Pulmonary Rehabilitation in Lung Cancer Management: An Investigative Study on Health-Related Quality of Life of Patients and the Perceived Views of Healthcare Professionals

A dissertation submitted to the Faculty of Medicine and Surgery in partial fulfilment of the requirements of the degree of Master of Science in Public Health

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Dedicated to my husband Clinton Paul and my children Francesca and Martina

and

In memory of my special Dad who departed halfway through this project.

You are dearly missed each and every day and not a day goes by without thinking of you.

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Summary

Background: Lung cancer is one of the most commonly diagnosed cancer and is the leading cause of mortality worldwide. It is a major challenge to global healthcare, making it an important public health issue. Patients suffering from lung cancer experience an array of symptoms that may include dyspnoea, fatigue, cough, and pain. All these symptoms can negatively influence the patients' physical function and impair their daily living activities. Pulmonary rehabilitation is a multidisciplinary intervention that is tailored to the individual patients' needs. It aims to assist patients to improve their respiratory function, exercise tolerance, physical capacity, and overall health-related quality of life. This research seeks to assess the impact of Pulmonary Rehabilitation on the health-related quality of life of patients with lung cancer and to understand its influence on the overall health system performance.

Methodology: A mix-method research design was employed. Patient reported outcome measures (EORTC QLQ-C30 and QLQ-LC29) were used to evaluate the effects of an 8-week pulmonary rehabilitation programme in patients diagnosed with lung cancer. Outcome measures were assessed pre and post the intervention. Structured interviews were used to explore perceptions of healthcare professionals on the impact of pulmonary rehabilitation within the oncology setting. Interviews were transcribed verbatim and analysed thematically.

Result: A total of 14 patients with lung cancer were eligible for data analysis: mean age 69; male 78.6%; disease stage *n* (%), I = 3 (21.4), III = 4 (28.6), IV = 7 (50.0%). All patients were receiving systemic anti-cancer treatment and/or radiotherapy except for one patient. Significant improvements were demonstrated in global health status/QoL ($p=0.03$), and lessening of symptoms including fatigue ($p=0.044$), dyspnoea ($p=0.018$) and pain ($p=0.013$) were observed following an 8-week pulmonary rehabilitation programme. In the qualitative part of the study 10 healthcare professionals were recruited. Five major themes were generated: holistic care approach; education and prevention; perceived physical and psychological benefits; impact on the healthcare sector; and

maximising the efficacy of the intervention. Most findings of this study are consistent with existing literature.

Discussion: Health-related quality of life is recognised as a valuable outcome measure in cancer care management. Healthcare professionals perceived pulmonary rehabilitation to have a central role in maintaining and/or improving health-related quality of life through patient education of physical activity, symptom management, and behavioural strategies. This was shown to contribute to a positive effect on the patient's anxiety levels and hospital admissions. Pulmonary rehabilitation has been demonstrated as an important healthcare service in lung cancer management. Promoting physical activity and healthy behaviours are crucial in today's ageing population and increased cancer incidence. Such health services facilitate integration back into the community and act as a tool for the work-age cohort to remain economically viable.

Conclusion: This study suggests that pulmonary rehabilitation should be promoted to improve physical/cognitive function as well as health-related quality of life throughout the disease trajectory in patients with lung cancer and other cancer diagnosis experiencing oncology-related pulmonary insufficiency. Based on the findings of this study, recommendations were suggested. These may inform future strategies to further improve patient experience and quality of care, ensuing better standards of care for all.

Keywords: Lung cancer, pulmonary rehabilitation, breathing exercises, physical activity, health-related quality of life, barriers, enablers, cancer care, health system performance

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List of Abbreviations

1RM	One Repetition Maximum
6MWT	6-Minute Walk Test
ACSM	American College of Sport Medicine
ADLs	Activities of Daily Living
CASP	Critical Appraisal Skills Programme
COPD	Chronic Obstructive Pulmonary Disease
CRF	Cancer Related Fatigue
CUA	Cost Utility Analysis
ECOG	Easter Cooperative Oncology Group
EORTC QLQ-C30	European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire Core 30
EORTC QLQ-LC13	European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire Lung Cancer 13
EPAAC	European Partnership for Action Against Cancer
ESAS	Edmonton Symptom Assessment System
FACT-F	Functional Assessment of Cancer Therapy-Fatigue
FACT-L	Functional Assessment of Cancer Therapy-Lung
FEV_1	Forced Expiratory Volume in 1 second
FEV_1/FVC	Forced Expiratory Volume in 1 second divided by the Forced Vital Capacity
FVC	Forced Vital Capacity
G-8	Geriatric 8

HADS	Hospital Anxiety and Depression Scale
HCPs	Healthcare Professionals
HRQoL	Health Related Quality of Life
LC	Lung Cancer
MDASI-LC	MD Aderson Symptom Inventory-Lung Cancer
MMR	Mix-Method Research
NSCLC	Non-Small Cell Lung Cancer
PA	Physical Activity
PR	Pulmonary Rehabilitation
PRISMA	Preferred Reporting Items for Systemic Review
PROMs	Patient Reported Outcome Measures
RCT	Randomised Control Trial
RS	Raw Score
SACT	Systemic Anti-Cancer Treatment
SAMOC	Sir Anthony Mamom Oncology Centre
SCLC	Small Cell Lung Cancer
SF-36	Short Form Item Questionnaire 36
SGRQ	St. George's Respiratory Questionnaire
SS	Standardised Score
VES	Vulnerable Elderly Survey
VO_2max	Maximal Oxygen Consumption

Chapter 1: Introduction

1.1 Background to the Study

Lung cancer (LC) is one of the most diagnosed cancers and leading cause of mortality worldwide (Zhang et al., 2021). It is a major challenge to global healthcare, making it an important public health issue (Kocarnik et al., 2021). In 2019, LC, along with cancers of the trachea and bronchi contributed to 45.9 million disability-adjusted life years of which 1.2% contributed towards years lost due to disability while the remaining majority contributed towards lost years of life (Kocarnik et al., 2021). These factors, augment a substantially increased concern for the health system and the global burden of this disease despite current advances in treatment modalities (Kocarnik et al., 2021).

Patients with LC experience an array of symptoms that may include dyspnoea, fatigue, cough, pain, and cancer related cachexia. All these symptoms can negatively influence the patients' physical function and impair daily living (Granger, 2016; Paramanandam & Dunn, 2015). Patients must not only learn how to cope with symptoms, but also with treatment side-effects. All treatment modalities including chemotherapy, immunotherapy, radiotherapy and/or surgery may result in reduced Health Related Quality of Life (HRQoL), limited lung function, psychological issues and impairments (Lehto, 2016). Physical inactivity is common and prevalent in patients with LC especially at advanced stages (Wang et al., 2016). Most patients are diagnosed at an advanced stage and may already be negatively impacted by symptoms and be experiencing poor HRQoL prior to even commencing treatment. Consequently, this may affect patient adherence to treatment due to the complexity of the disease management. Hence, maintaining a good general condition during their cancer journey can enable patients to withstand and combat the debilitating side-effects of the disease and treatment undertaken (Park et al., 2018).

1.2 Epidemiology of Lung Cancer

In 2020, LC accounted for 2.2 million cases and 1.8 million deaths worldwide (WHO, 2022). According to the GLOBOCAN Estimates 2020, LC is the second most leading cause of cancer-related deaths in Europe representing 1 in 10 cancers diagnosed and 1 in 5 deaths (Sung et al., 2021). Incidence and mortality are approximately two times higher in men than in women, data which varies across regions worldwide. In men, LC is the second most common cancer after prostate cancer and in women, the second most common after breast cancer (Sung et al., 2021). In Malta, in 2020, the incidence of LC for males and females was 125 and 37 cases (with 46.24 and 14.86 per 100, 000) respectively, while mortality for males and females was 136 and 37 cases (with 51.06 and 14.86 per 100, 000) respectively (Malta National Cancer Register, 2023).

LC is associated with a relatively low survival rate after diagnosis when compared to breast and colorectal cancers. Across EU countries, the average five-year net survival rate increased from 11% to 15% between 2000-2004 and 2010-2014 (OECD & EU, 2020). Similarly, in Malta, a substantial increase in LC was observed between 2000-2004 and 2010-2014, with a survival rate of 15%, on a par with the EU average (OECD, 2021). This may be a result of more effective treatments and enhanced care integration implemented over the past years.

A causative agent for LC is tobacco smoking (Doll & Hill, 1950). It is found to account for 80% of global mortality and is the leading cause of preventable death (Thandra et al., 2021). Tobacco smoking prevalence various across regions and different socio-economic cohorts. Over the past years, developed countries have seen a decline in cigarette smoking due to increased health campaigns with a consequent decrease in the incidence of LC. However, developing countries face major challenges when attempting to initiate tobacco cessation campaigns (Sung et al., 2021). There is a need for efforts aimed at narrowing existing health inequalities in developing countries for global cancer control.

1.3 The Role of Pulmonary Rehabilitation in Lung Cancer Management

Pulmonary Rehabilitation (PR) is an evidence-based intervention for patients with chronic respiratory conditions. Benefits of PR in the management of patients with Chronic Obstructive Pulmonary Disease (COPD) are well documented (Charikiopoulou et al., 2019; Yohannes et al., 2021; Schroff et al., 2017). However, research on patients with LC remains scarce. PR is a multidisciplinary intervention that is tailored to the individual patients' needs. It integrates breathing exercises, aerobic exercises, strength training, and instils behavioural changes through an educational component, including nutritional support, psychosocial support, smoking cessation, and coping skills to help manage the disease. Referrals to other relevant health care professionals and services are also an essential component in this programme, allowing for a more comprehensive approach (Rivas-Perez & Nana-Sinkam, 2015; Wang et al., 2016).

PR equips patients with multiple tools to help improve respiratory function, general physical function, and overall HRQoL, thus reducing disease burden both on the individual patient and on their caregivers (Kuebler, 2019; Nwosu et al., 2012). Symptom management and coping mechanisms are taught to empower the patient throughout their care pathway. Patients with LC face several complications throughout the course of their disease which may lead to the need of repeated hospital admissions (Handley et al., 2018). Evidence suggests that improved HRQoL and symptom management diminishes patient anxiety, reduces hospitalisations and the overall healthcare burden in COPD patients (Ko et al., 2017; Kjaergard et al., 2020). Thus, beneficial factors at the level of the individual and healthcare system need to be taken into consideration when adapting and evaluating the impact of PR on LC patients.

1.4 Rationale of the Study and its Implications in Public Health

Despite the increased health, social and economic burden associated with LC, research involving patients with LC significantly lacks behind when compared to other cancer types (Aggarwal et al., 2016). LC is characterised by its aggressive disease progression and lack of early noticeable symptoms leading to late diagnosis and consequent delayed treatment with poor prognosis (Zhang et al., 2021).

According to the Europe's Beating Cancer plan, focus should address all angles of the care pathway including prevention, diagnosis, treatment, and survivorship. Additionally, it should incorporate society wide effort and measures to integrate patients back to the community and the workplace as soon as possible especially after the completion of the acute treatment (EC, 2021). In joining efforts with the EU Mission on Cancer, one of the four objectives identified in this plan is to improve patients' quality of life during and beyond their cancer treatment (EC, 2021; 2021b). This is also reflected in the second National Cancer Plan 2017-2021, where HRQoL is identified as a valuable outcome measure for cancer patients in addition to survival (MFH, 2017). In cancer care, the challenge goes beyond addressing how long people live after they are diagnosed, but how well they live from the moment of diagnosis onwards (EC, 2021).

Rehabilitation is defined as "a set of interventions designed to optimize functioning and reduce disability in individuals with health conditions in interaction with their environment" (WHO, 2023). This definition is deeply embedded in the definition of health as "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity" (WHO, 2020).

In an oncology setting, rehabilitation is a relatively new concept. However, rehabilitation is increasingly being moved towards becoming a standard part of cancer care. Moreover, PR should be made available as a valuable component in the management of LC patients (Granger et al., 2018; Pilotto et al., 2022). Physical inactivity is common especially in the later stages of the disease due to symptoms and the side-effects of treatment. Consequently, physical inactivity contributes towards

decline in the physical, psychological, emotional, and social aspects of the patients HRQoL within this cohort (Wang et al., 2016). PR should be advocated as an integrated approach which has been demonstrated to be safe and feasible for patients with LC (Ester et al., 2021; Granger et al., 2018). Studies suggests that PR is indispensable but still an underutilised intervention in patients with LC (Bade et al., 2021).

To date, few studies evaluating the impact of PR in patients with LC throughout their care pathway have been conducted and further studies are recommended to confirm and improve the potential impact of PR on this population (Edbrooke et al., 2019; Rutkowska et al., 2019). In Malta, studies have shown significant improvements in functional status and HRQoL in patients with chronic respiratory conditions when PR was administered (Sciriha et al., 2015; Bianco et al., 2018; Schembri, 2020). However, locally, only one study has investigated the preference of physical activity in LC patients (Azzopardi, 2020).

Despite the growing evidence that benefits gained from PR can be shifted onto patients with LC, PR is not always translated into clinical practice. Granger et al. (2018) demonstrated that physical activity should be considered as a routine clinical care in LC patients as it facilitates return to ADLs, employment, symptom management, offers support and access to services. However, Payne et al. (2018) highlights that healthcare professionals are often reluctant to advise and recommend exercise-base rehabilitation due to a lack of knowledge and belief in the practice.

1.5 Research Approach, Research questions and Hypotheses

This research employed a mix-method approach and is described in more detail in Chapter 3. In this study, the integration of both qualitative and quantitative data was utilised to answer the research problem and to address the existing research gap within the local context. Existing literature recommends that more research is required to investigate the impact of PR on the HRQoL of patients with LC. Even though evidence on the effects of PR on the patients' health behavioural habits exists and healthcare resources and services are gradually increasing, more research is required to support

PR in the management of LC. This study aims to augment the available literature within the local context on PR in the LC population to optimise patient experience and quality of care.

The integration of the quantitative data and qualitative data aimed at answering the following mix-method research questions and hypotheses:

1. What is the impact on the HRQoL and on the use of healthcare services and resources when PR is included in the care pathway of patients with LC?
2. Does an 8-week PR programme have an impact on the HRQoL in patients with LC?
3. What are the perceptions of healthcare professionals on PR in LC management?
4. What are the barriers and enablers faced by healthcare professionals vis-a-vis PR in order to improve patient care? What are the barriers and enablers faced by patients as reported by healthcare professionals?

Null Hypotheses: The integration of an 8-week PR programme in the disease management pathway of LC patients has no effect on their HRQoL and health system performance.

Alternative Hypotheses: The integration of an 8-week PR programme in the disease management pathway of LC patients has a positive effect on their HRQoL and improved health system performance, thus enhancing patient quality care.

1.6 Aims and objectives of the study

The purpose of this research study is to assess the impact on the HRQoL of patients diagnosed with LC following an 8-week PR carried out on an out-patient basis at Sir Anthony Mamo Oncology Centre (SAMOC). Additionally, this research seeks to explore the perceptions of healthcare professionals on the use of PR in LC management and its effect on the healthcare services and overall health system performance.

The aims of this research study were to:

1. identify the role of PR within the oncology setting for LC patients
2. identify the barriers and enablers faced by patients and healthcare professionals towards PR.
3. evaluate the influence of PR on the performance of the health system in terms of patient behavioural habits, services offered to patients, and hospital admissions.

The main objectives of this research were to:

1. assess the impact of PR on the patients' physical well-being and overall HRQoL.
2. explore in-depth the perceptions of healthcare professionals on the use of PR in the disease management of LC.
3. evaluate whether patient participation in PR has an influence on their health behavioural habits, on the utilisation of other healthcare services and potential patient hospital admissions.
4. develop recommendations for better patient care in the LC management pathway.

1.7 Contribution to Knowledge

PR has been recognised as fulfilling a large service gap within the healthcare service (Granger et al., 2016). Narrowing this research-to-practice gap to improve patient health outcomes within healthcare is always challenging and a multidisciplinary approach within the LC pathway is essential. Currently at SAMOC, PR is becoming increasingly important in the management of LC patients. However, a lack of knowledge on the benefits of PR amongst healthcare professionals involved in the care of patients with LC has been shown to limit patient participation (Granger et al., 2016; 2018).

The researcher envisaged that this study would contribute towards reducing this knowledge gap by increasing awareness on the importance of facilitating access to more symptom management approaches and physical activity in this vulnerable group of patients. It is important to address the needs of people living with LC, thus ensuring the appropriate services are available. Furthermore, a better understanding on how to improve the clinical service will be gained through a deeper insight

into the beliefs regarding physical activity and the barriers and enablers presented by healthcare professionals. The findings of this study, together with the recommendations may also contribute to the development of new policies aiming at promoting PR and improving health outcomes for LC patients throughout their cancer care continuum.

1.8 Conclusion

In this chapter the background of this research study was discussed and an overview of the global and local epidemiology on LC were outlined. The role of PR in the disease management pathway of LC was introduced, followed by the rationale for the study and its implications in the public health setting. The research approach, research questions and hypotheses were defined along with the aims and objectives of the study. Lastly, the potential of this research to further existing knowledge were discussed. The ensuing chapter presents the literature review on the role of PR in the management of patients diagnosed with LC, its effect on HRQoL, and the perceived impact on the health system planning and performance.

Chapter 2: Literature Review

2.1 Introduction

There is a strong body of evidence suggesting that Pulmonary Rehabilitation (PR) is a valuable treatment for patients diagnosed with Chronic Obstructive Pulmonary Disease (COPD) (Charikiopoulou et al., 2019; Sciriha et al., 2015; Yohannes et al., 2021). However, research on patients with lung cancer (LC) is limited and merits further investigation. Most of the current studies evaluating the impact of PR in LC involve patients who have non-small cell lung cancer (NSCLC) which is the commonest type of LC (Ester et al., 2021; Rosero et al., 2020; Rutkwoska et al., 2021). Small cell lung cancer (SCLC) and mesothelioma are less common but more aggressive and are often diagnosed in an advanced stage, so that consequently, medical treatment is more often provided with a palliative intent. Studies on SCLC and mesothelioma are scarce, but data does not report any harmful effects from such an intervention or this being ineffective (Edbrooke et al., 2019; Quist et al., 2020). Therefore, PR could be considered for all stages and types of LC.

This chapter explores existing evidence on the impact of PR/exercise-based interventions on the health-related quality of life (HRQoL) of patients diagnosed with LC and on the health system performance by exploring the current rationale, attitudes, and perceptions of healthcare professionals (HCPs). Limited research is available that identifies enablers and barriers vis-à-vis the inclusion of PR/exercise-based interventions into routine LC clinical care (Granger et al., 2016; 2018). Thus, this review contributes to the evaluation of embedding PR/exercise-based interventions, as well as identifying factors that may influence other healthcare services and potentially, the health system as a whole.

2.2 Search Strategy

A rigorous search strategy was conducted to identify relevant literature (Appendix A). The Preferred Reporting Items for Systematic Review and Meta-Analyses (PRISMA) was adopted as it helps to facilitate the search for relevant literature in a systematic way, thus enhancing transparency and reproducibility (Page et al., 2021). Inclusion and exclusion criteria were drawn to guide the selection of the articles (Table 2.1) and records sought in two electronic databases, the University of Malta library portal HyDi and EbscoHost.

Table 2.1 *Inclusion and Exclusion Criteria applied to the Search Strategy*

	Inclusion	Exclusion	Justification
Study design	Qualitative, quantitative, mix-method studies and reviews	Not applicable	Different research designs allow for a more comprehension evaluation of the subject inquiry
Article	Peer-reviewed articles	Not published in a peer reviewed journal	Peer reviewed articles are high quality articles that have undergone strict review processes
Participants	Patients with any stage and histology of LC; HCPs working with patients with LC	Mixed cancer cohort studies	Allows for an exclusive analysis in relation to the research question
Exposure	Participation of patients with LC in PR/exercise-based intervention; Patients with LC receiving oncology treatment and/or radiotherapy	Pre-operative interventions and post-operative interventions	Relevance to the research question
Outcomes	Impact on HRQoL in LC patients and on the health system and/or healthcare services; Barriers and enablers to PR/exercise-based interventions; Perceptions of patient with LC and HCPs	Not applicable	Allows a wider understanding on the impact of PR to answer the research question
Language	Published in English	Published in other languages other than English	The researcher's primary language is English
Publications	Published between January 2016 and October 2022	Articles not falling within the specified publication dates	Articles published within these dates are used to acquire current and relevant literature

Search keywords utilised included ‘pulmonary rehabilitation’, ‘lung cancer’, ‘exercise’, ‘physical activity, ‘fatigue’, ‘quality of life’, ‘health-related quality of life’, ‘barriers’, ‘facilitators’, ‘rehabilitation’, ‘training’, ‘aerobic exercises’, ‘exercise training’, ‘strength training,’, ‘breathing exercises’, ‘public health’, ‘health system’, and ‘hospital admission’. These were combined with Boolean operators (AND/OR) for articles and the search was set to consider ‘title’ and ‘title and abstract’.

Studies evaluating the impact of PR/exercise-based interventions on the HRQoL in LC patients, the impact on the health system performance and barriers and enablers to PR/exercise for patients with LC were included. Articles were identified through a database search and duplicates were removed. All articles were screened by titles and abstracts. Thereafter, the remaining articles were reviewed for eligibility to meet the inclusion and exclusion criteria. The process of the selection of articles is illustrated in the PRISMA flow diagram, Figure 2.1. The articles identified were then evaluated using the Critical Appraisal Skills Programme (CASP) which enabled the researcher to systematically assess the quality of the information provided, thus ensuring trustworthiness and relevance of the evidence. A CASP standard check list was used to facilitate analysis (CASP, 2020). Articles are presented in table form and organised by author, year of publication, study design, the aim of the study, population, intervention, outcome measures, and main findings (Appendix B).

A total of 16 articles were considered for inclusion in this review. Table 2.2 shows the country of origin of the articles selected. Most of the studies utilised a quantitative approach (n=10), three studies used a qualitative approach, one study used a mix-method approach, while another study was a meta-analysis. A cost-utility analysis (CUA) article was also included.

Figure 2.1 *PRISMA flow diagram showing the selection process of search results*

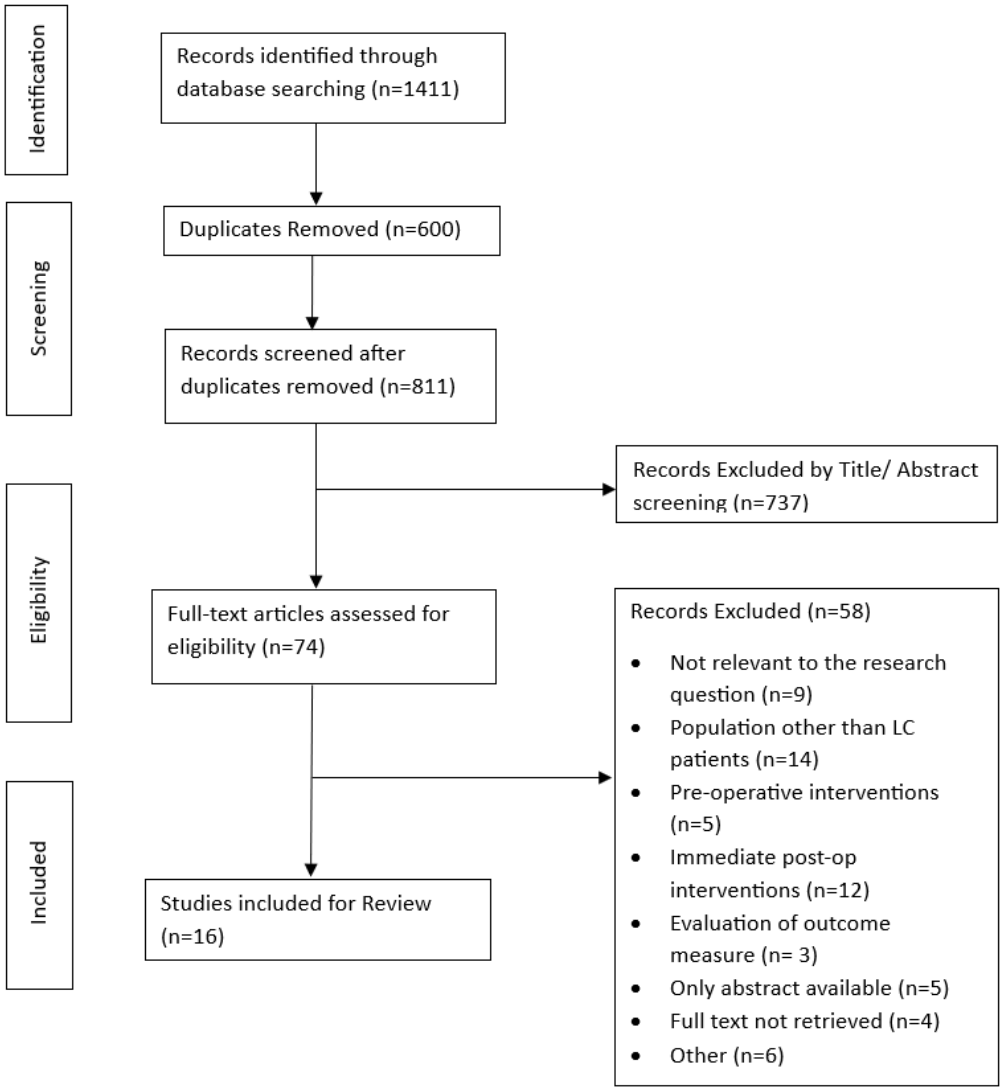


Table 2.2 *Articles included in the literature review sorted by country of origin*

Country	Article
Australia	(Edbrooke et al., 2019; 2020; 2021) (Dhillon et al., 2017) (Granger et al., 2018)
Canada	(Ester et al., 2021)
Denmark	(Quist et al., 2020)
Poland	(Rutkowska et al., 2019; 2021)
Republic of Korea	(Lee. J., 2021)
Spain	(Martínez-Velilla et al., 2021); (Rosero et al., 2020)
Thailand	(Saetan et al., 2020)
United Kingdom	(Payne et al., 2018)
United States	(Sloan et al., 2016)
Worldwide	(Pilotto et al., 2022)

Most of the studies (56%) investigated the impact of PR on patients exclusively with NSCLC (Edbrooke et al., 2019; 2020; Ester et al., 2021; Martínez-Velilla et al., 2021; Payne et al., 2018; Rosero et al., 2020; Rutkowska et al., 2019; 2021; Saetan et al., 2020), while only four studies had no restrictions to the histological diagnosis (NSCLC and SCLC) (Dhillon et al., 2017; Quist et al., 2020; Lee et al., 2021; Sloan et al., 2016). All the stages of LC were included with a performance status between 0-2. A performance status is a measure used to quantify the general well-being of cancer patients and their ability to perform ordinary tasks and activities of daily living, with the Eastern Cooperative Oncology Group (ECOG) being the one more commonly included in research studies. This scale ranges from 0 to 4, with 0 indicating good health and asymptomatic and 4 indicating bedridden (West & Jin, 2015). Studies conducted whilst patients were undergoing systemic anti-cancer treatment (SACT) and/or radiotherapy accounted for 69% of the articles included (Edbrooke et al., 2019; 2020; Ester et al., 2021; Lee et al., 2021; Payne et al., 2018; Quist et al., 2020; Rosero et al., 2020; Rutkowska et al., 2019; 2021; Saetan et al., 2020; Sloan et al., 2016) and only one study investigated the effects of PR post-SACT and/or radiotherapy (≥ 4 weeks) (Dhillon et al., 2017).

Approximately 63% of the studies involved PR/exercise-based interventions and their duration ranged between four to twelve weeks (Edbrooke et al., 2019; Ester et al., 2021; Dhillon et al., 2017; Lee et al., 2021; Quist et al., 2020; Rosero et al., 2020; Rutkowska et al., 2019; 2021; Saetan et al., 2020; Sloan et al., 2016). Close to 25% of the studies of the studies explored the views of patients and HCPs (Ester et al., 2021; Granger et al., 2018; Payne et al., 2018; Pilotto et al., 2022). Only one study evaluated the overall survival in relation to physical activity (PA) in LC survivals (Martínez-Velilla et al., 2021). Another study by Edbrooke et al. (2021) analysed the cost-effectiveness of home-based rehabilitation in patients with advanced LC. This cost utility analysis (CUA) was investigated in another randomised control trial by Edbrooke et al. (2020), also included in this review. A CUA is an essential economic evaluation that assesses the cost and effectiveness of alternative interventions in terms of both quantity and quality of life. Since CUA measures health effects, it was deemed relevant to include this article in this review. Furthermore, limited evidence

on the impact of PR/exercise-based intervention on the hospital admissions, healthcare resources and utilisation exist. One study investigated this matter and was also deemed relevant for inclusion in this review (Martínez-Velilla et al., 2021).

In this review, nearly 60% of the articles utilised patient reported outcome measures (PROMs) to evaluate changes in the physical and psychological dimensions of HRQoL, symptom burden, fatigue, and pain in patients with LC. The three most frequently employed PROMs within these studies are the Functional Assessment of Cancer Therapy – Lung (FACT-L) (25%), the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire Core 30 and Lung Cancer 13 (EORTC QLQ-C30, QLQ-LC13) (13%), and the Hospital Anxiety and Depression Scale (HADS) (13%). PROMs are widely used in the management of LC and evidence suggests that PROMs used in clinical care can provide the clinicians with valuable prognostic information to predict survival in LC patients (Friis et al., 2021). Additionally, PROMs can be utilised to guide decision making in patients with deteriorating health. (Cavanna et al., 2020; Friis et al., 2021). The EORTC QLQ-C30 and QLQ-C13 are the preferred PROMs to be used in research when evaluating the HRQoL in patients with LC (Bouazza et al., 2017; Cavanna et al., 2020). However, in this review, the FACT-L was the most utilised PROM. Both tools are rather comprehensive, a factor which might be exhaustive for patients required to use these tools. In addition, PROMs are increasingly being used in research to evaluate HRQoL following the completion of PR (Rutkowska et al., 2019; Saetan et al., 2020).

2.3 Critical Appraisal

The aim of this process was to evaluate the impact of PR on the HRQoL of patients diagnosed with LC and on the health system performance using the literature identified for this review. A thorough analysis of the articles generated the following main themes which shall be discussed below.

i. The physiological and psychological changes experienced by LC patients during PR/exercise-based intervention and the influence on the patient's HRQoL.
ii. The perceived enablers and barriers to PR/exercise by patients and HCPs.
iii. The impact on the healthcare system, utilisation of resources and overall survival.

2.3.1 Effects of Pulmonary Rehabilitation on Health-related Quality of Life in Lung Cancer Patients

HRQoL is an important prognostic factor in patients with cancer. Evidence evaluating the relationship between the HRQoL prior to the initiation of any systemic anti-cancer treatment (SACT) and/or radiotherapy and the prognosis in patients with LC have suggested that higher HRQoL scores could predict longer survival, whereas decreased HRQoL scores is correlated with to poor treatment outcome. Thus, HRQoL is envisaged as a valuable factor that could identify patient prognosis, aid in the choice of treatment provided and the likelihood of successful treatment outcomes (Fiteni et al., 2016; Liu et al., 2022). LC is often associated with poor HRQoL when compared to other cancer types due to the number and severity of disease symptoms especially fatigue, dyspnoea and pain experienced in this cohort of patients (McIntyre & Ganti, 2017; Polanski et al., 2016). Thus, effective management of symptoms is recommended (Polanski et al., 2016).

Planned, individualised, and supervised exercise-based programmes have been demonstrated to be practical and beneficial in patients with advanced LC during SACT and/or radiotherapy when compared to patients who undergo no exercise interventions, and are therefore sedentary (Rutkowska et al., 2019). Individualised interventions are recommended by various studies (Ester et al., 2021; Quist et al., 2020) as exercise can be tailored to the patient's capabilities which

contribute to increased patient compliance. Patients diagnosed with LC appreciate that a structured programme can guide them in aspects such as symptom management, enhance behavioural change to improve their HRQoL and increase their knowledge related to their disease (Edbrooke et al., 2019; Rutkowska et al., 2019).

2.3.1.1. Physiological Changes in Patients with Lung Cancer. PR within the oncology setting aims to promote functional independence, improve exercise capacity and HRQoL. Rutkowska et al. (2019) assessed the impact of a 4-week hospital-based exercise training programme in patients with inoperable NSCLC (stages IIIB or IV) whilst undergoing chemotherapy treatment. The recruited participants received chemotherapy during their in-patient stay for four consecutive weeks with one week off treatment in between. A total of 46 patients were recruited and were randomised into the intervention group and the control group. Patients within the control group did not perform any kind of exercise. PR was conducted five times per week under the supervision of a physiotherapist and consisted of resistance training, specific respiratory exercises, 20-30 minutes of endurance training and fitness exercises.

Statistically significant improvements were noted in most physical performance tests for participants enrolled in the intervention group. These included the time up and go test ($p=0.01$), chair stand ($p=0.01$), arm curl ($p=0.01$) and 6-minute walk test (6MWT) distance ($p=0.01$). Such improvements have been attributed to the level of intensity of the exercises, this being a high-intensity programme and one carried out over a short period of time in adherence with the American College of Sports Medicine (ACSM) guidelines for patients with cancer. These guidelines recommend twice weekly resistance training and 3-5 times per week of moderate intensity, 30-minutes duration in patients with cancer (Schmitz et al., 2019). However, a relatively small number of participants were enrolled in this study which makes it difficult to generalise findings.

