Feasibility and preliminary efficacy of a combined therapeutic yoga and resistance exercise intervention for individuals with lung cancer and their caregivers

By

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ABSTRACT

Purpose: The aim of the study was to determine the feasibility of a combined therapeutic yoga and resistance exercise intervention for individuals with lung cancer and their caregivers

Methods: A pilot feasibility study measuring recruitment rate, completion rate, intervention adherence and adverse events was conducted from May 2017 to December 2017. Participants and their caregivers were recruited from Cross Cancer Institute outpatient clinics and through self-referral. An 8-week intervention was conducted comprising therapeutic yoga and resistance exercise. The primary outcome for individuals with lung cancer was dyspnea. Secondary outcomes included quality of life, fatigue, chest expansion, muscular strength, pulmonary function and shoulder range of motion. The outcomes for caregivers were quality of life, fatigue and muscle strength. Post-study interviews were conducted to inform a future study.

Results: The findings support feasibility with high recruitment and completion rates of 85% and 78% respectively. Adherence to the yoga and resistance intervention was 87%. There were no adverse events during testing or intervention sessions. For individuals with lung cancer, a significant difference was found from baseline to post-intervention in outcomes of dyspnea ($p=0.01$), fatigue ($p=0.02$), muscular strength ($p<0.05$) and chest expansion at xiphisternum ($p=0.03$). For caregivers, a significant difference was found from baseline to post-intervention in symptoms of fatigue ($p=0.04$).

Conclusion: A combined low to moderate intensity yoga and resistance exercise intervention is feasible and shows preliminary benefit for individuals with lung cancer and their caregivers.

PREFACE

This thesis is an original work by Shreya Ashesh Rewar and Co-Authored by Dr. Margaret L. McNeely, Dr. Jill Turner, Dr. Mark Hall and Dr. Anil Abraham Joy.

DEDICATION

This thesis is the progeny of my great-grandmother's ambition and dream to see my grandfather becoming a cancer researcher. I am privileged to attempt to fulfill my great-grandmother's dream.

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DEFINITIONS AND ABBREVIATIONS

1. **Lung Cancer:** The abnormal, uncontrolled division of a mutated cell in the body that can result in a malignant tumor, and has the potential to spread to surrounding tissue and metastasize to other parts of the body. If the cell mutation begins in the tissues of the lung, it is known as primary lung cancer, and if it is due to metastases from another primary cancer (in another part of the body), it is known as secondary or metastatic lung cancer.[1]
2. **Cancer-related fatigue (CRF)**: CRF is a chronic self-perceived feeling of weakness, loss of energy, tiredness, exhaustion, heaviness, which may be physical, emotional or mental. CRF does not consistently improve with sleep or rest. CRF may result from cancer treatment or the cancer itself.[2]
3. **Dyspnea:** A subjective feeling of breathlessness or shortness of breath. It can also be described as an inability to get enough air into the lungs; a feeling of suffocation; or uncomfortable breathing.[2]
4. **Caregiver:** A caregiver is defined as a person who had either provided physical or emotional help, care and support to the person with cancer. A caregiver could be a spouse, a child, a family member or a friend.[2]
5. **Intervention:**
    - 5.1. Therapeutic Yoga (Yoga): For the proposed study, yoga is defined as a practice of āsanas prāṇāyāma and dhyāna that are modified to address and/ or accommodate impairments and functional limitations of participants enrolled in the study.
    - 5.2. Āsanas: The postures or āsanas are the third limb of the eight-limbed path of yoga.[3]
    - 5.3. Prāṇāyāma: It means breath control or extension of breath. Prāṇa is defined as breath, respiration, life, vitality, wind, energy or strength. Āyāma is defined as

length, expansion, stretching or restraint. It is the fourth limb of eight-limbed path of yoga.[3]

5.4. Dhyāna: Meditation or uninterrupted flow of concentration.[3]

5.5. Resistance exercise (RE): The form of exercise which uses external resistance such as free weights, bands, tubes and machines or body weight to strengthen various muscles of the body.[4]

6. **Outcome measures:**

6.1. Eligibility rate: The number of individuals eligible divided by the number of individuals approached for the study

6.2. Recruitment rate: The number of individuals recruited to the study divided by the number of individuals eligible for the study

6.3. Completion rate: The percentage of individuals completing the 8-week intervention as well as the baseline and post-intervention outcomes.

6.4. Adherence rate: The total number of sessions attended divided by the total number of sessions scheduled for therapeutic yoga and RE. The total number of participants submitted a completed home exercise diary.

6.5. D-12: Dyspnea 12 Questionnaire

6.6. FACT-F: Functional Assessment of Cancer Therapy-General Scale plus the Fatigue Subscale.

6.7. CarGOQoL: Caregiver Oncology Quality of Life Questionnaire

6.8. 1RM: One repetition maximum

6.9. FEV_1: Forced expiratory volume in 1 second is the amount of air a person can exhale during the first second of a forced expiration

6.10. FVC: Forced vital capacity is the total amount of air exhaled during the pulmonary function test

7. **Study Acronym:**

ASSURE: Yog*a* and Re*s*i*s*tance Exercise for Individuals with L*u*ng Cance*r* and their Ca*r*egivers

CHAPTER 1: INTRODUCTION

According to the 2017 Canadian Cancer Statistics, 50% of the newly developed cancers include cancers of the lung and bronchus, breast, colorectal region and prostate.[5] Lung cancer is the second most common cancer to be diagnosed in both males and females in 2017, each accounting for 14%. It is also the most common cancer for individuals of 70+ years of age and the main cause of cancer-related death, contributing to 26% of deaths. Reductions in smoking rates among males since the 1980s has resulted in a lower incidence of lung cancer, and subsequent decline in the lung cancer-specific mortality rate for males.[5] Recent advances in cancer treatment have also improved 5-year survival and reduced overall mortality rates.

Lung cancer leads to debilitating symptoms from both cancer itself and side effects of the treatment. The symptoms experienced may be both physical and psychological.[6] A recent qualitative study summarized the physical symptoms commonly reported by individuals with lung cancer. These symptoms included pain, breathlessness, cough, fatigue, nausea, vomiting, loss of appetite, changes in sensation of taste, indigestion, constipation, numbness, sweating, and weight change. A range of psychological problems were also reported including depression, anxiety, impaired concentration, and sleep disturbance.[7]

Dyspnea/breathlessness and fatigue are two of the most common symptoms experienced by individuals with advanced lung cancer.[7–10] Dyspnea is a self-reported subjective feeling of breathlessness or shortness of breath that affects the individual's function and quality of life (QoL).[9] Breathlessness is reported to occur as brief episodes resulting from, or exacerbated by, physical activity or extremes of temperature.[7] The fear of worsening dyspnea with movement and physical activity is a primary reason for the individual with lung cancer's unwillingness to participate in exercise.[11–14] Although the impact of dyspnea cannot be fully elucidated, individuals

of all stages of lung cancer suffer distress due to its interference with physical and psychological function.[15] Dyspnea has been generally unexplored in the rehabilitation setting despite being reported as a primary concern among survivors of lung cancer.[16]

Another major symptom observed in individuals is cancer-related fatigue (CRF). CRF is identified as a feeling of weakness, lack of energy or exhaustion that does not consistently improve with rest or sleep.[2,17] A recent meta-analysis, including 245 articles demonstrated the effectiveness of various interventions to manage CRF; however, studies were predominantly focussed on women with breast cancer and in mixed survivor groups.[18] Interventions such as relaxation, massage, cognitive behavioural therapy (CBT) combined with physical activity, aerobic and resistance training (alone or combined), yoga, tai-chi, aerobic exercise and interval training have all been shown to help reduce CRF.[18,19] The study findings highlight the benefits of yoga and resistance exercise in reducing CRF during cancer treatment.[18] Unfortunately, to date, the benefits of combined yoga and resistance exercise on CRF specifically within the lung cancer population is largely unexplored.

The impact of dyspnea and fatigue together can be profound. Molassiotis et al. performed a qualitative study and found that individuals with lung cancer reported persistent coughing as a trigger to dyspnea and that dyspnea further led to symptoms of fatigue.[7] Moreover, fatigue is worsened by sleep disturbance, commonly resulting from worsening of cough in the supine position.[7] In a study examining 171 individuals with lung cancer, over half reported dyspnea and fatigue as interfering with daily chores and routine tasks.[10] Moreover, mood, enjoyment, relationships and sleep can be all negatively influenced by the combination of dyspnea and fatigue.[10] Although episodes of dyspnea are often brief, they can provoke higher anxiety than either

coughing or fatigue.[7] To date; there is a lack of research examining non-pharmacological interventions to manage symptoms of dyspnea and CRF in individuals with lung cancer.

Cancer and cancer treatment affects not only the individuals with cancer but also their caregivers, who play a vital role in their cancer journey. Caregiving can become a full-time job once the individual with cancer requires assistance with their day-to-day activities.[20] In a 2012 survey, caregivers reported providing care most frequently for a spouse, followed by a friend, neighbour or colleague; other family member; parent, or grandparent with cancer.[21] Caregiving requires physical, psychological as well as emotional strength and well-being. A recent systematic review of the experiences of caregivers shows both positive and negative feelings associated with caring for a cancer survivor. The negative feelings include shock, denial, disbelief, panic, fear, helplessness, and uncertainty. The positive feelings include pride in the caregiving role and the positive support of friends and family.[20] The study reports that caregivers, however, often overlook their health and well-being during this time period. Including caregivers in supportive interventions has been found to improve the attendance, adherence and program satisfaction of individuals with cancer.[22] Hence, to facilitate patient-centred care, an exercise intervention including both individuals with lung cancer and their caregivers may prove beneficial in improving the QoL outcomes of both the individual with cancer and their caregiver.[23,24]

Yoga is the way of life as scripted in the ancient Hindu scriptures of India and one of the six systems of Indian philosophy.[3] It is now widely practiced worldwide as a mind-body therapy. It is also considered as an effective part of complementary and alternative medicine. It consists of eight principal components, namely yama (ethics), niyamā (self-discipline), āsanas (physical postures), prāṇāyāma (breath control), pratyāhāra (withdrawal of senses), dhāraṇā (concentration), dhyāna (meditation) and samādhi (enlightenment). Asana, prāṇāyāma and dhyāna are the three

components recognized and practiced in the western culture. Numerous studies provide evidence supporting the benefit of yoga in breast cancer survivors as a means to manage CRF. [25,26] Moreover, breast cancer survivors have gained benefit in psychological outcomes including anxiety, depression and sleep disturbances.[27–29] In principle, yoga can be helpful for all cancer survivors as it is based on the holistic wellbeing of an individual including both those with, and without the disease. To date, studies examining yoga for lung cancer, have been limited in number and scope; with most studies involving early-stage lung cancer, and focusing on outcomes of QoL, fatigue, and sleep disturbance.[11,12,24,30] Only a single research study has measured objective measures related to dyspnea.[12]

Resistance exercise (RE) has been proven safe and feasible with positive benefits on symptoms of CRF for individuals with early-stage Non-Small Cell Lung Carcinoma (NSCLC).[19,31] RE has also been shown to be feasible for individuals with advanced stage NSCLC in a hospital-based setting, with improvements seen in muscular strength and reduced symptom burden.[32] Moreover, studies support the benefits of RE in both improving and preventing declines in muscular strength.[16]

In summary, a novel intervention is needed that promotes uptake and participation in exercise for individuals with lung cancer. Thus, I propose that an intervention including (1) caregivers, (2) yoga with a focus on breathing, gentle movement with postures, and meditation, combined with gentle progressive RE may prove beneficial and acceptable to individuals with lung cancer.[11–13]

1.1 Objectives

1. To determine the feasibility of an eight-week combined therapeutic yoga and RE intervention for individuals with lung cancer and their caregivers.

