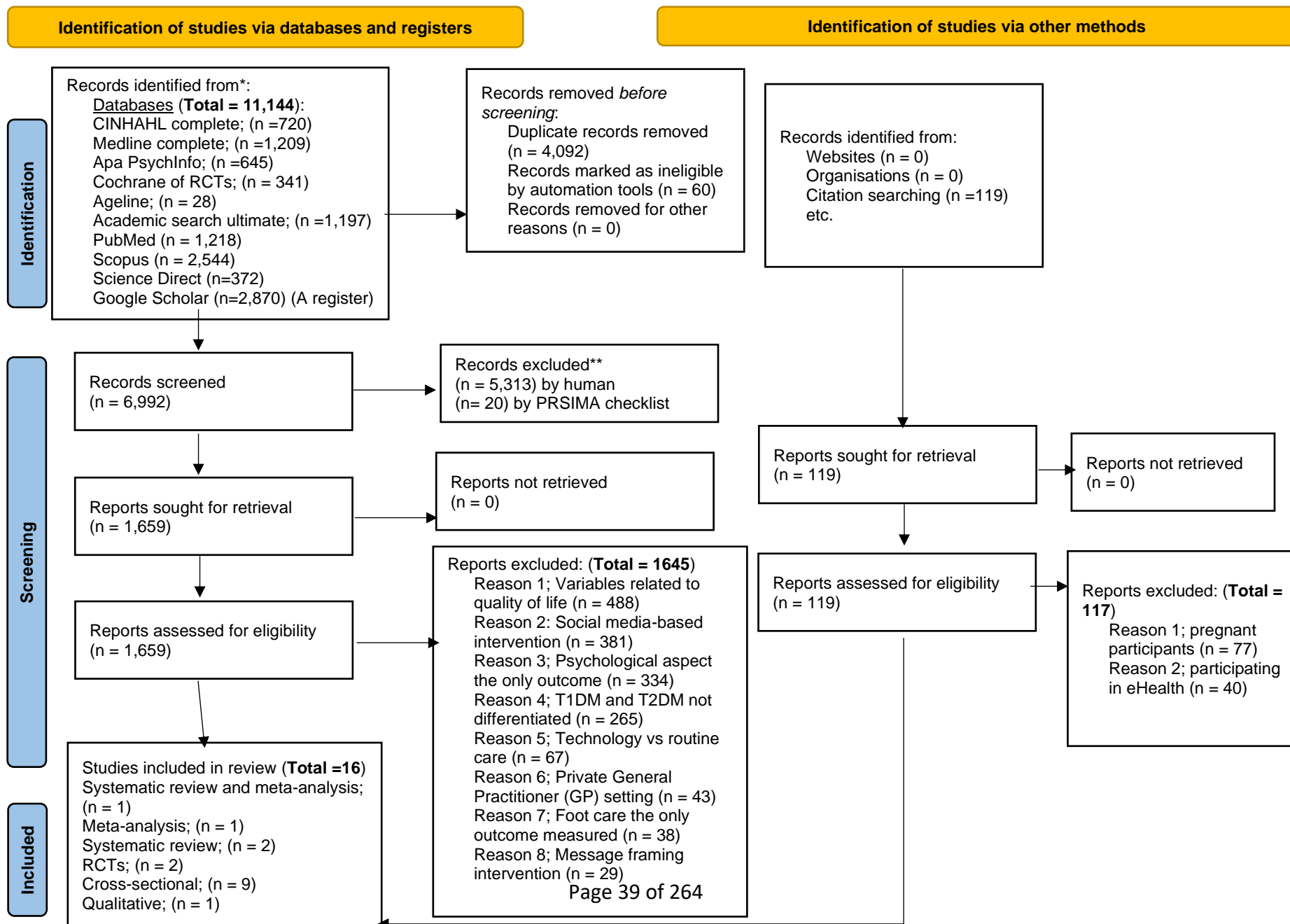
systematic reviews	AND “self-?management” OR “self-?care” OR “self-?administration” OR “self-?medication” OR “self-?testing” OR “blood glucose self-?monitoring” AND "diabetes mellitus" OR "diabet*" OR "type 2 diabetes" OR “diabetes mellitus type 2” OR “Type II diabetes mellitus” OR “T2DM” OR “hyperglyc?emia” OR “glucose intolerance”			
Cochrane central register of controlled trials:	“Health literacy” OR “health education” OR “consumer health information” OR “information literacy” OR “health information” AND “self-?management” OR “self-?care” OR “self-?administration” OR “self-?medication” OR “self-?testing” OR “blood glucose self-?monitoring” AND "diabetes mellitus" OR "diabet*" OR "type 2 diabetes" OR “diabetes mellitus type 2” OR “Type II diabetes mellitus” OR “T2DM” OR “hyperglyc?emia” OR “glucose intolerance”	435	English language	341
Age line	“Health literacy” OR “health education” OR “consumer health information” OR “information literacy” OR “health information” AND “self-?management” OR “self-?care” OR “self-?administration” OR “self-?medication” OR “self-?testing” OR “blood glucose self-?monitoring” AND "diabetes mellitus" OR "diabet*" OR "type 2 diabetes" OR “diabetes mellitus type 2” OR “Type II diabetes mellitus” OR “T2DM” OR “hyperglyc?emia” OR “glucose intolerance”	28	English language	28
Academic search ultimate	“Health literacy” OR “health education” OR “consumer health information” OR “information literacy” OR “health information” AND “self-?management” OR “self-?care” OR “self-?administration” OR “self-?medication” OR “self-?testing” OR “blood glucose self-?monitoring” AND "diabetes mellitus" OR "diabet*" OR "type 2 diabetes" OR “diabetes mellitus type 2” OR “Type II diabetes mellitus” OR “T2DM” OR “hyperglyc?emia” OR “glucose intolerance”	1,249	English language	1,197

PubMed	health literacy" AND "diabetes self-management"	1,268	English language	1,218
Scopus	"health literacy" AND "diabetes self-management"	2,604	English language	2,544
ScienceDirect	"health literacy" AND "diabetes self-management"	372	N/A	372
Google Scholar	"health literacy" AND "diabetes self-management"	8,350	Past two years (2019-2021)	2,870
				Total: 11,144

2.4.5 Screening Process

Post searches, the screening of inclusion and exclusion criteria was conducted for the eligibility of titles and abstracts. The full-text of retained papers was then retrieved. Consequently, no contact needed to be made with the authors. Accurate identification of papers with reference to the PRISMA 2020 checklist was made for literature selection (Page et al., 2020). Figure 2 below shows a detailed PRISMA flow diagram for the new SR. New for the fact that no SR available had been conducted with all the identified inclusion and exclusion criteria, for example studies found excluded qualitative research. The flow diagram includes various types of sources and the number of records included or excluded with specific reasoning. Duplicates were excluded with the aid of RefWorks i.e., a bibliographic software database. A total number of 16 hits resulted. Appendix 2 summarises the 16 papers included in this SR. Ranging from 1 SR with meta-analysis, 1 meta-analysis, 2 SR's, 2 Randomised controlled trials (RCTs), 9 cross-sectional and 1 qualitative study.

Figure 2: PRISMA 2020 flow diagram for new systematic reviews which includes searches of databases, registers and other sources (Page et al., 2020).



*Consider, if feasible to do so, reporting the number of records identified from each database or register searched (rather than the total number across all databases/registers).

**If automation tools were used, indicate how many records were excluded by a human and how many were excluded by automation tools.

2.5 Literature Mapping and Appraisal Tools

Literature mapping presented in Appendix 3, according to Creswell, (2014) is a bi-diagrammatic dimension where links are annotated by arrows (Creswell, 2014). The mapping was based on the above-mentioned theoretical framework i.e., IMHL (Sørensen et al., 2012).

‘Critical Appraisal Skill Programme’ (CASP) has different tools for the appraisal of studies with different study designs; in fact, its tools to appraise SR and meta-analyses, RCTs and qualitative studies were used (CASP, 2018, 2020). The 22-item checklist entitled “Strengthening the Reporting of Observational Studies in Epidemiology” (STROBE) guidelines ensured the quality of observational studies i.e., cross-sectional studies (Guedes-Martins et al., 2015).

2.6 Methodological review of papers and their critical appraisal

2.6.1 Descriptive and critical approach of SR and meta-analyses

2.6.1.1 The appropriate study approach

The literature search found a combination of SR with meta-analysis which is considered the best type of study design in the hierarchy of evidence (Kim & Lee., 2016). Moreover, two relevant SR’s, one by Dahal & Hosseinzadeh, (2019) and the other by Fransen et al., (2011) and a meta-analysis by Guo et al., (2020) were found to be relevant (Dahal & Hosseinzadeh, 2019; Guo et al., 2020; Fransen et al., 2011).

Low health literacy amongst individuals was the main focus in two studies (Fransen et al., 2011, Kim & Lee., 2016). Conversely, health literacy variables and ~~the~~ different levels of health literacy levels on diabetes self-care were studied in two studies (Dahal &

Hosseinzadeh, 2019; Guo et al., 2020). One SR included the right type of studies i.e., RCTs where interventions included community-based health literacy and the control included patient-focused health literacy (Dahal & Hosseinzadeh, 2019). Whilst the other SR included observational studies (Fransen et al., 2011).

2.6.1.2 Subjects' age group and gender

The SR papers by Fransen et al., (2011) had a common mean age of 50+, mostly females whilst, in the other SR review by Dahal & Hosseinzadeh, (2019) the participant's age was ≥ 18 , with no indication whether these had more females compared to males (Dahal & Hosseinzadeh, 2019; Fransen et al., 2011). The meta-analysis did not state a mean age of papers, however, it included young and older adults in their pooled papers (Guo et al., 2020). The SR with meta-analysis did not indicate mean ages but split studies into different categories (Kim & Lee., 2016).

2.6.1.3 Inclusion of relevant studies by SR and meta-analyses

All high-quality studies searched the PubMed database through various years (Dahal & Hosseinzadeh, 2019; Fransen et al., 2012; Guo et al., 2016; Kim & Lee, 2016). Almost all studies except for one also searched the reference list of relevant studies (Fransen et al., 2012; Guo et al., 2016; Kim & Lee, 2016). However, the study that did not mention reference lists screening, was the only study to search grey literature, for example, dissertations, conferences and governmental reports (Dahal & Hosseinzadeh, 2019).

2.6.1.4 Authors' rigour

Two researchers independently assessed the study's quality (Kim & Lee, 2016). The "Cochrane Back Review Group" was used as a guide to identify RCTs quality, resulting in an acceptable score (Guo et al., 2016; Dahal & Hosseinzadeh, 2019). The "Mixed Methods Appraisal Tool" (MMAT) resulted in a high-quality percentage and discrepancies were resolved via discussions (Kim & Lee, 2016). The MMAT is a quantitative tool that examines study's quality (Pluye et al., 2011). Other than the study's interventions found, for individuals with lower health literacy, additional rigorous interventions identified strategies leading to positive health outcomes are still to be found (Kim & Lee, 2016).

Another SR used "Cochrane collaboration" guidelines for cohort studies (Fransen et al., 2012). All studies had sufficient population characteristics. Most of the studies in the SR by Fransen et al., (2012), had sufficient outcome measures description and valid measures (Bains & Egede, 2011; Cavanaugh et al., 2008; Karter et al., 2010; Kim et al., 2004; Mbaezue et al., 2010; Mancuso et al., 2010; Osborn et al., 2010; Powell et al., 2007; Sarkar et al., 2006; Wallace et al., 2009). While the quality assessment of the meta-analysis included a valuation of cross-sectional and cohort studies via the "National Heart, Lung, and Blood Institute, 2020". It's studies included an adequate rate with regards to the research question, study population, sample size, response and study outcomes. Moreover, no significant publication bias resulted as not only databases were searched but also unpublished studies (Guo et al., 2016).

2.6.1.5 Results of the review combined

Only one SR with meta-analysis was found relevant for this study that combined review results (Kim & Lee, 2016). It supported similar results from another SR with the outcome of interventions reducing the literacy-related disparities (Bailey et al., 2014; Kim & Lee, 2016).

2.6.1.6 Results presentation

Using a 95% confidence interval (CI) with ranges was presented (Fransen et al., 2012; Guo et al., 2016; Kim & Lee, 2016). However, one SR did not present a CI (Dahal & Hosseinzadeh, 2019). A Heterogeneity (Q) test, degrees of freedom (*df*) and Inconsistency levels (I^2) showing the extent of heterogeneity were generated (Kim & Lee, 2016). Odds ratio (OR) was used in another study to measure sociodemographic variables (Guo et al., 2016). As an asset, forest plot was presented with an overall estimate in two studies (Guo et al., 2016; Kim & Lee, 2016). Both SRs did not identify how results were expressed (Dahal & Hosseinzadeh, 2019; Fransen et al., 2012). All studies presented a *p*-value of $\leq .05$, as a level of significance (Dahal & Hosseinzadeh, 2019; Fransen et al., 2012; Guo et al., 2016; Kim & Lee, 2016).

2.6.2 Descriptive and critical approach of RCTs

2.6.2.1 The appropriate study approach

Two RCTs were included, both having two arms (Xu et al., 2014; Lee et al., 2017). Where one group completed the ‘diabetes self-management programme’ that included meetings to learn about diabetes self-management and considered individual’s health literacy while the other group was the control group. The latter received usual care entitled standard lectures

with no consideration about individuals' health literacy. Both health literacy and the effect on diabetes self-management behaviours were evaluated (Lee et al., 2017). The other RCT was clustered, where groups rather than individuals were randomised. The intervention group received an additional health literacy strategy, an educational tool, whilst the control group received 'usual care'. The latter was also well-explained as with the other RCT however, here 'usual care' followed recent national guidelines (clinical consultation, treatment provision and no tools were used). Self-management behaviours were studied as secondary outcomes (Xu et al., 2014).

2.6.2.2 Subjects' age groups and genders

One RCT included older adults with a mean age of 74.5 years (Lee et al., 2017). The other RCT age range varied from 18-85 years and was considered a strength by the authors due to the vast age range (Xu et al., 2014).

2.6.2.3 Randomisation and blinding

One of the RCTs used a randomised programme for participants (Lee et al., 2017). This was carried out by an independent researcher; participants were also blind to their assignment and outcomes, known as double-blinding. The other RCT followed a clustered randomisation, where pre-existing groups were randomised to the intervention or control grouping. However, a lack of information regarding blinding, this was a limitation in this study when compared to the other RCT (Xu et al., 2014).

2.6.2.4 Follow-up

The study by Xu et al., (2014) followed individuals at 2, 6, 12 and 24 months, an asset when compared to the study by Lee et al., (2017) who only followed individuals after 3 months (Lee et al., 2017; Xu et al., 2014). Drop-out rates were accounted for with 30% in

the paper by Xu et al., (2014) and 20% in the paper by Lee et al., (2017). No study used the intention-to-treat analysis, limiting both papers (Lee et al., 2017; Xu et al., 2014).

2.6.2.5 Grouping similarity at the start of the trial

Baseline characteristics such as socio-economic statuses, gender and age were set-out with studies indicating whether these characteristics were comparable at baseline. Moreover, health literacy levels and diabetes self-management variables via a scoring system were clear (Lee et al., 2017; Xu et al., 2014).

2.6.2.6 Treated equally

All individuals/clusters were treated equally except for the experimental groups, due to the nature of the study. Both studies used a standard protocol for RCT. Moreover, follow-up intervals were the same for both groups (Lee et al., 2017; Xu et al., 2014).

2.6.2.7 Effect of intervention

Both RCTs presented a power calculation (80%) (Lee et al., 2017; Xu et al., 2014). Health literacy and diabetes self-management outcomes were both specified. Results were expressed as binary variables (Xu et al., 2014).

Sociodemographic results were analysed using either values/ percentages/ means/ standard deviations (SD). A Chi-square test (χ^2) or a Fisher's exact were used as analysing tools to show the difference amongst categorical groups (Lee et al., 2017; Xu et al., 2014). For continuous variables either an independent *t* test or a Mann-Whitney U test was used.

Paired *t*-test and the Wilcoxon test calculated before and after HbA1c values (Lee et al., 2017). Moreover, the other study used multivariable general linear models to modify age and gender. For continuous variables, Wilcoxon rank-sum tests were used in addition to the

analysis of variance (ANOVA) to calculate HbA1c level improvement (Xu et al., 2014).

Both presented *p*-values as overall results (Lee et al., 2017; Xu et al., 2014).

The studies presented outcomes for each follow-up. No missing or incomplete data was present in one study (Lee et al., 2017). However, the other study performed multiple imputation, for their missing data and could be due to the extensive follow-up period (1 year) and greater drop-out rate of 10% when compared to the other RCT (Xu et al., 2014).

2.6.2.8 Precision of estimate and cost analysis

Only the study by Xu et al., (2014) stated an overall 95% CI for clinical outcomes and cost-effectiveness analysis between groups unlike the study by Lee et al., (2017). However, no CI ranges were presented due to no statistical results presentation, therefore, posing a limitation (Xu et al., 2014).

2.6.3 Descriptive and critical approach of cross-sectional studies

2.6.3.1 The appropriate study approach

Nine studies were cross-sectional designs (Almigbal et al., 2020; Bains & Egede, 2011; İlhan et al., 2020; Kim, 2021; Niknami et al., 2018; Rachmawati et al., 2019; RobatSarpooshi et al., 2020; Saleh et al., 2021; Yarmohammadi et al., 2019). Due to the type of research question, firstly, this design is the most appropriate for investigating the prevalence of the disease. Secondly, it is suitable to study the knowledge and attitudes of both HCPs and patients. Thirdly, it allows comparing measuring scales (Kesmodel, 2018).

The common type of sampling was convenience sampling (Almigbal et al., 2020; Bains & Egede, 2011; İlhan et al., 2020; Niknami et al., 2018; RobatSarpooshi et al., 2020; Yarmohammadi et al., 2019). Another study used clustered sampling of five specific areas (Rachmawati et al., 2019). While another study used purposive/judgemental sampling (Saleh et al., 2021).

All cross-sectional studies in this review studied health literacy and tried to explain or explore the relationship of the aforementioned independent variable on the dependent variables of diabetes self-management, in particular the effect on behaviours. Some studies explored interplaying factors such as knowledge and its link between health literacy, diabetes self-management and glycaemic control, which are highlighted in section 2.9.2 below (Bains & Egede, 2011; Kim, 2021). Another study included self-efficacy as an additional variable (Saleh et al., 2021).

2.6.3.2 Subjects' age groups and genders

A cross-sectional study identified participants' mean age of 51.5 years, mostly males (Kim, 2021). Similarly, another cross-sectional study had more male participants ≥ 18 -years-old (Almigbal et al., 2020). Whereas the other cross-sectional studies' mean age was approximately 60, with the majority accounting for female individuals (İlhan et al., 2020; Rachmawati et al., 2019; Saleh et al., 2021; Yarmohammadi et al., 2019). Likewise, in another paper females were more prominent; however, the age limit was < 65 years (Bains & Egede, 2011). Similarly, a study had slightly more female participants aged ≥ 18 (Niknami et al., 2018).

2.6.3.3 Title and abstract

Out of nine cross-sectional studies, only one study contained the study's design in its title (Rachmawati et al., 2017). In their summaries, all studies included performance and findings (Almigbal et al., 2020; Bains & Egede, 2011; İlhan et al., 2020; Kim, 2021; Niknami et al., 2018; Rachmawati et al., 2019; RobatSarpooshi et al., 2020; Saleh et al., 2021; Yarmohammadi et al., 2019).

2.6.3.4 Study methods

Key elements of the study designs were presented at the beginning of the papers (Almigbal et al., 2020; Bains & Egede, 2011; İlhan et al., 2020; Kim, 2021; Niknami et al., 2018; Rachmawati et al., 2019; RobatSarpooshi et al., 2020; Saleh et al., 2021; Yarmohammadi et al., 2019).

Most studies took place in a hospital environment (Almigbal et al., 2020; İlhan et al., 2020; Kim, 2021; Saleh et al., 2021; Yarmohammadi et al., 2019). Other studies took place in primary health areas (Bains & Egede, 2011; Niknami et al., 2018; Rachmawati et al., 2019; RobatSarpooshi et al., 2020). Table 4 contains supplementary characteristics of primary studies according to published year mainly including 0%-11% drop-out and studies inclusion and exclusion criteria. Most probably due to the study's design and topic, no follow-up analysis was presented in the studies (Almigbal et al., 2020; Bains & Egede, 2011; İlhan et al., 2020; Kim, 2021; Niknami et al., 2018; Rachmawati et al., 2019; RobatSarpooshi et al., 2020; Saleh et al., 2021; Yarmohammadi et al., 2019). A study adjusted for potential confounders in the analysis via multiple regression models (Bains & Egede, 2011).

Only one study acknowledged the biases made. Firstly, the method of self-reporting led to bias, however, the counter-factor of anonymous questionnaires reduced this bias. Moreover, the cross-sectional design itself may be biased in reporting causal conclusions. A longitudinal study may have been ideal to study the effects of various constructs on health literacy and HbA1c changes (Yarmohammadi et al., 2019).

A sample size equation was used by certain studies (İlhan et al., 2020; Niknami et al., 2018; Rachmawati et al., 2019; Saleh et al., 2021). This leaves other studies which did not present how the actual sample size was affected (Almigbal et al., 2020; Bains & Egede, 2011; Kim, 2021; RobatSarpooshi et al., 2020; Yarmohammadi et al., 2019).

2.6.3.5 Results presentation and other information

Sensitivity analysis for health literacy was only used in two studies, showing a 0.79 sensitivity for detecting inadequacy (Kim, 2021; Niknami et al., 2018). All studies had a *p*-value of $\leq .05$, as level of significance (Almigbal et al., 2020; Bains & Egede, 2011; İlhan et al., 2020; Kim, 2021; Niknami et al., 2018; Rachmawati et al., 2019; RobatSarpooshi et al., 2020; Saleh et al., 2021). Table 4 includes details of further statistical tests used.

Certain studies were funded by the University of the locality where the research was conducted (Almigbal et al., 2020; Rachmawati et al., 2019; RobatSarpooshi et al., 2020). Another study was funded as part of national research (Kim et al., 2021). On the contrary, some other studies had no funding or did not give detail regarding funding (Niknami et al., 2018; Bains & Egede, 2011). All studies declared no conflict of interest (Almigbal et al., 2020; Bains & Egede, 2011; İlhan et al., 2020; Kim, 2021; Niknami et al., 2018; Rachmawati et al., 2019; RobatSarpooshi et al., 2020; Saleh et al., 2021).

Table 4: Study characteristics of each included primary study

Study	Kim, (2021)	Saleh et al., (2021)	Almigbal et al., (2020)	İlhan et al., (2020)	Yarmohammadi et al., (2019)	Niknami et al., (2018)	RobatSarpooshi et al., (2020)	Rachmawati et al., (2019)	Bains & Egede, (2011)
Country of study	South Korea	Indonesia	Saudi Arabia	Turkey	Iran	Iran	Iran	Indonesia	US (South Carolina)
Period of study	N/A	November-December 2018	December 2016-February 2017	1st March-1st April 2019	May-September 2018	September 2013-November 2016	N/A	February -June 2016	June-August 2008
Sample size	155	68	352	264	300	394	400	106	125
Age range	18 or older	Older adults (60+)	18 or older	Over 18	18 or older	18 or older	Age 30 and over	Older adults (60+)	18-64
Baseline characteristics	Reported	Reported	Reported	Reported	Reported	Reported	Reported	Reported	Reported
Inclusion criteria	Diagnosed with T2DM	Diagnosed with T2DM, willing to participate	Diagnosed with T2DM	Diagnosed with T2DM for at least 1 year	Diagnosed with T2DM, ability to read and communicate	Diagnosed with T2DM, for at least 1 year, living in Iranshar including its rural areas	Diagnosed with T2DM, with at least 6 months history, willing to participate, Iranian nationality	Diagnosed with T2DM, proficient in communicating, reading and writing in Bahasa	Clinic patients, medical records contain T2DM diagnosis

Exclusion criteria	T1DM	T1DM and below the age of 60	Below 18 years	Mental health issues.	Mental or cognitive disorders, and pregnant	Mental health issues.	Issues with diabetes, gestational diabetes and other medical barriers to self-care behaviours (such as unable to exercise)	Having difficulties during both speaking and hearing.	Did not speak English or if the intermediary determined via interaction or chart documentation that individuals were too ill or cognitively impaired
Drop-out rate	0%	0%	0%	N/A	0%	11%	0%	0%	0%
Assessment of outcomes analysis	Chi-square test	Descriptive statistics, correlations, multivariate analysis using the logistic regression analysis	SPSS version 23. Frequencies, Chi-square test between two categorical variables and logistic regression analysis. Hosmer-Lemeshow tested the goodness-of-fit or stated how well the data fits the	Descriptive statistics, one-way ANOVA, Student's t-test, Pearson correlation test, and multiple regression analysis.	Structural equation modeling (SEM) for hypotheses testing, Mplus version 7 for statistical analysis. Chi-square test. Confirmatory factor analysis (CFA) was tested for models.	Univariate statistics to generate sample characteristics, independent sample t-test for the association between health literacy and demographics, multiple regression analysis to identify if health literacy	SPSS 21, Spearman correlation coefficient, the independent t-test, and ANOVA.	Bivariate t-independent test, the Pearson product-moment correlation, and logistic regression for multivariate analysis to identify any relationship of independent and dependent variable.	STATA version 10. Comparison of sample demographics using χ^2 statistics for categorical variables and t test or ANOVA for continuous variables. Third, Spearman's correlation to test the association

			model.			is a significant predictor and multiple regression analysis to determine predictor power of health literacy to diabetes self-management. Correlation statistics was also used			among health literacy, diabetes knowledge, and self-care behaviours. Fourth, multiple regression was performed
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2.6.4 Descriptive and critical approach of a qualitative study

2.6.4.1 The appropriate study approach

Although a qualitative study is not rated at the top of the hierarchy of evidence it does not mean that it is not valid, in fact, such study was relevant. The study explored the different health literacy levels via semi-structured interviews and experiences in the engagement of diabetes self-management behaviours (Ayre et al., 2021).

2.6.4.2 Subjects' age group and gender

The qualitative study had more male participants who were >60-years-old (Ayre et al., 2021). Ideally, a study has an equal proportion of genders.

2.6.4.3 Clear aims

The qualitative study included in this dissertation had a clear aim. This explored T2DM individuals, with distinct health literacy levels, the experiences and efforts made to engage in diabetes self-management and addressed gaps in literature (Ayre et al., 2021).

2.6.4.4 The appropriateness of the methodology

The researchers sought to interpret actions and/or subjective experiences of their participants during the transcription analysis. The phenomenological approach was adequate in providing additional information related to the topic of interest. This design focused on experiences, however, as attitudes and perceptions of diabetes self-management were of interest, a framework analysis was also conducted by researchers. Purposive sampling was used to ensure a diverse population consisting of; different genders, cultures,

education and both insulin and non-insulin users. A total of 50 primary care clinics were chosen from Sydney Australia. ‘Consolidated Criteria for Reporting Qualitative Studies’ (COREQ) was used as a guide during the semi-structured interviews. These were audio-recorded and coded until saturation of data, meaning until no new codes were produced and later transcribed (Ayre et al., 2021).

2.6.4.5 Recruitment strategy

HCPs in the qualitative study approached the individuals first by administering an information letter, where participation was expressed via written consent form. Therefore, the researchers did not have initial contact. Interviews were either face-to-face or via telephone. No individuals refused to participate. The researcher had informed participants that the research was part of his PhD. Analysts were blind to data on health literacy scores until themes and subthemes were classified. A qualitative approach added to the patterns across the study’s aim (Ayre et al., 2021).

2.6.4.6 Ethical approvals

The University and the local district of the studied population ethically approved the study (Ayre et al., 2021).

2.6.4.7 Data analysis and findings

Framework analysis was conducted to analyse transcripts (Ritchie et al., 2013). This included: data familiarising, indexing, coding of themes, synthesising and interpretation. A critical realist paradigm was subjectively used (Brawn & Clarke, 2013). During interviews, willpower was apparent in those with limited health literacy whilst, problem-solving orientation was seen in individuals with adequate health literacy. Perception and attitudes

towards diabetes self-management were seen. Findings were consistent with other discussed studies in the qualitative paper. To and against statements were also discussed. Lastly, this study found that cognitive demands i.e., health literacy levels as identified in the article itself, suggested the self-management and strategies adopted. The research question was included in the analysis. It is indecisive whether the findings support other chronic diseases. The study suggests the addition of quantitative designs to clearly understand health literacy and diabetes self-management together with the qualitative design used to outline theories. It was highlighted that future research should identify health literacy patterns and self-management interventions, moreover, target individuals with minimal health literacy (Ayre et al., 2021).

2.7 Measuring scales

2.7.1 Health Literacy tools

A variety of tools measured health literacy in general or diabetes literacy in the 16 papers integrated in this review. The SR +/- meta-analysis and the meta-analysis commonly used tools were the “Rapid Estimate of Adult Literacy in Medicine” (REALM) and the long or short “Test of Functional Health Literacy in Adults” (TOFHLA/STOFHLA) (Guo et al., 2020; Fransen et al., 2012; Kim & Lee, 2016). Moreover, the meta-analysis reported other tools used as shown in Table 5 below (Guo et al., 2020). Nevertheless, the SR by Dahal & Hosseinzadeh, (2019) did not account for common or used tools, portraying a limitation (Dahal & Hosseinzadeh, 2019). One RCT used the “Korean Health Literacy Assessment Tool”, based on the REALM tool (Lee et al., 2017). Whilst the other RCT used the “Chinese version of the Health Literacy Management Scale” (Xu et al., 2014).

Two cross-sectional papers utilised the STOFHLA to score health literacy (Almigbal et al., 2020; Kim, 2021). Another cross-sectional study used the revised REALM-R (Bains &

Egede, 2011). Two other cross-sectional studies used the “Functional, Communicative and Critical Health Literacy scale” (FCCHL) scale (Rachmawati et al., 2019; Saleh et al., 2021). Moreover, another study used the aforementioned scale but with a Persian version (Yarmohammadi et al., 2019). A study used the “Turkish version of the European Health Literacy Survey Questionnaire” (HLS-EU-Q-TR) (İlhan et al., 2020). Another cross-sectional study used the “Brief Health Literacy Screening Tool” (BRIEF) (Niknami et al., 2018). Whilst another cross-sectional study used the “Health Literacy for Iranian Adults” (HELIA) scale (RobatSarpoooshi et al., 2020). The qualitative study adapted the “Newest Vital Sign” scale (NVS) as a screening tool to measure health literacy (Ayre et al., 2021).

It is highlighted that in one study found in the meta-analysis, the RCTs and certain cross-sectional studies’ health literacy scales were customized as local versions (Guo et al., 2020; İlhan et al., 2020; Lee et al., 2017; RobatSarpoooshi et al., 2020; Xu et al., 2014; Yarmohammadi et al., 2019).

2.7.2 Diabetes self-management tools

The SR with meta-analysis to measure diabetes self-management used different interventions for the fact that the inclusion criteria were limited to RCTs (Kim & Lee, 2016). The studies included in the SR used the “Summary of Diabetes Self-Care Activities scale” (SDSCA) (Fransen et al., 2012). The meta-analysis used the “Diabetes Self-Management and Education” (DSME) scale to measure diabetes self-management (Guo et al., 2020).

One RCT measured diabetes self-management via the Korean SDSCA version scale (Lee et al., 2017). Similarly, the other RCT used the Chinese version of the SDSCA scale (Xu et al., 2014).

As portrayed in Table 5, most of the cross-sectional studies used the SDSCA to measure diabetes self-management (Bains & Egede, 2011; RobotSarpoooshi et al., 2020; Kim, 2021; Saleh et al., 2021; Yarmohammadi et al., 2019). Notably, the cross-sectional study by Kim, (2021) customised the aforementioned scale into a “revised Korean version” (Kim, 2021). Another cross-sectional study used the “diabetes self-care scale” (DSCS) (İlhan et al., 2020). Whilst another study used the “difficulty of diabetes self-management behaviour” (DDSMB) scale (Niknami et al., 2018). While two other studies used the “Diabetes Self-Management Questionnaire (DSMQ)” (Rachmawati et al., 2019; Almigbal et al., 2020).

Due to the qualitative nature of the study by Ayre et al., (2021), interviews, and open-ended questions were used. Moreover, to explore diabetes self-management the word ‘lulls’ was used when describing a decrease in diabetes self-management engagement (Ayre et al., 2021).

Table 5: Summary of scales used in different study designs

Systematic review and meta-analysis		
Study	Health literacy scale/s	Diabetes self-management scale
Systematic review with meta-analysis		
1. Kim & Lee, 2016	Rapid Estimate of Adult Literacy in Medicine (REALM) and the Short Test of Functional Health Literacy in Adults (STOFHLA)	Measured with different intervention for the fact that the inclusion criteria were set to RCTs
Meta-analysis		
2. Guo et al., 2020	Rapid Estimate of Adult Literacy in Medicine (REALM), Short Test of Functional Health Literacy in	Diabetes Self-Management and Education (DSME)

	Adults (STOFHLA), Test of Functional Health Literacy in Adults (TOFHLA), Health Literacy for Iranian Adults (HELIA); Newest Vital Sign scale (NVS); Diabetes Health Literacy scale (DHL); Spoken Knowledge in Low Literacy in Diabetes (SKILLD); eHealth Literacy Scale; Functional, Communicative and Critical Health Literacy scale (FCCHL)	
Systematic reviews		
3.	Dahal & Hosseinzadeh, 2019	N/a
4.	Fransen et al., 2012	Rapid Estimate of Adult Literacy in Medicine (REALM) and the Test of Functional Health Literacy in Adults (TOFHLA)
		Summary of diabetes self-care activities scale (SDSCA)
Randomised controlled trials		
5.	Lee et al., 2017	Korean Health Literacy Assessment Tool which was based on the Rapid Estimate of Adult Literacy in Medicine (REALM)
		Korean version of the Summary of Diabetes Self-Care Activities (SDSCA) Questionnaire
6.	Xu et al., 2014.	Chinese versions of the Health Literacy Management Scale
		Chinese version of Summary of Diabetes Self-Care Activities (SDSCA)
Cross-sectional studies		

7. Kim, 2021	Short Form of the Korean Functional Health Literacy Test (S-KHLT)	Revised Korean version of the Summary of Diabetes Self-Care Activities (SDSCA)
8. Saleh et al., 2021	Functional Communicative and Critical Health Literacy (FCCHL)	Summary of Diabetes Self-Care Activities (SDSCA)
9. Almigbal et al., 2020	Short Test of Functional Health Literacy (S-TOFHLLA)	Diabetes Self-Management Questionnaire (DSMQ)
10. İlhan et al., 2020)	Turkish version of the European Health Literacy Survey Questionnaire (HLS-EU-Q-TR)	Diabetes Self-Care Scale (DSCS)
11. Yarmohammadi et al., 2019	A Persian version of the Functional Communicative and Critical Health Literacy scale (FCCHL)	Summary of Diabetes Self-Care Activities (SDSCA)
12. Niknami et al., 2018	Brief Health Literacy Screening Tool (BRIEF)	Difficulty of Diabetes self-management behaviour (DDSMB) scale
13. RobatSarpoooshi et al., 2020	Health Literacy for Iranian Adults (HELIA)	Summary of Diabetes Self-Care Activities (SDSCA)
14. Rachmawati et al., 2019	Functional Critical and Communicative Health Literacy” (FCCHL)	Diabetes Self-Management Questionnaire (DSMQ)
15. Bains & Egede, 2011	Revised Rapid Estimate of Adult Literacy in Medicine (REALM-R),	Summary of Diabetes Self-Care Activities (SDSCA)
Qualitative		
16. Ayre et al., 2021	Semi-structured interview using open-ended questions and the ‘Newest Vital Sign’ (NVS) scale	Experiences where ‘lulls’ was used to describe a decrease in diabetes self-management engagement

2.8 The integrated model of healthy literacy (IMHL) and antecedents of health literacy

2.8.1 Social and environmental antecedents

Social and environmental antecedents of health literacy include “demographic situation”, “culture”, “language”, “political forces” and “societal system”. In fact, the SR with meta-analysis highlighted these domains and addressed them in the form of strategies (Kim & Lee, 2016). For example, papers contained in the aforementioned review highlighted that language and cultural diversity in minority ethnic groups were accounted for by language assistance, cultural beliefs consideration or improved cross-cultural skills. Spoken communication that was clear, with the application of teach-back methods and follow-up of individuals were found to have a positive impact on psychological/cognitive, self-care and health outcomes (Cavanaugh et al., 2009; Gerber et al., 2005; Hill-Briggs et al., 2011; Kandula et al., 2009; Khan et al., 2011; Moussa et al., 2013; Negarandeh et al., 2013; Wallace et al., 2009).

2.8.2 Situational determinants

Situational determinants incorporate; “family” and “social support”, “peer influences”, “media use” and “physical environment”. Two cross-sectional studies highlighted the importance of educating both the patient and his/her family (Almigbal et al., 2020; Rachmawati et al., 2019). A cross-sectional study recognised health literacy as a direct influence of social support via social motivation ($r = 0.02, p < .01$), which indirectly enhanced self-management ($r = -0.07, p < .05$) and glycaemic control ($r = -0.01, p < .05$) (Osborn et al., 2010). A qualitative study identified the physical environment as a strategic element of eating habits (Ayre et al., 2021). Besides, it also affected the course of diabetes

as green space and walkability lowered risk of T2DM (Dendup et al., 2018; Klinovszky et al., 2021). Additionally, a cross-sectional study found that health information is mainly expanded from family to peers (Rachmawati et al., 2017).

2.8.3 Personal antecedents

Personal antecedents include: “race”, “age”, “gender” “socioeconomic status”, “income”, “educational attainment”, “work/occupation”, “physical and cognitive abilities”, “social skills”, “numeracy and literacy levels”. A meta-analysis found that younger adults had an adequate health literacy when compared to older ones (mean score $M = -5.2$ years; 95% CI (-7.2, -3.2), $p < .05$) (Guo et al., 2020). This was also evident in a cross-sectional study (OR 0.03, 95% CI (0.33, 0.94) (Almigbal et al., 2020). However, an RCT stated that findings are unclear whether age is related to health literacy (Lee et al., 2017). Researchers also found that educational attainment was directly related to the functional health literacy (FHL) level ($p < .001$). In fact, those with above secondary school levels, had higher scores of health literacy in comparison to primary education only (OR: 0.33, 95% CI (0.18, 0.59) (Almigbal et al., 2020). Another cross-sectional study identified that health literacy had a stronger influence on T2DM self-management in: young male adults, educated, employed and living in urban areas. Therefore, health literacy positively and significantly affected different socioeconomic groups (Niknami et al., 2018). Moreover, the qualitative study found lower health literacy levels amongst older adults (60+), showing a positive relationship between health literacy and age. Although, the latter group had a decline in participants therefore, the results were not consistent (Ayre et al., 2021). On the contrary, an RCT and a cross-sectional study found no significant differences between sociodemographic variables and health literacy (Lee et al., 2017; Yarmohammadi et al., 2019). To comprehend the different aspects of health literacy and socioeconomic groups, further studies are needed (Lee et al., 2017; Niknami et al., 2018).

2.9 Consequences of limited health literacy in relation to diabetes self-management

(where applicable)

Screening and prevention for DM are of no interest in individuals already diagnosed with T2DM. In view of this, the aspects included in this review in relation to health literacy and diabetes are chronic disease and co-morbidity, disease knowledge and medication adherence. Moreover, the possibility of decreased self-management, glycaemic control (HbA1c) and gaps in the literature were identified.

2.9.1 Chronic disease and co-morbidity

DM, being a progressive chronic disease poses a great risk (Saeedi et al., 2019). During the comparison of scores, individuals living with T2DM had significantly lower FHL levels (Klinovszky et al., 2021). Furthermore, a SR found that those with low health literacy had less chance of managing their chronic disease well (DeWalt et al., 2004; Fransen et al., 2012). Due to non-compliance prevention, organ failure was coupled with inadequate health literacy in chronically diseased individuals (Lee et al., 2010). No paper found an inverse connection between reduced health literacy, chronic disease and co-morbidity.

2.9.2 Disease knowledge

Studies identified that individuals with limited health literacy had inadequate diabetes knowledge. Therefore, diabetes knowledge was then set as inclusion criteria by researchers (Al Sayah et al., 2013; Kim & Lee, 2016). It was positively highlighted that individuals with a decreased health literacy level showed interest to learn (Moussa et al., 2013). Health literacy was weakly positively correlated to disease knowledge ($r = 0.29$) (95% CI (0.09, 0.48); $p < .001$) (Guo et al., 2020). In the literature review of previously cited meta-analysis and in this present dissertation being conducted, a cross-sectional study identified the possibility of health literacy as an indirect effect on glycaemic control via diabetes

knowledge (Bains & Egede, 2011). While, in another study, it was stated that additional research is required on the possible role of knowledge on health literacy and diabetes self-management (Fransen et al., 2012). Following recommendations, more recent cross-sectional studies found that diabetes knowledge and patient activation are two indirect mediators between health literacy and diabetes self-care activities (Kim, 2021; van der Heide et al., 2014). Those with high diabetes knowledge had better diabetes self-management scores, whilst highly educated individuals had lower diabetes self-management scores, therefore creating uncertainty about the relationship between knowledge and education (Schmitt et al., 2013). Lastly, a qualitative study similarly identified a moderate relation between diabetes knowledge and diabetes self-management behaviours (Ayre et al., 2021).

2.9.3 Medication adherence

A SR stated that studies were inconclusive when it comes to the fact that health literacy mirrors better T2DM self-management outcomes such as medication (Dahal & Hosseinzadeh, 2019). Five studies in the SR by Fransen et al., (2012) did not establish a significant link amongst health literacy and diabetes self-management activity mainly that of medication adherence (Bains & Egede, 2011; Kim et al., 2004; Mancuso, 2010; Osborn et al., 2010; Sarkar et al., 2006). However, two studies from the aforementioned SR found a significant link amongst health literacy and medication adherence (Cavanaugh, 2008; Karter et al., 2010).

In an RCT, it was detected that no statistical significance was observed between intervention and control groups for diabetes medication adherence (Mann-Whitney U test 300, $p > .05$) (Lee et al., 2017). Whilst another RCT associated a positive relationship amongst low health literacy vs medication errors (Xu et al., 2014). Furthermore, a statistically significant relationship between medication adherence and health literacy was

found in a cross-sectional study ($p < .05$) (RobatSarpooshi et al., 2020). However other studies did not measure medication adherence, however, in the authors' discussion, it was noted that self-efficacy is an influencing factor on medication adherence ($p < .05$) (Park et al., 2010; Saleh et al., 2021). Self-efficacy is not of interest however, here one can see the relationship of this variable to the present study. A cross-sectional study found that 63.1% forgot to take their medications whilst assessing participants' diabetes self-management behaviours. However, this was not matched with the health literacy levels (Niknami et al., 2018). No conclusion was drawn in another cross-sectional study (Almigbal et al., 2020).

2.9.4 Decrease self-management, glycaemic control (HbA1c) and gaps in the literature

Specific papers included in the SR by Fransen et al., (2012), found no direct relationship amongst health literacy and diabetes self-management (Fransen et al., 2012; Nouhjah, 2015; Parham et al., 2014; Shakibazadeh et al., 2009; Hamadzadeh et al., 2013; Barati, 2014; Baghaei et al., 2008; Shahbaz et al., 2016). Researchers also stated that this goes against what is generally expected. Studies continue to emphasise that current research cannot conclude that the level of health literacy is directly related to diabetes self-management or glycaemic control (HbA1c) due to inconsistency in the results and the passage of time (Schillinger et al., 2002; Kim et al., 2004; Osborn et al., 2010; Williams et al., 1998; Tang et al., 2010). In fact, a significant relationship between health literacy and HbA1c in the SR by Fransen et al., (2012), was only evident in two studies (Cavanaugh et al., 2008; Powell et al., 2007). Moreover, this is considered a gap by researchers and adds to the study by Guo et al., (2020) for the fact that there may be other intermediate factors between health literacy and diabetes self-management (Guo et al., 2020). Additionally, as T2DM is a progressive disorder, results must be taken with caution (Fonseca, 2009).

Another SR found inconsistency between health literacy and diabetes self-care in the reporting of outcomes (Caruso et al., 2018). Additionally, when health literacy was linked

to glycaemic control and diabetes self-care specifically subscales for; self-monitoring of blood glucose, diet, foot care and treatment association were inconclusive (Dahal & Hosseinzadeh, 2019). However, a positive correlation in health literacy only results for physical activity and self-efficacy (Beverly et al., 2013; Shi et al., 2010). A meta-analysis found a weak but statistically significant correlation when comparing health literacy and diabetes self-care ($r= 0.24$, 95% CI (0.16, 0.31); $p < .05$). Moreover, when comparing health literacy and HbA1c a significant inverse association was found ($r= -0.08$; 95% CI (-0.14, -0.03); $p = .001$) (Guo et al., 2020). This meant that if one variable increases the other decreases, showing positive results. Furthermore, 67% had adequate health literacy levels, found amongst highly educated and high-income groups (Guo et al., 2020). When comparing health literacy and diabetes self-care it was also positively correlated in four out of seven studies that were included in the SR by Bailey et al., (2014) (Bailey et al., 2014).

A study by Kim & Lee, (2016), with a focus on research containing health-literacy-sensitive diabetes intervention groups meaning papers that contain strategies for accommodation individual's with low health literacy vs the usual care group with routine medical services and no strategies for individuals with limited health literacy, found a minimal significant decrease in HbA1c between the two regardless of health literacy levels (-0.18%; 95% CI: (-0.36, -.004), $Q= 34.6$, $df= 8$, $p < .05$, $I^2 = 76.88$). Additionally, a subgroup meta-analysis was carried out and subjects were stratified according to their health literacy levels in the intervention group. A significant effect on HbA1c was identified amongst low health literacy levels individuals ($M= -0.42\%$; 95% CI: (-0.81, -0.04), $Q=10.49$, $df= 2$, $p = .005$, $I^2 = 80.93$). While those who had high levels of health literacy no significant effects resulted on their HbA1c levels ($M= -0.13\%$; 95% CI: (-0.80, 0.54), $Q= 22.94$, $df= 2$, $p > .05$, $I^2 = 91.28$) (Kim & Lee, 2016). These results showed that low health literacy individuals benefitted more from interventional strategies accommodating their limited health literacy levels.

In the RCT by Lee et al., (2017) health literacy programmes statistically improved diabetes self-management in comparison to control groups ($t = -2.62, p = .012$). The significant behavioural factors were for self-monitoring (Mann Whitney U test = 162, $p = 0.002$), diet ($t = -2.26, p = .029$) and medication adherence as highlighted earlier (Mann-Whitney U test = 300, $p > .05$). No statistical significance between intervention and control groups was observed for foot care ($t = 1.30, p > .05$). The overall effect size for health literacy vs diabetes self-management was that of 0.73, showing a strong significant relationship and therefore, effective. In the previous RCT, no significant differences in HbA1c between groups resulted as almost all participants remained with an HbA1c $< 7.5\%$. Authors suggested that this may be due to the limited study duration (Lee et al., 2017). When compared to another RCT included in this current literature review, posed a great limitation as no statistical results were presented (only methods presented). It was only stated in the discussion section that the results which addressed low health literacy in true world setting may improve T2DM skills; both clinical and managerial. Moreover, a 1-year intervention was assumed enough to decrease HbA1c (Xu et al., 2014).

The recent cross-sectional study by Kim, (2021) added to the knowledge of the possibility of mediating variables which were mentioned in the studies by Fransen et al., (2012) and Guo et al., (2020) (Fransen et al., 2012; Guo et al., 2020; Kim, 2021). The study by Kim (2021), identified that health literacy and diabetes self-management showed no direct significant relationship (standardized $\beta = -0.07, SE = 0.04, p = .099$). Knowledge and patient activation showed an indirect significant relationship on diabetes self-management and health care (β indirect = 0.23, $SE = 0.06, p = .010$). This study presented the average HbA1c of participants i.e., 9.12% but did not study its relationship (Kim, 2021).

A cross-sectional study by Saleh et al., (2021) found that health literacy and self-management both correlate with glycaemic control i.e., HbA1c $p < .05$ (Health literacy; 95% CI (0.092, 1.274), $p < .05$, self-management; 95% CI (0.081, 0.728). This correlation

may have accounted for higher number of older adults. This implied that individuals with lower self-care were compared, those holding a high health literacy had within range HbA1c levels and those with high self-care had 0.24 times better HbA1c levels (Saleh et al., 2021). Moreover, another secondary study by Ilhan et al., (2021) found that when diabetes self-management mean score was low, these participants had also lower health literacy levels. Therefore, the health literacy mean score, educational level, and physical activity resulted in a significant relationship to diabetes self-management ($R^2 = 0.245, p < .001$). Regarding HbA1c; a weak significant inverse relationship was found with DSCS where the overall HbA1c reduction was -0.127 (Mean \pm SD; $93.85\pm 12.02, p < .05$). Furthermore, no significance amongst HLS-EU-Q-TR and HbA1c ($26.79\pm 7.78, p > .05$) resulted (Ilhan et al., 2021). However, a study by Almigbal et al., (2020), comparing health literacy and diabetes self-management found a relationship which was not significant ($p > .05$). In the latter study, the mean FHL score was 16.64 (range: 0-36) with 50% of the individuals having low health literacy, whilst the DSMQ median score was 39 (range: 7-47), representing high diabetes self-management overall (Almigbal et al., 2020). Therefore, this relationship does not suggest that increasing the levels of health literacy improves self-management in diabetes. This further indicates a gap in the literature (Schmitt et al., 2013). The study by Almigbal et al., (2020), was related to a similar study that also found no significant relationship between FHL and glycaemic control. Therefore, inconsistency may have resulted due to demographic factors that may have affected health literacy (Al Sayah et al., 2013; Poureslami et al., 2017). Moreover, since the sample size is small, results cannot be generated (Almigbal et al., 2020).