Whilst undergoing SACT and/or radiotherapy, patients with LC experience an array of symptoms associated with the condition and their treatment which may contribute to a reduced HRQoL. Interestingly, in contrast with the physical improvements observed in Rutkowska et al.

(2019), in a recent RCT by these same authors (Rutkowska et al. 2021) no statistical difference in HRQoL of patients diagnosed with stage IIIB and stage IV NSCLC resulted despite using the same study setting. In Rutkowska et al. (2021) study, HRQoL was the only outcome measure being investigated. HRQoL was assessed using 3 main questionnaires, these being the St. George's Respiratory Questionnaire (SGRQ), Short Form Health Survey (SF-36) and the FACT-L before and after PR. No statistically significant changes HRQoL were reported in both groups. Together with this, the FACT-L questionnaire revealed no statistically significant changes in the intervention group, but a statistically significant deterioration in physical well-being ($p< 0.02$) was noted in the control group. PROMs used in Rutkowska et al. 2021 study are validated tools which contribute to robust, meaningful, and objective measurements when evaluating the patient's HRQoL. Thus, these findings may imply that a 4-week programme could have been too short to observe changes in HRQoL affecting the results of the study.

Quist et al. (2020) evaluated the effect of an exercise intervention in patients with advanced LC. Patients with NSCLC (88.1%) and SCLC (11.9%) with stage III/IV who participated in supervised group sessions on an out-patient basis were recruited. A total of 218 patients were randomly assigned to the intervention group and the control group (1:1). Patients in the intervention group were divided into groups of 10-12 patients. The 12-week intervention consisted of twice weekly strength, cardio and relaxation exercises. The control group received usual care and were advised to maintain their level of activity while receiving chemotherapy. In this study, the primary outcome was the maximal oxygen consumption (VO_2 max) and was measured using cardiorespiratory exercise testing on a cycle ergometer. Secondary outcomes included muscle strength measured by 1 repetition maximum (1RM) tests, functional capacity measured by the 6MWT, Forced Expiratory Volume in 1 second (FEV_1) measured by spirometry test, anxiety and depression evaluated using the Hospital Anxiety and Depression Scale (HADS) and HRQoL assessed with the FACT-L instrument. Assessors were blinded to the patient group allocation, therefore decreasing bias and increasing internal validity. No significant improvements in VO_2 peak ($p=0.17$) were observed between the two

groups and the 6MWT difference approached significance in between group comparison (p=0.09). However, both individual groups demonstrated significant difference in the 6MWT (p<0.01).

This study's results are not consistent with those presented by Rutkowska et al. (2019) since the latter reported significant improvements in the 6MWT for participants in the intervention group (p=0.01) and also close to significance change between groups (p=0.09) with no significant difference in the control group (p=0.09). This could have been due to the different exercise frequencies, the duration of the programme and the mode of intervention (individualised or group-based). Moreover, Quist et al. (2020) recommended that participants recruited in the control group were to stay active while those in Rutkowska et al's (2019) study did not perform any exercise. Thus, an element of confounding bias was introduced in Quist et al. (2020), masking the actual association between the impact of the exercise intervention and HRQoL, contributing to inconclusive results. Nonetheless, significant improvement was observed in muscle strength in both studies when compared to their control group assessed by the arm curl test in Rutkowska et al. (2019) study and 1RM test in Quist et al. (2020)'s study.

Findings reported by Quist et al (2020) are somewhat congruent with those reported in another RCT by Dhillon et al. (2017). A group of patients with advanced staged LC participated in an 8-week physical intervention and were compared with standard care. Participants included patients with NSCLC (94%) and SCLC (6%) with stage III/IV. The exercise programme was structured, individualised and predominantly aerobic. Home-based exercises were also recommended. The primary aim of this study was to evaluate whether PA had an influence on fatigue and HRQoL. Fatigue was measured using the FACT-L and HRQoL was measured using the EORTC-QLQ-C30 and LC-13. Fatigue scores did not produce statistically significant differences between the two groups even when adjusted for sex, age, disease stage and baseline fatigue (p=0.82). The study also demonstrated no improvement in HRQoL, symptoms and functional status. This study was an open label intervention which may introduce an element of bias when administering patient outcome measures. Information is not withheld from participants in an open label intervention and this may

influence their views and their reporting of symptoms. Physical function, activity, and fitness were also assessed in this study using the 6MWT with no significant difference between-groups after two months (p=0.97). Similarly, in both studies control groups were not discouraged from undertaking any other exercise during the length of the intervention.

Interest in embedding PR/exercise-based programmes in LC care is gaining momentum. A meta-analysis by Lee (2021) investigated the effectiveness of exercise-based interventions for patients with LC during chemotherapy. A total number of six RCTs with a low risk of bias within the trial were included in this meta-analysis. Studies recruited NSCLC and SCLC patients. Intervention and control groups within the studies received both radical and palliative chemotherapy, while control groups received only standard care with no exercise involvement. Results of this meta-analysis demonstrated favourable effects with significant increase in muscle strength, force expiratory volume, HRQoL including physical well-being, functional well-being, and social well-being. Despite the small number of studies included in this meta-analysis, the outcome measures utilised within each trial were similar. Outcome measures included 6MWT for functional capacity, arm curl for muscle strength, spirometry tests and pain. Hence, this study yielded similar outcome measure results in increased measurement consistency which facilitated comparability between studies. This meta-analysis suggests that LC patients receiving chemotherapy ideally engage in supervised resistance and aerobic exercise for the duration of their chemotherapy. To improve physical and psychosocial function, a 1-hour intervention five times a week at a moderate to vigorous level was suggested.

2.3.1.2 Psychological Well-Being. Struggles associated with coping with depression and anxiety are common in patients with LC. These psychological effects may further contribute to the worsening of symptoms which impact patient social well-being and HRQoL. Quist et al. (2020) has demonstrated that an exercise intervention in patients with advanced LC showed a significant reduction in anxiety (p=0.02) and depression (p=0.01) levels in the intervention group. These were measured using the HADS scale. Also, the FACT social well-being subscale score showed a significant difference between the intervention and control groups (p=0.04), with a decrease in the control

group. Despite the low adherence rate (44%) observed in this study due to disease progression, symptom burden, hospital appointment and death, improvement in the secondary outcomes, which included anxiety and depression, were observed.

However, in a meta-analysis by Lee (2021), depression rates had a medium effect size (d=-0.55, 95% [CI] -0.81- -0.29, p<0.01) while anxiety was not statistically significant (d= -0.06, 95% [CI] -0.31-0.20, p=0.67) when measured by the HADS. In this meta-analysis, the control groups were not involved in any kind of exercise whilst in Quist et al. (2020) the control group were recommended to stay active which could justify the incongruent results.

2.3.2 Pulmonary Rehabilitation in Symptom Management

Patients with LC experience physical and psychological symptoms that are associated with a decline in HRQoL, and any improvement is limited to the number and severity of disease symptoms. Thus, educating the patient on strategies regarding symptom management should be implemented on diagnosis and throughout the patient cancer journey (Edbrooke et al., 2020; Granger et al., 2018).

2.3.2.1 Cancer Related Fatigue (CRF). CRF is one of the most common symptoms experienced by patients with cancer and typically increases during SACT and/or radiotherapy. Since CRF is present throughout the whole course of the disease, day-to-day living and overall HRQoL may be negatively affected. Ester et al. (2021) concluded that a 12-week PA intervention for patients with advanced LC has potential benefits on HRQoL with meaningful reduction in fatigue and tiredness and improvement in energy levels. This study used a prospective mixed-method design and the intervention included in-person group exercise class, nutrition and symptom management guidance along with a tailored home-exercise programme. Exercise intensities were based on the individual capabilities progressed towards reaching the ACSM cancer exercise guidelines. Patient reported scores on symptom burden, fatigue and energy were collected before and after each class. Edmonton Symptom Assessment System (ESAS) was used to measure symptom burden, fatigue and energy and FACT-F single item fatigue score was also used to measure fatigue. HRQoL was also

investigated by using the FACT-L, ESAS, and FACT-F outcome measures. Throughout the intervention, no statistical significance was observed in the total symptom burden (ESAS total, p =0.854), fatigue (FACT-F, p=0.429) and HRQoL (FACT-L total, p=0.736). However, using single-item thermometers before and after exercise class, substantial reductions in individual ESASA scores after 12-weeks were observed in tiredness (p=0.015), and significant improvements observed in fatigue (p <0.001) and energy (p <0.001).

In this study, 10 participants were recruited in the PA intervention and only 7 completed the post intervention follow up in which optional semi-structured interviews were conducted. Participants perceived both physical and psychological benefits throughout the intervention. An increase in energy levels, decrease in fatigue, anxiety and pain, improved sleeping and HRQoL was reported. Triangulation within this study enhanced the credibility of the findings. However, only statistically significant changes were reported for tiredness levels and more research is warranted. Nonetheless, Dhillon et al. (2017), reported high levels of fatigue in their participants at baseline and no significant difference was recorded between groups after 2 months (p=0.62) of individualized PA programme when measured using FACT-L subscale.

2.3.2.2 Dyspnoea. Another common symptom experienced in patients with LC is dyspnoea. LC patients can make use of a variety of coping skills to alleviate dyspnoea and a PR programme is one of the strategies that patients can utilise. Breathing exercises are an important component of PR which include pursed lip breathing, diaphragmatic breathing, and the active cycle of breathing techniques. Respiratory muscles are strengthened through targeted breathing training which stimulate the respiratory muscles and diaphragm. These techniques improve respiratory muscle function and reduce the symptoms of dyspnoea.

An RCT by Saetan et al. (2020) evaluated the effects of respiratory rehabilitation programmes on dyspnoea in patients with LC. Participants were patients with NSCLC stage IV. Twenty-eight patients were recruited and allocated equally within two groups. The intervention group received

educational sessions on causes of symptoms, self-management, use of hand-held fans, breathing exercises, coughing techniques, and exercises to strengthen respiratory muscles. Participants were thereafter followed up by phone. Outcome measures were used at pre-test, fourth week and eighth week of the programme. These included a self-efficacy assessment and the Cancer Dyspnoea Scale. The mean score of perceived self-efficacy and dyspnoea score showed significant improvement between groups ($p < 0.05$) and suggests that respiratory rehabilitation equip patients with coping skills to manage dyspnoea and delay exacerbation, thus promoting self-efficacy.

On the other hand, Rutkowska et al. (2019) showed no significant improvement in the intervention group in the mean values of the modified Medical Research Council questionnaire ($p=0.18$) and Baseline Dyspnoea Index ($p=0.83$). In Rutkowska et al. (2019) RCT, the intervention group underwent a 4-week hospital-based exercise programme. However, significant improvements in perception of dyspnoea were recorded through the Borg Dyspnoea Scale ($p=0.04$). Spirometry results showed statistically significant improvements in FEV_1 % predicted ($p=0.01$), FVC % predicted ($p=0.01$) and FEV_1/FVC ($p=0.04$) in the intervention group. In contrast, aerobic capacity measured by VO_2 max in Quist et al. (2020) showed no significant difference between the intervention and control groups. Various factors could have led to these inconsistencies in results which include adherence level to the intervention, duration of intervention and commencement of intervention.

2.3.3 Pulmonary Rehabilitation Setting and Time of Enrolment

The mode of delivery and the time of PR intervention, that is before, during or after receiving SACT and/or radiotherapy may affect patient adherence and effectiveness of the programme. In comparison to two previous mentioned studies (Dhillon et al., 2017; Quist et al., 2020), patients recruited by Edbrooke et al (2019) participated in an 8-week home-based intervention programme. This programme was patient centred and tailored to meet the needs of the patient. It consisted of resistance training mainly focusing on lower limb functional exercises, a minimum of 10-minute walks twice a week, behaviour change strategies, and symptom management. Following completion of the 8-week programme up to trial completion, all participants were contacted for review and

progress exercises accordingly. Like Quist et al. (2020) and Dhillon et al. (2017), patients within the control group were not prevented from participating in any other form of exercise which could potentially have a diluting effect on the intervention group. In contrast to the study by Dhillon et al. (2017), assessors involved in the studies by Quist et al. (2020) and Edbrooke et al. (2019) were blinded to minimise bias. However, neither of these three studies demonstrated a between-group difference in functional status measured by the 6MWT.

In Edbrooke et al's. (2019) study, 92 patients were randomised and stratified into the intervention group and standard care control group. Functional exercises capacity was measured using the 6MWT, HRQoL was assessed using the FACT-L questionnaire and symptom severity was assessed using the MD Aderson Symptom Inventory – Lung Cancer (MDASI-LC). Outcome measures were taken at baseline, at 9-weeks and at 6-months. No significant difference between groups for the 6MWT was recorded at 9-weeks (p=0.308) and at 6-months (p=0.979). Likewise, the change in HRQoL (FACT-L total score, p=0.365) and symptom severity (p=0.153) were not significantly different at 9-weeks, but statistically significant benefits favoured the intervention groups after a 6-month follow-up (FACT-L, p=0.005; MDASI-LC, p=0.001). Quist et al. (2020) demonstrated significant differences between the groups in social well-being (FACT-L, p= 0.04) after a 12-week supervised exercise-based intervention.

The difference in HRQoL outcomes between those presented by Edbrooke et al. (2019) and Dhillon et al. (2017) could be linked to the time of enrolment of the participants within the study where Edbrooke et al. (2019) recruited patients on commencement of active treatment and Dhillon et al. (2017) after completing chemoradiotherapy. On diagnosis, patients might be already experiencing some symptoms, which can be further augmented whilst receiving oncological treatment. Side effects such as fatigue, pain, peripheral neuropathy and nausea may contribute to a decline in patient's HRQoL and may affect patient's participation in a rehabilitation programme. On the other hand, on completion of the oncological treatment, patients may have started to build resilience to the side effects of the chemoradiotherapy, or some side effects may have started to

subside contributing to a better HRQoL. Thus, Edbrooke et al. (2019) might have observed better results in HRQoL and symptom severity at 6-months because the study was conducted whilst the patients were undergoing active treatment and patients were still adjusting to their condition and the treatment side effects resulting in changes in HRQoL and symptom burden.

2.3.4 Perceptions Towards Pulmonary Rehabilitation

Insights gained from patients with LC and HCPs working within the field may offer increased understanding on how to facilitate the integration of PR into clinical practice. Edbrooke et al. (2020), in another study, explored the views of PR on patients with NSCLC (stage III-IV). Semi-structured interviews were conducted, transcripts were cross checked, and conventional content analysis was used to extract themes from the data collected. Participants were contacted and 55% (n=25) completed the interviews. Most participants perceived PR to be strongly beneficial throughout their cancer journey. Exercises were individually tailored, monitored, and modified according to the patient capabilities. This was mostly valued by the participants as an individualised programme facilitated a safe environment where to be more active. Interviews were undertaken by phone and results may have differed compared to when interviews were conducted face-to-face. Moreover, re-call bias is inevitable in this study due to interviews being conducted post-intervention. However, transcripts were cross-checked by a second researcher to ensure accuracy and coded by two other independent researchers. Participants within this study stated that a home-based programme was ideal as it fitted well within their demanding schedule and most participants valued the aerobic component of the programme stating that walking was their preferred exercise. Furthermore, guidance and support on how to self-manage symptoms were perceived of great importance. Hence, participants reported an increased confidence in symptom management. However, participants mentioned heightened symptoms to be the most challenging to complete the programme, but few (n=5) stated that they did not exercise during those periods.

Payne et al. (2018) supports outcomes from this study and additionally explores the views of HCPs. Semi-structured interviews were conducted following a six-week home-based rehabilitation

which consisted of individualised behavioural change strategies, combined PA, and nutritional guidance. Results discussed the utility and the benefits gained from the rehabilitation approach in patients with NSCLC faced with functional decline due to disease progression, treatment side-effects and other co-morbidities. It has been suggested that rehabilitation should be recommended to maintain or prevent functional decline, support patient well-being and HRQoL (Payne et al., 2018). In contrast to the study by Edbrooke et al. (2020), who conducted interviews by phone, interviews in this study were conducted face-to-face, hence, capturing emotional and behavioural clues which otherwise would not have been captured. The credibility of this study was further enhanced by comparing transcripts with the field notes.

Limited published research exploring the perceptions of HCPS on PR was identified following the process of the selection of articles according to the inclusion and exclusion criteria. Thus, this suggests a research gap within this field on the use of PR for patients diagnosed with LC from the HCPs perspective. Consequently, this limits in-depth deliberation on the perceived benefits and barriers of PR along with improvements in healthcare service and quality of care in LC management.

2.3.5 Patient Pre-Health Status and Pulmonary Rehabilitation

The previous health condition and age of the patient may have an influence on the effectiveness of the PR programme. A non-randomised controlled longitudinal study by Rosero et al. (2020) investigated the effects of a 10-week individualised exercise-based programme in older adult patients (≥70 years) with NSCLC (I-IV) whilst receiving adjuvant treatment. In contrast to the previous studies (Dhillon et al., 2017; Edbrooke et al., 2019; 2020; Payne et al., 2018; Quist et al., 2020; Rutkowska et al., 2019; 2021), approximately 50% of the patients within this cohort had undergone surgery prior to the study at a non-defined time. These included video-assisted thoracic surgery and open surgery and data was accessed through the patient medical records. A total of 34 patients were allocated to the control group (n=13) and the intervention group (n=21). The programme consisted of a combination of strength, endurance, balance, coordination, and flexibility training aimed at achieving and/or maintaining a satisfactory level of independence in activities of daily living. Patients

included in the control group received only normal care including physiotherapy, if necessary, with no participation in any kind of supervised exercises conducted. The physical/cognitive function and mental well-being were assessed pre- and post-intervention. The participants and researchers were not blinded in this study, but the primary investigator was not involved in the exercise programme. Statistical analysis was carried out by another independent researcher to further minimise bias.

Rosero et al.'s (2020) reports significant increases in the total score of the functional capacity tests (p=0.004) and muscle performance in the intervention group. This may have resulted due to the relatively high drop-out of subjects (n=6) in the control group compared to the intervention group (n=2). In the control group drop out was due to death (n=3) and lost to follow up (n=3), whereas in the intervention group drop out was due to withdrawal for oesophageal surgery and death. Only 7 patients within the control group and 19 patients within the intervention group were eligible for analysis. Thus, this unequal group analysis might have limited comparison between the groups and contributed to these findings. Another factor that might have led to these results is the proportion of the patients within the intervention group (n=7) that underwent surgery at an undefined stage before the study as compared to the control group (n=1). Furthermore, a significant improvement in the physical function (p=0.037) and global health status/HRQoL (p=0.029) domains of the EORTC QLQ-C30 questionnaire were observed. Significant decreases in symptoms of pain (p= 0.030), dyspnoea (p=0.025) and other body pain (p=0.025) were also noted. By contrast, the control group showed no differences in the HRQoL domains. The fact that 8 out of 21 patients within this study had surgery sometime prior to the study may have led to inconclusive results and may be a cause of confounding bias. No stated measures were taken within this study to account for this limiting factor and no indication was given to whether the results attained were the effect of PR and/or an effect of the surgery as no indication of when the surgery was done was reported.

2.3.6 Barriers Towards Pulmonary Rehabilitation

One of the major barriers encountered within the literature was a lack of knowledge and awareness amongst HCPs on the benefits of PR and exercise programmes within the oncology setting

(Payne et al., 2018; Pilotto et al., 2022). Granger et al. (2018) states that some patients are poorly informed and recall not being encouraged to stay active. Furthermore, patients with LC acknowledge the need to maintain general PA. However, lack the knowledge and guidance on how to reach the desired goals and manage their symptoms effectively (Granger et al., 2018).

Due to the lack of knowledge amongst HCPs, rehabilitation is often not considered until patients experience a physical decline in function and present with symptoms. Early support, rehabilitation, and education to prevent deterioration of health status is important in patients with LC. In a qualitative study by Granger et al. (2018), physiotherapists' perspectives were viewed through focus groups, transcribed verbatim and cross-checked independently. A lack of resources, services availability, and a lack of referral pathways were identified as major barriers to refer patients with LC for rehabilitation during cancer treatment (Granger et al., 2018). Unfortunately, in this study physiotherapists perceived the healthcare system as being very reactive, meaning that its focus is on discharge planning and not on promoting strategies to prevent further deterioration in health status because of disease progression and/or oncology treatment (Granger et al., 2018). It is imperative to tackle barriers affecting delivery of rehabilitation services offered to patients with LC and encourage their participation by optimising HCPs knowledge on the available services and improving the availability of the resources required within the healthcare system (Pilotto et al., 2022).

Patients often perceive exercise-based programmes as a cause for increase in symptom burden including fatigue and dyspnoea (Granger et al., 2018; Edbrooke et al., 2020). Moreover, the perception that exercise can worsen symptoms is prevalent and family and peer support tend to advise patients to rest. Such perceptions are predominantly reported as hindering patients from participating in PA even when the patients are willing to do so (Granger et al., 2018; Payne et al., 2018). Contrastingly, social support such as from family and friends can be used as a vehicle to encourage patients with LC to participate in PR.

2.3.7 Enablers Towards Pulmonary Rehabilitation

Payne et al. (2018) explored patients' and HCP's views following the completion of individualised rehabilitation programmes during advanced LC treatment. It is noteworthy that negative attitudes by HCPs impeding recommendation of rehabilitation in this population changed to a positive attitude where rehabilitation was perceived as a means to support and maintain or improve HRQoL. These findings are further extrapolated in a survey exploring HCP's perceptions of exercise in patients with LC where 99% of HCPs perceived exercise as safe, beneficial, and effective even in patients with advanced lung cancer. HCPs expressed the view that exercise could improve cancer-related fatigue and overall physical fitness. Furthermore, 87% of the respondents stated that exercise intervention should be a standard part of cancer care (Pilotto et al., 2022). Hence, encouragement from the HCPs, especially from the patient's oncologist was perceived as crucial to promote participation and maintain adherence with exercise interventions (Granger et al., 2018; Pillotto et al., 2022). Additionally, Edbrooke et al. (2020) states that the support and experience from HCPs was valued by patients while physiotherapists facilitated a safe environment to exercise.

2.3.8 A Public Health Perspective

LC is often associated with a relatively higher disease burden when compared to most other cancer types due to the severity, experienced side effects and the burden imposed on families with significant impact on the health system (Zhang et al., 2021). Most patients are diagnosed with LC at an advanced stage leading to treatment delays and consequent poorer treatment outcomes and decline in HRQoL. Thus, LC contributes to increased utilisation of health resources and recurrent admissions especially towards end-of-life phases (Wang et al., 2019).

There is growing body of evidence supporting the positive impact of PR/exercise-based rehabilitation on patients diagnosed with LC. However, the implementation of these valuable tools is continuously being hindered by a mesh of interrelated barriers across the health system (Granger et al., 2018; Pillotto et al., 2022). Organisations such as the American Society of Clinical Oncology and American College of Sport Medicine have endorsed exercise guidelines for people with cancer during

treatment and after completing cancer treatment (ACSM, 2019; Ligibel et al., 2022). These organisations recommend regular aerobic and resistance exercises during and after completing active treatment. Additionally, the American College of Chest Physicians recommends supervised exercise-based PR in post-operative LC patients and in advanced, inoperable LC patients whilst receiving oncological treatment to improve functional capacity and cardiorespiratory fitness (Deng et al., 2013). Despite these recommendations, these guidelines are infrequently followed, and patients are not engaged in PR/exercise-based programmes that have been proven to elicit significant benefits. This may be due to a lack of awareness amongst HCPs to advise patients to follow these guidelines (Ester et al., 2021).

Implementation of PR/exercise-based programmes directed towards symptom management and promoting a comprehensive approach within routine cancer care have been shown to improve patient health outcomes and potentially reduce health system utilisation. This may possibly be achieved by educating patients to control symptom severity and frequency or treat some adverse side effects including fatigue, and dyspnoea (Cormie et al., 2017). However, more research is warranted to explore practice beyond the general exercise guidelines and develop better policies to improve the efficiency and effectiveness outcomes of healthcare services for LC patients (Cormie et al., 2017; Granger et al., 2019).

2.3.8.1 Effect on the Frailty Status of Patients. Elderly patients present with multiple comorbidities which may affect treatment tolerance and adherence. A secondary analysis of the study of Rosero et al. (2020) study, Martínez-Velilla et al. (2021) argues that a multicomponent exercise programme can aid to improve the frailty status in newly diagnosed elderly patients (≥70 years) with NSCLC stage I-IV receiving active treatment. In this longitudinal study, a 10-week exercise programme consisting of resistance, endurance, balance, and flexibility training exercises resulted in a reversal of frailty effects in 21.1% of the participants enrolled in the intervention group as measured by the Fried scale. The change in frailty status was measured using the Vulnerable Elders Survey (VES), Geriatric 8 (G-8) screening tool and the Fried Index scale, despite no significant changes

observed between group differences of each outcome measure. Only the Fried scale seemed to be able to detect changes after the intervention. This was a non-randomised study which could have limited comparability between the intervention and the control group due to selection bias. Moreover, a relatively small number of participants were recruited limiting extrapolation of findings.

2.3.8.2 Effect on the Overall Survival. Limited studies are available evaluating the prognostic importance of PA level on overall survival in LC patients. In a longitudinal investigation, Sloan et al. (2016) examined the relationship of PA with HRQoL and the overall survival at various time points in a large cohort (n=1466) of LC survival. The sample was equally divided by gender. HRQoL was assessed using the Lung Cancer Symptom Scale and PA was measured using the Baecke Questionnaire. Patients were asked to complete questionnaires starting at six months post initial diagnosis and then once a year thereafter. Cox model and Kaplan-Meier analysis were used for survival analysis in relation to PA. Approximately half of the LC survivors were diagnosed with advanced stages and 61%, 54%, and 33% had surgery, chemotherapy, and radiotherapy respectively. It was concluded that patients who were physically active had an average of four more years of survival than patients who were inactive (8.4 years vs 4.4 years respectively, log rank $p < 0.0001$). It is challenging to use PA outcome measures accurately due to their subjective nature. However, in this study a large sample size was used which contributes to a smaller margin of error. Hence, a positive gain could be seen between PA and survival in LC survivors suggesting increased likelihood of a positive impact of PA in the management pathway of LC patients.

In contrast, Dhillon et al. (2017) carried out an exploratory analysis of the overall survival from the time of randomisation to death using the Kaplan-Meier analysis. No significant difference in survival between groups ($P_{log\text{-}rank}=0.75$) was observed with a median survival of 15.4 months in the intervention group and 13.2 months in the control group. Hence, overall survival does not show congruency with Sloan et al. (2016)'s findings which could be related to the small sample size (n=112) in contrast to the large cohort enrolled within Sloan et al. (2016)'s study, thus, limiting comparability.

2.3.8.3 Effect on Healthcare Services and Use of Resources. Secondary analysis of findings from Rosero et al.'s study (2020) involved assessing the health status of the participants one year after completion of the intervention. Primary outcomes included mortality rate, readmissions, and visits to the emergency department. Of interest, a significant difference in frequency of visits to the emergency department between groups was noted (p=0.034) with higher numbers in the control group. However, no difference was noted in mortality rate (p=0.686) and readmissions (2 vs 0; p=0.092) with an increased trend in the control group when compared to the intervention group (Martínez-Velilla et al., 2021). Therefore, a supervised exercise-based programme can be beneficial to minimise the number of times a patient with LC visits the emergency department. This may consequently result in a decreased burden on the emergency department. In addition, healthcare resources can be employed better for the benefit of the whole health system.

Similarly, Dhillion et al. (2017) observed no difference in the number of hospital admissions or length of stay in patients with advanced LC within the intervention group. Admissions were recorded at intervals throughout the study. Even though both studies involved LC patients with stage III/IV, these studies are inconclusive when evaluating hospital admissions or length of stay. Dhillon et al. (2017) involved inoperable patients' post-cancer treatment (≥4 weeks) and Martinez-Velilla et al. (2021) study was conducted one year post intervention with a sample consisting of approximately 50% of patients who had surgery at an undefined time before being recruited in Rosero et al.'s (2020) study. Thus, this factor may have affected results due to improved symptoms that may have been experienced in patients who had surgery at an undefined period before the study and also the time when the outcome measure was taken may have affected findings.

On the other hand, more research is available on the impact of PR on the healthcare system in patients with other chronic respiratory disease that investigate the number of emergency admissions, hospitalisation rate, healthcare resources and utilisation. In a retrospective cohort study by Özmen et al. (2018), the effect of PR on emergency admissions and hospitalisation rate was investigated in 51 patients with Chronic Obstructive Pulmonary Disease (COPD) (73%) and non-COPD

(27%). Despite not falling in the exclusion criteria of the study, patients with LC were not part of the sample. PR was delivered over a period of 8-weeks, twice weekly. Data on emergency admissions and hospitalisation were collected through the hospital registration system, medical records, and the patient. A significant decrease in emergency admissions (p=0.001) and hospitalisation (p=0.001) was observed after PR. Considering the cost of hospitalisation and utilisation of health resources, PR is recommended as an adjuvant to the management of patients with chronic respiratory conditions. However, research investigating the impact and benefits of PR in LC patients on the health-related resources and overall health system is still very scarce and more research is warranted.

2.3.8.4 Economic Evaluation of Pulmonary Rehabilitation. Limited studies are available evaluating the cost-effectiveness of PR in LC patients. PR might be a cost-effective strategy as it is an intervention which encompasses within its framework a multidimensional approach, considering nutritional, psychological and behavioural aspects (Edbrooke et al., 2021). Edbrooke et al. (2021) is one of the first studies to investigate the cost-effectiveness of home-based rehabilitation compared to standard care in patients with inoperable LC. This cost-utility analysis was conducted alongside an RCT, and the economic evaluation was based on Edbrooke et al. (2019) RCT study. The Assessment of QoL (AQoL) Questionnaire was used to evaluate the QALYs at nine-weeks and six-months follow-up. Moreover, a health economic questionnaire regarding the participants' health services utilisation was developed by the researchers and used at nine-weeks, four months, and six months follow-up. Incremental cost-effectiveness ratio results showed that home-based rehabilitation during and following LC treatment has a 75% probability of being cost-effective when compared to standard care. A high degree of uncertainty exists due to lack of evidence. Consequently, more research and economic evaluations are required to establish whether PR is cost-effective and to further support its implementation into standard care management Of LC patients.

2.4 Conclusion

This literature review sought to delve deeper into changes in HRQoL following PR/exercise-based interventions undertaken by patients with LC. Findings frequently showed that physical, psychological, and social aspects are key factors driving LC patients' HRQoL. Patients with LC may experience a decline in their physical and mental well-being which may be further augmented whilst undergoing SACT and/or radiotherapy. This chapter looked for published research and evidence to elicit the rationale, benefits, and impact of PR/exercise-based intervention on the symptoms experienced by LC patients and how they can be alleviated through alternative interventions with the consequent impact on the health system and the healthcare services provided to these patients.

Knowledge regarding barriers faced by patients with LC as well as the identified enablers should be utilised when developing new policies/strategies or when designing changes to existing health services. This review explored how LC burden may affect the health system and utilization of healthcare resources. Thus, effective implementation of an exercise component within cancer management paradigm can contribute to a reduction in cancer burden. The literature pointed out that extremely limited evidence is currently available from investigations on the impact of PR/exercise-based intervention on the whole health system. This status merits and motivates further research in this key area that impacts both the patients and their families/carers as well as society through the services provided to them. Additionally, this literature review has shown that a systematic, multidimensional approach involving all HCPs and encompassing several sectors within the health system, is a vital component to help optimise patient standard care and patient outcomes.

Chapter 3: Methodology

3.1 Introduction

The aim of this chapter is to provide an overview of the research design employed in order to answer the research questions. This chapter describes and explains the methodological approaches and the sampling, data collection and analysis procedures utilised for each section of the research study. In addition, the relevant ethical issues that were taken into consideration will also be addressed.

3.2 Research Design

A mixed-method research design was adopted in this study in order to seek in-depth understanding on the impact of Pulmonary Rehabilitation (PR) for patients with LC on both the healthcare services and overall impact on the individual patient's HRQoL. The study fieldwork was conducted between November 2022 and February 2023. Data was collected through a patient reported outcome measure questionnaire, administered by the researcher to patients with LC and through structured interviews with HCPs involved in the health management of LC patients.

3.2.1 Rationale for Mixed Method Research

In mixed-method research (MMR), the researcher bases the research analysis on the assumptions that collecting different type of data can provide added value to understand the research problem (Creswell & Creswell, 2018). Acknowledging that all research methods have limitations, MMR seeks to neutralise biases of one method by mitigating them with the strengths of other methods. Consequently, this approach offers increased validity through triangulation, where the detailed, contextualised insights collected through the qualitative data are integrated with the generalisable, external insights of quantitative data (Creswell & Creswell, 2018; Şahin & Özturk, 2019). Furthermore, MMR improves the research study's potential and credibility by expanding and complementing data obtained through different methods. It allows a deeper understanding of the

research problem through different perspectives and comparison of data (Bryman, 2012). Moreover, it implies that the gaps arising from one method are countered by another method in the study.

An MMR offers a more comprehensive account to understand and evaluate the impact of PR on the HRQoL of patients diagnosed with LC and the health system performance. Employing this approach to assess changes in HRQoL can be fruitful to further understand unexpected findings that may be generated by one method when comparing with the findings of the other method. However, it must be kept in mind that a mix-method approach is time consuming and adequate time is required to ensure that good research quality is maintained (Bryman, 2012; Creswell & Creswell, 2018).