2. To determine the preliminary efficacy of an eight-week combined therapeutic yoga and RE intervention on subjective outcomes of dyspnea, QoL and fatigue; and objective outcomes of chest expansion, muscular strength, lung volumes and capacities, and shoulder range of motion in individuals with lung cancer.

3. To determine the preliminary efficacy of an eight-week combined therapeutic yoga and RE intervention on subjective outcomes of QoL and fatigue; and objective outcome of muscular strength in caregivers of individuals with lung cancer.

1.2 Hypotheses

1.2.1 Hypothesis related to feasibility

A combined intervention of therapeutic yoga and RE will be feasible for individuals with lung cancer and their caregivers.

1.2.2 Hypothesis related to the preliminary efficacy of outcomes

1. A combined intervention of yoga and RE will show promise in reducing symptoms of dyspnea and fatigue, improve QoL, chest expansion, muscular strength, lung volumes and capacities, and shoulder range of motion in individuals with lung cancer.
2. A combined intervention of yoga and RE will show promise in improving QoL and muscular strength, as well as in reducing fatigue of caregivers of individuals with lung cancer.

1.3 Delimitations

1. Lung volumes and capacity were measured and evaluated by the MicroLab™ spirometer.
2. The design was a single group pilot feasibility study with a combined intervention of yoga (once per week) and resistance exercise (once per week) for eight weeks. No planned follow-up measures were conducted after the study intervention period of eight weeks.

3. Dyspnea for survivors with lung cancer was evaluated using the Dyspnea (D-12) questionnaire, and fatigue was assessed using the Functional Assessment of Cancer Therapy-Fatigue (FACT-F) scale.
4. Measurement of caregiver's QoL was determined by the Caregiver Oncology Quality of Life Questionnaire (CarGOQoL) and fatigue using the Chalder fatigue scale.

1.4 Limitations

1. Sample size: n=13 for survivors with lung cancer and n=9 for caregivers
2. Changes in sleep quality, pattern and disturbances were not measured as a part of the study

1.5 Ethics and informed consent

Ethical approval was received from the Alberta Cancer Research Ethics: Cancer Committee on 19th April 2017. Written informed consent including the right to withdraw, confidentiality, risks, and the benefits of participating in the study was obtained from each individual with lung cancer taking part in the study as well as their respective caregivers. Participants could withdraw from the study at any time point, for any reason. All information gathered was coded using study identification number and participant initials only. All study documents were maintained in a locked filing cabinet at the Cancer Rehabilitation Clinic in Corbett Hall at the University of Alberta. An amendment to the consent and ethics application was approved to allow for the inclusion of Stage IV lung cancer patients on 17th May 2017. A further amendment was obtained to allow for the post-study participant satisfaction questionnaire and focus group session on 26th February 2018

CHAPTER 2: A SCOPING REVIEW OF COMBINED YOGA AND RESISTANCE EXERCISE FOR DYSPNEA IN LUNG CANCER SURVIVORS
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Key Words: exercise, yoga, physical therapy, scoping review, respiratory muscle retraining, dyspnea

Abbreviations: Six-minute walk test: 6MWT; Randomized controlled trial: RCT

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Abstract

Introduction: Lung cancer is the second most common cancer and is the leading cause of death from cancer. Dyspnea, a self-reported subjective feeling of shortness of breath or breathlessness, is a common symptom experienced by survivors, especially those with advanced stage lung cancer.

Objectives: The purpose of this paper was to (1) perform a scoping review of the literature on yoga and resistance exercise interventions that included a breathing or pulmonary rehabilitation component to address dyspnea in survivors with lung cancer and (2) propose a physiotherapeutic protocol combining yoga with resistance exercise.

Results: A total of 3 single-group studies were found that examined supervised yoga interventions for survivors with lung cancer, and 5 RCTs were found examining resistance exercise including a pulmonary rehabilitation component. The three yoga studies involved a total of 28 survivors with non-small cell lung cancer. Findings support the feasibility and preliminary efficacy for sleep, mood, anxiety and aspects of QoL. Five studies, involving 257 survivors with both small cell and non-small cell lung cancer, were found that examined a combined resistance exercise intervention and pulmonary rehabilitation component. Three studies were prehabilitation interventions carried out prior to lung cancer surgery. Benefits were found for measures of lung capacity, six-minute-walk-test distance and QoL. Based on the findings, a physiotherapeutic protocol is proposed.

Conclusions: Given the scope of practice of physiotherapists and their training in cardiorespiratory therapy, it is hoped that this paper will encourage collaboration with yoga professionals to lead future research in the area.

2.0 Introduction

Fifty percent of newly diagnosed cancers include those of lung and bronchus, breast, colorectal and prostate cancer.[5] Lung cancer is the second most common cancer diagnosed among males and females each accounting for 14% of all new cases and is the leading cause of death from cancer.[5] The diagnosis of lung cancer leads to debilitating symptoms for the survivor, not only from cancer itself but also from the side effects of the treatment.[7]

The largest proportion of cancer cases occur in older adults, and lung cancer is the most common cancer for individuals 70+ years of age for both genders.[5] Unfortunately, older age is associated with increased symptom burden from the disease and its treatment.[33] Authors of a recent qualitative study reported adverse effects including pain, fatigue, weakness and dyspnea.[7] Dyspnea, a self-reported subjective feeling of shortness of breath, or breathlessness, is a common symptom experienced by survivors, especially those with advanced stage lung cancer.[7,34,35] Although highly prevalent and distressing, the impact of dyspnea is often under-recognized despite its negative effects on physical and psychological functioning.[34]

Exercise has shown benefit in addressing pain, fatigue, physical fitness and QoL across cancer types.[36,37] Exercise may prove beneficial for those with lung cancer by increasing muscle strength, attenuating losses in muscle mass, reducing fatigue, and by helping survivors cope with physical and emotional adverse effects related to the disease and its treatment.[13] Survivors, however, report numerous barriers to exercise including low motivation; fear to exercise; lack of knowledge about benefits; and external barriers related to the environment, social support, and symptoms.[38] In particular, the fear of worsening dyspnea with movement and physical activity is a primary reason for survivor unwillingness to participate in exercise.[11,13] Thus, there is a need for

further exploration of personalized exercise interventions for survivors of lung cancer that address overall fitness and functioning, while considering symptoms such as dyspnea.

Resistance exercise training may prove valuable to attenuate both sarcopenia and disease-related declines in muscle mass commonly seen in survivors with lung cancer.[39] In addition to improving muscle mass, resistance exercise has been shown to increase peak oxygen uptake in deconditioned individuals and muscle strength in older adults.[40] Importantly, resistance exercise training has been shown to improve an individual's ability to carry out daily activities, and to reduce symptoms of fatigue in both healthy and chronic disease populations.[41,42]

Yoga is now widely practiced throughout the world as a mind-body therapy and is considered part of complementary and alternative medicine. Given its gentle nature and focus on breathing and meditation, yoga may address barriers related to dyspnea, and thus prove a viable exercise option for survivors of lung cancer.[11]

The purpose of this paper was to review the potential of a physiotherapeutic approach to address dyspnea in survivors with lung cancer that involves combining yoga with resistance exercise training. First, we provide a summary of the evidence on the benefits of exercise interventions in survivors with lung cancer by highlighting findings of key systematic reviews in the area. Next, we present the findings of our scoping review on yoga and resistance exercise interventions for dyspnea in lung cancer. Noting the limited direct research in the area of combined yoga and resistance exercise interventions, we propose a protocol for a physiotherapeutic approach involving yoga and resistance exercise for survivors of lung cancer with a focus on dyspnea.

Exercise in Lung Cancer

A Cochrane Systematic Review examined exercise interventions following lung cancer resection.[43] Three randomized controlled trials (RCTs), with 178 patients, were included in the

review. Studies examined combinations of aerobic and resistance exercise training, with only one study including a focus on breathing /dyspnea management. Findings showed a statistically and clinically significant benefit for six-minute walk test (6MWT) distance (50.4m; 95% confidence interval (CI): 15.4, 85.2). No significant benefits were found for QoL or measures of lung function.

Another recent systematic review examined the benefits of home-based prehabilitation and rehabilitation programs for survivors with non-small cell lung cancer.[44] The review included 11 intervention studies comprising home-based or combined home and clinic/hospital-based supervised exercise. While benefits were shown for physical fitness outcomes, most of the studies involved survivors with early-stage lung cancer, and only two studies included a focus on breathing/ dyspnea management. Importantly, low adherence rates to exercise were common, with studies involving regular supervision and personalized exercise resulting in better adherence and retention of participants.[44]

Exercise training has also shown promise for managing dyspnea, both as a prehabilitation intervention and also when delivered as an intervention in the early post-surgical period for lung cancer.[41] In a systematic review, including 15 studies, interventions primarily involved aerobic (walking and cycling) and breathing exercises. Eight studies involved prehabilitation exercise training (n = 8 studies) and findings showed shorter lengths of hospital stays, decreased postoperative complications, and increased 6MWT distance. Seven studies involved postoperative exercise interventions and were found to improve both the 6MWT distance and dyspnea score in survivors.[41]

2.1 Scoping review on Yoga and Resistance Exercise for Dyspnea

2.1.1 Methods

A scoping literature search of various databases including Medline, CINAHL, Embase and PEDRO was performed to find articles related to lung cancer and combined yoga and resistance exercise with a focus on breathing/ dyspnea. As no studies were found examining the combination of interventions, we turned our attention to articles involving (1) yoga with an emphasis on breathing/ dyspnea and (2) resistance exercise intervention that included a breathing or pulmonary rehabilitation component.

2.1.2 Participants

Participants were required to be adults (17 years and older), diagnosed with lung cancer, where the intervention was in an outpatient hospital or a community-based setting. Participants could be actively receiving cancer treatment or be in the post-treatment phase at the time of the intervention.

2.1.3 Intervention

The primary intervention was supervised yoga with a breathing or meditation component *OR* supervised resistance exercise intervention with a breathing or pulmonary rehabilitation component. Programs that comprised home-based interventions alone were excluded.