A significant association between health literacy levels and diabetes self-management was found in the study of Yarmohammadi et al., (2019). Furthermore, the aforementioned self-management had a mediating role in the relationship of health literacy scores on HbA1c ($\beta = -0.24, p = .042$) (Yarmohammadi et al., 2019). In line with the previously cited study, the

study by Niknami et al., (2018) found a significant association between health literacy and diabetes self-management. Moreover, it was inversely correlated with HbA1c after controlling demographics. This relationship accounted for low health literacy levels of 8.2 (range: 0-20) (SD= 14.0), mainly amongst rural, unemployed and with no formal education individuals. However, results cannot be generated due to a convenience sampling method and cross-sectional design as data is gathered at that moment. Authors suggest intervention research i.e., RCTs to trace the use of health literacy on T2DM self-management (Niknami et al., 2018). In another study, a significant relationship amongst health literacy, educational level and income was found via the mean score of self-management (33.52 ± 13.27) ($p < .05$) (RobatSarpooshi et al., 2020). These findings were consistent with another study that also established a relationship amongst diabetes literacy and self-management ($r = 0.246$, $p = .01$) (Rachmawati et al., 2019). However, the last two cited articles did not measure HbA1c (Rachmawati et al., 2019; RobatSarpooshi et al., 2020). Results were inconsistent with a different study finding a lack of association amongst health literacy and glycaemic control ($\beta = 0.03$; 95% CI (-0.19, 0.13), $p > .05$). Moreover, health literacy and diabetes self-management behaviours were not associated with HbA1c ($r = -0.03$, 95% CI -0.19, 0.13), general diet ($r = -0.50$, 95% CI (-0.56, 0.35), exercise ($r = -0.03$, 95% CI (-0.23, 0.16) and foot care ($r = -0.6$, 95% CI (-0.27, 0.18) (Bains & Egede, 2011). A possible reason between the latter study and other previous cited studies results is the gap year of completion.

In the qualitative study, 54% (n= 14) of the individuals had minimal health literacy, whereas only 38% (n= 10) had a sufficient health literacy, according to the NVS. Regardless of their health literacy levels, individuals reported low diabetes self-management ('lulls') (Ayre et al., 2021). Due to the nature of the study, no statistical tests were carried out. The results mentioned are listed in Table 6 below.

Table 6: Summary of results of individual studies

Study	Relationship between health literacy and diabetes self-management	Relationship with glycaemic control	Other information including health literacy levels/ diabetes self-management scores/socio demographic variables
1. Kim & Lee, (2016)	N/A	<p>Regardless of the health literacy levels, the SR with meta-analysis found a small significant reduction in HbA1c in the health-literacy-sensitive intervention group when compared to the usual care group (-0.18%; 95% CI (-0.36 to -.004), Heterogeneity Q= 34.6, degrees of freedom (df)=8, $p < .05$, $I^2 = 76.88$).</p> <p>In the sub-group meta-analysis <u>low</u> health literacy levels, had a significant moderate effect on their HbA1c resulted (-0.42%; 95% CI (-0.81, -0.04), Q= 10.49, df= 2, $p = .005$, $I^2 = 80.93$). While, those who had <u>high</u> levels of health literacy no significant effects resulted on their HbA1c levels (-0.13%; 95% CI (-0.80, 0.54), Q= 22.94, df= 2, $p > .05$, $I^2 = 91.28$)</p>	N/A
2. Guo et al., 2020	Weak correlation yet significant between health literacy and diabetes self-management ($r= 0.24$, 95% CI (0.16, 0.31); $p < .05$). This correlation was mainly seen with self-monitoring ($r= 0.19$; 95% CI (0.11, 0.27); $p < .00001$), dietary and physical care ($r=$	Significant inverse association between health literacy and HbA1c ($r= -0.08$; 95% CI (-0.14, -0.03); $p= .001$).	Health literacy adequacy rate was 67%, 95% CI (57, 76). Compared with patients with inadequate HL, patients with adequate HL were younger (mean difference -5.2 years; 95% CI (7.2, 3.2); $p < .00001$),

	0.12; 95% CI (0.07, 0.18); $p < .009$), diabetes knowledge ($r= 0.29$; 95% CI (0.09, 0.45); $P < .001$), self-efficacy ($r= 0.28$; 95% CI (0.15, 0.41); $p < .00001$), formal education ($r 0.35$; 95% CI (0.18, 0.53); $p < .00001$) and social support ($r= 0.2$; 95% CI (0.07, 0.33); $p =.00001$).		had high school/ education (odds ratio (OR) 8.39; 95% CI (5.03, 13.99); $p < .00001$) and with a high-income (OR 0.36; 95% CI (0.23, 0.56); $p < .00001$). Patient age ($r= 0.28$; 95% CI (0.39, 0.17); $p < .00001$) was inversely correlated with HL. Overall diabetes monitoring was $I^2 = 96.3%$, $p < .05$. Overall diet care and physical activity was $I^2= 95.6%$, $p < .05$. Both showing statistical significance.
3. Dahal & Hosseinzadeh, (2019)	Inconclusive results for health literacy in relation to self-management specifically; self-monitoring of blood glucose, foot care, diet and treatment. Results for physical activity and self-efficacy were positively correlated with health literacy $p > .05$, CI: N/A in the intervention group i.e., community-based HL interventions when compared to the control patient-focused heal literacy group	Inconclusive relation between health literacy and glycaemic control	N/A
4. Fransen et al., (2012)	Found no significant direct relationship $p > .05$, CI: N/A	Non-consistent data for heath literacy on the impact of glycaemic control $p > .05$, CI: N/A	Socio-cognitive variables such as knowledge and social support mediate in the pathway of health literacy and diabetes self-management.
5. Lee, Song, &	When compared to the control group, the intervention group in a health	No significant differences in HbA1c between groups resulted as almost all	No statistical significant between socio demographic

<p>Im, (2017).</p>	<p>literacy programme had a significantly higher diabetes self-management ($t = -2.62, p = .012$). The significant behavioural factors were; self-monitoring of blood glucose (SMBG) (Mann Whitney U test= 162, $p = .002$) and diet ($t = -2.26, p = .029$). The overall effect size for health literacy in relation to diabetes self-management was that of 0.73</p> <p>No statistically significant differences between intervention and control groups were observed regarding diabetes medication adherence (overall Mann-Whitney U test 300, $p > .05$) and foot care ($t = -1.30, p > .05$).</p>	<p>participants remained with an HbA1c $< 7.5\%$.</p>	<p>groups at pre-test; age ($t = 0.20, p > .05$), marital status (Fisher's exact test= 2.15, $p > .05$), income ($t = 0.20, p > .05$) and education (Fisher's exact test= 3.89, $p > .05$). Findings are unclear whether age is related.</p>
<p>6. Xu et al., (2014).</p>	<p>No statistical results were presented. It is only written in the discussion section where it states that the results addressing poor health literacy in the 'real world setting' can significantly improve T2DM skills; both managerial and clinical.</p> <p>low health literacy was positively associated with medication errors</p>	<p>No statistical results. It was stated that assuming 1-year intervention will decrease HbA1c</p>	<p>N/A</p>
<p>7. Kim, (2021)</p>	<p>Health literacy and diabetes self-management had no direct significant relationship (standardized $\beta = -0.07$,</p>	<p>N/A</p> <p>This study gave the average HbA1c of participants i.e., 9.12% but did not</p>	<p>Health literacy had an indirect significant relationship on diabetes self-care through knowledge and patient</p>

	SE = 0.04, $p = .099$).	study its relationship	activation (β indirect = 0.23, SE = 0.06, $p = .010$).
8. Saleh et al., (2021)	N/A	Health literacy and self-management both correlate with glycaemic control i.e., HbA1c $p < .05$ (Health literacy; 95% CI: (0.092, 1.274), $p < .05$, self-management; 95% CI (0.081, 0.728)	The significance was studied on older adults.
9. Almigbal et al., 2020	No statistically significant relationship	No relationship between diabetes self-management and HbA1c (OR= 1.9; 95% CI (0.64, 2.22), SE; 0.31, $p > .05$)	Mean functional health literacy score was 16.64 (0-36) with 50% of the individuals having low health literacy, whilst the DSMQ median score was 39 (range: 7-47), Sociodemographic variables were significantly associated with lower health literacy levels. These included 50+ age group (OR 0.03, 95% CI: (0.33 to 0.94), female gender (OR: 2.61, $p < .05$), low levels of education (such as primary) (OR: 0.33, 95% CI: (0.18 to 0.59). Marital status and employment status accounted for no statistical significance ($p > .05$). The aforementioned factors except for gender were not significant with diabetes self-management ($p > .05$).

<p>10. Ilhan et al., (2021)</p>	<p>Health literacy scale (HLS-EU-Q-TR) mean score, physical activity resulted in significant relationship to diabetes self-management ($R^2 = 0.245, p < .001$).</p>	<p>Regarding HbA1c; a weak significant inverse relationship was found with diabetes self-care scale (DSCS) where the overall HbA1c reduction was -0.127 (Mean\pmSD $93.85\pm 12.02, p < .05$). No significant differences resulted amongst HbA1c and HLS-EU-Q-TR ($26.79 \pm 7.78, p > .05$)</p>	<p>40.2% of individuals with diabetes had an inadequate level of health literacy, 41.3% were problematic-limited, 15.5% sufficient, and 3% excellent</p> <p>A weak negative relationship was found between the age of the patients and the DSCS (-0.327) and HLS-EU-Q-TR (-0.259) Overall ($p < .001$)</p> <p>Educational level was significant related to diabetes self-care ($R^2 = 0.245, p < .001$)</p> <p>The HLS-EU-Q-TR mean scores of the patients who reported their income status as good-very good were significantly higher than those who reported their income status as bad-medium ($p < .001$)</p>
<p>11. Yarmohammadi et al., (2019),</p>	<p>Health literacy levels were significantly associated with diabetes self-management</p>	<p>Self-care had a mediating role in the relationship of total health literacy scores (functional, communication and mostly critical health literacy) towards HbA1c that of ($\beta = -0.24, p = 0.042$)</p>	<p>Health literacy, self-care, and HbA1c were investigated, and none of these variables had a significant relationship with socio-demographic variables.</p>
<p>12. Niknami et al., (2018)</p>	<p>Health literacy levels were significantly associated with diabetes self-management</p>	<p>Health literacy was significantly inversely correlated with HbA1c</p>	<p>This relationship accounted for low health literacy levels of $8.2/20$ (SD\pm14.0). This result mainly accounted for rural</p>

			individuals, unemployed and with no formal education.
13. RobatSarpooshi et al., (2020)	Self-management (33.52±13.27) had a significant relationship to health literacy. A significant relationship between health literacy and medication adherence ($p < .05$)	N/A	Self-management (33.52±13.27) had a significant relationship to educational level and income ($p < .001$).
14. Rachmawati et al., (2019)	Positive significant relationship between diabetes literacy and diabetes self-management ($r= 0.246, p = .01$)	N/A	N/A
15. Bains & Egede, (2011)	No significant association between health literacy and glycaemic control ($\beta=0.03; 95\% \text{ CI } (-0.19, 0.13), p > .05$). Health literacy may have an indirect effect on glycaemic control via diabetes knowledge. No significant relationship between health literacy and medication adherence	Health literacy and diabetes self-management behaviours were not associated with HbA1c (health literacy coefficient -0.03, 95% CI (-0.19, 0.13), general diet (-0.50, 95% CI (-0.56, 0.35), exercise (-0.03, 95% CI (-0.23, 0.16) and foot care (-0.05, 95% CI (-0.27, 0.18)	Age (-0.85, 95% CI (-1.81, 0.12), gender (-0.78, 95% CI (-1.78, 0.23), race (0.74, 95% CI (-0.24, 1.73), education (-0.72, 95% CI (-1.81, 0.37) and income (-0.24, 95% CI (-1.26, 0.77) were not significantly associated with glycaemic control.
16. Ayre et al., (2021)	Regardless of their health literacy levels, individuals reported low diabetes self-management ('lulls'). Due to the nature of the study no statistical tests were carried out to identify statistically significance differences	N/A	54% of participants had limited HL, whereas 38% adequate health literacy.

Note: p -values of $\leq .05$ are considered statistically significant, CI- confidence interval mostly 95%, β - beta is the probability of Type II error, SE- standard error, Q- Heterogeneity, df – degrees of freedom, I^2 – Inconsistency, N/A- not available

2.10 Summary

2.10.1 The relationship between health literacy and diabetes self-management

Most papers ranging from meta-analysis, RCTs and cross-sectional studies found a relationship between health literacy and diabetes self-management which was significant (Guo et al., 2020; Ilhan et al., 2021; Lee et al., 2017; Niknami et al., 2018; Rachmawati et al., 2019; RobatSarpooshi et al., 2020; Yarmohammadi et al., 2019). Other studies found no significant association between the variables (Almigbal et al., 2020; Bains & Egede, 2011; Fransen et al., 2012; Kim, 2021). Moreover, the qualitative study found that low diabetes self-management was reported irrelevant to the health literacy levels found (Ayre et al., 2021). A SR determined an inconclusive result when comparing health literacy levels and diabetes self-management (Dahal & Hosseinzadeh, 2019). Three studies did not present results for the relationship between the two variables, therefore limiting these studies (Kim & Lee, 2016; Saleh et al., 2021; Xu et al., 2014).

2.10.2 The relationship of health literacy, diabetes self-management with glycaemic control

In the health-literacy-sensitive group, only those with low health literacy levels had a significant moderate effect on their HbA1c levels (Kim & Lee, 2016). Moreover, a meta-analysis amongst health literacy and HbA1c identified a relationship which was inversely significant, indicating an improvement in glycaemic control (Guo et al., 2020). However, two SRs found an inconclusive/non-consistent relation between health literacy and glycaemic control (Dahal & Hosseinzadeh, 2019; Fransen et al., 2012). An RCT found no significant differences in HbA1c between groups but this may have resulted due to a constant Hba1c value (<7.5%) (Lee et al., 2017). Again, the RCT by Xu et al., (2014), did not present statistical result for HbA1c which further weakens and shows study's irrelevance (Xu et al., 2014).

A study found that both health literacy and diabetes self-management correlated with glycaemic control (Saleh et al., 2021). Additionally, a study found a weak, inverse significant relationship between HbA1c and diabetes self-care scores, however, health literacy scores and HbA1c had no relationship (Ilhan et al., 2021). This goes against another study by Almigbal et al., (2020) where an insignificant relationship between diabetes self-management and HbA1c was found (Almigbal et al., 2020). While another two cross-sectional studies identified that health literacy was significantly inversely related to HbA1c (Niknami et al., 2018; Yarmohammadi et al., 2019). Conversely, in another study there was no statistical significance amongst health literacy and/or diabetes self-management to Hba1c (Bains & Egede, 2011). In another four studies, no relationship was determined between glycaemic control, health literacy or diabetes self-management (Ayre et al., 2021; Kim, 2021; Rachmawati et al., 2019; RobatSarpooshi et al., 2020).

2.10.3 Other information related to sociodemographic variables

Studies found that individuals which were younger, highly educated, had higher income and lived in urban areas accounted for better health literacy levels (Almigbal et al., 2020; Guo et al., 2020; Ilhan et al., 2021; Niknami et al., 2018). However, another study stated that it is unclear whether age is related (Lee et al., 2017). A study suggested that both positive correlations of health literacy and diabetes self-management on HbA1c could have accounted for older age (Saleh et al., 2021). A study identified that females had higher scores of health literacy and diabetes self-management. The latter could be somewhat reliable because the participation of males was higher than females (Almigbal et al., 2020). Other studies found a significant association between educational attainment and diabetes self-care (Ilhan et al., 2021; RobatSarpooshi et al., 2020). Health literacy, diabetes self-management and HbA1c were not significantly related to sociodemographic variables (Yarmohammadi et al., 2019; Bains & Egede, 2011). Other studies did not show results concerning sociodemographic variables (Ayre et al., 2021; Dahal & Hosseinzadeh, 2019;

Kim, 2021; Kim & Lee, 2016; Rachmawati et al., 2019; Xu et al., 2014). The recent cross-sectional study by Kim, (2021) added to the knowledge found by Fransen et al., (2012) and Guo et al., (2020), showing an indirect significant relationship amongst health literacy and diabetes self-management via knowledge and patient activation (Fransen et al., 2012; Guo et al., 2020; Kim, 2021).

2.11 Conclusion

The literature review identified 16 relevant studies. Different results between studies were presented. However, although health literacy is infinite, it was seen as an essential element in the relationship between individual's characteristics, diabetes self-management and glycaemic control.

Chapter 3- Methodology

3.1 Introduction

The methodology section starts by the objectives and hypotheses. Philosophical underpinnings are briefly mentioned. This chapter also highlights the methods chosen. Furthermore, the population studied, collection of data, research tools used and their translation, pilot study and data analysis are also presented. Subsequently, ethical considerations are outlined. The limitations of the study and how they were minimised were clearly stated.

3.2 Objectives

The overall aim of the study was to identify the relationship between health literacy, diabetes self-management and blood glucose control in adults living with type 2 diabetes mellitus (T2DM).

All objectives are as follows:

1. To describe the health literacy of individuals living with T2DM
2. To identify any sociodemographic variables of individuals differences in health literacy (such as age, gender, marital status, geographical region, education, working status, diabetes duration, salary, information media used, treatment regimen, family history of diabetes).
3. To explore the self-management of individuals living with T2DM
4. To explore the relationship between health literacy and diabetes self-management
5. To explore any possible relationship between health literacy and glycaemic control (operationalised in terms of HbA1c)
6. To explore any possible relationship between diabetes self-management and glycaemic control (via HbA1c)

3.2.1 Hypotheses testing

Based on these dissertation objectives; the null hypotheses are as follows.

Null Hypothesis 1: There are no differences in the levels of health literacy between individuals with T2DM.

Null Hypothesis 2: There is no association between sociodemographic variables and individual differences in health literacy.

Null Hypothesis 3: There are no differences in the measurements of diabetes self-management between individuals with T2DM.

Null Hypothesis 4: Health literacy scores are not associated with diabetes self-management scores.

Null Hypothesis 5: There is no association between health literacy and glycaemic control.

Null Hypothesis 6: There is no association between diabetes self-management and glycaemic control.

3.3 Philosophical underpinnings

The researcher's 'philosophical world view' also known as 'paradigms' followed to an extent the 'post-positivism' approach. The latter was expanded after the so-called limitation in the 'positivism' approach (Tanlaka, Ewashen, & King-Shier, 2019). In fact, the 'ontology' focused on 'critical realism' where reality exists driven by natural laws; humans do not perceive it with their imperfect senses and can never be sure of the ultimate. This implies that both the researcher and the participants have imperfect senses. The 'epistemology' is 'modified objectivist' where it is impossible not to interact with the subjects during the research, in fact, the researcher is also a healthcare professional (HCP). To counteract this, the intermediary approached the participants first. The 'methodological'

aspect followed the quantitative research approach, using close-ended questions via questionnaires and statistically analysing their scores (Creswell & Creswell, 2017).

3.4 Research design

A cross-sectional survey study approach was used to target study's the objectives. It examines the population at one fixed point in time. This is used to measure the relationship between variables, prevalence or risk factors of a given population and association with service use (Aggarwal & Ranganathan, 2019; Bowling, 2014). Generally, cross-sectional studies are simple and inexpensive to carry out when compared to other observational, quantitative designs such as cohort or case-control studies (Mann, 2012). The drawback of this design is that it entails a large, heterogeneous sample size with a possibility of an increased sampling bias (Wang & Cheng, 2020). Moreover, a high response rate is needed to generalise results.

3.4.1 Target Population

The two diabetes outpatients departments located at the two main acute hospitals that reach and follow-up people living with T2DM were studied. Both Maltese and Gozitan participants were recruited. It was not feasible to study various health centres and General Practitioners (GPs). The two main hospitals chosen for data collection was based on their strategic positions and uniformity in their management strategies. Moreover, these two hospitals offer healthcare free of charge and numerous individuals attend from vast localities.

3.4.2 Determining sample size

Very large population size does not necessarily entail a very large sample size as it has a negligible effect on the number required for a sample size as shown below in Table 7. A 95% confidence interval (CI) was selected. According to a national study, it was stated that 10% of the Maltese population lives with T2DM in Malta therefore, the population size is estimated to be **51,610** (“A National Public Health Priority: A National Strategy for Diabetes 2016-2020”). The latter resulted from the total number of populations according to the National Statistics Office (NSO) i.e., 516,100 divided by 10%= 51,610 (NSO, 2021). With the aid of the statistician and by using the sample size calculator available online figures are found below in Table 7 and Figure 3.

Table 7: Calculating the required sample size

<p>Assuming a 95% confidence level and a population size of 51,610 then to reach:</p> <ul style="list-style-type: none">a margin of error of 5%, a sample size of 381 individuals is required.a margin of error of 6%, a sample size of 265 individuals is required.a margin of error of 7%, a sample size of 195 individuals is required.a margin of error of 8%, a sample size of 150 individuals is required.a margin of error of 9%, a sample size of 118 individuals is required.a margin of error of 10%, a sample size of 96 individuals is required.

Figure 2: Sample size calculator results

The figure consists of two screenshots of online calculators. The top screenshot, titled "Determine Sample Size", shows a form with the following fields: "Confidence Level" with radio buttons for 95% (selected) and 99%; "Confidence Interval" with a text input field containing "5"; "Population" with a text input field containing "51610"; and two buttons labeled "Calculate" and "Clear". Below the buttons, the result "Sample size needed: 381" is displayed in a text input field. The bottom screenshot, titled "Find Confidence Interval", shows a form with the following fields: "Confidence Level" with radio buttons for 95% (selected) and 99%; "Sample Size" with a text input field containing "381"; "Population" with a text input field containing "51610"; "Percentage" with a text input field containing "50"; and two buttons labeled "Calculate" and "Clear". Below the buttons, the result "Confidence Interval: 5" is displayed in a text input field.

In most dissertations, the margin of error ranges between 5% and 10%. The suggestion was a balance between eliminating a large margin of error that reduces the statistical analysis power and not having a large sample size that is unmanageable to collect. However, the larger the sample size, the larger the statistical inference and the less margin of error. The smaller the margin of error the stronger the inference. It was concluded that a 5% margin of error was satisfactorily low, manageable due to enough time and the abundant number scheduled and attendance per day of individuals visiting the two diabetes outpatients clinics included in this study. Using a convenience sample to obtain a proportional representation of individuals in Malta and Gozo, with a 5% margin of error, the sample sizes from Malta and Gozo were 352 and 29 respectively. This formulates to a total of 381 eligible individuals and ensures a large enough sample size to detect true differences and not due to chance, therefore, reducing 'Type II error' in 'Hypotheses testing' (Shreffler & Huecker, 2020).

Figure 4 shows an equation used to calculate the maximum margin of error. To be calculated, one must specify the CI, sample size (n) and population size (N). The below equation containing N is known i.e., 51,610 and n is 381. The prevalence rate is the population proportion p , which in most cases is unknown. However, one sets it to 0.5 as it yields a larger value for standard error (SE). The margin of error is given by $z \sigma_p$ where z ranges between -1.96 to 1.96 when one considers the middle 95% of the area score. A 95% CI was assumed.

Figure 3: The maximum margin of error

Since a 95% degree of confidence is used $z = 1.96$.

$$\sigma_p = \sqrt{\frac{p(1-p)}{n} \left(\frac{N-n}{N-1} \right)} = \sqrt{\frac{(0.5)(0.5)}{381} \left(\frac{51,610-381}{51,610-1} \right)} = \sqrt{0.000651} = 0.0255 \text{ (SE)}$$

SE is the Standard Error=0.0255

Maximum margin of error= $z \sigma_p = (1.96)(0.0255) = .0500 = \underline{5\%}$

3.4.3 Inclusion and exclusion criteria of participants

Maltese people living with T2DM 18 years of age or over and satisfying the selection criteria as found in Table 8 below were recruited for the study. Participants had their Identification Number ending in G/H (Gozitans) or M/L (Maltese) excluding A/F/P (foreigners). This implied a true representation of the Maltese nationality/population and excluded foreigners. Different genders were considered eligible for this study. This age group required less ethical issues and permissions. Due to data protection issues, the researcher had no access to the list of patients attending the two diabetes clinics included in this study from which eligible participants were selected via convenience sampling. Persons

who were unable to read and write were included in this study. Therefore, this study included both literate and illiterate individuals. Individuals with severe mental impairment (SMI) were excluded such as schizophrenia spectrum disorders, bipolar disorder, and major depression (Lean et al., 2019). Moreover, individuals with brain disorders such as the umbrella term 'dementia', which mainly includes 'Alzheimer's disease' and 'vascular dementia' amongst others were also excluded. Exclusion for these needs was performed as other specifically designed tools/scales to quantitatively measure health literacy, and diabetes self-management would have been needed to cater for these individuals. These conditions were previously identified by the intermediaries who were HCPs who had access to the patient's medical/surgical history.

Table 8: Inclusion and exclusion criteria

Type	Included	Excluded
Age year	Born in 2003 and earlier	After 2003
Nationality	Persons of Maltese nationality	Persons of other nationality residing in Gozo or Malta
Identification Number	Ending in G/H/M/L for Maltese, showing that these have lived years in Malta. Where Gozitans are also Maltese. (Note G is for Gozitans born from the year 1900 onwards, H is for Gozitans registered after the year 2000. Similarly, M is for those Maltese citizens and L is for the younger Maltese generation).	Excluding other id ending such as A/F/P (Note A is for aliens therefore, not Maltese, F represents the foreigners and P stands for provisional card for those who fail to present a birth certificate yet have been living in Malta for years (Identity Malta, 2017).
General literacy ability	Literate and illiterate i.e., not necessarily able to read and write	Severe mental impairment (SMI) for example; schizophrenia spectrum disorders, bipolar disorder, and major depression (Lean et al., 2019). Together with brain disorders such as the umbrella term dementia; which mainly includes ‘Alzheimer’s disease’ and ‘vascular dementia’. As other specifically designed tools would have needed to be used. These conditions were previously identified by the intermediaries who are both HCP and have access to the patient’s history
Fluent language	Maltese or English	Other languages

3.5 Sampling type and initial contact

A non-probability sampling method was used, specifically a convenience sampling. This sampling method was used as the researcher did not have access to a pre-list of all individuals living with T2DM in Malta or a list of persons attending the diabetes clinics

included in the study. This type of sampling is frequently used in clinical research as it is quick, convenient, and inexpensive (Elfil & Negida, 2017). As the term convenient sampling implies, participants were recruited according to the researcher's accessibility and proximity (Gravetter & Forzano, 2012).

Eligible individuals were allocated to the researcher by the intermediaries whilst waiting for their doctor's visit. Once the target number of required participants was reached, the study halted. One of the drawbacks of convenience sampling is that generalisability is limited to the sample drawn (Andrade, 2021). However, this was counteracted as the sample included persons from various age groups (18-60+) and different localities in Malta although not stratified. Therefore, this study was not limited to a particular geographical region (ranging from 'Southern Harbour', 'Northern Harbour', 'Western', 'Northern', 'South Eastern', 'Gozo and Comino').

3.6 Recruitment procedure and data collection method

Potential participants were approached by the intermediary according to their Identification Number ending in M/L/G/H. Firstly, the intermediary administered the information letter. Secondly, the consent form was offered and duly signed via an informed-decision making process. The consent form was kept separately from the questionnaire. Individuals were free to ask questions, to make an informed consent, withdraw any time and if they refused to participate, their usual care was guaranteed and therefore, not affected. This requirement ensured privacy, no pressure or prejudice, is free from misleading jargon and no conflict of interest. If one refused to participate the next individual was chosen.

The questionnaire was either filled by participants i.e., self-administered or the intermediary offered assistance by reading the questionnaire word by word and aiding in

filling it in with no prompting i.e., structured interview. Paper-based questionnaires were aimed to reach a large sample of individuals living with T2DM; however, this may cause a low response rate due to literacy levels (Ebert et al., 2018). To counteract this, structured interview questionnaires, which may be more time-consuming were used to increase the response rate and ensure equity within the eligible population and therefore, reach illiterate or semi-illiterate literacy participants (Wang & Cheng, 2020). This was also offered to participants with visual impairment or illiterate. This ensured equity within the eligible population. The intermediaries i.e., the charge nurse and diabetes practice nurse allocated the eligible participants to the researcher to administer the three-section questionnaire.

Subjects met the researcher once, during one's diabetes outpatients visit, prior to entering the doctor's appointment. This was carried out from the beginning of November 2021 to the beginning of December 2021, between Mondays and Saturdays, for an abundant number of hours, except during the researchers' working duties or other commitments. The time allocated to each participant was approximately 15-20 minutes.

The rationale for the population type and location of recruitment, a traditional way i.e., paper-based questionnaires and structured interview questionnaires were considered ideal for this study as opposed to online surveys where the essential populations are missed (Kelfve et al., 2020). In cross-sectional studies, paper-based questionnaires may cause selection bias due to a decline in response rate by younger cohort when compared to online resources (Ebert et al., 2018). However, the elderly population may be less fluent with online surveys. Moreover, ensuring equitability and agreeing with the health literacy definition, structured interviews were appropriately used. If COVID-19 in Malta had continued to persist during this timeframe, telephone-based questionnaires were going to be considered for the fact that outpatients follow-up during the pandemic were done via telephone calls and it is also an effective way to reach participants. Postal services had also

been considered to be an effective way for recruitment and most economic (Sinclair et al., 2012).

3.6.1 Data management

Personal data i.e., the consent forms and questionnaires were stored separately in two box files. These hard copies were then kept in a locked drawer. Questionnaires were inputted onto SPSS and stored on the researcher's personal laptop and on a separate pen-drive for the purpose of inputting data and backup. These soft copies were encrypted, and password protected. Only the researcher had access to it. The academic supervisor/s and the examiners had access to coded (numerical) data only. Data collected was processed in accordance with the latest 'Data Protection Act' (DPA) and as per ethical principles of the 'University Research Ethics Committee' (UREC). Participants had the right to access, update, and request the removal of personal data under the 'General Data Protection Regulation' (GDPR) and national law that implements and further specifies the relevant elements of said regulation. The removal of personal data was applicable that moment in time referring to the hard copies as at a later stage, the questionnaires were not traceable to particular individuals. The intermediaries who are both HCPs, only had access to the data concerning participants' health as they had a daily list of patients that attended the diabetes outpatients.

3.7 Tool development

3.7.1 Health literacy tool

In this dissertation, after an extensive literature search to identify quantitative measures of health literacy, a shorter version of the "European Health Literacy Survey Questionnaire"

(HLS-EU-Q47) hence, HLS-EU-Q16 was deemed to be the best and the most valid tool for use in the present research project. The questionnaire is concise, easily self-administered and was already used in a Maltese based population entitled “Health Literacy Survey: Malta,” 2014 (NSO, 2014; Sørensen et al., 2013). However, no value regarding Cronbach’s alpha (α) was given for the study previously held in Malta. This tool is a well-known published tool and was tested by the authors themselves. The HLS-EU-Q16 in two studies held in Iceland and Germany accounted for Cronbach’s α of 0.88, showing high internal consistency for all items combined (Gustafsdottir et al., 2020; Tiller et al., 2015). The study included in this dissertation review using a Turkish version of the HLS-EU-Q had a higher Cronbach’s α of 0.92 (Ilhan et al., 2021). This high value when compared to the other studies may negatively suggest paraphrasing of each question, where related questions regarding for example understanding; doctor’s information, pharmacist instruction and health warnings were all answered in the same manner.

Moreover, HLS-EU-Q47 was tested for validity in the diabetes population of interest i.e., individuals with T2DM and was consequently deemed to be particularly suitable for use in the present study for this reason (Finbråten et al., 2018). It questions self-reported elements related to decision-making, health promotion and disease prevention in healthcare. It follows the following aspects: assesses, understands, appraises, and applies information. HLS-EU-Q also questions health status, health behaviour, services usage, participation in the community, socio-demographic and socio-economic factors (Sørensen et al., 2013).

The “5-point Likert scale” as shown in Table 9 ranging from; 'very easy', 'fairly easy', 'fairly difficult' and 'don't know' was retained as originally done by the authors. To generate scores, health literacy was originally dichotomised by authentic authors as in Table 10: 'very easy' and 'fairly easy' into a score of 1, while, 'fairly difficult' and 'very difficult' were given a score of 0. Therefore, excluding those who marked the option 'don't know'.

Subsequently, these were summed to range a total score from 0-16 (Sørensen et al., 2013; Storms et al., 2017). Categorized as ‘inadequate’ (<9), ‘problematic’ (9–12) or ‘sufficient’ (13–16) health literacy as pictured in Table 11 below (Bas-Sarmiento et al., 2020; Röthlin et., 2013; Sørensen et al., 2012).

Table 9: The 5-point Likert scale of HLS-EU-Q16

5-point Likert scale of HLS-EU- Q16	Very easy	Fairly easy	Fairly difficult	Very difficult	Don't know
	1	2	3	4	5

Table 10: Health literacy scores (Sørensen et al., 2013; Storms et al., 2017).

‘very easy’ and ‘fairly easy’	‘fairly difficult’ and very difficult’
1	0

Table 11: Categories of health literacy (Röthlin et., 2013; Sørensen et al., 2012).

Health Literacy Score	Health Literacy status
<9	Inadequate
9-12	Problematic
13-16	Sufficient

3.7.2 Diabetes self-management tool

The “diabetes self-management questionnaire” (DSMQ) was initially developed in 2012 to identify both type 1 diabetes mellitus (T1DM) and T2DM self-management activities and

their association with glycaemic outcomes (Schmitt et al., 2013). This questionnaire was revised in 2015 and 2020 subsequently adding 'R' to the DSMQ (Schmitt, 2016, 2021). The latest version of 2020 was used for this dissertation. The DSMQ-R is a 27-item questionnaire; however, the last 7 items are specifically indicated for T1DM therefore, as the population of this study was T2DM, these last 7 items were eliminated as also instructed by authors leaving a 20-item questionnaire. The internal consistency for the 20-item DSMQ-R in T2DM was equal to Cronbach's α of 0.87 as reported by authors and was classified as high (Schmitt, 2021).

As this dissertation also includes HbA1c levels, the DSMQ was more appropriate when compared to the commonly identified used tool in the literature review in the previous chapter 2 i.e., the "summary of diabetes self-care activities" (SDSCA). This is because DSMQ subscales statistically significantly correlated better with HbA1c when compared to SDSCA. This significant correlation resulted in specifically only T2DM individuals ($Z = -2.20, p < .05$). However, both questionnaire types measure self-management in diabetes mellitus (DM) (Schmitt et al., 2013).

Scoring the scale as per recently published guidelines followed the DSMQ-R 4-point Likert scale as shown in Table 12. If an item ticked "not required as a part of my treatment" was not scored and in SPSS was classified as 'system missing'. The larger value on the scale did not always imply the best management due to some negative statement format in the original questionnaire. This was accounted for by reverse coding where for negative statements 3 represented 0, 2 represented 1, 1 represented 2 and 0 represented 3. Table 13 highlights questions in bold to aid readers to identify where this process was used. Moreover, Table 13 also shows that the DSMQ-R contains five subscales with specific items/questions assigned to these subscales. These were "eating behaviour" (6 items), "medication-taking" (2 items), "glucose monitoring" (3 items), "physical activity" (3 items) and "cooperation with diabetes team" (4 items) (Schmitt et al., 2021). The other 2 items left

out (original tool Q16 and Q20, for this dissertation questionnaire Q32 and Q36) are included in the ‘total score’ only and not found in the subscales. After, as per original authors, each subscale was transformed into a scale ranging from 0-10 as shown by the equation in Figure 5 below. Better explained; the ‘actual sum of item scores’ is the total score after reverse-scoring negatively keyed items. ‘The maximum possible sum of items’ is the sum score of a given scale meaning the number of its items *3. For example, for eating behaviour subscale has 6 items so transforming to a scale of 1-10 results in equation: $sum\ score/18*10$. Additionally, the 20 item-total final score for the whole tool is also transformed to a scale ranging from 0-10 after reverse coding. This is better explained in Figure 5.

Table 12: The 4-point Likert scale of DSMQ-R (Schmitt, 2021).

4-point Likert scale of DSMQ- R	Applies to me very much	Applies to me to a considerable degree	Applies to me to some degree	Does not apply to me
	3	2	1	0

Table 13: Diabetes self-management questionnaire (DSMQ-R) subscales (Schmitt et al., 2021).

DSMQ-R subscales and their respective question number
<ul style="list-style-type: none"> Eating behaviour (Q2, 5, 9, 13, 17, 18) for this study (Q18, 21, 25, 29, 33, 34)
<ul style="list-style-type: none"> Medication taking (Q4, 12) for this study (Q20, 28)
<ul style="list-style-type: none"> Glucose monitoring (Q1, 6, 10) for this study (Q17, 22, 26)
<ul style="list-style-type: none"> Physical activity (Q8, 11, 15) for this study (Q24, 27, 31)
<ul style="list-style-type: none"> Cooperation with diabetes team (Q3, 7, 9, 14) for this study (Q19, 23, 25, 30)

Note: item no 16 (for this questionnaire no **32**) and item no 20 (for this questionnaire no **36**) were calculated only in the total score. Also, note that those in bold were reverse coded.

Figure 4: Scoring the DSMQ-R scale equations after reverse coding negatively worded questions (Schmitt et al., 2021).

<p>For subscales;</p> $\frac{\text{actual sum of item scores}}{\text{maximum possible sum of items (X 3)}} \times 10$ <p>(Example) for eating behaviour the maximum possible sum of items is 18. For medication taking the maximum possible sum of items is 6. For glucose monitoring and physical activity, the maximum possible sum of items is 9. For cooperation with diabetes team the maximum possible sum of items is 12.</p> <p>For the total final score;</p> $\frac{\text{sum score}}{60} \times 10$

Table 14 presents values for glycaemic control via HbA1c. However, authors in the literature only presented the unit values in ‘Diabetes Control and Complications Trial’ units / ‘National Glycohaemoglobin Standardization Programme’ (DCCT/NGSP) meaning in % and therefore, according to the latest guidelines by the ‘American Diabetes Association’ (ADA), the units should be in the ‘International Federation of Clinical Chemistry’ (IFCC) i.e., mmol/mol. Therefore, from % to mmol/mol a reliable online calculator was used to give the following referencing values. HbA1c of ≤ 58 mmol/mol ($\leq 7.5\%$) showed ‘good glycaemic control’ while values ≥ 75 mmol/mol ($\geq 9\%$) showed ‘poor glycaemic control’ (Schmitt et al., 2013). The questionnaire used for this current study gathered HbA1c values already in mmol/mol. Lastly, the DSMQ-R does not include ‘foot care’ and may be considered as a limitation of this tool as foot care is of paramount importance in diabetes management.

Table 14: Glycaemic control value range (Schmitt et al., 2013).

Glycaemic control (HbA1c)	
Good	$\leq 58 \text{ mmol/mol}$ ($\leq 7.5\%$)
Medium	$59-74 \text{ mmol/mol}$ ($7.6-8.9\%$)
Poor	$\geq 75 \text{ mmol/mol}$ ($\geq 9\%$)

3.7.3 Other information

Other information presented in the questionnaire included questions about oneself. These are referred to as demographic data and include; gender, age, marital status, geographical region, educational level, working status, diabetes duration, salary, information media used, treatment regimen and family history of DM.

Certain aspects of the questionnaire were kept as wide as possible, reducing the possibility of identifying participants. The section on gender had the option ‘prefer not to tell’ as part of inclusion. Six districts were included according to NSO regional statistics; ‘Southern Harbour’, ‘Northern Harbour’, ‘Western’, ‘Northern’, ‘South Eastern’, ‘Gozo and Comino’, with bracket symbols hinting the localities (NSO, 2021). The latter was used as when the researcher spoke to a second statistician, it was highlighted that not everyone knows their geographical region, but they obviously know their locality. The treatment regimen in the questionnaire did not include insulin solely but included the option insulin and OHAs as those on insulin only would be classified as T1DM individuals. ‘Income,’ although sensitive information, was presented in ranges not to identify any participants. Ranges rather than from literature were acquired from the NSO website in Malta (NSO, 2020). It was interesting to explore if income influences the level of health literacy or otherwise the system is faulty. Participants were instructed if they had no idea what their HbA1c values were, to ask their doctor during their visit to fill it in. All individuals at the clinics in this

study had a recent HbA1c value that individuals were requested to take before their visits. In fact, HbA1c testing is part of the department's routine procedure. Then, once the questionnaire was completed, one was instructed to post it in a box at the respective outpatients reception desk.

3.7.4 Tools translation

As the target population were Maltese, the questionnaire was presented in both Maltese and English. The HLS-EU-Q16 is available online to the public in both English and Maltese. The Maltese translation tool (except for instructions) is available on a report of the by Mr. Emmanuel Cachia (NSO, 2014). In the same report, most questions about oneself such as the demographics were reported in English.

The DSMQ-R is available in English. However, the DSMQ-R and the information about oneself were not initially available in Maltese. Therefore, these were translated using a process similar to that in a study by Jović-Vraneš et al., (2014) (Jović-Vraneš et al., 2014). After the full English questionnaire was combined by the researcher (questions ranged from 1-44), two competent bilingual translators were recruited who were familiar with the topic; one translated and the other independently back-translated to the original tool, without viewing the original tool. A review panel consisting of; bi-linguists, the researcher herself, and T2DM individuals during the pilot study; refined the translation if it had to, assess the equivalence, congruence, any colloquialism and defined any medical jargon used (Bowling, 2014). This was compiled to ensure participants' true understanding leading to correct responses. Any discrepancies were counteracted by a third bilingual translator; consequently, altering the English and Maltese versions. All this work, with thanks to © 'Projectra Solutions+' company, was made possible. This company is found in Malta and is qualified in translating, proofreading, social media content creation and designs. As translators are not experts to check face and content validity of the translated tools a pilot

study had to be followed by the researcher with the aid of the intermediaries.

3.7.5 Pilot study

The tools used are all available online and were tested for reliability and validity therefore, there was no need to retest (Bowling, 2014). However, as these were translated to Maltese, therefore new and previously untested in this version, a pilot study was conducted from mid-October 2021 to the end of October 2021. This was first performed in the week starting 10th October 2021. The questionnaire was handed to the eligible participants with the aid of the intermediaries both in English and Maltese versions. The questionnaire was re-administered to the same participants approximately two weeks apart. The latter period was considered enough for the participants not to change behaviour and not to remember their responses previously given. This was compiled by the intermediary via telephone calling the participants to re-respond to the original questionnaire, as follow-up in the clinic would be longer than two weeks. Again, the intermediaries had the telephone number of participants on their system entitled 'CPAS'. The '**test re-test reliability**' of repeated measures was used via the statistical test specifically called the '**intra-class correlation coefficient**' (ICC) (Field, 2018; Koo & Li, 2016). Where values between; 0.5-0.75 were considered as 'moderate reliability', 0.75-0.9 were considered as 'good reliability' and values >0.90 were considered as 'excellent reliability' (Koo & Li et al., 2016). A *p*-value of .05 was used as a cut-off point for statistical significance. The '**internal consistency**' identified whether the items in the scales were measuring the same concept. Specifically, included tools in the questionnaire were measured with an acceptable '**Cronbach's α** ' cut off ≥ 0.7 (Taber, 2018). Reverse coding was used for any negative wording in the questionnaire, in this case for the DSMQ-R (specifically Q21, Q23, Q26, Q27, Q28, Q29, Q30, Q31, Q32, Q34, Q36).

For the pilot study, a total of 39 individuals, 3 from Gozo and 36 from Malta were recruited to make a total of 10% of the original amount needed (29 and 352 respectively, a total of 381). All required individuals for the pilot study from Gozo participated (3/3) and only two from the required participation from Malta did not participate (34/36), resulting in a total of 37 participants. Participation took approximately 15 minutes in total. No major changes were made to the questionnaire after the pilot study. The only suggestion was that when turning the page, the participants had forgotten what each score represented, therefore, the scoring part was added to each printed page for the participants' convenience.

Cronbach's α for internal consistency for the HLS-EU-Q16 as a whole carried out in this pilot study was 0.99. As shown in Table 15 below, a high internal consistency is evident. Moreover, Cronbach's α for the total DSMQ-R carried out in this pilot study was 0.93 as shown in Table 16. The values are both in line with the literature found under section 3.7.5.

Table 15: Health literacy internal consistency

Reliability Statistics	
Cronbach's Alpha	N of Items
0.99	16

Table 16: DSMQ-R internal consistency

Reliability Statistics	
Cronbach's Alpha	N of Items
0.93	20

The test-retest reliability of the whole study was carried out at time one and time two using the ICC. As shown in Figure 6 below the average measure of the ICC is 0.997, showing minimal variability. Therefore, there is consistency between each test.

Figure 5: Test re-test reliability analysis

Intraclass Correlation Coefficient							
	Intraclass Correlation ^b	95% Confidence Interval		F Test with True Value 0			
		Lower Bound	Upper Bound	Value	df1	df2	Sig
Single Measures	.995 ^a	.989	.997	397.874	31	31	.000
Average Measures	.997 ^c	.994	.999	397.874	31	31	.000

Two-way mixed effects model where people effects are random and measures effects are fixed.

a. The estimator is the same, whether the interaction effect is present or not.

b. Type A intraclass correlation coefficients using an absolute agreement definition.

c. This estimate is computed assuming the interaction effect is absent, because it is not estimable otherwise.

3.8 Data Analysis

IBM SPSS software was used specifically, latest SPSS version 28. Data was inputted directly to SPSS where on the top row, the questions were coded. Then, every single row represented one person with individual results also coded.

Statistical tests were used corresponding to the objectives. **Descriptive analysis** consisting of averages and frequencies of different scores into percentages was used to describe health literacy and diabetes self-management. A normality test i.e., a “Shapiro-Wilk test”, was performed to recognise if data were normally dispersed or not. This was carried out as the independent variable i.e.; health literacy is a non-categorical variable. A **correlation** was firstly used to explore the relationship between, health literacy and diabetes self-management. Secondly, a correlation was used to identify the relationship between health literacy and glycaemic control (HbA1c). Thirdly used to identify the relationship between self-management and glycaemic control. When data is normally distributed the ‘Pearson correlation coefficient’ is performed while if data is not normally distributed a ‘Spearman’s correlation’ is used. For the objective of identifying any variables of individual characteristics such as sociodemographic data for differences in health literacy, an initial ‘t-

test' for parametric or 'Mann Whitney U test' for nonparametric had to be performed. According to the data parameters, either the 'Analysis of variance' (ANOVA) or 'Kruskal–Wallis H test' were respectively carried out. Table 17 portrays an exclusive summary of objectives and their corresponding statistical tests. Later, Table 18 shows that multiple regression was performed to categorise the best predictors of health literacy.

Table 17: Objectives and their corresponding statistical tests

Objectives	Corresponding Statistical tests
1. To describe health literacy	Descriptive analysis- average, frequency of different scores into percentages
2. To measure diabetes self-management	Descriptive analysis- average, frequency of different scores into percentages
3. To explore the relationship between, health literacy and diabetes self-management	Normality test i.e., Shapiro-Wilk test (standard for all research studies) Correlations – Pearson correlation coefficient if normally distributed, Spearman's correlation if not normally distributed
4. To identify the relationship between health literacy and glycaemic control (HbA1c)	Correlations – Pearson correlation coefficient if normally distributed, Spearman's correlation if not normally distributed
5. The relationship between self-management and glycaemic control	Correlations – Pearson correlation coefficient if normally distributed, Spearman's correlation if not normally distributed
6. To identify any variables of individual characteristics such as sociodemographic/socioeconomic data for differences in health literacy	i) T test – for parametric or Mann Whitney U test (2 groups)– for nonparametric ii) ANOVA or Kruskal–Wallis H test

Note that health literacy (independent variable) is non-categorical.

Table 18: Additional test used for best predictors of health literacy

Dependent variable	Independent variable/s	Statistical technique
Health literacy	Sociodemographic/socioeconomic variables	Multiple regression

3.9 Ethical issues

Permission was granted for all tools being used and translated i.e., HLS-EU-Q16 and DSMQ-R. Besides, permissions were also granted from both Mater Dei Hospital (MDH) and Gozo General Hospital (GGH) chairpersons (responsible for the patients), intermediaries, hospital data protection officers and CEOs. As this study included patients, if the latter felt distressed due to participation, a HCP at the Psychological service found at MDH was available for both MDH and GGH participants at no financial cost. Later, ethical approval from the ‘Faculty Research Ethics Committee’ (FREC) at the University of Malta (UM) was granted with an ethical approval no of V:15062020 9193. According to the FREC, no further application had to be sent to the UREC. All ethical permissions and approvals are found in Appendix 4.

The intermediary initially approached the potential participants as they may feel pressured if approached by the researcher who is also a HCP. The information letter and consent forms administered by the intermediaries were also approved by FREC. This aimed to enhance the response rate, study’s credibility, emphasize confidentiality and explain the study’s purpose and value (Bowling, 2014). Moreover, ensure an informed consent. The consent form was offered and duly signed **voluntarily** and **autonomously** by mentally fit individuals prior to participation. **Self-direction** interrelated to the principles of **self-determination** was key as individuals had the ability and/or right to freely make their own

decisions with no repercussions on treatment effect. The consent forms were kept separate from the questionnaires ensuring that there was no tracing back to the individual. Participants had the option to fill the questionnaire by themselves or illiterate participants and/or those with visual impairment or those that expressed an interest that they needed help, were offered assistance with no prompting. Moreover, structured interviews were held individually by the intermediary in a private room provided at the respective outpatients, further ensuring **confidentiality**. It was assured that answers were treated as confidential; personal data i.e., consent forms and questionnaires will be erased after a period of 7 years for further analysis or a comparative study later on if need be. Furthermore, there is no way to trace back the individual, further ensuring anonymity. The questionnaire was **anonymous** as participants were not asked information that revealed their identity. Moreover, age was kept as wide as possible, ensuring that participants were not identified. Both tools used i.e., HLS-EU-Q16 and DSMQ-R, were translated to Maltese in order to reach the target population, ensuring applicability and reducing potential bias within the populations. The translation process was compiled after permissions had been granted. The information letter, consent form and the questionnaire are found in Appendix 5 in both English and Maltese.

3.10 Summary

Six hypotheses were highlighted related to health literacy, self-management and glycaemic control that will be later tested. The philosophical underpinning of ‘post-positivist’ approach was acknowledged. A cross-sectional survey was appropriately utilised. A total of 381 individuals was calculated for a representative sample with 5% margin of error. Inclusion and exclusion criteria of participants was identified mainly to include Maltese adult population. With the aid of the intermediaries, convenience sampling was applied after an informed consent. Paper-based questionnaires were either self-administered or structured interviews were held individually. Prior, ethical approval was granted from the

UM and hospitals. Tools used i.e., HLS-EU-Q16 and DSMQ-R were readily available from the literature. After the pilot study, tools were tested for internal consistency via Cronbach's α and re-tested via the ICC for stability, agreeing with results. Tools original scoring guidelines were adhered to. Data analysis was accounted for via statistical tests depending on the distribution of objectives.