In this study, questionnaires were used to measure the relationship between PR and HRQoL. At the same time, the perceptions of HCPs on PR in this cohort of patients were explored using structured interviews. The reason for combining both quantitative and qualitative data is to better understand the research problem by converging both numerical trends at the patients' level and detailed data on the insights from the professionals' perspectives. Thus, triangulated findings may be mutually corroborated resulting in increased credibility and validity of the findings.

3.3 Research Setting

This study was conducted at Sir Anthony Mamo Oncology Centre (SAMOC) among patients who had been diagnosed with LC and had a performance status of 0-2 (Figure 3.1). These patients were assessed by the oncologist at SAMOC outpatient clinic, and a treatment pathway was planned. During this session, oncological treatment was discussed and any further support and/or referrals to other HCPs were offered if required. Patients who were frailer were assessed on an individual basis by the oncologist and treated accordingly. A patient performance status is considered one of the most important factors in cancer care. It is a score that gives an estimation of the patient's present level of independence in carrying out activities of daily living. The patient performance status aids the oncologist to determine the best choice of treatment for patients with cancer and help shape the

patient's prognosis. The scale ranges from 0 to 4, 0 being fully functional and asymptomatic and 4 refers to patient being bedridden (West & Jin, 2015).

Figure 3.1 *Eastern Cooperative Oncology Group (ECOG) Performance Status*

Grade	ECOG
0	Fully active, able to carry on all pre-disease performance without restriction
1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g. light house work, office work
2	Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours
3	Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours
4	Completely disabled. Cannot carry on any selfcare. Totally confined to bed or chair
5	Dead

Source: Oken et al. (1982) as cited in ECOG-ACRIN Cancer Research Group. (2022). *ECOG Performance Status Scale - ECOG-ACRIN Cancer Research Group.* https://ecog-acrin.org/resources/ecog-performance-status/

Currently, PR is offered to oncology patients at the Physiotherapy Department at SAMOC when referred. In 2021, a total of 98 patients with LC were referred for PR at SAMOC with an average of 8 patients per month. The PR programme is delivered by a physiotherapist as per SAMOC standard operating procedures (Appendix C). A thorough initial assessment is conducted prior to commencement of the PR programme to determine the suitability of the patient to attend PR. If patients are not eligible for PR, they are offered modified treatment sessions according to their needs. Outcome measures including the 6-minute walk test, or 1-minute sit-to-stand to measure exercise tolerance, chest expansion measurements and Modified Borg Dyspnoea Scale are carried out pre- and post-intervention to quantify the effectiveness of the programme. Thereafter, patients follow an individualised programme starting with a warm-up and followed with breathing exercises, aerobic

exercises, resistance exercises, behavioural change strategies, and education on symptom management. Aerobic and resistance exercises are progressively increased accordingly from one session to the next, depending on the patient current condition. PR is an 8-week programme delivered at least once a week and patients are provided with a home exercise programme along with an information booklet. Each session lasts approximately 45 minutes which varies depending on the patient needs. Patients are supervised and parameters (blood pressure, heart rate and oxygen saturations) are continuously monitored during this programme for safety reasons. Patients are then followed up after one month from completion of PR. Additionally, patients are advised to contact the physiotherapist before if required. Moreover, patients may be referred to other HCPs if needed throughout the PR programme.

3.4 Target Population and Sample Selection

Purposive sampling was used. The main goal of this sampling technique is to ensure that representatives of the population that can best answer the research question are included. Purposive sampling is commonly used in qualitative or mixed-method studies and samples are selected in order to gain rich and in-depth information from the limited resources available (Campbell et al., 2020; Palinkas et al., 2015). However, since it is a type of non-probability sampling it does not allow the researcher to generalise over a whole population and to other populations with similar characteristics (Bryman, 2012). Since the total of number patients referred for PR in 2021 was relatively small with an average of 8 patients per month, it was planned that a sample size of 10-20 patients would be recruited during the 4-month evaluation period bearing in mind the 8-week duration of the programme. Patients were recruited based on the inclusion and exclusion criteria (Table 3.1). 5-10 HCPs were planned to be recruited in this study following the inclusion and exclusion criteria as illustrated in Table 3.2.

Table 3.1 *Inclusion and Exclusion Criteria for Patients*

Patient inclusion criteria	**Justifications**
Patients referred to SAMOC for continuum of care	Research question is related to patients with oncological diagnosis
Patients with primary LC diagnosis	Relevance to the research question
Performance status (PS) of ≤ 2	Patients with PS ≤2 are more capable of participating in PR
Patients that were aware of their diagnosis	Relevant due to the nature of the questions asked in the questionnaire
Patients referred for PR by nurse navigator and/or medical team	Patients are given clearance to participate in PR
Patients that were already attending physiotherapy department and assessed to be ideal candidates for PR	Patients are capable of participating in PR
Patients over 18 years of age	Due to ethical considerations
Patient exclusion criteria	**Justifications**
Patients not referred to SAMOC	Research question related to patients who are attending SAMOC for oncology reasons
Patients with other diagnosis not related to the lung or where the lung is not affected and patients that do not have LC	Relevance to the research question
Patients who do not manage to complete the PR programme (for any reason)	Patients must complete PR programme to be able to carry out the second questionnaire

Table 3.2 *Inclusion and Exclusion Criteria for Healthcare Professionals*

Healthcare professional inclusion criteria	**Justifications**
Participant must have been directly involved in the care of patients who have attended PR	Participants with direct involvement would be more able to express their experience on the change in HRQoL in patients with LC
Participants must have reviewed patient more than once	To observe changes in HRQoL of the patient, patient must be reviewed more than once by the participant
Participants may include consultants, medical doctors, nurses, physiotherapists, occupational therapists, and social workers working at SAMOC	A multidisciplinary team perspective is sought
Healthcare professional exclusion criteria	**Justifications**
Participants who had only one encounter with patients who are/were enrolled in the PR	Unable to observe changes in the patient HRQoL
Participants who are involved indirectly in the patient care	HCPs who do not have direct contact with the patient, therefore, unable to detect changes in HRQoL e.g.: lab analyst

All patients diagnosed with LC who were referred for PR programme at SAMOC were assessed for eligibility and invited to participate between November 2022 and December 2022. A total of 20 patients were recruited in this study. However, only 14 patients were eligible for data analysis as 6 patients dropped out from the study. From these 6 patients, 2 patients stated that they had too many hospital appointments with transport being an issue. Another patient dropped out due to chemotherapy side-effects and preferred to carry out PR after completing oncological treatment. The remaining 3 patients deteriorated and had to halt the PR programme before it was completed. An intermediary was responsible for recruiting participants for the study (Appendix D). The intermediary was another physiotherapist working at the Physiotherapy Department in SAMOC. An information sheet was physically disseminated to the invited participants who fitted the inclusion criteria (Appendix E). A written consent form was provided when the patient accepted to participate in the study (Appendix F).

An invitation letter was also sent to the HCPs by their respective heads. The researcher's contact details were included in this letter (Appendix G). Subsequently on acceptance to participate in the study, an information sheet along with a consent form was disseminated (Appendix H & I). Ten HCPs were recruited in this study and structured interviews were conducted. These HCPs were the ones who contributed in one way or another towards the care of patients with LC diagnosis throughout their cancer journey and assisted them through various issues (medical, physical, social, etc) over a period of time.

HCPs were invited to participate in this study to capture a wider holistic understanding of the impact of PR on the HRQoL of patients with LC and the utilisation of other healthcare services. Furthermore, the views of a multidisciplinary group of professionals can provide complementary insights on the enablers and barriers for PR participation and/or referral. Providing effective healthcare for oncology patients is challenging in relation to the limited resources and the increasing healthcare needs. Thus, HCPs are uniquely positioned to uncover limitations within the healthcare system and services provided to patients. Also, the lived experiences of HCPs offer a better

understanding on how to handle challenging situations and match healthcare needs. Potentially, HCPs perspectives can offer an opportunity for recommendations to be drawn for the improvement of the management pathway for LC patients.

3.5 The Research Tool

Questionnaires were the research instruments employed for the data collection in this study (Appendix J) together with structured interviews (Appendix K). The European Organisation for Research and Treatment in Cancer-Quality of Life Questionnaire-EORTC QLQ-C30 and EORTC QLQ-LC29 were the questionnaires utilised in this study. Data collected from the questionnaires were in numerical format and data collected through structured interviews were audio-recorded and transcribed verbatim in text format.

3.5.1 Questionnaires

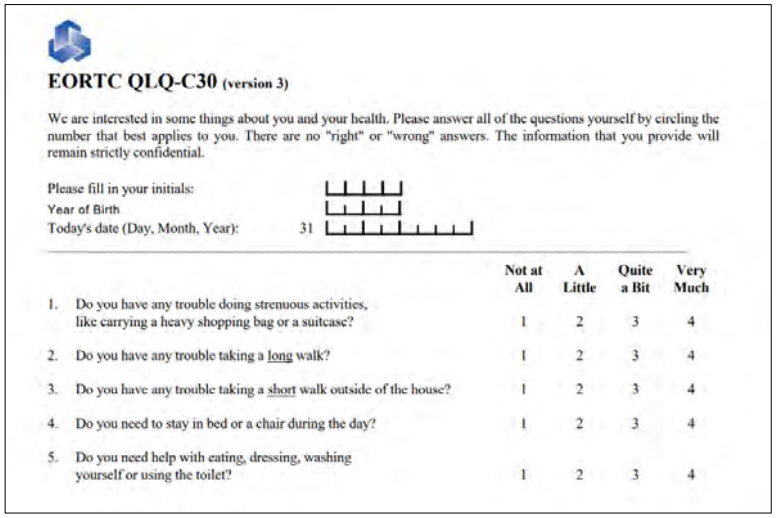
Patient reported outcome measures (PROMs) were used as part of the research tools. Following the patient's initial assessment by the physiotherapist at SAMOC and on receiving the patient consent, a PROM recording questionnaire was administered to the patient by the researcher before commencing the PR programme. A second repeat of the PROM tool was carried out on completion of the PR sessions (after the 8th session). Both completed PROM compilations were conducted within the Physiotherapy Department at SAMOC.

PROMs are elicited from standardised questionnaires that can provide the researcher with valuable information on the patient's symptoms, functional status, patient well-being and HRQoL. Additionally, they provide a means of assessing patient satisfaction with the service and can subsequently contribute to healthcare service evaluation and subsequent improvements (Graupner et al., 2021; Mejdahl et al., 2018). The EORTC QLQ-C30 questionnaire was the PROM based tool that was used to assess aspects of HRQoL in cancer patients while EORTC QLQ-LC29 was also used as an adjunct to the previous questionnaire to offer a more focused investigation on LC. Permission for the

use of the EORTC-QLQ-C30 and LC29 questionnaires was obtained prior to the initiation of study from the EORTC Quality of Life Group (Appendix L).

The EORTC QLQ-C30 questionnaire is one of the most widely used research tool to assess HRQoL in research that focuses on patients with cancer (Figure 3.2) (Ahn et al., 2021; Bade et al., 2021; Bouazza et al., 2017). It is a validated, 30-item questionnaire that focuses on important domains and assesses global HRQoL, physical functioning, cognitive functioning, social functioning, and common symptoms associated with cancer (Giesinger et al., 2016). All scores are inputted into a scale ranging from 0 to 100. Higher functioning scores correspond to higher levels of functioning and higher symptoms scores indicate more symptom burden. Giesinger et al. (2020) have successfully defined thresholds for clinical importance in all functional domains and symptom scales. These thresholds facilitate interpretation of HRQoL scores and identify patients with clinically important issues requiring further interventions by HCPs. Through the availability of the thresholds for clinical importance, the EORTC QLQ-C30 is made more accessible and is recommended for daily clinical practice and clinical research. Furthermore, associated cancer symptoms and side effects were assessed using the adjunct questionnaire, EORTC-QLQ-LC29, which covers LC patients with different disease staging and treatment modalities (Figure 3.3).

Figure 3.2 *Sample of EORTC QLQ-C30 questionnaire*



EORTC QLQ-C30 (version 3)

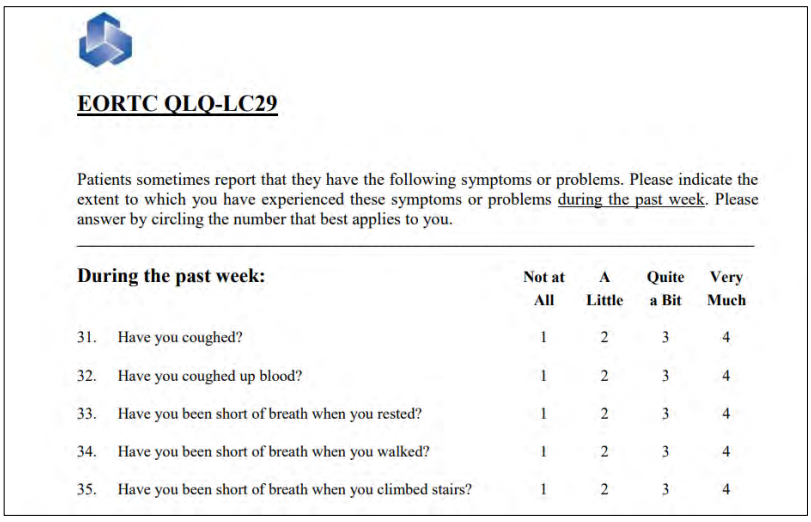
We are interested in some things about you and your health. Please answer all of the questions yourself by circling the number that best applies to you. There are no "right" or "wrong" answers. The information that you provide will remain strictly confidential.

Please fill in your initials:
Year of Birth
Today's date (Day, Month, Year): 31

		Not at All	A Little	Quite a Bit	Very Much
1.	Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	1	2	3	4
2.	Do you have any trouble taking a long walk?	1	2	3	4
3.	Do you have any trouble taking a short walk outside of the house?	1	2	3	4
4.	Do you need to stay in bed or a chair during the day?	1	2	3	4
5.	Do you need help with eating, dressing, washing yourself or using the toilet?	1	2	3	4

Source: Aaronson et al. (1993). The European Organisation for Research and Treatment of Cancer QLQ-C30: A quality-of-life instrument for use in international clinical trials in oncology. *Journal of the National Cancer Institute*. 85: 365-376.

Figure 3.3 *Sample of EORTC QLQ-LC29 questionnaire*



EORTC QLQ-LC29

Patients sometimes report that they have the following symptoms or problems. Please indicate the extent to which you have experienced these symptoms or problems during the past week. Please answer by circling the number that best applies to you.

During the past week:		Not at All	A Little	Quite a Bit	Very Much
31.	Have you coughed?	1	2	3	4
32.	Have you coughed up blood?	1	2	3	4
33.	Have you been short of breath when you rested?	1	2	3	4
34.	Have you been short of breath when you walked?	1	2	3	4
35.	Have you been short of breath when you climbed stairs?	1	2	3	4

Source: Aaronson et al. (1993). The European Organisation for Research and Treatment of Cancer QLQ-C30: A quality-of-life instrument for use in international clinical trials in oncology. *Journal of the National Cancer Institute*. 85: 365-376.

By nature, PROMs are subjective, and are thus prone to bias. Validity and reliability are important aspects to consider when assessing the data collected from PROMs based tools. However, various studies have demonstrated good evidence of validity of the EORTC QLQ- C30 and concluded that this questionnaire is an acceptable and reliable instrument for use with patients at different cancer stages (Cocks et al., 2023; Davda et al., 2021; Shih et al., 2013). Validation serves to demonstrate that the research instrument is measuring what it is proposed to measure. Nevertheless, the mode of administration is important to consider when using questionnaires as it may lead to bias (Chang et al., 2019).

PROMs were administered by the researcher which may have introduced interviewer bias, social desirability bias and acquiescent response bias. However, efforts to reduce bias were made by administering the questionnaires solely by the researcher in this study, and by reading the questions in the same order, word by word. Questionnaires were administered twice during the study when the researcher was aware that the patient was going to begin or had just completed the programme. Consequently, this contributed towards consistency in interviewer bias.

3.5.2 Interviews

Structured interviews provided the researcher with further insights on the impact of PR from the HCPs' perspective. They ensured the researcher obtained relevant information while at the same time allowing the participant the freedom to answer in their own words (Bryman, 2012). Structured interviews were used to standardise and ensure that the same data from each respondent in the study was collected irrespective of the professional background of each participant. Interview questions were read word by word and in the same order to improve reliability, reduce bias and ensure a level of consistency between interviews. HCPs involved in the patient cancer care were invited to participate in this part of the study through an opt-in method.

Interviews were conducted face to face at SAMOC and were audio-recorded to keep interview transcription-related error to a minimum. Interviews lasted approximately 30-minutes each. Audio-recordings were coded and thereafter, interviews were transcribed verbatim followed by a thematic analysis. Transcripts were re-checked against the audio-recording for accuracy.

Interview questions were self-designed by the researcher. A combination of open and closed ended questions were used. These two types of questions differ from each other in terms of response expected and obtained from the participant, with both encompassing strengths and weaknesses. Open-ended questions are the type of questions that allow the respondent freedom to express their experiences, knowledge, and thoughts in more detail. They require more effort from the respondent to construct an answer and they are more time-consuming. Open and broad questions ensure that the responses are minimally influenced by the researcher. On the other hand, closed-ended questions restrict the respondent to a diminutive answer which is straightforward and easy to respond to. Moreover, closed-ended questions enhance the comparability of responses between participants.

The opening questions of the interview were broad and aimed at gaining an understanding on how HCPs defined rehabilitation in cancer care and invited HCPs to discuss their views on PR in general within the LC care pathway. Subsequent questions focused on factors related to the patient's HRQoL, enablers and barriers, clinical care and outcome, and any impact on the healthcare services. This interview aided the researcher to obtain increased awareness on the role of PR within the limits of the oncology setting and to suggest modifications, support and/or improve delivery of health services in said setting for optimum care. Additionally, it assisted the research to explore the impact of PR on the health system performance.

3.5.3 Pilot Study

A pilot study is a small-scale study conducted to evaluate the adequacy of the research design and research tools to be utilised and to identify potential flaws before the main study is undertaken (Bryman, 2012). For the purpose of this research study, both research instruments were assessed for acceptability and ease of understanding by the participants. The EORTC QLQ-C30 and EORTC QLQ-C29 questionnaires were not piloted on patients who qualified to be part of the sample that was employed in the full study. Two non-patients with known case of a respiratory condition participated in this pilot study. The reasons behind this were because the population of patients diagnosed with LC referred for PR is relatively small, ease of access and time constraints.

The questionnaires took approximately 10 minutes and both participants mentioned that the questionnaires were easy to understand and straightforward to complete. One participant stated that despite the two questionnaires being different there was some overlapping between the two questionnaires to a certain extent. However, minimal overlapping of questions ensures consistency between the responses and overall analysis.

The interview schedule was also piloted to ascertain whether the questions were easy to comprehend, to assess the flow of the interview process and to gain a better idea on what to expect from the participants in the actual study. This pilot study helped the researcher to familiarise with the research instruments and enhance confidence to carry out the interview. A physiotherapist working at SAMOC participated in this pilot study to assess the tool. The participant was not part of the actual study. The time taken to complete the interview was 25 minutes. Based on the feedback, the interview schedule was feasible, interesting, and only one of the questions was slightly modified to be easier to understand by all participants.

3.6 Data Analysis

3.6.1 Statistical Analysis from the patients' quantitative tool

Data was analysed using descriptive statistics. Data collected from the questionnaires were analysed using the EORTC QLQ-LC30 and QLQ-LC29 manual scoring procedures. For each multi-item scale, the mean of the component items, known as the Raw Score (RS) was calculated manually. This was then followed by a linear transformation to standardise the raw score. A linear transformation was done to standardise the RS to a 0-100 range where a high scale score and single-item measure represents a higher response level. Thus, a higher score in global health status and functional scale represents high HRQoL and a higher level of functioning respectively and a higher score in symptom scale/items represent a high level of symptomatology/problems. The RS of the component items were determined using the following equation where 'I' is the individual item score and 'n' is the number of items included in a scale.

$$\text{Raw Score} = \frac{(\text{I}_1 + \text{I}_2 + \ldots + \text{I}_\text{n})}{\text{n}}$$

The standardisation of the RS was determined by the following equations depending on the scales /item.

Functional Scale:

$$\text{Score} = \left\{1 - \frac{(RS - 1)}{range}\right\} X\ 100$$

Symptom Scale/items and Global health status/HRQoL:

$$\text{Score} = \left\{\frac{(RS - 1)}{range}\right\} X\ 100$$

In the above equations 'range' represents the difference between the maximum and minimum possible values of RS. Most items are scored between 1 to 4, giving a range of 3 except for the global health status/HRQoL with a range of 6.

Data was converted into numerical format in Microsoft Excel 2017 and imported into the Statistical Package for the Social Sciences version 28. Statistical analysis was used to compare changes in patient HRQoL from baseline at the start of the PR programme and again at its completion after 8 sessions. To evaluate if the score distribution was normal or skewed, the Shapiro Wilk test was applied. If the p-value is more than the threshold of significance of 0.05, it was acceptable to accept the null hypothesis, which states that the score distribution is normal. If the p-value is less than the 0.05 threshold, the alternative hypothesis was adopted, which states that the score distribution is skewed. Both parametric and non-parametric tests were performed to further assess the data since some Shapiro Wilk p-values were greater than the 0.05 level of significance. The Paired t-test (parametric) and the Wilcoxon test (non-parametric) were used to compare the global health status/QoL, functional and symptom scores at baseline and after 8 weeks PR.

3.6.2 Qualitative Data Analysis

Following the transcription of the interviews, thematic analysis was chosen to analyse the qualitative data and compare it with the analysed data captured through the PROMs. Thematic analysis is one of the most common approaches used to analyse qualitative data. It helps the researcher to systematically organise and analyse complex data sets (Brayman, 2012). Thematic analysis is a process of reading through the data set and searching for patterns (themes) that emerge as important in the subject under investigation. Thus, themes are developed, and sub-themes are identified to give structure to a particular large and complex theme (Braun & Clarke, 2006). This approach of analysing data is an effective way to capture and understand the in-depth experiences of HCPs and enrich the understanding on PR in relation to LC patient's HRQoL and to improve services provided in cancer care.

Themes were derived from data and were not identified in advance. Data were analysed line by line and was read more than once to gain a whole picture of a participant's perspective. No software programmes were used to manage these data. Pieces of information that share the same concepts were coded and were grouped by similarity to generate themes. Emergent themes and sub-themes were supported by verbatim extracts to assess validity of the interpretation. Furthermore, confirmation bias was minimized by following Braun & Clarke (2006) guidelines to formulate the analysis (Figure 3.4).

Braun & Clarke (2006) suggests six phases to guide the researcher through the thematic analysis and ensure rigour in the analysis process. A thematic analysis approach offers flexibility, as it is not a linear process but more of a recursive process which allows for movement between the different phases of the analysis (Braun & Clarke, 2006).

Figure 3.4 *Phases of Thematic Analysis*

Phase	Description of the process
1. Familiarizing yourself with your data:	Transcribing data (if necessary), reading and re-reading the data, noting down initial ideas.
2. Generating initial codes:	Coding interesting features of the data in a systematic fashion across the entire data set, collating data relevant to each code.
3. Searching for themes:	Collating codes into potential themes, gathering all data relevant to each potential theme.
4. Reviewing themes:	Checking if the themes work in relation to the coded extracts (Level 1) and the entire data set (Level 2), generating a thematic 'map' of the analysis.
5. Defining and naming themes:	Ongoing analysis to refine the specifics of each theme, and the overall story the analysis tells, generating clear definitions and names for each theme.
6. Producing the report:	The final opportunity for analysis. Selection of vivid, compelling extract examples, final analysis of selected extracts, relating back of the analysis to the research question and literature, producing a scholarly report of the analysis.

Source: Braun, V., & Clarke, V. (2006). Using thematic analysis in psychology. *Qualitative Research in Psychology*, *3*(2), 77–101.

3.7 Establishing Trustworthiness

Trustworthiness is a vital element that enriches the research process by improving the validity and reliability standards in a research study (Zohrabi, 2013). Lincoln & Guba (1985) proposed four criteria to achieve rigour and ensure trustworthiness. These include credibility, transferability, dependability, and confirmability (as cited in Bryman, 2012).

3.7.1 Credibility/Internal Validity

Credibility is one of the most important criteria in establishing trustworthiness. It refers to the measures taken to enhance and ensure the integrity of the findings (Bryman, 2012). In this study, a triangulation approach was employed using an MMR design. Thus, the two sets of data were compared with each other to ensure that the research findings are both rich and comprehensive in order to demonstrate the truth to answer the research question. Furthermore, the questionnaires utilised, EORTC-QLQ-C30 and QLQ-LC29, are validated research tools which are widely used to assess health related quality of life for cancer patients.

3.7.2 Transferability/External validity

Transferability is defined as the process to which research findings can be applied to other contexts, circumstances, and settings. Lincoln & Guba (as cited in Bryman, 2012) encourage thick, rich description to facilitate transferability of findings to other milieus. Thus, in this study the views and experiences of the HCPs were used to provide the readers with enough data to judge the level of transferability. However, small samples were recruited within this study which may limit external validity.

3.7.3 Dependability/Reliability

Dependability/reliability refers to the extent to which the research method produces consistent and reasonable results over time and across methods. In this research study, a detailed methodology was described in order to ensure dependability. Furthermore, questionnaires and interview questions were read word by word to encourage reliability.

3.7.4 Confirmability

Confirmability is concerned with the neutrality of the research findings and their interpretation. The researcher acknowledges the existent biases and efforts are made not to overtly allow personal values to sway the findings of the research study. In this study, confirmability was ensured through the triangulation approach where concrete numbers increased accuracy and objectivity of findings.

3.8 Ethical Considerations

Ethical approval was sought and obtained from the Faculty of Medicine and Surgery (MED-2022-00163) Research Ethics Committee of the University of Malta prior to commencement of the study (Appendix M). Permission from the Data Protection Office at Mater Dei Hospital, the Chief Executive Officer at Mater Dei Hospital, the Clinical Chairperson at SAMOC and Director at SAMOC were also obtained (Appendix N). The necessary permission from the respective heads of the HCPs involved within this study were also sought. These include permissions from the Professional Lead of Physiotherapy Services, the head of Occupational Therapy Department at SAMOC, and the Director of Nurses (Appendix O). Lastly, an approval from the Foundation for Social Welfare Services (FSWS) was obtain in order to include the Social Workers working at SAMOC within this study (Appendix P).

Participants were given an information sheet with full details of the purpose and nature of the study. Contact information of the researcher, supervisor and co-supervisor were also provided on the information sheet should the participant have required further details on the study. Participants were informed that their participation was completely voluntary, and they had the possibility of withdrawing from the study at any time. A consent form was delivered before participation in the study. Participants were also informed that strict confidentiality was to be maintained throughout the study and the identity of all participants would not be revealed in any publications arising from this study. All data collection was pseudonymised to ensure confidentiality and anonymity in the research results and data was only accessed by the researcher.

Patients who participated in this study were offered psychological support at SAMOC if required (Appendix Q). All the participants were made aware of their right to access, rectify and where applicable, request the deletion of data under the General Data Protection Regulation (GDPR) and the national legislation. Once the study is completed and the results are published, all data collected shall be deleted.

3.9 Conclusion

This chapter provided a detailed description on the methodological framework adopted within this research study. A concurrent mixed method approach was used. Questionnaires and structured interviews were utilised to assess the impact of PR on the health system performance and HRQoL of patients with LC and to capture HCPs perceptions respectively. In the next chapter, the results of the study will be presented in detail along with the interpretation of these findings.

Chapter 4: Results

This chapter presents the data collected through the quantitative and qualitative components of the mixed method research design. In the first part, the statistical analysis of the quantitative data collected from the patient reported outcome measures shall be presented and discussed. This is followed by the results of the qualitative data obtained through the interviews.

4.1 Quantitative Data Analysis

4.1.1 Demographic Data

The active fieldwork of this study was conducted between November 2022 and February 2023. A total of twenty patients were eligible for the study, however only fourteen completed the 8-week Pulmonary Rehabilitation (PR) programme and were eligible for data analysis. Six patients dropped out. Three patients deteriorated and had to stop the PR programme, two other patients stated that they had too many hospital appointments with transport being an issue, while the other patient dropped out due to chemotherapy side-effects. Demographic data is presented in Table 4.1 by gender, stage of cancer and age. All patients were receiving systemic anti-cancer treatment and/or radiotherapy at the time of PR. Only one patient was not receiving any kind of medical treatment. All patients had an Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 1. This was documented in the medical notes by the oncologist and in the initial physiotherapy assessment.

Table 4.1 *Demographic data of patients*

	Category	Number of Patients	Percentage of Patients %
Gender	Female	3	21.4
	Male	11	78.6
Stage of Cancer	I	3	21.4
	II	0	0
	III	4	28.6
	IV	7	50.0
Age	≤44	0	0
	45 – 54	1	7.1
	55 – 64	3	21.4
	65 – 74	7	50
	75 - 84	3	21.4
	≥85	0	0

4.1.2 Statistical Analysis for QLQ-C30 Questionnaire

The European Organisation for Research and Treatment in Cancer-Quality of Life Questionnaire-EORTC QLQ-C30 was the patient reported outcome measure (PROM) used to assess aspects of HRQoL in patients suffering from cancer. It is a validated, 30-item questionnaire that focuses on important domains and assesses global HRQoL, be it physical, cognitive and social functioning, as well as common symptoms associated with cancer (Giesinger et al., 2016).

The Shapiro-Wilk normality test was computed for the raw mean scores and the standardised score to determine whether data was normal distributed or skewed. The global health status/QoL, physical functioning and the emotional functioning scales showed a normal distribution while the rest of the scales and single-item measures were skewed (Appendix R). In view of this, both parametric and non-parametric tests were used to analyse the data further. The Paired sample t-test and the Wilcoxon test were used to compare the mean percentage of the global health status/QoL, functional scales and symptoms scales/items scores at baseline and after 8-weeks of PR completion. One-sided p-values were used for the Wilcoxon test (Table 4.2 and Table 4.3).

The null hypothesis specified that the mean percentage of global health status/QoL, functional scales and symptom scales/items scores vary marginally between the two phases where a

p-value exceeding the 0.05 level of significance is acceptable. The alternative hypothesis specified that the mean percentage of the global health status/QoL, functional scales and symptom scales/items scores vary significantly between the two phases and a p-value smaller than the 0.05 criterion is acceptable.

Significant differences resulted in the mean raw scores (RS) and mean standardised scores (SS) of the global health status/QoL, physical functioning scale and emotional scale when analysed pre and post intervention. The change in global health status/QoL was found to be significantly different after 8-weeks of PR in both the RS ($p=0.03$) and the SS ($p=0.03$). Similarly, the change from pre to post PR scores in physical functioning was observed to be significantly highly different in both scores with a p-value of <0.001. The mean RS and mean SS for the emotional functioning scale showed a significant difference with a p-value of 0.008 and 0.005 respectively.

A significant difference also resulted in the mean scores for social functioning (RS $p=0.038$; SS $p=0.025$), pain (RS $p=0.02$; SS $p=0.013$), dyspnoea (RS $p=0.029$; SS $p=0.018$), insomnia (RS $p=0.002$; SS $p=0.002$), and fatigue (RS $p=0.045$; SS $p=0.044$). No significant differences in the mean scores of the role functioning, cognitive functioning and the rest of the symptoms/items were obtained.

Interestingly, the p-values of the mean RS and the mean SS are close to similar with minimal discrepancy or have the same values. These may indicate that results of the standardised mean scores are representative of the mean raw scores.