2.1.4 Outcomes

Studies were required to include one of the following outcomes: dyspnea or a measure of lung function, fatigue, muscle strength and QoL.

2.1.5 Study Design

As we anticipated fewer trials in the yoga area, we considered clinical trials including single group pre-post designs, controlled trials and randomized controlled trials. Only randomized

controlled trials were included for the resistance exercise studies. Studies were required to be published in English.

2.1.6 Scoping Review Protocol

Four review members screened the articles for inclusion in the review (SR, MAO, KB, MM). Studies meeting the eligibility criteria underwent independent data abstraction and review by three members of the review team (SR, MAO, KB). Information regarding study population, tumour group, methods, interventions, outcomes and adverse events were collected using a structured data abstraction form. Discrepancies were settled by consensus and if necessary, involved a fourth member of the review team (MM).

2.2 Results

A total of 3 studies [11,24,30] were found that examined supervised yoga interventions for survivors with lung cancer and a total of 5 RCTs [45–49] were found examining resistance exercise including a pulmonary rehabilitation component. The three yoga studies used a single-group design and involved a total of 28 survivors with non-small cell lung cancer. Interventions involved Hatha or Tsa Lung yoga, and all involved a breathing component. One study included both survivors and their caregivers. Findings support the feasibility and preliminary efficacy for sleep, mood, anxiety and aspects of QoL. No studies reported outcomes related to dyspnea or a measure of lung function. Further details on the included studies are provided in Table 1.

Five studies [45–49], involving 257 survivors with both small cell and non-small cell lung cancer, were found that examined resistance exercise along with a pulmonary rehabilitation component (Table 2). One study was carried out in the post-treatment phase and involved a 10-week group-based supervised exercise program, once a week. No significant differences were found between the intervention and control group for any outcomes. Three studies were

prehabilitation interventions carried out prior to lung cancer surgery. Benefits were found for measures of lung capacity, 6MWT distance and QoL. The final study examined exercise during palliative chemotherapy and showed benefit for daily activities, functional capacity and symptoms of dyspnea.

2.3 Discussion

2.3.1 Proposed physiotherapeutic yoga protocol

Current exercise guidelines for cancer largely reflect physical activity recommendations for the general population.[50] At present, the most beneficial exercise regimen for survivors of lung cancer in terms of type, frequency, and duration is currently not known.[16,40,43,44] Based on current evidence, it is likely that an exercise program including a therapeutic yoga focus on the mechanics of breathing as well as a resistance exercise program that includes inspiratory muscle training would be both acceptable to, and beneficial for survivors (Figure 1). Table 3 includes a rationale for a combined physiotherapeutic yoga and resistance exercise protocol that aims to address the needs of survivors of lung cancer. Key components of the combined intervention include yoga practice with attention to the mechanics of breathing, resistance exercise including inspiratory muscle retraining, and a cool-down with a focus on stretching of key muscles of respiration.

2.3.2 Resistance exercise

Resistance exercise training optimizes physical efficiency and performance.[51,52] With repeated bouts of appropriately prescribed resistance exercise the musculoskeletal system undergoes a progressive, positive adaptation to the imposed stress, and the survivor's ability to resist physical fatigue is enhanced.[51] Moreover, using similar principles, respiratory muscle training may be used to optimize lung function by targeting the strength of inspiratory muscles. Deeper, more efficient breathing allows more oxygen to enter the bloodstream with each breath

while strengthening the breathing muscles. Interventions may include teaching diaphragmatic breathing, segmental and pursed-lip breathing; and inspiratory muscle training (IMT) using a breathing device.[53,54] In other disease conditions, IMT has been shown to improve inspiratory muscle function, decrease symptoms of dyspnea and allow patients to exercise more comfortably.[55] As seen in the results of this scoping review, early evidence supports its use in survivors of lung cancer.

2.3.3 Yoga Component

Yoga is a way of life based on the eastern traditions of India, Tibet and China. Yoga consists of three principal components as pranayama (breathing exercises), meditation, and asanas (postures).[56] There are many different styles and types of yoga commonly practiced in the western world. Hatha yoga is a traditional form of yoga from India. Hatha yoga involves a series of physical postures and breathing techniques and is a method used to calm the body, mind and spirit in preparation for meditation. Hatha yoga includes the styles of Ashtanga, Iyengar, Anusara, Vivekananda, and Vinyasa. Tsa Lung, a Tibetan form of yoga, uses breath retention techniques with physical movements and visualizations to promote relaxation and healing and to still the mind. Early evidence from this scoping review suggests a potential benefit from yoga for symptoms of dyspnea. Given other reported benefits of yoga for sleep, cancer-related fatigue, psychosocial distress, and musculoskeletal symptoms[56]; further investigation of yoga as an intervention for survivors with lung cancer is warranted.

2.5.4 Exercise Safety Considerations

Prior to performing exercise testing or training, information must be collected on important diagnostic and treatment variables such as the survivor's type and stage of lung cancer, cancer treatments received or ongoing, and identify any acute or chronic adverse effects related to the

cancer and/or cancer treatment.[50] Table 4 provides a list of precautions/ potential contraindications to exercise that includes considerations specific to lung cancer. Given the older age of survivors with lung cancer, further screening for co-morbid conditions is needed. Following a simple screening tool such as the Revised PAR-Q (Canadian Society for Exercise Physiology's website http://www.csep.ca) may be useful to identify survivors of lung cancer who require further medical evaluation prior to taking part in exercise testing or training.

Pre-exercise screening should include assessment of the survivor's vital signs (blood pressure, heart rate, oxygen saturation, respiration rate and dyspnea evaluation), as an indication of overall health status.[52] Prior to assessment, survivors should rest for a period of at least 10 minutes. A heart rate monitor can be provided to the survivor with lung cancer to wear while exercising so that heart rate response can be easily observed. Vital signs should be taken before, during and after exercise testing and training to ascertain the safety of exercise. Survivors with abnormal readings should refrain from exercise until normal readings are obtained, or if remaining abnormal should be referred to their oncologist or primary care physician for further medical evaluation.[52] A dyspnea visual analog scale, such as the modified Borg Scale, can be used to measure the perceived level of breathlessness before and after the intervention.[57] Oxygen saturation levels can be monitored during exercise and may inform the need for rest/ recovery.

2.3.4 Special Considerations for Dyspnea during Exercise

Simple interventions to relieve breathing distress during exercise, such as performing exercise in a supported sitting position, may be introduced to allow for increased lung expansion. In survivors with lung congestion, chest physical therapy techniques may be incorporated to open airways prior to exercise.[58] Recovery or *escape positions* to ease breathing should be demonstrated to the survivor with lung cancer and their caregivers as a means to manage episodes of dyspnea

during exercise or daily activities.[58] Importantly, survivors should be taught to use *escape positions* to increase ventilatory capacity when experiencing dyspnea during exercise testing and training sessions. As an example, one escape position involves leaning forward in a seated position and supporting the thorax by bracing the forearms against a chair or on the knees. Alternatively, the survivor can lean against a wall in a similarly supported standing position.[58] *Pacing* is another important aspect for those with dyspnea and is critical to ensure exercise performance falls within the limits of a survivor's ventilatory capacity. If a survivor becomes slightly short of breath, they are instructed to stop the exercise, attain an *escape position*, and use controlled purse-lip breathing (to increase end-expiratory pressure and improve oxygenation) until the symptoms subside.[58]

2.3.5 Future Directions

As can be seen from the foregoing review of the literature on yoga and resistance exercise for survivors of lung cancer, the body of literature is small, and research supporting the efficacy of interventions is limited. There is a need for further research examining the benefits of a lung cancer-specific program involving combined yoga and resistance exercise training for symptoms of dyspnea. Given the scope of practice of physiotherapists and their training in cardiorespiratory therapy, it is hoped that this paper will encourage collaboration with yoga practitioners to lead future research examining rehabilitation strategies for dyspnea in survivors of lung cancer.

Table 1: Yoga Studies with Breathing Component

Author/ Year/ Country	Study Design/ Sample size (N)	Patient Details	Intervention Details	Outcome Measures	Study Results	Key Features
Fouladbakhsh et al./ 2014/ United States[11]	One-group, repeated-measured design **Sample size:** N = 9	NSCLC Stages I-IIIa Post initial cancer treatment	Hatha Yoga: Viniyoga method 1 x 40 mins/week for 14 weeks 3-week pre-intervention, 8-week yoga intervention, 3-week post-intervention Follow up: 3 & 6 months	• Sleep quality • QoL • Stress (salivary cortisol)	**Significant improvement** • sleep efficiency over time ($p < 0.02$) • mood ($p < 0.02$) • QoL mental & physical subscales ($p < 0.014$) • increase in physical health scores ($p < 0.0001$)	• Modification of poses for individual needs • Patient education • Focus on meditation, postures, and, breathing exercises to deepen and slow the breath
Milbury et al./ 2015/ United States[30]	Pilot couple based yoga program **Sample size:** Patient (n = 10) Caregiver (n = 10)	NSCLC Stages I–IV Receiving at least 5 weeks of radiation therapy	Couple-based Tsa Lung yoga 2-3 x 45-60 min/week over the course of 5-6 week	• QoL • Psychological distress • Sleep disturbances • Fatigue • Health-related QoL • Spiritual well-being	Feasibility: 80% attended at least 50% of sessions **Significant:** Increase in spiritual well-being ($p = 0.03$) **Medium effect:** Sleep disturbance ($d = 0.60$), decreased depressive symptoms ($d=0.52$)	• Dyadic intervention and analysis • Program well accepted with high rates of class & at home practice • **Caregiver results: a** significant decrease in fatigue, and anxiety

Milbury et al./ 2016/ United States[24]	**Study Design:** Single-arm feasibility study **Sample size:** (N = 9)	NSCLC Stages I-IIIB Receiving at least 5 weeks of radiotherapy	Hatha Yoga (Vivekananda Method: couple-based) 2-3 sessions for a total of 60 mins/week 15 sessions over course of 5-6 weeks of radiotherapy	• QoL • Psychological distress • Well-being • Fatigue	**Significant:** Decrease in anxiety (p = 0.04), increase in mental health aspects of QoL (P = 0.04) **Medium/Small effect:** • Sleep disturbance (d = 0.65) • Spiritual well-being (d = 0.64) • Somatization (d=0.65) *No p-values given	• Couples-based program (dyadic approach) • Feasible, acceptable, and safe for the lung cancer population **Caregiver results:** **Significant:** Sleep disturbances **Medium effect:** improved physical aspects of QoL

NSCLC: Non-Small Cell Lung Cancer; QoL: Quality of Life

Table 2: Resistance Exercise Studies with Breathing or Respiratory Muscle Retraining