Chapter 4- Results

4.1 Introduction

The study's main aim was to explore the health literacy levels of Maltese adults living with type 2 diabetes mellitus (T2DM) and whether this relates to their diabetes self-management and glycaemic control. This chapter starts by presenting the internal consistency reliability of this actual survey. The representativeness of the sample, followed by normality testing, descriptive analysis of health literacy and predictors related to health literacy were conducted. Next, multiple regression was carried out. Later on, correlation statistics were conducted for the following: health literacy scores vs diabetes self-management scores, health literacy scores vs HbA1c values, and diabetes self-management scores vs HbA1c values.

4.2 Reliability of the scales

The reliability of the scales was repeated for the actual study apart from the pilot study that was highlighted in chapter 3. As already explained in chapter 3, it was ensured that all statements were scored in the same direction where certain questions in the diabetes self-management questionnaire-revised (DSMQ-R) were recoded.

4.2.1 European health literacy survey (HLS-EU-Q16)

Internal consistency by using Cronbach's alpha (α) for the European health literacy survey (HLS-EU-Q) having 16 items/questions resulted in 0.975 as portrayed in Table 19. This value was classified as high internal consistency.

Table 19: HLS-EU-Q16 internal consistency

Reliability Statistics	
Cronbach's Alpha	N of Items
.975	16

4.2.2 Diabetes self-management questionnaire-revised (DSMQ-R)

Cronbach's α for the DSMQ-R containing 20 items resulted in 0.914 as portrayed in Table 20. Therefore, a high internal consistency was recorded.

Table 20: DSMQ-R internal consistency

Reliability Statistics	
Cronbach's Alpha	N of Items
.914	20

4.3 Descriptive analysis of the study's sample

As specified in the previous chapter entitled methodology, a convenience sampling technique was utilised aiming for 381 individuals with a 5% margin of error. Specifically, a sample size of 29 from Gozo and 352 from Malta for a representative study had to be recruited.

4.3.1 Response rate

A total of 381 adult individuals, ≥ 18 -years-old, were recruited from the diabetes outpatients. An overall percentage response rate cannot be explicit due to a convenience sampling method used. When one individual refused to participate, another individual was conveniently approached by the intermediaries until the acquired sample size was reached.

4.3.2 Representativeness

Table 21 shows the distribution of age groups and gender. Moreover, it presents other socio-demographic/economic variables such as marital status, geographical regions, educational level, working status, years from diabetes diagnosis, household monthly (Net) income (based on NSO guidelines), information media usage, treatment regimen, family history of diabetes and HbA1c levels. These characteristics were all grouped into categorical variables.

From the descriptive characteristics, as shown in Table 21, most participants were ≥ 60 –years-old (37%, n= 143) whilst the lowest participation age was for persons between 32-38-years-old (3%, n= 13). This may have accounted for an ageing population. When compared to females, males (61%, n= 234) and from the Northern Region of Malta (26%, n= 98) were more prominent in this study. Most participants were married individuals (61%, n= 234) with tertiary education (such as university level) (35%, n= 133) and working for pay or profit (51% n= 193), closely followed by those in retirement or retired (29%, n= 113). The common Net monthly household income was between €580-813 (16%, n= 60) followed by €1,629-1,978 (13%, n= 48) and $>€2446$ (13%, n= 48). Most participants had been living with diabetes for 1-10 years (62%, n= 237). However, those living with T2DM for 51-60 had no participation (0%, n= 0) and those living with T2DM for 61-70 years only

resulted in one participant (1%, n= 1). The most common information media used was television (31%, n= 118), and secondly placed was television together with the internet and social media (13%, n= 48). Oral hypoglycaemic agents (OHAs) (49%, n= 187) were the most common treatment usage followed by the cumulative usage of OHAs and insulin (43%, n= 163), with the least participation in the diet and exercise (31%, n= 8) regimen. Immediate family history of diabetes (74%, n= 283) was most common with an HbA1c range of 59-74 mmol/mol (48%, n= 181), indicating moderate glycaemic control.

Table 21: Descriptive characteristics of the study's sample

Characteristics		Frequency	Percentage/ %
Age	18-24	21	6
	25-31	35	9
	32-38	13	3
	39-45	37	10
	46-52	60	16
	53-59	72	19
	60+	143	37
	Total	381	100
Gender	Male	234	61
	Female	125	33
	Other	22	6
	Prefer not to tell		
	Total	381	100
Marital status	Single	64	17
	Married	234	61
	Divorced/separated	31	8
	Widowed	45	12
	Other	7	2
	Total	381	100
District	Southern Harbour	51	13
	Northern Harbour	98	26
	Western	46	12
	Northern	108	28
	South Eastern	49	13
	Gozo and Comino	29	8
	Total	381	100

Education level	No formal education	54	14
	Primary education	39	10
	Lower secondary education	39	10
	Upper secondary education	74	20
	Post-secondary but non-tertiary education	42	11
	Tertiary education	133	35
	Total	381	100
Working status	Working for pay or profit	193	51
	Working for non-profit	20	5
	Unemployed	23	6
	Housework/stay at home	21	5
	In retirement or early retirement	113	29
	Unable to work due to disability or illness	7	2
	Student	2	1
	Other	2	1
Total	381	100	
Years of diabetes diagnosis in group	1-10	237	62
	11-20	73	19
	21-30	16	4
	31-40	30	8
	41-50	24	6
	51-60	0	0
	61-70	1	1
Total	381	100	
Household monthly income (Net) (based on NSO guidelines)	< €465	20	5
	€466-579	13	3
	€580-813	60	16
	€814-929	55	14
	€930-1,162	34	9
	€1,163-1,395	46	12
	€1,396-1,628	20	5
	€1,629-1,978	48	13
	€1,979-2446	37	10
	>€2446	48	13
Total	381	100	
Information media usage	Magazines	0	0
	Books	10	2
	Radio	14	3
	Television	118	31
	Internet	59	16
	Social media	40	11
	All of the above	27	7
Other sources	24	6	
	41	11	

	Book, Television, internet, social media	48	13
	Television, internet, social media	381	100
	Total		
Treatment regimen	Diet and exercise only	31	8
	Oral hypoglycaemic agents (OHAs)	187	49
	Insulin + oral hypoglycaemic agents (OHAs)	163	43
	Total	381	100
Family history of diabetes	Yes	283	74
	No	98	26
	Total	381	100
HbA1c values in mmol/s in groups	0-58	103	27
	59-74	181	48
	75-121	97	25
	Total	382	100

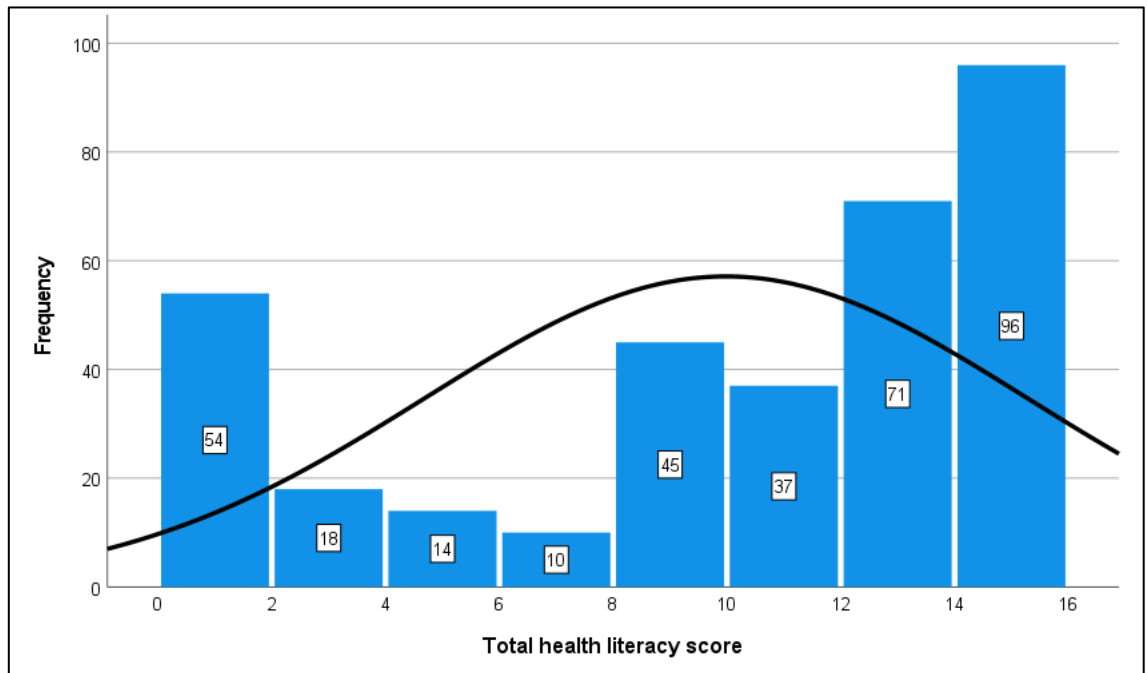
4.4 Assessing normality

‘Shapiro-Wilk test’ which is a standard test for all research studies was performed below (section 4.4.3). It was utilised to conclude whether a score dispersion is skewed (non-normal) or normal. The latter normality is based on the score dispersion where the null hypotheses is accepted if the p -value is $\geq .05$ level of significance. If the score dispersion is skewed, the alternative hypothesis is adhered to where the p -value is $< .05$ (Mishra et al., 2019). Both graphical and statistical values for normality were presented.

4.4.1 Graphical representation for normality of health literacy

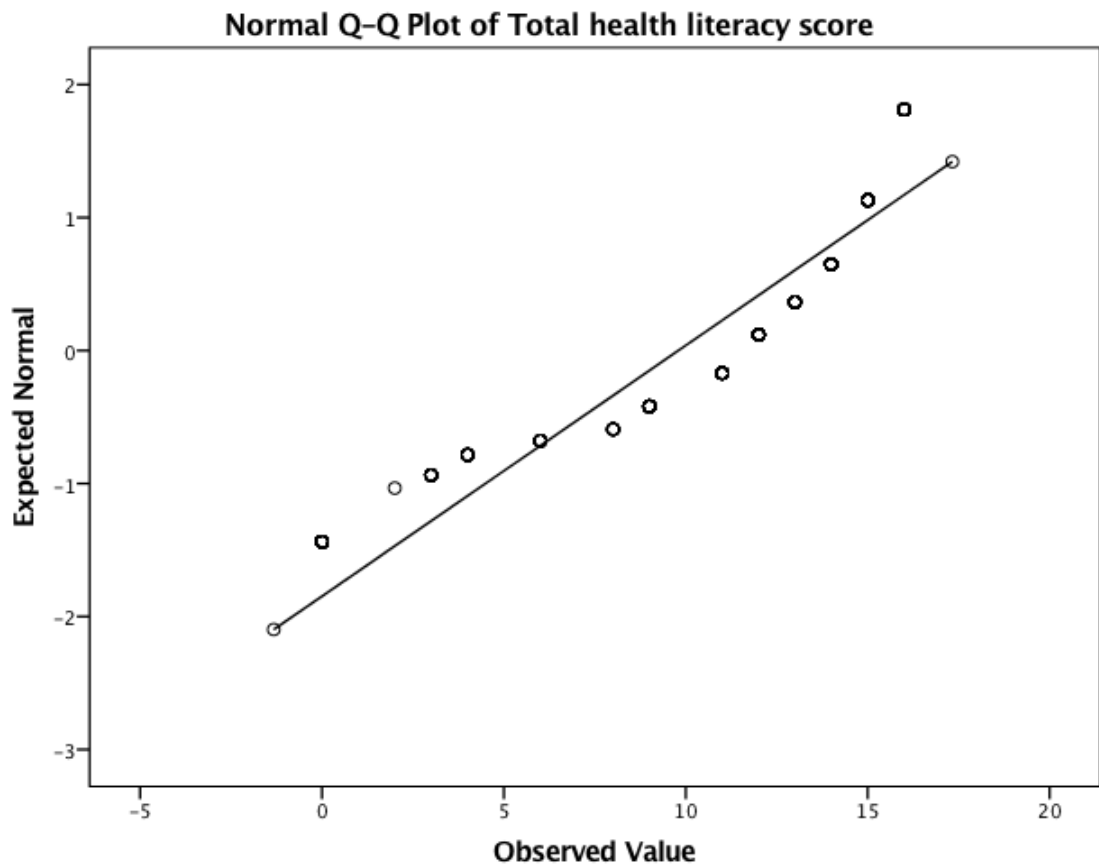
As shown in Figure 7, total health literacy scores are not normally distributed or non-Gaussian distributed as the highest bars are not presented in the center of the histogram. It also portrays that some individuals scored 0, meaning the lowest. Additionally, in Figure 8 i.e., a Q-Q plot continues to emphasise the non-normal distribution as data points do not stand on the line of best fit but are scattered. The scores were rechecked, finding no error.

Figure 6: Histogram for assessing normality of health literacy



Mean 9.96, SD= 5.325, N=381

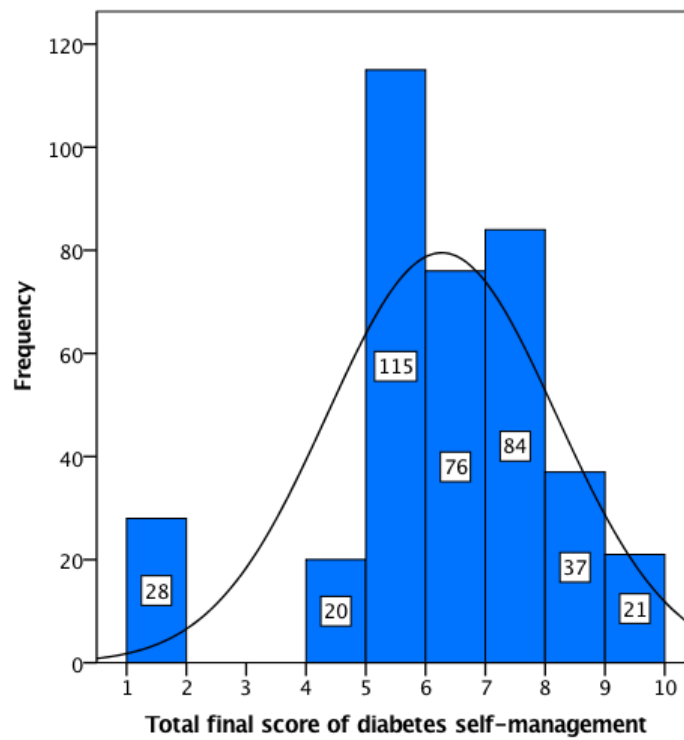
Figure 7: Q-Q Plot for the total health literacy



4.4.2 Graphical representation for normality of diabetes self-management

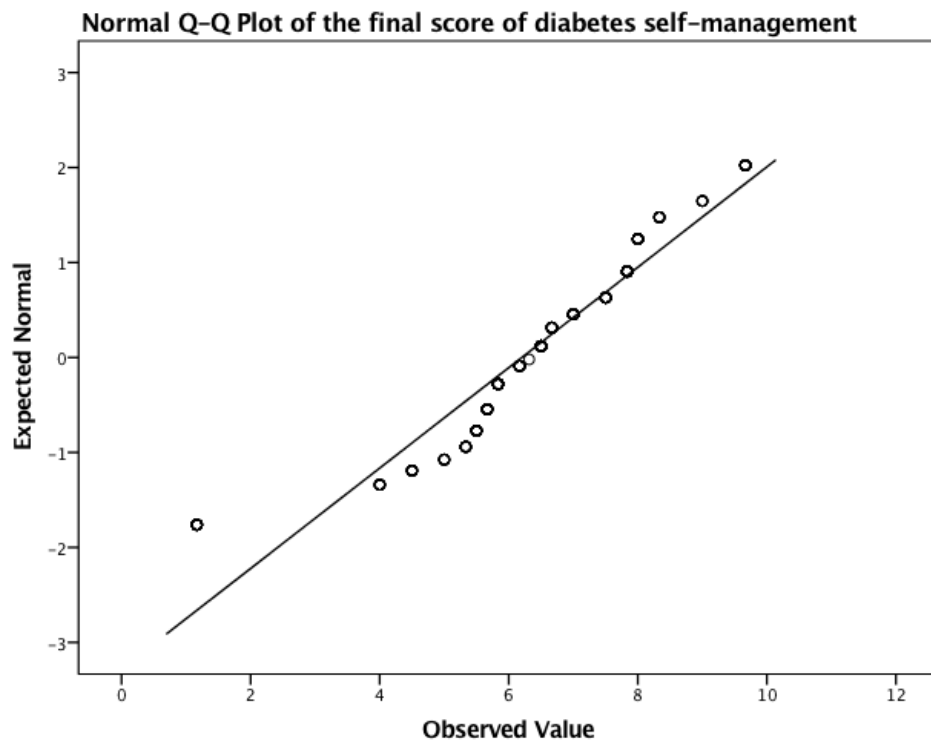
In line with health literacy, the total diabetes self-management is not normally distributed as shown in Figures 9 and 10 below. However, there is an abundant number of data points that sit on the line of best fit for diabetes self-management when compared to the health literacy data, showing that data for self-management is less skewed. It is highlighted that no one scored from 0 to 1 and from 2 to 4. Nonetheless, 28 individuals scored from 1 to 2. The majority, as seen in bulk, scored between 5 and 8. The scores were rechecked, finding no error.

Figure 8: Histogram of the total final score of DSMQ-R



Mean= 6.20, SD= 1.892, N= 381

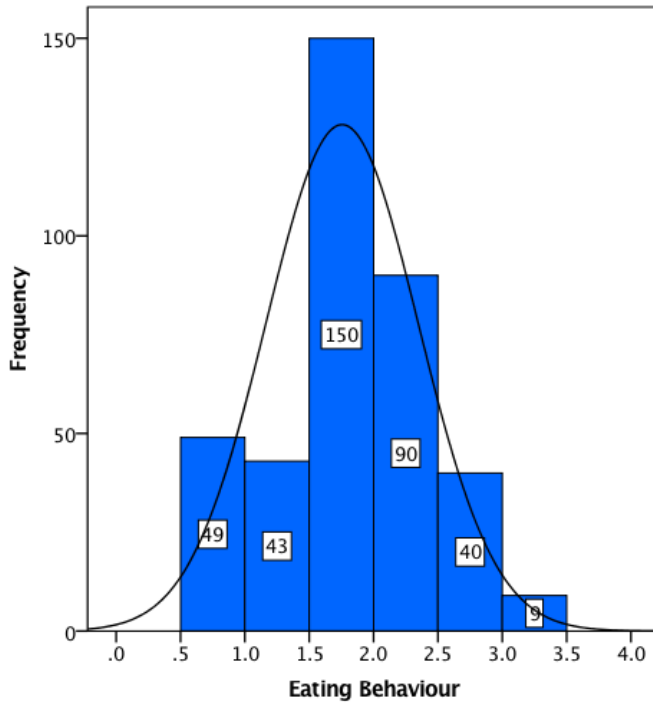
Figure 9: Q-Q Plot for the total diabetes self-management



4.4.2.1 Additional histograms of individual subscales of diabetes self-management

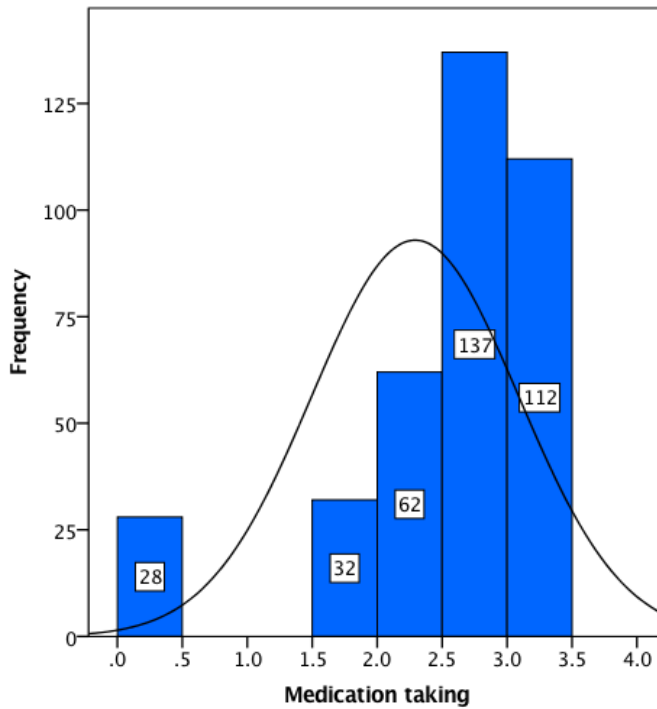
To further clarify the skewness whilst identifying those points that lie on the line of best fit of diabetes self-management, a histogram was carried out displaying the normal curve for each diabetes self-management subscale. This ranged from Figures 11 to 15. For example, Figure 11 - eating behaviour and Figure 15 - cooperation with diabetes team respectively showed that their data is favouring normal distribution.

a) Figure 10: Histogram for eating behaviour



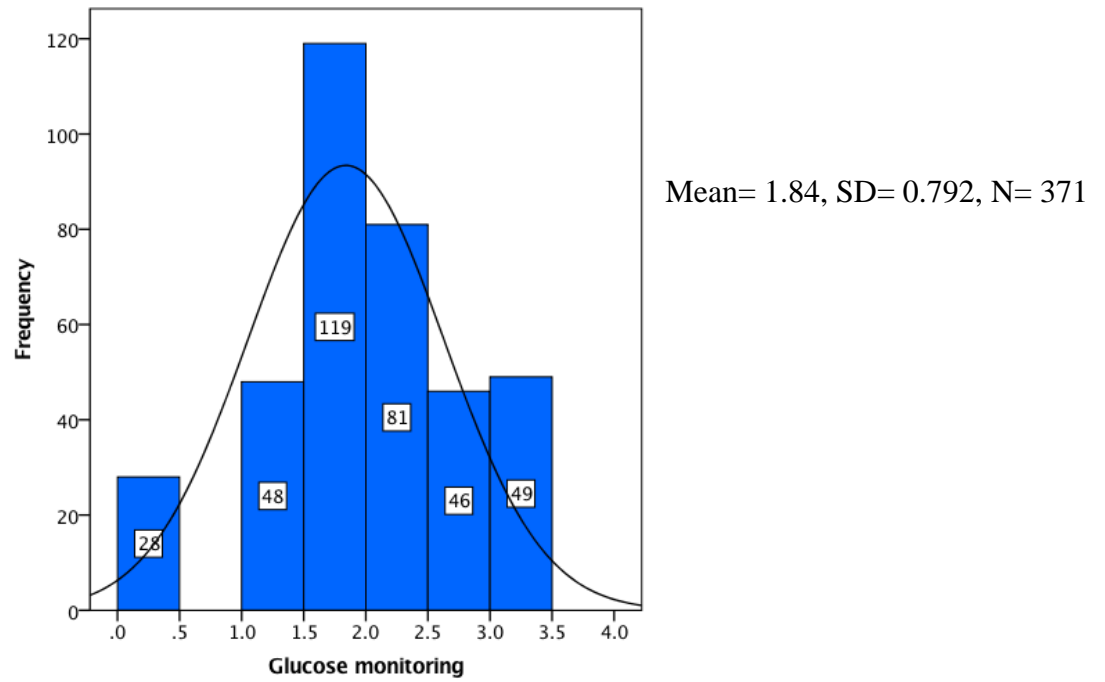
Mean= 1.75, SD= 0.593, N= 381

b) Figure 11 : Histogram for medication taking

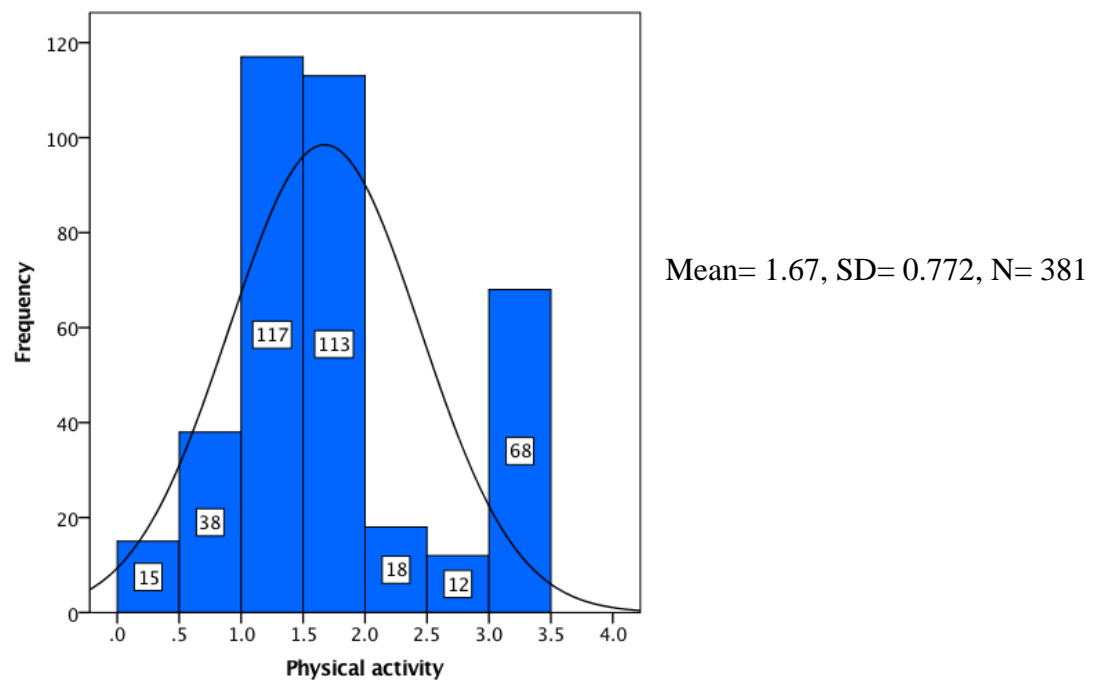


Mean= 2.29, SD= 0.796, N= 381

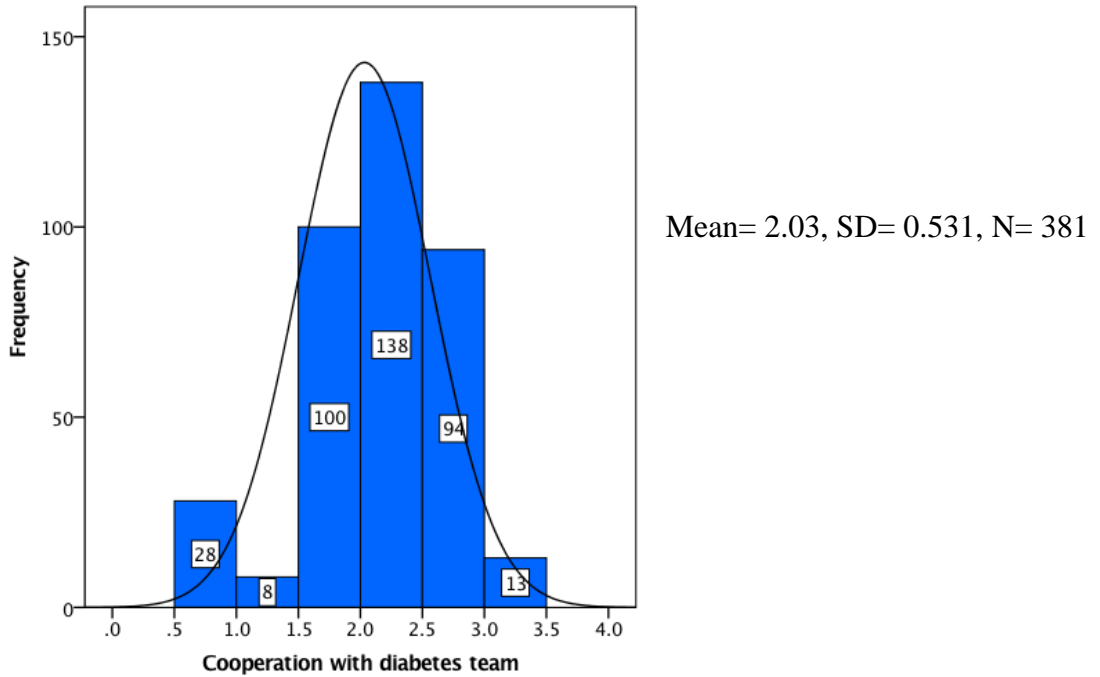
c) Figure 12: Histogram for glucose monitoring



d) Figure 13: Histogram for physical activity



e) Figure 14: Histogram for cooperation with diabetes team



4.4.3 Statistical representation for normality of both health literacy and diabetes self-management

To further clarify previous results by using the ‘Shapiro-Wilk test’, Table 22 represents precise values for; total health literacy, total diabetes self-management and individual subscales of diabetes self-management. All p -values for the ‘Shapiro-Wilk test’ resulted in $p < .001$, therefore further clarifying that both health literacy and diabetes self-management are not normally distributed. Thus, to analyse the data further non-parametric tests were used. Hence, the ‘Kruskall-Wallis test’ and ‘Spearman correlation’ were used instead of the one-way ‘Analysis of variance’ (ANOVA) and the ‘Pearson correlation’. As the latter two tests are used for normally distributed parameters.

Table 22: Tests of normality for the total health literacy, diabetes self-management subscales and the total diabetes self-management.

	Statistic	Shapiro-Wilk	
		df	<i>p</i> -value
Total health literacy	.852	371	.000
Total final score of diabetes self-management	.889	371	.000
Eating behaviour	.938	371	.000
Medication taking	.755	371	.000
Glucose monitoring	.913	371	.000
Physical activity	.877	371	.000
Cooperation with diabetes team	.917	371	.000

4.5 Descriptive analysis of the sample's health literacy (HLS-EU-Q16)

All 381 participants (100%) compiled the 16-item questionnaire i.e., HLS-EU-Q16. A descriptive analysis showing averages in standard deviation (SD) and frequencies of different scores into percentages are presented in Table 23 with the aid of SPSS. These described the health literacy levels of participants. The measure of dispersion hence, SD was used to identify the extent of variability around the sample mean, as having the same mean for two data sets can be completely different (Andrade, 2020; Manikandan, 2011). All SD as shown in Table 23 were similar, varying between 1.10 to 1.33. The three questions with the highest SD having spread-out values were; 'understand why you need health screenings' (SD= 1.33) followed by, 'understand what your doctor says to you' (SD= 1.32) and 'judge which everyday behaviour is related to your health' (SD= 1.31). The three lowest SD having values close to their mean were; 'decide how you can protect yourself from illness based on information in the media' (SD= 1.10), followed by 'find out

about activities that are good for your mental well-being' (SD= 1.11), and 'find out where to get professional help when you are ill' (SD= 1.12).

The average/mean score (M) question with its highest value, being the most difficult to perform and the poorest health literacy rating score was for; 'decide how you can protect yourself from illness based on information in the media' (M= 2.7). This was followed by the averages on mental health i.e., 'find out about activities that are good for your mental well-being' (M= 2.56) and 'find information on how to manage mental health problems like stress or depression' (M= 2.55). Whilst the three lowest averages meaning the very easy part of health literacy were; firstly, 'understand health warnings about behaviour such as smoking, low physical activity and drinking too much' (M= 1.98) secondly, 'find out where to get professional help when you are ill' (M= 2.02) and thirdly, 'understand why you need health screenings' (M= 2.05).

Table 23: Descriptive analysis of health literacy as a continuous variable.

On a scale from very easy to very difficult, how easy would you say it is to:							Average score (on scale 1-5) (SD)
		Very easy	Fairly easy	Fairly difficult	Very difficult	Don't know	
1	...find information on treatments of illnesses that concern you?	37.3% (n=142)	33.6% (n=128)	5.2% (n=20)	8.9% (n=34)	15.0% (n=57)	2.15 (1.23)
2	...find out where to get professional help when you are ill? (Instructions: such as doctor, pharmacist, psychologist)	38.2% (n=146)	38.1% (n=145)	1.6% (n=6)	7.3% (n=28)	14.7% (n=56)	2.02 (1.12)
3	...understand what your doctor says to you?	41.2% (n=157)	26.8% (n=102)	2.1% (n=8)	12.1% (n=46)	17.8% (n=68)	2.17 (1.32)
4	...understand your doctor's or pharmacist's instruction on how to take a prescribed medicine?	36.2% (n=138)	40.2% (n=153)	1.6% (n=6)	12.1% (n=48)	9.7% (n=37)	2.13 (1.27)
5	...judge when you may need to get a second opinion from another doctor?	27.6% (n=105)	38.6% (n=147)	3.7% (n=14)	9.2% (n=35)	21.0% (n=80)	2.28 (1.18)
6	...use information the doctor gives you to make decisions about your illness?	37.5% (n=143)	28.6% (n=109)	7.1% (n=27)	9.2% (n=35)	17.6% (n=67)	2.22 (1.27)
7	...follow instructions from your doctor or pharmacist?	39.1% (n=149)	28.6% (n=109)	5.0% (n=19)	9.2% (n=35)	18.1% (n=69)	2.17 (1.26)
8	...find information on how to manage mental health problems like stress or depression?	27.6% (n=105)	17.1% (n=65)	8.7% (n=33)	9.2% (n=35)	37.5% (n=143)	2.55 (1.24)

9	...understand health warnings about behaviour such as smoking, low physical activity and drinking too much?	46.5% (n=177)	27.6% (n=105)	3.7% (n=14)	7.3% (n=28)	15.0% (n=57)	1.98 (1.19)
10	...understand why you need health screenings? (Instructions: breast exam, blood sugar test, blood pressure)	47.2% (n=180)	27.3% (n=104)	5.5% (n=21)	10.8% (n=41)	9.2% (n=35)	2.05 (1.33)
11	...judge if the information on health risks in the media is reliable? (Instructions: TV, Internet or other media)	27.6% (n=105)	18.6% (n=71)	5.2% (n=20)	7.3% (n=28)	41.2% (n=157)	2.46 (1.16)
12	...decide how you can protect yourself from illness based on information in the media? (Instructions: Newspapers, leaflets, Internet or other media?)	19.2% (n=73)	15.9% (n=57)	8.4% (n=32)	7.3% (n=28)	50.1% (n=191)	2.7 (1.10)
13	...find out about activities that are good for your mental well-being? (Instructions: meditation, exercise, walking, pilates etc.)	12.9% (n=49)	44.4% (n=169)	5.8% (n=22)	10.0% (n=38)	27.0% (n=103)	2.56 (1.11)
14	...understand advice on health from family members or friends?	23.1% (n=88)	39.4% (n=150)	6.3% (n=24)	9.4% (n=36)	21.8% (n=83)	2.40 (1.18)
15	...understand information in the media on how to get healthier? (Instructions: Internet, newspapers, magazines)	24.7% (n=94)	32.8% (n=125)	8.9% (n=34)	9.4% (n=36)	24.1% (n=92)	2.46 (1.22)
16	... judge which everyday behaviour	31.8% (n=121)	23.4% (n=89)	3.6% (n=14)	12.6% (n=48)	28.6% (n=109)	2.40 (1.31)

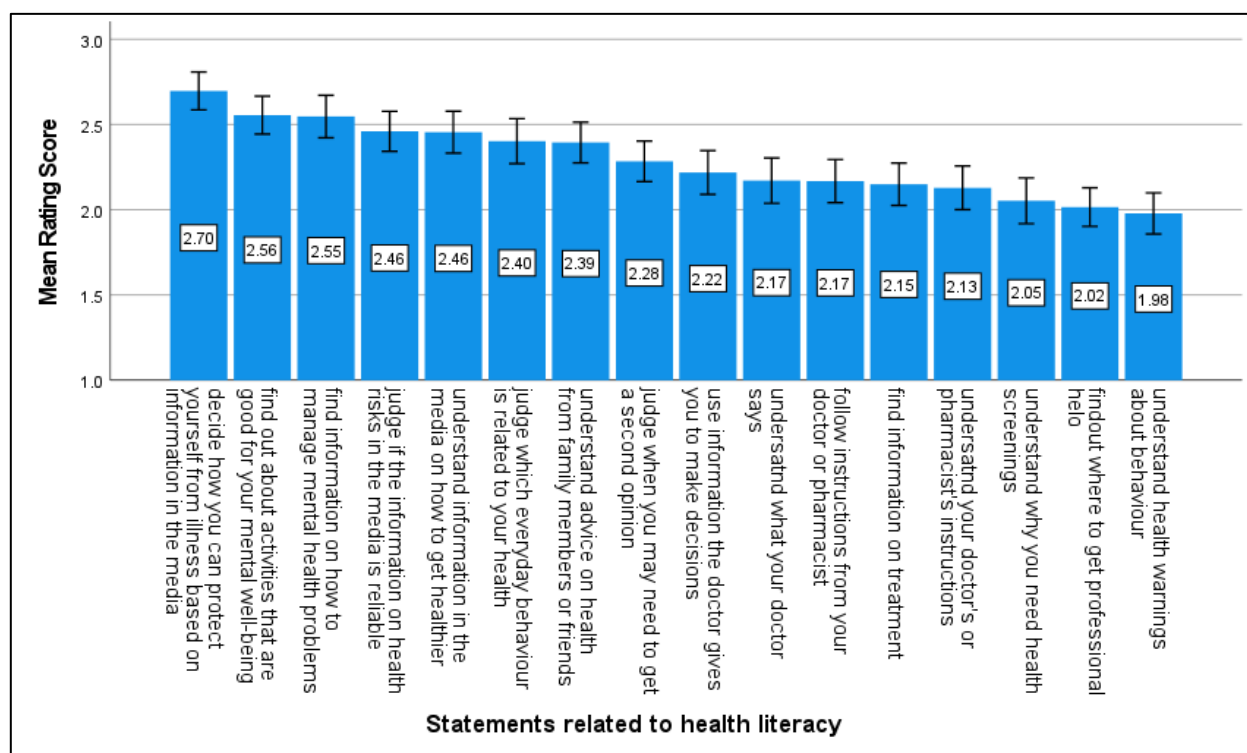
	is related to your health? (Instructions: Drinking and eating habits, exercise etc.)						
--	---	--	--	--	--	--	--

'n' is the number of participants or frequency, SD is the Standard Deviation.

Additionally, a test known as ‘Friedman’s test’ (non-parametric test) was used to compare the rating of mean scores (Likert scale) between several related statements. These ranged from 1 to 5 where 1 corresponded to ‘very easy’ and 5 corresponded to ‘don’t know’. When the mean rating scores between statements are similar, the null hypothesis is accepted with a p -value $> .05$ level of significance. However, if the mean rating scores between statements significantly differ, the alternative hypothesis is accepted with a the p -value $< .05$. The total score for ‘Friedman’s test’ accounted for $\chi^2(15) = 602.67, p < .001$ therefore, mean scores significantly differ from each other. The number in brackets represents the degrees of freedom (df) and the chi-squared distribution is represented by χ^2 . The highest mean scores for health literacy are represented in descending order in Figure 16 below.

To compare the mean rating scores of two statements at a time, an ‘error bar graph’ was conducted as shown in Figure 16 below. It displays the 95% confidence interval (CI) of the actual mean rating score provided to statements if the whole population of T2DM patients had to be recruited. If two CIs do not overlap (icon ‘I’), this indicated that the two mean rating scores differ significantly. Conversely, if the two CIs overlap, this indicated that the two mean rating scores are similar and do not differ significantly. For example, as shown in Figure 16, the most far left-hand sidebar (‘decide how you can protect yourself from illness based on information in the media’) and the most far right-hand sidebar (‘understand health warnings about behaviour such as smoking, low physical activity and drinking too much’); represent a CI which does not overlap. This implied that the two mean rating scores differ significantly. When the latter statement was compared to another question, for example to the adjacent question in Figure 16, (‘find out where to get professional help when you are ill’) CIs overlap. This shows that the two mean rating scores do not differ significantly as they are similar.

Figure 15: Error bar graph for health literacy elements



Friedmann's test $\chi^2(15) = 602.67, p < .001 \rightarrow$ note that χ^2 in the equation represents the chi-squared distribution and the number in brackets is the degrees of freedom (df) that represents the amount of values present -1.

As previously described in chapter 3 (section 3.7.1) health literacy scores were classified into three groups; inadequate (<9), limited (9-12) and sufficient (13-16). Table 24 presents the frequencies and percentages of the grouped health literacy levels from the total scores that were previously dichotomised into 'very easy' and 'fairly easy' giving a score of 1. Meanwhile, 'fairly difficult' and 'very difficult' were given a score of 0 as followed by the original tool authors described in chapter 3 (Röthlin et., 2013; Sørensen et al., 2012). This excluded the 'don't know' scoring that scored 5. Table 24 shows health literacy scores of this dissertation sample; 47% (n= 179) classified as inadequate, 12.6% (n=48) classified as problematic and 40.4% (n=154) classified as sufficient.

Table 24: Frequencies and percentages of the grouped health literacy levels.

Health literacy level (HLS-EU-Q16 score)	Frequency (n)	Percentage / %
Inadequate (<9)	179	47
Problematic (9-12)	48	12.6
Sufficient (13-16)	154	40.4
	Total: 381	100

4.6 Predictors of health literacy

When considering the variables related to health literacy, the ‘Kruskal-Wallis H test’ was used to identify any present differences. In the presence of a significant difference, the ‘Mann Whitney U-test’ acted as a post-hoc test (Laerd statistics, 2018). Also, ‘Bonferroni correction’ was used following the Mann Whitney test. To compare more than one group at a time, error bars were also performed.

Interpreting the Kruskal-Wallis H test; when the health literacy scores between groups vary marginally, the null hypothesis is adhered to via a p -value of $> .05$ level of significance. While, if health literacy scores differ significantly between groups, the alternative hypothesis is adhered with a p -value is $\leq .05$ criterion. Similarly, the Mann Whitney test also follows the p -value of $\leq .05$ as a level of significant difference by rejecting the null hypothesis. Nevertheless, in view of many comparisons, ‘Bonferroni correction’ was used for the Mann Whitney test where the significance level of $.05$ was divided by the number of comparisons carried out to identify the true level of significance. A p -value equal to or less than that of Bonferroni correction was set as the level of significance. The reason for this test is that the greater the number of comparisons carried out, the more likely is the significant difference. The CIs between groups can be visually interpreted in error bars where if CIs overlap, there is no statistical significance between groups. If CIs do not overlap, there is statistical significance between groups. However, the latter results must be

taken with caution as the significance of the Mann Whitney test did not always match the CIs significance.

4.6.1 Health literacy and age group.

A statistically significant difference in health literacy scores between different age groups was identified via the Kruskal-Wallis H test, $H(6) = 70.88, p < .001$. The highest mean rank health literacy score was 15.69 for the age group '32-38' and the lowest mean rank health literacy score was 6.76 for the age group '18-24' as shown in Table 25. Following a post hoc test, the Mann Whitney test showed that health literacy in the age group 32-38 was statistically significantly higher than age group 18-24 ($U = 0.001, p < .001$). Later, when Bonferroni correction was carried out (equation: $0.05/7 = 0.0071$), the p -value was set for $p = .0071$. The level of significance of the Mann Whitney test was lower than Bonferroni correction, showing true statistical significance. In addition, the error bar graphs presented in Figure 17 visually agree and identified that those aged 32-38 are significantly scoring higher than other age groups, as the CI is disjointed.

Comparing the health literacy scores between age group 18-24 to age groups; 25-31 ($U = 75, p < .0071$), 39-45 ($U = 41, p < .0071$), 46-52 ($U = 314, p = .000472$), resulted in statistical significance. However, no statistical differences resulted in health literacy scores between age groups 18-24 to ages 53-59 ($U = 518, p = .026$) and 60+ ($U = 1137, p = .68$) as the p -values were $> .0071$. In fact, in Figure 17 error bars CIs intersect.

The health literacy between those aged 25-31 to ages; 32-38 ($U = 29, p < .0071$), 39-45 ($U = 353, p = .000503$), and 53-59 ($U = 758, p = .000715$), was statistically significant as p -values were all $\leq .0071$. However, there was no statistically significant difference in health literacy

scores between those aged 25-31 to those aged 46-52 ($U = 926, p = .330$) and 60+ ($U = 2084, p = .120$).

Scores of health literacy between those aged 32-38 to ages; 39-45 ($U = 67.7, p = .000034$), 46-52 ($U = 42.5, p < .0071$), 53-59 ($U = 70.5, p < .0071$) and 60+ ($U = 93.5, p < .0071$), were all statistically significant. Furthermore, health literacy scores between those aged 39-45 to those aged: 46-52 ($U = 586.5, p = .000073$), 53-59 ($U = 674, p = .000015$) and 60+ ($U = 1219, p < .0071$), were all statistically significant.

Conversely, the health literacy scores between those aged 46-52 to those aged 53-59 ($U = 2151, p = .967$) and 60+ ($U = 3343.5, p = .012$) were both not statistically significant. Moreover, the health literacy score between those aged 53-59 and 60+ ($U = 4987.5, p = .706$) was also not statistically significant. Furthermore, this insignificance is portrayed in the error bars which have overlapping CIs.

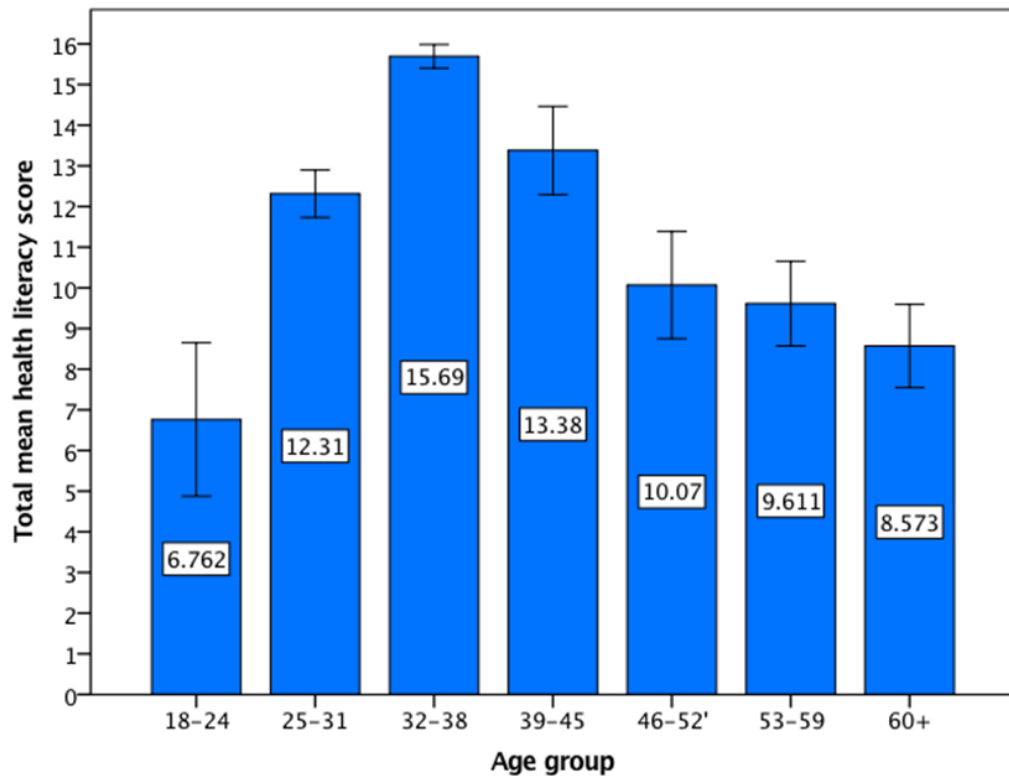
Table 25: Descriptive statistics between health literacy and age groups

Descriptive statistics between health literacy and age groups

Age	Sample size (N)	Mean	Std. Dev.	Std. Error	95% Confidence Interval for Mean	
					Lower Bound	Upper Bound
18-24	21	6.76	4.146	.905	4.87	8.65
25-31	35	12.31	1.694	.286	11.73	12.90
32-38	13	15.69	.480	.133	15.40	15.98
39-45	37	13.38	3.260	.536	12.29	14.47
46-52	60	10.07	5.102	.659	8.75	11.38
53-59	72	9.61	4.420	.521	8.57	10.65
60+	143	8.57	6.208	.519	7.55	9.60

$H(6) = 70.88, p < .001$

Figure 17: Error bar graph for the total health literacy score and age



4.6.2 Health literacy and gender

A statistically significant difference in health literacy scores between genders was identified via the Kruskal-Wallis H test, $H(2) = 26.89, p < .001$. The highest mean rank health literacy score was for 'other' meaning 13.18 and the lowest mean score for females was of 8.86 as shown in Table 26. The post hoc Mann Whitney test showed that health literacy in group 'other' ($U = 399.5, p < .01$) was significantly higher than in females. Carrying out Bonferroni correction (equation: $0.05/3 = 0.017$) resulted in a $p = .017$, showing that the p -value of the Mann Whitney test quoted above is statistically significant as it resulted in a lower value than Bonferroni correction. Results for the group 'other' must be taken with caution due to low sample size ($n = 22$). While comparing the health literacy scores between males and females, a statistically significant difference was identified via the post hoc test ($U = 10965.5, p =$

0.000084). Also, there was statistical significance in health literacy scores between females and 'other' ($U = 399.5, p < .017$). Figure 18 presents the error bar graph for gender, where visually interpreting results of CIs must be taken with caution as the CIs of males (95% CI (9.52, 10.97) and females (95% CI (8.03, 9.69) overlap showing no difference. However, as explained above this is false as there is statistical significance.