Table 4.2 *Paired test for raw mean scores*

		Median (Min-Max)	IQR	Mean	Std. Deviation	T-value	Z-value	P-value
Global Health Status/ QoL								
Global Health Status/ QoL	Pre-test			4.54	1.232	-2.065		**0.03**
	Post-test			4.93	1.158			
Functional Scales								
Physical Functioning	Pre-test			2.07	.512	4.418		**<0.001**
	Post-test			1.75	.435			
Role Functioning	Pre-test	1.50 (1.00-3.50)	1.00				-1.387[a]	0.08
	Post-test	1.00 (1.00-3.00)	1.00					
Emotional Functioning	Pre-test			2.39	.812	2.776		**0.008**
	Post-test			2.07	.646			
Cognitive Functioning	Pre-test	1.00 (1.00-3.00)	.63				-0.541[a]	0.29
	Post-test	1.00 (1.00-2.50)	.63					
Social Functioning	Pre-test	1.50 (1.00-4.00)	.63				-1.778[a]	**0.038**
	Post-test	1.50 (1.00-3.00)	1.00					
Symptoms Scales/Items								
Fatigue	Pre-test	2.165 (1.000-3.670)	.91				-1.703[a]	**0.045**
	Post-test	2.00 (1.00-2.67)	1.08					
Nausea and Vomiting	Pre-test	1.00 (1.00-2.00)	.50				-0.378[a]	0.353
	Post-test	1.00 (1.00-2.50)	.50					
Pain	Pre-test	2.00 (1.00-4.00)	1.13				-2.058[a]	**0.02**
	Post-test	1.75 (1.00-3.00)	0.63					
Dyspnoea	Pre-test	2.00 (1.00-4.00)	2.00				-1.890[a]	**0.029**
	Post-test	2.00 (1.00-3.00)	1.00					
Insomnia	Pre-test	3.00 (1.00-4.00)	1.50				-2.919[a]	**0.002**
	Post-test	2.00 (1.00-3.00)	1.25					
Appetite Loss	Pre-test	1.00 (1.00-4.00)	.00				-1.000[a]	0.159
	Post-test	1.00 (1.00-4.00)	.00					
Constipation	Pre-test	1.00 (1.00-4.00)	.25				-0.368[a]	0.357
	Post-test	1.00 (1.00-4.00)	.25					
Diarrhoea	Pre-test	1.00 (1.00-2.00)	.00				-1.000[a]	0.159
	Post-test	1.00 (1.00-2.00)	.00					
Financial Difficulties	Pre-test	1.00 (1.00-4.00)	2.00				-1.414[a]	0.079
	Post-test	1.00 (1.00-4.00)	1.25					

[a] based on positive ranks

Table 4.3 *Paired test for standardised scores*

		Median (Min-Max)	IQR	Mean	Std. Deviation	T-value	Z-value	P-value
Global Health Status/ QoL								
Global Health Status/ QoL	Pre-test			58.93	20.531	-2.063		**0.030**
	Post-test			65.47	19.310			
Functional Scales								
Physical Functioning	Pre-test			64.31	17.109	-4.407		**<0.001**
	Post-test			75.00	14.476			
Role Functioning	Pre-test	83.30 (16.70-100.0)	33.30				-1.445[a]	0.074
	Post-test	100.0 (33.30-100.0)	33.30					
Emotional Functioning	Pre-test			53.59	27.065	-2.968		**0.005**
	Post-test			66.70	19.550			
Cognitive Functioning	Pre-test	100.0 (33.30-100.0)	20.85				-0.541[a]	0.294
	Post-test	100.0 (50.00-100.0)	20.85					
Social Functioning	Pre-test	75.00 (.00-100.00)	24.95				-1.949[a]	**0.025**
	Post-test	83.30 (33.30-100.0)	33.30					
Symptom Scale/ Items								
Fatigue	Pre-test	38.80 (.00-89.0)	30.42				-1.703[b]	**0.044**
	Post-test	33.30 (.00-55.70)	36.05					
Nausea and Vomiting	Pre-test	.000 (.00-33.30)	16.70				-0.552[a]	0.290
	Post-test	.000 (.00-50.00)	16.70					
Pain	Pre-test	33.30 (.00-100.00)	33.30				-2.217[b]	**0.013**
	Post-test	25.00 (.00-66.70)	20.78					
Dyspnoea	Pre-test	33.30 (.00-100.00)	66.70				-2.081[b]	**0.018**
	Post-test	33.30 (.00-66.70)	33.30					
Insomnia	Pre-test	66.70 (.00-100.00)	50.05				-2.836[b]	**0.002**
	Post-test	33.30 (.00-66.70)	41.65					
Appetite Loss	Pre-test	.0000 (.00-100.00)	.00				-1.000[b]	0.158
	Post-test	.0000 (.00-100.00)	.00					
Constipation	Pre-test	.0000 (.00-100.00)	8.33				-0.368[b]	0.356
	Post-test	.0000 (.00-100.00)	8.33					
Diarrhoea	Pre-test	.0000 (.00-33.30)	.00				-1.000[b]	0.158
	Post-test	.0000 (.00-33.30)	.00					
Financial Difficulties	Pre-test	.0000 (.00-100.0)	66.70				-1.342[b]	0.090
	Post-test	.0000 (.00-100.0)	41.65					

[a] based on negative ranks
[b] based on positive ranks

4.1.3 Statistical Analysis for QLQ-LC29 Questionnaire

The EORTC-QLQ-LC29 was used as an adjunct questionnaire to the previous research tool to offer a more focused investigation on LC. This questionnaire was utilised to assess associated cancer symptoms and side effects experienced by patients suffering from LC with different disease staging and treatment modalities.

Through computation of the Shapiro-Wilk normality test, the coughing, shortness of breath and the fear of progression scales resulted as normal distributed, while the rest of the scales and single-item measures showed a skewed distribution (Appendix R). The Paired samples t-test and the Wilcoxon test were both computed to compare the mean percentage symptoms scales/items scores at baseline and after 8-weeks of PR completion (Table 4.4 and Table 4.5).

Table 4.4 *Paired test for raw scores*

		Median (Min-Max)	IQR	Mean	Std. Deviation	T-value	Z-value	P value
Symptoms Scales/ Items								
Coughing	Pre-test			1.79	.642	-1.546		0.073
	Post-test			2.14	.969			
Shortness of Breath	Pre-test			2.00	.628	0.260		0.400
	Post-test			1.95	.639			
Side Effects of Treatment	Pre-test	1.33 (1-2)	0				-3.103[a]	**0.001**
	Post-test	1.20 (1-2)	0					
Fear of Progression	Pre-test			2.37	1.142	3.034		**0.005**
	Post-test			1.86	.719			
Coughing blood/ Haemoptysis	Pre-test	1.00 (1-2)	0				-0.577[a]	0.282
	Post-test	1.00 (1-2)	0					
Pain in chest	Pre-test	1.50 (1-3)	1				-0.816[a]	0.207
	Post-test	1.50 (1-2)	1					
Pain in arm or shoulder	Pre-test	2.00 (1-4)	2				-2.530[a]	**0.0055**
	Post-test	1.00 (1-3)	1					
Pain in other parts of the body	Pre-test	2.00 (1-4)	2				-2.121[a]	**0.017**
	Post-test	2.00 (1-3)	1					
Weight Loss	Pre-test	1.00 (1-4)	2				-1.414[a]	0.078
	Post-test	1.00 (1-4)	1					

[a] based on positive ranks

Table 4.5 *Paired test for standardised scores*

		Median (Min-Max)	IQR	Mean	Std. Deviation	T-value	Z-value	P-value
Symptom Scales/ items								
Coughing	Pre-test			26.20	21.395	-1.545		0.073
	Post-test			38.10	32.307			
Shortness of Breath	Pre-test			33.33	20.950	0.260		0.399
	Post-test			31.73	21.307			
Side Effects of Treatment	Pre-test	11.0 (2.67-30.70)	11.68				-3.062[a]	**0.001**
	Post-test	7.00 (2.66-25.00)	11.33					
Fear of Progression	Pre-test			45.65	38.064	3.034		**0.005**
	Post-test			28.57	23.943			
Coughing blood/ Haemoptysis	Pre-test	.0000 (.00-33.30)	.00				-0.577[a]	0.282
	Post-test	.0000 (.00-33.30)	.00					
Pain in chest	Pre-test	16.65 (.00-66.70)	33.30				-1.069[a]	0.142
	Post-test	16.65 (.00-33.30)	33.30					
Pain in arm or shoulder	Pre-test	33.30 (.00-100.0)	66.70				-2.414[a]	**0.008**
	Post-test	.0000 (.00-66.70)	33.30					
Pain in other parts of the body	Pre-test	33.30 (.00-100.0)	66.70				-2.032[a]	**0.021**
	Post-test	25.00 (.00-66.70)	33.30					
Weight Loss	Pre-test	.0000 (.00-100.0)	66.70				-1.342[a]	**.0090**
	Post-test	.0000 (.00-100.0)	41.65					

[a] based on positive ranks

The Paired t-test resulted in no significant difference in the mean RS and mean SS in coughing (p=0.073) and shortness of breath scale (p=0.40) while a significant difference was observed in the fear of progression scale (p=0.005). The p-values of these three mentioned scores were the same or close to similar for the RS and SS.

Significant improvements in the mean scores for the side effects of treatment scale (RS p=0.001; SS p=0.001), pain in other parts of body (RS p=0.017; SS p=0.021), and pain in arm or shoulder (RS p=0.0055; SS p=0.008) was also noted. The remaining mean scores which include coughing blood (RS p=0.282; SS p=0.282), pain in chest (RS p=0.207; SS p=0.142) and the mean RS in weight loss (p=0.078) did not show significance between baseline scores and scores after 8-weeks PR. However, the mean SS in weight loss showed significance improvement (p=0.009) after PR completion.

4.2 Qualitative Data Analysis

4.2.1 Demographic Data

A total of ten face-to-face interviews were conducted with HCPs between November 2022 and February 2023. Interviews were conducted in SAMOC at a time convenient for the participants and each interview lasted for an average of 25 minutes. A multidisciplinary perspective was collected from the interviews with most of the professionals (60%) being physiotherapists (Table 4.6). Participants recruited for the study consisted of 7 females and 3 males. All participants worked at SAMOC and were experienced in working with patients suffering from cancer for a length of time ranging from 5 months to 5 years. Only two of the participants worked specifically with LC patients.

Table 4.6 *Demographic data of Healthcare Professionals*

Profession	Number of Participant
Physiotherapist (PT)	6
Occupational Therapist (OT)	1
Nurse	1
Medical Professional	1
Clinical Social Worker (CSW)	1

4.2.2 Themes

Following thematic analysis, five main themes were identified. Each of these main themes contained a number of sub-themes (Table 4.7).

Table 4.7 *Themes and sub-themes which emerged from the analysis*

Themes	Sub-Themes
1. Holistic Care Approach	• Role of Rehabilitation in the Oncology setting • Communication • Patient and relative/carer support
2. Education and Prevention	• Promoting Physical Activity • Awareness of PR • Symptom Management through Patient Education
3. Perceived physical and psychological benefits	• Patient resilience and improved functionality • Psychological Benefits
4. Impact on the Healthcare Sector	• Smoking behaviours • Improved Patient Experience and Quality of Care • Perceived effect on Hospital admissions
5. Maximising the efficacy of the intervention	• Challenges and Barriers to PR • Timing of PR

4.2.2.1 Holistic Care Approach. The theme of holistic care approach was predominant throughout the whole data collection and was attributed great importance by all participants. This theme combines the role of rehabilitation within the disease management pathway of patients with cancer and reinforces the importance of communication within a multidisciplinary team to enhance patient care. This theme is further divided into three sub-themes.

4.2.2.1.1 The role of Rehabilitation in the oncology setting. All participants demonstrated a good understanding of what cancer rehabilitation and PR entail in the oncology setting. Participant 7 described rehabilitation as having a very important role in the oncology setting, as "it allows the patient to do much more than otherwise they would be doing" (Occupational Therapist, OT). Participant 8 supported such a statement, saying that rehabilitation "assist the patient regain some form of independence and return to being close as normal as possible pre-diagnosis" (Clinical Social

Worker, CSW). Moreover, all participants stressed that rehabilitation looks into the elements of prevention, education, restoration and supportive care to improve HRQoL throughout their oncological treatment and beyond.

Most participants (n=8) emphasised the fact that PR is a structured, supervised programme which is tailored to the individual patient's needs, thus providing a sense of a plan and a structure in the patient care. Moreover, all participants mentioned that PR incorporates an element of safety as patients are monitored and supervised on a one-to-one basis. All participants stated that patients who attended PR observed improvement in their HRQoL, enjoyed attending the session and no harm was incurred. However, the CSW said that while most of the patients perceived PR as beneficial, a few did not observe much of a difference in their HRQoL. An element that was perceived as important in PR by two participants was the outcome measures utilised in the programme to monitor patient performance as they may offer the patient a sense of empowerment and/or acceptance of their condition.

Moreover, one participant, a physiotherapist, argued that PR may also be offered to patients with other cancer diagnosis since most patients receiving SACT and/or radiotherapy may experience lethargy, muscle weakness, decreased exercise tolerance and breathlessness on exertion. Thus, PR is a tool that can offer benefits to a wide spectrum of cancer conditions experiencing oncology-related pulmonary insufficiency including breathlessness and fatigue.

4.2.2.1.2 Communication. Communication with the patient (n=10) and liaising between HCPs (n=9) were perceived as important by participants to ensure patient safety and effective all-inclusive care. Effective communication between HCPs encourages a multidisciplinary approach to patient care and is crucial to enhance treatment and improve patient experience. Hence, patients are provided with holistic care, individualised for their needs. Participant 8 stated that: "It (referring to PR) encourages discussion between different HCPs as well as learning" (CSW). Thus, the exchange of knowledge between HCPs promotes increased awareness and understanding of PR.

4.2.2.1.3 Patient and Relative support. Living with cancer is a very difficult situation for both the patients and their relatives/carers. It was sensed by most of the participants (n=7) that PR offers a comfort zone for the patients and also the relatives/carers where they feel they are being helped in their basic needs and not left alone in this situation. It was mentioned that patients perceive PR as a reference point and a link to the medical team since they are followed up on a weekly basis.

Most participants (n=6) mentioned that PR offers an opportunity to correct misinformation and misbeliefs by patients and relatives/carers on physical activity whilst being diagnosed with LC and undergoing cancer treatment. Relatives/carers are also educated on the benefits of PR and supported throughout. Participant 8 stated: “they (relatives/carers) come and tell me because he (patient) is going physio, and they are doing this, this and that. For them, somehow, seeing something being done is something extremely important……even psychologically” (CSW).

In addition, resources provided to the patient during PR offer additional support to their relatives/carers and a reference point when they are at home and unsupervised. Participant 10 stated: “I think a good element is that you give them a booklet where there are written exercises. At least when they (the patient) go home, their daughter knows what exercises her father needs to do” (Nurse).

Participants disclosed that PR helps patients understand their limitations in their current health status and create realistic goals to meet the patient’s expectations. As patients are shown added attention within their care pathway, trust in the HCPs and the healthcare system follows. Hence, this factor may enhance compliance with their cancer care. Throughout the whole cancer pathway, patients are supported by a diverse group of HCPs. Additionally, a few participants (n=4) divulged that throughout the PR session more time is dedicated to the patient. This offers space for more discussion with the patient vis-a-vis their needs such as lack of support, negative thoughts, financial difficulties so that patients can be offered and/or referred to other governmental entities or non-governmental organisations as required.

4.2.2.2 Education and Prevention. The theme of education and prevention was mentioned by all participants as it was deemed important in the management of LC. This theme encompasses three sub-themes which promote physical activity (PA), awareness of PR and symptom management through patient education.

Participant 4 stated:

> "PR can be a means of prevention or a means of educating the patient from before…. From before maybe the problem has started (referring to side-effects of treatment) ……. It can start from the preventative aspect but gradually it can be helping the patients when they start developing symptoms and also sort of equipping the patient with tools." (Physiotherapist, PT4)

4.2.2.2.1 Promoting Physical Activity. The importance of PA was predominant for each participant and was viewed to be beneficial for everyone, from the healthy individual to people with ill health. PA prevents a sedentary lifestyle which may consequently contribute to other health conditions and further deterioration in health. Participant 7 stated "It (referring to PR) gives them the opportunity to be more active in their lifestyle and prevent them from being more sedentary and staying in bed etc. and leading to other conditions after that" (OT).

Another HCP described the patient like entering a viscous cycle where physical inactivity leads to decreased independence, decreased HRQoL, increased co-morbidities and increased burden on the caregiver and potentially, society: "With PR we get the patient to move, so we do solve a lot of comorbidities that might happen. For example: more weakness, being bedridden, chest infections, psychological problems……. They end up in a whole circle themselves" (PT5). This cycle can be further augmented if other underlying conditions are present such as COPD, asthma, osteoarthritis.

Health deterioration may lead to increased burden on the patient and caregivers. Thus, three participants (2 physiotherapists and 1 CSW) mentioned the importance of engaging in PR especially for patients who live alone to maintain and/or improve their physical function and independence as

much as possible. Patients are referred for further community care support when required. Empowering the patients to lead an active lifestyle may allow the patient to do much more than what they otherwise would be doing. A physiotherapist stated that through PR the patient is educated to pace their activities while carrying out their basic needs: “Overall helping the patient to continue his daily activities and continue his life basically… and maximising his potential” (PT3).

4.2.2.2.2 Awareness on PR. Low awareness on PR amongst the HCPs was noted by all the participant HCPs. Three HCPs (not physiotherapists) stated that despite acknowledging the importance of PR in the management of LC, they have limited knowledge on the benefits and the criteria for referring patients for PR: *“*I don’t know a lot about it, I have to admit but my understanding is that……the physiotherapist…… through exercises, breathing exercises and other form of exercises help the patient maximise their functional reserve” (Medical professional). Participant 4 continued by stating that: “It is like they’re (patient) missing a big component that can help them in their quality of life” (PT4).

Thus, this lack of knowledge may lead to decreased patient compliance when they are referred for PR programme as they are not informed on the benefits that may be gained through their participation prior to referral. Most of the HCPs (n=7) reinforced the importance of patients being encouraged by other HCPs and especially the medical professionals to participate and engage in PR. Patients tend to give more importance to what is said to them by their oncologist/doctor and are therefore more complaint if positive messages are communicated by them. Hence, increased awareness ought to be more widespread across different healthcare sectors, including in the primary healthcare setting and elsewhere within Mater Dei Hospital.

4.2.2.2.3 Symptom management through patient education. Patient education of symptom management is a fundamental component in PR and overall LC management. Throughout the interviews various symptoms and treatment side-effects were mentioned. These include dyspnoea, shortness of breath, decreased exercise tolerance, fatigue and nausea. However, the most common

symptom discussed was breathlessness which is one of the commonest symptoms experienced by patients with LC and which hinders the patient HRQoL.

All participants discussed that PR is an opportunity to teach the patient on how to control their symptoms. Patients are equipped with coping skills to control and minimise symptoms and/or side-effects during treatment or post-treatment. Participant 4 said that “the physiotherapist would be explaining to the patient, she will be explaining why these symptoms are occurring” (PT4). Hence, patients will have a better understanding of the condition and normalise the symptoms that they experience which further contributes to increased acceptance of the condition and compliance with the overall patient treatment. Participant 3 further elaborates that:

> “Giving the patient knowledge on how to control his symptoms… I think that’s one of the most important things. Maybe for us we are not doing anything, but I feel that the patient really appreciates that you’re explaining what can happen and how to deal with it if it happens…… They feel that they have a lot of things in their toolbox to know how to control their symptoms as well.” (PT3)

During PR, patients are taught and made more aware on how the exercises can help them in their daily activities. One of the participants mentioned that “the patient started to become more aware in what they can use the exercises you (referring to the physiotherapist) give them” (CSW). Furthermore, patients learn to recognise their limits and when to stop before they experience an exacerbation of their symptoms.

4.2.2.3 Perceived physical and psychological benefits. This theme is strongly linked with the previous topic. It offers an overview of the physical and psychological benefits perceived by HCPs on patients with LC who have participated in PR. All participants affirmed that PR has a positive effect on the HRQoL, a combination of improved functionality, increased independence and better psychological well-being. This theme is divided in two sub-themes.

4.2.2.3.1 Patient resilience and improved functionality. Physical function may be limited due to the condition and the side-effects associated with the disease and treatment. A participant supported this statement when stating that "they feel they cannot perform in activities because of their health limitations" (CSW). Moreover, most participants discussed how patients expressed their fears concerned the possibility of their symptoms worsening when participating in PA or may claim that they have no symptoms because they have a sedentary lifestyle. Participant 4 stated that "When you ask them, they start opening up that they are not experiencing certain things because they are not doing certain things." (PT4).

A small number of participants (n=3) said that a feeling of worthlessness is expressed by patients with LC as a result of their inability to continue with their everyday life. However, participants noted that patients recognise the usefulness of the programme to manage their needs and help them in their activities of daily living. Consequently, this contributes to increased resilience and compliance towards PR and their oncological treatment. Participant 4 argued that:

> "When we start carrying out the activities and the exercises, they realize what a big help it is……. very often during the session, when they are carrying out the exercises and we're monitoring them at the same time, they realise that they can do this, and they are following the cues of when to rest and when not to rest. They start relating these things and use them during their day-to-day basis." (PT4)

Hence, patients realise they can carry out simple tasks, control their breathing and are comfortable carrying out their activities of daily living such as cooking and cleaning even if they have to use oxygen. Body adaptation was mentioned by two participants, physiotherapists, and they emphasised the importance of explaining to the patient and help them understand that the body can adapt to the current health status whilst maintaining realistic goals.

All participants expanded on how PR can help patients improve their lung function and lung capacity, increase exercise tolerance, improve range of movement, and overall strength. Additionally,

participants elaborated on the importance of helping the patient improve and/or maintain their current health status especially during their oncological treatment to prevent further deterioration in health. Participant 3 said: “helping to strengthen muscles will also try to prevent, as much as possible, the patient from becoming worse” (PT3). Another participant spoke about a family member who participated in PR at SAMOC and said: “I knew that from the bedroom to the bathroom he found it difficult to take breaths and then he started the programme…… it made a difference…… even the fact that he remained walking” (PT6).

4.2.2.3.2 Psychological benefit. Two participants discussed the qualitative difference perceived from their patients throughout the PR programme. They perceived patients had a better understanding of their condition and associated symptoms and showed increased acceptance of their illness. Even though all participants acknowledged the benefits of PR, not all participants mentioned the importance of helping the patient to realise that PR will only help them reach their maximum potential and not their previous level of activity. Thus, in the data collected, it was reinforced that patients and relatives’ expectations are important considerations in all aspect of LC management and realistic goals should be maintained. Participant 9 said:

> “The most important element is again empowerment because they lose that confidence and also to help realise that they are never going to be as fit as they were before but close to it……. a bit of reality check sometime in a kind, gentle way.” (Medical professional)

The holistic approach encompassed by PR towards patients with LC helps to widen their horizon so that life no longer appears to have stopped and by promoting activities that are meaningful to them. Participant 5 stated that “doing some exercise, even in its lowest intensities depending on the patient’s abilities can be a milestone for the rest of their treatment” (PT5). Hence, empowering patients, increasing compliance to their oncological treatment and PR sessions, and improving HRQoL are some of the benefits. Participants also mentioned that patients who participated in PR felt a sense of control over their own health, a sense of usefulness and felt they are not alone in this situation. Participant 8 said:

> "They feel they are at least doing something to improve their condition. Especially when they are giving up, they feel they have something else to do, they feel they are actually contributing, they are in control of something, they know they can actually attend and help improve their own situation by something which is not beyond their control." (CSW)

In addition, educating the patient on symptoms management has been perceived by participants as a valuable coping skill to help decrease anxiety, depression and improve morale. Breathlessness has been associated with anxiety episodes and Participant 3 said that "if the patient already knows what to do from before you are helping in decreasing their anxiety levels as well" (PT3).

4.2.2.4 Impact on the healthcare sector. This theme combines the relation of health behaviours to LC and looks into the impact of PR on the quality of care provided to patients and their experience throughout their cancer journey. The perceived effect on hospital admissions shall be discussed. This theme is divided into three sub-themes.

4.2.2.4.1 Smoking behaviour. An important sub-theme that was identified during the interviews was the association of cigarette smoking as a contributing factor to LC. It was mentioned by two participants that most patients with LC have a history of smoking and the symptoms experienced by the patient such as shortness of breath may be augmented as a result of the damage caused to the lungs through both smoking and LC. Participant 10 stated:

> "Most of the patients will already have a problem with smoking. So, there is LC and smoking…… from the PR side I feel that the patient will have the opportunity to help control their breathlessness…… decreasing a symptom that can be a result of LC or from smoking habits." (Nurse)

Moreover, participant 9 viewed PR as a tool that "might help them to reduce smoking if not stop it. But reducing is good enough" (Medical professional).

4.2.2.4.2 Improved patient experience and quality of care. PR was considered by all participants as a vital piece in LC management and most voiced their opinion that the concept of PR should be introduced to the patient from the beginning by giving the patient some explanation of the benefits and reasons behind their referral to PR. Some participants expressed that patients are less anxious when they have an idea of what to expect during their first encounter with the physiotherapist, thus influencing patient belief in the PR programme and automatically increasing its effectiveness. This factor is unfortunately strongly linked to the lack of knowledge amongst the professionals and the referring HCPs. Apart from awareness to refer patients for PR two participants mentioned that the referring HCPs may not have time to explain to the patients the role of PR and its likely impact on their HRQoL. Consequently, the patient may not be referred.

A participant referred to the physiotherapist delivering the PR programme as a 'gatekeeper', and all participants identified PR as a link referral to other healthcare services. Another participant continued by saying that "there is like a domino effect of referral of services." It was appreciated that the patient health status may change from one day to another and may require input from various healthcare services. Patients attend PR on a weekly basis and the physiotherapist may recognise issues where the patient may require further support and refer to other appropriate entities such as occupational therapists, social workers, psychologists, etc. and/or require immediate attention by a medical professional. This reinforces the importance of an all-inclusive approach. Participant 10 stated:

> "As healthcare professionals you (physiotherapist) are seeing patients more frequently than we see them (referring to medical team) ..... There are issues that maybe we don't notice since we would not be seeing them ourselves during that period. You are seeing them and tackling these problems..... you call me when you notice a particular issue." (Nurse)

This comment was further reinforced by Participant 9: "sometimes by speaking to other healthcare professionals (referring to the patient) because they deal with the patient from a different

angle, they might uncover a problem that was not highlighted in the medical consultation" (Medical professional).

As previously mentioned, a holistic approach promotes space for discussion between HCPs and increases awareness. It was argued by a few participants (n=4) that if HCPs work in a more synergistic manner, this could possibly reduce duplication of work and unnecessary referrals. This would minimise the waste of resources and these resources could then be utilised in a better way and further improve the healthcare services offered to patients. Nevertheless, a lack of communication exists between HCPs which may lead to fragmented rehabilitation, delays of referral to the appropriate services and increased patient frustration. Participant 7 reinforced this argument my stating that: "I think having a more cohesive approach would make a difference in the patient experience, even without them (referring to the patients) having to answer the same question all over again" (OT).

Moreover, most participants put forward their suggestions to further improve the care provided to patients seen within SAMOC. Participant HCPs suggested inclusion of informative sessions for all HCPs in different healthcare sectors especially within SAMOC which may contribute to increased awareness on the importance of PR amongst HCPs and prevent sedentary behaviour in patients. Furthermore, inclusion of classes for patients with LC was seen as an option to be considered which may offer added value to the patient care. Patients within a small group can offer support to each other by sharing their experiences, feeling they are not alone, and consequently more empowered throughout their cancer pathway.

4.2.2.4.3 Perceived effect on hospital admissions. It was perceived by most HCPs (n=9) that PR may aid to minimise hospital admissions in patients with LC through the education of both the patients and the relatives/carers. Participant 9 reasoned that "the fitter they (patients with LC) become, the less hospital admissions they will have" (Medical professional). This sub-theme was strongly related to the management of symptoms where Participant 3 said "if we're teaching the

patient how to control any symptoms you are actually giving an extra set of care to the patient which can help him avoid hospital admissions as well" (PT3). Furthermore, another participant continued by elaborating that:

> "If they are empowered to actually know the technique that they can use for better breathing, breathing exercises, at that point ….it already makes it much easier, even if they still need medical attention…. that waiting time is not as bad as it would have been otherwise." (OT)

4.2.2.5 Maximising the efficacy of the intervention. This theme delved into the enablers and barriers faced by HCPs and patients vis-a-vis PR and the perceived time to engage in PR. Hence, such data may contribute to improved healthcare services. This theme is further divided into two sub-themes.

4.2.2.5.1 Enablers and Barriers to PR. All of the participants mentioned an array of challenges and barriers faced both by patients and HCPs that affected adherence, compliance and referral towards PR. One of the most observed barriers was lack of knowledge amongst HCPs which consequently limited patient's awareness as previously mentioned. A lack of awareness and misinformation by HCPs may result in incorrect referrals or patients not being referred when needed. Participant 10 stated that*:* "Due to a lack of awareness of such programmes…… due to a lack of reminders such programmes are missed" (Medical professional).

Hence, promotion to help utilise such valuable programmes is indispensable. It was suggested by the medical professional and other participants that reminders of the existence and benefits of the programme, are important to improve the existent knowledge and have a ripple effect on the improvement of services across different health sectors and overall patient care. Moreover, as previously mentioned by some HCPs, the role of the medical profession has a great influence on the patient and is a strong enabler to facilitate participation in PR. In contrast, a lack of knowledge by the same medical profession is a barrier.

Another important challenge that was mentioned by all participants was the individual patient character and attitude which required continuous reinforcement and encouragement throughout this difficult time. These included lack of engagement and commitment, previous activity levels, fear of experiencing worsening of symptoms, and feelings of hopelessness and futility. Again, participants argued that such challenges may be overcome through increased awareness and knowledge on PR and through reinforcement. Moreover, the fear and over-protection of family members who are not aware of the benefits of PR on the patient's HRQoL is a challenge. Increased trust in the HCPs and dissemination of knowledge would help to overcome this challenge.

Other challenges include multiple hospital appointments and parking issues which are added burdens on the patient and relatives. Consequently, most participants (n=5) mentioned efforts underway to co-ordinate hospital appointments when possible. Four participants mentioned limited human resources as a barrier and emphasized that there ought to be appropriate provision of resources to provide for this intervention as it is a valuable tool for patients with LC.

It was noted by the medical professional that more younger patients were being referred for cancer care and one has to keep in mind that the younger generations may have other dependences such as children and work schedules that may limit them from engaging in PR. It was argued that flexibility for the younger generation is an important factor to consider in the spectrum of LC management and to accommodate this group of patients and maximise patient care.

4.2.2.5.2 Timing of PR. A consensus between all participants is that PR should be part and parcel of patient LC treatment when referred to SAMOC for continuum of care. When patients are referred for PR in the beginning of their oncological treatment, this may help maintain and slow down physical deterioration, maintain or improve HRQoL, and aid in symptom management whilst promoting independence. PR may also contribute to increased adherence to the oncological treatment. Participant 9 stated: "It's best to refer patients at the beginning of their treatment in an attempt to maintain their quality of life and help them in their symptoms" (Medical professional).

Nonetheless, most of the participants mentioned that patients would still benefit from PR if it were offered at any point during their cancer journey, though patient preferences should also be taken into consideration. Participant 5 explained that:

> "If it's pre-cycle (pre-oncological treatment) you're preventing, if it's in the middle you're helping them get the best they can to the end and solve the side effects already undergone. But if it's at the end it's good as well because the patient has undergone all the trauma (referring to physical deterioration) and you try to get him the best he can after the trauma. So, in each case you're getting the patient at his optimum." (PT5)

4.3 Conclusion

This chapter provided an overview of the results collected following a thorough data analysis process from both the quantitative and qualitative data collected. Results demonstrated significant improvements in the overall global health status/QoL with lessening of symptoms including fatigue, dyspnoea, insomnia and pain in patients diagnosed with LC following an 8-week PR programme. Interviews with HCPs generated themes encompassing the role of rehabilitation and the importance of a holistic care approach in the oncology setting. Patient education on physical activity, symptom management and behavioural habits were also highlighted along with the perceived physical and psychological benefits. Lastly, the impact on the healthcare sector and ways to contribute to better patient experience and quality care were deliberated. The following chapter shall discuss in further detail the results obtained bringing together the aims and objectives of this study whilst comparing them to the identified literature presented in Chapter 2. The strengths and limitations of the study shall also be presented in the next chapter.

Chapter 5: Discussion

5.1 Introduction and Summary of Results

This chapter discusses the results obtained in this study. The results will also be compared with the literature presented in Chapter 2 within the context of the aims and objectives of this research as outlined in the introduction chapter. As far as the researcher is aware, this is the first local study evaluating the impact of PR on the HRQoL of patients diagnosed with LC.

This study demonstrated improvements in the overall global health status/QoL and a lessening of symptoms including fatigue, dyspnoea and pain in patients with LC diagnosis following an 8-week PR programme. Themes were also identified encompassing the role of rehabilitation in the oncology setting as an integrated approach involving various HCPs, patients, and relatives/carers. PR has been perceived to play an important role in preserving and/or ameliorating HRQoL through patient education on physical activity (PA), symptom management, and behavioural habits. Education and prevention arising from the PR were also perceived by HCPs as having a positive effect on anxiety levels and hospital admissions. The holistic approach which is embedded within PR has also been observed to contribute to better patient experience and quality of care, ensuring better standards of care. However, insufficient awareness of PR was predominant and was viewed as one of the challenges when delivering this service to oncology patients because it limits the chances of referral for the otherwise eligible patients.

This chapter shall initially delve into the elements of PR and its effect on the HRQoL and symptom management. The importance of an integrated multidisciplinary approach shall be discussed followed by the barriers and enablers encountered for the implementation and participation in PR. Additionally, this chapter looks into the role of PR from a public health perspective. The benefits of PR within the ageing and working-age population and its value to enhance patient quality of care is discussed. To conclude, the strengths and limitations of this research are addressed towards the end of this chapter.

5.2 The role of Pulmonary Rehabilitation in the Lung Cancer Care Pathway

The notion of rehabilitation within the oncology setting is relatively new in cancer management but it is being given increasingly more importance. Research acknowledges that PR is a valuable tool within LC management. Various studies support PR/exercise-based programmes for improvements in physical function, increased exercise tolerance, and increased independence to better HRQoL in LC patient throughout their continuum of care. However, more research is recommended (Edbrooke et al., 2019; Ester et al., 2021; Rutkowska et al., 2019). This was also attested by HCPs who participated in this study. These HCPs described PR as a comprehensive tool looking into the elements of education, prevention, supportive and restorative care to improve HRQoL in patients diagnosed with LC at the onset of diagnosis and beyond. These elements are also captured withing the Europe's Beating Cancer Plan (EC, 2021) and embedded in the National Cancer Plan, 2017-2021 (MFH, 2017).