Author/ Year/ Country	Study Design & Sample size	Patient Characteristics	Intervention Details	Outcome Measures	Study Results	Key Features
Huang et al./2017/ China[47]	Three-arm RCT **Sample size:** N=90	• NSCLC • Pre-lobectomy • Age (mean ± SD): 63.6±6.8 • Stage I-III • COPD with a heavy smoking history	1) Combined Pre-operative Pulmonary Rehabilitation (PR) group: one week with high-intensity preoperative PR (inspiratory muscle training (IMT) + resistance exercise 2) IMT-alone group: conventional single-mode IMT 3) control group: routine preoperative care	• 6-MWD • Peak expiratory flow (PEF) • Fatigue • Dyspnea index • QoL (EORTC-QLQ-C30 and EORTC–LC13)	**PR vs Control:** • **6-MWD** (P=0.002) • **PEF** (P=0.001) • **QOL scores:** significant difference (P=0.035) Global QoL in favour of PR **PR vs IMT group:** • **PEF** (P=0.004) in favour of PR	• Short term • High-intensity pulmonary prehabilitation program including IMT and resistance exercise.
Henke/2014/ Germany[46]	RCT **Sample size:** N=46 (29 patients completed the trial)	• NSCLC and SCLC • Stages IIIA/IIIB/IV • Receiving inpatient palliative platinum-based chemotherapy	Intervention group (IG): Endurance training (walking exercise) and breathing techniques, (5 days/week) + resistance training (every other day) Control group (CG): Conventional physiotherapy	• Barthel Index • 6MWD • Staircase walking • Dyspnea: Modified Borg Scale (MBS) • QoL: (EORTC QLQ-C30/LC13)	**Barthel Index** ($p = 0.041$) in favour of IG **Functional capacity:** 6MWD, staircase walking exercise, and strength capacity in favour of IG ($p<0.05$) **Dyspnea:** Significant	• Benefit of enhanced physiotherapy including endurance training and strength training*

					decrease in the level of dyspnea in the IG, ($p<0.05$) **QoL:** Significant differences in specific component scores only	
Barbara Cristina Brocki[45]	RCT **Sample size:** N=78	• Age (mean ± SD): 64.5±9.5 • Radical Surgery for lung cancer	10-week group-based supervised exercise programme, once a week: 15 min warming up, followed by 20 min aerobic exercise, 15 min muscle strength training and 10 min cooling down/relaxation Intervention included dyspnea management techniques.	• Health-related QoL: 36-Item Short Form Health Survey version 2 (SF36) • Functional exercise capacity: 6MWT • Lung function: spirometry	No difference between groups at any time-point. Both groups increased their walking distance (IG: 61 m, 95% CI: [43;79] and CG: 55 m, 95% CI: [40;70]) and this increase was sustained after one year	• The exercise programme was personalized according to physical capability and submaximal exercise test. • Home exercises given to both groups
Morano et al./ 2014/ Brazil[49]	Study design: Randomized single-blinded exploratory studies Sample size: N=19; Control n=9 PR n=10	Patients undergoing lung cancer resection and with moderate-severe COPD	10 face to face sessions in one week (twice a day) Preoperative pulmonary rehabilitation: **1. Endurance training** 20 min target: treadmill or Nu-step or	Postoperative pulmonary complications and mechanical ventilation (they measured only baseline values of pulmonary	Short-term preoperative pulmonary rehabilitation is feasible. No statistically significant findings.	Finding of shorter time of chest tube may indicate a better lung re-expansion, a result that may be associated with routine use of IMT

			arm ergometer or arm-R-size exercise **2. Strengthening** (UE/LE alternating every other day) using theraband: 2 sets of 10-12; **3. Inspiratory muscle training IMT:** 15-20 min of daily use **Slow breathing**: 10 min each session, prolonged expiratory time using pursed lips **Weekend exercise:** Individuals goals set collaboratively	function and dyspnea scores)		
Morano et al./ 2013/ Brazil[48]	Randomized clinical trial **Sample Size:** n=24 Pulmonary rehabilitation (PR) group: n=12(recruited) n=12 completed Chest physiotherapy (CPT):	Patients undergoing lung cancer resection for NSCLC **Age:** CPT: 68.8±7.3 PR: 64.8±8 **Stage:** **I/II:** CPT: 9, PR: 11 **IIIA:** CPT:3, PR:1	4 weeks of preoperative pulmonary rehabilitation (PR) VS CPT PR: **1**. UE PNF pattern with lightweight **2**. LE endurance on treadmill, 10 mins week 1, ↑ 10 mins each week, 30 mins week4, 80% of max **3.** IMT 10-30 mins daily, 20% of max	**Spirometry:** • FEV_1 • FVC • MIP (maximal inspiratory pressure) • MEP (maximal expiratory pressure) **Quality of life:** Medical Outcomes Study 36-Item short form	**Significant increase:** • FVC in Litres and % (p=.02, p=.00 respectively) • MIP (P=.00) • MEP (P=.00) • SF-36 physical component summary (p=0.07)	Improvement in preoperative functional capacity, fewer postoperative pulmonary complications, postoperative stay.

	n=12 recruited, n=9 postoperative outcome completed		inspiratory pressure, ↑ 5-10% each session, reach 60% by the end of the month. CPT: lung expansion techniques, sustained maximal inspiration, fractional inspiration, pursed lips, flow-based spirometry. All participants: Counselling for pre and postop care, energy conservation, relaxation, nutrition.	health survey (SF-36)		

Table 3: Precautions/ Potential Contraindications to Exercise

Body System	Precautions/ Potential Contraindications Requiring Medical Approval	Comments
Musculoskeletal	• Bone, back or joint pain of recent origin • Unusual muscular weakness • Severe Cachexia • Unusual/extreme fatigue	• High risk of bone metastases if presenting with bone pain or onset of unusual muscle weakness • Cachexia and exhaustion may be seen in advanced lung cancer and may limit exercise tolerance
Cardiovascular	• Chest pain • Resting pulse >100/min or < 50/min • Resting blood pressure > 160 mm Hg systolic or < 85 mmHg and >110 mmHg Diastolic or < 50 mmHg • Irregular pulse • Swelling of ankles	• Presenting factors indicate a higher risk of a cardiac event with exercise
Pulmonary	• Severe dyspnea: respiration rate >14 breaths/ minute at rest • Coughing, wheezing • Chest pain increased by a deep breath • Oxygen saturation < 90% • Dyspnea > 4 on Borg 10-point	• Inadequate ventilator capacity for exercise

Table 4: Proposed Protocol for Physiotherapeutic and Yoga Exercise Program

Program components	**Program details**
Warm-up	Options: • Breathing exercises, shoulder range of motion exercises with breath regulation *OR* • Low-intensity aerobic exercise
Yoga	• Hold a physiotherapeutic yoga session in a quiet area with minimal distraction • Facilitate breathing through supported positions that relax abdominals and enhance diaphragmatic excursion • Ensure focus is on proper breathing pattern • Progress exercises from gravity assisted to gravity-eliminated positions: e.g., sitting or standing to supine • Use manual contacts and manual techniques to cue proper breathing and chest wall movement • Progress exercises to functional positions and activities • Enhance self-management by teaching home exercises and escape positions for managing dyspnea • Frequency: 1-2 days per week; consider a group-based session
Resistance exercise training	• 6 to 8 major muscle groups • Start at 40% of 1 Repetition Maximum, 2 sets of 8-10 repetitions progress repetitions to 2 sets 12-15 then increase resistance intensity 5%. • Intensity: no greater than 2-3 on the Modified Borg Scale for dyspnea • Frequency: minimum 2 days per week • Consider Inspiratory Muscle Retraining with respiratory training device: 10 minutes progressing to 30 minutes daily
Cool-down: focus on stretching of inspiratory & expiratory muscles	• Scalenes, pectoralis major & minor, latissimus dorsi, serratus anterior, rectus abdominus and internal & external obliques
Reduce workload/ discontinue exercise	• Excessive fatigue post-exercise • Muscle soreness > 48 hours • Exacerbation of dyspnea (> 3), excessive coughing or increase in pain during or following sessions

CHAPTER 3: METHODS AND PROCEDURES

3.1 Subjects

Participants self-referred to the study after reading the study brochure or were referred directly by an oncologist at the Cross Cancer Institute or (Appendix A). Brochures were available at Wellspring Edmonton and the Psychosocial Department at the Cross Cancer Institute, or were provided to the patient by the oncologist at the Cross Cancer Institute. Participants included both individuals with lung cancer and their caregivers. Participants referred to the study were contacted, and further details about the study were provided prior to enrolment.

3.2 Inclusion/exclusion criteria

3.2.1 Inclusion criteria for participants

1. Diagnosis of primary lung cancer Stage I-IV, those with advanced metastatic disease required oncologist approval to participate;
2. Lung cancer diagnosis including Small Cell Lung Cancer (SCLC) and Non-Small Cell Lung Cancer (NSCLC);
3. Age: 18 years or above;
4. Individuals could be at any point in time following diagnosis including during or after treatment;
5. Karnofsky Performance Status ≥ 50 (Appendix C);[59,60]
6. Life expectancy of at least one year

3.2.2 Exclusion Criteria for participants

1. Advanced metastatic lung disease that precluded safety of exercise testing or training;
2. Secondary lung cancer due to metastasis from another type of cancer;

3. Uncontrolled comorbid conditions such as diabetes, congestive heart failure, dementia, cerebrovascular diseases;
4. Unable to provide consent in English;
5. Unable to complete either testing or intervention components (e.g. extended holiday)

Eligible and interested individuals with lung cancer were then screened for the safety of exercise using the Physical Activity Readiness Questionnaire (PARQ+) (Appendix B). If concerns were identified, consent or approval was obtained from either the family physician (co-morbid conditions) or the oncologist (cancer-related issues) for the individual to participate in the study.

3.2.3 Inclusion and exclusion criteria for caregivers

Eligible and interested caregivers were screened using the PAR-Q + and were required to obtain approval from a family physician if any safety concerns were identified.

3.3 Sample size

A convenience sample of participants was proposed for the pilot study. The program completion rate for the pilot study was used as the primary outcome to evaluate the feasibility and was set at > or = 80%. On the basis of this premise, if 20 participants including both individuals with lung cancer and their caregivers were enrolled and at least 16 were evaluable at study completion, the estimated 95% confidence width for the proportion of successful completion would be 11-20 subjects. Therefore, the accrual goal for this study was set at a minimum of 20 participants in total.

3.4 Study design

The study was a prospective single group before and after partner-based intervention feasibility study. The pilot study design was chosen to evaluate and identify issues in the study design or recruitment strategy to inform a future large-scale scientific study. The feasibility focus

allows for unanticipated issues to be addressed in future studies by revising the study methods and/ or design as needed. Rolling recruitment of participants was carried out until the desired sample size was reached. The acronym used for the present study was ASSURE: Yog*a* and Re*s*i*s*tance Exercise for Individuals with L*u*ng Cance*r* and their Ca*r*egivers.