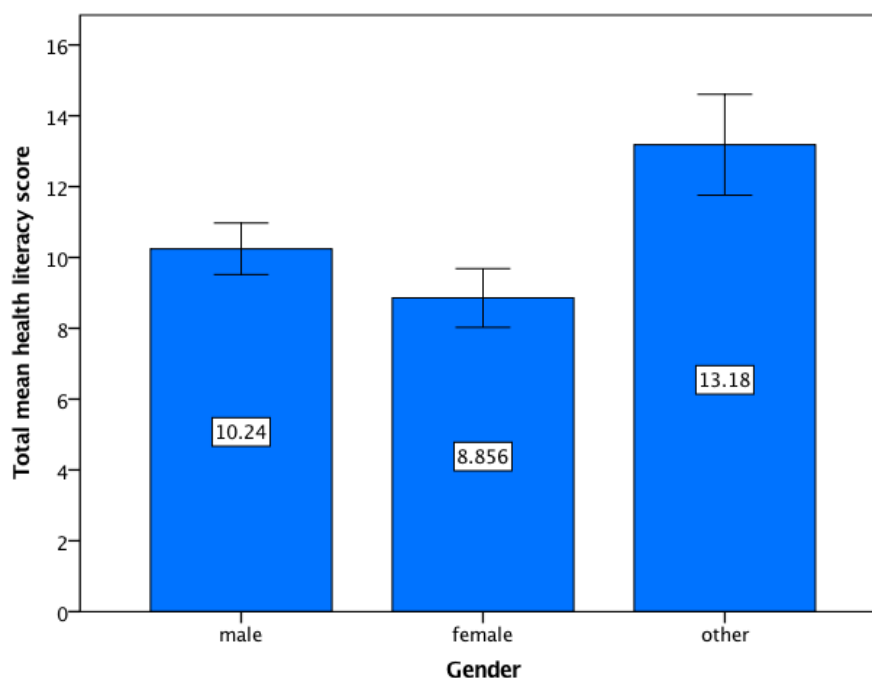
Table 26: Descriptive statistics of the relationship between health literacy and gender

Descriptive statistics between health literacy and gender

Gender	Sample size (N)	Mean	Std. Dev.	Std. Error	95% Confidence Interval for Mean	
					Lower Bound	Upper Bound
male	234	10.24	5.647	.369	9.52	10.97
female	125	8.86	4.690	.419	8.03	9.69
other	22	13.18	3.217	.686	11.76	14.61

$H(2) = 26.89, p < .001$

Figure 16: Error bar graph for the total health literacy score and gender



4.6.3 Health literacy and marital status

A statistically significant difference in health literacy scores within the marital status was identified via the Kruskal-Wallis H test, $H(4) = 19.72, p < .001$. The highest mean was 11.55 for divorced/separated and the lowest mean was 7.84 for widowed. Table 27 shows another higher mean score for 'other' where its sample size is small to be interpreted ($n = 7$). Moreover, Table 27 and Figure 19 show a wide CI for subgroup 'other' (95% CI (8.12, 19.31), indicating that more reliable results had to be collected for better precision (Clarke, 2012). Similarly, results must be taken with caution for the divorced/separated strata due to a small sample size ($n = 31$). The Mann Whitney test showed that health literacy scores between those divorced/separated and widowed were not significant ($U = 574.5, p = .184$). Moreover, when Bonferroni correlation was carried out (equation: $0.05/5 = 0.01$) the p -value resulted in .01 as a level of statistical significance, emphasising that the above are not statistically significant.

The Mann Whitney test showed that health literacy for a married status, when compared to widowed individuals, was statistically significant ($U = 3809.5, p = .003$). However, it was not statistically significantly different to single status ($U = 6373, p = .066$) due to a larger p -value ($> .01$). Moreover, the health literacy score for married individuals was not statistically significantly different than divorced/separated ($U = 3549, p = 0.845$). This is visually presented by an intersecting CI in Figure 19.

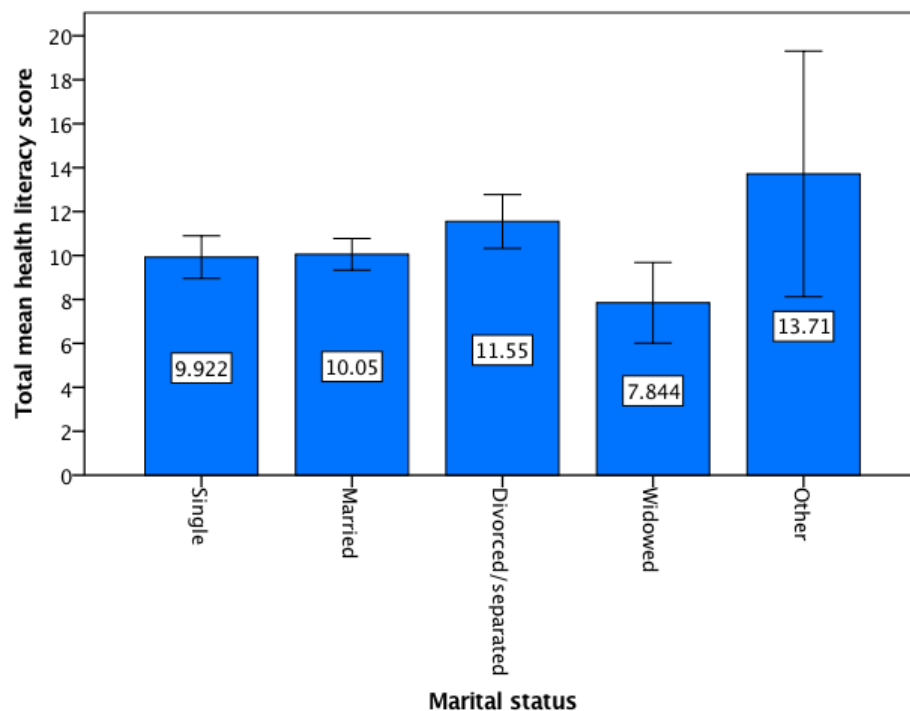
When comparing health literacy scores between single individuals to divorced/separated, a statistically significance resulted from the Mann Whitney test ($U = 621.5, p = 0.002$). However, when scores for single individuals were compared to widowed individuals an insignificant result was generated ($U = 1357.5, p = 0.605$). Lastly, insignificance also resulted in the health literacy scores of those divorced/separated and widowed ($U = 574.5, p = .184$).

Table 27: Descriptive statistics between health literacy and marital status

Marital status	Sample size (N)	Mean	Std. Dev.	Std. Error	95% Confidence Interval for Mean	
					Lower Bound	Upper Bound
Single	64	9.92	3.880	.485	8.95	10.89
Married	234	10.05	5.580	.365	9.33	10.77
Divorced/separated	31	11.55	3.335	.599	10.33	12.77
Widowed	45	7.84	6.101	.910	6.01	9.68
Other	7	13.71	6.047	2.286	8.12	19.31

H(4)= 19.72, $p < .001$

Figure 17: Error bar graph for the total health literacy score and marital status



4.6.4 Health literacy and Maltese geographical region

A statistically significant difference in health literacy scores between regions was identified via the Kruskal-Wallis H test, $H(5) = 75.34$, $p < .001$. The highest mean rank in health literacy was 12.76 for those living in the Southern Harbour region. This was followed by;

mean of 12.11 for the Northern, a mean of 10.08 for the Southern Eastern, a mean of 9.72 for Gozo and Comino and a mean of 8.81 for the Northern Harbour region. Furthermore, the lowest mean of 4.26 was for the Western region. The above results are portrayed in Table 28. Moreover, when comparing the highest and lowest means, the Mann Whitney test showed that health literacy in the Southern Harbour region was statistically significantly higher to the Western region ($U = 345, p < .01$). Bonferroni correlation (equation: $0.05/6 = 0.0083$) was carried out and the statistical significant level of the post-hoc test was set to .0083. Other possible comparisons to the Southern Harbour included comparing its health literacy scores to Northern Harbour ($U = 1244.5, p < .0083$) and Southern Eastern ($U = 701, p = .000091$), both resulted in statistical significance respectively. However, when Southern Harbour was compared to Northern ($U = 2641.6, p = .674$) and Gozo and Comino ($U = 680, p = .536$), these resulted in statistical insignificance.

When health literacy scores of the Northern Harbour were compared to the Western ($U = 1232, p = .000009$) and Northern regions ($U = 2691.5, p < .0083$) a significance resulted. However, when Northern Harbour health literacy scores were compared to those residing in South-Eastern ($U = 1846, p = .022$) or Gozo and Comino regions ($U = 1186, p = .173$), both resulted in insignificance.

Comparing the health literacy scores of Western regions to; Northern ($U = 904, p < .0083$) South Eastern ($U = 573.5, p = .000016$) and Gozo and Comino ($U = 365, p = .000309$), all resulted in statistical significance as their p -values were less than .0083 ($p \leq .0083$). This significance is further portrayed in Figure 20 where the Western CI is disjointed from the rest.

Comparing the health literacy scores of Northern regions to; South Eastern ($U = 1979, p = .01$) and Gozitan and Comino region ($U = 1558, p = .966$), both resulted in insignificance as

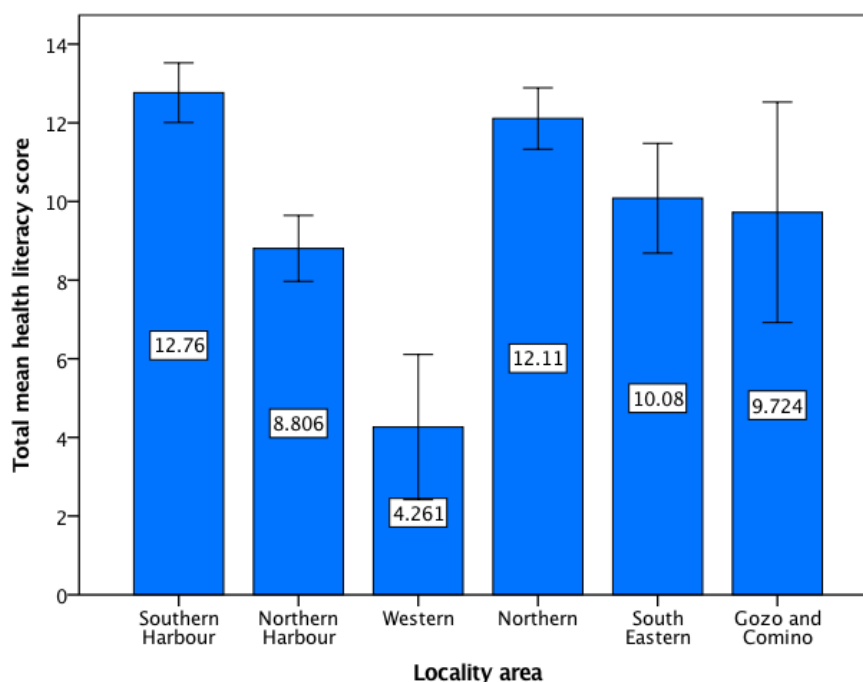
the p -values are more than .0083 ($p > .0083$). Lastly, when comparing South Eastern to Gozo and Comino region an insignificance resulted ($U = 550, p = .091$).

Table 28: Descriptive statistics between health literacy and region

Districts	Sample size (N)	Mean	Std. Dev.	Std. Error	95% Confidence Interval for Mean	
					Lower Bound	Upper Bound
Southern Harbour	51	12.76	2.695	.377	12.01	13.52
Northern Harbour	98	8.81	4.183	.423	7.97	9.64
Western	46	4.26	6.220	.917	2.41	6.11
Northern	108	12.11	4.089	.393	11.33	12.89
South Eastern	49	10.08	4.868	.695	8.68	11.48
Gozo and Comino	29	9.72	7.367	1.368	6.92	12.53

$H(5) = 75.34, p < .001$

Figure 18: Error bar graph for the total health literacy score and locality area



4.6.5 Health literacy and levels of education

A statistically significant difference in health literacy scores between education was identified via the Kruskal-Wallis H test, $H(5) = 159.31, p < .001$. The highest mean rank

health literacy score was of 12.81 for post-secondary education and the lowest mean rank health literacy score of 0.96 for no formal education. The aforementioned data is shown in Table 29. After conducting the Mann Whitney test, it was evident that health literacy significantly differed between post-secondary education and no formal education ($U = 33.5$, $p < .001$). Moreover, when Bonferroni correction was carried out (equation: $0.05/6 = 0.0083$) the p -value resulted in .0083. The p -value of the aforementioned Mann Whitney test was less than the p -value of Bonferroni correction, showing statistical significance between the two educational levels. Other comparisons of post-secondary education to other forms of education that showed statistical significance were primary education ($U = 370.5$, $p = .000017$) and lower secondary education ($U = 425.5$, $p = .000149$). However, post-secondary education was not statistically significantly different from upper secondary ($U = 1276.5$, $p = .103$) and tertiary education ($U = 2327.5$, $p = .099$). Both latter p -values exceed Bonferroni correction p -value of .0083.

Statistical significance was evident when comparing health literacy scores for primary education to no formal education ($U = 435.5$, $p < .0083$). This is also portrayed in Figure 21 via disjointed CIs. However, when health literacy scores for primary education were compared to lower secondary education, statistical insignificance occurred ($U = 633.5$, $p = .198$). This is ambiguous as to when primary education was compared to other forms of educational levels; apart from lower secondary education, all other forms resulted in statistically significant health literacy scores. Furthermore, statistical significance was also found for upper secondary education ($U = 435.5$, $p < .0083$) and tertiary education ($U = 1698.5$, $p = .000916$).

Comparing health literacy scores for lower secondary education to; no formal education ($U = 143$, $p < .0083$), upper secondary education ($U = 590.5$, $p < .0083$), and tertiary education

($U = 1321, p < .0083$), all resulted in statistical significance as with post-secondary education, showing differences between forms of education.

Health literacy scores between those with upper secondary education to those with no formal education resulted in statistical significance ($U = 97.5, p < .0083$). While insignificance resulted between upper secondary education and tertiary education ($U = 1276, p = .103$). Lastly, there was statistical significance between the two far most educational levels included in this sample i.e., no formal educational and tertiary education ($U = .001, p < .0083$).

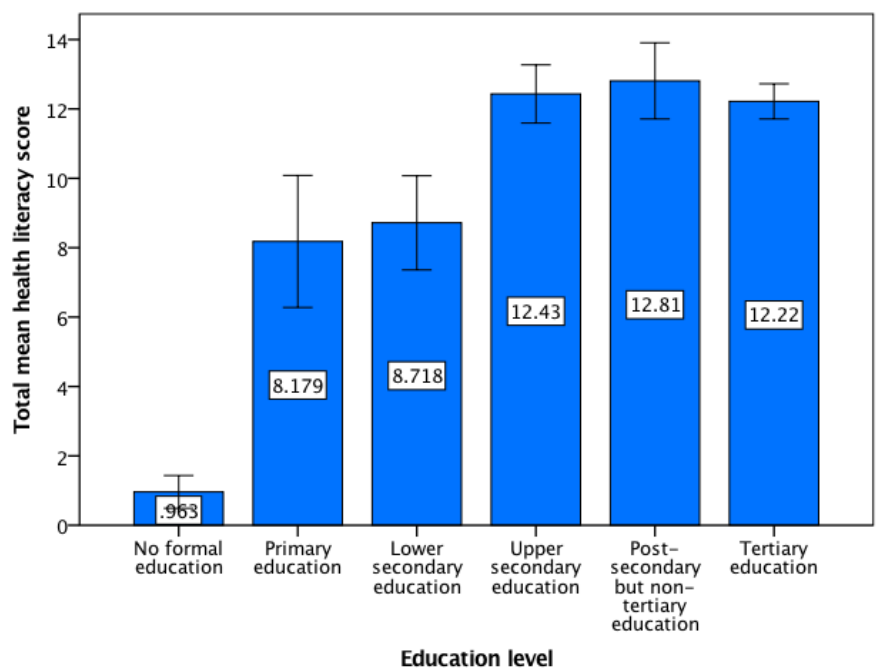
Table 29: Descriptive statistics between health literacy and levels of education

Descriptive statistics between health literacy and levels of education

Levels of education	Sample size (N)	Mean	Std. Dev.	Std. Error	95% Confidence Interval for Mean	
					Lower Bound	Upper Bound
No formal education	54	.96	1.726	.235	.49	1.43
Primary education	39	8.18	5.871	.940	6.28	10.08
Lower secondary education	39	8.72	4.186	.670	7.36	10.07
Upper secondary education	74	12.43	3.619	.421	11.59	13.27
Post-secondary but non-tertiary education	42	12.81	3.522	.543	11.71	13.91
Tertiary education	133	12.22	2.952	.256	11.71	12.72

$H(5) = 159.31, p < .001$

Figure 19: Error bar graph for the total health literacy score and education level



4.6.6 Health literacy and current working status

A statistically significant difference in health literacy scores between the diverse working statuses was identified via the Kruskal-Wallis H test, $H(7) = 79.84$, $p < .001$. The highest mean rank health literacy score was 11.81 for those working for pay/profit and the lowest mean rank health literacy score was 2.60 for those working for non-profit as shown in Table 30. The aforementioned mean must be taken with caution due to a relatively small sample size ($n = 20$). Moreover, Table 30 has higher and lower means than stated. However, due to a very small sample size under the current working statuses, minimal importance was given to these subgroups ($n \leq 7$). The Mann Whitney test showed that health literacy in those working for pay/profit was statistically significantly higher than in those working for non-profit ($U = 362.5$, $p < .01$). Furthermore, Bonferroni correction (equation: $0.05/8 = 0.00625$) presented a p -value of .00625, showing that the aforementioned Mann Whitney test is truly statistically significant as the p -value is less than Bonferroni correction. Statistical significance was also seen between those working for pay/profit when compared to unemployed ($U = 879$, $p = .000002$) or in retirement/early retirement ($U = 8346.5$, $p = .00084$). However, insignificance resulted between working for pay/profit and housework/staying at home ($U = 1501.5$, $p = .057$).

Statistical significance was evident when comparing the health literacy scores for those working for non-profit to housework/stay at home ($U = 71$, $p = .000067$). Due to a larger p -value than Bonferroni's correction, statistical insignificance occurred when comparing working for non-profit to unemployed ($U = 189$, $p = .134$) or to retirement/early retirement ($U = 845$, $p = .015$).

When comparing health literacy scores for those unemployed to; housework/stay at home ($U = 154, p = 0.35$) or in retirement/early retirement ($U = 920, p = .025$) an insignificance resulted. Likewise, when comparing the health literacy scores between housework/stay at home and retirement/early retirement an insignificant result occurred ($1033.5, p = .337$). Furthermore, these insignificances are shown in Figure 22 with overlapping CIs.

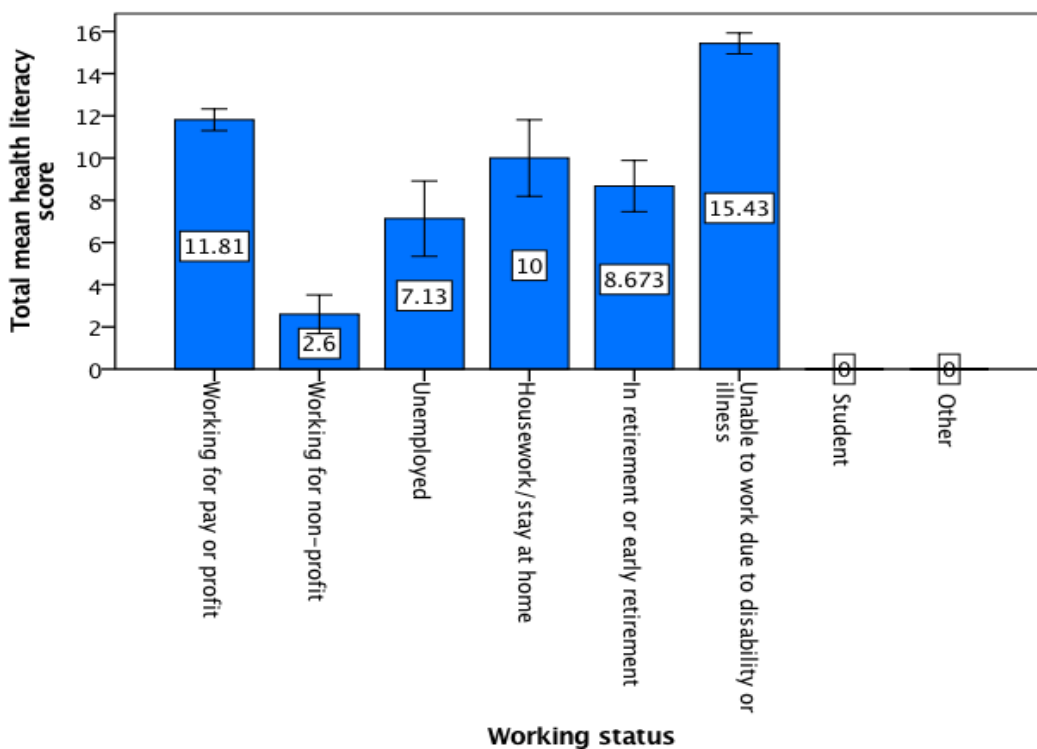
Table 30: Descriptive statistics between health literacy and current working status

Descriptive statistics between health literacy and current working status

Current working status	Sample size (N)	Mean	Std. Dev.	Std. Error	95% Confidence Interval for Mean	
					Lower Bound	Upper Bound
Working for pay/profit	193	11.81	3.619	.261	11.30	12.33
Working for non-profit	20	2.60	1.957	.438	1.68	3.52
Unemployed	23	7.13	4.137	.863	5.34	8.92
Housework/stay at home	21	10.00	3.987	.870	8.18	11.82
In retirement/early retirement	113	8.67	6.524	.614	7.46	9.89
Unable to work due to disability or illness	7	15.43	.535	.202	14.93	15.92
Student	2	.00	.000	.000	.00	.00
Other	2	.00	.000	.000	.00	.00

$H(7) = 79.84, p < .001$

Figure 20: Error bar graph for the total health literacy score and working status



4.6.7 Health literacy and years of living with T2DM

A statistically significant difference in health literacy scores between various years of living with DM was identified via the Kruskal-Wallis H test, $H(6) = 99.65, p < .001$. The highest mean rank health literacy score was 15.00 for the longest years of living with DM in this sample, meaning 61-70 years. However, only one individual ($n = 1$) was classified between these years, therefore, interpretation must be taken with caution. This score was followed by those living with DM for 11-30 years ($M = 12.66$). On the other hand, as shown in Table 31, the lowest mean rank health literacy score was 6.35 for those living with DM for 31-40 years. Following a post hoc test, the Mann Whitney test showed that health literacy in those 61-70 years of living with DM was not statistically significantly higher than in those living with DM for 31-40 years ($U = .001, p = .063$). Moreover, Bonferroni correction (equation: $0.05/7 = 0.0071$) was carried out where the level of significance was set to .0071. Results showed that there was no statistical significance between those living with DM for 61-70 from all the other groups meaning 1-10 ($U = 48, p = .414$); 11-20 ($U = .001, p = .027$); 21-30 ($U = 7, p = .941$); 41-50 ($U = .001, p = .083$). All p -values were $> .0071$. Notably, no individuals in this sample lived with DM for 51-60.

When comparing health literacy scores amongst those living with DM for 1-10 years, to those living with DM for 11-20 years ($U = 6456.5, p = .000650$) and those living for 31-40 years ($U = 1847, p = .000006$) statistical significance transpired. Whilst when living with DM for 1-10 years was compared to those living for 21-30 ($U = 1466.5, p = .131$) and 41-50 ($U = 2162, p = .104$) statistical insignificance resulted.

A comparison between health literacy scores of those living with DM for 11-20 years to those living for 31-40 ($U = 183, p < .0071$) and 41-50 ($U = 149.5, p < .0071$), statistical significance

resulted. However, when those living for 11-20 were compared to those living for 21-30 ($U = 495.5, p = .259$) statistical insignificance transpired.

Furthermore, statistical insignificance occurred when comparing health literacy scores of those living with DM for 21-30 years to those living for 31-40 ($U = 186, p = .156$) and 41-50 ($U = 138, p = .196$). Comparing the latter two, meaning 31-40 to those 41-50 ($U = 234, p = .029$) also resulted in an insignificance. Even though the latter p -value is $< .05$ however, it is greater than Bonferroni correction of $> .0071$ therefore, statistically insignificant. As shown in Figure 23 below the insignificances were portrayed via overlapping CIs.

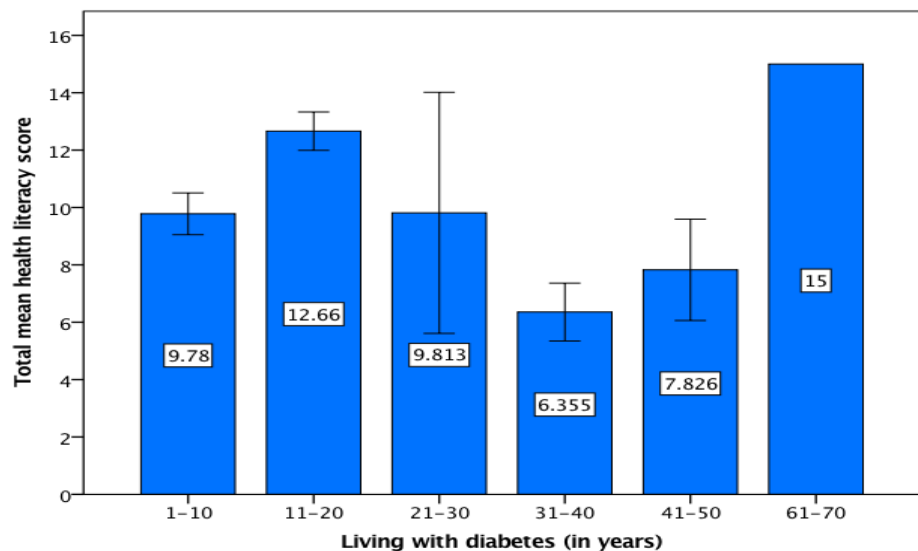
Table 31: Descriptive statistics between health literacy and years of living with diabetes

Descriptive statistics between health literacy and years of living with diabetes

Years of living with T2DM	Sample size (N)	Mean	Std. Dev.	Std. Error	95% Confidence Interval for Mean	
					Lower Bound	Upper Bound
1-10	237	9.78	5.671	.369	9.05	10.51
11-20	73	12.66	2.892	.339	11.99	13.33
21-30	16	9.81	7.884	1.971	5.61	14.01
31-40	30	6.35	2.751	.494	5.35	7.36
41-50	24	7.83	4.086	.852	6.06	9.59
51-60	0	0	0	0	0	0
61-70	1	15.00	5.325	.273	9.42	10.49

$H(6) = 99.65, p < .001$

Figure 21: Error bar graph for the total health literacy score and living with diabetes (in years)



4.6.8 Health literacy and household Net monthly income

A statistically significant difference in health literacy scores between various household Net monthly income was identified via the Kruskal-Wallis H test, $H(9) = 110.84, p < .001$. The highest mean rank health literacy score was 14.50 for the highest Net monthly income value in this sample i.e., > 2446 ($n = 48$). On the contrary, the lowest mean rank health literacy score was of 4.20 for those who had a Net monthly income of €580-813 ($n = 60$). The latter analysis is found in Table 32. Following a post hoc test the Mann Whitney test showed that health literacy in those having an income > 2446 was statistically significantly higher than those with a lower income, meaning €580-813 ($U = .001, p < .01$). Following a Bonferroni correction, the p -value was set for .005 (equation: $0.05/7 = 0.005$). In fact, the p -value between the aforementioned monthly incomes was $< .005$. Moreover, a household Net income of > 2446 was statistically significantly higher than the following: $< €465$ ($U = 0.001, p < 0.005$), €466-579 ($U = 0.001, p < .005$), €814-929 ($U = 690, p = .00005$), €930-1,162 ($U = 440, p = .000116$), €1,396-1,628 ($U = 118, p < .005$), €1,629-1,978 ($U = 250, p < .005$) and €1,979-2446 ($U = 534, p = .001128$). However, it was not statistically significantly different than €1,163-1,395 ($U = 760, p = .007$) due to a higher p -value than Bonferroni correction. The CI range (95% CI (14.31, 14.69) for $> €2446$ income was narrow, indicating reliability and credibility.

Comparing the health literacy scores of individuals with a household Net monthly income of $< €465$ to other incomes that had statistically significant results between the scores were; €1,396-1,628 ($U = 80, p = .001$), €1,629-1,978 ($U = 272, p = .003$) and €1,979-2446 ($U = 184, p = .001376$). However, an insignificant result between $< €465$ to the following: €466-579 ($U = 208, p = .434$), €580-813 ($U = 428, p = .047$), €814-929 ($U = 424, p = .097$), €930-1,162 ($U = 226, p = .035$), €1,163-1,395 ($U = 422, p = .585$) was exposed.

Health literacy scores for those households whose Net monthly income was of €466-579 to all the following resulted in statistical insignificance: €580-813 ($U = 387, p = .964$), €814-929 ($U = 241, p = .062$), €930-1,162 ($U = 101, p = .003$), €1,163-1,395 ($U = 191, p = .041$), €1,396-1,628 ($U = 77, p = .052$), €1,629-1,978 ($U = 220.5, p = .097$) and €1,979-2446 ($U = 126, p = .009$). Furthermore, health literacy scores for those household whose Net monthly income was of €580-813 was also statistically significant to all the following incomes: €814-929 ($U = 1020, p = .000276$), €930-1,162 ($U = 248.5, p < .005$), €1,163-1,395 ($U = 486, p < .005$), €1,396-1,628 ($U = 255, p = .00081$), €1,629-1,978 ($U = 555, p < .005$) and €1,979-2446 ($U = 345, p < .005$).

Conversely, health literacy scores for those whose household Net monthly income was of €814-929 to all the following: €930-1,162 ($U = 830, p = 0.3695$), €1,163-1,395 ($U = 1242.5, p = .876$), €1,396-1,628 ($U = 539, p = .893$), €1,629-1,978 ($U = 1317.5, p = .987$) and €1,979-2446 ($U = 950, p = .589$) resulted in statistical insignificance. Similarly, health literacy scores for those households whose Net monthly income was of €930-1,162 to all the following: €1,163-1,395 ($U = 650.5, p = .192$), €1,396-1,628 ($U = 327.5, p = .818$), €1,629-1,978 ($U = 7845, p = .762$) and €1,979-2446 ($U = 522.5, p = .214$) resulted in statistical insignificance.

Furthermore, statistical insignificance was also shown when health literacy scores for those household Net monthly income of €1,163-1,395 was compared to the following: €1,396-1,628 ($U = 416, p = .522$), €1,629-1,978 ($U = 1082, p = 0.866$), €1,979-2446 ($U = 803, p = .615$). Likewise, when comparing health literacy scores for those household whose Net monthly income of €1,396-1,628 to the following: €1,629-1,978 ($U = 305.5, p = .301$) and €1,979-2446 ($U = 358.5, p = .841$), resulted in statistical insignificance. Also, when comparing the household Net monthly income of €1,629-1,978 to €1,979-2446 ($U = 695.5,$

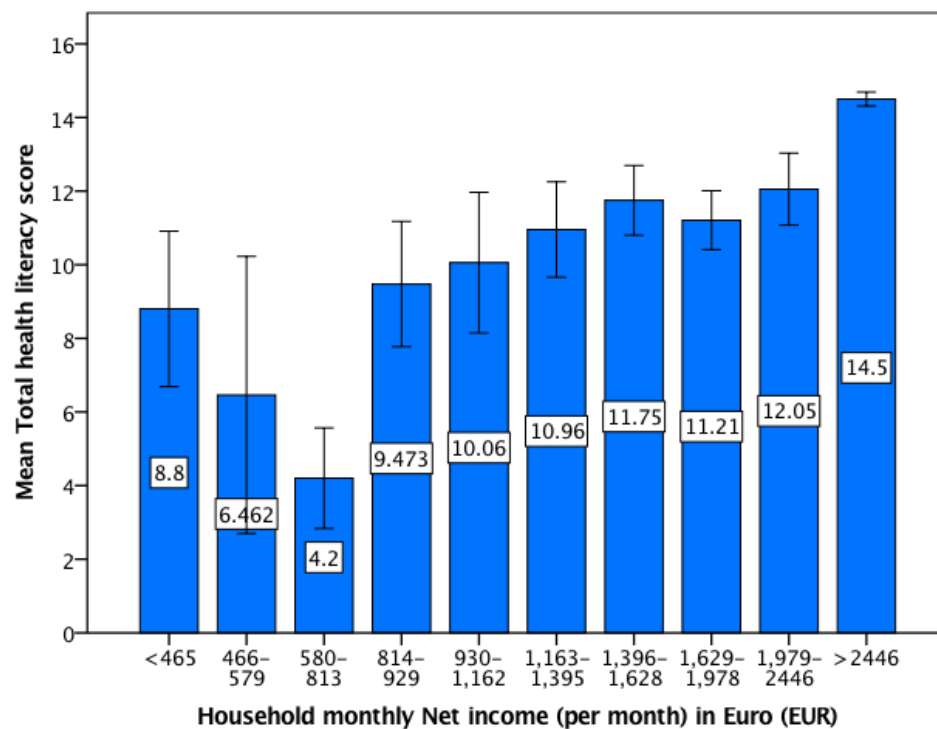
$p = .082$), statistical insignificance was presented. Moreover, the error bars shown in Figure 24 visually identify the aforementioned results due to overlapping CIs.

Table 32: Descriptive statistics between health literacy and household Net monthly income

Household Net monthly income	Sample size (N)	Mean	Std. Dev.	Std. Error	95% Confidence Interval for Mean	
					Lower Bound	Upper Bound
< €465	20	8.80	4.514	1.009	6.69	10.91
€466-579	13	6.46	6.226	1.727	2.70	10.22
€580-813	60	4.20	5.288	.683	2.83	5.57
€814-929	55	9.47	6.292	.848	7.77	11.17
€930-1,162	34	10.06	5.471	.938	8.15	11.97
€1,163-1,395	46	10.96	4.366	.644	9.66	12.25
€1,396-1,628	20	11.75	2.023	.452	10.80	12.70
€1,629-1,978	48	11.21	2.752	.397	10.41	12.01
€1,979-2446	37	12.05	2.934	.482	11.08	13.03
>€2446	48	14.50	.652	.094	14.31	14.69

$H(9) = 110.84, p < .001$

Figure 22: Error bar graph for the total health literacy score and household monthly Net income in Euro.



4.6.9 Health literacy and information media usage

A statistically significant difference in health literacy scores between various information media usage was identified via the Kruskal-Wallis H test, $H(8) = 61.66, p < .001$. As shown in Table 33, almost all means are close, with the highest mean rank health literacy score of 13.20 for the cumulative use of books, television, the internet, and social media. However, this close relationship is excluded in the lowest mean rank health literacy score of 2.29 for radio. Following a post hoc test, the Mann Whitney test showed that health literacy in the group which cumulatively used books, television, the internet, and social media was statistically significantly higher than those that used radio ($U = 68.00, p < .01$). Bonferroni correction was carried out (equation: $0.05/9 = 0.0056$) showing a p -value of .0056. Notably, no participants selected the usage of magazines ($n = 0$).

Health literacy scores of those that used books vs those that used the following; radio ($U = 29, p = .016$), television ($U = 325.5, p = .018$), internet ($U = 143, p = .007$), social media ($U = 119, p = .34$), all of the above ($U = 90.5, p = .130$), other sources ($U = 75, p = .93$) and the cumulative use of television, internet, social media ($U = 96, p = .002$), all resulted in statistical insignificance.

Meanwhile, when comparing health literacy scores of those that used radio vs the following: television ($U = 269, p = .000034$), social media ($U = 86, p = .000059$), all the above ($U = 55, p = .000103$), other sources ($U = 968, p = .002$) and the cumulative use of television, internet, social media ($U = 96, p = .000019$) all resulted in statistical significance. However, there was an exception for the use of the internet ($U = 263, p = .024$) which resulted in statistical insignificance. As portrayed in Figure 25, the lower confidence limit for radio is the only negative outcome in this study, where the negative

delta indicates the lower bound of equivalence margin crossing the line of no difference.

Therefore, the 0 represents the midline of no difference (Hazra, 2017).

Comparing the health literacy scores of television vs the cumulative use of television, internet, social media ($U = 1912, p = .001$) all resulted in statistical significance. Whilst when health literacy scores of television was compared to other mediums meaning; internet ($U = 2613.5, p = .007$), social media ($U = 2058, p = .224$), all the above ($U = 1098.5, p = .011$) and other sources ($U = 1386.5, p = .872$) statistical insignificance resulted.

When comparing the health literacy scores of those that use internet vs the following: social media ($U = 759.5, p = .002$), all the above ($U = 424, p = .00039$), the cumulative use of television, internet, and social media ($U = 896, p < .001$) statistical significance occurred. This was with an exception to other sources ($U = 525, p = .059$) which resulted in statistical insignificance. Similarly, statistical insignificance was also apparent when comparing health literacy scores of social media usage to; all the above ($U = 359.5, p = .018$), other sources ($U = 448, p = .643$) and cumulative use of television, internet, social media ($U = 944, p = .89$).

Health literacy scores of those who ticked all of the above were compared to the following: other sources ($U = 210, p = .029$), the cumulative usage of television, internet, social media ($U = 616, p = .714$), portrayed statistical insignificance. Lastly, when other sources were compared to the cumulative usage of; television, internet, and social media ($U = 466, p = .171$) statistical insignificance also resulted.

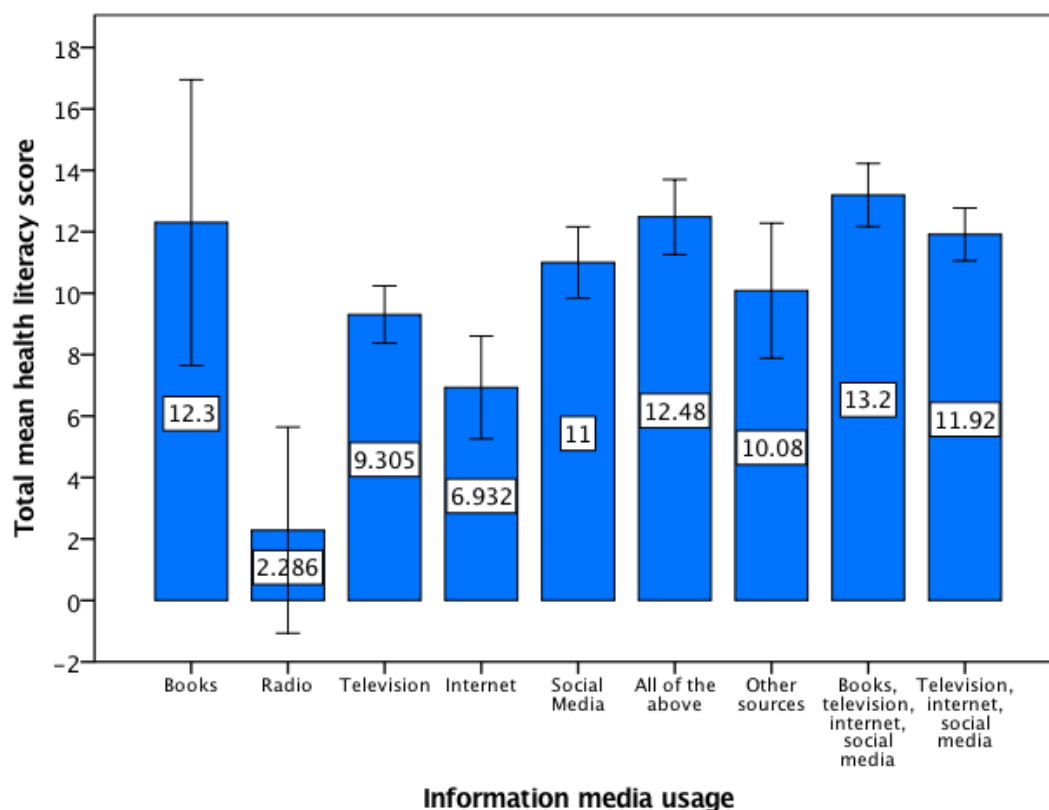
Table 33: Descriptive statistics between health literacy and information media usage

Descriptive statistics between health literacy and information media usage

Information media usage	Sample size (N)	Mean	Std. Dev.	Std. Error	95% Confidence Interval for Mean	
					Lower Bound	Upper Bound
Magazines	0	0	0	0	0	0
Books	10	12.30	6.499	2.055	7.65	16.95
Radio	14	2.29	5.810	1.553	-1.07	5.64
Television	118	9.31	5.105	.470	8.37	10.24
Internet	59	6.93	6.416	.835	5.26	8.60
Social media	40	11.00	3.637	.575	9.84	12.16
All of the above	27	12.48	3.081	.593	11.26	13.70
Other sources	24	10.08	5.208	1.063	7.88	12.28
Books, television, internet, social media	41	13.20	3.250	.508	12.17	14.22
Television, internet, social media	48	11.92	2.960	.427	11.06	12.78

H(8) = 61.66, $p < .001$

Figure 23: Error bar graph for the total health literacy score and information media usage



4.6.10 Health literacy and treatment regimen

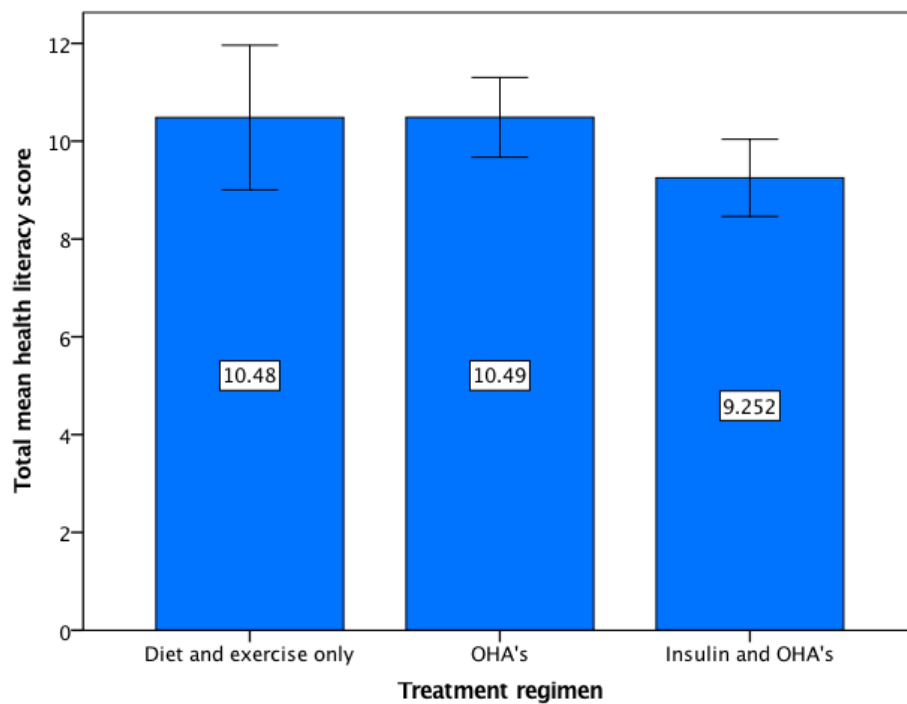
A statistically significant difference in health literacy scores between various treatment regimens was identified via the Kruskal-Wallis H test, $H(2) = 11.07, p < .004$. The highest mean rank health literacy score was 10.49 for OHAs, closely followed by 10.49 for diet and exercise only. The lowest mean rank health literacy score was 9.25 for insulin and OHAs as shown in Table 34. Following a post hoc test for the highest and lowest means, the Mann Whitney test showed that health literacy for those on OHAs was statistically significantly higher than those on both insulin and OHAs ($U = 11988.5, p < .001$). When Bonferroni correction (equation: $0.05/3 = .017$) was carried out the p -value was set for .017. In fact, the p -value between those on OHAs only vs those on insulin and OHAs resulted in a true statistical significance ($p < .017$). However, when those on OHAs were compared to its closest mean; meaning those on diet and exercise only ($U = 2665.5, p = .468$), resulted in statistical insignificance. Lastly, when those on diet and exercise only were compared to those on insulin and OHAs ($U = 2483.5, p = .88$), statistical insignificance also resulted. In addition, the error bar graph shown in Figure 26 visually identifies this insignificance. However, the aforementioned figure lacks statistical significance.

Table 34: Descriptive statistics between health literacy and treatment regimen

Treatment regimen	Sample size (N)	Mean	Std. Dev.	Std. Error	95% Confidence Interval for Mean	
					Lower Bound	Upper Bound
Diet and exercise only	31	10.48	4.032	.724	9.00	11.96
OHAs	187	10.49	5.651	.413	9.67	11.30
Insulin and OHAs	163	9.25	5.096	.399	8.46	10.04

$H(2) = 11.07, p < .004$

Figure 24: Error bar graph for the total health literacy score and treatment regimen



4.6.11 Health literacy and family history of diabetes

A statistically significant difference in health literacy scores between positive family history and negative family history of DM was identified via the Kruskal-Wallis H test, $H(1) = 22.64$, $p < .001$. As shown in Table 35, the highest mean rank health literacy score was 10.87 for those that had a family history of DM, while the lowest mean rank health literacy score was 7.33 for those that had no family history. Following a post hoc test, the Mann Whitney test showed that health literacy in the group that responded yes to family history of DM was statistically significantly higher than those that responded no ($U = 9423$, $p < .001$). When Bonferroni correction (equation: $0.05/2 = 0.025$) was carried out the p -value resulted in .025, clarifying that the aforementioned p -value between yes and no to family history of DM is truly significant. In addition, the error bar graph shown in Figure 27 visually identifies this statistical significance as the CI of both groups does not intersect.

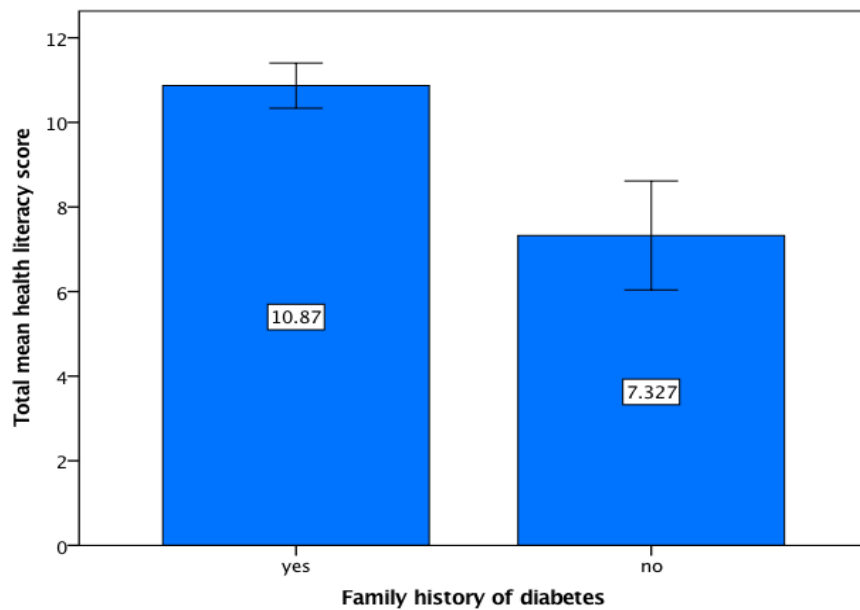
Table 35: Descriptive statistics between health literacy and family history of diabetes

Descriptive statistics between health literacy and family history of diabetes

Family history of diabetes	Sample size (N)	Mean	Std. Dev.	Std. Error	95% Confidence Interval for Mean	
					Lower Bound	Upper Bound
Yes	283	10.87	4.561	.271	10.34	11.40
No	98	7.33	6.418	.648	6.04	8.61

H(1) = 22.64, $p < .001$

Figure 25: Error bar graph for the total health literacy score and family history of diabetes.



4.7 Multiple regression

Table 36 shows that all variables in this study, except for ‘treatment regimen’ which is related more to diabetes, were inputted into the model as independent variables. This shows which variables are important and which ones are not to predict health literacy. Moreover, it helps to present the strongest predictors via the application of the backward elimination technique which retains those that had a $p \leq .05$ and eliminates those variables that had a $p \geq .10$.

The ‘coefficient of determination’ denoted by an adjusted R^2 resulted in .484 as shown in Table 37 below for model 1. Model 2 via backward elimination removed the age groups from the variables which slightly increased the previous adjusted $R^2 = .485$. Model 3 removed the information media usage variable, and the same $R^2 = .485$ remained. When compared to the previous model, model 4 removed the locality area variable, which slightly increased the $R^2 = .486$. In model 4 the ‘goodness of fit’ was assessed by $R^2 = .497$. It was identified that all the independent variables except for age group, information media usage and locality area could account for 49.7% of the variation in health literacy. This also meant that 49.7% of the independent variables could be explained by health literacy, leaving 50.3% for other influencing variables. An ideal R^2 is a result of 1 which indicates the perfect fit of data on the regression line (Hamilton et al., 2015).

Table 36: Variables entered/ removed via backward translation

Variables Entered/Removed			
Model	Variables Entered	Variables Removed	Method
1	Family history of diabetes, Locality area, Information media usage, Gender, Living with diabetes (in years), Marital status, Educational level, Age group, Working status, Household monthly Net income (per month) in Euro (EUR) ^b		Enter
2		Age group	Backward (criterion: Probability of F-to-remove $\geq .100$).
3		Information media usage	Backward (criterion: Probability of F-to-remove $\geq .100$).
4		Locality area	Backward (criterion: Probability of F-to-remove $\geq .100$).

a. Dependent Variable: Total health literacy score

b. All requested variables entered.

Table 37: Model summary

Model Summary

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Change Statistics				
					R Square Change	F Change	df1	df2	Sig. F Change
1	.705 ^a	.497	.484	3.826	.497	36.608	10	370	.000
2	.705 ^b	.497	.485	3.821	.000	.069	1	370	.793
3	.704 ^c	.496	.485	3.820	-.001	.690	1	371	.407
4	.704 ^d	.496	.486	3.817	-.001	.574	1	372	.449

a. Predictors: (Constant), Family history of diabetes, Locality area, Information media usage, Gender, Living with diabetes (in years), Marital status, Educational level, Age group, Working status, Household monthly Net income (per month) in Euro (EUR)

b. Predictors: (Constant), Family history of diabetes, Locality area, Information media usage, Gender, Living with diabetes (in years), Marital status, Educational level, Working status, Household monthly Net income (per month) in Euro (EUR)

c. Predictors: (Constant), Family history of diabetes, Locality area, Gender, Living with diabetes (in years), Marital status, Educational level, Working status, Household monthly Net income (per month) in Euro (EUR)

d. Predictors: (Constant), Family history of diabetes, Gender, Living with diabetes (in years), Marital status, Educational level, Working status, Household monthly Net income (per month) in Euro (EUR)

Reports of the ANOVA are presented in Table 38, where all models are significant ($p < .001$), therefore reject the null hypothesis. This significance shows that the regression model overall predicts a satisfactorily health literacy.

Table 39 below contributes to the model parameters via the t values and their level of significance. It is shown in model 4 that; gender, marital status, educational level, working status, household monthly Net income, family history of DM, and years of living with DM are significant due to a p -value of $p < .05$. Leaving out the following 3 out of 10 variables: age group, locality area and information media usage that had an insignificant result ($p > .05$). The three most significant values having a $p < .001$ and showing the best predictors of health literacy were as follows; educational level, household monthly Net income and family history of DM.