5.2.1 The Impact on Health-Related Quality of Life (HRQoL)

According to the National Cancer Plan, 2017-2021, due consideration should be given to the quality of life of patients diagnosed with cancer throughout their whole journey, from diagnosis onwards (MFH, 2017). Symptoms experienced by patients due to the disease and/or the side-effects of the treatment greatly contribute to their HRQoL status and may substantially hinder their ability to perform daily living activities and ability to live a fulfilling life to their maximum potential. Therefore, effective management should address patient needs in an all-encompassing manner. HCPs in this study opined that PR offers a structured programme in which patients feel involved in their care process, giving them a sense of empowerment and acceptance. This is further reinforced by the European Partnership for Action Against Cancer (EPAAC) where the patients' role is being given increased recognition in their care process, and patient-centred cancer rehabilitation programmes as well as self-management programmes are being encouraged along with wide-ranging social support (Albreht et al., 2015). In addition, various studies (Edbrooke et al., 2019; Rutkowska et al., 2019)

argue that PR/exercise-based programmes offer guidance and support on symptom management and assist patients in health behavioural changes.

Lee (2021) also demonstrated consistent results similar to our study with regard to amelioration in HRQoL, improved functional capacity, and muscle strength. Most participants in this study who are physiotherapists by profession attested to the importance of helping the patients maintain muscle strength, improve lung function, increase exercise tolerance and prevent fast deterioration in their HRQoL. This is supported by Rutkowska et al. (2019) and Quist et al. (2020) who observed significant improvements in muscle strength following the intervention suggesting that patients with LC would benefit from PR/exercise-based programmes as part of their cancer management.

5.2.1.1 Effects on HRQoL at Different Stages of the Cancer Journey. Following an 8-week PR programme, this research revealed statistically significant improvements in the global health status/QoL domain ($p=0.03$) as assessed through the EORTC-QLQ-C30 questionnaire, with increased benefits in the physical ($p <0.001$), emotional ($p=0.005$) and social functioning domains ($p=0.025$). These findings differ from those reported by Dhillon et al. (2017) who report no improvements in HRQoL when using the EORTC-QLQ-C30 and LC-13 reported outcome measures. In our research study, 79% of the patients had been diagnosed with advanced LC (stage III/IV). Dhillon et al. (2017) also investigated the effects of an 8-week programme of PA in patients with advanced LC (stage III/IV).

The incongruency in the results observed between the two studies may be attributed to the time in which the PR was initiated in the patient care pathway. In this study, all patients were concurrently undergoing SACT and/or radiotherapy except for one patient, whilst Dhillon et al. (2017) recruited their patients after the completion of their active treatment. Other studies (Lehmann et al., 2023; Licht et al., 2021) report better outcomes in HRQoL in cancer survivors when rehabilitation is initiated after completion of active treatment. Despite Dhillon et al. (2017) recruiting their

participants more than or equal to 4 weeks after completing chemo-radiotherapy, patients may have started engaging in recreational PA and/or have got accustomed to their current health status during this time period. Thus, outcomes arising from PR may have been less favourable.

On the other hand, in our study, patients may have been still adapting to their disease and the treatment side-effects. Rehabilitation during this vulnerable period may have helped to slow deterioration in physical function, and mitigate worsening of symptoms. Therefore, during this time, rehabilitation may have contributed to the improvements observed in the functioning domains and overall global health status/QoL. Furthermore, studies conducted by Ester et al. (2021) and Payne et al. (2018) document that exercise interventions during oncological treatment in patients with advanced LC demonstrated no significant decline (Ester et al. 2021) but rather showed improvement (Payne et al. 2018) in HRQoL.

5.2.1.2 Effects of Home-base Versus Hospital-based Programmes. The setting of the intervention may play a role on the desired outcomes. Edbrooke et al. (2019) demonstrated statistically significant benefits in HRQoL favouring the intervention group following an 8-week home-based PR programme after 6-months ($p=0.005$) but not at 9-weeks on commencement of this intervention. Patients were monitored through two telephone calls per week to review the exercise programme and for symptom management after the 8-week programme. Beyond the 8-weeks, exercise intensity was gradually increased, and this may have contributed to the positive affect seen in HRQoL at 6-months. In contrast, in our study, PR was conducted within the physiotherapy department at SAMOC. Patients participating in PR were supervised, monitored, continuous encouragement was provided, and exercises were progressed accordingly. These factors may have affected outcomes following 8-weeks of PR favouring the intervention.

Through our study and other studies (Ester et al., 2021; Lee et al., 2021) one can deduce that a progressive exercise-based programme conducted within the hospital/out-patient setting may be correlated with increased improvements in the overall global health status and HRQoL. Moreover, an

8-week supervised PR programme is suggested to be adequate to observe changes. Hospital/out-patient settings offer a positive environment and a source of encouragement to patients whilst providing the opportunity for early intervention to optimise function during their cancer care (Dennett et al., 2021). Nonetheless, home-based PR seems safe and feasible for patients with advanced LC and an opportunity for those who wish to engage in PA without disrupting their daily lives (Edbrooke et al., 2019; Payne et al., 2018). Likewise, safety was also discussed amongst the HCPs in our study who viewed PR as safe because it is individualised and supervised by a physiotherapist.

5.2.2 Symptom Management

Patients with cancer frequently experience symptoms such as breathlessness, cancer related fatigue (CRF), and pain which may increase during SACT and/or radiotherapy. These may influence patients' abilities to maintain physical function and have a negative impact on HRQoL (Ester et al., 2021; Rosero et al., 2020).

5.2.2.1 Breathlessness. Evidence suggests that PR may assist patients to control their symptoms in particular shortness of breath (Rutkowska et al., 2019; Saetan et al., 2020). A physiotherapist in our study stated that patients may deny any symptoms such as breathlessness on a daily basis because they lead a sedentary lifestyle. However, they may complain of shortness of breath on exertion such as when going up a flight of stairs. This may be attributed to the fact that patients may have adjusted their lifestyle to fit their current condition by limiting themselves to any type of PA. Moreover, fear of worsening symptoms upon minimal exertion was mentioned by HCPs within our study which further contributes to a sedentary lifestyle with increased symptoms on minimal physical effort.

Differing findings exist within our study when evaluating dyspnoea using the EORTC-QLQ-C30 and EORTC-QLQ- LC29 patient reported outcome measure. A significant improvement was observed in the EORTC-QLQ-C30 dyspnoea score ($p=0.018$) and non-significant improvement in the EORTC-QLQ-LC29 shortness of breath score ($p=0.399$). This discrepancy may have resulted due to the fact

that in the EORTC-QLQ-C30 questionnaire, the question related to shortness of breath was general: 'were you short of breath during the past week?'. Since the questionnaires were conducted within the physiotherapy department, patients may have replied to the question in relation to exercise which may have affected the results observed. Whilst in the EORTC-QLQ-LC29, three specific questions on shortness of breath while resting, walking and climbing stairs were asked. In the latter, questions were more specific and patients may have related more to the physical function in question. However, the significant improvement in dyspnoea noted in the EORTC-QLQ-C30 suggests that shortness of breath is a symptom that negatively impacts patients' HRQoL. This is reinforced by the HCPs who perceived breathlessness as a major symptom affecting patients' HRQoL and viewed PR as an opportunity to manage such debilitating symptoms. Moreover, Rutkowska et al. (2019) and Saetan et al. (2020) demonstrated significant improvements in dyspnoea using the Borg Dyspnoea Scale ($p=0.04$) and Cancer Dyspnoea Scale ($p<0.05$) respectively suggesting that PR/exercise-based programmes equip the patient with coping skills to manage shortness of breath, delays exacerbations and promotes self-efficacy.

5.2.2.2 Insomnia, Fatigue, Coughing and Pain. In our study, statistically significant improvement in fatigue ($p=0.044$), pain ($p=0.013$), and insomnia ($p=0.002$) were observed following an 8-week PR programme. Similarly, Ester et al. (2021) reported highly statistically significant improvements in fatigue ($p<0.001$) and energy levels ($p<0.001$) after a 12-week exercise intervention. However, the study conducted by Dhillon et al. (2017) contradicts these findings as no significant difference ($p=0.62$) between the intervention group and control group was observed in fatigue levels. Additionally, in our study no significant improvements were demonstrated in coughing ($p=0.073$). This could be due to the fact that some patients were receiving radiotherapy treatment which may induce coughing as one of its side-effects.

In our study, improvement in pain was observed in both EORTC questionnaires which reinforces the positive effect of PR in relation to the pain experienced by the patient. Decreased general pain ($p=0.013$) was established in the EORTC QLQ-C30 and lessened pain in arm/shoulder

(p=0.008) and pain in other parts of the body (p=0.021) were observed in the EORTC QLQ-LC29. However, since radiotherapy is administered over the chest area this may have contributed to no improvements to pain felt in the chest (p=0.142) in this study.

5.2.2.3 Self-Management. According to the EPAAC, a cancer rehabilitation programme should incorporate and support self-management programmes (Albreht et al., 2015). Edbrooke et al. (2020) stated that HCPs perceived PR as an opportunity to offer guidance and support on how to self-manage symptoms. Physiotherapists in our study perceived PR as a means of educating patients about how their body can adapt to their current health status. This is an opportunity to provide guidance on how to safely and gradually increase exercise intensity to improve their physical function, exercise tolerance and overall HRQoL. Hence, striving to live an independent life within their current limitations as far as possible.

5.2.2.4 Psychological Benefits. Educating patients on symptom management has an added value on the patient's psychological well-being. Most HCPs interviewed in our study emphasised the importance of teaching patients about symptom management, mainly on coping strategies for shortness of breath and how to control their anxiety levels. However, reference was also made to the need to refer patients to the psychology team within the oncology hospital if required. In congruence with the qualitative part of this study, a statistically significant improvement in the emotional functioning score (p=0.005) and fear of disease progression score (p=0.005) was observed in the patient reported outcome measurements. These findings further reinforce that PR has a positive effect on the patient psychological well-being. Supporting these outcomes, Quist et al. (2020) has also demonstrated significant reduction in anxiety (p=0.02) and depression (p=0.01) following a 12-week intervention programme.

Additionally, in our study, PR has been identified as a link between the patient, and other HCPs promoting an all-inclusive care approach which may contribute to increased compliance in their cancer care and further support for their relatives/carers. Family members may perceive exercise to

be contraindicated for their relatives with LC due to the fear of worsening of symptoms (Granger et al., 2018; Payne et al., 2018). This was also reported in our study by most HCPs from patients under their care. Thus, constant support and reassurance for relatives/carers on the benefits of PR is fundamental. Family members and friends should be seen as a vehicle to encourage patients to participate in PR.

5.2.3 A Cultural Shift to Oncology Rehabilitation

In this study, respondents mentioned elements that revolve around the definition of oncology rehabilitation, defined as a supportive programme that aims to maximise patient independence, increase function and improve HRQoL following diagnosis and beyond (Mayer & Engle, 2022). Literature advocates that exercise in cancer care should be a standard part of cancer care and PR should be made available as a valuable component in the management of LC (Granger et al., 2018; Pilotto et al., 2022). Granger et al. (2018) describes the inclusion of PR/exercise-based rehabilitation in LC care as a positive cultural shift. Rehabilitation objectives within a surgical ward is driven by the push to facilitate discharge while a poor outlook persists towards exercise and rehabilitation in the oncology setting especially with end-stage metastatic LC undergoing palliative treatment (Granger et al., 2018).

5.2.3.1 A Multidisciplinary Approach. A multidimensional and biopsychosocial care approach is important in LC patients and across all types of cancer to improve efficacy to PA (Grander et al., 2018). Payne et al. (2018) emphasise the importance that HCPs must understand the multifactorial factors influencing patient motivation to engage in an exercise-based programme, and the need to increase their awareness for better patient care. Hence, lack of multidisciplinary involvement may contribute to inadequate support and responsiveness to patients' and carers' needs (Granger et al., 2018; Payne et al., 2018).

All the above was echoed in the findings of our study and supported in the joint action of the EPAAC (Marin-Moreno et al., 2013). Moreover, similar to our findings, in a qualitative study by

Granger et al. (2018), physiotherapists emphasised that a two-way communication between the physiotherapist and the multidisciplinary team is valuable and may contribute to a spill-over effect to facilitate referrals to other services across different healthcare settings from which the patient may benefit (Granger et al., 2018).

5.3 Barriers and Enablers towards Pulmonary Rehabilitation

PR has been recognised as filling a large service gap within the healthcare service (Granger et al., 2016) and narrowing this research-to-practice gap to improve patients' health outcomes is always challenging.

5.3.1 Lack of Awareness and Communication

This study has identified various challenges for the PR programme, but one of the most predominant barriers is lack of information and knowledge amongst the HCPs. This includes a lack of knowledge on what PR entails, and the benefits that can be gained by patients (Granger et al., 2018; Payne et al., 2018; Pilotto et al., 2022). Decreased awareness amongst HCPs acts as a barrier for referral to available programmes and limits discussion about PR with the patient. Similarly, in our study, low levels of awareness amongst the HCPs within the oncology hospital was noted by all the HCPs participating in the study. As one physiotherapist stated, few HCPs have the knowledge that PR is being offered within SAMOC. This lack of knowledge may also reflect the lack of communication between different HCPs and across different healthcare settings. Thus, increased awareness ought to be reinforced within the oncology hospital and across different healthcare sectors, so that professionals and patients are more educated and empowered throughout their care pathway. This aspect is also reflected in the National Cancer Plan, 2017-2021.

Evidence suggests that patients with LC are willing to receive advice and recommendations about exercise and how to manage their symptoms (Edbrooke et al., 2020; Payne et al., 2018). Likewise, from a local study, patients with LC showed interest in participating in an exercise programme during their cancer care (Azzopardi, 2020). Hence, in order to enable optimum quality of

care, facilitate timely access to PR and meet standards of care, it is important to tackle the barriers affecting the delivery of PR service, primarily by facilitating dissemination of knowledge amongst HCPs and patients.

Additionally, various studies (Granger et al., 2018; Pilotto et al., 2022) showed that encouragement and reinforcement by the HCPs, especially the oncologists, was perceived as an important enabler to promote participation and increase adherence to PR. The medical professional represents a particularly powerful tool to directly influence patient behaviour (Payne et al., 2018; Pilotto et al., 2022). The idea of patients giving more weight to the oncologist's advice was mentioned by almost all the HCPs in our research study. Granger et al. (2018) and Pilotto et al. (2022), reported that the medical professional/oncologists have little time to include information related to the importance of PA during their consultation and physiotherapists were perceived to be the best profession to deliver this message effectively. Contrary to the literature, the medical professional participating within this study recommended that reminders about the services offered and the patient eligibility criteria would be ideal to help keep such beneficial services in mind and to ensure that referrals happen when indicated. Thus, apart from having a strong influence on the patient, the medical professional can be seen as an enabler towards PR and improving compliance by increasing familiarity with the programme.

Furthermore, HCPs within our study mentioned the role of the nurse navigator as the common link between physiotherapist and patient to introduce the programme and refer patients appropriately. This continues to highlight the importance of a multidisciplinary approach within the LC care pathway in order to offer better comprehensive care.

5.3.2 Time of Intervention

LC is frequently associated with a rapid deterioration in physical and pulmonary function (Granger et al., 2016). Thus, the timing of the intervention is a factor that has been perceived to be important for patients with LC within the literature (Edbrooke et al., 2019; Granger et al., 2018) and

this study. According to EPPAC, a personalised rehabilitation plan should already be introduced by the time the patient initiates SACT and/or radiotherapy treatment (Albreht et al., 2015). However, HCPs within our study opined that patients benefit from PR at any stage, be it prior to, during or after cancer treatment in terms of prevention, symptom management and promoting physical independence and autonomy.

Edbrooke et al. (2020) also discussed that fear of exacerbating symptoms while participating in a PR programme was challenging, and it may also contribute towards patients not participating in the programme. In this study, one of the patients dropped off because of increased chemotherapy and radiotherapy side-effects. Nevertheless, outcomes showed improvements in side-effects of treatment ($p=0.001$). Therefore, it is important to weigh the advantages and disadvantages associated with the PR programme at each stage of the disease trajectory to determine the ideal time to enrol patients within the PR programme and optimise benefit.

5.3.3 Healthcare Facilities and Resource Use

Another barrier that was viewed as hindering patient participation in PR within the literature review was the lack of resources, services availability and capacity, as well as undefined referral pathways (Granger et al., 2018; Pilotto et al., 2022). In this study, the occupational therapist, clinical social worker and physiotherapists mentioned that human resources limitations can have a negative effect on the availability of such a valuable service. At the European level, an evaluation of the available healthcare workforce is recommended to assess how to optimise use of resources in view of the projected demographic changes and associated changes in the cancer burden for improved standard of care (Albreht et al., 2015; Martin-Moreno et al., 2013).

5.4 A Public Health Perspective

Efforts to improve cancer care pathways are being increasingly prioritised at a European Union level and at a global level through various agencies. Actions to minimise the burden of LC on the health system should span the entire disease pathway. This includes primary prevention,

secondary prevention and earliest possible diagnosis, treatment choices, tertiary prevention and palliation, survivorship, and end-of-life care (as applicable according to the patient's clinical and social situation) by improving HRQoL wherever possible (EC, 2021, 2021b). Efforts should be made at all levels of the health system leadership and public policy, and at both the secondary healthcare and community care levels (Zhang et al., 2021).

5.4.1 Health-Related Quality of Life as a Health Indicator in Cancer Care

Literature exploring the impact of PR/exercise-based interventions on the HRQoL of patients diagnosed with LC from a public health perspective is rather limited. However, with any type of cancer, improvement in patient experience and HRQoL was one of the identified objectives within the Europe's Beating Cancer Plan, 2021 (EC, 2021). This plan is closely linked to the EU Mission on Cancer (EC, 2021b) and objectives are reflected in the National Cancer Plan, 2017-2021 (MFH, 2017). Because of the disease and the treatment complexity, patients often require prolonged and repeated healthcare services and support. According to the National Cancer Plan, patients, their relatives and society as a whole value HRQoL, patients' experience, and care at a level that is equal or even higher than survival. Even though survival is a crucial outcome measure in cancer control services, the above-mentioned outcomes merit special consideration within the cancer plan pathway (MFH, 2017).

Furthermore, literature does support investigation of HRQoL to evaluate aspects of the health system performance (Kaplan & Hays, 2022). Outcome measures assessing HRQoL have been recognised as essential tools to evaluate health interventions (Kaplan & Hays, 2022) and an important source of health information (Albreht et al., 2013).

5.4.2 Catering for Demographic changes in the Population

Healthcare services, including cancer services, need to take into account the rapid changes in the population socio-demographics that can impose increase in costs and increased disease burden on the health system, the patient and society (MFH, 2022). People are living longer, and the age profile of society is rapidly developing. According to the WHO (2022b) the proportion of the world's

population over 60 years is expected to increase from 12% to 22% between 2015 and 2050. In Malta, the demographic projections are being anticipated to increase at a fast rate with life expectancy at birth to increase to 85.1 and 89.1 years for men and women respectively by 2060 (Albreht et al., 2015).

Moreover, the ageing population is resulting in an ever-increasing incidence of cancer, where it is being projected that cancer incidence is expected to approach 3270 annually by 2040 with 1890 and 1380 for males and females respectively (Wild et al., 2020). Thus, the population of people who will be diagnosed with cancer, who need care and live with and beyond cancer is expected to continue increasing in substantial numbers. Locally, based on 2020, LC cases are projected to increase to 191 and 52 for males and females respectively by 2040 (NSO & Malta National Cancer Register, personal communication, August, 2023). This may contribute to long-term psychosocial needs and increased interest in issues revolving around the HRQoL of cancer patients and survivors in a comprehensive approach (Albreht et al., 2015; Martin-Moreno et al., 2013). Therefore, as most HCPs within our study argued, having a sustainable number of human resources to adequately support cancer services is fundamental. Waiting lists for health services for this vulnerable population can be expected to increase if the present limitations if human resources are not addressed.

The new national Health Work Force Strategy, 2022-2030, is promoting innovative ways of work and supporting the staff to enhance effectiveness and efficacy (MFH, 2022b). In view of scarce resources, policymakers should also identify areas which offer increased benefits in cancer care and improved patient experience. Furthermore, increased attention should also be given to the aspect of HRQoL in survivorship planning when allocating resources (Albreht et al., 2015; Martin-Moreno et al., 2013).

5.4.2.1 The Physical Inactivity Cycle and Frailty Status. LC incidence increases with age. A considerable rise is observed in people over sixty years of age predominantly in men (Malta National Cancer Register, 2023). LC may contribute to increased dependence and deterioration of HRQoL in old

age. The need to map health and long-term care needs is important especially within the elderly cohort of an ageing population. Hence, the aim should be on re-integrating patients back to the community wherever possible, to regain their autonomy as much as possible and focus on means to safeguard sustainability of the healthcare system (Albreht et al., 2015; MFH, 2022).

Avoidance of symptom triggering factors especially PA due to fear of increased breathlessness, fatigue and other symptoms promotes a vicious cycle of inactivity. This results in loss of muscle mass and function which further contribute to physical deterioration, and worsening of symptoms on minimal exertion (Scalabrin & Caporossi, 2016). Older adults are increasingly viewed as active contributors to their families and the whole of society (WHO, 2002). Therefore, within an age-integrated society providing health services that contributes to improved HRQoL, increased independence and decreased burden on families and society is vital. This contributes to the role of PR and exercise in LC patients to slow physical decline and maximise or restore physical status and HRQoL before, during and following SACT and/or radiotherapy treatment.

Within our study, HCPs referred to the physical inactivity cycle and its association with the patient current co-morbidities, decreased HRQoL and increased burden experienced by their relatives/caregivers and social care systems. HCPs emphasised the importance of PR at different stages of the disease pathway and most HCPs asserted that PR is an essential tool to prevent a sedentary lifestyle. However, due to a lack of awareness amongst HCPs on the benefits of PR in the oncology setting, patients are often not referred for rehabilitation until patients have physically deteriorated and experience symptoms (Granger et al., 2018).

The physical inactivity cycle is strongly linked to the cycle of frailty (Tolley et al., 2021; Zhao et al., 2022). Frailty is a major public health problem for today's ageing population. Frailty is defined as a complex geriatric state of physiological decline, characterised by increased vulnerability to adverse health outcomes and is independent of age (Thillainadesan et al., 2020). The cycle of frailty results from prolonged sedentary lifestyle leading to sarcopenia and consequently decreased muscle

strength and VO_2max (maximum rate of oxygen attainable during physical exertion) (Clegg & Young, 2011). Frailty leads to further decreased physical performance and PA which reinforces the benefits of PR within the oncology setting especially with patients experiencing oncology-related pulmonary insufficiency. Moreover, Martínez-Velilla et al. (2021) demonstrated a reversal of frailty effects in 21.1% of the twenty-one patients enrolled in the intervention group measured by the Fried scale (Fried et al., 2001) after a 10-week programme. These patients were diagnosed with NSCLC and were on active treatment similar to our study.

5.4.3 The Working-age Population

Focus on rehabilitation should not only be limited to the elderly but should spread over all age groups and all cancer types. In our study, the medical professional stated that increasingly more younger patients are being diagnosed with LC. The physical and psychological effects that the patient may experience during their cancer journey may impede their ability to work and remain in employment with the consequent collateral effects throughout society. Hence, a strong social and economic incentive lies within this cohort due to decreased productivity, loss of wages and increased demands on healthcare and social services (Albreht et al., 2015; MFH, 2017). This is yet another reason why rehabilitation should be promoted to target work-related issues to aid patients return to work, remain economically viable and resume activities they carried out prior to diagnosis.

5.4.4 Moving Towards a Vertical or Horizontal Approach to Healthcare Services

Of interest, in our study, one HCP opined that PR is not solely beneficial for patients with LC but also for patients with other cancer diagnosis experiencing oncology-related pulmonary insufficiency. Due to the cancer proximity to the lungs and/or the side-effects experienced by the patient receiving SACT and/or radiotherapy, PR may provide additional support to the patient in terms of symptom management and overall HRQoL.

The impact on the whole society and on the health system may depend on the approach chosen for the delivery of healthcare services. The delivery of PR may be levered by either a vertical

or horizontal approach. The vertical approach refers to when the intervention is delivered to patients with a specific disease such as LC, while the horizontal approach is more comprehensive and seeks to expand the intervention to also benefit patients with different cancer types (Kirwin et al., 2022). An opportunity cost exists between the vertical and horizontal approach. However, ideally the horizontal approach should be favoured as patients with diagnoses other than LC experiencing oncology-related pulmonary insufficiency may also benefit from such an intervention when recommended. This may contribute to the facilitation of an increased number of patients to return to work or remain economically viable and live within the community.

A horizontal approach may result in a substantial influx of patients and increased demand on the healthcare services which will necessitate support by an adequate number and optimisation of resources, expertise and facilities to allow for a resilient expansion for service provision. Barriers such as finite resources should be considered when developing clinical services and policies as a step towards providing patients with improved quality care. This will allow for a horizontal coordinated integration with different HCPs and healthcare services. Furthermore, EPAAC, advocates that although challenging, it is imperative to strive for a seamless care pathway (Martin-Moreno et al., 2013).

5.4.5 Health Behavioural Changes in LC Patients

Improving HRQoL ought to be an important service aim throughout the cancer continuum. Ideally, behavioural change strategies are incorporated to assist in achieving a sustainable increase in physical activity along with nutritional advice and smoking cessation support (Granger et al., 2018).

5.4.5.1 Smoking Behaviours. Dunn et al. (2017) argues that there is a strong stigma linking a smoking lifestyle and LC patients. Hence, patients may blame their smoking habits for their disease. Furthermore, this health-related stigma might prevent patients from seeking early medical attention and support throughout their cancer care (Dunn et al., 2017). The causal relationship between LC and smoking habits was established by Doll and Bradford-Hill in 1950s (Doll & Bradford, 1950). Their work

was a milestone in this field and more research continues to support their findings (Lee et al., 2012; Lewandowska et al., 2022). Within the literature, behaviour changing strategies including smoking cessation were deemed as important components and were provided as part of the PR/exercise-based programme (Granger et al., 2018).

Smoking cessation is an integral part of cancer survivorship, as smoking has a negative impact on cancer-related health outcomes (Eng et al., 2020). Symptoms such as shortness of breath may be more severe as a result of the long-term tissue damage caused by smoking (Lu et al., 2018). PR should be seen as an opportunity to educate patients and refer to other healthcare services accordingly. In our study smoking was also mentioned as a contributing factor to LC and HCPs emphasised that PR was a valuable tool to aid patients to stop or at least decrease smoking behaviour.

5.4.5.2 Promoting Physical Activity. Educating patients towards increased PA has also been considered as an important factor by HCPs within our study especially in older adult patients who may have other existing co-morbidities. Nevertheless, most LC patients are diagnosed in the advanced stages and most of the patients would have already been negatively impacted by symptoms and deterioration in their general condition and HRQoL prior to the initiation of any cancer treatment (Kartolo et al., 2016). However, evidence suggests that LC patients can safely participate in PR and exercise-based programmes at any stage of their disease trajectory and during oncological treatment (Rutkowska et al., 2019).

5.4.6 Enhanced Patient Quality of Care

A growing consensus exists across the European healthcare institutions supporting comprehensive cancer care plans to help minimise patients' unmet needs and promote higher quality care. Cancer services should ideally integrate the patients' needs and perspectives to alleviate and improve HRQoL, and increase compliance and patient satisfaction in all disease phases (MFH, 2017; Martin-Moreno et al., 2013). The needs and preferences of their relatives/carers should also be

considered. It is important to keep in mind that the health system and healthcare services cannot function at their optimum when independent of each other. An integrated care plan offers joint responsibilities for all the healthcare professions involved and envisions the patient at the centre of the care process. Greater consideration should be given to the availability of the right number and breadth of resources including human resources with the right skills to ameliorate patient care and health outcomes (MFH, 2022).

Improved patient HRQoL and striving to achieve maximal function and independence throughout their cancer journey may contribute to reduce the number of hospital re-admissions (Martínez-Vellilla et al., 2021). The medical professional participating in this study perceived PR as an aid that may help patients with LC to minimise their hospital admissions (number and also length of stay). Additionally, the occupational therapist stated that educating the patient on breathing exercises and symptom management may help decrease anxiety levels in patients who still require medical attention.

In a secondary analysis by Martínez-Velilla et al. (2021) of Rosero et al. (2020) study, a statistically significant difference between groups in the frequency of LC patients requiring emergency admission one year post intervention ($p=0.03$) was observed resulting in potentially minimising the burden on the emergency department. In this study, most HCPs commented that the benefits of exercise and patient education on symptom management and behavioural changes may also improve referrals to appropriate services when required and in a more proactive manner. Furthermore, EPAAC and the National Cancer Plan, 2017-2021, supports early access to rehabilitation is important as it can facilitate reduction in emergency admission and enable a faster home discharge (Albreht et al., 2015; MFH, 2017). PR may be viewed as an opportunity to support patients throughout their care journey with the aim to maximise and retain independence as far as possible.

5.4.6.1 Transfer of Knowledge into Practice. Cancer research is one of the cornerstones of overall cancer management, but knowledge transfer is limited (Albreht et al., 2015; Martin-Moreno

et al., 2013). Evidence on the effectiveness of PR in patients diagnosed with cancer is increasing but it is still underutilised in clinical practice (Granger et al., 2018). The National Health System Strategy (NHSS), 2023-2030, acknowledges the importance of translating evidence into practice within the health sector. It offers direction for critically added value to improve healthcare delivery and implementation of enhanced healthcare services. Connecting current evidence with the provision of healthcare services provides the opportunity to improve standards of care and enhance the overall performance of the health system. One example proposed by the NHSS is to increase case managers/nurse navigators for different disease groups and the development and introduction of patient reported outcomes and experience measures (MFH, 2022). Hence, patient reported outcome measures evaluating HRQoL, similar to the EORTC questionnaires, may be utilised as key performance indicators when implementing PR thus contributing to better standards of care.

5.5 Strengths, Limitations and Biases of the Study

As with all research studies, this study has its strengths and limitations. The researcher employed a triangulation approach by using a mix-method research design to combine the strengths of one method with the weaknesses of the other method. The qualitative approach was employed to enrich the quantitative aspect of the research study, thus increasing reliability and validity of the study. Moreover, the questionnaires utilised within the study, EORTC-QLQ-C30 and QLQ-LC29, are validated research tools that are widely used to assess the HRQoL in cancer patients contributing to further increase in reliability and validity of the results.

Another strength identified in the study was that PR was conducted within the oncology hospital. This factor may have contributed to increased patient adherence throughout the PR programme. Moreover, the researcher performed a pilot study to enhance the quality of the research tools used and the patient outcome measures were administered solely by the researcher to ensure consistency in all questions asked.

The sample size recruited in the quantitative aspect of the study was small which limits generalisability of the findings. In 2021, an average of 8 patients per month were referred for PR at SAMOC. Thus, all patients diagnosed with LC who were referred for PR programme at SAMOC were assessed for eligibility and invited to participate in this arm of study during the data collection period. This was regarded as crucial to determine the representativeness and wider applicability of the findings. Patient with LC diagnosis who were not eligible for the PR programme were still offered modified treatment session according to their needs. The majority (79%) of the patients were diagnosed with stage III/IV LC resulting in decreased variability in the participants. However, this factor gave an opportunity to explore the effects of PR on the most common stages of LC at diagnosis currently registered in Malta. Time constrains was another limitation encountered during this study as only four months were dedicated to data collection keeping in mind that the duration of the PR programme is eight weeks.

The researcher conducting this study acknowledges the active role in the area of exercise and the oncology setting, therefore, interviewer bias towards exercise may have influenced participants' responses and led to social-desirability bias. Hence, the researcher explained to the participants the importance of answering questions with their own personal views. Additionally, most of the HCPs (60%) who participated in the study were physiotherapists which could have led to information bias. Moreover, recall bias may have occurred during the interviews with the HCPs. Attempts to mitigate this constraint were employed by asking the same question in different ways to the same interviewee to gain one response. Furthermore, triangulation helped to mitigate limitations arising from the individual approaches employed to ensure neutrality of the research findings and their interpretations. Another respondent bias that may have occurred include the misunderstanding of questions by patients and HCPs. This was countered with the pilot study that assessed the level of clarity of the questions being asked.

Lastly, the researcher made every effort to rigorously follow ethical procedures so as to protect the patients' and the HCPs' confidentiality throughout every stage of the research process.

5.6 Conclusion

This chapter deliberated the findings of this study and compared them to the current literature to gain a wider picture on the impact of PR within the oncology setting and from a public health perspective. PR has been acknowledged to assimilate an all-inclusive approach that contributes towards enhanced HRQoL, improved health outcomes, better healthcare standards and quality care and efficient use of healthcare resources. Identified strengths and limitations of this research were also discussed. The final chapter shall provide an overview of the key findings of the study and explore whether the study objectives were met. In addition, recommendations on possible lines of action and further research are presented and discussed.

Chapter 6: Conclusion and Recommendations

6.1 Introduction

This chapter presents a summary of the key findings of the study on the effect of PR programme on LC patients as well as the impact of PR on the health management and healthcare services and health systems. Based on the findings and discussion of this research, recommendations for the incorporation of PR in the cancer care services, public health and health systems management, and healthcare service improvements are included in this chapter. Further recommendations are also detailed for future research in this domain to encourage more studies within the oncology setting to offer better quality care and patient outcomes and to evaluate how to continuously improve the efficient and effective use of the healthcare resources available through the inclusion of innovative programmes such as PR.

6.2 Key Findings

This study investigated the impact of PR within the oncology setting and its influence on HRQoL of patients living with LC throughout their disease trajectory. An 8-week PR resulted in statistically significant improvements in the global health status/QoL with increased benefits in the physical, emotional, and social functional domains in patients with LC while undergoing systemic oncological treatment and/or radiotherapy treatment. Psychological benefits were also reported quantitatively and qualitatively with improvements in the reportage of anxiety and fear of disease progression. These findings are echoed in other studies within the literature (Edbrooke et al., 2019; Rutkowska et al., 2019).