3.5 Intervention

The individuals with lung cancer and their caregivers participated in a combined intervention of therapeutic yoga (Appendix D: Yoga intervention) and resistance exercise (Appendix E: Resistance Exercise Intervention) for an 8-week period, two times per week. Participants attended a one-to-two hour resistance exercise intervention and a one-hour yoga class with a minimum of a one-day break between interventions. The resistance exercise training involved one-on-one supervised exercise sessions, while the yoga intervention was offered in a supervised class setting. The participants were allowed to make up for any missed resistance exercise session based on the availability of the instructors. The intervention was carried out in the Cancer Rehabilitation Clinic at the Faculty of Rehabilitation Medicine, University of Alberta. A home exercise program comprising breathing exercises, postural correction exercises, and core resistance exercises were prescribed to supplement the program (Appendix F: Home Exercise Sheet). Each participant was provided with a home exercise diary to log exercises performed at home throughout the 8-week duration (Appendix G: Home Exercise Diary).

3.6 Data collection

Data supporting feasibility were collected through the 8-week intervention period. Data on demographics and contact information were collected directly from participants. Medical variables were abstracted from the electronic health records at the Cross Cancer Institute. The participants completed the baseline and post-intervention questionnaires electronically at the time of the testing

session at the Cancer Rehabilitation Clinic. The pre- and post-intervention objective assessments were recorded on a testing sheet. The data collected for spirometry were saved and printed using the MicroLab^{TM} spirometer.

3.6.1 Measures evaluating Feasibility

The primary outcome measures related to feasibility included eligibility rate, recruitment rate, outcome completion rate, adherence rate and adverse events. Eligibility rate was defined as the total number of individuals with lung cancer and their caregivers eligible divided by the total number of eligible screened for the study. Recruitment rate was defined as the total number of individuals enrolling in the study divided by the total number of eligible individuals. Completion rate was defined as the number of participants completing the baseline assessment, intervention, and the post-intervention assessment. Serious and minor adverse events were recorded. Adherence to the intervention was recorded by the number of sessions attended by the participants divided by the total number of sessions scheduled.

3.6.2 Measures evaluating Preliminary Efficacy

For individuals with lung cancer, the primary symptom outcome measure was self-reported dyspnea using the Dyspnea-12 questionnaire (Appendix H). The secondary outcomes included fatigue and QoL using the Functional Assessment Cancer Therapy-Fatigue questionnaire (FACT-F) (Appendix I), chest expansion at three levels using a tape measure, muscle strength using the one repetition maximum (1 RM) test, lung volumes and capacities using a MicroLab^{TM} spirometer for a pulmonary function test and shoulder range of motion using a hand-held goniometer.

The caregivers QoL was measured using the American version of the Caregiver Oncology Quality of Life Questionnaire (CarGOQol) (Appendix J), fatigue using Chalder Fatigue scale (Appendix K) and muscle strength using the 1RM test.

3.7 Subjective and objective outcome measures

3.7.1 Dyspnea-12

The Dyspnea-12 consists of a 12-item scale in which survivors reported their perception of their current state of breathlessness. The scale quantifies breathlessness using descriptions of both physical (7 questions) and emotional (5 questions) aspects of dyspnea. The questions are rated on a 4 point Likert scale with 0 being no dyspnea and 3 being severe dyspnea. The total dyspnea score ranges from 0-36, with higher scores representing worse dyspnea. The scale has demonstrated good internal reliability (α=0.9) and good test-retest reliability (ICCC=0.90; $p<0.001$).[61] The Dyspnea-12 is simple to use and has shown utility in both practice and research settings.[62] Moreover, the Dyspnea-12 has been shown to be valid and reliable for use in lung cancer patients (Cronbach's alpha for total, physical, and emotional subscale as 0.95, 0.92 and 0.94 respectively).[63]

3.7.2 FACT-F

The FACT-F was developed to measure QoL and fatigue in oncology patients. The scale has 27 items, which cover physical well-being (7 items), functional well-being (7 item), emotional well-being (6 items), and social and family well-being (7 items). The fatigue subscale consists of 13 questions identifying symptoms of fatigue and its effects on activities of daily living. The questions are scored on a 5-point Likert scale, with a higher score representing less fatigue and better QoL. The scale has been shown to be stable (test-retest r=0.87) and internally consistent to measure QoL in cancer patients.[64] The fatigue subscale has demonstrated very good internal consistency (coefficient alpha range=0.95-0.96) and good stability (test-retest range: r=0.84-0.90).[64]

3.7.3 Chest Expansion

The circumference of the chest was measured after inspiration and expiration using a measuring tape at three levels: axilla, nipple and xiphisternum. Participants were measured in a standing position, using two different arm positions: hands on head and arms at the side. In a previous study, the interclass correlation coefficient, 95% confidence interval, and p-value showed good intra-tester (intraclass coefficient range=0.85-0.97) and very good inter-tester reliability (intraclass coefficient range=0.93-0.97) for chest expansion measurement in clients with ankylosing spondylitis and healthy individuals.[65]

3.7.4 One Repetition Maximum test (1RM)

All participants performed a 1RM test before and after the 8-week intervention to measure the muscular strength of their upper extremity (bench press and seated row) and lower extremity (leg press). The test procedures involved an initial warm-up of 5-10 repetitions at a light load (10-20 lbs). Following the warm-up, the participant was asked to rate their perceived exertion with the starting weight on a scale of 1 (very light) to 5 (maximum exertion). After a brief rest period, the load was increased with a weight determined by the rating (rating of 1-2 = additional 20-50 lbs were added; the rating of 3 = additional 10-30 lbs were added; the raing of 4 = additional 5-10 lbs was added. Three to five repetitions were completed at the second weight. After this, a small increase in the weight was added, and a 1RM was attempted. The goal was to determine the participant's 1RM in a maximum of 3 trials. Ample rest (at least 3-5 minutes) was allowed before each 1RM attempt. If at any time a rating of 5 was reported, indicating maximum exertion, the test was terminated. The leg press test was completed as the second test to allow adequate rest of the upper limbs between upper extremity seated row and vertical bench tests.

3.7.5 Pulmonary Function Test

The lung volumes and capacities were measured using the spirometer in a sitting position. The forced expiratory volume in one second (FEV_1) and the forced vital capacity (FVC) were recorded. The individuals with lung cancer were asked to take a deep breath in after clipping the nose; then to exhale as fast and forcefully as possible for at least six seconds into the mouthpiece followed by a full deep inhalation through the mouthpiece.

3.7.6 Shoulder Range of Motion

Active flexion and abduction were measured using a handheld goniometer with the participant in the sitting position.

3.7.7 Caregiver Oncology Quality of Life Questionnaire (CarGOQoL)

The Caregiver Oncology Quality of Life (CarGOQoL) questionnaire is a 29-item, multidimensional, self-administered questionnaire, that was initially validated using a large sample of participants from France.[66] It demonstrated high internal consistency with Cronbach's $\alpha > 0.70$ and correlated significantly with all Short Form Health Survey (SF-36) dimension scores except the physical component score (Pearson correlation: 0.28-0.70). The American version of the CarGOQoL, used in the present study, was developed to measure QoL in caregivers of cancer survivors in the United-States.[66]

3.7.8 Chalder Fatigue Scale

The Chalder Fatigue Scale consists of 11 items assessing symptoms of fatigue such as tiredness, sleepiness, lack of energy, lack of strength in the muscles, and difficulties in concentration and memory. The scale is scored on a Likert scale of 0-3, with a total score ranging from 0-33. Higher scores represent higher levels of fatigue. Cronbach's alpha reliability scores for

the entire scale was 0.92 for patients with chronic fatigue syndrome and 0.88 for a nonclinical group.[67]

3.8 Procedures

3.8.1 Screening for adverse events

Participant vital signs (blood pressure and pulse) were measured before and after the intervention to ensure safe, stable levels and rule out contraindications to exercise. Guidelines were developed outlining procedures to be followed in the event that any issues related to the safety of exercise were identified (Appendix L).

3.8.2 Ethical Considerations

The ASSURE study received ethics approval from the Health Research Ethics Board of Alberta Cancer Committee (HREBA) (Appendix M). Informed consent including the right to withdraw, confidentiality, and risks and benefits to participating in the study was obtained from each participant including the individual with lung cancer and their caregiver (Appendix N). The participants were advised that they could withdraw from the study at any time, and for any reason. All information gathered was kept anonymous using a study identification number and participant initials. All files were maintained in a locked filing cabinet in the Cancer Rehabilitation Clinic in Corbett Hall at the University of Alberta. Further ethics approval for conducting a focus group was received from the Alberta Cancer Research Ethics: Cancer Committee (Appendix O: HREBA Approval). Informed consent for both optional components of survey and focus group discussion was obtained from participants (Appendix P: Participant consent form for the focus group).

3.9 Statistical analysis

Demographic variables are presented in a tabulated form as median/range for interval data, and frequency/percentage for nominal data. As the primary objective of the pilot study was to test

feasibility; the eligibility rates, completion rates, and adherence rates were calculated, and the mean percentage was reported. Objective measures and self-reported questionnaires involved interval data and are presented as the median and range for the descriptive statistic. Analysis of outcome data was performed using the paired t-test for the purposes of determining point estimates and measures of variability. Due to the small sample size, outcomes were further analyzed to determine significance of findings using nonparametric tests.

3.10 Timeline

The ethics application to the Health Research Ethics Board of Alberta Cancer Committee (HREBA) was submitted on 8th February 2017, and was approved on 19th April 2017. An amendment to include individuals with Stage IV lung cancer was added on 10th May 2017 and was approved on 17th May 2017. Brochures were distributed at Cross Cancer Institute from 1st April 2017 until 1st June 2017. Participants were enrolled in a rolling recruitment format from May 2017 to November 2017. Participants followed individual timelines of 8-weeks in duration. The last four participants were tested on 21st December 2017. The amendment for a focus group was submitted on 18th February 2018 and approved on 26th February 2018. The focus group session was conducted on 15th March 2018.

3.11 Satisfaction Survey and Focus group

To further explore the benefits of, and participant satisfaction with the pilot study, and inform future directions the following was conducted:

1. A post-study survivor and caregiver satisfaction surveys:

Participants with lung cancer and their caregivers had the option to complete a post-study satisfaction questionnaire. Data were collected on perceived benefits, support and satisfaction with

programming. (Appendix Q: Participant feedback survey for individuals with lung cancer; Appendix R: Participant feedback survey for caregivers)

2. Post-study Survivor and Caregiver Focus Group Session:

Participants had the option to take part in a post-study focus group session. Two separate group sessions were conducted: one for participants with lung cancer and one for participating caregivers. Each focus group involved a single session of approximately 90 minutes in length, and was transcribed and audiotaped.