Table 38: Analysis of variance (ANOVA)

ANOVA^a

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	5358.997	10	535.900	36.608	.000 ^b
	Residual	5416.331	370	14.639		
	Total	10775.328	380			
2	Regression	5357.991	9	595.332	40.771	.000 ^c
	Residual	5417.337	371	14.602		
	Total	10775.328	380			
3	Regression	5347.922	8	668.490	45.819	.000 ^d
	Residual	5427.406	372	14.590		
	Total	10775.328	380			
4	Regression	5339.546	7	762.792	52.342	.000 ^e
	Residual	5435.782	373	14.573		
	Total	10775.328	380			

a. Dependent Variable: Total health literacy score

b. Predictors: (Constant), Family history of diabetes, Locality area, Information media usage, Gender, Living with diabetes (in years), Marital status, Educational level, Age group, Working status, Household monthly Net income (per month) in Euro (EUR)

c. Predictors: (Constant), Family history of diabetes, Locality area, Information media usage, Gender, Living with diabetes (in years), Marital status, Educational level, Working status, Household monthly Net income (per month) in Euro (EUR)

d. Predictors: (Constant), Family history of diabetes, Locality area, Gender, Living with diabetes (in years), Marital status, Educational level, Working status, Household monthly Net income (per month) in Euro (EUR)

e. Predictors: (Constant), Family history of diabetes, Gender, Living with diabetes (in years), Marital status, Educational level, Working status, Household monthly Net income (per month) in Euro (EUR)

Table 39: Coefficients

Model	Unstandardised Coefficients		Standardised Coefficients	t	Sig
	B	Std. Error	Beta		
1 (Constant)	-.045	1.665		-.027	.978
Age group	.037	.139	.013	.262	.793
Gender	.926	.383	.105	2.421	.016
Marital status	.890	.254	.154	3.505	.001
Locality area	-.120	.138	-.034	-.870	.385
Educational level	1.440	.139	.491	10.367	.000
Working status	.361	.149	.129	2.430	.016
Living with diabetes (in years)	-.353	.173	-.083	-2.036	.042
Household monthly Net income (per month) in Euro (EUR)	.564	.111	.288	5.094	.000
Information media usage	.085	.106	.037	.801	.423
Family history of diabetes	-2.491	.499	-.205	-4.990	.000
2 Constant	.122	1.537		.079	.937
Gender	.899	.368	.102	2.446	.015
Marital status	.910	.242	.157	3.767	.000
Locality area	-.117	.137	-.033	-.855	.393
Educational level	1.440	.139	.491	10.377	.000
Working status	.374	.141	.133	2.652	.008
Living with diabetes (in years)	-.353	.173	-.082	-2.037	.042
Household monthly Net income (per month) in Euro (EUR)	.559	.109	.285	5.146	.000
Information media usage	.088	.106	.038	.830	.407
Family history of diabetes	-2.491	.499	-.205	-4.997	.000
3 Constant	.672	1.386		.485	.628
Gender	.847	.362	.096	2.340	.020
Marital status	.876	.238	.152	3.681	.000
Locality area	-.103	.136	-.029	-.758	.449
Educational level	1.456	.137	.496	10.600	.000
Working status	.356	.139	.127	2.556	.011
Living with diabetes (in years)	-.392	.167	-.092	-2.353	.019
Household monthly Net income (per month) in Euro (EUR)	.578	.106	.295	5.441	.000
Family history of diabetes	-2.472	.498	-.203	-4.965	.000
4 Constant	.459	1.356		.338	.735
Gender	.820	.360	.093	2.277	.023
Marital status	.868	.238	.150	3.652	.000
Educational level	1.458	.137	.497	10.629	.000
Working status	.332	.135	.118	2.450	.015
Living with diabetes (in years)	-.393	.166	-.092	-2.360	.019
Household monthly Net income (per month) in Euro (EUR)	.566	.105	.289	5.391	.000
Family history of diabetes	-2.425	.494	-.199	-4.912	.000

a. Dependent Variable: Total health literacy score

4.8 Descriptive analysis of diabetes self-management (DSMQ-R) and HbA1c

As per health literacy, all 381 participants compiled the 20-item questionnaire i.e., DSMQ-R. Descriptive analysis with the aid of SPSS was also analysed as in section 4.5 i.e., averages in SD and frequencies of different scores were converted into percentages as presented in Table 40 below. Altogether, this measured diabetes self-management.

As shown in Table 40, as with the HLS-EU-Q16, the DSMQ-R measured a similar dispersion (SD) varying between 1.388 to 0.795. Moreover, the highest SD showing that values are spread out were for; 'I check my blood sugar levels with care and attention' (SD = 1.388) followed by 'I tend to forget or skip taking my diabetes medication (e.g. insulin, tablets)' (SD = 1.249) and 'I take my diabetes medication consistently and reliably' (SD = 1.248). The three lowest SD showing that values were close to the mean were; 'I occasionally eat large amounts of sweets or other foods rich in carbohydrates' (SD = 0.795), 'I regularly see the doctor (/specialist) regarding my diabetes' (SD = 0.843), followed by 'sometimes I have real 'food binges' (not triggered by hypoglycaemia)' and 'I eat without regard to my diabetes', both having an identical SD (SD = 0.820).

The highest average mean score question, being the most difficult behaviours to carry out, was for the following: 'I take my diabetes medication consistently and reliably' (M= 2.60), followed by 'I regularly see the doctor (/diabetes specialist) regarding my diabetes' (M= 2.44) and 'the food I choose to eat makes it easy to achieve optimal blood sugar levels' (M= 2.28). Similarly, the lowest averages meaning the least behaviours carried out were for the following two statements; 'I tend to forget or skip taking my diabetes medication' (M= 0.94); and 'I occasionally eat large amounts of sweets or other foods rich in carbohydrates' (M=1.10). This was followed by a slightly higher average from the previous statement i.e., 'I avoid physical activity, although it would improve my diabetes' (M= 1.13).

Table 40: Descriptive analysis of diabetes self-management

The following statements describe self-care activities related to your diabetes. Thinking about your self-care over the last 8 weeks, please specify the extent to which each statement applies to you.	Applies to me very much	Applies to me to a considerable extent	Applies to me to some degree	Does not apply to me	Blood sugar measurement is not required as part of my treatment	Average (SD)
<i>17. I check my blood sugar levels with care and attention.</i>	30.9% (n=118)	39.4% (n=150)	10.5% (n=40)	12.6% (n=48)	6.6% (n=25)	2.22 (1.388)
18. The food I choose to eat makes it easy to achieve optimal blood sugar levels.	64.3% (n=245)	12.3% (n=47)	10.0% (n=38)	13.4% (n=51)	N/A	2.28 (1.098)
19. I regularly see the doctor (/diabetes specialist) regarding my diabetes.	60.1% (n=229)	31.5% (n=120)	1.0% (n=4)	7.3% (n=28)	N/A	2.44 (0.843)
<i>20. I take my diabetes medication (e. g. insulin, tablets) consistently and reliably</i>	51.7% (n=198)	30.8% (n=118)	2.6% (n=10)	7.8% (n=30)	6.6% (n=25)	2.60 (1.248)
21. I occasionally eat large amounts of sweets or other foods rich in carbohydrates.	9.2% (n=35)	9.4% (n=36)	63.5% (n=242)	17.8% (n=68)	N/A	1.10 (0.795)

22. <i>I keep a diary/log of my glucose levels to inform and improve my diabetes management.</i>	31.8% (n=121)	22.0% (n=84)	36.2% (n=138)	7.3% (n=28)	2.6% (n=10)	1.91 (1.179)
23. I tend to avoid seeing the doctor (/diabetes specialist) regarding my diabetes.	4.7% (n=18)	12.1% (n=46)	24.4% (n=93)	58.5% (n=224)	N/A	0.63 (0.872)
24. I am regularly physically active to improve my diabetes and health.	27.4% (n=105)	5.0% (n=19)	50.9% (n=194)	16.3% (n=62)	N/A	1.45 (1.086)
25. I follow the current dietary recommendations for people with diabetes (e.g. given to me by my doctor or diabetes specialist).	25.2% (n=96)	22.3% (n=85)	42.8% (n=163)	9.7% (n=37)	N/A	1.63 (0.966)
26. I do not check my glucose levels frequently enough for achieving good glucose control.	10.2% (n=39)	25.7% (n=98)	36.2% (n=138)	25.2% (n=96)	2.6% (n=10)	1.34 (1.209)
27. I avoid physical activity, although it would improve my diabetes.	9.7% (n=37)	15.2% (n=58)	53.0% (n=202)	22.0% (n=84)	N/A	1.13 (0.864)

28. I tend to forget or skip taking my diabetes medication (e. g. insulin, tablets).	10.4% (n=40)	3.9% (n=15)	38.6% (n=147)	44.4% (n=169)	2.6% (n=10)	0.94 (1.249)
29. Sometimes I have real ‘food binges’ (not triggered by hypoglycaemia).	14.4% (n=55)	14.7% (n=56)	63.3% (n=241)	7.6% (n=29)	N/A	1.36 (0.820)
30. Regarding my diabetes care, I should see my doctor (/diabetes specialist) more often.	18.6% (n=71)	11.3% (n=43)	61.9% (n=236)	8.1% (n=31)	N/A	1.40 (0.882)
31. I am less physically active than would be good for my diabetes.	12.9% (n=49)	23.4% (n=89)	45.1% (n=172)	18.6% (n=71)	N/A	1.30 (0.919)
32. I could improve my diabetes self-care considerably.	14.6% (n=56)	12.9% (n=49)	50.4% (n=192)	22.0% (n=84)	N/A	1.20 (0.948)
33. I estimate the carbohydrate content of my meals (to improve my diabetes control).	28.9% (n=110)	12.3% (n=47)	45.4% (n=173)	13.4% (n=51)	N/A	1.57 (1.046)
34. I eat without regard to my diabetes.	14.4% (n=55)	14.7% (n=56)	63.3% (n=241)	7.6% (n=29)	N/A	1.36 (0.820)
35. I check and discuss my diabetes treatment with the doctor (/diabetes specialist) regularly.	31.8% (n=121)	24.1% (n=94)	36.2% (n=138)	7.3% (n=28)	N/A	1.83 (1.016)

36. My diabetes self-care is poor.	14.7% (n=56)	12.9% (n=49)	50.4% (n=192)	22.0% (n=84)	N/A	1.20 (0.948)
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Questions in **bold** were recoded where 0 represented 3, 1 represented 2 and so on (specifically; Q21, Q23, Q26, Q27, Q28, Q29, Q30, Q31, Q32, Q34, Q36). Additionally, questions in *italics* had the option ‘not required as part of my treatment’ and obviously, the empty boxes had to be filled in by N/A (specifically questions that had the option; Q17, Q20, Q22, Q26, Q28).

As explained in chapter 3, after reverse coding the negatively worded statements, a scale score was generated for each diabetes self-management subscale ('medication taking', 'eating behaviour', 'glucose monitoring', 'physical activity' and 'cooperation with diabetes team'). Thereafter, the larger the subscale score, ranging from 0-3, the better is the diabetes self-management. As originally conducted by the authors, these subscales and the total final score were all then transformed to a scale out of 10 via an equation, to counteract the number of different items in each subscale. If an item was not required as part of the treatment plan option, 'system missing' was ticked in SPSS. Only 10 individuals responded to the 'not required treatment for all options'. Therefore, the scores were based on 371 individuals, except for the total score (in the descriptive statistics Table 41 and error bar graph Figure 29) which was based on 381 individuals.

A '**Friedman test**' was carried out to compare where the highest scores and the lowest scores fall. This resulted in $\chi^2(4) = 1066.301, p < .001$ implying that the mean scores significantly differ from each other. The highest mean score as shown in Table 41 was for 'medication-taking (M= 2.29) followed by; 'cooperation with diabetes team' (M= 2.01), 'glucose monitoring' (M= 1.84), 'eating behaviours' (M= 1.74) and the least mean score was for 'physical activity' (M= 1.65). Moreover, Table 41 presents the total final score of DSMQ-R, which adds all the five subscales into a mean of 6.20 and a median of 6.50. The latter total scores were higher as all items were included unlike specific subscales containing few items. Figure 28 shows an error bar graph which easily compares the mean rating scores of two statements simultaneously. Notably, the CIs for 'glucose management' and 'medication taking' do not intersect, indicating that the two mean rating scores are dissimilar and significantly differ. However, when 'glucose management' is compared with 'eating behaviour', CI overlap. This indicates that the two mean rating scores are similar and do not differ significantly. Figure 29 shows an error bar graph including the total final score of the DSMQ-R.

Table 41: Means and standard deviations of the classification of the diabetes self-management subscale scores in ascending order and total final score.

Descriptive Statistics				
	Mean	Median	Mode	Std. Deviation
Medication taking	2.29	2.50	3	0.796
Cooperation with diabetes team	2.01	2.25	2	0.525
Glucose monitoring	1.84	1.67	2	0.792
Eating behaviour	1.74	1.83	2	0.589
Physical activity	1.65	1.67	2	0.766
Total final score of DSMQ-R	6.20	6.50	7	1.892

$\chi^2(5) = 1066.301, p < .001$

Figure 26: Error bar graph for diabetes self-management subscales

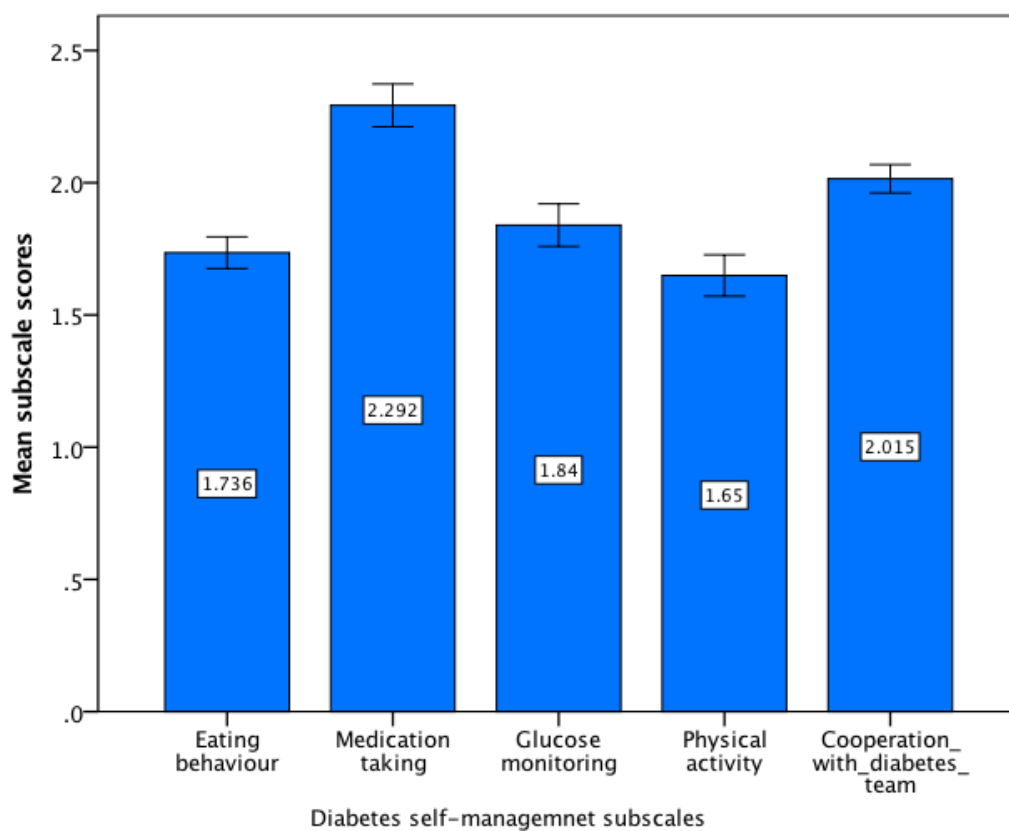


Figure 27: Error bar graph for diabetes self-management subscales and total score

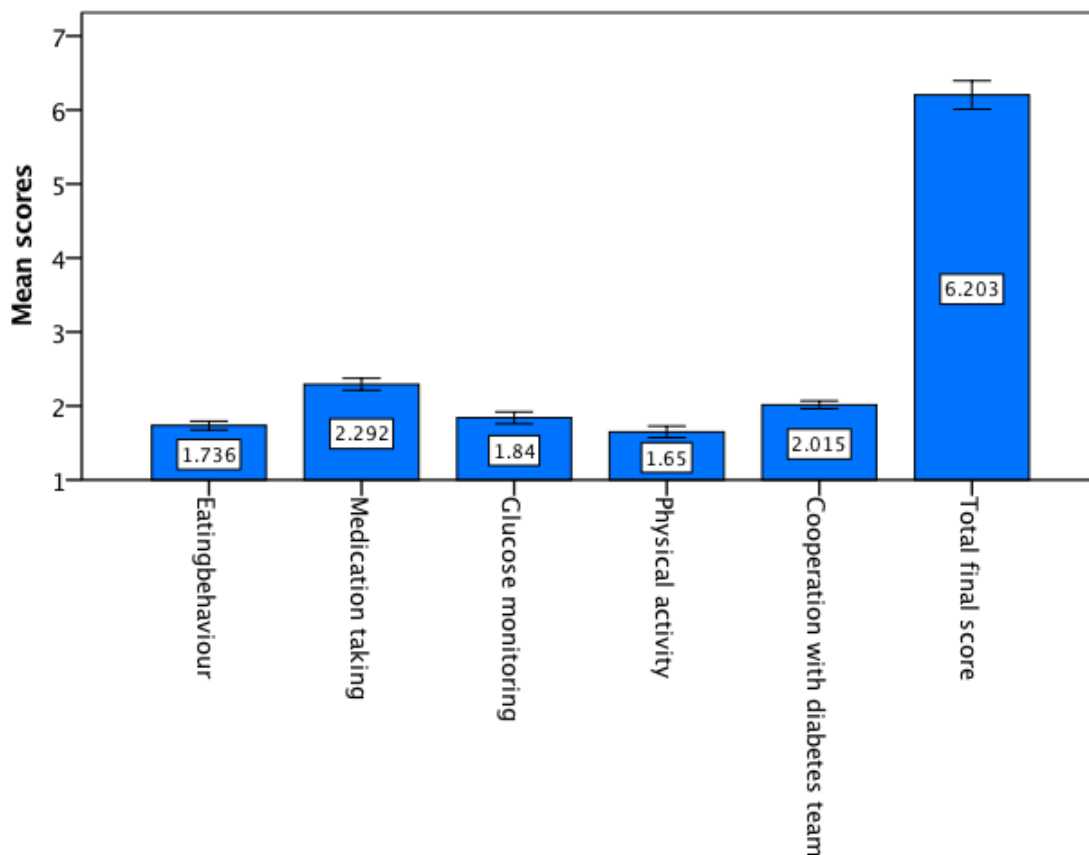


Table 42 identifies the ranges of HbA1c values in mmol/mol while, Table 43 classifies HbA1c ranges. Notably, the common HbA1c value was 64 mmol/mol, falling within range of the intermediate diabetes control. Moreover, the mean score was 71.61 and the median was 64.00 while the SD was 20.323. Out of all HbA1c values, 27% had good glycaemic control, 47.5% had medium glycaemic control and 25.5% had poor glycaemic control.

Table 42: Ranges of HbA1c in mmol/mol

Frequencies	HbA1c in mmol/mol
Mean	71.61
Median	64.00
Mode	64
SD	20.323

Table 43: Classification of HbA1c ranges, frequencies and percentages.

Glycaemic control (HbA1c)		Frequency	Percent (%)
Good	$\leq 58 \text{ mmol/mol}$ ($\leq 7.5\%$)	103	27.0
Medium	59-74 <i>mmol/mol</i> (7.6-8.9%)	181	47.5
Poor	$\geq 75 \text{ mmol/mol}$ ($\geq 9\%$)	97	25.5

4.9 Correlation statistics

A ‘Spearman correlation’ was used and its coefficient ranges from -1 to 1. A coefficient close to the latter positive value of 1 implied a strong positive relationship, whilst a negative coefficient value of -1 implied a strong negative relationship between the variables. The hypothesis of no difference specifies that there is no relationship between the variables and is accepted via a *p*-value of $> .05$ level of significance. The alternative hypothesis states that a significant relationship exists between the variables and is accepted if the *p*-value is $< .05$ level of significance.

4.9.1 Correlation between; health literacy and diabetes self-management

Health literacy is positively correlated to diabetes self-management as shown in Table 44 below. The correlation coefficient between health literacy and diabetes self-management is statistically significant that of 0.671 ($p < .001$). Therefore, it is indicating that individuals who have higher health literacy levels tend to better diabetes self-management.

4.9.2 Correlation between; health literacy and HbA1c, diabetes self-management and HbA1c

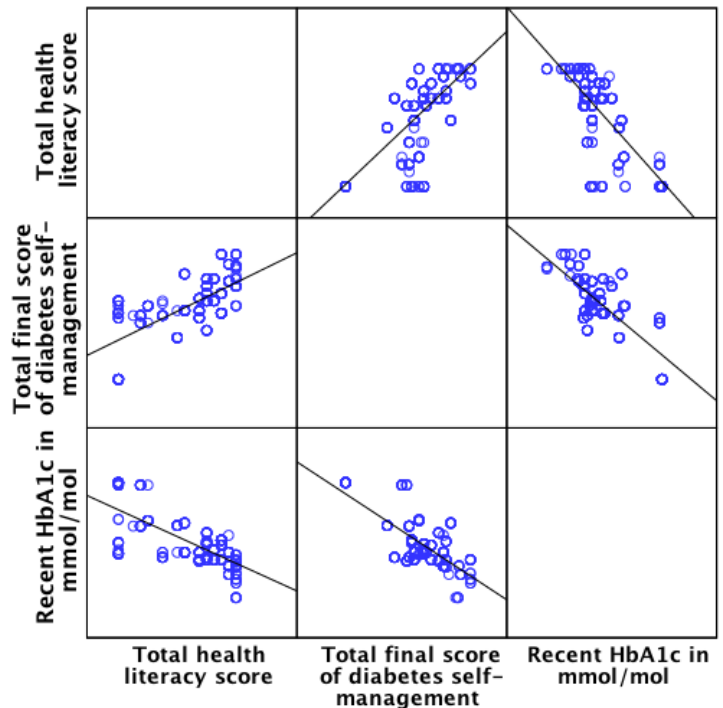
Also, in Table 44, health literacy and diabetes self-management are both negatively related to HbA1c levels. The correlation coefficient between health literacy and HbA1c is -0.606 ($p < .001$) and the correlation coefficient between diabetes self-management and HbA1c is -0.542 ($p < .001$). This indicates that individuals with lower health literacy and lower diabetes self-management tend to have higher HbA1c levels. Moreover, these negative relationships are significant since their p -values are $< .05$ level of significance. To further clarify this relationship, a scatter plot is presented in Figure 30 where a positive upward gradient indicates a positive relationship while a downward slope indicates a negative gradient, all previously highlighted. Appendix 6 presents further correlations that include all the diabetes self-management subscales.

Table 44: Summary of the correlation statistics

		Spearman Correlations		
		Health literacy	Diabetes Self-Management (total final score)	Recent HbA1c in mmol/mol
Health literacy	Correlation Coefficient	1.000	.671	-.606
	<i>P</i> -value	.	.000	.000
Diabetes Self-Management (total final score)	Correlation Coefficient	.671	1.000	-.542
	<i>P</i> -value	.000	.	.000
Recent HbA1c in mmol/mol	Correlation Coefficient	-.606	-.538	1.000
	<i>P</i> -value	.000	.000	.

Note correlation 1 means that when one variable is correlated with itself 1 will result. The highlighted numbers are what interest us most and they are statistically significant due to a p -value of $< .001$.

Figure 28: Scatter plot for the correlation between health literacy, diabetes self-management and HbA1c



4.10 Summary

A high internal consistency resulted in the reliability of both HLS-EU-Q16 and DSMQ-R scales due to Cronbach's alpha of > 0.9 . Due to the nature of the study, a high response rate cannot be identified. The 'Shapiro-Wilk test' showed that both health literacy and diabetes self-management data were skewed ($p < .001$). Therefore, non-parametric tests were used. The 'Kruskall-Wallis test' showed that all predictors of health literacy resulted in statistical significance ($p < .05$). However, when this was followed by the 'Mann Whitney test', not all predictors were statistically significant between their own classified groups. Moreover, Bonferroni corrections were also carried out and its p -value was set as the reference point of statistical significance. 'Multiple regression' was carried out for several independent variables predicting health literacy with an $R^2 = .497$. This showed that approximately 50% of the independent variables could be explained by health literacy. The best predictor of health literacy was educational level ($p < .001$). 'Spearman's correlations' identified that health literacy was positively and significantly related to diabetes self-management ($r_s = 0.671, p < .001$). This indicated that individuals who had higher health literacy levels tend

to have better diabetes self-management. Moreover, health literacy ($r_s = -0.606, p < .001$) and diabetes self-management ($r_s = -0.542, p < .001$) were both negatively and significantly related with HbA1c levels. This indicated that individuals with lower health literacy and lower diabetes self-management had higher HbA1c levels.

Chapter 5- Discussion

5.1 Introduction

This chapter presents a critical discussion of the findings in relation to this study's hypotheses, starting with the identification of health literacy levels amongst individuals with type 2 diabetes mellitus (T2DM) and the relationship between demographic variables and health literacy. This is followed by a critical discussion on diabetes self-management skills amongst individuals studied. Furthermore, the relationship between health literacy and diabetes self-management is discussed as well as between the aforementioned two variables and HbA1c. Outcomes are discussed in relation to the literature reported in chapter 2 and the theoretical framework for this study, the "Integrated Model of Healthy Literacy" (IMHL), with the presentation of practical implications and further research highlighted (Sørensen et al., (2012). Lastly, the strengths, weaknesses and biases of this study are identified.

5.2 Health literacy among persons living with T2DM.

This current study showed that low health literacy is highly prevalent in Maltese adults living with T2DM; 47% (n= 179) of the participants were classified as having inadequate health literacy and 12.6% (n= 48) were classified as having problematic health literacy, a total of 59.6%. Compared to a European study using the same tool as this study i.e., the European Health Literacy Survey Questionnaire (HLS-EU-Q16) where the general population in various EU countries was studied, namely Australian, Bulgarians, Germans, Greek, Irish, Dutch, Polish and Spanish, inadequate and problematic health literacy was reported to stand at 47% (n= 8000) of the sample (Sørensen et al., 2015). The results of the current study, therefore, demonstrated that persons living with T2DM in Malta had lower levels of health literacy than those in the latter European study.

The results of this current study also indicate that health literacy in this patient group is lower than that of the most recent study conducted earlier amongst the general Maltese population; the latter reported that 45.8% (n= 687) had inadequate and problematic health literacy (Attard, 2017; NSO, 2014). Both the current study and the aforementioned study used the same tool i.e., the HLS-EU-Q16. This shows that the latest yet old version of the ‘Health Literacy Survey: Malta 2014’ may need to be updated and/or that there may be lower health literacy amongst persons with T2DM. Moreover, when the latter survey was compared to that held in other EU countries mentioned above, it had less rate of individuals with limited health literacy (NSO, 2014; Sørensen et al., 2015). These results are important as international studies have highlighted that limited health literacy in T2DM increases adverse health outcomes (Kim, 2021; RobatSarpoooshi et al., 2020). In fact, when health literacy levels are low, these affect health awareness, preventive behaviours, and the ability to adhere to health-care programmes (RobatSarpoooshi et al., 2020). Health policies and practices are significantly challenging in Europe due limited health literacy in the latter population, however, different extent exists between countries and certain chronic diseases including T2DM. In fact, health literacy levels varied by 29-62% between countries studied in the European survey (Sørensen et al., 2015).

Less than half of the participants, specifically 40.4% (n= 154) classified as having sufficient health literacy in this current study, again lower than the EU and Maltese survey (NSO, 2014; Sørensen et al., 2015). A meta-analysis that specifically studied T2DM found that when using various tools to measure health literacy, adequacy rates of 67% (95% CI (57, 76) resulted (Guo et al., 2020). The level of health literacy of this current study is therefore much lower than the average health literacy rate previously mentioned. Moreover, two cross-sectional studies; one held in Iran and one held in Saudi Arabia, also reported that individuals living with T2DM had high health literacy adequacy rate of 50% or more when using the “Brief Health Literacy Screening Tool” (BRIEF) or “short-Test of

Functional Health Literacy in Adults” (sTOFHLLA) tools respectively (Niknami et al., 2018; Almigbal et al., 2020). Both aforementioned tools measure health literacy and are different from the tool used in this current study, yet also valid and well-known. However, a study conducted amongst Turkish individuals living with T2DM reported that only 15.5% (n= 41) of the sample had sufficient health literacy levels. Moreover, Turkish individuals with T2DM had poorer levels of health literacy than their general population, as in the current study (Ilhan et al., 2021, Tanrıöver et al., 2014). Both the current study and the latter cited study used the HLS-EU-Q to quantify health literacy. This resulted in T2DM Maltese having better health literacy scores than Turkish ones. As highlighted in chapter 2, this could be because Europe amongst other international countries classifies health literacy as an important aspect for practices and regulations in policy development (Hernandez et al., 2017). For example, health literacy was being emphasised at the workplace in corporate social responsibility, health education and clinical areas (Sørensen et al., 2017). However, results in this current study for adults living with T2DM in Malta were worse than those individuals living with T2DM in China, Iran and Saudi Arabia. This result could account for the fact that latter countries experienced exponential growth in health literacy research therefore, further empowerment, emphasis and outcome knowledge on this topic, leading to better health literacy levels (Bazm et al., 2019). Considering interventions involving simple oral communication, written communication, encouragement and linguistic or cultural sensitive may increase health literacy levels (Kim & Lee, 2016; Wang et al., 2018).

In line with the theoretical framework of IMHL presented in chapter 2, individual antecedents such as culture and political forces; integrate health literacy into their existing policies, health literacy goals and interventions. Moreover, the IMHL identifies consequences such as new knowledge that leads to an increase in health literacy (Freedman et al., 2009; Mancuso, 2008; Paasche-Orlow et al., 2007; Sørensen et al., 2012). All have an effect on the increase in health literacy levels.

5.3 Health literacy and sociodemographic variables

5.3.1 The relationship between educational levels and health literacy

The results of the multiple regression direct that the most positive and the strongest associated sociodemographic variable was between health literacy and a high level of education attainment ($t = 10.629, p < .001$). In line with other cross-sectional studies, one by Almigbal et al., (2020) (OR = .33, $p < .001$, 95% CI (0.18 to 0.59) and the other by Ilhan et al., (2021) ($R^2 = 0.245, p < .001$) found this significant relationship between the two variables (Almigbal et al., 2020; Niknami et al., 2018; Ilhan et al., 2021). Furthermore, high educational levels were also strongly seen in association with health literacy in a meta-analysis (OR: 8.39; $p < .001$, 95% CI (5.03, 13.99) (Guo et al., 2020). This finding is in line with previous results from a local survey which reported that those having tertiary education had higher health literacy levels than those with lower education (NSO, 2014). The positive relationship which resulted in higher levels of education to health literacy, implies the importance of diabetes education. Taking into account individual's educational level, in those who are at greatest risk of low health literacy, adapted educational materials customised to various levels of literacy should be used (Ilhan et al., 2021). However, these positive results must be taken with caution mainly because education does not consider lifelong learning, therefore, limiting education to a formal school setting. Moreover, the experience and skills gained through the healthcare system that all may have an account on the health literacy levels are not part of educational attainment. Lastly, education is broad and not every country has the same privileged levels of educational systems (Hahn & Truman, 2015). Malta when compared to other EU countries as explained in chapter 1 section 1.3.2, had the second highest basic level of education corresponding to lower secondary education (40.3%). However, few had upper secondary or post-secondary levels (31.7%) and fewer had tertiary levels of education (28%) (Eurostat, 2020). This current

study found the highest mean rank health literacy score for post-secondary education ($M = 12.81$) yet was not statistically significantly different to tertiary education ($U = 2327.5$, $p = .099$).

5.3.2 The relationship between household monthly Net income and health literacy

Secondly placed via multiple regression, a strong and significant association was between health literacy and the highest household monthly Net income ($t = 5.391$, $p < .001$). This significant result was in line with a meta-analysis by Guo et al., (2020) ($OR = 0.36$, 95% CI (0.23, 0.56); $p < .001$) and a cross-sectional study by Ilhan et al., (2021) ($F = 14.466$, $p < .001$), where those having high income had higher health literacy levels (Guo et al., 2020; Ilhan et al., 2021). Also, this significant relationship was found in another cross-sectional study where only the p -value was presented ($p < .05$), limiting the study (Niknami et al., 2018). Moreover, other countries outside Europe such as China identified that low-income is one of the health inequalities and found a positive relationship between income and health literacy (Tang et al., 2019). Also, the US and Denmark identified that low health literacy was commonly associated with the low socioeconomic groups (Rikard et al., 2016; Svendsen et al., 2020). A health literacy survey held in European countries also found that income is a significant predictor of health literacy (van der Heide et al., 2016). Moreover, the Maltese health literacy survey also found a positive relationship between the two (NSO, 2014). It is known that the less privileged are the most difficult to access education and information, portraying a social gradient (Ilie, Rose & Vignoles, 2021). Moreover, the poverty trap exists where it is an economic situation that one faces and is difficult to escape from. However, anti-poverty has always been an issue and may be reduced via public services (Chen et al., 2017). Furthermore, these health inequalities may be reduced by the right mix of governmental policies (WHO, 2018). This implies that interventions need to target income levels to improve health literacy. The interventions may be significant to

policymakers via financial incentives from both governmental and non-governmental organisations positively discriminating those with health inequalities.

5.3.3 The association between family history of diabetes and health literacy

Most individuals in this current study had a positive family history of DM as with another cross-sectional study (RobatSarpoooshi et al., 2020). Multivariate analysis, thirdly placed family history of diabetes as statistically significant to health literacy in this current study ($t = -4.912, p < .001$). In fact, positive family history of DM had higher health literacy scores when compared to no family history ($U = 9423, p < .001$). Nevertheless, no studies included in this current literature review studied this sociodemographic factor on health literacy. A study not included in this study literature review due to different aims and objectives mainly as did not study self-management, however, similarly found that individuals with a positive family history of T2DM had higher health literacy levels due to experiences gained from their family exposures (Tefera et al., 2020). Having a family history of DM may lead to an increased interest in the subject area. Results show that investing in one individual to increase in health literacy may lead to passed on/gained experiences through other family members. However, another study found that lower health literacy levels are significantly related to a positive family history of T2DM (Nacanabo et al., 2021).

5.3.4 The relationship between marital status and health literacy

The results of the multiple regression indicate that marital status is significantly and positively associated with health literacy ($t = 3.652, p = .001$). Married individuals having one of the best mean health literacy scores ($M = 10.05$) to its number of participants; being the most prominent in this study ($n = 234$) could suggest a form of support from their

spouse leading to an increase in health literacy when compared to other statuses. This significance was seen in another study not included in this current study's systematic review (SR) due to distinct inclusion and exclusion criteria of participants (Joveini et al., 2019). Results show the importance of including family members in one's care. However, no statistical significance was found in other studies included in this study's SR (Almigbal et al., 2020; Guo et al., 2020; Lee et al., 2017). Moreover, the 'Health Literacy Survey: Malta 2014' also had found no significant association (NSO, 2014).

5.3.5 The relationship between gender and health literacy

The results of the multiple regression indicate that gender is statistically significantly associated with health literacy ($t = 2.277, p = .016$). Males had statistically significantly higher health literacy rates than women ($U = 10965.5, p < .001$). This result must be taken with caution as the ratio of males to females was not the same but higher. Other literature contradicted the results of this current study as it showed that women are more proactive in taking care of their health than men towards diabetes (Almigbal et al., 2020; Quartuccio et al., 2018). The theoretical framework of IMHL did not include gender in its model (Sørensen et al., 2012).

5.3.6 The relationship between current working status and health literacy

Multivariate analysis identified working status as statistically significant ($t = 2.45, p = .016$) to health literacy. This statistical significance was present between working for pay/profit and unemployed ($U = 879, p < .001$). The significance of higher health literacy scores for the employed vs the unemployed was also seen in another two cross-sectional studies, one by Ilhan et al., (2021) ($t = -0.384, p < .05$) and the other by Niknami et al., (2018) ($t = 8.6, p$

< .05) (Ilhan et al., 2021; Niknami et al., 2018). This result may have accounted for due to the higher levels of education and income. However, the Maltese local survey contradicted the results as it found that the unemployed had better health literacy (NSO, 2014). For more accurate results as the population in this current study is predominantly older adults, with a chronic disease (T2DM), future research should also measure previous employment prior to retirement to reflect the health literacy levels more accurately.

5.3.7 The relationship between years of living with T2DM and health literacy

The results of the multivariate analysis for this current study identified living with DM as statistically significant ($t = -2.36, p = .042$) to the levels of health literacy. The highest mean health literacy score was for the greatest years of living with DM in this sample meaning between 61-70 years ($M = 15$ out of 16). However, this result must be taken with caution due to a low sample size ($n = 1$). Compared to the highest number of participants ($n = 237$), found those living with DM for 1-10 years had lower mean health literacy scores ($M = 9.78$). Although there was no statistically significant difference between those living with DM for 61-70 years to those living for 1-10 years ($U = 48, p = .414$). Acquiring knowledge from healthcare professionals (HCPs), seeking information from informal channels and learning from experience are all gained through the years of living with DM. From all the studies included in this study's SR, only one study studied this relationship and had statistically significant results for the longer years of living with DM ($t = -4.3, p < .001$) (Niknami et al., 2018).

5.3.8 The relationship between age group and health literacy

A statistically significant difference in the health literacy score for different age groups was identified via the Kruskal-Wallis H test $H(6) = 70.88, p < .001$. However, multiple

regression results identified no statistically significant difference between health literacy and age group ($SE = 0.139$, $t = 0.262$, $p = .793$). Results of this current study showed that most participants were 60+ ($n = 143$). In fact, persons with T2DM tend to be older (Khan et al., 2020). Therefore, this current study showed that age is not related to health literacy levels.

As the second model for multivariate analysis had no change from its initial model in R^2 of 0.497, age group in relation to health literacy is also explained here. A study found a positive association between T2DM in young adults and adequate health literacy scores, implying patients' age as an inverse correlation to health literacy (Guo et al., 2020).

Furthermore, other studies supported the aforementioned significant findings (Almigbal et al., 2020; Ilhan et al., 2021). Moreover, a local study found that young adults (≥ 25 years) had significantly higher levels than middle-aged (46-55 years) (NSO, 2014). The latter study has more reliable results due to a stratified sampling method used. Nonetheless, a randomised controlled trial (RCT) had unclear findings regarding health literacy and age (Lee et al., 2017).

5.3.9 The relationship between the use of information media and health literacy

A statistically significant difference in health literacy scores between various information media was identified via the Kruskal-Wallis H test, $H(8) = 61.66$, $p < .001$. However, multivariate analysis identified information media usage as statistically insignificant to health literacy ($SE = 0.106$, $t = 0.801$, $p = 0.423$). Therefore, this may indicate that formal health education programmes are required.

As the third model for multivariate analysis from its first model had a negligible change in R^2 of 0.497 to 0.496, information media in relation to health literacy is also explained here.

A cross-sectional study by Rachmawati et al., (2017) identified a relationship between health literacy and media usage. As respondents do not attend healthcare facilities frequently, there is a need for alternative, reachable and consistent media through which health information may be conveniently obtained (Newbold & Campos, 2011; Rachmawati et al., 2017). This media is the internet which could be used to maintain high health literacy amongst T2DM via content marketing to boost health and reduce the complexity of the healthcare system (Nicholson, 2019). In this current study, the use of social media and other media including books, television and the internet had the highest mean health literacy score for their cumulative usage ($M = 13.2$).

5.3.10 The relationship between locality area and health literacy

A statistically significant difference in health literacy scores between different localities was identified via the Kruskal-Wallis H test, $H(5) = 75.34$, $p < .001$. However, multiple regression identified no statistical significance between health literacy and locality area ($SE = 0.138$, $t = -0.870$, $p = .385$). As the fourth model for multivariate analysis had negligible change from its first model in R^2 of 0.497 to 0.496, locality area in relation to health literacy is also explained here. In keeping with the results, the insignificant result obtained between the two variables was also found in a local health literacy survey (NSO, 2014). The latter study due to the stratified sampling used could justify a more reliable result when compared to the current study. Accounting for the mixed results obtained in this current study, may suggest that as Malta is a small island, individuals may not always live in the same locality that they had lived during childhood, therefore, a definite difference in health literacy scores based on locality is difficult.

5.4 Self-management amongst persons living with T2DM.

The current study by using the diabetes self-management questionnaire-revised (DSMQ-R)

found medium-high diabetes self-management scores with a median of 6.5 (range: 1-10) (6.20 ± 1.892). The latter values in brackets portray the mean and standard deviation (SD) respectively. The latter indicates that data is quite close to the means and therefore, somewhat reliable. Similarly, a cross-sectional study that used an older version of the DSMQ (not the revised) found that T2DM individuals from Saudi Arabia had a median score of 39 (range: 7-47), mirroring high overall diabetes self-management (Almigbal et al., 2020). Due to an old version of this tool used in the previously cited study, its results must be taken with caution.

This current study identified the lowest subscale score for **physical activity** (1.65 ± 0.766). This implies the lack of physical activity five times per week (≥ 150 minutes), which was found adequate in T2DM (Shakoor et al., 2021). While, the study by Almigbal et al., (2020) had a moderate score for physical activity (5.8 ± 1.10). A low score for the aforementioned study resulted in healthcare-use (4.8 ± 1.2) (Almigbal et al., 2020). The highest mean subscale for this current study was for **medication taking** (2.29 ± 0.796) while for the study by Almigbal et al., (2020) was for glucose management (8.8 ± 2.30) (Almigbal et al., 2020). The result of the highest mean with regards to medication adherence in this current study was identical to a previous Maltese study also conducted on T2DM adults in 2008 (6.48 ± 0.57) (Gatt & Sammut, 2008). This could be because most diabetes medications are dispensed free by the local government to those entitled (has schedule V) and collected by the individual from pharmacies close to their home. Moreover, medication taking requires the least effort in terms of lifestyle change when compared to regular physical activity which requires effort and commitment. Once the new diabetes medication being studied locally; targeting insulin cells not to die is out on the market, may be the way forward (Falzon, 2022). Diverse groups of people have different preferences and beliefs toward medicine, highlighting the interplaying role of self-efficacy (Jarbøl et al., 2017).

An RCT by Lee et al., (2017) had a high and significant overall diabetes self-management

(83.27±11.62) post interventional behavioural educational programme involving: teach-back methods, goal-setting strategies, problem-solving skills, and short discussions (Lee et al., 2017). This programme may be suitable for use with the population of Maltese persons living with T2DM and should be tested in further research to explore whether diabetes self-management rates are improved. Moreover, this aforementioned programme may not only aid T2DM individuals but also improve diabetes nurse specialists' practices. In particular, diabetes nurse specialists in assisting with the diabetes self-management programme via initiating and following-it up. Similar to the current study but using the "Summary of Diabetes Self-Care Activities" (SDSCA) scale, the aforementioned RCT also found the highest mean subscale for medication adherence but post-test of the intervention. However, this high mean was not statistically significant between the intervention and control groups, where the latter did not consider individual's health literacy levels (intervention: 6.85±0.61, control: 6.82±0.56, overall $p > .05$). The lowest mean finding of the RCT was for diet which was also not statistically significant between groups (intervention: 4.53±1.3, control: 4.04±1.29, overall $p > .05$) (Lee et al., 2017). When the latter study was compared to a cross-sectional study that also used the SDSCA, the study by Kim (2021) held in South Korea had a lower overall SDSCA (3.54±1.21) score. The latter study had the highest mean subscale score for medication adherence (4.96±2.60) as with the study by Lee et al., (2017) and this current study (Kim, 2021; Lee et al., 2017). Nonetheless, the lowest mean score for the study by Kim (2021) was for blood glucose monitoring (2.02±2.65) (Kim, 2021). While another two cross-sectional studies that also used the SDSCA, only the study by RobatSarpoooshi et al., (2020) held in Iran presented an overall mean score which was classified as medium (34.85±12.19) (RobatSarpoooshi et al., 2020). Unlike the study by Bains & Egede, (2011) held in South Carolina which lacked overall presentation of diabetes self-management score when compared to the latter study (Bains & Egede, 2011). The two aforementioned studies contradicted the lowest mean subscale score of the RCT by Lee et al., (2017) regarding diet whereas the studies by Bains & Egede, (2011) (18.19±6.39) and

RobatSarpoooshi et al., (2020) (4.60 ± 0.20) scored the highest on a healthy diet. In the latter two cross-sectional studies' lowest mean scores were classified for physical activity (2.70 ± 0.20 ; 3.15 ± 2.51 , respectively) (Bains & Egede, 2011; RobatSarpoooshi et al., 2020). This result of low physical activity is similar to this current dissertation study.

In this current study, **blood glucose monitoring** ranked the third out of five scores of self-management ($M = 1.84$), meaning not very high. This implies that although the local government administers free self-test blood glucose devices with a prick, there is a need for non-invasive blood glucose monitoring. It would have been ideal to identify experiences of why local individuals are not adhering to blood glucose monitoring. A study in the US identified the need for a non-invasive blood glucose device to eliminate the common self-injecting fear and pain (White & Knezevich et al., 2020). However, no study is available in Malta to identify this in T2DM. The non-invasive device was piloted in Maltese children/adolescents with T1DM and was highly researched abroad also in T2DM resulting in positive outcomes (Sansone, 2021; Villena Gonzales, Mobashsher & Abbosh, 2019). However, this technology is suitable for mobile literate individuals only as it connects to one's mobile phone. This suggestion is still the way forward to eliminate overload on the public/private healthcare and one can manage his/her condition better. In fact, one can adjust diet and physical activity according to the readings together with the use of a provided diary/log containing guidelines.

This study fourthly placed **eating behaviour** with a low mean ($M = 1.74$) implying the lack of interventions on a very low-calorie diet that was found to put T2DM into remission (Juray et al., 2021; Shakoor et al., 2021). Teaching individuals how to make healthy food choices, especially incorporating food-assistance programmes or inspiring the cultivation of local crops is the way forward. Encouraging individuals to acquire food competency via healthy diet strategies may accept and show positive attitude abilities (Petroni et al., 2021).

Referral to and regular follow-up by dietitians and physiotherapists with expertise in diabetes management is the key (Harris-Hayes et al., 2020). Also, possibly behavioural or cognitive therapy to aid with lifestyle change. It is vital that the whole diabetes team reinforce what has been learnt. This would lead to an effective behaviour due to this current study classifying the subscale score of ‘cooperation with diabetes team’ as the second-best (2.01 ± 0.525). The government may consider reducing the tax on healthy food and exercise equipment. Moreover, marketing strategies via the media, posters, banners/billboards and leaflets to convey the message (Mattei & Alfonso, 2020).

Classifying individuals into adequate or inadequate diabetes self-management is “difficult to find a general threshold for suboptimal behaviours” (Schmitt et al., 2021, p.11).

Furthermore, required behaviours may differ widely by diabetes type, regimen or individual necessities.

5.5 The relationship between health literacy and diabetes self-management.

Correlation statistics, using a ‘Spearman’s correlations’ showed that health literacy was statistically significantly positively related to diabetes self-management ($r_s = 0.671, p < .001$). This indicates that individuals with high health literacy levels tend to have better diabetes self-management. In line with the results of other studies, this significant relationship was seen across five cross-sectional studies that were previously included in this dissertation literature review (Ilhan et al., 2021; Niknami et al., 2018; Rachmawati et al., 2019; RobatSarpooshi et al., 2020; Yarmohammadi et al., 2019). From the latter cited studies, only one study measured health literacy via the HLS-EU-Q, as this current study (Ilhan et al., 2021). Besides, measuring diabetes self-management via the DSMQ as this current study was only used by one study (Rachmawati et al., 2019). Additionally, a meta-analysis found a significant relationship between health literacy and diabetes self-care, yet weak ($r = 0.24, 95\% \text{ CI } (0.16, 0.31); p < .05$) (Guo et al., 2020). This weak relationship was

similar to the value of a cross-sectional study cited earlier ($r = 0.246, p = .01$) (Rachmawati et al., 2019). An RCT also found a significant association between health literacy and diabetes self-management scores ($p < .05$) (Lee et al., 2017). In line with the IMHL, it specifies that health literacy has various associated factors like behaviours that effect the individuals to function their role (Sørensen et al., 2012). Also, another researcher identified that positive health behaviours imply better health literacy (Baker, 2017).

As reported earlier, poor health literacy was identified in the sample of T2DM Maltese adults, yet their diabetes self-management was medium to high. This shows that there are other confounding factors between health literacy and diabetes self-management in this current sample. For example, self-efficacy or other forms of social support that were found to have statistically significant effect between both variables in a meta-analysis but were not studied in this current study (Guo et al., 2020). Additionally, through diabetes knowledge and patient activation mediators, health literacy had an indirect impact on diabetes self-care actions leading to further information processing and encouragement (Kim, 2021). Therefore, future research may study these additional confounders.

Although previously cited literature included in this dissertation review appears to point towards an association, other studies including cross-sectional studies found no significant association between health literacy and diabetes self-management (Almighal et al., 2020; Bains & Egede, 2011; Kim, 2021). The absence of association in all three latter studies may be ascribed to the design and small sample size. Moreover, a SR found no association between the variables (Fransen et al., 2012). Lastly, inconclusive results between health literacy levels and diabetes self-management were found in a SR, opening the field to more research (Dahal & Hosseinzadeh, 2019).

Targeting health warning behaviour to convey the message may be the most ideal source for the population of interest. This is based on the fact that participants in this current study's health literacy part questionnaire found health warning behaviour very easy to understand ($M = 1.98$). This may in turn lead to positive T2DM self-management, aiming for improvement in physical activity and eating behaviours as emerged low from this current study results. Therefore, for the population of interest, campaigns may creatively and effectively promote preventive health services overuse, the initiation of health literacy related interventions and diabetes self-management programmes (Liao, 2020).

5.6 The relationship between health literacy and glycaemic control (HbA1c).

In this current study, 'Spearman's correlation' showed a statistically significant negative correlation between health literacy and HbA1c ($r_s = -0.606, p < .001$). This shows that individuals with low health literacy have significantly higher HbA1c, indicating poorer control of blood glucose. Similarly, two cross-sectional studies found the same association (Niknami et al., 2018; Yarmohammadi et al., 2019). Furthermore, a SR with meta-analysis showed a significant association between levels of health literacy and their glycaemic control (Kim & Lee, 2016). Moreover, a meta-analysis also presented this inverse significant relationship between health literacy and HbA1c in its pooling of results ($r = -0.08; 95\% \text{ CI } (-0.14, -0.03); p = .001$) (Guo et al., 2020).