Furthermore, statistically significant improvements were observed in the reporting of symptoms of fatigue, dyspnoea and insomnia, with improvements in general pain. PR has been demonstrated to offer guidance and support to cope with symptoms and facilitate referrals to other healthcare services when required. Moreover, in this study, PR has been advocated by HCPs as an

opportunity to promote physical activity to prevent a sedentary lifestyle in patients with LC while it may assist patients in health behavioural changes. Health behaviours including smoking habits and physical inactivity may contribute to worsening of symptoms such as dyspnoea and decreased exercise tolerance which may consequently hinder ADLs and general function. HCPs stated that educating patients on symptom management and health behavioural changes may aid to minimise unnecessary hospital admissions and decrease anxiety levels. Additionally, all HCPs recruited in this study supported PR and the benefits gained when patients with LC and other cancer diagnosis participate in PR at any stage of the disease course. Most of these findings are congruent with findings from other studies (Edbrooke et al., 2020; Pilotto et al., 2022, Saetan et al., 2020). Nevertheless, inconsistencies were observed in other studies with no difference reported in fatigue and HRQoL (Dhillon et al., 2017).

This study also explored perceptions of HCPs towards PR in LC management and the challenges and barriers faced by both patients and HCPs. Lack of knowledge and awareness on the role of PR within the oncology setting is a major barrier mentioned by all HCPs and which findings are consistent with existing literature (Edbrooke et al., 2020; Granger et al., 2018). PR may be viewed as a necessary service which supports the patient in a multidisciplinary and personalised manner contributing to better comprehensive and quality care. Additionally, since the patient is seen by the physiotherapist more frequently when attending for PR, the physiotherapist is viewed as a link between the patient and other HCPs, especially when additional attention may be required.

An interesting point that was highlighted by an HCP is that PR is not only beneficial for patients with LC but also for patients with different cancer diagnoses experiencing oncology-related pulmonary insufficiency. Adequate human resources are required to support cancer services, and, in this study, limited resources was an important negative factor mentioned by most participants. This may contribute to increased waiting lists for health services and/or increased burden on the healthcare workforce because patient symptoms and complaints are not addressed in a proactive manner.

6.3 Recommendations

In view of the research findings, some recommendations in relation to health service improvement in cancer care and public health and health system management can be suggested along with recommendations for future research.

6.3.1 Recommendations for Health Service Improvement in Cancer Care

Barriers and challenges identified by HCPs reflect the obstacles faced by patients to access PR. In order to improve patient care, overall patient satisfaction questionnaires would be an ideal tool to use to assess patient experiences after completing the PR programme and any other rehabilitation programme within the oncology hospital. Patient experiences are vital to the design and implementation of service and consequent improvement whilst ensuring and enhancing access and adherence (Larson et al., 2019). Hence, patient experiences and education are essential when introducing exercise-based interventions into the management and routine care of LC patients. Also, patient reported outcome measures used to assess HRQoL can be utilised to monitor existing rehabilitation programmes along with patient satisfaction questionnaires in order to further improve and expand existing healthcare services.

Further recommendations include PR being more accessible to a larger spectrum of cancer patients experiencing breathlessness other than LC patients. Therefore, the need to enhance awareness amongst HCPs on the eligibility criteria for PR and how to refer patients is recommended. Nonetheless, all patients with any cancer diagnosis may benefit from rehabilitation services even when not eligible for PR. In addition, it is also recommended that the benefits and criteria for inclusion of available healthcare services provided at SAMOC, including PR, are communicated regularly to all HCPs working in the oncology as well as in other healthcare domains. This may help such valuable services not to be overlooked, facilitate communication amongst HCPs and referral for the benefit of the patient when indicated.

Healthcare systems are slowly shifting away from disease focused models to more patient centred models (MFH,2022). Hence, patients play a central role in their care pathway and should be more involved in decision-making and empowered throughout their cancer journey. Consequently, leading to increased patient compliance towards their oncology treatment and rehabilitation. Thus, increased awareness on PR amongst HCPs may further contribute to enhance patient empowerment and improve their overall HRQoL.

This study provides a better understanding on the effect of PR on the HRQoL of patients diagnosed with LC within the local situation at SAMOC. While all indicated patients are given the opportunity to participate in PR at SAMOC in Malta, it is suggested that PR should be considered as a healthcare service that can be offered at the Gozo General Hospital so all patients may have equal opportunities and improved access while allaying any travelling issues that may arise.

6.3.2 Recommendations for Public Health and Health System Management

HRQoL is an outcome measure that is recently being increasingly used in the healthcare sector (Kaplan &Hays, 2022). In the past years, health has shifted from the medical model to a bio-psychosocial model where HRQoL is a multidimensional concept that measures the patient's overall well-being (Sajid et al., 2021). Thus, HRQoL outcome measures may be utilised to gather information on the patient's experience and the effectiveness of healthcare intervention in order to improve existing services and/or implement new services to enhance patient care and target unmet needs. Information on HRQoL is not readily available in cancer registries and other mainstream databases (such as hospital activity analysis) but is frequently used in research projects (Martin-Moreno et al., 2013). HRQoL serves as a useful indicator for policymakers to assess the progress of cancer care and healthcare interventions (Albreht et al., 2015; Martin-Moreno et al., 2013). Therefore, it is suggested that patient reported outcome measures for HRQoL are used as key performance indicators to observe, assess improvements, and optimise healthcare interventions/processes to improve standard of care and increase patient satisfaction.

Knowledge transfer and improved education may facilitate early detection in patient needs and access to healthcare services from which the patient may benefit. According to the EU Network of Comprehensive Cancer Centres, integrating clinical care and outcomes of research strengthens the quality-of-care delivered and encourages continuous evaluation of the quality of cancer care throughout the entire disease pathway (Obsert et al., 2021). Pursuing the improvements in HRQoL observed in our study, it is suggested that PR is an essential component within the LC care pathway and other cancers as it aims to facilitate/restore HRQoL and maximise independence through an integrated approach.

Nowadays, cancer is being considered as a chronic condition requiring prolonged treatment, regular follow-ups and prolonged use of healthcare services (Martin-Moreno et al., 2013). It is encouraging that all HCPs acknowledged the importance of PR in LC management. On the other hand, all HCPs identified a lack of awareness of PR as a barrier to patient access. This study supports the need for increased awareness on the impact and benefits of PR on patients diagnosed with LC within the oncology hospital and across the health sector. However, one must weigh the costs of increasing demands to such services in view of the finite resources available which may contribute to an increased burden on the healthcare workforce. Thus, it is necessary to allocate resources as efficiently as possible. Opportunity cost measured by health benefits can be used as a basis for determining the value associated with resource allocation decisions when investing in healthcare intervention such as PR.

Findings in this study support the need for the health system management to invest in programmes that provide comprehensive care with long-term benefits for patients affected by cancer and their relatives/carer during and after cancer treatment. Hence, an increase in capacity at the facility at SAMOC is recommended to support the provision of more coordinated care should the demand for PR increase. It is also recommended that the number of facilities in which PR is offered is increased to include the Gozo General Hospital (GGH) and St Vincent de Paul to facilitate access for Gozitan patients and elderly patients across a wider catchment area.

6.3.3 Recommendation for Further Research

This research project provides insight on the influences on HRQoL following an 8-week PR programme and explored HCPs' attitudes and perspectives towards PR in patients diagnosed and treated with LC in the Maltese healthcare system. Further research can delve deeper into the patient's perspectives following PR completion to evaluate patient experience and improve delivery of care. Research employing a qualitative methodology that builds on a previous local study by Azzopardi (2020), who explored the preferences of patients with LC on physical activity can be used to assess the challenges and benefits perceived by patients following PR.

Increasing the breadth of the research population and extending the time dedicated for data collection in the quantitative aspect of the study may provide more robust findings. Furthermore, future studies should also employ other outcome measures, such as 6-minute walk test, and dyspnoea score to further measure the efficacy of the intervention.

In addition, research on the impact of PR on a mixed-cancer cohort is recommended in view of the findings from this research. Ideally, the impact on the increased workload, including the time involved needs to be assessed and adequate evaluation of the required resources, should be conducted. This may aid to minimise the burden on the clinical services already being provided within the physiotherapy department at the oncology hospital and prevent any detrimental consequences that may lead to decreased quality of care. Therefore, the costs and benefits must be weighed together to determine if the benefits outweigh the costs through a cost-benefit analysis. Moreover, a cost-benefit analysis is recommended to quantify the effect of PR given to eligible patients on the health system such as reduced admissions and shorter length of stay in hospital.

Similar to Martínez-Velilla et al. (2021)'s study, further studies investigating the use of health resources to assess changes in frailty status in older adults within the Maltese society following PR is suggested. We are living in an ageing society and due to their co-morbidities older patients tend to tolerate systemic oncological treatment and/or radiotherapy treatment less than younger patients

(Foster et al., 2010). Therefore, promoting PR/exercise-based interventions whilst older patients are undergoing treatment is fundamental to ensure that patients remain independent to their maximum potential, stay active, and continue to enjoy life as much as possible. Additionally, home-based PR programmes may be another option for further studies especially in patients with advanced disease who have difficulties in attending clinic on an out-patient basis due to lack of social support and transportation issues.

6.4 Concluding Remarks

To conclude, this study identified PR as having a central role in the management of patients with LC and offers another useful service that can form part of the comprehensive cancer care approach. PR is a non-pharmacological intervention which may also be delivered to benefit patients other than those with LC experiencing oncology-related pulmonary insufficiency. Growing evidence on PR throughout the cancer continuum supports its use to improve patients' HRQoL or to slow down or prevent physical deterioration. PR offers a myriad of benefits when viewed from a public health perspective. These include promoting physical activity and healthy behavioural changes, preventing deterioration in overall HRQoL and possible unnecessary hospital admissions, better support for patients and relatives/carers, restoring physical function and independence within existing and forecasted limitations and facilitate return to economic and/or social engagement.

Finally, in view of increased cancer incidence, the researcher hopes that this research may help to promote awareness on the importance of PR in the cancer care pathway when indicated. In the case of LC patients, ideally PR is introduced from the beginning of their cancer journey, to offer guidance and support during this vulnerable period of their life, improve patient experience and strive to maximise HRQoL and independence.

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Appendices

Appendix A: Example of search strategy used to search for literature in databases considered relevant for the research topic

Example of search strategy used in MEDLINE:

#	Searches
1	(lung cancer or lung neoplasms or lung tumour or lung adenocarcinoma). tw.
2	(health related quality of life or quality of life). tw.
3	pulmonary rehabilitation. ti.
4	(respiratory rehabilitation or breathing exercises). ti.
5	(physical activity or exercise* or aerobic exercises or training* or exercise training or strength training). tw.
6	(barriers or facilitators or enablers). tw.
7	(patient perspective* or healthcare* perspective*). tw.
8	(public health or healthcare* or hospital admissions). ab.
9	1 and 2
10	3 or 4 or 5
11	9 and 10
12	6 and 7 and 8 and 11

Limits applied: Only peer reviewed journals; English language; year 2016 onwards

Appendix B: Summary of studies included in the systematic literature review

Author/ Year	Study Type	Aim	Population	Intervention	Outcome measure (if applicable)	Result
Dhillon et al. 2017	RCT	To evaluate the effect of a structured, individualized, 8-week PA intervention on fatigue and QOL in people with advanced lung cancer.	The study included 112 patients with advanced lung cancer; performance status ≤2	Participants were allocated (1:1) to usual care. Intervention consisted of individualised physical activity programme.	Primary outcome: FACT-F; Secondary outcome: EORTC-QLQ-C30 and LC-13; 6MWT; Senior's fir test; hand grip strength; Sedentary behaviour questionnaire; FEV1; FVC	There were no significant differences in fatigue between the groups at 2, 4 or 6 months. No significant difference in QoL, Symptoms, physical or functional status or survival
Edbrooke et al. 2019	RCT	To assess the efficacy of a rehabilitation package, compared with usual care (UC), on change in physical function (functional exercise capacity (primary aim), PA and muscle strength) and patient-reported outcomes including HRQoL.	Ninety-two participants	Eligible participants were allocated (1:1) to usual care (UC) plus 8 weeks of aerobic and resistance exercise with behaviour change strategies and symptom support (intervention group (IG)) or UC alone. Assessments occurred at baseline, 9 weeks and 6 months	6 min walk test; Assessment of Quality of Life; Behavioural Regulation of Exercise Questionnaire, version 2; Connor-Davidson Resilience Scale 10-item version; FACT-L; Hospital Anxiety and Depression Scale; health-related quality of life; International Physical Activity Questionnaire;	This trial of home-based rehabilitation resulted in significant improvements in patient-reported secondary outcomes at 6 months without significant changes in objective measures of physical function.

Author/Year	Study Type	Aim	Participants	Intervention	Outcome measure (if applicable)	Results
Edbrooke et al. 2020	RCT	To characterise the views and experiences of participants with inoperable lung cancer who completed a home-based rehabilitation program	Ninety-two participants were recruited (45 intervention group, 47 usual care)	Individual semi-structured interviews were conducted with participants randomised to the IG of a trial of home-based exercise,	/	This home-based rehabilitation program was acceptable to most participants with multiple benefits reported including improved fitness, motivation and ability to manage symptom
Edbrooke et al., 2021	Cost Utility Analysis	To assess the cost-effectiveness of a home-based rehabilitation programme for inoperable lung cancer compared to usual care	Seventy patients with stage IV lung cancer	A cost-utility analysis based on patient-level data from a previous RCT, Ebdrooke et al., 2019.	Primary outcome: Quality-adjusted life years gained.	Home-base rehabilitation is 75% likelihood of being cost-effective compared to standard care
Ester et al. 2021	Mix-method study	To assess feasibility of a novel 12-week trimodal intervention, including PA, nutrition and palliative symptom management in advanced NSCLC, an underserved advanced cancer population. To assess intervention impact on patient reported QOL, PA, symptom burden, and physical function.	10 participants	Participants received an individually tailored 12-week intervention featuring in-person group-based exercise classes, at-home physical activity prescription, behaviour change education, and nutrition and palliative care consultations	Physical activity: Godin leisure time exercise questionnaire; QoL: FACT-L, ESAS and FACT-F; Fatigue: ESAS, FACT-F	The study indicates that a multimodal exercise, nutrition, and palliative symptom management intervention is safe and feasible in patients with advanced NSCLC. and shows potential benefits on quality of life that warrant further investigation in a larger cohort trial

Author/Year	Study Type	Aim	Participants	Intervention	Outcome measure (if applicable)	Results
Granger et al. 2018	Qualitative study	To explore physiotherapists perceptions regarding barriers and enablers to incorporate exercise into lung cancer management	Eight physiotherapists working in the area of lung cancer	Participants attended a focus group interview.	/	Data generated 5 themes: evidence justifying exercise; staffing and services; maximising efficacy of interventions and hospital culture
Lee et al. 2021	Systematic review and Meta-analysis of RCTs	To investigate the effectiveness of exercise interventions in patients with lung cancer during chemotherapy	Six studies involving 244 participants with LC. Patients participated in exercise interventions during chemotherapy	/	/	Significant increase in strength, forced expired volume and quality of life. Significant decrease in pain observed. Combined aerobic and resistance exercise, 5 times a week, moderate to vigorous intensity, 1-hour session recommended
Martinez-Velilla et al. 2020	Non-RCT	To examine the impact of an exercise programme in the use of health resources in older adults and to assess their changes in frailty status	26 newly diagnosed patients with NSCLC stage I–IV	Multicomponent 10-week exercise programme that combined resistance, endurance, balance and flexibility exercises. Each session lasted 45–50 minutes, and the exercise protocol was performed twice a week over 10 weeks	Mortality, readmissions and Visits to the Emergency Department. Change in frailty status according to Fried, VES-13 and G-8 scales.	Significant between-group differences were obtained on visits to the emergency department during the year post-intervention; No differences were found in mortality rate and readmissions, where an increasing trend was observed in the CG compared with the IG in the latter; Change in frailty status according to Fried, after the intervention

Author/Year	Study Type	Aim	Participants	Intervention	Outcome measure (if applicable)	Results
Payne et al., 2018	Qualitative	To explore the experiences and perceptions of patients and healthcare professionals on the feasibility, acceptability, benefits and burden of palliative rehabilitation during advanced lung cancer treatment	Eight patients and six healthcare professionals	Semi-structured interviews conducted after completing a 6-week individualised behavioural change programme	/	Five themes from patient interviews: Challenges encountered, reason for participation, applicability of rehabilitation content, barriers and enablers, positive impact on self and others. Three themes from healthcare professionals' interviews: perceptions of rehabilitation, perceived benefits, lessons for future research
Pilotto et al. 2022	Cross-sectional survey	Aim to: (i) understand the assessment of exercise in the current lung cancer clinical practice; (ii) identify the knowledge about exercise guidelines for patients with lung cancer; (iii) examine clinicians' perceptions, barriers, and facilitators to promote exercise in patients with lung cancer, and (iv) examine the oncology providers' characteristics associated with exercise assessment.	141 respondents completed the survey who are members of the European Organisation for Research and Treatment of Cancer (EORTC) Lung Cancer Group	Survey consisted of 32 open and closed short items and was divided into five sections: (i) characteristics; (ii) exercise in current clinical practice; (iii) knowledge of guidelines for exercise in cancer; (iv) perceptions about exercise; and (v) barriers and facilitators for promoting exercise.	/	63% of the study participants declared that they frequently assessed exercise level in their patients; 43% of them reinforced the importance of exercise; 10% referred patients to an exercise program or specialist; two-thirds of clinicians reported not having adequate training about exercise counselling; 53% reported to lack of knowledge of guidelines referring to exercise in patients with cancer

Author/Year	Study Type	Aim	Participants	Intervention	Outcome measure (if applicable)	Results
Quist et al. 2020	RCT	The aim of this study was to evaluate the effect of a physical exercise program comprising 12 weeks of supervised, structured aerobic, strength, and relaxation training twice weekly for patients with advanced inoperable lung cancer	Chemotherapy and radiotherapy, male (49.1%) and female (50.9%), 64.4 ± 8.3 years old, NSCLC, or SCLC	12 weeks, supervised exercise (aerobic, strength and relaxation training), 2 times/week, supervised exercise	Maximal oxygen uptake, leg press, chest press, lat machine, leg extension, 6-min walk test, FEV, FACT-L (physical well-being, social well-being, emotional well-being, functional well-being, lung cancer subscale, trial outcome index, FACT-General, FACT-L, HADS	There was no significant difference between the intervention and control groups in VO2 peak. There was a significant improvement in muscle strength. There was also a significant difference between the two for social well-being (Functional Assessment of Cancer Therapy—Lung, FACT-L), anxiety, and depression.
Rosero et al. 2020	Non-randomised, opportunistic control, longitudinal trial	Investigate the efficacy and safety of exercise programs for NSCLC during adjuvant/palliative treatment	26 patients NSCLC stage I-IV	Supervised 10-week multi-component exercise program	Short Physical Performance Battery (SPPB); GVT; TUDs; 6MWTs; independence of activities in daily living (IADL), muscular performance, Mini-mental state examination; EORTC QLQ-C30/LC13	A significant group time interaction for SPPB ($p = 0.004$), 5-m GVT ($p = 0.036$), TUG ($p = 0.007$), and muscular performance (chest and leg power; $p < 0.001$) was observed. Significant changes between groups for cognitive functioning ($p = 0.021$) and quality of life for EUROQoL 5D ($p = 0.006$)

Author/Year	Study Type	Aim	Participants	Intervention	Outcome measure (if applicable)	Results
Rutkowska et al. 2019	RCT	To assess the impact of exercise training in patients with non–small cell lung cancer during chemotherapy in comparison to a usual care condition.	40 patients diagnosed with NSCLC at stages IIIB or IV, who were ot eligible for surgery.	6 weeks, 5 times/week, 30-min of fitness and respiratory exercise, specific respiratory exercise for 30a-min, cycle ergometer or treadmill for 20 to 30 min at 30% to 80% of peak work rate. Resistance exercise: 40% to 70% of 1-RM, Nordic walking for 45-min, relaxation training, in-hospital exercise for 2 weeks and supervised exercise for 4 weeks	6-week Fullerton Test (arm curl, chair stand, chair sit and reach, up and go, back scratch, 6-min walk test), spirometry test (forced expiratory volume, forced vital capacity), dyspnoea (functional impairment, magnitude of effect, Borg dyspnoea scale)	This study has revealed that exercise training is beneficial for lung capacity. The patients in the exercise group displayed significant improvements in FEV1, FVC, and FEV1/FVC. a significant improvement in dyspnoea was observed only in the Borg scale in contrast to the CG, who showed a nonsignificant increase of dyspnoea.
Rutkwoska et al. 2021	RCT	To assess the impact of exercise training on the quality of life (QoL) of patients diagnosed with stage IIIB and stage IV non–small cell lung cancer (NSCLC) compared to a passive control group	The study included 40 patients diagnosed with stage IIIB or stage IV NSCLC who were disqualified from surgery	The ETG used a 4-week stationary exercise program based on a rehabilitation program used in patients with chronic obstructive pulmonary disease (COPD), which was performed in 2-week cycles interspersed with consecutive chemotherapy infusions.	Short Form (36) Health Survey (SF-36), St. George's Respiratory Questionnaire (SGRQ), and the Functional Assessment of Cancer Therapy-Lung (FACT-L)	QoL assessment did not show any significant improvements in the group of patients undergoing comprehensive exercise training, although deterioration of QoL was noted in the CG

Author/Year	Study Type	Aim	Participants	Intervention	Outcome measure (if applicable)	Results
Saetan et al. 2020	quasi-experimental research	To examine the effects of the respiratory rehabilitation program on perceived self-efficacy and dyspnoea in patients with lung cancer	28 patients with NSCLC Stage 4 equally distributed to a control group and experimental group	The control group received routine nursing care only, whereas the experimental group received the respiratory rehabilitation program. The program comprised dyspnoea educating, breathing exercise, using handheld fans, effective coughing, respiratory strengthening training, and follow-up by phone in the third and sixth week	Perceived Respiratory Rehabilitation Self-Efficacy Assessment Scale; Cancer Dyspnoea Scale	Significant different in the mean score of perceived self-efficacy and dyspnoea between the experimental group and the control group ($p < .050$). The respiratory rehabilitation program should be used to promote self-efficacy and relieve dyspnoea in patients with lung cancer.
Sloan et al., 2016		To evaluate the impact of physical activity on the quality and quantity of life of lung cancer survivors	1466 lung cancer survivors (NSCLC and SCLC)	Participants completed a questionnaire and a measure of physical activity between January 1997 and December 2009	A questionnaire with patient reported outcome for quality of life, demographics, disease and clinical characteristics and a measure of physical activity (Baecke Questionnaire). Kaplan-Meier estimates and Cox models to evaluate overall survival	Physical activity patients reported increased benefits in quality of life and survival

Appendix C: SOP for Oncology Pulmonary Rehabilitation Programme

SIR ANTHONY MAMO	SOP: CSS-PT-ONC-003	Version: 02
	Issue Date: 25/07//2019	Review Date: 16/03/2025

Oncology Pulmonary Rehabilitation Programme

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Change History

Version No.	Revision Date	Change Description
2	16/03/22	6.1.2 Exclusion Criteria

This document is not valid without all the number of pages specified

1. Purpose

1.1. The principal objective of this SOP is to standardise the procedure to be followed when referring patients and when delivering the Pulmonary Rehabilitation Programme for patients with oncology-related pulmonary insufficiency.

1.2. It will ensure that physiotherapists working at SAMOC have a clear understanding of referral procedures, eligibility criteria and the mode of delivery. A standardised approach enhances effectiveness and patient satisfaction and data collection.

1.3. The SOP will facilitate early screening of patients by a physiotherapist so as to offer a timely intervention for identified needs.

2. Scope

2.1. This SOP applies to physiotherapists working at Sir Anthony Mamo Oncology Centre. The rehabilitation programme takes place at the physiotherapy outpatients department, SAMOC.

2.2. This SOP is to be followed when cancer patients are referred for pulmonary rehabilitation including the management of breathlessness.

3. Terms & Definitions

Pulmonary rehabilitation programme: an exercise programme aiming to improve the physical function and quality of life of patients with oncology-related pulmonary insufficiency including breathlessness.

Exercise tolerance refers to the level of physical exertion an individual may be able to achieve before reaching a state of exhaustion. (Mosby's Medical Dictionary, 9th edition. © 2009, Elsevier.)

Spirometer is an instrument that measures pulmonary function (both lung volume and lung capacity) by recording the volume of inhaled and exhaled air. (Mosby's Medical Dictionary, 9th edition. © 2009, Mosby.)

6MWT refers to the six minute walking test. The test assesses exercise tolerance (Appendix 10.2).

1 min sit-to-stand is a test used to assess exercise capacity and leg muscle strength. (Appendix 10.2)

Maximum Heart Rate refers to the number of beats per minute of the heart when working at its maximum according to age.

Unstable medical conditions inclusive of conditions such as seizures, hypotension, acute cardiac heart failure, uncontrolled diabetes, acute pulmonary oedema, pulmonary embolism, chest infection.

4. Reference Documents

4.1. SOP: ONC 007 Version 02: Medical Emergency Procedure – Clinical Support Services and Radiotherapy Department (SAMOC).

4.2. SOP: CSS-PT-ONC-002 Version 02: Request for physiotherapy consultation by nurse navigators, SAMOC.

5. Responsibilities

5.1. The physiotherapy department, SAMOC shall provide training to all members of staff on how to follow this SOP.

5.2. Physiotherapists working at SAMOC are required to follow this SOP for referral procedures and for the principles and method of delivering the programme (Refer to Section 7).

5.3. The physiotherapist may be required to modify the treatment regime according to the individual patient needs based on assessment findings.

5.4. Physiotherapists delivering the Pulmonary Rehabilitation Programme should be aware of the steps to follow in case of a medical emergency or CPR as defined in SOP: ONC 007 Version: 02.

6. Safety Issues

6.1. Patients need to be assessed by a physiotherapist and eligibility and exclusion criteria adhered to.

6.1.1 Eligibility criteria:

- Patients experiencing oncology-related pulmonary insufficiency which may include breathlessness who have been referred for physiotherapy assessment and management. Physiotherapy referral forms filled by a medical officer are accepted from all health care settings. Referrals are also accepted through the cancer nurse navigator as per CSS-PT-ONC-002 Version 02.

6.1.2 Exclusion criteria:

- Patients who are unaware of their diagnosis or who are unable to follow commands;
- Patients with unstable medical conditions;
- Patients who are chair bound or need assistance with transfers;
- Patients with a satuaration of less than 92% and/or severe dyspnoea on minimal exertion. The Modified Borg's Scale should be taken into consideration if the patient has other respiratory comorbidities eg: COPD.Patients are deemed eligible if they have a resting Borg Scale rating of 1 or 2.

6.2. All sessions should be supervised by a physiotherapist. Patients are not to be left unattended during performance of any exercise.

6.3. Physiotherapists are to ensure that the rehabilitation setting and equipment used minimise any risk of injury to the participants.

6.4. A supply of oxygen should be available throughout the sessions. The gym is equipped with oxygen ports and an ambulatory oxygen cylinder is available at the department.

6.5. Exercise should be performed at 75% of the maximum heart rate. The exercise should be performed with a minimum oxygen saturation of 92%. If saturation drops less than 92% exercise should be stopped. However, if patient suffers from other respiratory comorbidities the Modified Borg's Scale must be taken into consideration and stopped if scale is 3 (moderate). Heart rate and oxygen saturation monitors are to be used during exercise.

6.6. Patients are requested to wash their hands before and after the session so as to follow infection control guidelines. Any used equipment should be cleaned with alcohol wipes at the end of the session.

7. Method

7.1 An initial assessment as outlined in Appendix 10.1 is carried out to determine the suitability to attend the pulmonary rehabilitation programme. The patient will then follow an individualised treatment programme of 8 sessions (Appendix 10.3). The

sessions consist of an educational talk followed by exercises. Each session lasts around 45 minutes but varies depending on the patients' needs.

7.2 The programme is held on a weekly basis until the 8 sessions are completed.

7.3 If patient does not attend physiotherapy sessions for more than three consecutive sessions, a 6MWT should be conducted during the next session.

7.4 Participants may also be referred to the dietitian or psychologist as required.

7.5 Participants should be reviewed and parameters taken prior to each session and the objective measures (exercise tolerance) re-assessed following the 8th session. Should a participant be deemed unfit to continue with the programme, alternative treatment sessions addressing the patient current needs or arrangements for community support are to be offered.

7.6 Participants are followed-up after one month with the aim of addressing any issues and to adapt the home exercise programme as necessary. A 6MWT should be done at one month appointment. Further follow-ups are planned as required.

8. Records

8.1 All pre and post assessments carried out for patients attending the programme should be duly filled in and updated regularly on MOSAIQ. Parameters should be recorded for every session.

8.2 Parameter readings taken during each session should also be recorded in the patient information booklet.

9 References

Mosby's Medical Dictionary, 9th edition, 2012, Mosby.

American Thoracic Society (2002) ATS Statement Guidelines for the Six-Minute Walk Test. *American Journal of Respiratory and Critical Care Medicine* vol 166(1) pp. 111–117.

Vaidya, Trija et al. (2016) "Is the 1-minute sit-to-stand test a good tool for the evaluation of the impact of pulmonary rehabilitation? Determination of the minimal important difference in COPD." *International journal of chronic obstructive pulmonary disease* vol. 11 pp 2609-2616.

10. Appendices

10.1 Respiratory Assessment

10.2 Instructions for Outcome measures: 6 minute walk-test; Sit-to-stand

10.3 Programme Outline

10.4 Pulmonary Rehabiliatation Flowchart

Appendix 10.1: Respiratory Assessment

SIR ANTHONY MAMO

Oncology Pulmonary Rehabilitation
Physiotherapy Department

Patient Assessment Form Date: _____

Patient's Name: _____ Age: _____

Address: _____

ID No: _____ Tel: _____

Referring Firm/Doctor: _____

Diagnosis: _____

SUBJECTIVE

HOPC

_____

_____

_____

Year of Surgery _____ Age at Diagnosis _____

No of years since medical treatment _____

Cancer Status: on Rx Palliative

Chemotherapy Yes [ ] No [ ] _____

Radiotherapy Yes [ ] No [ ] _____

Infections: _____

CC _____

PMH

Cardiac disease _____

Respiratory disease _____

Neurological conditions _____

Others _____

DH

_____

_____

Reports and Investigations

_____

_____

_____

_____

Body Mass Index

Weight (kg)	Height (cm)	**BMI**			
		Obese *(>30)*	☐	Normal *(18.5-25)*	☐
		Overweight *(25-30)*	☐	Underweight *(<18.5)*	☐

SH _____

_____

_____

OBJECTIVE

On examination:

_____

_____

Evaluation of the Pulmonary System

Chest type:	_____			
Fremitus:	Tactile	___	Vocal	___
Colour:	Central Cyanosis	___	Peripheral Cyanosis	___
Fingers:	Digital Clubbing	___		

Breathing

Breathing Rate	___
Dyspnoea	___
Other	_____

Borg's Shortness of Breath Scale **Activity:**_____

0	-	Nothing at all
0.5	-	Very very slight
1	-	Very slight
2	-	Slight
3	-	Moderate
4	-	Somewhat severe
5	-	Severe
6		
7	-	Very Severe
8		
9	-	Very very severe
10	-	Maximal

Type of Breathing

Apical ___ Costal ___ Diaphragmatic ___

Auscultation

Breath Sounds Normal ___ Abnormal ___

Location _____

_____

_____

Cough & Sputum

Expectoration _____

Quantity _____

Viscosity _____

Colour _____

Frequency _____

Time of day _____

Eased by _____

Chest Expansion

	Inspiration	Expiration	Difference
Axilla			
10th Costal			
X-P			

Breathlessness

Onset: _____

Aggravating factor: _____

Relieving factors: _____

Rapidity of Onset: _____

Sleeping Pattern: _____

Relationship to exercise: _____

Relation to Anxiety: _____

Activities of Daily Living:

	I	S/D	D	Comments
Bathing				
Eating				
Dressing				
Toileting				
Cooking/Cleaning				

Gait _____

_____

Maximum Heart Rate: _____ bpm (220-Age)

75% Maximum Heart Rate: _____

Exercise tolerance tests

- **Six minute walking test**

	Before	During	After	After 5mins
SpO2				
Heart Rate				
Blood pressure		/	/	
Dyspnoea Score				

Distance _____

- **Sit-to-stand***

	Before	During	After	After 5mins
SpO2				
Heart Rate				
Blood pressure		/	/	
Dyspnoea Score				

Number of repetitions _____

** Sit to stand test is carried out only if for any reason the patient is unable to do the 6min walk test.*

Problem List

	Problem	Active	Inactive

Analysis

_____

_____

_____

_____

_____

Plan

1. _____
2. _____
3. _____
4. _____

_____ _____

Physiotherapist Date

	Date	BP	HR	SPo2	Comments
1.					
2.					
3.					
4.					
5.					
6.					
7.					
8.					
9.					
10.					

GEN1016v01.0

Appendix 10.2 : Instructions for Outcome Measures

6 min walking test

The purpose of this test is to walk as far as possible for 6 minutes to assess exercise tolerance. This is measured in terms of SpO2, heart rate, blood pressure and a dyspnoea score. Explain to the patient the objective of the test and what it entails.

Instructions to the patient:

"You will walk back and forth in this corridor.