The primary aim of the focus group was to explore the participants' experiences, perspectives and perceived benefits of the program. This allowed us to examine and probe further into study findings. The barriers and facilitators to program participation were also explored with a focus on the different intervention components: therapeutic yoga, resistance exercise, and home exercise programming. We finished the session by exploring participant views on future directions for exercise programming and research. (Appendix S: Focus group questions). A priori, we considered only those barriers and facilitators that were reported by a majority of participants, and/ or where a consensus was reached among the group.

CHAPTER 4: RESULTS

A total 22 adults, 13 individuals with lung cancer and nine caregivers, were recruited to the study. (Figure 1) The individuals with lung cancer included 12 females and one male with a mean age of 66.5 years. The caregivers included five females and four males with a mean age of 62.4 years.

Further information on the baseline characteristics and demographics of individuals with lung cancer and caregivers are outlined in Table 5. The relationship of the caregiver to the individuals with lung cancer is outlined in Table 6. The medical data related to the type of lung cancer, stage at diagnosis and the type of treatment undergone by the individuals with lung cancer is summarized in Table 7.

Table 5: Baseline Characteristics/Demographics

N=22		**Individuals with lung cancer (n=13)**	**Caregivers (n=9)**
Gender	Male	1	4
	Female	12	5
Age (years)	Mean ± SD	66.5 ± 8.9	62.4 ± 18.3
Education		**Frequency**	**Frequency**
Completed High school		3 (23%)	3 (33%)
Some University/College		2 (15%)	1 (11%)
Completed University/College		6 (46%)	5 (56%)
Completed Graduate School		2 (15%)	0

Annual Family Income		
<20,000	1 (8%)	1 (11%)
20-39,999	3 (23%)	0
40-59,999	1 (8%)	3 (33%)
60-79,999	4 (31%)	2 (22%)
80-99,999	0	2 (22%)
>100,000	4 (31%)	1 (11%)
Marital Status		
Married/ Common Law	7 (54%)	6 (67%)
Never married	0	1 (11%)
Widowed	3 (23%)	2 (22%)
Divorced/ Separated	3(23%)	0
Employment		
Homemaker/ Working at Home	0	1 (11%)
Working Full Time	1 (8%)	1 (11%)
Working Part-Time	0	1 (11%)
Temporarily Unemployed	0	1 (11%)
On Long/ Short-term Disability	3 (23%)	0
Retired	9	5 (56%)

Residence		
Edmonton	10 (77%)	8 (89%)
Edmonton surrounding area	3 (23%)	1 (11%)
Ethnic Status		
Asian	2 (15%)	2 (22%)
Caucasian	11 (85%)	7 (78%)
Smoking		
Never Smoked	4 (31%)	7 (78%)
Ex-Smoker	7 (54%)	2 (22%)
Occasional Smoker	1 (8%)	0
Regular Smoker	1 (8%)	0
Drinking		
Never Drank	2 (15%)	1 (11%)
Social Drinker	9 (70%)	8 (89%)
Ex-Drinker	2 (15%)	0

Table 6: Caregiver's Relationship

Caregiver relationship to the individual with lung cancer	
Friend	3
Spouse	4

Family member	2

Table 7: Medical Data

Type	Details	Number (%)
NSCLC	**Stage**	
n = 11 (85%)	I	3 (23%)
	II	2 (15%)
	III	0
	IV	6 (46%)
SCLC	**Stage**	
n = 2 (15%)	Limited	1 (8%)
	Extensive	1 (8%)
Treatment	Surgery	7 (54%)
	Radiation Therapy	7 (54%)
	Chemotherapy	8 (61%)
	Targeted therapy	3 (23%)
	Immunotherapy	1 (8%)

4.1. Outcomes Evaluating Feasibility

4.1.1. Eligibility Rate

All the individuals with lung cancer who self-identified or were referred by their oncologist were eligible for the ASSURE study. A total of 26 participants including individuals with lung cancer and their caregivers were eligible to participate. Seven participants required medical approval to take part following PARQ+ screening. Approval was obtained from the family

physician (n = 4), or the oncologist (n = 3) for these participants. Thus, of participants contacting the investigators, the eligibility rate was 100%. (Figure 2)

4.1.2. Recruitment Rate

From May 2017 to November 2017, a total of 22 participants of the 26 eligible participants were enrolled in the ASSURE study for an overall recruitment rate of 85%. The recruitment rate for individuals with lung cancer was 81% (n=13 of 16), and caregivers was 90% (n=9 of 10). (Figure 2)

4.1.3 Completion Rate

Individuals with lung cancer

A total of 13 individuals with lung cancer entered the study. All (n=13) completed the baseline questionnaires while only 10 were able to complete all the baseline objective measurements. One participant withdrew from the study prior to completing any of the baseline objective measurements. Another participant did not undergo pulmonary function testing due to the use of supplemental oxygen (as it is contraindicated) nor did she complete the 1RM testing for the seated row due to mobility issues. Three participants did not complete the 1RM test for leg press at baseline due to hip pain (n=1), knee arthritis (n=1) and knee replacement surgery (n=1).

Three participants withdrew from the study. One participant withdrew prior to completing the objective assessments due to worsening of hip arthritis pain (unrelated to study participation). One participant withdrew from the study after three sessions due to the diagnosis of progressive metastatic bone disease. One participant was unable to complete the intervention due to progressive disease and subsequently passed away.

Ten participants completed the full 8-week intervention. All 10 completed the post-intervention questionnaires, and eight completed the post-intervention objective assessments.

Therefore, the completion rate for self-reported measures was 77% (10/13), and the overall completion rate for all objective outcome measures was 62% (8/13). Further details are provided in Table 8.

Figure 1: Flow Diagram showing the Number of Participants

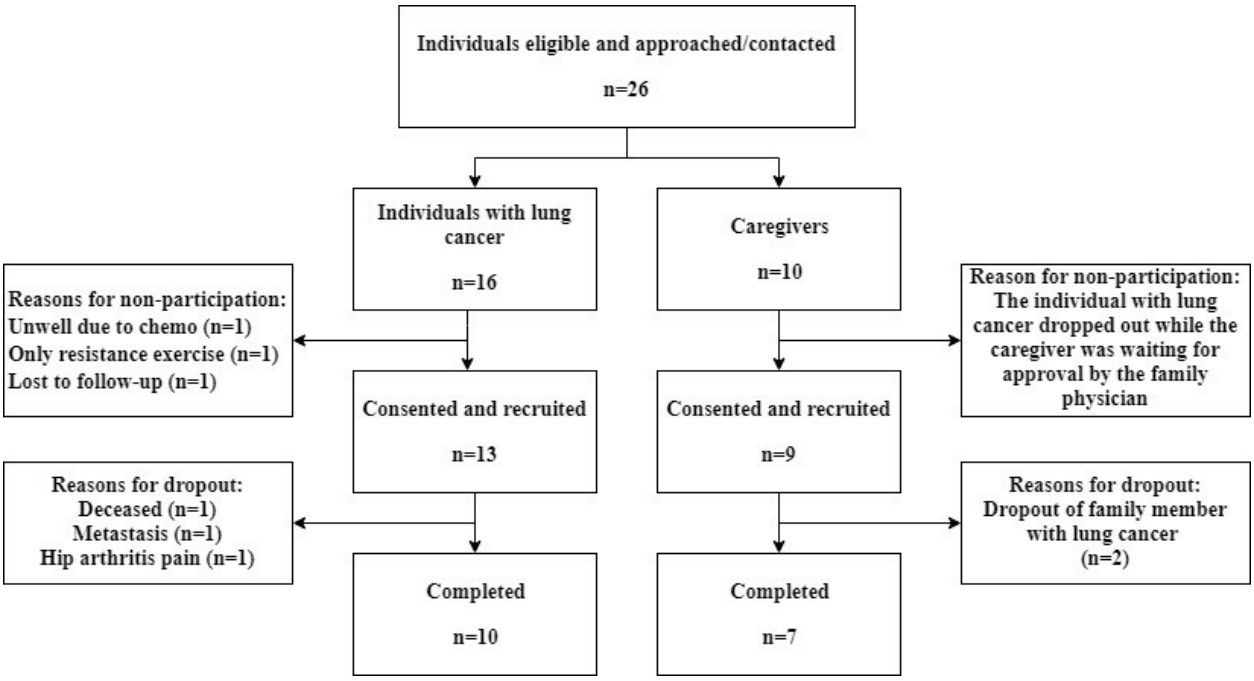


Table 8: Completion Rates by Test

TEST	BASELINE n = 13	8-WEEK n= 10
Spirometry	11 (85%)	10 (77%)
Shoulder Range of Motion	13 (100%)	10 (77%)
Chest Expansion	12 (92%)	10 (77%)
1 Repetition Maximum (1RM)		
Bench Press	12 (92%)	10 (77%)
Leg Press	10 (77%)	8 (62%)
Seated Row	11 (85%)	10 (77%)

Questionnaires	13 (100%)	10 (77%)

Caregivers

All the caregivers completed the baseline questionnaires and assessments. Two caregivers withdrew from the study, both due to the withdrawal of the family member with lung cancer. The remaining seven caregivers completed all post-intervention subjective and objective measurements. (Figure 2 and 3)