Contrastingly, two cross-sectional studies showed no relationship between health literacy scores and HbA1c (Bains & Egede, 2011; Ilhan et al., 2021). It is worth noting that the cross-sectional study by Bains & Egede, (2011) was included in a SR by Fransen et al., (2012), amongst other studies that also accounted for no relationship between health literacy and HbA1c (Bains & Egede, 2011; Fransen et al., 2012; Mancuso, 2010; Osborn et al., 2010). Besides no relationship, the SR by Fransen et al., (2012) also found inconstancy

between the association of health literacy and glycaemic control (Fransen et al., 2012). In fact, inconsistent data on the impact of health literacy on glycaemic control has been reported across the years (Fransen et al., 2012; Rothman et al., 2002; Schillinger et al., 2002; Mancuso et al., 2010; Osborn et al., 2010; Williams et al., 1993; Tang et al., 2008). Later, an RCT found no significant association post-test for the intervention and control group between the two variables (HbA1c for; intervention 6.51 ± 0.83 , control; 6.73 ± 1.29 ; $t = 1.08$, overall $p > .05$) (Lee et al., 2017). While the other RCT included in this dissertation review did not present results for HbA1c and wrote in the discussion section that the association between health literacy and HbA1c level can be assumed after a 1-year intervention, showing weakness of the study in addition to the lack of no statistical results presentation (Xu et al., 2014). Inconclusive results were also obtained for the association between health literacy and HbA1c in a particular SR (Dahal & Hosseinzadeh, 2019). This opens up for further research.

A clinical recommendation for HCPs is the initiation of a health literacy assessment tool for those newly diagnosed with T2DM. The latter diagnosis criteria should be based on that of the ‘American Diabetes Association’ (ADA) as found in chapter 1 under section 1.2.1.3. Subsequently, identify if one is able to manage his/her condition effectively on their own (Cawthon et al., 2014). In this way targeting those with the greatest need given the high demand for education and healthcare.

5.7 The relationship between diabetes self-management and glycaemic control (HbA1c).

As with health literacy and HbA1c, a ‘Spearman’s correlation’ identified diabetes self-management as statistically significant and negatively correlated with HbA1c levels ($r_s = -0.542$, $p < .05$). This shows that individuals with low diabetes self-management have significantly higher HbA1c, indicating poorer control of blood glucose. This correlation

was also seen in two cross-sectional studies (Ilhan et al., 2021; Saleh et al., 2021). However, no association was found in four cross-sectional studies included in this dissertation review (Almigbal et al., 2020; Bains & Egede, 2011; Niknami et al., 2018; Yarmohammadi et al., 2019). Additionally, no association was found in another study design i.e., an RCT (Lee et al., 2017). No study included in this dissertation review found inconsistency between diabetes self-management and glycaemic control (HbA1c). Besides, other studies included in this dissertation review did not study this relationship (Dahal & Hosseinzadeh, 2019; Fransen et al., 2012; Guo et al., 2020; Kim, 2021; Kim & Lee, 2016; Rachmawati et al., 2019; RobotSarpooshi et al., 2020; Xu et al., 2014).

Implications of current study results show that the ability to maintain glycaemic control has been connected to adequate diabetes self-management. Therefore, the individual needs to be at the center of the health team and needs to be empowered to self-manage T2DM (Arda Sürücü et al., 2018; Hurst, Rakkapao, & Hay, 2020).

5.8 Strength, weaknesses and bias

5.8.1 Design

A cross-sectional study was appropriately used due to the research topic being non-experimental that of health literacy and diabetes self-management. Moreover, this type of design allowed the measurement and estimation of the correlation between scores. Also, cross-sectional designs are easy and inexpensive. This design gives a snapshot of this particular topic at a single point in time (Kesmodel, 2018). However, the drawback of the design is that it does not infer causality as only the relationship between variables is presented (Wang & Cheng, 2020). Moreover, experiences affecting both the lack of health

literacy and diabetes self-management were missed to be directly targeted. Also, **recall bias** may have occurred due to past exposure and knowledge.

5.8.2 Methodology

A convenience sample was used in this current study. This is an easy and simple technique however, it lacks generalizability and causality, unlike probability samples that yield large generalisability (Jager et al., 2017). However, for probability sampling, details of the patients had to be known leading to breaching of confidentiality. Moreover, if stratification had been used, detailed information apart from age such as residency of the individuals had to be known which could have led to the identification of the participant. Thankfully though the sample size consisted of participants from different localities as individuals from all over Malta attended the outpatients departments. All T2DM individuals who were classified as eligible by the intermediary after an informed and autonomous decision-making process; had no initial contact with the researcher. Moreover, the researcher did not have access to the patients' daily list and all individuals satisfying the inclusion and exclusion criteria had the opportunity to join this study. This reduced **selection biases** however, those who did not attend were missed. Blinding of subjects was not possible as T2DM individuals were attending their diabetes appointment. It would not have been feasible to study patients attending health centres and GP too; hence the two main outpatients departments were chosen. This was based on the latter's strategic positions, uniformity in their management strategies, free healthcare and time. However, those individuals that attended health centres and GP, who could also have been eligible were missed.

5.8.3 Internal and external validity of tools used and drawbacks

No gold standard health literacy tool exists to measure health literacy, leading to inevitable methodological issues when comparing results. This is mostly seen with self-reporting of health literacy leading to **subjective bias** (Schulz et al., 2021). To reduce this, the latest and shortest version of the HLS-EU-Q was used. Moreover, the HLS-EU-Q16 tool was chosen as it had already been used in the Maltese population (NSO, 2014).

The DSMQ-R was used as it is a recently available diabetes self-management tool revised in 2020 therefore, assesses the latest behaviours since these may change over time. Moreover, it is superior and practical to others as it has specific questions targeted and classified for T2DM (Schmitt et al., 2021).

The HLS-EU-Q16 and DSMQ-R were previously validated and reliably tested. Besides, internal and external validity were conducted by the original authors, these were also performed for this current study's pilot study and the actual study, all leading to positive results. These were performed by using Cronbach's alpha (α) for the internal validity of both the pilot and actual study whilst, test re-test reliability via the intra-class correlation coefficient (ICC) was only used for the pilot study for stability. Cronbach's α in the pilot study for the HLS-EU-Q16 resulted in 0.99 and for the DSMQ-R resulted in 0.93. While the ICC resulted in 0.997, showing minimal variability, therefore, consistent between each test. For the actual study, the HLS-EU-Q16 resulted in 0.975 and the DSMQ-R resulted in 0.914, showing high internal consistency. The DSMQ-R tool originally had negatively worded statements, these were kept and recoded after the actual study to reduce **acquiescence bias** where the participant had to read all the questions and not agree with the previous question.

The HLS-EU-Q16 being printed or read-out-loud, from the personal health literacy definition, rightly studied individual's ability to; locate, comprehend, apply information and services to inform health-related decisions and actions for themselves but did not study the effect on others. The drawback of the DSMQ-R included the exclusion of foot care as part of the measurement which is a critical diabetes self-care practice (Hirpha, Tatiparthi, & Mulugeta, 2020).

5.8.4 Response and representativeness

The short period (November-December 2021) of the study was overcome by the consistent attendance of the researcher from Monday to Saturday. Questionnaires were compiled either as self-administrative or as structured interviews wherein the latter, the intermediary aided illiterate and visually impaired individuals. Structured interviews reduced **observer bias**, ensured equity and inclusion within the eligible population and agreed with the health literacy definition. In fact, most respondents required assistance. However, those with 'severe mental impairment' (SMI) were excluded as other tools had to be used for those not mentally fit to respond. To have identified whether the response rate was high, a random sample would have been ideal. Nonetheless, a full required sample size for the study was achieved with a 95% confidence level, a 5% margin of error, resulting in 381 participants that were conveniently recruited and this reduced 'Type II' error. A p -value of .05 was used as a cut-off point for statistical significance. With the exception to the 'Bonferroni correction'; performed between health literacy and the various demographic factors. As the latter significant result followed the smaller p -value of the 'Bonferroni correction' to identify true significance. The survey study was comprehensive, and a direct recruitment strategy was applied. However, generalisability beyond this sample must be taken cautiously since no stratified random sampling was carried out, leading to a disproportionate number of males and females. Moreover, at first glimpse participants may

have responded to questions in the questionnaire in the desired manner that they think the researcher wants without reading the proper instructions leading to social **desirability bias**. Furthermore, the inclusion and exclusion criteria were set for the topic of interest on real-life basis and target population, hindering generalisability beyond this subject.

5.9 Summary

The research results aimed to help influence practice with the hope of promoting change, for the ultimate benefit of the patients.

Implications of low health literacy in this sample show that oral communication, written communication, encouragement and linguistic or cultural sensitive interventions may be suitable to improve health literacy levels. During interventions, educational levels need to be considered due to a positive strong relationship between health literacy on higher levels of education in this study. Moreover, by adapting educational material customised to various levels of literacy. Therefore, diabetes education is the key. Furthermore, due to a significant association between health literacy and income, policymakers may ensure the right mix of governmental policies by for example positively discriminating those with health inequalities via financial assistive interventions. Also, investing in one individual to increase health literacy may lead to passed on/gained experiences through other family members.

Increasing the medium-high diabetes self-management that was found in this current study particularly by targeting physical activity, dietary control and blood glucose monitoring. The latter three behaviours were found lower in this current study when compared to the other subscales of medication taking and cooperation with the diabetes team. Moreover, diabetes self-management programmes involving: teach-back methods, goal-setting strategies, problem-solving skills, and short discussions may be useful in increasing

diabetes self-management. This programme should be tested in further research to explore whether diabetes self-management rates are improving. Referral to and regular follow-up by dietitians and physiotherapists with expertise in diabetes management is the key. Also, possibly behavioural or cognitive therapy to aid with lifestyle change. It is vital that the whole diabetes team reinforce what has been learnt. The government may consider reducing the tax on healthy food and exercise equipment. Additionally, free administration of non-invasive blood glucose monitors to those living with T2DM. Then, one can adjust healthy food choices and amount of physical activity according to the readings together with the use of a provided diary/log containing guidelines.

Glycaemic control is the main target between both an increase in health literacy and diabetes self-management. Therefore, health warnings about behaviour and diabetes education are the key. Due to a positive result between health literacy and glycaemic control, the initiation of a health literacy assessment tool for use with those newly diagnosed with T2DM is recommended. In this way targeting those with the greatest need in view of the high demand for education and healthcare. Additionally, the statistically significant relationship between diabetes self-management and glycaemic control showed that the individual needs to be at the center of the health team and needs to be empowered to self-manage T2DM (Hurst, Rakkapao, & Hay, 2020).

Chapter 6- Conclusion and recommendations

6.1 Introduction

This chapter concludes this dissertation and presents recommendations for improving health literacy and diabetes self-management. This is based on a summary of the work of this dissertation based in light of earlier identified evidence

6.2 Main points that emerge from this research

6.2.1 Association between health literacy and glycaemic control (HbA1c).

Health literacy was inversely and statistically significantly associated with HbA1c. This indicated that individuals with low health literacy levels had significantly higher HbA1c, indicating poorer control of blood glucose.

6.2.2 Association between health literacy scores and diabetes self-management scores.

This current study showed that both health literacy and diabetes self-management were positively and statistically significantly associated. This meant that individuals living with type 2 diabetes mellitus (T2DM) having higher health literacy levels increases the likelihood of having better diabetes self-management. Implications of results showed that glycaemic control is the main target between both variables. However, an overall low health literacy level was identified in this sample of Maltese adults living with T2DM, yet their diabetes self-management was scored medium to high. This showed that there are other confounding factors between health literacy and diabetes self-management other than glycaemic control in this current study.

6.2.3 Association between diabetes self-management and glycaemic control (HbA1c).

As with health literacy and HbA1c, diabetes self-management was inversely and statistically significantly associated with HbA1c levels. This indicated that individuals with low diabetes self-management had significantly higher HbA1c, again indicating poorer control of blood glucose.

6.2.4 Differences in the levels of health literacy between individuals with T2DM.

This current dissertation showed that reduced health literacy is highly prevalent in Maltese adults living with T2DM with a ratio of 1:5 individuals having inadequate or problematic health literacy respectively. Where 47% had inadequate health literacy and 12.6% had problematic health literacy. Besides, 40.4% had sufficient health literacy levels when using the 'European health literacy survey questionnaire' (HLS-EU-Q16).

6.2.5 Association between sociodemographic variables and individual differences in health literacy.

Firstly, and secondly, health literacy was positively and significantly associated with high levels of education and household monthly Net income as identified via multiple regression conducted in this current study. The highest mean scores were for individuals with post-secondary education and the highest income group included in this dissertation (>€2446). Thirdly, in this current study family history of diabetes was statistically significantly related to health literacy. Fourthly, multiple regression showed that marital status mainly among married individuals was significantly and positively associated with health literacy. Fifthly, gender was also statistically significantly associated with health literacy in this current

study; men had higher health literacy scores when compared to females. Sixthly, multivariate analysis identified working status as statistically significant to health literacy. This significant result was mainly seen between working for pay/profit to those unemployed. Seventhly, years of living with T2DM was statistically significantly related to health literacy. In fact, a higher mean health literacy score was present in the longest years of living with diabetes mellitus (DM) (61-70 years), however not statistically significant between other group years, therefore, this result must be taken with caution.

On the other hand, multiple regression identified no statistical significance between health literacy and the following: age group, information media usage and locality. Considered with other variables via multiple regression the latter three variables did not remain as important variables as other variables compensated for. The latter result agreed with the null hypothesis of no association between certain sociodemographic variables and individual differences in health literacy. However, all variables were kept in the model due to no change or negligible change in R^2 of 0.497 to 0.496 when excluding the insignificant variables.

6.2.6 Differences in the measurements of diabetes self-management amongst persons living with T2DM.

Diabetes self-management in this current study found that Maltese adults living with T2DM had a medium-high adequacy rate when using the 'diabetes self-management questionnaire-revised' (DSMQ-R). The highest subscale score was for medication taking, followed by cooperation with the diabetes team, glucose management, eating behaviour and the lowest subscale score was for physical activity.

As to adequate and inadequate diabetes self-management behaviours the DSMQ-R tool did

not classify them due to the difficulty in finding a general threshold for suboptimal behaviours (Schmitt et al., 2021). Moreover, various behaviours differ widely by diabetes type, regimen or individual necessities.

6.3 Recommendations

6.3.1 Recommendations for practice

A clinical recommendation for healthcare professionals (HCPs) is the initiation of a health literacy assessment tool for use with those diagnosed with T2DM at their first outpatients appointment. This targets those with greatest need in view of the high demand for education and healthcare. The individual needs to be at the center of the health team and needs to be empowered to self-manage T2DM. Therefore, improving their glycaemic control is the main target between health literacy and diabetes self-management.

Formal health literacy and behavioural educative programmes are needed to increase health literacy and diabetes self-management levels in Maltese adults living with T2DM. Health literacy interventions involving simple oral communication, written communication, encouragement and linguistic or cultural sensitive are vital. Diabetes self-management involving teach-back methods, goal-setting strategies, problem-solving skills, and short discussions are ideal. These programmes may not only aid T2DM individuals but also improve diabetes nurses' practices in initiating and following them up.

Early referral to and regular follow-up by dietitians and physiotherapists with expertise in diabetes management is the key. Also, possibly behavioural or cognitive therapy to aid with lifestyle change. The whole diabetes team must reinforce what has been learnt. All this leads to reduced therapeutic inertia, which impairs glycaemic targets and increases diabetes-related complications (Karam et al., 2020).

Policymakers should ensure the right mix of governmental health literacy policies and financial incentives from both governmental and non-governmental organisations positively discriminating those with health inequalities. Investing in one individual to increase health literacy may lead to passed on/gained experiences through other family members previously diagnosed with DM. Including family members in one's care is an important form of support.

Administration of free non-invasive blood glucose monitors may increase blood glucose monitoring. Therefore, eliminate overload on the public/private healthcare and one can self-manage his/her condition better. In fact, as recommended by the World Health Organisation (WHO) digital health strategies in investing in clinical and medical data in real-time should be adopted (WHO, 2021). The latter is currently being done with the use of paperless documents due to Covid-19 and should continue to further ensure continuity of care. Furthermore, introduce technology enabling models of care that aid in diabetes self-management and psychosocial support such as mobile apps, digital treatments, online programmes, and online peer groups including either local or international communities (Davis et al., 2022). The government may consider reducing the tax on healthy food and exercise equipment.

6.3.2 Recommendations for education

Health warning behaviour to convey the message may be the most ideal source. This could be done via marketing strategies such as the media, posters, banners/billboards and leaflets to convey the message. Also, campaigns may creatively and effectively promote preventive health services overuse and the initiation of health literacy and behavioural educational programmes (Liao, 2020). Educational material customised to various levels of literacy should be adopted in programmes to include all the population.

Educating the public on how to: use non-invasive monitors, adjust diet and physical activity according to the readings and providing a diary/log with guidelines may improve diabetes self-management. Moreover, teaching individuals how to make healthy food choices, incorporating food-assistance programmes or inspiring the cultivation of local crops. Encouraging individuals to acquire food competency via healthy diet strategies may accept and show positive attitude abilities. Once the Maltese obesity strategy guidelines are out, T2DM individuals must follow them. In particular healthy eating and regular physical activity, due to the latter two factors resulted in low self-management in this current study. Increasing adherence, educating the public via oral and written communication strategies, empowerment, and linguistic or cultural sensitivity may in turn prevent diabetes complications.

6.3.3 Recommendations for research

Future research may study additional confounders between health literacy and diabetes self-management. Health literacy programmes and behavioural educative programmes should be tested in further research to explore whether health literacy and diabetes self-management rates respectively improved. A mixed-method approach to identify experiences of individuals of what is hindering or aiding their diabetes self-management and target them accordingly is an addition to this research.

6.4 Conclusion

This dissertation is an asset to the limited studies on health literacy and diabetes self-management found in Europe and a basis for future research. Moreover, low health literacy as found prevalent in this dissertation was associated with worse diabetes self-management, yet this study resulted in medium-high diabetes self-management. This opens the field for more research to study other confounders in addition to glycaemic control. As the European

population is following an ageing curve, this implies an increase in; chronic diseases, health outcomes, higher costs and healthcare use. Therefore, improving health literacy and diabetes self-management offers activation in society and leads to independence (Visscher et al., 2018). Addressing social determinants of health literacy may positively lead to optimal health outcomes and reduced inequalities.

References

- “A National Public Health Priority: A National Strategy for Diabetes 2016-2020.”
Available from <https://deputyprimeminister.gov.mt/en/Documents/National-Health-Strategies/NDS-EN.pdf>
- Adu, M., Malabu, U., Malau-Aduli, A., & Malau-Aduli, B. (2019). Enablers and barriers to effective diabetes self-management: A multi-national investigation. *PLOS ONE*, 14(6), e0217771. doi: 10.1371/journal.pone.0217771
- Aggarwal, R., & Ranganathan, P. (2019). Study designs: Part 2 - Descriptive studies. *Perspectives in clinical research*, 10(1), 34–36.
https://doi.org/10.4103/picr.PICR_154_18
- Al Sayah, F., Majumdar, S. R., Williams, B., Robertson, S., & Johnson, J. A. (2013). Health literacy and health outcomes in diabetes: a systematic review. *Journal of general internal medicine*, 28(3), 444-452. doi: 10.1007/s11606-012-2241-z
- Almighal, T. H., Almutairi, K. M., Vinluan, J. M., Batais, M. A., Alodhayani, A., Alonazi, W. B., Sheshah, E., & Alhoqail, R. I. (2019). Association of health literacy and self-management practices and psychological factor among patients with type 2 diabetes mellitus in Saudi Arabia. *Saudi medical journal*, 40(11), 1158–1166.
<https://doi.org/10.15537/smj.2019.11.24585>
- Alvarez, S., Coffey, R., & Algotar, A. M. (2017). Prediabetes.
- American Diabetes Association. (2014). Diagnosis and classification of diabetes mellitus. *Diabetes care*, 37(Supplement 1), S81-S90.
- American Diabetes Association. (2021). Obesity management for the treatment of type 2 diabetes: Standards of Medical Care in Diabetes—2021. *Diabetes Care*, 43(Supplement 1), S89-S97. DOI: 10.2337/dc21-S008
- American Diabetes Association’ (ADA), (2020). Classification and Diagnosis of Diabetes: Standards of Medical Care in Diabetes—2020. <https://doi.org/10.2337/dc20-S002>
- Andrade C. (2020). Understanding the Difference Between Standard Deviation and Standard Error of the Mean, and Knowing When to Use Which. *Indian journal of psychological medicine*, 42(4), 409–410.
<https://doi.org/10.1177/0253717620933419>
- Andrade C. (2021). The Inconvenient Truth About Convenience and Purposive Samples. *Indian journal of psychological medicine*, 43(1), 86–88.
<https://doi.org/10.1177/0253717620977000>

- Ansari, R. M., Hosseinzadeh, H., Harris, M., & Zwar, N. (2019). Self-management experiences among middle-aged population of rural area of Pakistan with type 2 diabetes: a qualitative analysis. *Clinical Epidemiology and Global Health*, 7(2), 177-183. <https://doi.org/10.1016/j.cegh.2018.04.003>
- Arda Sürücü, H., Büyükkaya Besen, D., & Erbil, E. Y. (2018). Empowerment and social support as predictors of self-care behaviors and glycemic control in individuals with type 2 diabetes. *Clinical nursing research*, 27(4), 395-413. <https://doi.org/10.1177/1054773816688940>
- Association of Diabetes Care and Education Specialists, & Kolb, L. (2021). An Effective Model of Diabetes Care and Education: The ADCES7 Self-Care Behaviors™. *The Science of Diabetes Self-Management and Care*, 47(1), 30-53.
- Asunta, P., Viholainen, H., Ahonen, T., & Rintala, P. (2019). Psychometric properties of observational tools for identifying motor difficulties—a systematic review. *BMC pediatrics*, 19(1), 1-13. doi.org/10.1186/s12887-019-1657-6
- Attard, J. (2017). Health Literacy: An Introduction. MAPHM. Retrieved 15 May 2021, from <https://maphm.org/2017/10/24/health-literacy-an-introduction/>.
- Ayre, J., Bonner, C., Muscat, D. M., Bramwell, S., McClelland, S., Jayaballa, R., Maberly, G., & McCaffery, K. (2021). Type 2 diabetes self-management schemas across diverse health literacy levels: A qualitative investigation. *Psychology & Health*. <https://doi-org.ejournals.um.edu.mt/10.1080/08870446.2021.1909023>
- Baghaei, P., Zandi, M., Vares, Z., Masoudi Alavi, N., & Adib-Hajbaghery, M. (2008). Self-care situation in diabetic patients referring to Kashan Diabetes Center, in 2005. *KAUMS Journal (Feyz)*, 12(1), 88-93. <http://feyz.kaums.ac.ir/article-1-23-en.html>
- Bailey, S. C., Brega, A. G., Crutchfield, T. M., Elasy, T., Herr, H., Kaphingst, K., ... & Schillinger, D. (2014). Update on health literacy and diabetes. *The Diabetes Educator*, 40(5), 581-604. [doi:10.1177/0145721714540220](https://doi.org/10.1177/0145721714540220)
- Bains, S. S., & Egede, L. E. (2011). Associations between health literacy, diabetes knowledge, self-care behaviors, and glycemic control in a low-income population with type 2 diabetes. *Diabetes technology & therapeutics*, 13(3), 335-341. <https://doi.org/10.1089/dia.2010.0160>
- Baker, D. W. (2006). The meaning and the measure of health literacy. *Journal of general internal medicine*, 21(8), 878-883.
- Baker, H. (2017). Limited health literacy: a key issue facing patients accessing the NHS. *Journal of Kidney Care*, 2(4), 216-218. <https://doi.org/10.12968/jokc.2017.2.4.216>

- Bandura, A. (2004). Health Promotion by Social Cognitive Means. *Health Education & Behavior*, 31(2), 143–164. <https://doi.org/10.1177/1090198104263660>
- Barati, M. (2014). Predicting factors related to self-care behaviors among type 2 diabetic patients based on health belief model. *Journal of Torbat Heydariyeh University of Medical Sciences*, 1(4), 16-25. DOI: 10.12691/ajnr-8-1-13
- Bas-Sarmiento, P., Poza-Méndez, M., Fernández-Gutiérrez, M., González-Caballero, J. L., & Falcón Romero, M. (2020). Psychometric Assessment of the European Health Literacy Survey Questionnaire (HLS-EU-Q16) for Arabic/French-Speaking Migrants in Southern Europe. *International journal of environmental research and public health*, 17(21), 8181. <https://doi.org/10.3390/ijerph17218181>
- Baumeister, A., Chakraverty, D., Aldin, A., Seven, Ü. S., Skoetz, N., Kalbe, E., & Woopen, C. (2021). "The system has to be health literate, too" - perspectives among healthcare professionals on health literacy in transcultural treatment settings. *BMC health services research*, 21(1), 716. <https://doi.org/10.1186/s12913-021-06614-x>
- Bazm, S., Bazm, R., & Sardari, F. (2019). Growth of health literacy research activity in three Middle Eastern countries. *BMJ health & care informatics*, 26(1). doi: 10.1136/bmjhci-2019-000027
- Berkman, N. D., Sheridan, S. L., Donahue, K. E., Halpern, D. J., Viera, A., Crotty, K., ... & Viswanathan, M. (2011). Health literacy interventions and outcomes: an updated systematic review. *Evidence report/technology assessment*, (199), 1-941.
- Beverly, E. A., Fitzgerald, S. M., Brooks, K. M., Hultgren, B. A., Ganda, O. P., Munshi, M., & Weinger, K. (2013). Impact of reinforcement of diabetes self-care on poorly controlled diabetes: a randomized controlled trial. *The Diabetes Educator*, 39(4), 504-514. doi:10.1177/0145721713486837
- Bowling, A. (2014). *Research methods in health: investigating health and health services*. McGraw-hill education (UK).
- Braun, V., & Clarke, V. (2013). *Successful qualitative research: A practical guide for beginners*. Sage.
- Bukhsh, A., Khan, T. M., Sarfraz Nawaz, M., Sajjad Ahmed, H., Chan, K. G., & Goh, B. H. (2019). Association of diabetes knowledge with glycemic control and self-care practices among Pakistani people with type 2 diabetes mellitus. *Diabetes, metabolic syndrome and obesity: targets and therapy*, 12, 1409–1417. <https://doi.org/10.2147/DMSO.S209711>
- Calleja, N., Azzopardi, M. N., Reiff, S., Fava, J., Vassallo, J., Torpiano, M., Grixti, Caruana, M., Theuma, R., Grixti, M., Camilleri, P., Zammit M.A (2016). Diabetes:

- Cangussú, L. R., Barros, I. R. P. D., Botelho, C. A. D. L., Sampaio, J. D. R., & Lopes, M. R. (2020). COVID-19 and health literacy: the yell of a silent epidemic amidst the pandemic. *Revista da Associação Médica Brasileira*, 66, 31-33.
<https://doi.org/10.1590/1806-9282.66.S2.31>
- Captieux, M., Prigge, R., Wild, S., & Guthrie, B. (2020). Defining remission of type 2 diabetes in research studies: A systematic scoping review. *PLoS medicine*, 17(10), e1003396. <https://doi.org/10.1371/journal.pmed.1003396>
- Caruso, R., Magon, A., Baroni, I., Dellafiore, F., Arrigoni, C., Pittella, F., Ausili, D., (2018). Health literacy in type 2 diabetes patients: a systematic review of systematic reviews. *Acta Diabetologica* 55, 1–12. doi:10.1007/s00592-017-1071-1
- Cavanaugh K. L. (2011). Health literacy in diabetes care: explanation, evidence and equipment. *Diabetes management (London, England)*, 1(2), 191–199.
<https://doi.org/10.2217/dmt.11.5>
- Cavanaugh, K., Huizinga, M. M., Wallston, K. A., Gebretsadik, T., Shintani, A., Davis, D., ... & Rothman, R. L. (2008). Association of numeracy and diabetes control. *Annals of internal medicine*, 148(10), 737-746. <https://doi.org/10.7326/0003-4819-148-10-200805200-00006>
- Cavanaugh, K., Wallston, K. A., Gebretsadik, T., Shintani, A., Huizinga, M. M., Davis, D., ... & Rothman, R. L. (2009). Addressing literacy and numeracy to improve diabetes care: two randomized controlled trials. *Diabetes care*, 32(12), 2149-2155. doi: 10.2337/dc09-0563
- Cawthon, C., Mion, L. C., Willens, D. E., Roumie, C. L., & Kripalani, S. (2014). Implementing routine health literacy assessment in hospital and primary care patients. *Joint Commission journal on quality and patient safety*, 40(2), 68–76.
[https://doi.org/10.1016/s1553-7250\(14\)40008-4](https://doi.org/10.1016/s1553-7250(14)40008-4)
- Centers for Disease Control and Prevention (2020). National Diabetes Statistics Report. Atlanta, GA: U.S. Department of Health and Human Services, 2020. Available from: <https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf>
- Centers for Disease Control and Prevention (CDC). (2021). What is health literacy? Take action. Find out... Retrieved 18 September 2021, from <https://www.cdc.gov/healthliteracy/learn/index.html>.
- Chen, L., Chuang, L. M., Chang, C. H., Wang, C. S., Wang, I. C., Chung, Y., Peng, H. Y., Chen, H. C., Hsu, Y. L., Lin, Y. S., Chen, H. J., Chang, T. C., Jiang, Y. D., Lee, H.

- C., Tan, C. T., Chang, H. L., & Lai, F. (2013). Evaluating self-management behaviors of diabetic patients in a telehealthcare program: longitudinal study over 18 months. *Journal of medical Internet research*, 15(12), e266. <https://doi.org/10.2196/jmir.2699>
- Chen, S., Li, J., Lu, S., & Xiong, B. (2017). Escaping from poverty trap: a choice between government transfer payments and public services. *Global health research and policy*, 2, 15. <https://doi.org/10.1186/s41256-017-0035-x>
- Chong, S., Ding, D., Byun, R., Comino, E., Bauman, A., & Jalaludin, B. (2017). Lifestyle changes after a diagnosis of type 2 diabetes. *Diabetes Spectrum*, 30(1), 43-50. <https://doi.org/10.2337/ds15-0044>
- Clarke, J. (2012). What is a CI?. Retrieved 29 December 2021, available from: <http://dx.doi.org/10.1136/ebnurs-2012-100802>
- Cortez, D. N., Macedo, M. M. L., Souza, D. A. S., Dos Santos, J. C., Afonso, G. S., Reis, I. A., & de Carvalho Torres, H. (2017). Evaluating the effectiveness of an empowerment program for self-care in type 2 diabetes: a cluster randomized trial. *BMC Public Health*, 17(1), 1-10. doi:10.1186/s12889-016-3937-5
- Creswell, J. W. (2014). *Qualitative, quantitative and mixed methods approaches*. Sage.
- Creswell, J. W., & Creswell, J. D. (2017). *Research design: Qualitative, quantitative, and mixed methods approaches*. Sage publications.
- Critical Appraisal Skills Programme (2018). CASP (Qualitative) Checklist. Retrieved from https://casp-uk.b-cdn.net/wp-content/uploads/2018/03/CASP-Qualitative-Checklist-2018_fillable_form.pdf
- Critical Appraisal Skills Programme (2020). CASP (Randomised Controlled Trial) Checklist. Retrieved from: https://casp-uk.b-cdn.net/wp-content/uploads/2020/10/CASP_RCT_Checklist_PDF_Fillable_Form.pdf.
- Cuschieri, S. (2020). The diabetes epidemic in Malta. *South Eastern European Journal of Public Health (SEEJPH)*.
- Cuschieri, S., & Mamo, J. (2014). Malta: Mediterranean Diabetes hub: a journey through the years.
- Dahal, P. K., & Hosseinzadeh, H. (2019). Association of health literacy and diabetes self-management: a systematic review. *Australian Journal of Primary Health*, 25(6), 526–533. <https://doi-org.ejournals.um.edu.mt/10.1071/PY19007>
- Davis, J., Fischl, A. H., Beck, J., Browning, L., Carter, A., Condon, J. E., Dennison, M., Francis, T., Hughes, P. J., Jaime, S., Lau, K. H. K., McArthur, T., McAvoy, K.,

- Magee, M., Newby, O., Ponder, S. W., Quraishi, U., Rawlings, K., Socke, J., ... Villalobos, S. (2022). 2022 National Standards for Diabetes Self-Management Education and Support. *The Science of Diabetes Self-Management and Care*, 48(1), 44–59. <https://doi.org/10.1177/26350106211072203>
- Dawson, A. Z., Walker, R. J., & Egede, L. E. (2017). Differential relationships between diabetes knowledge scales and diabetes outcomes. *The Diabetes Educator*, 43(4), 360–366. <https://doi.org/10.1177/0145721717713316>
- Dendup, T., Feng, X., Clingan, S., & Astell-Burt, T. (2018). Environmental Risk Factors for Developing Type 2 Diabetes Mellitus: A Systematic Review. *International journal of environmental research and public health*, 15(1), 78. <https://doi.org/10.3390/ijerph15010078>
- DeWalt, D. A., Berkman, N. D., Sheridan, S., Lohr, K. N., & Pignone, M. P. (2004). Literacy and health outcomes. *Journal of general internal medicine*, 19(12), 1228–1239. <https://doi.org/10.1111/j.1525-1497.2004.40153.x>
- Di Bitetti, M. S., & Ferreras, J. A. (2017). Publish (in English) or perish: The effect on citation rate of using languages other than English in scientific publications. *Ambio*, 46(1), 121–127. <https://doi.org/10.1007/s13280-016-0820-7>
- Ebert, J. F., Huibers, L., Christensen, B., & Christensen, M. B. (2018). Paper- or Web-Based Questionnaire Invitations as a Method for Data Collection: Cross-Sectional Comparative Study of Differences in Response Rate, Completeness of Data, and Financial Cost. *Journal of medical Internet research*, 20(1), e24. <https://doi.org/10.2196/jmir.8353>
- Elfil, M., & Negida, A. (2017). Sampling methods in Clinical Research; an Educational Review. *Emergency (Tehran, Iran)*, 5(1), e52.
- Eurostat, (2020). Europe 2020 indicators – education: Statistics Explained. Available from: https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Europe_2020_indicators_-_education&oldid=301033%20#Continuous_decrease_in_early_school_leaving
- Eyth, E., & Naik, R. (2021). Hemoglobin A1C. *StatPearls* [Internet]. Available from <https://www.ncbi.nlm.nih.gov/books/NBK549816/>
- Falzon, G. (2022). Maltese researchers step closer to developing drug to delay onset of diabetes. *TVM.mt*. Retrieved 23 May 2022, from <https://tvmnews.mt/en/news/maltin-qrib-li-jizviluppaw-medicina-gdida-ghad-dijabete/>.
- Field, A. (2009). *Discovering statistics using spss third edition*.

- Finbråten, H. S., Wilde-Larsson, B., Nordström, G., Pettersen, K. S., Trollvik, A., & Guttersrud, Ø. (2018). Establishing the HLS-Q12 short version of the European Health Literacy Survey Questionnaire: latent trait analyses applying Rasch modelling and confirmatory factor analysis. *BMC health services research*, 18(1), 1-17. <https://doi.org/10.1111/jan.13342>
- Fitipaldi, H., McCarthy, M. I., Florez, J. C., & Franks, P. W. (2018). A global overview of precision medicine in type 2 diabetes. *Diabetes*, 67(10), 1911-1922. doi:10.2337/dbi17-0045
- Fonseca V. A. (2009). Defining and characterizing the progression of type 2 diabetes. *Diabetes care*, 32 Suppl 2(Suppl 2), S151–S156. <https://doi.org/10.2337/dc09-S301>
- Fransen, M. P., von Wagner, C., & Essink-Bot, M.-L. (2012). Diabetes self-management in patients with low health literacy: ordering findings from literature in a health literacy framework. *Patient Education and Counseling*, 88(1), 44–53. <https://doi-org.ejournals.um.edu.mt/10.1016/j.pec.2011.11.015>
- Freedman, D. A., Bess, K. D., Tucker, H. A., Boyd, D. L., Tuchman, A. M., & Wallston, K. A. (2009). Public health literacy defined. *American journal of preventive medicine*, 36(5), 446–451. <https://doi.org/10.1016/j.amepre.2009.02.001>
- Friis K, Vind BD, Simmons RK, Maindal HT (2016) The relationship between health literacy and health behaviour in people with diabetes: a Danish population-based study. *Journal of Diabetes Research* 2016, 7823130. doi:10.1155/2016/7823130
- Funnell, M. M., Brown, T. L., Childs, B. P., Haas, L. B., Hosey, G. M., Jensen, B., Maryniuk, M., Peyrot, M., Piette, J. D., Reader, D., Siminerio, L. M., Weinger, K., & Weiss, M. A. (2011). National Standards for diabetes self-management education. *Diabetes care*, 34 Suppl 1(Suppl 1), S89–S96. <https://doi.org/10.2337/dc11-S089>
- Gatt, S., & Sammut, R. (2008). An exploratory study of predictors of self-care behaviour in persons with type 2 diabetes. *International journal of nursing studies*, 45(10), 1525-1533. <https://doi.org/10.1016/j.ijnurstu.2008.02.006>
- Gauci, T.M., (2021) An analysis of educational attainment in Malta. Available from <https://www.centralbankmalta.org/site/Publications/Economic%20Research/2021/policy-note-educational-attainment-in-Malta.pdf?revcount=4564>
- Gazmararian, J. A., Williams, M. V., Peel, J., & Baker, D. W. (2003). Health literacy and knowledge of chronic disease. *Patient education and counseling*, 51(3), 267-275. [https://doi.org/10.1016/S0738-3991\(02\)00239-2](https://doi.org/10.1016/S0738-3991(02)00239-2)
- Gazzaz Z. J. (2021). Diabetes and COVID-19. *Open life sciences*, 16(1), 297–302. <https://doi.org/10.1515/biol-2021-0034>

- Gerber, B. S., Brodsky, I. G., Lawless, K. A., Smolin, L. I., Arozullah, A. M., Smith, E. V., ... & Eiser, A. R. (2005). Implementation and evaluation of a low-literacy diabetes education computer multimedia application. *Diabetes care*, 28(7), 1574-1580. doi: 10.2337/diacare.28.7.1574
- Goyal, R., & Jialal, I. (2018). Diabetes mellitus type 2.
- Graumlich, J. F., Wang, H., Madison, A., Wolf, M. S., Kaiser, D., Dahal, K., & Morrow, D. G. (2016). Effects of a patient-provider, collaborative, Medication-Planning tool: a randomized, controlled trial. *Journal of Diabetes Research*, 2016. doi:10.1155/2016/2129838
- Gravetter, F., & Forzano, L. (2012). Selecting research participants. *Res. Methods Behav. Sci*, 125-139.
- Grillo, M. D. F. F., Neumann, C. R., Scain, S. F., Rozeno, R. F., Beloli, L., Perinetto, T., ... & Leitão, C. B. (2016). Diabetes education in primary care: a randomized clinical trial. *Cadernos de saude publica*, 32, e00097115. doi:10.1590/0102-311X00097115
- Guedes-Martins, L., Gaio, R., Saraiva, J., Cerdeira, S., Matos, L., Silva, E., Macedo, F., & Almeida, H. (2015). STROBE Statement—checklist of items that should be included in reports of observational studies. *Figshare*.
- Guo, X., Zhai, X., & Hou, B. (2020). Adequacy of health literacy and its effect on diabetes self-management: a meta-analysis. *Australian Journal of Primary Health*, 26(6), 458–465. <https://doi-org.ejournals.um.edu.mt/10.1071/PY20079>
- Gustafsdottir, S. S., Sigurdardottir, A. K., Arnadottir, S. A., Heimisson, G. T., & Mårtensson, L. (2020). Translation and cross-cultural adaptation of the European Health Literacy Survey Questionnaire, HLS-EU-Q16: the Icelandic version. *BMC public health*, 20(1), 1-11. <https://doi.org/10.1186/s12889-020-8162-6>
- Hahn, R. A., & Truman, B. I. (2015). Education Improves Public Health and Promotes Health Equity. *International journal of health services: planning, administration, evaluation*, 45(4), 657–678. <https://doi.org/10.1177/0020731415585986>
- Hamadzadeh, S., Ezatti, Z. H., Abedsaeidi, Z. H., & Nasiri, N. (2013). Coping Styles and Self-Care Behaviors among Diabetic Patients. *Iran Journal of Nursing (2008-5923)*, 25(80).
- Harnegie M. P. (2013). SciVerse Science Direct. *Journal of the Medical Library Association: JMLA*, 101(2), 165. <https://doi.org/10.3163/1536-5050.101.2.020>
- Harris-Hayes, M., Schootman, M., Schootman, J. C., & Hastings, M. K. (2020). The Role of Physical Therapists in Fighting the Type 2 Diabetes Epidemic. *The Journal of*

orthopaedic and sports physical therapy, 50(1), 5–16.
<https://doi.org/10.2519/jospt.2020.9154>

- Haun, J., Luther, S., Dodd, V., & Donaldson, P. (2012). Measurement variation across health literacy assessments: implications for assessment selection in research and practice. *Journal of health communication*, 17 Suppl 3, 141–159.
<https://doi.org/10.1080/10810730.2012.712615>
- Hazra A. (2017). Using the confidence interval confidently. *Journal of thoracic disease*, 9(10), 4125–4130. <https://doi.org/10.21037/jtd.2017.09.14>
- Hernandez, L., French, M., & Parker, R. (2017). Roundtable on health literacy: Issues and impact. *Stud Health Technol Inform*, 240, 169-185
- Hill-Briggs, F., & Gemmell, L. (2007). Problem Solving in Diabetes Self-management and Control. *The Diabetes Educator*, 33(6), 1032–1050.
<https://doi.org/10.1177/0145721707308412>
- Hill-Briggs, F., Lazo, M., Peyrot, M., Doswell, A., Chang, Y. T., Hill, M. N., ... & Brancati, F. L. (2011). Effect of problem-solving-based diabetes self-management training on diabetes control in a low-income patient sample. *Journal of General Internal Medicine*, 26(9), 972. doi:10. 1007/s11606-011-1689-6
- Hirpha, N., Tatiparthi, R., & Mulugeta, T. (2020). Diabetic Foot Self-Care Practices Among Adult Diabetic Patients: A Descriptive Cross-Sectional Study. *Diabetes, metabolic syndrome and obesity: targets and therapy*, 13, 4779–4786.
<https://doi.org/10.2147/DMSO.S285929>
- Holt, R. I., DeVries, J. H., Hess-Fischl, A., Hirsch, I. B., Kirkman, M. S., Klupa, T., ... & Peters, A. L. (2021). The management of type 1 diabetes in adults. A consensus report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD). *Diabetologia*, 1-44.
<https://doi.org/10.1007/s00125-021-05568-3>
- Hope, S. V., Wienand-Barnett, S., Shepherd, M., King, S. M., Fox, C., Khunti, K., ... & Shields, B. M. (2016). Practical Classification Guidelines for Diabetes in patients treated with insulin: a cross-sectional study of the accuracy of diabetes diagnosis. *British Journal of General Practice*, 66(646), e315-e322. DOI: <https://doi.org/10.3399/bjgp16X684961>
- Hurst, C. P., Rakkapao, N., & Hay, K. (2020). Impact of diabetes self-management, diabetes management self-efficacy and diabetes knowledge on glycemic control in people with Type 2 Diabetes (T2D): A multi-center study in Thailand. *PloS one*, 15(12), e0244692. <https://doi.org/10.1371/journal.pone.0244692>

- Identity Malta (2017). Identity Malta says ID card system up to international standards. Available from https://www.maltatoday.com.mt/news/national/76116/identity_malta_says_id_card_system_up_to_international_standards#.YeAjzFjML-Y
- İlhan, N., Telli, S., Temel, B., & Aştı, T. (2021). Health literacy and diabetes self-care in individuals with type 2 diabetes in Turkey. *Primary Care Diabetes*, 15(1), 74–79. <https://doi-org.ejournals.um.edu.mt/10.1016/j.pcd.2020.06.009>
- Ilie, S., Rose, P., & Vignoles, A. (2021). Understanding higher education access: Inequalities and early learning in low and lower-middle-income countries. *British Educational Research Journal*, 47(5), 1237-1258. <https://doi.org/10.1002/berj.3723>
- International diabetes federation (IDF), (2021). IDF Atlas 10th ed. Retrieved 28th May 2022, from <https://diabetesatlas.org/atlas/tenth-edition/>
- International Standard Classification of Education (ISCED) (2011). UNESCO UIS. Uis.unesco.org. Retrieved 11 October 2021, from <http://uis.unesco.org/en/topic/international-standard-classification-education-isced>.
- Jager, J., Putnick, D. L., & Bornstein, M. H. (2017). II. More than just convenient: The scientific merits of homogeneous convenience samples. *Monographs of the Society for Research in Child Development*, 82(2), 13-30. <https://doi.org/10.1111/mono.12296>
- Jarbøl, D. E., Larsen, P. V., Gyrd-Hansen, D., Søndergaard, J., Brandt, C., Leppin, A., Barfoed, B. L., & Nielsen, J. B. (2017). Determinants of preferences for lifestyle changes versus medication and beliefs in ability to maintain lifestyle changes. A population-based survey. *Preventive medicine reports*, 6, 66–73. <https://doi.org/10.1016/j.pmedr.2017.02.010>
- Joveini, H., Rohban, A., Askarian, P., Maheri, M., & Hashemian, M. (2019). Health literacy and its associated demographic factors in 18–65-year-old, literate adults in Bardaskan, Iran. *Journal of Education and Health Promotion*, 8. DOI: 10.4103/jehp.jehp_26_19
- Jović-Vraneš, A., Bjegović-Mikanović, V., Marinković, J., & Vuković, D. (2014). Evaluation of a health literacy screening tool in primary care patients: evidence from Serbia. *Health promotion international*, 29(4), 601-607.
- Juray, S., Axen, K. V., & Trasino, S. E. (2021). Remission of Type 2 Diabetes with Very Low-Calorie Diets-A Narrative Review. *Nutrients*, 13(6), 2086. <https://doi.org/10.3390/nu13062086>
- Kandula, N. R., Nsiah-Kumi, P. A., Makoul, G., Sager, J., Zei, C. P., Glass, S., ... & Baker, D. W. (2009). The relationship between health literacy and knowledge improvement

after a multimedia type 2 diabetes education program. *Patient education and counselling*, 75(3), 321-327. doi: 10.1016/j.pec.2009.04.001

- Karam, S. L., Dendy, J., Polu, S., & Blonde, L. (2020). Overview of therapeutic inertia in diabetes: prevalence, causes, and consequences. *Diabetes Spectrum*, 33(1), 8-15. <https://doi.org/10.2337/ds19-0029>
- Karter, A. J., Subramanian, U., Saha, C., Crosson, J. C., Parker, M. M., Swain, B. E., ... & Marrero, D. G. (2010). Barriers to insulin initiation: the translating research into action for diabetes insulin starts project. *Diabetes care*, 33(4), 733-735. <https://doi.org/10.2337/dc09-1184>
- Kelfve, S., Kivi, M., Johansson, B., & Lindwall, M. (2020). Going web or staying paper? The use of web-surveys among older people. *BMC Medical Research Methodology*, 20(1), 1-12.
- Kesmodel, U. S. (2018). Cross-sectional studies—what are they good for?. *Acta obstetrica et gynecologica Scandinavica*, 97(4), 388-393. <https://doi.org/10.1111/aogs.13331>
- Khan, M. A., Shah, S., Grudzien, A., Onyejekwe, N., Banskota, P., Karim, S., ... & Gerber, B. S. (2011). A diabetes education multimedia program in the waiting room setting. *Diabetes Therapy*, 2(3), 178-188. doi: 10.1007/s13300-011-0007-y
- Khan, M., Hashim, M. J., King, J. K., Govender, R. D., Mustafa, H., & Al Kaabi, J. (2020). Epidemiology of Type 2 Diabetes - Global Burden of Disease and Forecasted Trends. *Journal of epidemiology and global health*, 10(1), 107–111. <https://doi.org/10.2991/jegh.k.191028.001>
- Kickbusch, I., Maag, D. (2008). Health literacy. *International encyclopedia of public health*. Oxford: Academic Press, 204–11.
- Kim, M. T., Kim, K. B., Huh, B., Nguyen, T., Han, H. R., Bone, L. R., & Levine, D. (2015). The effect of a community-based self-help intervention: Korean Americans with type 2 diabetes. *American Journal of Preventive Medicine*, 49(5), 726-737. doi:10.1016/j.amepre.2015.04.033
- Kim, S. H. (2021). Health literacy and diabetes self-care activities: The mediating effect of knowledge and patient activation. *International Journal of Nursing Practice*, e12925. <https://doi-org.ejournals.um.edu.mt/10.1111/ijn.12925>
- Kim, S. H., & Lee, A. (2016). Health-Literacy-Sensitive Diabetes Self-Management Interventions: A Systematic Review and Meta-Analysis. *Worldviews on Evidence-Based Nursing*, 13(4), 324–333. <https://doi-org.ejournals.um.edu.mt/10.1111/wvn.12157>