You may feel exhausted or out of breath. You can slow down, stop, and rest as necessary.

You may also lean against the wall while resting, but resume walking as soon as you are able. You will be walking back and forth around the cones.

Now I'm going to show you.

Remember that the object is to walk AS FAR AS POSSIBLE for 6 minutes, but don't run or jog. Start now, or whenever you are ready." (ATS, 2002)

Reasons for immediately stopping a 6MWT include the following: chest pain, intolerable dyspnoea, leg cramps, staggering, diaphoresis and pale or ashen appearance.

1 min sit-to-stand

The purpose of the test is to assess exercise capacity and leg muscle strength. This is measured in terms of SpO2, heart rate, blood pressure and a dyspnoea score. The movement required is to get up from a chair with the legs straight and sit back continuing the repetitions as fast as possible within one minute.

Instructions to patient:

"I will give you the countdown '3, 2, 1 Go' as an indication to start and also I will tell you when we are at the 15 remaining seconds. If required, you can take a break and resume the test as soon as possible". (Vaidya et al., 2016)

Modified Borg Dyspnoea Scale

Instructions to the patient:

"This is a scale that asks you to rate the difficulty of your breathing. It starts at number 0 where your breathing is causing you no difficulty at all and progresses through to number 10 where your breathing difficulty is maximal. How much difficulty is your breathing causing you right now?"

Appendix 10.3: Programme Outline

- *Heart rate and oxygen saturation monitors should be worn during exercise.*
- *Treadmill speed, stationary bike level, weights and repetitions are just guidelines. They can be varied based on the professional judgement of the physiotherapist.*
- *All exercises can be done in sitting or in standing.*

Assessment

1. An initial assessment should be carried out following referral.
2. **Talk 1:** Explain the scope of the rehabilitation programme and discuss fatigue and breathlessness together with breathing exercises and ACBTs to remove sputum. Refer to information booklet.

Session 1

1. **Talk 2:** Explain relaxation exercises, positioning, review breathing exercises and ACBT's. Refer to information booklet.
2. Check spirometry reading.
3. Practice breathing and relaxation techniques, positioning and ACBT's.
4. Stretches: Shoulder stretch, triceps stretch, side stretch, calf stretch and hamstring stretch
5. Exercises with emphasis on controlled breathing, repeated for 10 times
    - Shoulder elevation and depression
    - Shoulder retraction and protraction
    - Shoulder circles backwards
    - Shoulder flexion and extension
    - Shoulder horizontal abduction and adduction
    - Shoulder abduction and adduction
    - Shoulder internal and external rotation
6. TAQs: Ankle dorsiflexion/plantarflexion/circles and VMOs
7. Finish off with stretches as above
8. Home exercise Programme: Above exercises + breathing exercises

Session 2

1. **Talk 3:** Managing activities of daily living. Refer to information booklet – managing breathlessness until leisure section.
2. Check spirometry reading.
3. Stretches: Shoulder stretch, triceps stretch, side stretch, calf stretch and hamstring stretch
4. Shoulder circular movements with breathing exercises
5. Lower limb exercises repeated for 10 times: (Include in HEP)

- Sit to stand
- Step ups (10 steps with left leading leg; 10 steps with right leading leg)
- Heel raises
- Knee extensions hold for 5-10 second
- Marching

6. Breathing exercises
7. TAQs
8. Above sequence can be repaeated as tolerated by patient.
9. Finish off with stretches as above.

Session 3

1. Check spirometry reading.
2. Stretches: Shoulder stretch, triceps stretch, side stretch, calf stretch and hamstring stretch
3. Exercises with emphasis on controlled breathing repeated for 10 times
    - Upper limb exercises: shoulder flexion and extension/ abduction and adduction
    - Walking on treadmill or Stationary bike (record intensity and time).
        a. Patients should be exercising at a maximum of Level 3 on the Borg scale. Should the patient exceed this level, the intensity needs to be lowered or the exercise stopped immediately
        b. Treadmill: 1.7 km/h*. Duration is determined by the Borg scale but not exceeding 10 mins
        c. Stationary bike: Level set at 1.5*. Duration is determined by the Borg scale but not exceeding 10 mins
    - Breathing and relaxation exercises
    - Upper limb exercises: biceps curls and shoulder press repeated for 6 times (preferably with weights starting from 1 to 0.5kg)*
    - Lower limb exercises: Hip extension and abduction, knee extension, knee flexion and marching on the spot
    - TAQ's
4. Breathing exercises
5. Finish off with stretches as above.

treadmill speed, stationary bike level, weights and repetitions are just guidelines. They can be varied based on the professional judgement of the physiotherapist.

Session 4

1. Check spirometry reading.
2. Stretches: Shoulder stretch, triceps stretch, side stretch, calf stretch and hamstring stretch
3. Walking on treadmill or Stationary bike (record intensity and time).
    a. Patients should be exercising at a maximum of Level 3 on the Borg scale. Should the patient exceed this level, the intensity needs to be lowered or the exercise stopped immediately
    b. Treadmill: Start at the same speed as session 3 . Duration is determined by the Borg scale; may increase time over previous session
    c. Stationary bike: Start at the same level as session 3. Duration is determined by the Borg scale; may increase time over previous session
4. Breathing and relaxation exercises
5. Exercises emphasis on controlled breathing repeated for 10 times
    - Rowing – In sitting with a 0.5kg weight wrapped around stick
    - Breathing and relaxation
    - Stepping (10 steps with left leading leg; 10 steps with right leading leg)
    - Lower limb exercises: Hip extension and abduction, knee extension and marching on the spot. Introduce weight as tolerated
    - TAQ's
6. Breathing exercises
7. Finish off with stretches as above.

Session 5 (circuit training) – Increase intensity according to patient

1. Start with spirometry
2. Stretches: Shoulder stretch, triceps stretch, side stretch, calf stretch and hamstring stretch.
3. Walking on treadmill or stationary bike (record intensity and time). Keep the same duration as achieved in session 4
4. Breathing and relaxation exercises
5. Exercises with emphasis on controlled breathing (suggested - 2 min of exercise and 30 to 60 secs rest; may require to decrease exercise time as per patient tolerance.)
   - Biceps curls
   - Stepping
   - Rowing
   - Squatting
   - Shoulder push up
   - Sideways walking (to cool down)
6. Finish off with stretches as above.

Session 6 (Circuit training) - Increase intensity according to patient

Repeat Session 5

Session 7 (Circuit training) - Increase intensity according to patient

Repeat Session 6

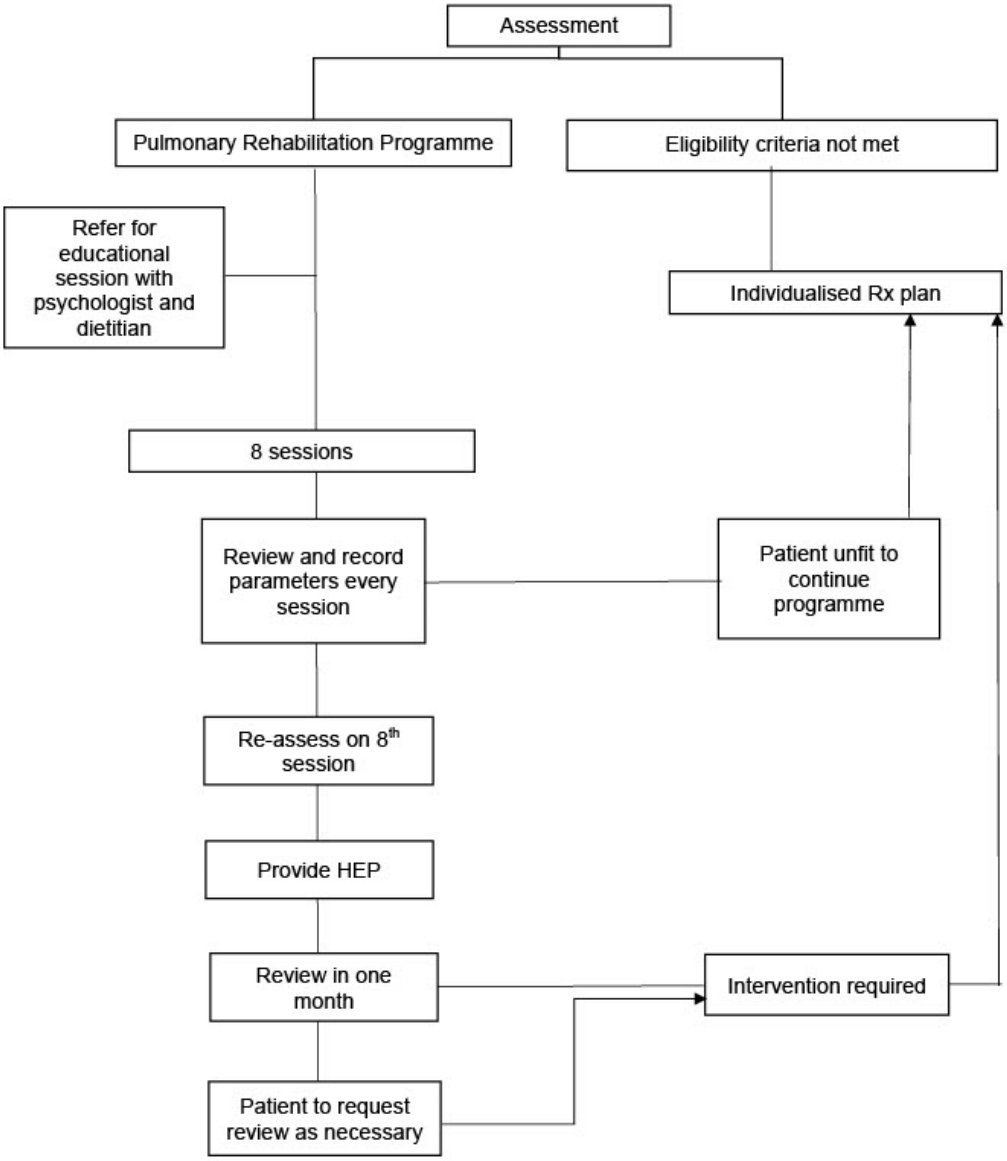
Session 8

6MWT should be re-assessed and personalised exercise programme should be revised.

One Month Review

6MWT should be re-assessed and any other issues related to physiotherapy should be discussed.

Appendix 10.4 Pulmonary Rehabilitation Programme Flowchart



Appendix D: Intermediary Consent Form

SAMOC Intermediary Declaration

I, the undersigned will be acting as the intermediary in the research study entitled: 'Evaluating the impact of Pulmonary Rehabilitation on the quality of life of patients diagnosed with lung cancer' by Bernardette Bezzina.

- I will be physically approaching potential patient participants to disseminate information sheets and obtain consent on the behalf of the researcher at SAMOC. I am aware that the researcher cannot approach directly potential participants.
- I will be communicating with the patients to obtain consent to access patient data on MOSAIQ.
- I will be accessing patient data on MOSAIQ after receiving patient consent. I am aware that the researcher cannot access MDH health information systems.

Signature: _____

Name in Block letters: PAULINE SANT

Email address: pauline.sant@gov.mt

Appendix E: Patient Information Sheet (English and Maltese Version)

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Information Sheet (English) – Patient

Dear Participant,

I, Ms. Bernardette Bezzina, am currently reading for a Master of Science in Public Health at the University of Malta. As part of my course requirements, I am conducting a research study entitled, "Evaluating the impact of Pulmonary Rehabilitation on the quality of life of patients diagnosed with lung cancer".

The aim of this study is to assess changes in quality of life following an 8-week Pulmonary Rehabilitation programme delivered to patients with lung cancer on an out-patient basis at SAMOC. Your participation in this study would help us gain a deeper insight on the beliefs about physical activity and the barriers and enablers faced by patients and healthcare professionals. Thus, this study shall help to contribute towards increasing awareness on the importance of facilitating access to patients with lung cancer to Pulmonary Rehabilitation and provide a better understanding on how to improve the clinical service and improve outcomes for lung cancer patients throughout their cancer care continuum. 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 questionnaire assessing your quality of life before and after an 8-week Pulmonary Rehabilitation programme. The questionnaire was developed by EORTC and will be conducted by the Researcher. It will take approximately 10 minutes and will be held at SAMOC prior to your physiotherapy session. Participation in this study may cause some psychological distress due to the nature of the questions. Psychological support shall be offered if required at the Clinical Support Service, Sir Anthony Mamo Oncology Centre. You are not obliged to answer all the questions and may withdraw from the study at any time without giving a reason.

Furthermore, withdrawal from the study shall not have any negative repercussions on you and any data collected will be erased. I can assure you that confidentiality shall be maintained throughout the study and that your identity and personal information will not be revealed in any

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publications, reports, or presentations arising from this research. All data collected shall be pseudonymised meaning that questionnaires shall be assigned codes and this data shall be stored securely in a locked cupboard. The list of codes shall be stored separately from the rest of the pseudonymised data (questionnaire) and consent forms. The list of codes may only be accessed by the researcher. The academic supervisor, and the examiner(s) shall only have access to the codified data without personal identification in case of verification. The list with the pseudonym names will remain only in my possession.

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 shall be provided for future reference. As a participant, you have the right under the General Data Protection Regulation (GDPR) and national legislation 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 list of codes with pseudonymised participants and consent forms shall be deleted by end of 2023.

Thank you for your time and consideration. Should you have any questions or concerns do not hesitate to contact me on 79276200 or by e-mail bernardette.schembri.09@gov.mt or my supervisor Dr. Miriam Dalmas on 99824521 or by e-mail on miriam.dalmas@um.edu.mt or my co-supervisor Dr. Anabel Sciriha on 23401573 or by e-mail on anabel.sciriha@um.edu.mt.

Yours Sincerely,

Researcher	Research Co-Supervisor	Research Co-Supervisor
Bernardette Bezzina	Dr. Miriam Dalmas	Dr. Anabel Sciriha

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Formola ta' Informazzjoni għall-Parteċipanti - Pazjenti

Għażiż Parteċipant/a,

Jiena, Ms Bernardette Bezzina, fil-preżent qed insegwi 'Master of Science in Public Health' fl-Universita' ta' Malta. Bħala parti mir-rekwiżiti tal-kors, qed nagħmel riċerka bit-titlu, "Evaluating the impact of Pulmonary Rehabilitation on the quality of life of patients diagnosed with lung cancer". Taħt is-superviżjoni ta' Dr. Miriam Dalmas u co-superviżjoni ta' Dr. Anabel Sciriha.

L-għan ta' dan l-istudju hu li nesplora u nevalwa -bidliet fil-kwalità tal-ħajja ta' persuna bil-kanċer tal-pulmun wara programm ta' 8 ġimgħat ta' Rijabilitazzjoni Pulmonari li jsir fl- 'out-patient' f'SAMOC. Is-sehem tiegħek f'dan l-istudju jista' jgħin biex ikollna aktar għarfien dwar it-twemmin fuq l-attività fiżika, l-ostakli u dawk l-affarijiet li jiffaċilitaw l-użu ta' dan il-programm mill-pazjenti u l-professjonisti tal-kura tas-saħħa. Għalhekk, dan l-istudju għandu jgħin biex jikkontribwixxi biex tiżdied l-għarfien dwar l-importanza li jiġi ffaċilitat l-aċċess għal pazjenti b'kanċer tal-pulmun għar-Rijabilitazzjoni tal-Pulmun u jipprovdi għarfien aħjar dwar kif jista' jitjieb is-servizz kliniku u jittejbu r-riżultati għall-pazjenti bil-kanċer tal-pulmun matul il-kors tal-kura tagħhom. Kull informazzjoni miġbura tintuża biss għall-għan jew l-għanijiet ta' dan l-istudju.

Bħala parteċipant/a inti qed tiġi mistieden/a biex tipparteċipa fi kwestjonarju li jivvaluta l-kwalità tal-ħajja tiegħek qabel u wara l-programm ta' Rijabilitazzjoni Pulmonari. Il-kwestjonarju ġie żviluppat mill-EORTC u se jiġi mmexxi mir-riċerkatriċi. L-kwestjonarju se jieħu madwar 10 minuti u f'SAMOC, qabel is-sezzjoni tal-fiżjoterapija. Il-parteċipazzjoni f'dan l-istudju tista' tikkawża xi tbatija psikoloġika minħabba n-natura tal-mistoqsijiet. Se jkun offrut appoġġ psikoloġiku jekk ikollok meħtieġ fiċ-Ċentru tal-Onkoloġija Sir Anthony Mamo. M'intix obbligat/a li twieġeb il-mistoqsijiet kollha u tista' twaqqaf l-parteċipazzjoni tiegħek fi xħin trid mingħajr ma tagħti l-ebda raġuni. Dan mhux ħa jkollu riperkussjonijiet negattivi fuqek u l-informazzjoni li tingħabar minn għandek titħassar.

Nassigurak li se tinżamm il-kunfidenzjalità matul l-istudju kollu u l-identità tiegħek u kull informazzjoni personali miġbura m'huma se jiġu żvelati mkien f-dan l-istudju , ir-rapporti, il-preżentazzjonijiet u il-pubblikazzjonijiet li jistgħu jirriżultaw minnha. Id-dejta kollha miġbura se tkun psewdonimizzata li jfisser li l-kwestjonarji se jiġu assenjati kodiċijiet u din id-dejta se tiġi miżmuma b'mod sigur f'armarju msakkra. Il-lista ta' kodiċijiet se tkun merfuha separatament mill-bqija tad-dejta psewdonimizzata (kwestjonarju) u formoli tal-kunsens. Il-lista ta' kodiċijiet tista' tiġi aċċessata biss mir-riċerkatur. Is-Superviżura akkademika u l-Eżaminatur/i ser ikollhom aċċess għall-informazzjoni kodifikata biss mingħajr identifikazzjoni personali f'każ ta' verifika. Il-lista bl-ismijiet psewdonimi se tibqa' biss fil-pussess tiegħi.

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Il-parteċipazzjoni tiegħek f'dan l-istudju hija għażla għal kollox volontarja u inti ħieles jew ħielsa li taċċetta jew tirrifjuta li tieħu sehem mingħajr ma jkun hemm konsegwenzi fil-konfront tiegħek. Se tingħata kopja tal-ittra ta' informazzjoni u tal-formola ta' kunsens sabiex tkun tista' taċċessahom fil-futur. Barra minn hekk, skont l-Att Dwar il-Protezzjoni u l-Privatezza tad-Data, inti għandek id-dritt li taċċessa, temenda u tħassar kull informazzjoni li tikkonċernak. L-informazzjoni personali kollha se titħassar hekk kif jintemm dan l-istudju ta' riċerka u jkunu ppubblikati r-riżultati miksuba. Il-lista ta' kodiċijiet b'parteċipanti psewdonimizzati u l-formoli tal-kunsens se jkun mħasra sa tmiem l-2023.

Grazzi ħafna tal-ħin u s-sehem tiegħek f'dan l-istudju. F'każ li jkollok xi mistoqsijiet jew tixtieq tiċċara xi ħaġa, tista' ċċempilli fuq 79276200 jew tibgħatli email fuq bernardette.schembri.09@um.edu.mt. Tista' wkoll tikkuntattja lis-superviżura tiegħi Dr. Miriam Dalmas fuq 99824521 jew billi tibgħat email fuq miriam.dalmas@um.edu.mt jew tista' tikkuntattja lil co-superviżura tiegħi Dr. Anabel Sciriha fuq 23401573 jew billi tibgħat email fuq anabel.sciriha@um.edu.mt.

Dejjem tiegħek,

Ir-Riċerkatriċi	Is-Superviżura tar-riċerka	Il-co-Superviżura tar-riċerka
Bernardette Bezzina	Dr. Miriam Dalmas	Dr. Anabel Sciriha

Appendix F: Patient Consent Form (English and Maltese Version)

L-Università ta' Malta

PATIENT CONSENT FORM

I _____, give my consent to participate in a research study entitled: "Evaluating the impact of Pulmonary Rehabilitation on the quality of life of patients diagnosed with lung cancer".

This study aims at assessing the changes in quality of life following an 8-week Pulmonary Rehabilitation programme delivered to patients with lung cancer on an out-patient basis at SAMOC.

The purpose and details of the study have been explained to me by the researcher Ms Bernardette Bezzina and any difficulties which I raised have been adequately clarified.

I give my consent to carry out the questionnaire by the Researcher before and after the 8-week Pulmonary Rehabilitation programme.

I am also aware that I may be subject to psychological distress due to the nature of the questions asked. However, psychological service at the Clinical Support Service in Sir Anthony Mamo Oncology Centre will be offered if required.

I am also aware that data will be treated with strict confidentiality and processed in accordance with the General Data Protection Regulations (GDPR) of the Data Protection Act, Chapter 586 of the Laws of Malta. I have the right to request, in writing, a copy of the personal information held about me by the Researcher. I have the right to request correction or erasure of such data, in line with the Data Protection Act.

I understand that the list of codes shall be stored safely and separately from the rest of the pseudonymised data and consent forms in a locked cupboard at Ms Bernardette Bezzina until the duration of the study and publication of results. I am also aware that the list of codes used for pseudonymisation shall only be accessed by the researcher. Supervisors and examiners will only have access to the codified data in case clarification would be needed. I understand I am under no obligation to participate in this study and am doing so voluntarily. I may withdraw from the study at any time, without giving any reason. This will not influence in any way the care and attention and treatment normally given to me.

In case of queries during the study I may contact the Researcher, Bernardette Bezzina.

Date: _____

Signature of participant: _____

Name of participant (in block letters): _____

Researcher	Research Supervisor	Research Co-Supervisor
Bernardette Bezzina	Dr. Miriam Dalmas	Dr. Anabel Sciriha

L-Università ta' Malta

PROPOSTA GHALL-FORMULA TAL-KUNSENS

Jien _____ qed nagħti l-kunsens tiegħi biex nipparteċipa fi studju ta' riċerka bl-isem ta': "Evaluating the impact of Pulmonary Rehabilitation on the quality of life of patients diagnosed with lung cancer".

Dan huwa studju li l-għan tiegħu hu li jivvaluta l-bidliet fil-kwalità tal-ħajja wara programm ta' Rijabilitazzjoni Pulmonari ta' 8 ġimgħat imwassal lil pazjenti b'kanċer tal-pulmun fuq bażi 'out-patient' f'SAMOC.

L-iskop u d-dettalji tal-istudju ġew spjegati lili u kull diffikultà u mistoqsijiet li kelli ġew iċċarati b'mod adegwat mir-riċerkatriċi Ms Bernardette Bezzina.

Nagħti l-kunsens tiegħi biex inwettaq il-kwestjonarju mir-riċerkatriċi qabel u wara l-programm ta' Rijabilitazzjoni Pulmonari ta' 8 ġimgħat.

Jiena konxju/a wkoll li nista' nkun suġġett ta' tbatija psikoloġika minħabba n-natura tal-mistoqsijiet li jsiru. Madankollu, servizz psikoloġiku f'SAMOC se jiġi offrut jekk jkun meħtieġ.

Id-data se tiġi proċessata skond ir-Regolament Ġenerali dwar il-Protezzjoni tad-Data (GDPR) ta' l-Att tal-Protezzjoni u l-Privatezza tad-Data, Kapitolu 586 tal-Ligijiet ta' Malta. Naf li l-informazzjoni migbura se tkun kodifikata u r-riċerkatriċi biss ikollha aċċess għaliha. Lis-supervizuri u ezaminaturi jista jkollhom aċċess għad-data kodifikata biss f'każ li jkun hemm bżonn. Jiena għandi d-dritt li nitlob, bil-miktub, kopja tal-informazzjoni personali miżmuma dwari mir- riċerkatriċi. Jien għandi id-dritt li nitlob korrezzjoni jew tħassir ta' din id-data, skond l-Att tal-Protezzjoni u l-Privatezza tad-Data.

Jiena nifhem il-lista ta' kodiċijiet se tiġi merfugħa b'mod sigur u separatament mid-dejta kodifikata u l-formoli tal-kunsens f'armarju msakkra għand Ms Bernardette Bezzina sakemm jitlesta l-istudju u jiġu ppublikati r-riżultati. Jiena konxju/a wkoll li l-lista ta' kodiċijiet se tkun aċċessibli biss mir-riċerkatura. Is-superviżuri u l-eżaminaturi se jkollhom aċċess għad-dejta kodifikata biss f'każ li tkun meħtieġa kjarifika. Jiena nifhem li ma għandi l-ebda dmir li nieħu sehem f'dan l-istudju u dan qed nagħmlu minn rajja. Jiena nista', meta rrid, ma nkomplix nieħu sehem fl-istudju, u mingħajr ma' nagħti raġuni. Jiena nista', meta rrid, ma nkomplix niehu sehem fl-istudju, u mingħajr ma' nagħti raġuni. Jekk nagħmel hekk xorta tibqa' tingħata lili l-kura li soltu tingħatali.

Jekk ikolli xi diffikulta' waqt l-istudju nista' nistaqsi lir-Ricerkatriċi, Bernardette Bezzina.

Data: _____

Firma tal-parteċipant: _____

Isem il-parteċipant (b'ittri kbar): _____

_____	_____	_____
Ir-Riċerkatriċi	Is-Superviżura tar-riċerka	Il-co-Superviżura tar-riċerka
Bernardette Bezzina	Dr. Miriam Dalmas	Dr. Anabel Sciriha

Appendix G: Healthcare Professionals Invitation Letter

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Dear Healthcare Professional,

I am Bernardette Bezzina and I am currently reading for a M.Sc. in Public Health at the University of Malta. I am presently conducting a research study for my dissertation entitled 'Evaluating the impact of Pulmonary Rehabilitation on the quality of life of patients diagnosed with lung cancer' under the supervision of Dr. Miriam Dalmas and co-supervisor Dr. Anabel Sciriha.

This letter is an invitation to participate in this study. Below you will find information about the study and about what your involvement would entail should you decide to take part.

The aim of this study is to assess changes in quality of life following an 8-week Pulmonary Rehabilitation programme delivered to patients with lung cancer on an out-patient basis at SAMOC. Your participation in this study would help contribute a deeper insight on the beliefs about physical activity and the barriers and enablers faced by patients and healthcare professionals. Thus, this study shall help to contribute towards increasing awareness on the importance of facilitating access to patients with lung cancer to Pulmonary Rehabilitation and provide a better understanding on how to improve the clinical service and improve outcomes for lung cancer patients throughout their cancer care continuum.

Consultants, Doctors, Nurses, Physiotherapists, Occupational therapists, and Social workers are invited to participate. Healthcare professionals interested to participate in this study must be currently involved or have been involved in the care pathway of patients with lung cancer who are attending or have been attending Pulmonary Rehabilitation programme at SAMOC Physiotherapy Department.

Should you choose to take part in this study you shall be asked to schedule an appointment at any time and place at SAMOC convenient to you. A series of questions regarding your insights on oncology rehabilitation and your perceived impact on Pulmonary Rehabilitation on the patient's quality of life and the healthcare system shall be asked. The interview will take approximately 45 minutes.

Should you be interested in participating in this study you can contact me on the contact details below. An information sheet and consent form shall be provided prior to participation.

Please also note that, as a participant, you have the right under the General Data Protection Regulation (GDPR) and national legislation 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, all data collected will be erased.

Should you have any questions or concerns do not hesitate to contact me on 79276200 or by email bernardette.schembri.09@um.edu.mt or my supervisor Dr. Miriam Dalmas on 99824521 or via email miriam.dalmas@um.edu.mt or my co-supervisor Dr. Anabel Sciriha on 23401573 or via email anabel.sciriha@um.edu.mt.

Thank you for your time and consideration.

Sincerely,

Researcher	Research Supervisor	Research Co-Supervisor
Bernardette Bezzina	Dr. Miriam Dalmas	Dr. Anabel Sciriha

Appendix H: Healthcare Professionals Information Sheet

L-Università ta' Malta

Information Sheet – Healthcare professional

Dear Participant,

I, Bernardette Bezzina, am a Physiotherapist currently reading for a Master of Science in Public Health at the University of Malta. As part of my course requirements, I am conducting a research study entitled, "Evaluating the impact of Pulmonary Rehabilitation on the quality of life of patients diagnosed with lung cancer". The study is under the supervision of Dr. Miriam Dalmas and co-supervisor Dr. Anabel Sciriha.

The aim of this study is to assess changes in quality of life following an 8-week Pulmonary Rehabilitation programme delivered to patients with lung cancer on an out-patient basis at SAMOC. Your participation in this study would help us gain a deeper insight on the beliefs about physical activity and the barriers and enablers faced by patients and healthcare professionals. Thus, this study shall help to contribute towards increasing awareness on the importance of facilitating access to patients with lung cancer to Pulmonary Rehabilitation and provide a better understanding on how to improve the clinical service and improve outcomes for lung cancer patients throughout their cancer care continuum. Furthermore, all data collected from this research shall be used solely for the purpose of this study.

You are being invited to participate in an interview exploring your experiences of patients with lung cancer who have participated in Pulmonary Rehabilitation. The interview will take approximately 45mins and shall be held at a time and place most suitable for you. You are not obliged to answer all the questions and may withdraw from the study at any time without giving a reason. Furthermore, any data collected shall be erased. Unless you have any objections, this interview will be audio-recorded. 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 and presentations arising from this research. All data collected will be pseudonymised meaning that the transcripts will be assigned codes and that this data shall be stored securely in a

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locked cupboard. The list of codes shall be stored separately from the rest of the pseudonymised data and consent forms. The list of codes may only be accessed by the researcher. The academic supervisor and the examiner(s) shall only have access to the coded data for assessment purposes without personal identification in case of verification. The coded audio-recordings, and transcripts shall 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 separately from the list of codes.

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 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 list of codes with pseudonymised participants and consent forms shall be deleted by end of 2023.

Thank you for your time and consideration. Should you have any questions or concerns do not hesitate to contact me on 79276200 or by e-mail on bernardette.schembri.09@um.edu.mt or my supervisor Dr. Miriam Dalmas on 99824521 or by e-mail on miriam.dalmas@um.edu.mt or my co-supervisor Dr. Anabel Sciriha on 23401573 or by e-mail on anabel.sciriha@um.edu.mt .

Yours Sincerely,

Researcher	Research Co-Supervisor	Research Co-Supervisor
Bernardette Bezzina	Dr. Miriam Dalmas	Dr. Anabel Sciriha

Appendix I: Healthcare Professionals Consent Form

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HEALTHCARE PROFESSIONAL CONSENT FORM

I, _____ give my consent to participate in a research study entitled: "Evaluating the impact of Pulmonary Rehabilitation on the quality of life of patients diagnosed with lung cancer".

This study aims at assessing the changes in quality of life following an 8-week Pulmonary Rehabilitation programme delivered to patients with lung cancer on an out-patient basis at SAMOC.

The purpose and details of the study have been explained to me and any difficulties which I raised have been adequately clarified by the researcher Ms Bernardette Bezzina.

I give my consent to be interviewed and have the session audio recorded.

I am aware that data will be treated with strict confidentiality and will be processed in accordance with the General Data Protection Regulations (GDPR) of the Data Protection Act, Chapter 586 of the Laws of Malta. I have the right to request, in writing, a copy of the personal information held about me by the Researcher. I have the right to request correction or erasure of such data, in line with the Data Protection Act.

I understand that the list of codes shall be stored safely and separately from the rest of the pseudonymised data and consent forms in a locked cupboard at Ms Bernardette Bezzina until the duration of the study and publication of results. I am also aware that the list of codes used for pseudonymisation shall only be accessed by the researcher. Supervisors and examiners will only have access to the coded data in case clarification would be needed. I understand I am under no obligation to participate in this study and am doing so voluntarily. I may withdraw from the study at any time, without giving any reason.

In case of queries during the study I may contact the Researcher, Ms Bernardette Bezzina on 79276200 or by e-mail on bernardette.schembri.09@um.edu.mt.

Date: _____

Signature of participant: _____

Name of participant (in block letters): _____

Researcher	Research Supervisor	Research Co-Supervisor
Bernardette Bezzina	Dr. Miriam Dalmas	Dr. Anabel Sciriha

Appendix J: EORTC QLQ-C30 and EORTC QLQ-C29 questionnaires

ENGLISH

EORTC QLQ-C30 (version 3)

We are interested in some things about you and your health. Please answer all of the questions yourself by circling the number that best applies to you. There are no "right" or "wrong" answers. The information that you provide will remain strictly confidential.