Figure 2: Eligibility Rate and Recruitment Rate

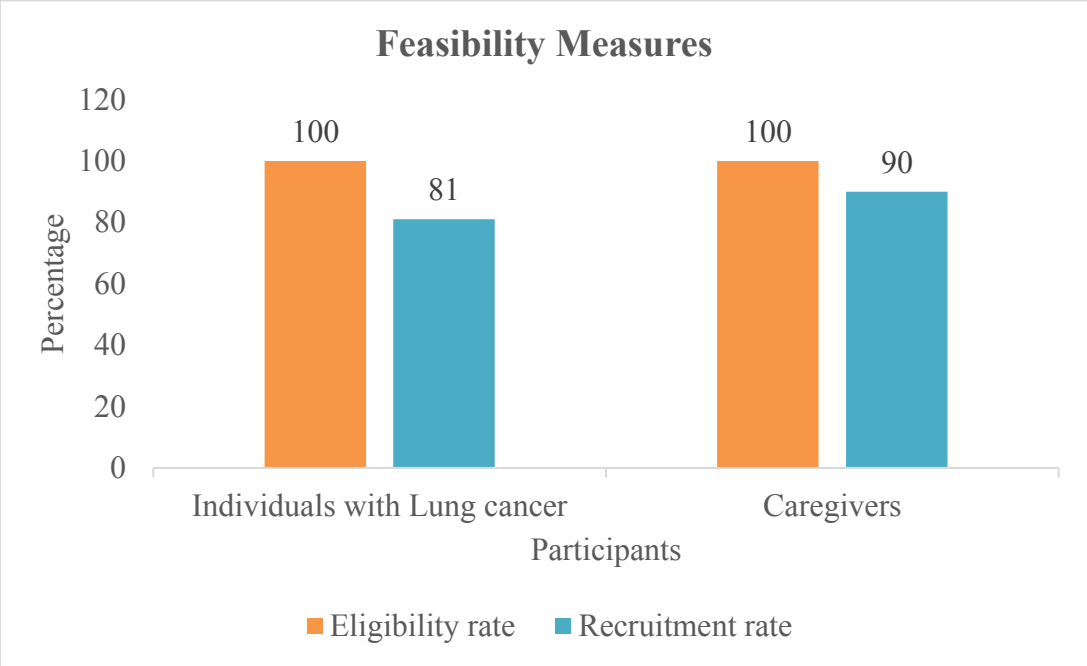
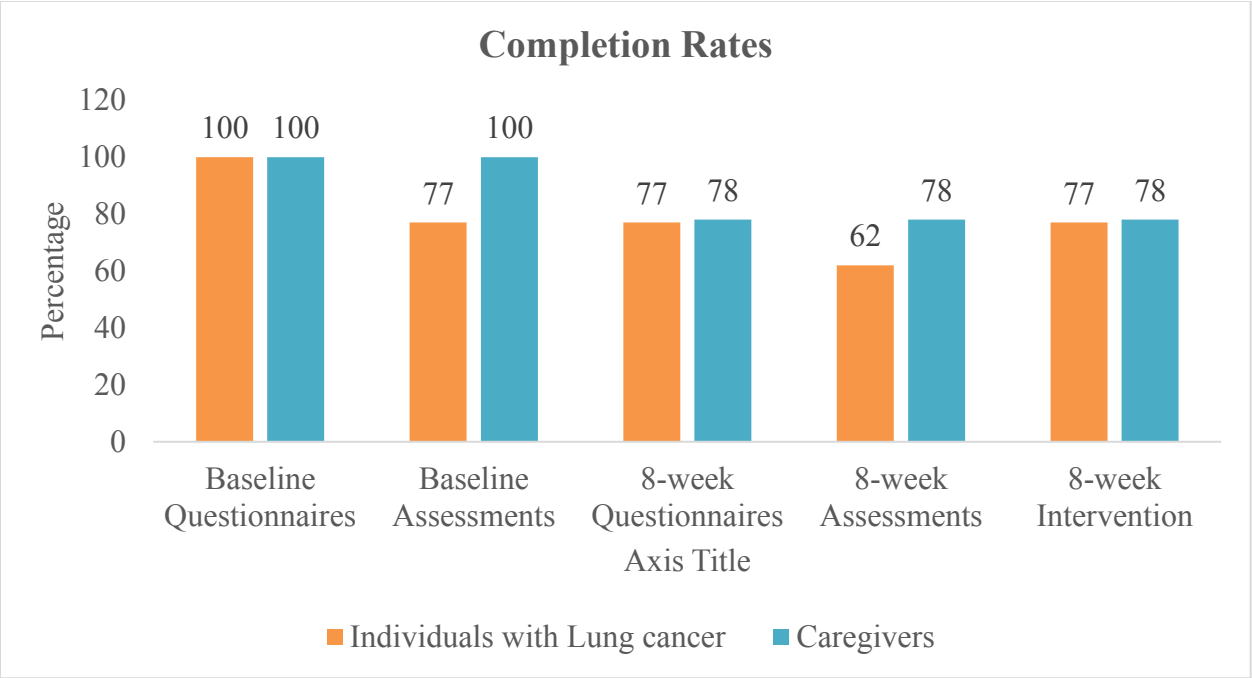


Figure 3: Completion Rates



4.1.4. Adherence to intervention

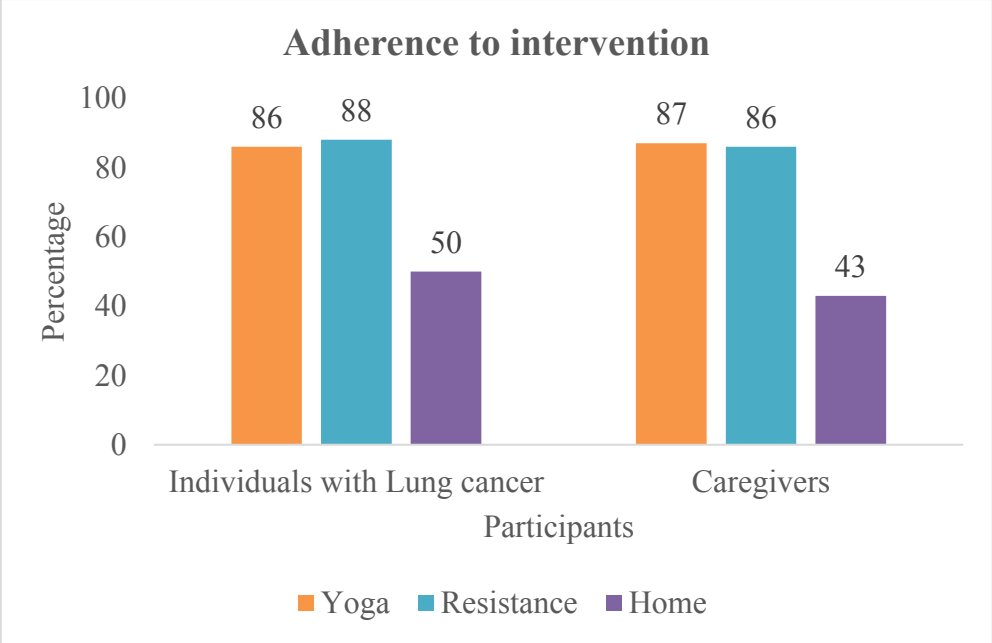
An adherence rate of 86% was achieved for yoga sessions and 88% for resistance exercise sessions with an overall adherence of 87% for individuals with lung cancer (n=12). The adherence for caregivers (n=9) was 87% for yoga and 85% for resistance exercise with an overall adherence of 86%. The total adherence for all participants (n=21) was 87%. (Table 9)

Table 9: Adherence to Intervention

	Yoga		Resistance Exercise		Total	
	Sessions attended	Sessions scheduled	Sessions attended	Sessions scheduled	Sessions attended	Sessions scheduled
Individuals with lung cancer	74	86	75	85	149	171
Caregivers	47	54	53	62	100	116

The adherence to the home exercise protocol was 50% as only five of the 10 individuals with lung cancer completed the home exercise program. Three participants reported exercising at home but did not record sessions in the diary, and two participants reported losing the diary while moving to a new residence. Overall caregiver adherence to the home exercise program was 43% with only three of seven caregivers completing the home exercise component. The total adherence to home exercise was 47% for all the participants combined. (Figure 4)

Figure 4: Adherence to Intervention



4.1.5. Adverse events

One individual with lung cancer experienced severe nausea during a resistance exercise session and had to discontinue exercising. The participant reported that the nausea resulted from not eating prior to the exercise session. The participant was provided with nourishment and

monitored until the nausea subsided. No other adverse events were reported during or following yoga and resistance exercise sessions or with exercise testing.

4.2. Outcomes Evaluating Preliminary Efficacy

4.2.1 Individuals with Lung Cancer: Subjective outcome measures

A significant within-group improvement (p=0.01) was found for the individual's experience of perceived dyspnea/breathlessness as measured on the D-12 questionnaire. Out of the six participants with a higher baseline dyspnea score, three had an average reduction of five points, and one had a reduction of 12 points.

No significant improvement was found in the overall FACT-F scale or for the subscales of physical, social, emotional and functional well-being; however, a significant benefit was found for the fatigue subscale (p=0.02). (Table 10)

Table 10: Mean, Confidence Interval and p-values for Questionnaires for Fatigue, Quality of Life (QoL) and Dyspnea

n=10	Pre-Intervention	Post-Intervention	Paired Differences	95% confidence interval		Paired Sample t-test (2-tailed) p<0.05	Wilcoxon Signed Rank test p<0.05
	Mean ± SD	Mean ± SD	Mean ± SD	Lower	Upper		
Dyspnea (D12)	7.0 ± 6.9	3.6 ± 4.9	3.4 ± 3.7	-6.0	-0.7	0.01*	0.01*
Fatigue (FACIT-F) Total score	120.0 ± 22.0	121.1 ± 21.3	1.1 ± 7.4	-4.2	6.4	0.6	0.6
Physical well-being	22.4 ± 4.0	22.5 ± 4.6	0.1 ± 2.2	-1.5	1.7	0.9	0.6
Social/Family	22.0 ± 4.8	20.9 ± 5.9	1.1 ± 3.4	-3.5	1.3	0.3	0.4

well-being							
Emotional well-being	18.9 ± 2.6	18.3 ± 2.0	0.6 ± 1.9	-1.9	0.7	0.3	0.3
Functional well-being	20.1 ±3.4	18.3 ± 4.6	1.8 ± 3.8	-4.5	0.9	0.2	0.2
Fatigue	36.6 ± 11.5	41.1 ± 8.7	4.5 ± 6.1	0.1	8.9	0.04*	0.02*

*FACIT: Functional assessment of chronic illness therapy; *significant difference at p<0.05*

4.2.2. Individual with Lung Cancer: Objective outcome measures

A significant improvement in the lower limb and upper back muscle strength was found for the one repetition maximum (1RM) test for leg press (p=0.02) and seated row (p=0.03) respectively. Although the improvement in shoulder range of motion for left shoulder flexion was significant (p=0.02), there is no significant improvement for right flexion, or right and left shoulder abduction. The chest expansion (difference of inspiration and expiration) measurement at the level of xiphisternum also showed a significant improvement (p=0.02). No significant improvements were found for the pulmonary function test measurements. (Table 11)

Table 11: Mean, Confidence Interval and p-values for Objective measurements

	Pre-Intervention	**Post-Intervention**	**Paired Differences**	**95% confidence interval**		**Paired sample t-test (2-tailed) p<0.05**	**Wilcoxon Signed Rank test p<0.05**
	Mean ± SD	**Mean ± SD**	**Mean ± SD**	**Lower**	**Upper**		
Chest Expansion (difference) Xiphisternum n=10	3.4 ± 1.1	4.5 ± 1.2	1.1 ± 1.3	0.1	2.0	0.03*	0.03*
1RM bench press	55.0 ± 17.3	59.7 ± 19.8	4.7 ± 7.5	-0.6	10.1	0.08	0.07

n=10							
1RM Seated Row n=10	74.0 ± 31.9	90.0 ± 26.7	16.0 ± 17.1	3.7	28.2	0.02*	0.02*
1RM Leg Press n=8	123.7 ± 44.5	148.1 ± 50.5	24.4 ± 26.0	2.6	46.1	0.03*	0.03*
FEV_1	1.9 ± 0.5	1.9 ± 0.5	0.01 ± 0.1	-0.1	0.05	0.6	0.4
FVC	2.7 ± 0.5	2.7 ± 0.5	0.04 ± 0.15	-0.1	0.1	0.4	0.4
FEV_1/FVC	70.8 ± 11.8	70.9 ± 11.1	0.10 ± 4.3	-3.0	3.2	0.9	0.6
Right Shoulder Flexion n=10	141.6 ± 10.8	143.0 ± 16.5	1.4 ± 11.3	-6.7	9.6	0.7	0.4
Left shoulder flexion n=10	140.0 ± 10.0	146.6 ± 10.4	6.6 ± 7.4	1.3	11.9	0.02*	0.02*
Right shoulder abduction n=10	130.7 ± 22.4	132.1 ± 26.2	1.4 ± 16.4	-10.3	13.2	0.8	0.7
Left shoulder abduction n=10	138.4 ± 17.4	141.2 ± 13.5	2.8 ± 10.8	-5.0	10.5	0.4	0.3