- Kim, S., Love, F., Quistberg, D. A., & Shea, J. A. (2004). Association of health literacy with self-management behavior in patients with diabetes. *Diabetes care*, 27(12), 2980-2982. <https://doi.org/10.2337/diacare.27.12.2980>
- Kindig, D. A., Panzer, A. M., & Nielsen-Bohlman, L. (Eds.). (2004). *Health literacy: a prescription to end confusion*.
- Klinovszky, A., Papp-Zipernovszky, O., & Buzás, N. (2021). Building a house of skills—A study of functional health literacy and numeracy among patients with type 2 diabetes in Hungary. *International Journal of Environmental Research and Public Health*, 18(4), 1547. doi:10.3390/ijerph18041547
- Koo, T. K., & Li, M. Y. (2016). A Guideline of Selecting and Reporting Intraclass Correlation Coefficients for Reliability Research. *Journal of chiropractic medicine*, 15(2), 155–163. <https://doi.org/10.1016/j.jcm.2016.02.012>
- Košir, U., & Sørensen, K. (2020). COVID-19: the key to flattening the curve is health literacy. *Perspectives in Public Health*, 1757913920936717.
- Kousoulis, A. A., Patelarou, E., Shea, S., Foss, C., Knutsen, I. A. R., Todorova, E., ... & Lionis, C. (2014). Diabetes self-management arrangements in Europe: a realist review to facilitate a project implemented in six countries. *BMC Health Services Research*, 14(1), 1-18. <https://doi.org/10.1186/1472-6963-14-453>
- Laerd statistics, (2018). Kruskal-Wallis H Test using SPSS Statistics. Retrieved January 20, 2022, from <https://statistics.laerd.com/spss-tutorials/kruskal-wallis-h-test-using-spss-statistics.php>
- Lean, M., Fornells-Ambrojo, M., Milton, A., Lloyd-Evans, B., Harrison-Stewart, B., Yesufu-Udechuku, A., Kendall, T., & Johnson, S. (2019). Self-management interventions for people with severe mental illness: systematic review and meta-analysis. *The British journal of psychiatry : the journal of mental science*, 214(5), 260–268. <https://doi.org/10.1192/bjp.2019.54>
- LeBrun, M., DiMuzio, J., Beauchamp, B., Reid, S., & Hogan, V. (2013). Evaluating the health literacy burden of Canada's public advisories: a comparative effectiveness study on clarity and readability. *Drug safety*, 36(12), 1179-1187.
- Lee, S. J., Song, M., & Im, E. (2017). Effect of a health literacy-considered diabetes self-management program for older adults in South Korea. *Research in Gerontological Nursing*, 10(5), 215-225. doi:<http://dx.doi.org.ejournals.um.edu.mt/10.3928/19404921-20170831-03>
- Lee, S. Y. D., Tsai, T. I., Tsai, Y. W., & Kuo, K. N. (2010). Health literacy, health status, and healthcare utilization of Taiwanese adults: results from a national survey. *BMC public health*, 10(1), 1-8. doi:10.1186/1471-2458-10-614

- Lee, Y.J., Shin, S.J., Wang, R.H., Lin, K.D., Lee, Y.L. and Wang, Y.H. (2015), “Patient education and counseling pathways of empowerment perceptions, health literacy, self-efficacy, and self-care behaviors to glycemic control in patients with type 2 diabetes mellitus”, *Patient Education and Counseling*, Vol. 1, pp. 1-8, doi: 10.1016/j.pec.2015.08.021.
- Levin-Zamir, D., & Wills, J. (2012). Health literacy, culture and community. *Health literacy in context: international perspectives*, 99, 123.
- Levin-Zamir, D., Baron-Epel, O. B., Cohen, V., & Elhayany, A. (2016). The Association of Health Literacy with health behavior, socioeconomic indicators, and self-assessed health from a national adult survey in Israel. *Journal of Health Communication*, 21(sup2), 61–68. <https://doi.org/10.1080/10810730.2016.1207115>
- Liao C. H. (2020). Evaluating the Social Marketing Success Criteria in Health Promotion: A F-DEMATEL Approach. *International journal of environmental research and public health*, 17(17), 6317. <https://doi.org/10.3390/ijerph17176317>
- Liu, C., Wang, D., Liu, C., Jiang, J., Wang, X., & Chen, H. et al. (2020). What is the meaning of health literacy? A systematic review and qualitative synthesis. *Family Medicine And Community Health*, 8(2), e000351. <https://doi.org/10.1136/fmch-2020-000351>
- Malloy-Weir, L. J., Charles, C., Gafni, A., & Entwistle, V. (2016). A review of health literacy: Definitions, interpretations, and implications for policy initiatives. *Journal of Public Health Policy*, 37(3), 334-352. doi:10.1057/jphp.2016.18
- Mancuso J. M. (2008). Health literacy: a concept/dimensional analysis. *Nursing & health sciences*, 10(3), 248–255. <https://doi.org/10.1111/j.1442-2018.2008.00394.x>
- Mancuso, J. M. (2010). Impact of health literacy and patient trust on glycemic control in an urban USA population. *Nursing & health sciences*, 12(1), 94-104. <https://doi.org/10.1111/j.1442-2018.2009.00506.x>
- Manikandan S. (2011). Measures of dispersion. *Journal of pharmacology & pharmacotherapeutics*, 2(4), 315–316. <https://doi.org/10.4103/0976-500X.85931>
- Mann, C. J. (2012). Observational research methods—Cohort studies, cross sectional studies, and case–control studies. *African Journal of Emergency Medicine*, 2(1), 38-46. <https://doi.org/10.1016/j.afjem.2011.12.004>
- Mattei, J., & Alfonso, C. (2020). Strategies for Healthy Eating Promotion and Behavioral Change Perceived as Effective by Nutrition Professionals: A Mixed-Methods Study. *Frontiers in nutrition*, 7, 114. <https://doi.org/10.3389/fnut.2020.00114>

- Mayo Clinic, (2021). Type 2 diabetes - Diagnosis and treatment - Mayo Clinic. Retrieved 16 December 2021, from <https://www.mayoclinic.org/diseases-conditions/type-2-diabetes/diagnosis-treatment/drc-20351199>.
- Miller, B. R., Nguyen, H., Hu, C. J., Lin, C., & Nguyen, Q. T. (2014). New and emerging drugs and targets for type 2 diabetes: reviewing the evidence. *American health & drug benefits*, 7(8), 452–463.
- Miller, C. K., Kristeller, J. L., Headings, A., & Nagaraja, H. (2014). Comparison of a mindful eating intervention to a diabetes self-management intervention among adults with type 2 diabetes: a randomized controlled trial. *Health Education & Behavior*, 41(2), 145-154. doi:10.1177/1090198113493092
- Ministry of Health, the Elderly and Community Care, (2010). The European Health Examination Survey. Available from: https://deputyprimeminister.gov.mt/en/dhir/Documents/european_health_examination_survey_pilot_2010_final_report.pdf
- Mishra, P., Pandey, C. M., Singh, U., Gupta, A., Sahu, C., & Keshri, A. (2019). Descriptive statistics and normality tests for statistical data. *Annals of cardiac anaesthesia*, 22(1), 67–72. https://doi.org/10.4103/aca.ACA_157_18
- Moussa, M., Sherrod, D., & Choi, J. (2013). An e-health intervention for increasing diabetes knowledge in African Americans. *International journal of nursing practice*, 19, 36-43. doi: 10.1111/ijn.12167
- Muller, I., Rowsell, A., Stuart, B., Hayter, V., Little, P., Ganahl, K., ... & Yardley, L. (2017). Effects on engagement and health literacy outcomes of web-based materials promoting physical activity in people with diabetes: an international randomized trial. *Journal of medical Internet research*, 19(1), e21. doi:10.2196/jmir.6601
- Nacanabo, R., Debussche, X., Rouamba, M., Kamouni, P., Mancini, J., & Kouanda, S. (2021). Health literacy and health-related quality of life in type 2 diabetes: A cross-sectional study in Burkina Faso. *Diabetes Epidemiology and Management*, 3, 100016. <https://doi.org/10.1016/j.deman.2021.100016>
- National Statistics Office (NSO), 2014. Health Literacy Survey:2014, 2015 Available from <https://deputyprimeminister.gov.mt/en/CommMentalHealth/Documents/health-literacy/health-literacy-survey-malta-2014.pdf>
- Niknami, M., Mirbalouchzahi, A., Zareban, I., Kalkalinia, E., Rikhtgarha, G., & Hosseinzadeh, H. (2018). Association of health literacy with type 2 diabetes mellitus self-management and clinical outcomes within the primary care setting of Iran. *Australian Journal of Primary Health*, 24(2), 162-170. Chicago <https://doi.org/10.1071/PY17064>

- Norris, S. L., Engelgau, M. M., & Narayan, K. V. (2001). Effectiveness of self-management training in type 2 diabetes: a systematic review of randomized controlled trials. *Diabetes care*, 24(3), 561-587.
<https://doi.org/10.2337/diacare.24.3.561>
- Nouhjah, S. (2015). Self-care behaviors and related factors in women with type 2 diabetes. *Iranian Journal of Endocrinology and Metabolism*, 16(6), 393-401.
- NSO. (2020). Diabetes: A National Public Health Priority A National Strategy for Diabetes 2016-2020 [Ebook]. Retrieved 24 October 2021, from
<https://deputyprimeminister.gov.mt/en/documents/national-health-strategies/nds-en.pdf>.
- NSO. (2020). e European Statistics on Income and Living Conditions (EU-SILC) 2019 [Ebook]. Retrieved 24 October 2021, from
https://nso.gov.mt/en/News_Releases/Documents/2020/08/News2020_135.pdf.
- NSO. (2021). Regional statistics Malta 2021 edition [Ebook]. Retrieved 17 October 2021, from https://nso.gov.mt/en/nso/Media/Salient-Points-of-Publications/Documents/2021/Regional%202021/Regional%20Statistics%202021_full%20publication.pdf.
- NSO. (2021). World Population Day [Ebook] (p. 1). National Statistics Office. Retrieved 17 October 2021, from
https://nso.gov.mt/en/News_Releases/Documents/2021/07/News2021_122.pdf
- Osborn, C. Y., Bains, S. S., & Egede, L. E. (2010). Health literacy, diabetes self-care, and glycemic control in adults with type 2 diabetes. *Diabetes technology & therapeutics*, 12(11), 913-919. <https://doi.org/10.1089/dia.2010.0058>
- Osborne, R.H., Batterham, R.W., Elsworth, G.R., Hawkins, M., Buchblinder., R. (2013). The grounded psychometric development and initial validation of the Health Literacy Questionnaire (HLQ). *BMC Public Health* 13, 658 (2013).
<https://doi.org/10.1186/1471-2458-13-658>
- Paakkari, L., & Okan, O. (2020). COVID-19: health literacy is an underestimated problem. *The Lancet. Public health*, 5(5), e249–e250. [https://doi.org/10.1016/S2468-2667\(20\)30086-4](https://doi.org/10.1016/S2468-2667(20)30086-4)
- Paasche-Orlow, M. K., & Wolf, M. S. (2007). The causal pathways linking health literacy to health outcomes. *American journal of health behavior*, 31(1), S19-S26. Doi: 10.5555/ajhb.2007.31.supp.S19
- Page, M. J., McKenzie, J., Bossuyt, P., Boutron, I., Hoffmann, T., Mulrow, c. d., ... Moher, D. (2020). The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. <https://doi.org/10.31222/osf.io/v7gm2>

- Parham, M., Rasooli, A., SAFAEIPOUR, R., & MOHEBI, S. (2014). Assessment of effects of self-caring on diabetic patients in Qom diabetes association 2013.
- Park, K. A., Kim, J. G., Kim, B. W., Kam, S., Kim, K. Y., Ha, S. W., & Hyun, S. T. (2010). Factors that affect medication adherence in elderly patients with diabetes mellitus. *Korean Diabetes Journal*, 34(1), 55-65., doi: 10.4093/kdj.2010.34.1.55
- Petroni, M. L., Brodosi, L., Marchignoli, F., Sasdelli, A. S., Caraceni, P., Marchesini, G., & Ravaioli, F. (2021). Nutrition in Patients with Type 2 Diabetes: Present Knowledge and Remaining Challenges. *Nutrients*, 13(8), 2748. <https://doi.org/10.3390/nu13082748>
- Pham, T. M., Carpenter, J. R., Morris, T. P., Sharma, M., & Petersen, I. (2019). Ethnic Differences in the Prevalence of Type 2 Diabetes Diagnoses in the UK: Cross-Sectional Analysis of the Health Improvement Network Primary Care Database. *Clinical epidemiology*, 11, 1081–1088. <https://doi.org/10.2147/CLEP.S227621>
- Plows, J. F., Stanley, J. L., Baker, P. N., Reynolds, C. M., & Vickers, M. H. (2018). The Pathophysiology of Gestational Diabetes Mellitus. *International journal of molecular sciences*, 19(11), 3342. <https://doi.org/10.3390/ijms19113342>
- Pluye, P., Robert, E., Cargo, M., Bartlett, G., O’cathain, A., Griffiths, F., ... & Rousseau, M. C. (2011). Proposal: A mixed methods appraisal tool for systematic mixed studies reviews. *Montréal: McGill University*, 2, 1-8.
- Poureslami, I., Nimmon, L., Rootman, I., & Fitzgerald, M. J. (2017). Health literacy and chronic disease management: drawing from expert knowledge to set an agenda. *Health promotion international*, 32(4), 743–754. <https://doi.org/10.1093/heapro/daw003>
- Powell, C. K., Hill, E. G., & Clancy, D. E. (2007). The relationship between health literacy and diabetes knowledge and readiness to take health actions. *The diabetes educator*, 33(1), 144-151. <https://doi.org/10.1177/0145721706297452>
- Powers, M. A., Bardsley, J., Cypress, M., Duker, P., Funnell, M. M., Fischl, A. H., Maryniuk, M. D., Siminerio, L., & Vivian, E. (2017). Diabetes Self-management Education and Support in Type 2 Diabetes: A Joint Position Statement of the American Diabetes Association, the American Association of Diabetes Educators, and the Academy of Nutrition and Dietetics. *The Diabetes Educator*, 43(1), 40–53. <https://doi.org/10.1177/0145721716689694>
- Protheroe, J., Rowlands, G., Bartlam, B., & Levin-Zamir, D. (2017). Health literacy, diabetes prevention, and self-management. <https://doi.org/10.1155/2017/1298315>

- Puttanna, A., & Padinjakara, R. N. K. (2014). Diabetic ketoacidosis in type 2 diabetes mellitus. *Practical Diabetes*, 31(4), 155-158. <https://doi.org/10.1002/pdi.1852>
- Qaid, M. M., & Abdelrahman, M. M. (2016). Role of insulin and other related hormones in energy metabolism—A review. *Cogent food & agriculture*, 2(1), 1267691
- Quartuccio, M., Simonsick, E. M., Langan, S., Harris, T., Sudore, R. L., Thorpe, R., Rosano, C., Hill-Briggs, F., Golden, S., & Kalyani, R. R. (2018). The relationship of health literacy to diabetes status differs by sex in older adults. *Journal of diabetes and its complications*, 32(4), 368–372. <https://doi.org/10.1016/j.jdiacomp.2017.10.012>
- Rachmawati, U., Sahar, J., & Wati, D. N. K. (2019). The association of diabetes literacy with self-management among older people with type 2 diabetes mellitus: a cross-sectional study. *BMC nursing*, 18(1), 1-8. <https://doi.org/10.1186/s12912-019-0354-y>
- Riemenschneider, H., Saha, S., van den Broucke, S., Maindal, H. T., Doyle, G., Levin-Zamir, D., Muller, I., Ganahl, K., Sørensen, K., Chang, P., Schillinger, D., Schwarz, P., & Müller, G. (2018). State of Diabetes Self-Management Education in the European Union Member States and Non-EU Countries: The Diabetes Literacy Project. *Journal of diabetes research*, 2018, 1467171. <https://doi.org/10.1155/2018/1467171>
- Rikard, R. V., Thompson, M. S., McKinney, J., & Beauchamp, A. (2016). Examining health literacy disparities in the United States: a third look at the National Assessment of Adult Literacy (NAAL). *BMC Public Health*, 16(1), 1-11. <https://doi.org/10.1186/s12889-016-3621-9>
- Ritchie, J., Lewis, J., Nicholls, C. M., & Ormston, R. (Eds.). (2013). *Qualitative research practice: A guide for social science students and researchers*. Sage.
- RobatSarpoooshi, D., Mahdizadeh, M., Alizadeh Siuki, H., Haddadi, M., Robatsarpoooshi, H., & Peyman, N. (2020). The Relationship Between Health Literacy Level and Self-Care Behaviors in Patients with Diabetes. *Patient related outcome measures*, 11, 129–135. <https://doi.org/10.2147/PROM.S243678>
- Rosal, M. C., Ockene, I. S., Restrepo, A., White, M. J., Borg, A., Olendzki, B., ... & Reed, G. (2011). Randomized trial of a literacy-sensitive, culturally tailored diabetes self-management intervention for low-income Latinos: Latinos en Control. *Diabetes care*, 34(4), 838-844. doi:10.2337/dc10-1981
- Röthlin, F., Pelikan, J. M., & Ganahl, K. (2013). Die Gesundheitskompetenz der 15-jährigen Jugendlichen in Österreich. Abschlussbericht der österreichischen Gesundheitskompetenz Jugendstudie im Auftrag des Hauptverbands der österreichischen Sozialversicherungsträger (HVSV).

- Rothman, R., Malone, R., Bryant, B., Dewalt, D., & Pignone, M. (2002). Health literacy and diabetic control. *Jama*, 288(21), 2687-2687. doi:10.1001/jama.288.21.2687-JLT1204-4-1
- Saeedi, P., Petersohn, I., Salpea, P., Malanda, B., Karuranga, S., Unwin, N., ... & Williams, R. I. D. F. (2019). IDF Diabetes Atlas Committee Global and regional diabetes prevalence estimates for 2019 and projections for 2030 and 2045: Results from the International Diabetes Federation Diabetes Atlas. *Diabetes Res Clin Pract*, 157(107843). doi:10.1016/j.diabres.2019.107843
- Saleh, A., Wirda, W., Irwan, A. M., & Latif, A. I. (2021). The relationships among self-efficacy, health literacy, self-care and glycemic control in older people with type 2 diabetes mellitus. *Working with Older People: Community Care Policy & Practice*, 25(2), 164–169. <https://doi-org.ejournals.um.edu.mt/10.1108/WWOP-08-2020-0044>
- Sansone, (2021). ‘Life-changing’ blood sugar monitor for diabetics is for keeps available from https://www.maltatoday.com.mt/lifestyle/health/110240/lifechanging_blood_sugar_monitor_for_diabetics_is_for_keeps#.YjRvlhDML-Z
- Sapra, A., & Bhandari, P. (2019). Diabetes mellitus.
- Sarkar, U., Fisher, L., & Schillinger, D. (2006). Is self-efficacy associated with diabetes self-management across race/ethnicity and health literacy?. *Diabetes care*, 29(4), 823-829. <https://doi.org/10.2337/diacare.29.04.06.dc05-1615>
- Schillinger, D., Grumbach, K., Piette, J., Wang, F., Osmond, D., Daher, C., ... & Bindman, A. B. (2002). Association of health literacy with diabetes outcomes. *Jama*, 288(4), 475-482. doi:10.1001/jama.288.4.475
- Schmitt, (2021). Diabetes Self-Management Questionnaire–Revised (DSMQ-R)-User Information and Scoring Guide.
- Schmitt, A., Gahr, A., Hermanns, N., Kulzer, B., Huber, J., & Haak, T. (2013). The Diabetes Self-Management Questionnaire (DSMQ): development and evaluation of an instrument to assess diabetes self-care activities associated with glycaemic control. *Health and quality of life outcomes*, 11(1), 1-14. <https://doi.org/10.1186/1477-7525-11-138>
- Schmitt, A., Reimer, A., Hermanns, N., Huber, J., Ehrmann, D., Schall, S., & Kulzer, B. (2016). Assessing Diabetes Self-Management with the Diabetes Self-Management Questionnaire (DSMQ) Can Help Analyse Behavioural Problems Related to Reduced Glycaemic Control. *PLoS one*, 11(3), e0150774. <https://doi.org/10.1371/journal.pone.0150774>

- Schulz, P. J., Pessina, A., Hartung, U., & Petrocchi, S. (2021). Effects of Objective and Subjective Health Literacy on Patients' Accurate Judgment of Health Information and Decision-Making Ability: Survey Study. *Journal of medical Internet research*, 23(1), e20457. <https://doi.org/10.2196/20457>
- Sentell, T., Vamos, S., & Okan, O. (2020). Interdisciplinary perspectives on health literacy research around the world: more important than ever in a time of COVID-19. <https://doi.org/10.3390/ijerph17093010>
- Shahbaz, A., Nejad, R. R., Hemmati M, P, M., Khalkhali H.R., (2016). The effect of implementing Orem's self-care program on self-care behaviors in patients with diabetic foot ulcer. *J Urmia Nurs Midwifery Faculty*. 14(2):108–117
- Shakibazadeh, E., Larigani, B., SHojaeizadeh, D., Frouzanfar, M., & KarimiShahanjerini, A. (2009). The relationship between efficacy and perceived barriers to self-care functioning in patients with type 2 diabetes. *J Hayat*, 15(4), 69-78.
- Shakoor,H.,Apostolopoulos,V.,Feehan,J.,Ali,H.,Ismail,L.,Al Dhaheri,A. & Stojanovska,L. (2021).Effect of Calorie Restriction and Exercise on Type 2 Diabetes. *PRILOZI*,42(1) 109-126. <https://doi.org/10.2478/prilozi-2021-0010>
- Sheridan, S. L., Halpern, D. J., Viera, A. J., Berkman, N. D., Donahue, K. E., & Crotty, K. (2011). Interventions for individuals with low health literacy: a systematic review. *Journal of health communication*, 16(sup3), 30-54. doi:10.1080/10810730.2011.604391
- Sherwani, S. I., Khan, H. A., Ekhzaimy, A., Masood, A., & Sakharkar, M. K. (2016). Significance of HbA1c Test in Diagnosis and Prognosis of Diabetic Patients. *Biomarker insights*, 11, 95–104. <https://doi.org/10.4137/BMLS38440>
- Shi Q, Ostwald SK, Wang S. (2010). Improving glycaemic control self-efficacy and glycaemic control behaviour in Chinese patients with type 2 diabetes mellitus: randomised controlled trial. *Journal of Clinical Nursing* 19(3–4), 398–404. doi:10.1111/j.1365-2702.2009.03040.x
- Shreffler, J., & Huecker, M. R. (2020). Type I and Type II errors and statistical power. Simonds, S. K. (1974). Health education as social policy. *Health Education Monographs*, 2(1_suppl), 1-10.
- Sinclair, M., O'Toole, J., Malawaraarachchi, M., & Leder, K. (2012). Comparison of response rates and cost-effectiveness for a community-based survey: postal, internet and telephone modes with generic or personalised recruitment approaches. *BMC medical research methodology*, 12(1), 1-8. <https://doi.org/10.1186/1471-2288-12-132>

- Smith, S.K., Nutbeam, D., & McCaffery, K.J. (2013). Insights into the concept and measurement of health literacy from a study of shared decision-making in a low literacy population. *J Health Psychol*, 18(8):1011-1022
- Sørensen, K., Pelikan, J. M., Röthlin, F., Ganahl, K., Slonska, Z., Doyle, G., ... & Brand, H. (2015). Health literacy in Europe: comparative results of the European health literacy survey (HLS-EU). *European journal of public health*, 25(6), 1053-1058. <https://doi.org/10.1093/eurpub/ckv043>
- Sørensen, K., Van den Broucke, S., Fullam, I., Doyle, G., Pelikan, I., Slonska, Z., & Brand, H. (2012). Health literacy and public health: a systematic review and integration of definitions and models. *BMC Public Health*, 12(1), 80. <https://doi.org/10.1186/1471-2458-12-80>
- Sørensen, K., Van den Broucke, S., Pelikan, J. M., Fullam, J., Doyle, G., Slonska, Z., ... & Brand, H. (2013). Measuring health literacy in populations: illuminating the design and development process of the European Health Literacy Survey Questionnaire (HLS-EU-Q). *BMC public health*, 13(1), 1-10.
- Spring H. (2020). Health literacy and COVID-19. *Health information and libraries journal*, 37(3), 171–172. <https://doi.org/10.1111/hir.12322>
- Stadler, L. K., & Farooqi, I. S. (2017). A new drug target for type 2 diabetes. *Cell*, 170(1), 12-14. doi:10.1016/j.cell.2017.06.024
- Storms, H., Claes, N., Aertgeerts, B., & Van den Broucke, S. (2017). Measuring health literacy among low literate people: an exploratory feasibility study with the HLS-EU questionnaire. *BMC public health*, 17(1), 1-10. <https://doi.org/10.1186/s12889-017-4391-8>
- Svendsen, M. T., Bak, C. K., Sørensen, K., Pelikan, J., Riddersholm, S. J., Skals, R. K., ... & Torp-Pedersen, C. (2020). Associations of health literacy with socioeconomic position, health risk behavior, and health status: a large national population-based survey among Danish adults. *BMC Public Health*, 20(1), 1-12. <https://doi.org/10.1186/s12889-020-08498-8>
- Taber, K.S (2018). The Use of Cronbach's Alpha When Developing and Reporting Research Instruments in Science Education. *Res Sci Educ* 48, 1273–1296. <https://doi.org/10.1007/s11165-016-9602-2>
- Tang, C., Wu, X., Chen, X., Pan, B., & Yang, X. (2019). Examining income-related inequality in health literacy and health-information seeking among urban population in China. *BMC Public Health*, 19(1), 1-9. <https://doi.org/10.1186/s12889-019-6538-2>

- Tang, Y. H., Pang, S. M., Chan, M. F., Yeung, G. S., & Yeung, V. T. (2008). Health literacy, complication awareness, and diabetic control in patients with type 2 diabetes mellitus. *Journal of advanced nursing*, 62(1), 74–83.
<https://doi.org/10.1111/j.1365-2648.2007.04526.x>
- Tanlaka, E. F., Ewashen, C., & King-Shier, K. (2019). Postpositivist critical multiplism: Its value for nursing research. *Nursing open*, 6(3), 740–744.
<https://doi.org/10.1002/nop2.306>
- Tanrıöver M., Yıldırım H., Ready F.N.D., Cakır B., Akalın E. (2014). Turkey Health Literacy Survey (1st ed). Available from: <http://www.sagliksen.org.tr>.
- Tefera, Y. G., Gebresillassie, B. M., Emiru, Y. K., Yilma, R., Hafiz, F., Akalu, H., & Ayele, A. A. (2020). Diabetic health literacy and its association with glycemic control among adult patients with type 2 diabetes mellitus attending the outpatient clinic of a university hospital in Ethiopia. *PloS one*, 15(4), e0231291.
<https://doi.org/10.1371/journal.pone.0231291>
- Thotta, S., & Akbar, A. (2021). Insulin. StatPearls [Internet]. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK560688/>
- Tiller, D., Herzog, B., Kluttig, A., & Haerting, J. (2015). Health literacy in an urban elderly East-German population—results from the population-based CARLA study. *BMC public health*, 15(1), 1-9. Doi: 10.1186/s12889-015-2210-7
- U.S. Department of Health and Human Services. (2021). Type 2 diabetes. National Institute of Diabetes and Digestive and Kidney Diseases. Retrieved September 30, 2021, from <https://www.niddk.nih.gov/health-information/diabetes/overview/what-is-diabetes/type-2-diabetes>.
- Van den Broucke, S., Van der Zanden, G., Chang, P., Doyle, G., Levin, D., & Pelikan, J. et al. (2016). Diabetes Literacy. Enhancing the Effectiveness of Diabetes Self-Management Education: . Final report. Louvain-la-Neuve: Université catholique de Louvain46(13), 933-938. <https://doi.org/10.1055/s-0034-1389952>. Available from: <https://cordis.europa.eu/docs/results/306/306186/final1-diabetesliteracyfinal.pdf>
- van der Heide, I., Uiters, E., Rademakers, J., Struijs, J. N., Schuit, A. J., & Baan, C. A. (2014). Associations among health literacy, diabetes knowledge, and self-management behavior in adults with diabetes: results of a dutch cross-sectional study. *Journal of health communication*, 19(sup2), 115-131.
<https://doi.org/10.1080/10810730.2014.936989>
- van der Heide, I., Uiters, E., Sørensen, K., Röthlin, F., Pelikan, J., Rademakers, J., ... & EPHORT consortium. (2016). Health literacy in Europe: the development and validation of health literacy prediction models. *The European Journal of Public Health*, 26(6), 906-911. <https://doi.org/10.1093/eurpub/ckw078>

- van Hoof, S. J., Spreuwenberg, M. D., Kroese, M. E., Steevens, J., Meerlo, R. J., Hanraets, M. M., & Ruwaard, D. (2016). Substitution of outpatient care with primary care: a feasibility study on the experiences among general practitioners, medical specialists and patients. *BMC family practice*, 17, 108. <https://doi.org/10.1186/s12875-016-0498-8>
- Villena Gonzales, W., Mobashsher, A. T., & Abbosh, A. (2019). The Progress of Glucose Monitoring-A Review of Invasive to Minimally and Non-Invasive Techniques, Devices and Sensors. *Sensors (Basel, Switzerland)*, 19(4), 800. <https://doi.org/10.3390/s19040800>
- Visscher, B. B., Steunenbergh, B., Heijmans, M., Hofstede, J. M., Devillé, W., van der Heide, I., & Rademakers, J. (2018). Evidence on the effectiveness of health literacy interventions in the EU: a systematic review. *BMC public health*, 18(1), 1414. <https://doi.org/10.1186/s12889-018-6331-7>
- Wallace, A. S., Seligman, H. K., Davis, T. C., Schillinger, D., Arnold, C. L., Bryant-Shilliday, B., ... & DeWalt, D. A. (2009). Literacy-appropriate educational materials and brief counseling improve diabetes self-management. *Patient education and counseling*, 75(3), 328-333. doi: 10.1016/j.pec.2008.12.017
- Wang, R. H., Hsu, H. C., Lee, Y. J., Shin, S. J., Lin, K. D., & An, L. W. (2016). Patient empowerment interacts with health literacy to associate with subsequent self-management behaviors in patients with Type 2 diabetes: A prospective study in Taiwan. *Patient Education and Counseling*, 99(10), 1626–1631. <https://doi.org/10.1016/j.pec.2016.04.001>
- Wang, X., & Cheng, Z. (2020). Cross-sectional studies: strengths, weaknesses, and recommendations. *Chest*, 158(1), S65-S71. <https://doi.org/10.1016/j.chest.2020.03.012>
- Watts, S. A., Stevenson, C., & Adams, M. (2017). Improving health literacy in patients with diabetes. *Nursing2020*, 47(1), 24-31. doi: 10.1097/01.NURSE.0000510739.60928.a9
- Weiss, B. D. (2007). Help patients understand. Manual for Clinicians. AMA Foundation.
- White, N. D., & Knezevich, E. (2019). Flash Glucose Monitoring Technology Impact on Diabetes Self-Care Behavior. *American journal of lifestyle medicine*, 14(2), 130–132. <https://doi.org/10.1177/1559827619890955>
- Wichit, N., Mnatzaganian, G., Courtney, M., Schulz, P., & Johnson, M. (2017). Randomized controlled trial of a family-oriented self-management program to improve self-efficacy, glycemic control and quality of life among Thai individuals

with Type 2 diabetes. *Diabetes research and clinical practice*, 123, 37-48.
doi:10.1016/j.diabres.2016.11.013

- Williams, M. V., Baker, D. W., Parker, R. M., & Nurss, J. R. (1998). Relationship of functional health literacy to patients' knowledge of their chronic disease: a study of patients with hypertension and diabetes. *Archives of internal medicine*, 158(2), 166-172. doi:10.1001/archinte.
- World Health Organisation. (2018). Health inequities and their causes. Retrieved 4 May 2022, from <https://www.who.int/news-room/facts-in-pictures/detail/health-inequities-and-their-causes>.
- World Health Organisation. (2021). Global strategy on digital health 2020-2025. Available from: https://www.who.int/health-topics/digital-health#tab=tab_1
- World Health Organisation. (2017). Policy brief 4: health literacy. The 9th global conference on health promotion. Shanghai, China.
- World Health Organisation. (2017). Promoting health in the SDGs: Report on the 9th Global conference for health promotion, Shanghai, China, 21–24 November 2016: all for health, health for all (No. WHO/NMH/PND/17.5).
- World Health Organisation. (2021). Diabetes epidemic in Europe. Retrieved September 30, 2021, from <https://www.euro.who.int/en/health-topics/noncommunicable-diseases/diabetes/news/news/2011/11/diabetes-epidemic-in-europe>.
- World Health Organisation. (2021). Diabetes. Retrieved 9 October 2021, from https://www.who.int/health-topics/diabetes#tab=tab_1
- Wu, Y., Ding, Y., Tanaka, Y., & Zhang, W. (2014). Risk factors contributing to type 2 diabetes and recent advances in the treatment and prevention. *International journal of medical sciences*, 11(11), 1185–1200. <https://doi.org/10.7150/ijms.10001>
- Xu WH, Rothman RL, Li R, Chen Y, Xia Q, Fang H, Gao J, Yan Y, Zhou P, Jiang Y, Liu Y, Zhou F, Wang W, Chen M, Liu XY, & Liu XN. (2014). Improved self-management skills in Chinese diabetes patients through a comprehensive health literacy strategy: Study protocol of a cluster randomized controlled trial. *Trials*, 15(1). <https://doi-org.ejournals.um.edu.mt/10.1186/1745-6215-15-498>
- Yadav, U. N., Hosseinzadeh, H., Lloyd, J., & Harris, M. F. (2018). How health literacy and patient activation play their own unique role in self-management of chronic obstructive pulmonary disease (COPD)?. *Chronic respiratory disease*, 16. doi:10.1177/1479973118816418
- Yarmohammadi, S., Momenyan, S., Ghaffari, M., Ali, R., & Azizpour, M. (2019). Impact of functional, communicative and critical health literacy on glycemic control among

patients with type 2 diabetes, and the mediating role of self-care. *Psychology Research and Behavior Management*, 12, 427-435.
doi:<http://dx.doi.org/ejournals.um.edu.mt/10.2147/PRBM.S207466>

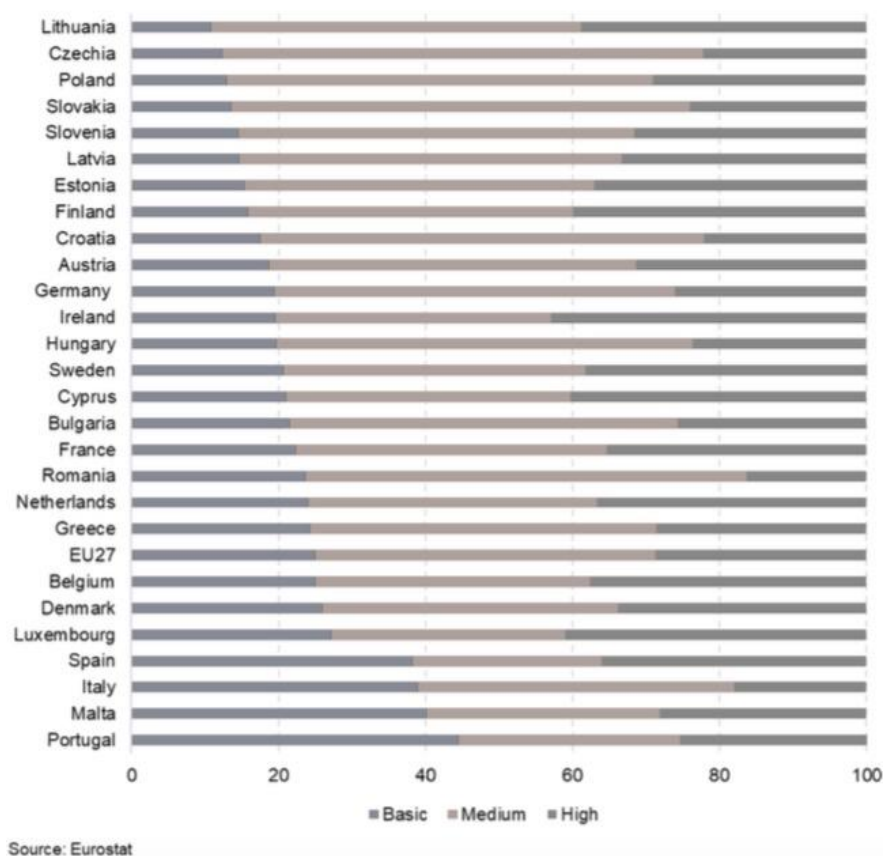
Appendices

Appendix 1: Coding levels of education and a graphical representation of education attainment in 2020 for different countries (Eurostat, 2020; ISCED, 2011).

Coding levels of education (ISCED, 2011).

Levels	Description	Levels of education
0	Early childhood education	Basic level of education
1	Primary education	
2	Lower secondary education	
3	Upper secondary education	Intermediate level of education
4	Post-secondary non-tertiary education	
5	Short-cycle tertiary education	High level of education
6	Bachelor's or equivalent level	
7	Master's or equivalent level	
8	Doctoral or equivalent level	

Population aged 15-64 years with educational attainment in 2020 (%) (Eurostat, 2020).

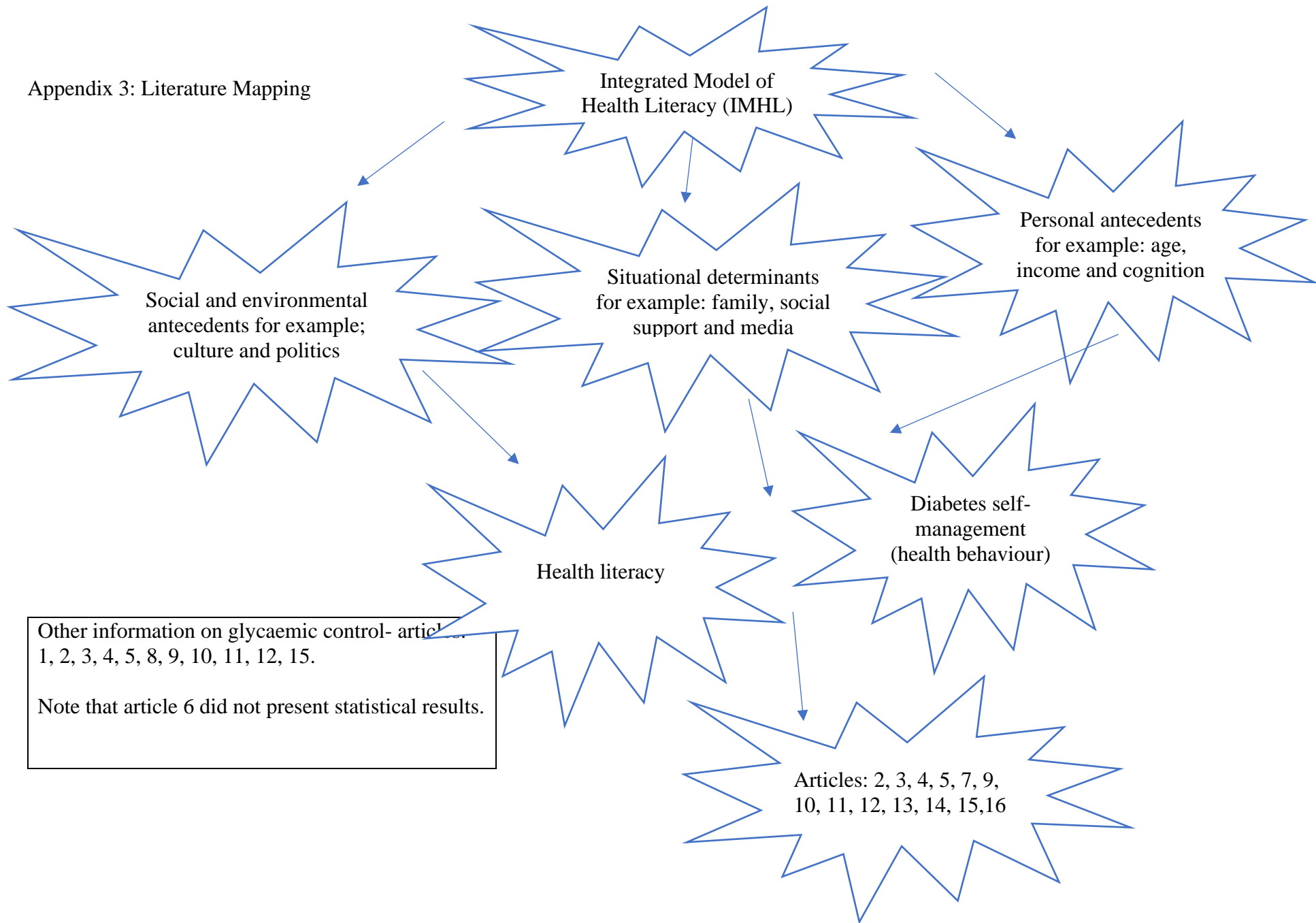


Appendix 2: Papers included in the systematic review of the literature review

Title, author and year	Type of study
1. Health-Literacy-Sensitive Diabetes Self-Management Interventions: A Systematic Review and Meta-Analysis (Kim & Lee, 2016)	Systematic Review and meta-analysis
2. Adequacy of health literacy and its effect on diabetes self-management: a meta-analysis. (Guo et al., 2020)	Meta-analysis
3. Association of health literacy and diabetes self-management: a systematic review (Dahal & Hosseinzadeh, 2019)	Systematic review (SR)
4. Diabetes self-management in patients with low health literacy: Ordering findings from literature in a health literacy framework (Fransen et al., 2012)	Systematic review (SR)
5. Effect of a Health Literacy-Considered Diabetes Self-Management Program for Older Adults in South Korea (Lee et al., 2017)	Randomised Controlled trial (RCT)
6. Improved self-management skills in Chinese diabetes patients through a comprehensive health literacy strategy: Study protocol of a cluster randomized controlled trial (Xu et al., 2014)	Randomised Controlled trial (RCT)
7. Health literacy and diabetes self-care activities: The mediating effect of knowledge and patient activation (Kim, 2021)	Cross-sectional
8. The relationships among self-efficacy, health literacy, self-care and glycemic control in older people with type 2 diabetes mellitus (Saleh et al., 2021)	Cross-sectional
9. Association of health literacy and self-management practices and psychological factor among patients with type 2 diabetes mellitus in Saudi Arabia (Almigbal et al., 2020)	Cross-sectional
10. Health literacy and diabetes self-care in individuals with type 2 diabetes in Turkey (İlhan et al., 2020)	Cross-sectional
11. Impact of functional, communicative and critical health literacy on glycemic control among patients with type 2	Cross-sectional

diabetes, and the mediating role of self-care (Yarmohammadi et al., 2019)	
12. Association of health literacy with type 2 diabetes mellitus self-management and clinical outcomes within the primary care setting of Iran (Niknami et al., 2018)	Cross-sectional
13. The relationship between health literacy levels and self-care behaviours in patients with diabetes (RobotSarpooshi et al., 2020)	Cross-sectional
14. The association of diabetes literacy with self-management among older people with type 2 diabetes mellitus: a cross-sectional study (Rachmawati et al., 2019)	Cross-sectional
15. Associations Between Health Literacy, Diabetes Knowledge, Self-Care Behaviours, and Glycemic Control in a Low Income Population with Type 2 Diabetes (Bains & Egede, 2011)	Cross-sectional
16. Type 2 diabetes self-management schemas across diverse health literacy levels: a qualitative investigation. (Ayre et al., 2021)	Qualitative

Appendix 3: Literature Mapping



Other information on glycaemic control- articles
1, 2, 3, 4, 5, 8, 9, 10, 11, 12, 15.
Note that article 6 did not present statistical results.

Appendix 4: Ethical approvals

Tool permissions to use and translate i.e., HLS-EU-Q16 and DSMQ-R



Tiffany Lori Nugent <tiffany-lori.nugent.16@um.edu.mt>

Wed, 23 Jun 2021, 10:26



to contact ▾

Dear Ms Sørensen,

I hope this email finds you well,

I am currently in the process of conducting a Masters Dissertation with the University of Malta in Nursing and will formally present information to the board of ethics. My title would be: "The association of Health Literacy with diabetes self-management of the Gozitan and Maltese population: A cross-sectional study"

Together with your colleagues you have developed the "European health literacy survey questionnaire" can you give me approval to use and translate your questionnaire in Maltese please?

Hope to hear from you soon,

Thank you
Regards
Tiffany L Nugent



Kristine Sorensen <contact@globalhealthliteracyacademy.org>

Wed, 23 Jun 2021, 11:27



to me ▾

Dear Tiffany,

Thanks a lot for your email. You are very welcome to use the questionnaire. This is exciting news. I wish you all the best in the process.

The original is attached along with some material that might be useful.

Best wishes

Kristine



--

Kristine Sørensen, PhD
Global Health Literacy Academy

Dear Tiffany Lori Nugent,

We are currently working on your request 2107115.

Request: <https://eprovide.mapi-trust.org/my-eprovide/my-requests/update/2107115>

- **Request type:** Questionnaire Distribution
- **Status:** On Going
- **Subject:** The Diabetes Self-Management Questionnaire (DSMQ)
- **Description:** To whom it may concern, I hope this finds you well, I am currently in the process of conducting a Masters Dissertation with the University of Malta in Nursing and will formally present information to the board of ethics. I was thinking of looking at the relationship between health literacy and diabetes self-care scores together with influencing factors such as demographics (quantitative method). Together with your colleagues you have developed "The Diabetes Self-Management Questionnaire (DSMQ)", can you kindly give me permission to use and translate it to Maltese please? I would be glad if you can guide or provide me with additional resources/information? Thank you Regards Tiffany L Nugent
- **Intruments:**
 - DSMQ - Diabetes Self-Management Questionnaire
- **Modules:** DSMQ
- **Other Instrument:** *Not specified*
- **Languages:** Maltese for Malta
- **Mode of administration:** No information
- **Study financing:** Not funded academic research/project, individual medical practice
- **Documents:** *Not specified*

Address

- University of Malta, Tal-Qroqq
- MSD2080 Msida
- Malta

Request Information

- **Study/Protocol number:** *Not specified*
- **PO Number:** *Not specified*

We will get back to you soon.

2021-05-17 08:28:49	Melissa Jourdan	<p>Dear Tiffany,</p> <p>Thanks for your request.</p> <p>We will be pleased to authorize you to translate this instrument in Maltese for Malta.</p> <p>To obtain permission to use this questionnaire, we'll ask you to please review and sign the attached 'Master User License Agreement' (MULA). The MULA will be valid for 10 years and we'll then only have to issue and sign Work Orders (WO) each time you want to use a questionnaire we license.</p> <p>We ask that you first please review and sign the enclosed MULA. <i>Please kindly note nothing needs to be completed after page 9 (the appendix includes an example of a WO, but we ask that you do not complete this one).</i></p> <p>Once the document is signed, please send back to me the whole document through the "Download Center".</p> <p>Kind regards,</p> <p>Mélissa</p>
---------------------	-----------------	--

Best regards,



MAPI RESEARCH TRUST	[USER]
Signature: _____	Signature: <i>Tiffany Lori Nugent</i>
Name: _____	Name: Tiffany Lori Nugent
Title: _____	Title: Student for Masters in Nursing (NOT Funded)
Date: _____	Date: 22/6/21

MULA_template_20210409

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MDH and GGH diabetes chairpersons



24/06/2021

Dear Profs Stephen Fava,

I believe you are the chairperson of the Endocrine Clinic at Medical outpatients 2 (MOP2) Mater Dei.

I am Tiffany Lori Nugent (32098G), undergoing a taught Masters program in Nursing with the University of Malta and I am a Staff Nurse by profession.

I am building my proposal with the main scope being the study of the Maltese adults (18 years and over) with Type 2 diabetes patients attending the diabetes clinic at MOP2. My dissertation supervisor is Dr Roberta Sammut. My title would be: "The association of Health Literacy with diabetes self-management of the Gozitan and Maltese population: A cross-sectional study". However, I would need approval from your side by kindly signing this letter.

Your approval will go a long way in turning my study into a success.

Thank you

Regards

Tiffany Lori Nugent

Signature

Profs Stephen Fava



Pace Adrian at GGH-Health

to Lawrence, me, Roberta ▾

Wed, 23 Jun, 18:03 (15 hours ago)



Dear Tiffany,

No objection from my end to pursue this study on diabetes patients in GGH. Once you have ethical approval, please liaise with the medical consultants who see diabetes patients at GGH (Drs Robert Sciberras, Joelle Azzopardi, Sarah Bigeni, Josephine Bigeni and John Paul Caruana Galizia) to get their go ahead to start recruitment.

This is an important area of enquiry. Once your study is completed, the hospital would very much appreciate receiving a copy of your submitted dissertation (either in soft or hard form) for our records.

Lawrence - we need to develop a repository of these studies the hospital participates in, for our records and reference. Can we discuss at some point on how to do this?

Kind regards

Adrian

Dr Adrian Pace MD PhD FRCP(Edin) FRCP(Lond)

Consultant Neurologist and Acting Clinical Director, Gozo General Hospital, Victoria Gozo

Visiting Consultant Neurologist, Karen Grech Hospital, Gwardamangia, Malta

Honorary Clinical Senior Lecturer in the Centre for Medical Education within Institute of Health Sciences Education, Queen Mary University of London

Twitter: [@gozoneurology](https://twitter.com/gozoneurology)

Intermediaries MDH and GGH

Intermediary Inbox x



Tiffany Lori Nugent <tiffany-lori.nugent.16@um.edu.mt>
to Roberta, moira.gixti@gov.mt

Wed, 23 Jun, 09:51 (1 day ago)



Dear Ms Gixti,

I hope this email finds you well, I believe you are the Diabetes Practice Nurse at MDH. I am a Nursing Masters student at the University of Malta (please also find my supervisor Dr. Roberta Sammut, in copy) and would like to study adults with Type 2 diabetes patients attending the diabetes clinic for my dissertation. My title would be : "The association of Health Literacy with diabetes self-management of the Gozitan and Maltese population: A cross-sectional study". However, can I please ask you to be my intermediary so basically, I will not initially communicate with participants (need approval as part of my ethics and data protection board)?

Hope to hear from you soon,
Thank you
Regards



Gixti Moira at Health-MDH

to me, Roberta

10:55 (1 minute ago)



Dear Ms Nugent,

Yes of course , I would gladly act as an intermediary for you study

Kind Regards

Moira Gixti
Senior Practice Nurse
Diabetes Education Unit
Health-Mater Dei Hospital

t +356 25455117/79847684 e moira.gixti@gov.mt
<https://health.gov.mt> | www.publicservice.gov.mt | fb.com/servizzpubbliku



MINISTRY FOR HEALTH

MATER DEI HOSPITAL, TRIQ ID-DONATURJI TAD-DEMM,
MSIDA, MALTA

Kindly consider your environmental responsibility before printing this e-mail

Intermediary External Inbox x



Tiffany Lori Nugent <tiffany-lori.nugent.16@um.edu.mt>
to Gatt, Roberta

Tue, 22 Jun, 07:56 (2 days ago)



Dear Ms Gatt,

I hope this email finds you well, I believe you are the Nursing Officer at GGH outpatients. I am a Nursing Masters student at the University of Malta (please also find my supervisor Dr.Roberta Sammut, in copy) and would like to study adults with Type 2 diabetes patients attending the diabetes clinic for my dissertation. My title would be : "The association of Health Literacy with diabetes self-management of the Gozitan and Maltese population: A cross-sectional study". However, can I please ask you to be my intermediary so basically, I will not initially communicate with participants (need approval as part of my ethics and data protection board)?