Please fill in your initials: _____

Year of Birth _____

Today's date (Day, Month, Year): 31 _____

	Not at All	A Little	Quite a Bit	Very Much
1. Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	1	2	3	4
2. Do you have any trouble taking a long walk?	1	2	3	4
3. Do you have any trouble taking a short walk outside of the house?	1	2	3	4
4. Do you need to stay in bed or a chair during the day?	1	2	3	4
5. Do you need help with eating, dressing, washing yourself or using the toilet?	1	2	3	4

During the past week:	Not at All	A Little	Quite a Bit	Very Much
6. Were you limited in doing either your work or other daily activities?	1	2	3	4
7. Were you limited in pursuing your hobbies or other leisure time activities?	1	2	3	4
8. Were you short of breath?	1	2	3	4
9. Have you had pain?	1	2	3	4
10. Did you need to rest?	1	2	3	4
11. Have you had trouble sleeping?	1	2	3	4
12. Have you felt weak?	1	2	3	4
13. Have you lacked appetite?	1	2	3	4
14. Have you felt nauseated?	1	2	3	4
15. Have you vomited?	1	2	3	4
16. Have you been constipated?	1	2	3	4

Please go on to the next page

During the past week:	**Not at All**	**A Little**	**Quite a Bit**	**Very Much**
17. Have you had diarrhea?	1	2	3	4
18. Were you tired?	1	2	3	4
19. Did pain interfere with your daily activities?	1	2	3	4
20. Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	1	2	3	4
21. Did you feel tense?	1	2	3	4
22. Did you worry?	1	2	3	4
23. Did you feel irritable?	1	2	3	4
24. Did you feel depressed?	1	2	3	4
25. Have you had difficulty remembering things?	1	2	3	4
26. Has your physical condition or medical treatment interfered with your family life?	1	2	3	4
27. Has your physical condition or medical treatment interfered with your social activities?	1	2	3	4
28. Has your physical condition or medical treatment caused you financial difficulties?	1	2	3	4

For the following questions please circle the number between 1 and 7 that best applies to you

29. How would you rate your overall health during the past week?

1	2	3	4	5	6	7
Very poor						Excellent

30. How would you rate your overall quality of life during the past week?

1	2	3	4	5	6	7
Very poor						Excellent

MALTESE

EORTC QLQ-C30 (it-tielet verżjoni)

Aħna interessati fuq xi affarijiet dwarek u dwar saħħtek. Jekk jogħġbok wieġeb il-mistoqsijiet kollha *im* billi tagħmel ċirku madwar in-numru li l-aktar japplika għalik. M'hemmx tweġiba "tajba" jew "ħażina". L-informazzjoni li tagħtina tinżamm strettament kunfidenzjali.

Jekk jogħġbok imla' l-ewwel ittra t'ismek u kunjomok. ⌊_⌊_⌊_⌊_⌋
Sena ta' twelid ⌊_⌊_⌊_⌋
Id-data tal-lum (Jum, Xahar, Sena). 31 ⌊_⌊_⌋_⌊_⌊_⌋

		L-Anqas xejn	Ftit	Mhux ħażin	Ħafna
1.	Issibha xejn diffiċli biex tagħmel attivitajiet ta' strapazz, bħal ngħidu aħna meta ġġorr xirja tqila jew bagoll?	1	2	3	4
2.	Issibha xejn diffiċli biex timxi mixja twila?	1	2	3	4
3.	Issibha xejn diffiċli biex timxi mixja qasira barra mid-dar?	1	2	3	4
4.	Matul il- ġurnata tħoss il-bżonn li tistrieħ, per eżempju, fis-sodda jew fuq siġġu?	1	2	3	4
5.	Tħoss il-bżonn li xi ħadd igħinek biex tiekol, tilbes, tinħasel jew tuża t-toilet?	1	2	3	4
	Matul din l-aħħar ġimgħa:	**L-Anqas xejn**	**Ftit**	**Mhux ħażin**	**Ħafna**
6.	Ħassejtek limitat biex tagħmel ix-xogħol tiegħek jew attivitajiet oħra ta' kuljum?	1	2	3	4
7.	Ħassejtek limitat biex tagħmel il-passatempi tiegħek jew attivitajiet oħra ta' mogħdija ta' żmien?	1	2	3	4
8.	Kont nifsek maqtugħ?	1	2	3	4
9.	Kont muġugħ?	1	2	3	4
10.	Kellek bżonn tistrieħ?	1	2	3	4
11.	Kellek problemi biex torqod?	1	2	3	4
12.	Ħassejtek dgħajjef?	1	2	3	4
13.	Naqaslek l-aptit?	1	2	3	4
14.	Ħassejtek imdardar?	1	2	3	4
15.	Irremetejt?	1	2	3	4
16.	Kont stitiku (sibtha diffiċli biex tipporga)?	1	2	3	4

Jekk jogħġbok kompli fil-paġna ta' wara

Matul din l-aħħar ġimgħa:

		L-Anqas xejn	Ftit	Mhux ħażin	Ħafna
17.	Kellek dijarea?	1	2	3	4
18.	Kont għajjien?	1	2	3	4
19.	L-uġigħ telfek fl-attivitajiet tiegħek ta' kuljum?	1	2	3	4
20.	Sibt diffikulta` biex tikkonċentra fuq affarijiet bħal meta taqra l-gazzetta jew tara t-televixin?	1	2	3	4
21.	Ħassejtek nervuż (kellek tensjoni)?	1	2	3	4
22.	Kont inkwetat?	1	2	3	4
23.	Ħassejtek irritabli (jitlagħlek malajr)?	1	2	3	4
24.	Ħassejtek imdejjaq (qalbek sewda)?	1	2	3	4
25.	Sibtha diffiċli biex tiftakar l-affarijiet?	1	2	3	4
26.	Taħseb li l-kundizzjoni fiżika tiegħek jew il-kura medika tiegħek telfitek fil-ħajja tiegħek tal-familja?	1	2	3	4
27.	Taħseb li l-kundizzjoni fiżika tiegħek jew il-kura medika tiegħek telfitek fl-attivitajiet soċjali tiegħek?	1	2	3	4
28.	Taħseb li l-kundizzjoni fiżika tiegħek jew il-kura medika tiegħek tagħtek diffikultajiet finanzarji?	1	2	3	4

Għall-mistoqsijiet li ġejjin, jekk jogħġbok agħmel ċirku madwar numru minn 1 sa 7 li l-aktar jgħodd għalik:

29. Xi grad tagħti lil saħħtek inġenerali matul din l-aħħar ġimgħa?

1 2 3 4 5 6 7

Ħażina ħafna Eċċellenti

30. Xi grad tagħti lill-kwalita` tal-ħajja tiegħek inġenerali matul din l-aħħar ġimgħa?

1 2 3 4 5 6 7

Ħażina ħafna Eċċellenti

ENGLISH

EORTC QLQ-LC29

Patients sometimes report that they have the following symptoms or problems. Please indicate the extent to which you have experienced these symptoms or problems during the past week. Please answer by circling the number that best applies to you.

During the past week:		**Not at All**	**A Little**	**Quite a Bit**	**Very Much**
31.	Have you coughed?	1	2	3	4
32.	Have you coughed up blood?	1	2	3	4
33.	Have you been short of breath when you rested?	1	2	3	4
34.	Have you been short of breath when you walked?	1	2	3	4
35.	Have you been short of breath when you climbed stairs?	1	2	3	4
36.	Have you had a sore mouth or tongue?	1	2	3	4
37.	Have you had problems swallowing?	1	2	3	4
38.	Have you had tingling hands or feet?	1	2	3	4
39.	Have you had hair loss?	1	2	3	4
40.	Have you had pain in your chest?	1	2	3	4
41.	Have you had pain in your arm or shoulder?	1	2	3	4
42.	Have you had pain in other parts of your body?	1	2	3	4
43.	Have you had allergic reactions?	1	2	3	4
44.	Have you had burning or sore eyes?	1	2	3	4
45.	Have you been dizzy?	1	2	3	4
46.	Have you had splitting fingernails or toenails?	1	2	3	4
47.	Have you had skin problems (e.g. itchy, dry)?	1	2	3	4
48.	Have you had problems speaking?	1	2	3	4

Please go on to the next page

ENGLISH

During the past week:	Not at All	A Little	Quite a Bit	Very Much
49. Have you been afraid of tumor progression?	1	2	3	4
50. Have you had thin or lifeless hair as a result of your disease or treatment?	1	2	3	4
51. Have you worried about your health in the future?	1	2	3	4
52. Have you had a dry cough?	1	2	3	4
53. Have you experienced a decrease in your physical capabilities?	1	2	3	4
54. Has weight loss been a problem for you?	1	2	3	4
Please answer the following questions only if you had surgery for lung cancer:	**Not at All**	**A Little**	**Quite a Bit**	**Very Much**
55. Have you had pain in the area of surgery?	1	2	3	4
56. Has the area of your wound been oversensitive?	1	2	3	4
57. Have you been restricted in your performance due to the extent of surgery?	1	2	3	4
58. Have you had any difficulty using your arm or shoulder on the side of the chest operation?	1	2	3	4
59. Has your scar pain interfered with your daily activities?	1	2	3	4

Appendix K: Healthcare Professionals Interview Schedule

L-Università ta' Malta

Structured interview questions for healthcare professionals

1. How do you define rehabilitation for people with cancer?
2. Can you explain what Pulmonary Rehabilitation (PR) means?
3. What is your understanding on the role of PR in patients with lung cancer?
4. Can you outline any benefits or harm associated with PR in patients with lung cancer?
5. a. Do you feel that PR has an impact on the patient quality of life?
   b. Why?
6. How important is it that these patients are offered PR in their care pathway?
7. a. Do you think that patient's participation in PR can have an influence on other healthcare services? Eg: Referral to other healthcare providers or services, unnecessary hospital admissions.

   b. How?
8. When do you think is the best time to introduce or encourage patients to participate in PR?
9. What do you think are the barriers faced by patients with lung cancer to participate in PR? If any.
10. What do you think are the barriers faced by healthcare providers to recommend PR? If any.
11. What do you think would help in assisting patients becoming more engaged in PR?
12. What do you think are the most important elements of rehabilitation for patients with lung cancer?

Appendix L: Author's Permission to use EORTC questionnaires

L-Università ta' Malta

Bernardette Bezzina <bernardette.schembri.09@um.edu.mt>

Your request for an EORTC-questionnaire Request ID : 81855

1 message

no-reply@eortc.be <no-reply@eortc.be> 22 March 2022 at 09:04
To: bernardette.schembri.09@um.edu.mt

Dear Bernardette Bezzina,

Thank you for registering on the EORTC Quality of Life Group website.

Your registration to obtain permission to use our tools has been approved. During the registration process you agreed to our terms and conditions regarding the academic use of our questionnaires. You can review the terms and conditions here.

Please find below the links to the requested tools:

QLQ-C30 Core Questionnaire - Maltese
QLQ-C30 Core Questionnaire - English
Lung Module (LC29) - English

Scoring Manuals:

C30 Scoring Manual
C30 Scoring Manual
LC29 Scoring Manual

EORTC

http://www.eortc.org

http://qol.eortc.org

NOTE:
This email was automatically generated. Since this email is an automatic notification, we are unable to receive replies. Please do not respond to this email address.

http://www.eortc.be/signatures/signature_stats_525x166_2018.jpg

Disclaimer |

Appendix M: Ethics Approval

L-Università ta' Malta

Faculty of Medicine & Surgery
University of Malta
Msida MSD 2080, Malta

Tel: +356 2340 1879/1891/1167
umms@um.edu.mt

www.um.edu.mt/ms

Ref No: MED-2022-00163

2 November 2022

Ms Bernardette Bezzina
53, SPRINGFIELD FLAT 4
TRIQ IL-QANPIENA
B'KARA
BKR4114

With reference to your application submitted to the Faculty Research Ethics Committee in connection with your research entitled:

Evaluating the impact of Pulmonary Rehabilitation on the quality of life of patients diagnosed with Lung Cancer

The Faculty Research Ethics Committee is granting ethical approval for the above-mentioned application.

Professor Anthony Serracino Inglott
Chair
Faculty Research Ethics Committee

Appendix N: Permission from the Data Protection Officer at MDH, the Chief Executive Officer at MDH, the Clinical Chairperson and Administrator at SAMOC

Data Protection Approval

20/06/2022, 10:59 University of Malta Mail - FW: Data Protection Approval Form - Bernardette Bezzina between Data Protection Approval For...

L-Università ta' Malta

Bernardette Bezzina <bernardette.schembri.09@um.edu.mt>

FW: Data Protection Approval Form - Bernardette Bezzina between Data Protection Approval Form and Bernardette Bezzina is Signed and Filed!

2 messages

Data Protection Approval Form at Health-MDH <dpaform.mdh@gov.mt> 17 June 2022 at 10:23
To: Bernardette Bezzina <bernardette.schembri.09@um.edu.mt>

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

SPTAR MATER DEI

T +356 25455334

E graziella.aquilina@gov.mt

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

MDH CEO Approval

L-Università ta' Malta

Bernardette Bezzina <bernardette.schembri.09@um.edu.mt>

Research study: Request for approval

CEO at Health-MDH <ceo.mdh@gov.mt> 16 June 2022 at 08:37
To: Bernardette Bezzina <bernardette.schembri.09@um.edu.mt>

Dear Ms Bezzina,

Kindly note that approval has been given by Ms Celia Falzon for you to conduct this study in line with applicable hospital protocols

Regards

Carmen Farrugia
Personal Assistant To CEO

SPTAR MATER DEI

T +356 +356 25454102

E carmen.farrugia@gov.mt

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

SAMOC Clinical Chairperson and Administration Manager Approval

SIR ANTHONY MAMO ONCOLOGY CENTRE

FORM :	**Oncology Proposal/Approval Audit/ Research purposes**
Document Code: ONCO-GeFO-P/A-001. Ver.01 001.Ver.01	Reference SOP : ONCO-Ge-PD.AP--

PROJECT TITLE: Evaluating the impact of Pulmonary Rehabilitation on the quality of life of patients diagnosed with lung cancer.

Name & Surname (Researcher/ Student): Bernardette Bezzina

Email address: bernardette.schembri.09@um.edu.mt

Tutor's name & Surname: Supervisor: Dr. Miriam Dalmas; Co-Supervisor: Dr. Anabel Sciriha

Proposal

Introduction:

Lung cancer is the most diagnosed cancer and is the leading cause of mortality worldwide (Zhang et al., 2021). It is a major challenge to global health care, making it an important public health issue (Fitzmaurice et al., 2019). Lung cancer patients experience an array of symptoms that may include dyspnoea, fatigue, cough, pain, and cancer cachexia. All these symptoms can negatively influence the patients' physical function and impair their activities of daily living (ADLs) (Granger, 2016). Patients must not only learn how to cope with the symptoms of the disease, but also with the side-effects of the treatment. All treatment modalities including chemotherapy, radiotherapy and/or surgery may result in reduced quality of life, limit lung function and contribute to psychological issues and impairments (Lehto, 2016). Physical inactivity is common and prevalent in patients with lung cancer especially in advanced stages (Wang et al., 2016).

Pulmonary Rehabilitation (PR) is a multidisciplinary intervention that is tailored to the individual patients' needs. It integrates aerobic exercises and strength training, and instils behavioural changes through an educational component, including nutritional support, psychosocial support, smoking cessation, and coping skills to help manage the disease. Evidence demonstrate that physical activity should be considered as a routine clinical care in lung cancer patients as it facilitates return to activities of daily living, symptom management, offers support and access to services. Despite the growing evidence, PR is not always being translated into clinical practice.

SIR ANTHONY MAMO ONCOLOGY CENTRE

FORM :	**Oncology Proposal/Approval Audit/ Research purposes**
Document Code: ONCO-GeFO-P/A-001. Ver.01 001.Ver.01	Reference SOP : ONCO-Ge-PD.AP--

Aim/s:

To assess changes in quality of life following an 8-week Pulmonary Rehabilitation programme delivered to patients with lung cancer on an out-patient basis at Sir Anthony Mamo Oncology Centre (SAMOC).

- To explore whether giving the patient the right tools to cope with the disease has an influence on the utilization of healthcare services
- To evaluate the impact of PR on the patients' physical well-being
- To explore the barriers and facilitators faced by patients towards PR

Research question: What is the impact on the health system and on the Quality of Life of patients when PR is included in the disease management pathway of lung cancer?

Method (include the sample size)

A mixed method, qualitative research design shall be adopted in this study to gain in-depth understanding on the impact on patients with lung cancer receiving PR at SAMOC and on the healthcare services that they will need to use. Study will be conducted over a period of 3-4 months. Data shall be collected from healthcare professionals involved/who have been involved in the care pathway of patients with lung cancer and from patients receiving PR. The research instruments that shall be utilized are structured interviews and questionnaires.

European Organization for Research and Treatment in Cancer-Quality of Life Questionnaire-EORTC QLQ-C30 is the patient reported outcome measure (PROM) research tool that shall be used to assess aspects of quality of life in cancer patients and EORTC QLQ-C29 shall also be used as an adjunct to the previous questionnaire to offer a more focused investigation on lung cancer. The PROM shall be conducted by the researcher before and after the 8-week programme at SAMOC. The intervention shall take approximately 10-15 minutes and patient shall be encountered only twice during the study. An intermediary shall be engaged to recruit the patients. The intermediary shall be another physiotherapist working at the physiotherapy department SAMOC.

Structured interviews shall be also used to provide the researcher with further insights on the impact of PR from the healthcare professional perspective. Structured interviews shall

be used to ensure that same data from each respondent in the research is collected. Healthcare professionals involved/have been involved in the patient cancer care shall be invited to participate in this arm of the study. Healthcare professionals will be invited by email through their respective heads and contact details will be made available should they wish to opt-in in the study. Interviews will be audio-recorded and transcribed verbatim followed by a thematic analysis. The structured interviews will be conducted at SAMOC.

Sample size: 10-20 patients and 5-10 healthcare professionals

Age: 18+

Sex: Male and female

Patient inclusion criteria:

- Patients referred to SAMOC for continuum of care
- Patients with primary lung cancer diagnosis
- Patients referred for Pulmonary Rehabilitation by nurse navigator and/or medical team
- Patients that are already attending physiotherapy department and are assessed to be ideal candidates for PR

Patient exclusion criteria:

- Patients that are not referred to SAMOC
- Patients that are unaware of their diagnosis
- Patients with other diagnosis not related to the lung or where the lung is not affected
- Patients who do not manage to complete the PR programme (for any reason)

Healthcare professional inclusion criteria:

- Participant must be/have been involved in the care of patients who are/have attended PR
- Participants must have reviewed patient more than once
- Participants may include consultants, doctors, nurses, physiotherapists, occupational therapists, psychologists, and social workers working/have worked at SAMOC

SIR ANTHONY MAMO ONCOLOGY CENTRE

FORM :	**Oncology Proposal/Approval Audit/ Research purposes**
Document Code: ONCO-GeFO-P/A-001. Ver.01	Reference SOP : ONCO-Ge-PD.AP--001.Ver.01

Healthcare professional exclusion criteria:

- Participants who had only one encounter with patients who are/were enrolled in the PR
- Participants who are involved indirectly in the patient care

Participants will be given an information sheet and consent form beforehand. Participation in this study will be completely on a voluntary basis. Participants shall be informed that confidentiality will be maintained throughout the study and no identification elements will be revealed in any publications arising from this study. All the participants shall be informed that they have the right under the General Data Protection Regulation (GDPR) and national legislation to access, rectify and where applicable ask for the data to be erased. Once the study is completed and the results are published, all data collected will be erased. Ethical approval shall be sought from the University of Malta Research Ethics Committee prior to commencement of the study.

Clinical Consultant Oncologist/s:
Name and Surname (in block letters) and Signature

_____

_____

_____

_____

Heads of:
(Name, Surname and Section (in block letters) and Signature)

Radiotherapy Department: *(if applicable)*

Radiography

_____

SIR ANTHONY MAMO ONCOLOGY CENTRE

FORM :	**Oncology Proposal/Approval Audit/ Research purposes**
Document Code: ONCO-GeFO-P/A-001. Ver.01 001.Ver.01	Reference SOP : ONCO-Ge-PD.AP--

Medical Physics

Nursing

Other SAMOC Departments/ Wards:

Clinical Chairperson (Haematology - Oncology):
Name and Surname (in block letters) and Signature:

Dr Nick Refalo
Chairman & Consultant Oncologist
Sir Anthony Mamo Oncology Centre
Reg No: 2662

14 VI 22

Quality Assurance Manager:
Name and Surname (in block letters) and Signature:

Donna Micallef
HR & Administration Manag
SAMOC/SPBH

An approval is granted to carry out the study/audit at any SAMOC Department. Patient information can be accessible only by complying with the following data protection principles, which are set out in the General Data Protection Regulation 2016. In summary these state that patient's data shall:

- ***Be obtained and processed fairly and lawfully and shall not be processed unless certain conditions are met. Therefore patient's information (including scans) should be made anonymous by an appointed radiotherapy staff (from the Head of section)***
- ***Be obtained for a specified and lawful purpose and shall not be processed in any manner incompatible with that purpose.***
- ***Be adequate, relevant and not excessive for those purposes (in the case of a study or audit).***
- ***Be accurate and kept up to date.***
- ***Not be kept longer than is necessary for that purpose***
- ***Be processed in accordance with the data subject's rights.***
- ***Be kept safe from unauthorised access, accidental loss or destruction.***
- ***Not be transferred to any third party unlawfully.***

Appendix O: Permission from Head of Departments of Healthcare Professionals

Lead of Physiotherapy Services

Massalha Victoria at Rehabilitation Services-Health <victoria.massalha@gov.mt> 3 June 2022 at 10:34
To: Bernardette Bezzina <bernardette.schembri.09@um.edu.mt>

Dear Bernadette

Good morning

You may proceed with your studies once all the permissions are in place.

I look forward to receiving your findings and recommendations.

Regards

Victoria Massalha

Lead Professional Management

Physiotherapy Services

t +356 23441318; + 356 25456609; Pager: 79847322

e victoria.massalha@gov.mt
https://health.gov.mt | www.publicservice.gov.mt | fb.com/servizzpubbliku

MINISTRY FOR HEALTH
MALTA

Head of Occupational Department SAMOC

Meilak Maria at Health-SAMOC <maria.meilak@gov.mt> 10 June 2022 at 11:08
To: Bernardette Bezzina <bernardette.schembri.09@um.edu.mt>

Dear Ms Bezzina

Good morning and thank you for the correspondence. Permission is granted for Occupational Therapists working at SAMOC to participate in your study.

Thanks and regards

Maria

Maria Meilak
Executive Allied Health Practitioner

Occupational Therapist

[Quoted text hidden]
[Quoted text hidden]

Director of Nurses

Damato Carmela at Health-MDH <carmela.damato@gov.mt> 3 June 2022 at 15:40
To: Bernardette Bezzina <bernardette.schembri.09@um.edu.mt>

Dear Ms. Bezzina

You have my approval and I wish you the very best for your study.

Regards

Ms. Carmela D'Amato

Director Nursing

Appendix P: Foundation for Social Welfare Services Approval

Foundation for Social Welfare Services
212, Cannon Road,
Santa Venera SVR 9034

8th November 2022

53, Springfield, Flat 4
Triq il-Qanpiena
Swatar, Birkirkara

To whom it may concern

Bernardette Bezzina's request to conduct research within the services of the Foundation for Social Welfare Services has been reviewed. The research aims to explore Evaluating the impact of Pulmonary Rehabilitation on the quality of life of patients diagnosed with lung cancer.

After reviewing this request, the Research Office has given approval for the researcher to conduct an interview.

Although the Research Office has approved the research, the service providers and participants still retain the right to refuse any research request.

It is very important for the applicant to keep in mind that the views expressed by research participants during interviews might not necessarily reflect the FSWS' official position on the topic in question, and this needs to be made very clear in the published study.

Regards,

Ronald Balzan

Ronald Balzan
Senior Research Executive

Section to be completed by FSWS Research Review Panel ONLY

We have examined the above proposal and advise

Approval **Conditional Acceptance** **Refusal**

For the following reason/s if any:
Full approval is being given for the applicant to conduct a one-to-one interview with **1 - 2 social workers** working within Sir Anthony Mamo Oncology Centre (SAMOC) who are/have been involved in the care of patients who are attending/have attended Pulmonary Rehabilitation at the Physiotherapy Department at SAMOC.

Ronald Balzan

Signature Date: 8th November 2022

Note: If conditionally accepted, the recommended changes must be confirmed with the Research Office before the research can proceed.

Section to be completed by the Research Office for Conditionally Accepted Research ONLY.

The recommended changes stipulated by the Conditional Acceptance have not been implemented and these changes have not been confirmed by the Research Office. As a result of these changes the research is now **Refused**. . ☐

The recommended changes stipulated by the Conditional Acceptance have been implemented and these changes have been confirmed by the Research Office. As a result of these changes the research is now **Approved**. . ☐

Signature Date

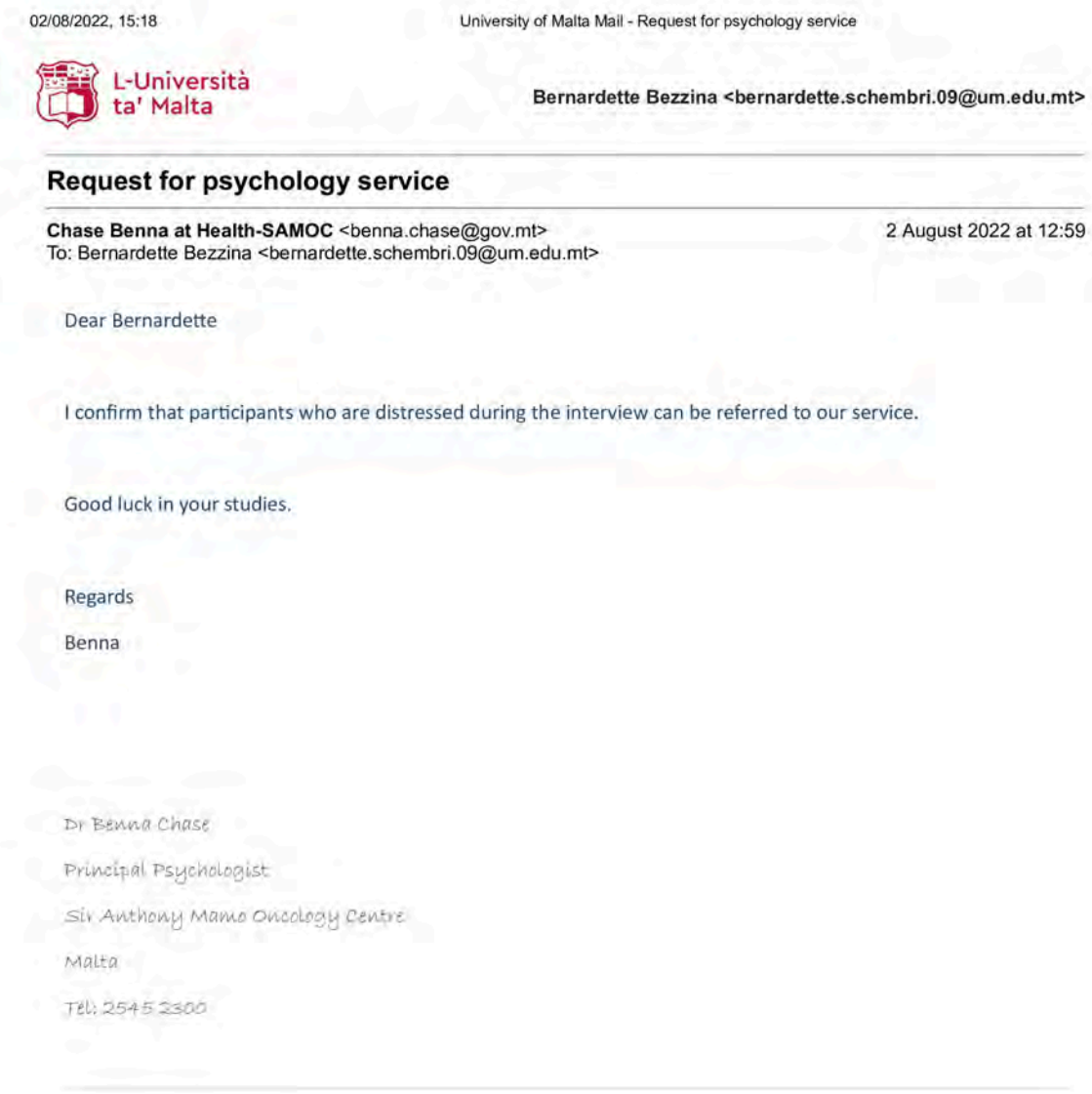
If Accepted/Conditionally Accepted to whom the study will be directed:

The Unit/s:
SAMOC Social Work Service

The person/s referred	Contact details
Ms Mary Anne Casha – Service Area Leader; SAMOC Social Work Service	mary-anne.casha@gov.mt

Foundation for Social Welfare Services
212, Cannon Road, Santa Venera SVR 9034
Tel: 22588000; Fax: 22588939

Appendix Q: Approval for Psychological Support Service



02/08/2022, 15:18 University of Malta Mail - Request for psychology service

L-Università ta' Malta

Bernardette Bezzina <bernardette.schembri.09@um.edu.mt>

Request for psychology service

Chase Benna at Health-SAMOC <benna.chase@gov.mt> 2 August 2022 at 12:59
To: Bernardette Bezzina <bernardette.schembri.09@um.edu.mt>

Dear Bernardette

I confirm that participants who are distressed during the interview can be referred to our service.

Good luck in your studies.

Regards

Benna

Dr Benna Chase

Principal Psychologist

Sir Anthony Mamo Oncology Centre

Malta

Tel: 2545 2300

Appendix R: Shapiro-Wilk normality test

EORTC QLQ-C30 Questionnaire: Raw Mean Scores

		Statistics	df	P-value
Global Health Status/ QoL				
Global Health Status/ QoL	Pre-test	.964	14	.791
	Post-test	.962	14	.752
Functional Scales				
Physical Functioning	Pre-test	.948	14	.529
	Post-test	.935	14	.354
Role Functioning	Pre-test	.814	14	.007
	Post-test	.741	14	.001
Emotional Functioning	Pre-test	.932	14	.324
	Post-test	.933	14	.334
Cognitive Functioning	Pre-test	.719	14	.001
	Post-test	.611	14	.000
Social Functioning	Pre-test	.789	14	.004
	Post-test	.819	14	.009
Symptoms Scales/Items				
Fatigue	Pre-test	.956	14	.655
	Post-test	.843	14	.018
Nausea and Vomiting	Pre-test	.627	14	.000
	Post-test	.636	14	.000
Pain	Pre-test	.943	14	.464
	Post- test	.871	14	.044
Dyspnoea	Pre-test	.882	14	.063
	Post- test	.750	14	.001
Insomnia	Pre-test	.819	14	.009
	Post- test	.798	14	.005
Appetite Loss	Pre-test	.447	14	.000
	Post-test	.411	14	.000
Constipation	Pre-test	.512	14	.000
	Post-test	.540	14	.000
Diarrhoea	Pre-test	.428	14	.000
	Post-test	.297	14	.000
Financial Difficulties	Pre-test	.696	14	.000
	Post-test	.631	14	.000

EORTC QLQ-C30 Questionnaire: Standardised Scores

		Statistic	df	P-value
Global Health Status/ QoL				
Global Health Status/ QoL	Pre-test	.964	14	.792
	Post-test	.962	14	.753
Functional Scales				
Physical Functioning	Pre-test	.948	14	.524
	Post-test	.934	14	.352
Role Functioning	Pre-test	.814	14	.007
	Post-test	.741	14	.001
Emotional Functioning	Pre-test	.932	14	.325
	Post-test	.898	14	.104
Cognitive Functioning	Pre-test	.719	14	<.001
	Post-test	.611	14	<.001
Social Functioning	Pre-test	.848	14	.021
	Post-test	.819	14	.009
Symptoms Scales/ Items				
Fatigue	Pre-test	.956	14	.653
	Post-test	.843	14	.018
Nausea and Vomiting	Pre-test	.627	14	<.001
	Post-test	.636	14	<.001
Pain	Pre-test	.924	14	.248
	Post-test	.871	14	.043
Dyspnoea	Pre-test	.882	14	.063
	Post-test	.750	14	.001
Insomnia	Pre-test	.819	14	.009
	Post-test	.798	14	.005
Appetite Loss	Pre-test	.447	14	<.001
	Post-test	.411	14	<.001
Constipation	Pre-test	.512	14	<.001
	Post-test	.540	14	<.001
Diarrhoea	Pre-test	.428	14	<.001
	Post-test	.297	14	<.001
Financial Difficulties	Pre-test	.696	14	<.001
	Post-test	.631	14	<.001

EORTC QLQ-LC29 Questionnaire: Raw Mean Scores

		Statistic	df	P-value.
Symptoms Scales/ Items				
Coughing	Pre-test	.900	14	.111
	Post-test	.881	14	.060
Shortness of Breath	Pre-test	.940	14	.418
	Post-test	.949	14	.539
Side Effects of Treatment	Pre-test	.906	14	.139
	Post-test	.826	14	.011
Fear of Progression	Pre-test	.885	14	.069
	Post-test	.908	14	.150
Coughing blood/ Haemoptysis	Pre-test	.428	14	<.001
	Post-test	.297	14	<.001
Pain in chest	Pre-test	.773	14	.002
	Post-test	.646	14	<.001
Pain in arm or shoulder	Pre-test	.836	14	.014
	Post-test	.627	14	<.001
Pain in other parts of the body	Pre-test	.882	14	.063
	Post-test	.796	14	.005
Weight Loss	Pre-test	.685	14	<.001
	Post-test	.611	14	<.001

EORTC QLQ-LC29 Questionnaire: Standardised Scores

		Statistic	df	P-value
Symptom Scales/ Items				
Coughing	Pre-test	.900	14	.112
	Post-test	.881	14	.060
Shortness of Breath	Pre-test	.940	14	.418
	Post-test	.949	14	.541
Side Effects of Treatment	Pre-test	.906	14	.137
	Post-test	.826	14	.011
Fear of Progression	Pre-test	.885	14	.069
	Post-test	.909	14	.150
Coughing blood/ Haemoptysis	Pre-test	.428	14	<.001
	Post-test	.297	14	<.001
Pain in chest	Pre-test	.773	14	.002
	Post-test	.646	14	<.001
Pain in arm or shoulder	Pre-test	.836	14	.014
	Post-test	.627	14	<.001
Pain in other parts of the body	Pre-test	.882	14	.063
	Post-test	.811	14	.007
Weight Loss	Pre-test	.685	14	<.001
	Post-test	.611	14	<.001