Hope to hear from you soon,

Thank you

Regards

Tiffany Lori Nugent



Gatt Sylvmarie at GGH-Health
to me, Roberta

22 Jun 2021, 08:11 (2 days ago)



Dear Mr Tiffany,

Yes of course I can help you with data collection. If you need to contact me you can on 2344 6214. As you said in the mail you need approval through the ethics and data protection board. Furthermore you need to contact Ms Georgene Xuereb georgene.xuereb@stewardmalta.org to guide you in data protection with regards to Gozitan patients. Thank you

Regards

Sylvmarie

Sylvmarie Gatt

Charge Nurse

Out-Patients Department

Health-Gozo General Hospital

t +356 23446214 e sylvmarie.gatt@gov.mt

<https://health.gov.mt> | www.publicservice.gov.mt | fb.com/servizzpubbliku

Kindly consider your environmental responsibility before printing this e-mail



MINISTRY FOR HEALTH

GOZO GENERAL HOSPITAL, TA' L-IBRAGG STREET,
IR-RABAT, GOZO, MALTA



Data Protection Clearance Declaration Form

REF: 175/2021

I hereby declare that I will respect the confidentiality and privacy of any personal data or information that I will come across at Mater Dei and will in no circumstance disclose any such information to third parties.

I confirm that information submitted for Data Protection Clearance is correct and that I will abide with conditions issued in same clearance notice.

1. This clearance does not cover ethical approval.
2. This clearance is only valid for your data collection at MOP 2 MDH and not elsewhere eg GGH, Primary Healthcare or any other institution than MDH (MOP 2)
3. All documents presented to your participants must include UOM's logo.
4. Your submitted documentation must remain unchanged.
5. What was declared during this clearance process is what you will abide to.
6. You must abide with all the articles of the GDPR (EU) 2016 / 679 throughout the data collection process and thereafter.
7. You are requested to submit a copy of your findings to this office at the end of your study.
8. Please communicate with Ms Moira Grixti to present this clearance email.

I also declare that I am aware of the provisions of the:

General Data Protection Regulation (2016)
(ref: <https://idpc.org.mt/en/Pages/gdpr.aspx>),
Computer misuse provisions of the Criminal Code
(ref: <http://www.justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=8574>),
and, the Professional Secrecy Act
(ref: <http://www.justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=8844&l=1>)

and that I will abide by all Government and Hospital regulations related to data, information and use of IT Systems and services (ref: <http://ictpolicies.gov.mt> , <http://www.kura.gov.mt>).

Full Name: Tiffany Lori Nugent

ID/ Passport: 0032098G

Approval Date from DPO: 25th June 2021

Approval Date from CEO: 25th June 2021

Data Collection Period (From – To): October 2021 – May 2022

MDH Official Approval Names: Prof S Fava

Name of Study / Audit: The relationship between health literacy and self-management in persons living with type 2 diabetes mellitus: A cross-sectional survey study

Applicant's Signature: *Tiffany Lori Nugent*
Tiffany Lori Nugent (Aug 5, 2021 08:11 GMT+2)

FW: Data Protection Approval Form - Tiffany Lori Nugent between Data Protection Approval Form and Tiffany Lori Nugent is Signed and Filed! External Inbox x



Data Protection Approval Form at Health-MDH <dpaform.mdh@gov.mt>
to me ▾

Mon, 9 Aug 2021, 08:41 ☆ ↶ ⋮

Good Morning

Form received. You may now proceed.

Regards

Graziella Aquilina

Personal Assistant to Health Informatics Director (A210 092)

https://health.intra.gov.mt/mdh/itservices/_layouts/15/start.aspx#/SitePages/Home.aspx



T +356 25455334

E graziella.aquilina@gov.mt

Mater Dei Hospital, Triq id-Donaturi tad-Demm, l-Imnsida, Malta MSD 2090 | Tel +356 2545 0000 | <https://deputyprimeminister.gov.mt/en/MDH/Pages/Home.aspx> | <https://www.facebook.com/materdeihospital/>

From: Adobe Sign <adobesign@adobesign.com>

Sent: Monday, 09 August 2021 08:11

To: Tiffany Lori Nugent <tiffany-lori.nugent.16@um.edu.mt>; Data Protection Approval Form at Health-MDH <dpaform.mdh@gov.mt>

Subject: Data Protection Approval Form - Tiffany Lori Nugent between Data Protection Approval Form and Tiffany Lori Nugent is Signed and Filed!

CEO MDH



Tiffany Lori Nugent <tiffany-lori.nugent.16@um.edu.mt>
to ceo.mdh, Roberta ▾

10:50 (2 hours ago) ☆ ↶ ⋮

Dear Ms Falzon,

I hope this email finds you well,
I believe you are the CEO (at Mater Dei). I am a Nursing Masters student at the University of Malta (please also find my supervisor Dr. Roberta Sammut, in copy) and would like to study adults with Type 2 diabetes patients attending the diabetes clinic for my dissertation (MOP2). My title would be : "The association of Health Literacy with diabetes self-management of the Gozitan and Maltese population: A cross-sectional study".

Attached please find: Chairperson approval and MDH data protection approval. I would also need approval from your side please.

Thank you
Regards
Tiffany Lori Nugent

2 Attachments



CEO at Health-MDH
to me ▾

13:10 (9 minutes ago) ☆ ↶ ⋮

Dear Ms Nugent,

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 approval from Ms Marsette Portelli our Legal Advisor on behalf of the CEO has to be sought before any data being published outside of hospital locally or abroad.

Regards

Carmen Farrugia
Personal Assistant To CEO



T +356 +356 25454102
E carmen.farrugia@gov.mt

Mater Dei Hospital, Triq id-Donaturi tad-Demm, I-Imsida, Malta MSD 2090 | Tel +356 2545 0000 | <https://deputyprimeminister.gov.mt/en/MDH/Pages/Home.aspx> | <https://www.facebook.com/materdeihospital/>

Think before you print.

This email and any files transmitted with it are confidential, may be legally privileged and intended solely for the use of the individual or entity to whom they are addressed.

GGH data protection officers and CEO



Tiffany Lori Nugent <tiffany-lori.nugent.16@um.edu.mt>
to dpo, Joseph, Georgene ▾

Fri, 25 Jun, 13:55 (20 hours ago) ☆ ↶ ⋮

To whom it may concern,

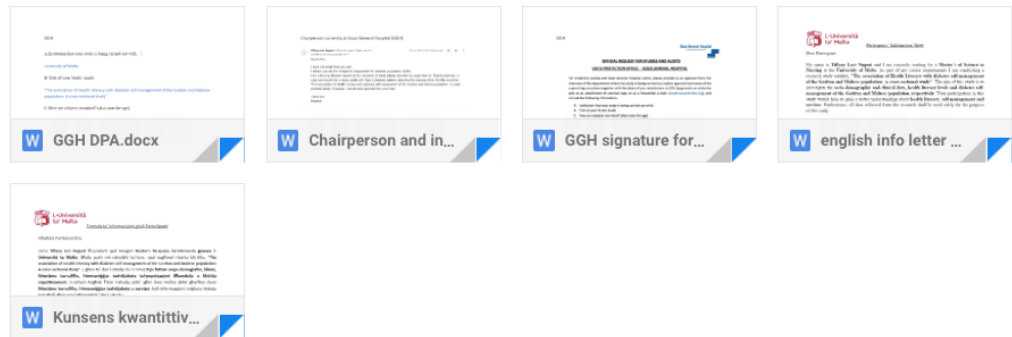
I hope this email finds you well,

I am a Nursing Masters student at the University of Malta (please also find my supervisor Dr. Roberta Sammut, in copy) and would like to study adults with Type 2 diabetes patients attending the diabetes clinic for my dissertation. My title would be : "The association of Health Literacy with diabetes self-management of the Gozitan and Maltese population: A cross-sectional study".

Can you give me approval including the CEO please?
I would appreciate if you reply as I have a deadline very soon.

Thank you
Regards,
Tiffany Lori Nugent

5 Attachments



Georgene Xuereb
to me, Joseph ▾


07:48 (2 hours ago) ☆ ↶ ⋮

Good morning Ms Nugent,

Kindly note that your request to conduct research has been approved by GGH Executive Director – Mr Joseph Fenech and Dr Luca Amato, Deputy General Counsel, Steward Health Care. Please forward a copy of your **Ethics Approval** once in hand.

You are also requested to provide both a hard and soft copy of your research to the hospital when finalised to keep for our records.

Kind Regards



Georgene Xuereb
Administration Manager, Gozo General Hospital

+356 23446365
georgene.xuereb@stewardmalta.org | https://www.stewardmalta.org/
Triq Id-Donaturi Tad-Demm, Victoria, VCT2520, Malta

f in t

This email and any files transmitted with it are confidential and intended solely for the use of the individual or entity to whom they are addressed. If you have received this email in error please notify the sender. This message contains confidential information and is intended only for the individual(s) named. If you are not the named addressee you should not disseminate, distribute or copy this e-mail. Please notify the sender immediately by e-mail if you have received this e-mail by mistake and delete this e-mail from your system. If you are not the intended recipient you are notified that disclosing, copying, distributing or taking any action in reliance on the contents of this information is strictly prohibited.[373353]

From: Tiffany Lori Nugent <tiffany-lori.nugent.16@um.edu.mt>
Sent: 26 June 2021 06:43
To: Joseph Fenech <joseph.fenech@stewardmalta.org>; Data Protection Officer <dpo@stewardmalta.org>
Cc: Georgene Xuereb <georgene.xuereb@stewardmalta.org>
Subject: [External] - Re: URGENT APPROVAL

Psychologist service



L-Università
ta' Malta

Dear Mr Paul Sciberras,

I believe you are working at the Psychological Department at MDH.

I am Tiffany Lori Nugent (32098G), undergoing a taught Masters program in Nursing with the University of Malta and I am a Staff Nurse by profession.

I am building my proposal with the main scope being the study of the Maltese adults (18 years and over) with Type 2 diabetes patients attending Mater dei (MDH) diabetes clinic at MOP2 and Gozo General Hospital (GGH) outpatients. My dissertation supervisor is Dr Roberta Sammut. My title would be: "The relationship between health literacy and self-management in persons living with type 2 diabetes mellitus: A cross-sectional survey study."

For the purpose of the study I would need someone to support my research if needed any psychological assistance if the participant feels distressed due to the study.

Can you kindly authorize please?

Regards

Tiffany Lori Nugent

Tiffany Lori Nugent

Approved.

**Paul Sciberras M.Sc.
Registered Clinical Psychologist
Managing Psychologist
Mater Dei Hospital**

24.08.2021.

‘Faculty Research Ethics Committee’ (FREC) approval



Rita Pace Parascandalo <rita.pace-p... 1 Sept 2021, 08:48



to me, Research, Roberta ▾

Dear Tiffany,

your recent amendment has been reviewed and approval for your study is granted oBo FREC. You may proceed with your study and collect the data. Kindly note that not all research applications need to be forwarded to UREC for further vetting. In your case no further approval is required from UREC.

Good luck

Regards

Dr Rita PP



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

Appendix 5: The information letter, consent form and the questionnaire in both English and Maltese languages.

Dear Participant,

My name is **Tiffany Lori Nugent** and I am currently reading for a **Master's of Science in Nursing** at the **University of Malta**. As part of my course requirements I am conducting a research study entitled, "**The relationship between health literacy and self-management in persons living with type 2 diabetes mellitus: A cross-sectional survey study.**" The aim of this study is to investigate the **relationship between demographic characteristics of the individual, health literacy levels and diabetes self-management. It also assesses the relationship between healthy literacy, diabetes self-management and glycated hemoglobin levels. This is probably known to you as HbA1c and is an indicator of diabetes control.** Your participation in this study would help us gain a better understanding about **health literacy and self-management.** Furthermore, all data collected from this research shall be used solely for the purpose of this study.

You are being invited to participate in a study which will investigate **your knowledge and understanding of health-related issues and how well you manage your diabetes.** If you agree to participate, you will meet the researcher once, at **Medical Outpatients 2 (MOP2) at Mater Dei Hospital (MDH) or Outpatients at Gozo General Hospital (GGH) during your diabetes visit,** for approximately **15-20 minutes.**

During the visit, **an intermediary will approach you and gain your written consent to participate in the study.** I, as the researcher will: **give you the questionnaire to fill in. If you do not feel you are able to fill in the questionnaire alone, the intermediary will read aloud the questions and wait for your reply. The questions will include:**

- 1. Questions which test your health literacy**
- 2. Questions about how you manage your diabetes**
- 3. Some general questions about you such as age, educational, occupational history and socioeconomic situation.**

Data on your HbA1c will be filled by your doctor if unknown.

Once you have finished filling in the questionnaire, you should post it in the box provided at the reception desk.

You are not obliged to participate in this study or to answer all the questions and you may withdraw from the study at any time without giving a reason. Furthermore, withdrawal from the study will not have any negative repercussions on you and any data collected will be erased. Data will be gathered and stored anonymously as you will not be asked information that reveals your identity. I can assure you that confidentiality will be maintained throughout the study and that your identity and personal information will not be revealed in any publications, reports or presentations arising from this research.

This data may only be accessed by the researcher. The academic supervisor/s and the examiners will typically have access to coded data only. Data files will be stored on the

researcher`s personal computer that is password protected and in an encrypted format. Any material in hard-copy form will be placed in a locked cupboard.

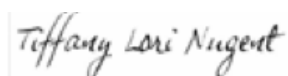
In the event that you feel distressed due to participation in this study the service of a healthcare professional at the **Psychological service at Mater Dei Hospital** will be available for both MDH and GGH participants at no financial cost on your part. Contact number is 25456900 and ask for Mr. Paul Sciberras, a psychologist.

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 the study is completed and the results are published, the data will be retained in anonymous form. Personal data i.e., consent forms and questionnaires will be erased after a period of 7 years

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 **+356 99142409** or by e-mail **tiffany-lori.nugent.16@um.edu.mt** or my supervisor **Dr Roberta Sammut** on Tel: **+35623401851/1831** or by e-mail **roberta.sammut@um.edu.mt**.

Yours Sincerely,



Tiffany Lori Nugent
Researcher



Dr Roberta Sammut
Research Supervisor



"The relationship between health literacy and self-management in persons living with type 2 diabetes: A cross-sectional survey study"

I, the undersigned, give my consent to take part in the study conducted by **Tiffany Lori Nugent**. The purpose of this document is to specify the terms of my participation in this research study.

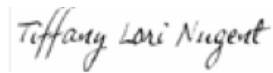
1. I have been given written and verbal information about the purpose of the study and all questions have been answered.
2. I understand that I have been invited to participate in a study, in which the researcher will ask questions and perform tests to investigate; **the relationships between sociodemographic characteristics, health literacy and self-management of diabetes including Hba1c scores.**
3. I am aware that the meeting will take approximately 15-20 minutes, whilst waiting for my diabetes doctor's outpatients appointment at MOP2 or GGH.
4. I am aware that data will be written on the prepared record forms.
5. I am aware that the data collected will be stored securely and separately from any codes and personal data.
6. I am aware 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.
7. I am also aware that data files will be stored on the researcher`s personal computer that is password protected and in an encrypted format. Any material in hard-copy form will be placed in a locked cupboard and kept for a period of 7 years.
8. I am aware that my identity and personal information will not be revealed in any publications, reports or presentations arising from this research.
9. I also 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. I also understand that once I withdraw from this study, data will be destroyed after a period of 7 years. Data will be stored anonymously as I will not be asked information that reveals your identity.
10. I also understand that my contribution will serve to **improve health literacy and diabetes self-management of persons living with type 2 diabetes.**
11. If I feel distressed as a result of participation in this study a **Psychological service at Mater Dei Hospital** will be available to provide a service at no financial costs on my part. Contact details are as follows: 25456900 and will ask for Mr. Paul Sciberras. **There are no other risks.**
12. I understand 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 also understand that once the study is completed and results are published the data will be retained in anonymous form. Data will be gathered and stored anonymously as I will not be asked information that reveals my identity in the questionnaire.

14. I will be provided with a copy of the information letter and consent form for future reference.
15. 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: _____



Tiffany Lori Nugent

Researcher
(+356 99142409)



Dr Roberta Sammut

Research Supervisor
(+356 2340 1851/1831)

Questionnaire in English:

Title of dissertation: **"The relationship between health literacy and self-management in persons living with type 2 diabetes mellitus: A cross-sectional survey study."**

Kindly tick (✓) one answer for every number if not indicated otherwise (1-48). You need to fill in all **3 sections**.

Section 1: European Health Literacy Survey Questionnaire (HLS-EU-Q16). (Adapted from Sørensen et al., 2013).

Tick (✓) the numbered box that applies to you.

Table 1:

On a scale from very easy to very difficult, how easy would you say it is to:						
		Very easy	Fairly easy	Fairly difficult	Very difficult	Don't Know (Spontaneous)
1	...find information on treatments of illnesses that concern you?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
2	...find out where to get professional help when you are ill? (Instructions: such as doctor, pharmacist, psychologist)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
3	...understand what your doctor says to you?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
4	...understand your doctor's or pharmacist's instruction on how to take a prescribed medicine?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
5	...judge when you may need to get a second opinion from another doctor?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
6	...use information the doctor gives you to make decisions about your illness?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
7	...follow instructions from your doctor or pharmacist?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
8	...find information on how to manage mental health problems like stress or depression?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
9	...understand health warnings about behaviour such as smoking, low physical activity and drinking too much?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

10	...understand why you need health screenings? (Instructions: breast exam, blood sugar test, blood pressure)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
11	...judge if the information on health risks in the media is reliable? (Instructions: TV, Internet or other media)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
12	...decide how you can protect yourself from illness based on information in the media? (Instructions: Newspapers, leaflets, Internet or other media?)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
13	...find out about activities that are good for your mental well-being? (Instructions: meditation, exercise, walking, pilates etc.)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
14	...understand advice on health from family members or friends?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
15	...understand information in the media on how to get healthier? (Instructions: Internet, newspapers, magazines)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
16	... judge which everyday behaviour is related to your health? (Instructions: Drinking and eating habits, exercise etc.)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

Section 2: Diabetes self-management questionnaire revised (DSMQ-R). (Adapted from Schmitt et al., 2021).

Tick (✓) the numbered box that applies to you **or** additional boxes on the left if an intervention is not required as part of their treatment plan.

Table 2:

The following statements describe self-management behaviours related to your diabetes. Thinking about your own self-management over the last 8 weeks, please specify to which extent each of these statements apply to you.	Applies to me very much	Applies to me to a considerable extent	Applies to me to some degree	Does not apply to me
17. I check my blood sugar levels with care and attention. <input type="checkbox"/> Glucose checking/monitoring measurement is not required as a part of my treatment.	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0
18. The food I choose to eat makes it easy for me to achieve good glucose levels.	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0
19. I regularly see the doctor (/diabetes specialist) regarding my diabetes.	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0
20. I take my diabetes medication (e. g. insulin, tablets) consistently and reliably <input type="checkbox"/> Glucose-lowering medication is not required as a part of my treatment.	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0
21. I occasionally eat large amounts of sweets or other foods rich in carbohydrates.	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0
22. I keep a diary/log of my glucose levels to inform and improve my diabetes management. <input type="checkbox"/> Glucose checking/monitoring is not required as a part of my treatment.	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0
23. I tend to avoid seeing the doctor (/diabetes specialist) regarding my diabetes.	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0
24. I am regularly physically active to improve my diabetes and health.	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0

25. I follow the current dietary recommendations for people with diabetes (e.g. given to me by my doctor or diabetes specialist).	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0
26. I do not check my glucose levels frequently enough for achieving good glucose control. <input type="checkbox"/> Glucose checking/monitoring is not required as a part of my treatment.	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0
27. I avoid physical activity although it would be good for my diabetes.	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0
28. I tend to forget or skip taking my diabetes medication (e.g. insulin, tablets). <input type="checkbox"/> Glucose-lowering medication is not required as a part of my treatment.	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0
29. Sometimes I have real 'food binges' (not triggered by hypoglycaemia).	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0
30. Regarding my diabetes care, I should see my doctor (/diabetes specialist) more often.	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0
31. I am less physically active than would be good for my diabetes.	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0
32. I could improve my diabetes self-care considerably.	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0
33. I estimate the carbohydrate content of my meals (to improve my diabetes control).	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0
34. I eat without regard to my diabetes.	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0
35. I check and discuss my diabetes treatment with the doctor (/diabetes specialist) regularly.	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0
36. My diabetes self-care is poor.	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0

Section 3: I would like to ask you some questions about yourself

Tick (✓) the box that applies to you.

37. What is your age (years)?

- 18-24
- 25-31
- 32-38
- 39-45
- 46-52
- 53-59
- 60+

38. What is your gender?

- Male
- Female
- Other
- Prefer not to tell

39. What is your marital status?

- Single
- Married
- Divorced/separated
- Widowed
- Other

40. Which district do you currently reside in?

- Southern Harbour (Cospicua; Fgura; Floriana; ̦al Luqa; ̦až-Žabbar; Kalkara; Marsa; Paola; Santa Luċija; Senglea; ̦al Tarxien; Valletta; Vittoriosa; Xgħajra, Birgu, Bormla, Isla; Raħal Ġdid)
- Northern Harbour (Birkirkara; Gżira; ̦al Qormi; ̦amrun; Msida; Pembroke; San Ġwann; Santa Venera; St Julian's; Swieqi; Ta' Xbiex; Tal-Pietà; Tas-Sliema)
- Western (̦ad-Dingli; ̦al Balzan; ̦al Lija; ̦'Attard; ̦až-Žebbuġ; Iklin; Mdina; Mtarfa; Rabat; Siġġiewi)
- Northern (Il-Mellieħa, L-Imġarr, Il-Mosta, San Pawl il-Baħar, Naxxar, ̦al Għargħur)
- South Eastern (Birżebbuġa, ̦al Għaxaq, Il-Gudja, ̦al Kirkop, Marsaxlokk, Marsaskala, L-Imqabba, Il-Qrendi, ̦al Safi, Iż-Žejtun, Iż-Žurrieq)
- Gozo and Comino (Kemmuna, Il-Fontana, Għajnsielem, L-Għarb, L-Għasri, Ta' Kerċem, Il-Munxar, In-Nadur, Il-Qala, San Lawrenz, Ta' Sannat, Ix-Xagħra, Ix-Xewkija, Ir-Rabat, Għawdex, Iż-Žebbuġ)

41. What is your highest level of education?
- No formal education
 - Primary education
 - Lower secondary education
 - Upper secondary education
 - Post-secondary but non-tertiary education
 - Tertiary education (For example University)
42. What is your current working status?
- Working for pay or profit
(including unpaid work for a family business or holding, including an apprenticeship or paid traineeship, including currently not at work due to maternity, parental, sick leave or holidays)
 - Working for non-profit for example with a non-governmental organisation (NGO)
 - Unemployed
 - Housework/stay at home
 - In retirement or early retirement
 - Unable to work due to disability or illness
 - Student
 - Other
43. How long have you been living with diabetes (years)? (write the actual number)
- _____
44. What is your household Monthly Net Income (per month)?
- < €465
 - €466-579
 - €580-813
 - €814-929
 - €930-1,162
 - €1,163-1,395
 - €1,396-1,628
 - €1,629-1,978
 - €1,979-2446
 - >€2446

45. What information media you use? (You can tick more than one answer)

- Magazines
- Books
- Radio
- Television
- Internet
- Social media
- All of the above
- Other sources (specify)_____

46. What is your treatment regimen?

- Diet and exercise only
- Oral hypoglycaemic agents (OHAs)
- Insulin + oral hypoglycaemic agents (OHAs)
(note: hypoglycaemia is low blood sugar)

47. Do you have family history of diabetes?

- Yes
- No

48. What is your recent glycosylated haemoglobin i.e., HbA1c value (mmol/mol)?

(Write the actual number)

Note: (if you do not know your value kindly ask your doctor to fill it in when you enter your appointment)

- _____

Once you have finished filling in the questionnaire, kindly leave it in the provided box at the reception desk.

In English (EN): Translation and back-translation by © 'Projectra Solutions+' except for Section 1 as previously available online by Mr Emmanuel Cachia entitled "Health Literacy Survey, Malta 2014" by the National Statistics Office on behalf of the office of the Commissioner for Mental Health (NSO, 2014).



Għażiż/a Parteċipant/a,

Jiena **Tiffany Lori Nugent** fil-prezent qed insegwi **Master's fix-xjenza tal-infermeria ġewwa l-Università ta Malta**. Bħala parti mir-rekwiżiti tal-kors, qed nagħmel riċerka bit-titlu: **"Ir-relazzjoni bejn il-litteriżmu dwar is-saħħa u l-awtoġestjoni f'persuni li jgħixu bid-dijabete tat-tip 2: studju ta' sħarriġ trasversali"**. L-għan ta' dan l-istudju hu li ninvestiga **r-relazzjoni bejn karatteristiċi demografici tal-individwu, l-litteriżmu tas-saħħa u l-awtoġestjoni tad-dijabete. Tevalwa wkoll ir-relazzjoni bejn l-litteriżmu tas-saħħa, l-awtoġestjoni tad-dijabete u livelli ta' emoglobina glikata. Dan huwa probabbilment magħruf għalik bħala HbA1c u huwa indikatur tal-kontroll tad-dijabete. Is-sehem tiegħek f'dan l-istudju jista' jgħin biex ikollna aktar għarfien dwar litteriżmu tas-saħħa u l-awtoġestjoni tad-dijabete. Kull informazzjoni miġbura tintuża biss għall-għan jew l-għanijiet ta' dan l-istudju.**

Bħala parteċipant/a inti se tinalab tiegħu sehem f'dan l-istudju sabiex ninvestigaw l-għarfien u l-fehim tiegħek ta' kwistjonijiet relatati mas-saħħa u kemm timmaniġġja d-dijabete tiegħek tajjeb. Jekk taċċetta li tiegħu sehem inti tinalab sabiex tiltaqa' mar-riċerkatur/riċerkatrici **darba ġewwa l-outpatients tal-medċina 2 (MOP2) fl-Isptar Mater Dei (MDH) jew fl-outpatients fl-Isptar Ġenerali ta' Ghawdex (GGH) waqt iż-żjara tad-dijabete tiegħek, għal madwar 15-20 il-minuta.**

Waqt din il-laqgħa, **l-intermedjarju jaffaċċjak u jikseb il-kunsens bil-miktub tiegħek biex tipparteċipa fl-istudju.** Jiena bħala riċerkatrici nista': **nagħtik kwestjonarju biex timla. Jekk ma thossx li inti kapaċi timla l-kwestjonarju wahdek, l-intermedjarju jaqra b'lehen għoli l-mistoqsijiet u jistenna t-twegiba tiegħek. Il-mistoqsijiet se jinkludu:**

- 1. Mistoqsijiet li jittestjaw il-litteriżmu tas-saħħa tiegħek**
- 2. Mistoqsijiet dwar kif timmaniġġja d-dijabete tiegħek**
- 3. Xi mistoqsijiet ġenerali dwarek bhal; età, edukazzjoni, storja okkupazzjonali u sitwazzjoni soċjoekonomika.**

Data dwar l-HbA1c tiegħek timtela mit-tabib tiegħek jekk mhux magħruf.

Ladarba tkun spiċċajt timla l-kwestjonarju, għandek tpoġġih fil-kaxxa pprovduta fir-'reception desk'.

M'intix obligat/a li twieġeb il-mistoqsijiet kollha u tista' twaqqaf l-istudju fi xhin trid mingħajr ma tagħti l-ebda raġuni. Dan mhux ħa jkollu riperkussjonijiet negattivi fuqek u l-informazzjoni li tingabar mingħandek tithassar. Id-data tingabar u tinħażen b'mod anonimu peress li ma tinalabx informazzjoni li tikxef l-identità tiegħek. Nassigurak li se tinzamm il-kunfidenzjalità matul l-istudju kollu u l-identità tiegħek u kull informazzjoni personali miġbura mhuma se jiġu żvelati mkien fit-teżi, ir-rapporti, il-prezentazzjonijiet u/jew il-pubblikazzjonijiet li jistgħu jirriżultaw minnha.

Ir-Riċerkatur / Riċerkatrici biss ser ikollu / ikollha aċċess għall-informazzjoni miġbura, filwaqt li s-Superviżur/a akkademiku/a (jew is-Superviżuri akkademiċi) u l-eżaminaturi se

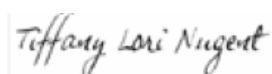
jkollhom biss aċċess għal data kkodifikata. Id-data kollha se jinħażnu fuq il-kompjuter personali tar-Riċerkatur/Riċerkatriċi permezz ta' kodifikazzjoni tad-data (data encryption) u li hi protetta b'password. Barra minn hekk, il-materjal stampat se jinqafel f'post sigur.

F'każ li tħoss li l-istudju ħoloqlok diffikultà u tixtieq li tiddiskuti x'qed tħoss ma' professjonist/a mill-qasam tal-kura tas-saħħa, **is- servizzi psikoloġiċi fl-Isptar Mater Dei** se j/tkun disponibbli kemm għall-parteciċipanti ta' MDH kif ukoll għal ta' GGH mingħajr ħlas min-naħa tiegħek. In-numru tal-kuntatt huwa 25456900 u staqsi għas-Sur Paul Sciberras, psikologu.

Il-parteciċipazzjoni tiegħek f'dan l-istudju hija għażla għal kollox volontarja u inti ħieles/ħielsa li taċċetta jew tirrifjuta li tiegħu sehem mingħajr ma jkun hemm konsegwenzi fil-konfront tiegħek. Se tingħata kopja tal-ittra ta' informazzjoni u tal-formula ta' kunsens sabiex tkun tista' taċċessahom 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 rilevanti tar-regolamenti msemmija, inti għandek id-dritt li taċċessa, tirretifika, u fejn japplika titlob sabiex tithassar id-data li tikkonċerna lilek. Ladarba jitlesta l-istudju u r-riżultati jiġu ppubblikati, id-data se tibqa' tinżamm f'forma anonima. Data personali jiġifieri l-formoli ta' kunsens u l-kwestjonarju, se jithassru wara perjodu ta' 7 snin. 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 haġa, tista' ċċempilli fuq **+356 99142409** jew tibgħatli email fuq **tiffany-lori.nugent.16@um.edu.mt**. Tista' wkoll tikkuntattja lis-Superviżur/a **Dr Roberta Sammut** Tel: **+35623401851/1831** jew billi tibgħat email fuq **roberta.sammut@um.edu.mt**.

Dejjem tiegħek,



Tiffany Lori Nugent

Isem ir-Riċerkatriċi



Dr Roberta Sammut

Isem is-Superviżura tar-riċerka



"Ir-relazzjoni bejn il-litteriżmu dwar is-sahha u l-awtoġestjoni f'persuni li jgħixu bid-dijabete mellitus tat-tip 2: studju ta' sħarriġ trasversali".

Jien, hawn taħt iffirmat/a, nagħti l-kunsens tiegħi biex nieħu sehem fl-istudju mmexxi minn **Tiffany Lori Nugent**. L-għan ta' dan id-dokument hu li jiġu speċifikati t-termini tal-parteċipazzjoni tiegħi f'dan l-istudju ta' riċerka.

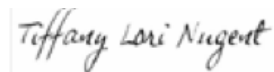
1. Jien inġatajt informazzjoni miktuba u verbali dwar l-għan tal-istudju u l-mistoqsijiet kollha twiegħbu.
2. Nifhem li se nkun qed nipparteċipa fi studju, fejn ir-Riċerkatur / Riċerkatriċi ħa j/tinvestiga r-relazzjoni bejn **fatturi soċjo-demografici, litteriżmu tas-sahha u l-awtoġestjoni tad-dijabete inklużi l-punteġġi Hb1c**.
3. Naf li l-istudju se jieħu madwar **15-20 il-minuta** waqt li nkun qed nistenna l-appuntament tat-tabib tiegħi tad-dijabete fl-outpatients MOP2 jew GGH.
4. Jien konxju/a li r-risposti tiegħi se jinkitbu fuq formuli apposta.
5. Jiena konxju li d-data miġbura se tinħażen b'mod sigur u separat minn kwalunkwe kodiċi u data personali.
6. Naf ukoll li r-Riċerkatur / Riċerkatriċi hu/hi l-uniku/a persuna li se jkollu/jkollha aċċess għal din l-informazzjoni, filwaqt li s-Supervizur/a akkademiku/a (jew is-Supervizuri akkademiċi) u l-eżaminaturi se jkollhom aċċess għal data kkodifikata biss.
7. Barra min hekk, naf li d-data se jinħażnu fuq il-kompjuter personali tar-Riċerkatur jew Riċerkatriċi 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 sikur u se jinżamm sakemm joħorġu r-riżultati għal perjodu ta' 7 snin.
8. Naf li l-identità tiegħi u l-informazzjoni personali mhuma se jinkixfu mkien fit-tezi, fir-rapporti, fil-preżentazzjonijiet u/jew fil-pubblikazzjonijiet li jistgħu jirriżultaw minnha.
9. Nifhem ukoll li jien liberu/a li naċċetta, nirrifjuta jew inwaqqaf il-parteċipazzjoni f'kull ħin bla ma nagħti raġuni. Dan mhux ħa jkollu riperkussjonijiet negattivi fuqi. Nifhem ukoll li la darba nirtira minn dan l-istudju, id-data se tinqered wara perjodu ta' 7 snin. Id-data tinħażen b'mod anonimu peress li mhux se tintalab informazzjoni li tikxef l-identità tiegħi.
10. Nifhem ukoll li l-kontribuzzjoni tiegħi ser isservi biex **jitjeb il- litteriżmu tas-sahha, l-awtoġestjoni f'persuni li jgħixu bid-dijabete tat-tip 2**.
11. Madanakollu, jekk inħoss li l-istudju ħoloqli diffikultà u nixtieq li niddiskuti x'qed inħoss, naf li **is- servizz psikoloġiku fl-Isptar Mater Dei** se j/tkun qed j/tipprovi servizz ta' għajjnuna mingħajr ħlas min-naħa tiegħi. Id-dettalji ta' kuntatt huma kif ġej: 25456900 u se jistaqsu għas-Sur Paul Sciberras. **M'hemm l-ebda riskju iehor**.
12. Nifhem ukoll, li 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, jiena għandi d-dritt li naċċessa, nirretifika, u fejn japplika nitlob sabiex titħassar id-data li tikkonċernani.

13. Nifhem ukoll li ladarba jitlesta l-istudju u r-rizultati jigu ppubblikati d-data tinzamm f'forma anonima. Id-data se tingabar u tinħażen b'mod anonimu minħabba li mhux se tintalab informazzjoni li tikxef l-identità tiegħi fil-kwestjonarju.
14. Fl-aħħar nett, naf ukoll li se ningħata kopja tal-ittra ta' informazzjoni u tal-formula ta' kunsens sabiex inkun nista' naċċessahom fil-futur.
15. Jien qrajt u fhimt il-punti u d-dikjarazzjonijiet f'din il-formula. Inħossni sodisfatt/a bit-tweġibiet li ngħatajt għall-mistoqsijiet li kelli, u qed naċċetta minn jeddi li nipparteċipa f'dan l-istudju.

Parteċipant: _____

Firma: _____

Data: _____



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Kwestjonarju bil-Malti:

Titlu tat-tezi: "Ir-relazzjoni bejn il-litteriżmu dwar is-saħha u l-awtoġestjoni f'persuni li jgħixu bid-dijabete mellitus tat-tip 2: studju ta' stharrig trasversali".

Ġentilment immarka (✓) twegiba waħda għal kull numru (1-48). Trid timla t-**3 sezzjonijiet kollha**.

Sezzjoni 1: Kwestjonarju tal-Istharrig Ewropew dwar il-Litteriżmu tas-Saħha (HLS-EU-Q16)-MALTI). (Adattat minn Sørensen et al., 2013).

Immarka (✓) il-kaxxa nnumerata li tapplika għalik.

Tabella 1

Fuq skala minn faċli ħafna għal diffiċli ħafna, kemm taħseb li jkun faċli li:						
		Faċli ħafna	Faċli	Diffiċli	Diffiċli ħafna	Ma nafx (Spontanju)
1	...ssib informazzjoni dwar kura jew trattament għall-mard li jkollok?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
2	...ssir taf fejn għandek tfittex għajnuna professjonali f'każ ta' mard? (Istruzzjonijiet: bħal tabib, spiżjar, psikologu)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
3	...tifhem x'jgħidlek it-tabib?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
4	... tifhem l-istruzzjonijiet tat-tabib jew l-ispizjar tiegħek dwar kif għandek tiegħu l-mediċina li jkun kitiblek it tabib?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
5	... tagħraf meta jkollok bżonn tiegħu opinjoni oħra minghand tabib iehor?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
6	... tagħmel użu mill-informazzjoni li jagħtik it-tabib biex tiegħu d-deċiżjonijiet dwar il-mard tiegħek?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
7	... ssegwi l-istruzzjonijiet tat-tabib jew l-ispizjar tiegħek?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
8	... ssib informazzjoni dwar kif tikkontrolla problemi ta' saħha mentali bħal stress jew dipressjoni?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
9	... tifhem twissijiet għas-saħha	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

	marbuta ma' mgieba bhal tipjip, nuqqas ta' attività fizika u xorb żejjed?					
10	... tifhem għalfejn għandek bżonn tagħmel 'screening' għal xi mard? (Istruzzjonijiet: eżami tas-sider, test taz-zokkor fid-demm, pressjoni)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
11	... tagħraf jekk l-informazzjoni dwar ir-riskji għas-saħħa li tingħata fuq il-mezzi tax-xandir tkunx tista' toqgħod fuqha? (Istruzzjonijiet: TV, Internet jew midja oħra)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
12	... tiddeċiedi kif tista' thares lilek innifsek mill-mard skont l-informazzjoni li tingħata fuq il-mezzi tax-xandir? (Istruzzjonijiet: Gazzetti, fuljetti, Internet jew midja oħra?)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
13	... ssir taf dwar attivitajiet li huma ta' għid għas-saħħa mentali tiegħek? (Istruzzjonijiet: meditazzjoni, eżerċizzju, mixi, 'pilates', eċċ.)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
14	... tifhem pariri dwar is-saħħa mingħand membri tal-familja jew mill-ħbieb?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
15	... tifhem informazzjoni dwar kif ittejjeb saħħtek li tingħata minn fuq il-mezzi tax-xandir? (Istruzzjonijiet: Internet, gazzetti, rivisti)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
16	... tagħraf liema mgieba ta' kuljum taffettwalek saħħtek? (Istruzzjonijiet: drawwiet tax-xorb u tal-ikel, eżerċizzju eċċ.)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

Sezzjoni 2: Kwestjonarju awtoġestiv tad-Dijabete (KAD). (Adattat minn Schmitt et al., 2021).

Immarka (✓) il-kaxxa nnumerata li tapplika għalik **jew** jekk l-intervent mhux meħtieġ bħala parti mill-pjan tat-trattament tiegħek, immarka l-kaxxa addizzjonali fuq ix-xellug.

Tabella 2:

Id-dikjarazzjonijiet li ġejjin jiddeskrivu l-attivitajiet ta' kura personali relatati mad-dijabete. Meta taħseb dwar il-kura personali tiegħek fuq dawn l-aħħar tmien ġimgħat, jekk jogħġbok, speċifika l-limitu li kull dikjarazzjoni tapplika għalik.	Tapplika hafna għalija	Tapplika għalija b'mod konsiderevoli	Tapplika għalija sa ċertu punt	Ma japplikax għalija
17. Jiena niċċekkja l-livelli ta' zokkor fid-demmm b'kura u attenzzjoni <input type="checkbox"/> Il-kejl taz-zokkor/ moniteraġġ fid-demmm mhux meħtieġ bħala parti mit-trattament tiegħi.	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0
18. L-ikel li nagħzel biex niekol jiffaċilita li nikseb livelli ta' zokkor fid-demmm ottimali.	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0
19. Nara regolarment lit-tabib (/speċjalista tad-dijabete) rigward id-dijabete tiegħi.	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0
20. Jiena niehu mediċina tad-dijabete (eż. insulin, pilloli) b'mod konsistenti u affidabbli <input type="checkbox"/> Medikazzjoni li tbaxxi z-zokkor ma tiffurmawx parti mit-trattament tiegħi.	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0
21. Normalment niekol hafna heġu jew ikel ieħor rikk fil-karboidrati.	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0
22. Inżomm djarju/nota tal-livelli taz-zokkor fid-demmm biex niffirma u ntejjeb l-immaniġjar tad-dijabete tiegħi. <input type="checkbox"/> Il-kejl taz-zokkor/ moniteraġġ fid-demmm mhux meħtieġ bħala parti mit-trattament tiegħi.	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0
23. Għandi tendenza li nevita li nara lit-tabib (/speċjalista tad-dijabete) rigward id-dijabete tiegħi.	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0

24. Nagħmel attività fiżika regolari sabiex intejjeb id-dijabete u s-saħħa tiegħi.	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0
25. Insegwi r-rakkomandazzjonijiet tad-dieta attwali għal persuni bid-dijabete (eż. mogħtija lili mit-tabib tiegħi jew speċjalista tad-dijabete).	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0
26. Ma niċċekjax il-livelli ta' zokkor fid-demmm b'mod regolari biżżejjed biex nilhaq kontroll tajjeb tal-glukożju fid-demmm. <input type="checkbox"/> Il-kejl taz-zokkor/ moniteraġġ fid-demmm mhux meħtieġ bħala parti mit-trattament tiegħi.	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0
27. Nevita l-attività fiżika, għalkemm naf li tghin biex itejjeb id-dijabete.	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0
28. Għandi tendenza li ninsa jew naqbez il-mediċina tad-dijabete (eż. Insulina, pilloli). <input type="checkbox"/> Il-mediċina tad-dijabete mhix rikjesta bħala parti mit-trattament tiegħi.	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0
29. Xi drabi jkolli aptit niekol 'bla rażan' (mhux attiv minħabba ipoglicemija)	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0
30. Rigward il-kura tad-dijabete, għandi bżonn nara t-it-tabib tiegħi (/speċjalista tad-dijabete) aktar ta' spiss	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0
31. Jien inqas fiżikament attiv milli jkun tajjeb għad-dijabete tiegħi.	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0
32. Nista' ntejjeb il-kura personali tad-dijabete tiegħi b'mod konsiderevoli.	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0
33. Nikkalkula l-kontenut tal-karboidrati tal-ikliet tiegħi (biex intejjeb il-kontroll tad-dijabete tiegħi).	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0
34. Jien niekol mingħajr ma nikkunsidra d-dijabete tiegħi	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0
35. Jien niċċekkja u niddiskuti t-trattament tad-dijabete tiegħi mat-tabib	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0

(/speċjalista tad-dijabete) regolarment.				
36. Il-kura tad-dijabete tiegħi hija fqira.	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0

Sezzjoni 3: Nixtieq insaqsik ftit affarijiet fuqek innifsek
Immarka (✓) l-kaxxa li tapplika għalik.

37. Kemm għandek żmien (snin)?

- 18-24
- 25-31
- 32-38
- 39-45
- 46-52
- 53-59
- 60+

38. X'inhum s-sess tiegħek?

- Raġel
- Mara
- Oħrajn
- Nippreferi ma nghidx

39. X'inhum l-istat ċivili tiegħek?

- Waħdek
- Miżżewweg
- Divorzjat/a / separat/a
- Armel/a
- Oħrajn

40. F'liema distrett toqgħod bħalissa?

- Port ta' Nofsinhar (Cospicua; Fgura; Floriana; Hal Luqa; Haż-Żabbar; Kalkara; Marsa; Paola; Santa Luċija; Senglea; Hal Tarxien; Valletta; Vittoriosa; Xgħajra, Birgu, Bormla, Isla; Raħal Ġdid)
- Port tat' Tramontana (Birkirkara; Gżira; Hal Qormi; Hamrun; Msida; Pembroke; San Ġwann; Santa Venera; St Julian's; Swieqi; Ta' Xbiex; Tal-Pietà; Tas-Sliema)
- Punent (Ħad-Dingli; Hal Balzan; Hal Lija; Ħ'Attard; Haż-Żebbuġ; Iklin; Mdina; Mtarfa; Rabat; Siġġiewi)
- Tramuntana (Il-Mellieħa, L-Imġarr, Il-Mosta, San Pawl il-Baħar, Naxxar, Hal Għargħur)
- Xlokk (Birzebbuġa, Hal Għaxaq, Il-Gudja, Hal Kirkop, Marsaxlokk, Marsaskala, L-Imqabba, Il-Qrendi, Hal Safi, Iż-Żejtun, Iż-Żurrieq)
- Għawdex u Kemuna (Kemmuna, Il-Fontana, Għajnsielem, L-Għarb, L-Għasri, Ta' Kerċem, Il-Munxar, In-Nadur, Il-Qala, San Lawrenz, Ta' Sannat, Ix-Xagħra, Ix-Xewkija, Ir-Rabat, Għawdex, Iż-Żebbuġ)

41. X'inhu l-ogħla livell ta 'edukazzjoni tiegħek?
- L-ebda edukazzjoni formali
 - Edukazzjoni primarja
 - Edukazzjoni sekondarja baxxa
 - Edukazzjoni sekondarja għolja
 - Edukazzjoni wara is-sekondarja iżda mhux terzjarja
 - Edukazzjoni terzjarja
42. X'inhu l-istatus tax-xogħol kurrenti tiegħek?
- Taħdem għall-paga jew għall-profitt
(inkluż xogħol għal negozju tal-familja mhux imħallas jew azjenda, inkluż apprendistat jew tipprattika u tithallas, inkluż li mhux fuq ix-xogħol bħalissa minħabba maternità, rilaxx tal-ġenituri, rilaxx tal-mard jew vaganzi)
 - Naħdem mingħajr skop ta 'qligħ pereżempju ma' organizzazzjoni mhux governattiva (NGO)
 - Ma naħdimx
 - Xogħol tad-dar / noqod id-dar
 - Irtirat jew irtirat kmieni
 - Ma nistax naħdem minħabba diżabilità jew mard
 - Student
 - Oħrajn
43. Kemm ilek tgħix bid-dijabete (snin)? (ikteb in-numru attwali)
- _____
44. X' inhu d-dhul f'idejk fix-xahar tad-dar (kull xahar)?
- < €465
 - €466-579
 - €580-813
 - €814-929
 - €930-1162
 - €1163-1395
 - €1396-1628
 - €1629-1978
 - €1979-2446
 - >€2446

45. Liema mezzi ta' informazzjoni li tuża?

- Magażins
- Kotba
- Radju
- Televiżjoni
- Internet
- Midja soċjali
- Kollha ta' hawn fuq
- Sorsi oħra (speċifika) _____

46. Kors tat-trattament:

- Dieta u eżerċizzju biss
 - Aġenti ipoglicemiku orali
 - Insulina + aġenti ipoglicemiku orali
- (Nota: ipoglicemija hija zokkor baxx fid-demm)

47. Għandek storja ta' dijabete fil-familja?

- Iva
- Le

48. X'inhu/i l-emoglobina glikosilata ('glycosylated haemoglobin') riċenti tiegħek jiġifieri l-valur ta' HbA1c (mmol/mol)? (Ikteb il-valur attwali)

Nota: (jekk ma tafx il-valur tiegħek ġentilment staqsi lit-tabib tiegħek biex jimlijiekk meta tidhol fl-appuntament tiegħek)

- _____

Ladarba tkun spiċċajt timla l-kwestjonarju, ġentilment mitlub thallih fil-kaxxa pprovduta fir-'reception desk'.

Bil-malti (MLT): Traduzzjoni bil-Malti u traduzzjonui b'lura bil-Malti għall-Ingliż u bl-Ingliż għall-Malti minn © 'Projectra Solutions+ ħlief għat-taqsim 1 li kienet faċilment disponibbli 'online' mis-Sur Emmanuel Cachia bit-tietlu "Health Literacy Survey, Malta 2014" mill-Uffiċċju Nazzjonali tal-Istatistika f'isem l-uffiċċju tal-Kummissarju għas-Saħħa Mentali (NSO, 2014).

Appendix 6: Correlations

Correlations

			Total health literacy score	Diabetes Self-Management (total final score)	Recent HbA1c in mmol/mol	Eating behaviour	Medication taking	Glucose monitoring	Physical activity	Cooperation with diabetes team	
Spearman's test	Total health literacy score	Correlation Coefficient	1.000	.671**	-.606**	.521**	.541**	.258**	.641**	.678**	
		Sig. (2-tailed)	.	.000	.000	.000	.000	.000	.000	.000	.000
		N	381	381	381	381	371	371	381	381	
	Diabetes self-management (total final score)	Correlation Coefficient	.671**	1.000	-.542**	.894**	.745**	.494**	.788**	.845**	
		Sig. (2-tailed)	.000	.	.000	.000	.000	.000	.000	.000	.000
		N	381	381	381	381	371	371	381	381	
	Recent HbA1c in mmol/mol	Correlation Coefficient	-.606**	-.542**	1.000	-.600**	-.270**	-.378**	-.434**	-.563**	
		Sig. (2-tailed)	.000	.000	.	.000	.000	.000	.000	.000	
		N	381	381	381	381	371	371	381	381	
	Eating behaviour	Correlation Coefficient	.521**	.894**	-.600**	1.000	.529**	.368**	.686**	.680**	
Sig. (2-tailed)		.000	.000	.000	.	.000	.000	.000	.000		
N		381	381	381	381	371	371	381	381		
Medication taking	Correlation Coefficient	.541**	.745**	-.270**	.529**	1.000	.469**	.411**	.680**		
	Sig. (2-tailed)	.000	.000	.000	.000	.	.000	.000	.000		
	N	371	371	371	371	371	371	371	371		
Glucose monitoring	Correlation Coefficient	.258**	.494**	-.378**	.368**	.469**	1.000	.129*	.434**		
	Sig. (2-tailed)	.000	.000	.000	.000	.000	.	.013	.000		
	N	371	371	371	371	371	371	371	371		
Physical activity	Correlation Coefficient	.641**	.788**	-.434**	.686**	.411**	.129*	1.000	.724**		
	Sig. (2-tailed)	.000	.000	.000	.000	.000	.013	.	.000		
	N	381	381	381	381	371	371	381	381		
Cooperation with diabetes team	Correlation Coefficient	.678**	.845**	-.563**	.680**	.680**	.434**	.724**	1.000		
	Sig. (2-tailed)	.000	.000	.000	.000	.000	.000	.000	.		
	N	381	381	381	381	371	371	381	381		

** . Correlation is significant at the 0.01 level (2-tailed).