******significant difference at p<0.05*

4.2.3 Caregiver Subjective Outcome Measures

A significant difference was found only for symptoms of fatigue (p=0.04). (Table 12 and 13)

Table 12: Mean, Confidence Interval and p-values for Questionnaires for Quality of Life (QoL) and Fatigue Questionnaires

n=7	Pre-Intervention	Post-Intervention	Paired Differences	95% confidence interval		Paired Sample t-test (2-tailed) p<0.05	Wilcoxon Signed Rank test p<0.05
	Mean ± SD	Mean ± SD	Mean ± SD	Lower	Upper		
CarOnQOL	65.3 ± 27.5	62.6 ± 23.3	2.7 ± 10.8	-12.7	7.3	0.5	0.5
Chalder Fatigue Scale	14.4 ± 5.4	9.8 ± 6.4	-4.6 ± 6.7	-10.8	1.6	0.1	0.04*

*****significant difference at p<0.05; CarOnQOL: Caregiver oncology Quality of Life questionnaire*

4.2.4 Caregiver Objective Outcome Measures

Table 13: Mean, Confidence Interval and p-values for Objective Measurements

n=7	Pre-Intervention	Post-Intervention	Paired Differences	95% confidence interval		Paired sample t-test (2-tailed) p<0.05	Wilcoxon Signed Rank test p<0.05
	Mean ± SD	Mean ± SD	Mean ± SD	Lower	Upper		
1RM Seated Row	117.1 ± 57.1	108.6 ± 57.3	8.6 ± 23.9	-30.7	13.6	0.4	0.5
1RM Bench press	77.8 ± 39.4	74.2 ± 30.0	3.6 ± 16.8	-19.1	11.9	0.6	0.4
1RM Leg Press	132.8 ± 65.9	145.0 ± 38.7	12.1 ± 63.4	-46.5	70.8	0.6	0.7

1RM: One repetition maximum

4.2.5 Additional measurements

A significant difference was noted for inspiration measured at the level of axilla (p=0.01). A significant difference for expiration measurement at the level of xiphisternum was found (p=0.05). Table 14.

Table 14: Additional Measurements for Individuals with Lung Cancer

n=10	Mean ± SD	95% confidence interval		Sig. (2-tailed) p<0.05	Wilcoxon Signed Rank test p<0.05
		Lower	Upper		
Chest Expansion (difference)					
Axilla	0.9 ± 2.1	-0.5	2.5	0.2	0.3
Nipple	0.7 ± 4.3	-3.8	2.4	0.7	0.2
Inspiration					
Axilla	1.4 ± 1.4	0.4	2.4	0.01*	0.01*
Nipple	1.6 ± 9.4	-8.3	5.1	0.6	0.2
Xiphisternum	0.5 ± 2.0	-1.9	0.9	0.5	0.7
Expiration					
Axilla	0.4 ± 2.1	-1.0	1.9	0.5	0.2
Nipple	0.9 ± 5.2	-4.6	2.8	0.6	0.4
Xiphisternum	1.5 ± 2.6	-3.4	0.3	0.1	0.05*

* *Significant difference at p<0.05*

4.3 Post-Study Survey and Interviews

Results from the focus group interview session are presented below.

4.3.1 Participant Feedback Survey

Nine individuals with lung cancer completed the feedback survey. All participants reported that the program was very beneficial or quite a bit beneficial overall. Seven out of the nine individuals with lung cancer reported enjoying the ASSURE program and perceived that continuing exercise would be "very much" beneficial for them. Even though a majority reported they felt "very much" or "quite a bit" motivated to continue exercising, half of them felt that it would be quite difficult to continue exercising. Seven of them felt "very much" or "quite" confident to exercise on their own. For the majority of participants (67%-89%), tasks like completing the assessments and questionnaires, attending yoga and resistance sessions were reported as "not difficult" or "a little difficult".

Six of the seven caregivers participated in the optional feedback survey. Five caregivers reported that overall the ASSURE program was of "very much" benefit to them and six reported that it was of "very much" benefit to the lung cancer survivor. All the caregivers reported they were either "very much" or "quite a bit" motivated to continue exercising. Moreover, all reported that continuing exercise would be of "very much" benefit to them.

4.3.2 Benefits of Therapeutic Yoga and Resistance Exercise

The information collected from the focus group on various benefits perceived by individuals with lung cancer and their caregivers is displayed in Table 15 and Table 16 and summarized in Figure 5 and 6 respectively.

Table 15: Benefits of the Intervention perceived by Individuals with Lung Cancer

Benefits for Individuals with Lung Cancer	**Yoga Only**	**Resistance Exercise Only**	**Benefits Reported from both Interventions**

Symptoms	• Relaxation • Improved focus and concentration	• Reduced fatigue • Improved mood • Improved sleep	• Improved breathing • Increased energy
Exercise-Related Self-Confidence and Motivation	• Success with initial yoga sessions provided ongoing motivation	• Developed increased confidence and motivation to exercise	• Learning correct form and technique of exercise
Fitness Benefits	• Improved flexibility	• Improved range of motion • Increased muscle strength • Improved balance	

Table 16: Benefits of the intervention perceived by the Caregivers

Benefits for Caregivers	**Yoga**	**Resistance Exercise**	**Both**
Symptoms	• Relaxation/feeling calm and grounded • Improved breathing • Improved concentration	• Improved memory	• Improved energy • Improved focus • Stress relief
Confidence and Motivation	• Improved body awareness	• Good base exercise to improve confidence • Increased determination to exercise	
Fitness Benefits	• Improved flexibility	• Increased strength • Improved endurance • Improved cardiopulmonary function • Improved posture	

Figure 5: Benefits of the Intervention perceived by Individuals with Lung Cancer

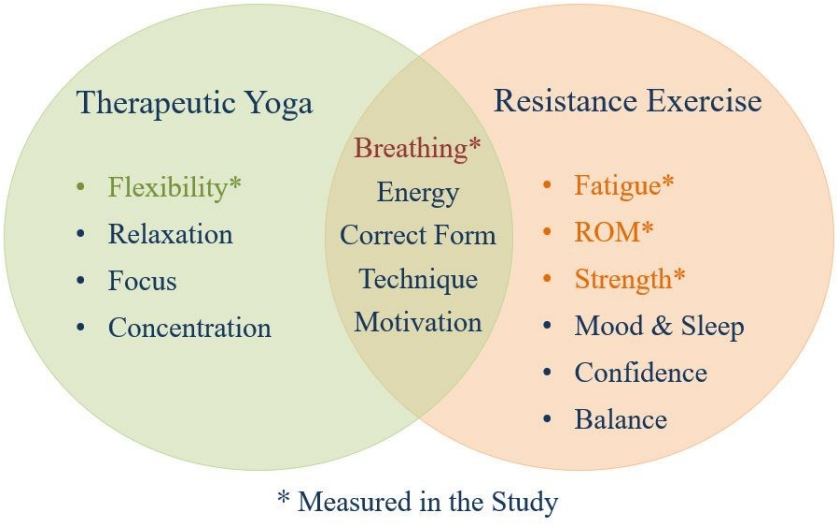
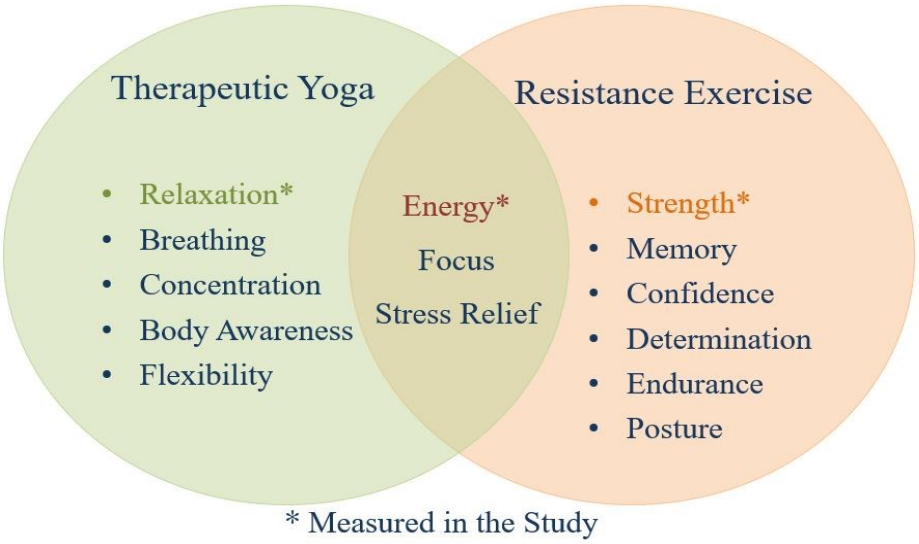


Figure 6: Benefits of the Intervention perceived by the Caregivers



4.3.3 Barriers and Facilitators

The barriers and facilitators for yoga, resistance exercise and home exercise program as perceived by the individuals with lung cancer and their caregivers are provided in Tables 17, 18 and 19:

Table 17: Barriers and Facilitators for Yoga and Resistance Exercise for individuals with lung cancer

Barrier	Facilitator
• Age • Side effects: fatigue and feeling unwell • Distance from home • Time involved to complete the exercise session	• Exercising with other lung cancer participants • Support from caregivers • Instructor: guidance, monitoring and correction of exercise performance, and positive and encouraging approach. • Scheduled sessions: commitment to attend • Environment: safe, fun and family orientated • Accessible: paid parking • Programming: focus on breathing, personalized and paced exercise program.

Table 18: Barriers and Facilitators for Yoga and Resistance exercise for caregivers

Barriers	Facilitators
• Lung cancer participant illness • Lung cancer participant symptoms • Caregiver's time constraint (taking time off work) • Travel time to the facility	• Motivation to help family/ friend with lung cancer. • Environment: welcoming, inclusive, positive and supportive instructors • Accessibility: parking pass, accessible location to transit • Group Setting • Programming components: instructor knowledge of cancer, personalized program, progression and modifications to exercise, correction for yoga postures and resistance exercise performance

Table 19: Barriers and Facilitators to home exercise for individuals with lung cancer

Barriers	Facilitators

Low motivation to complete home program: • Lack of discipline: no one around to encourage completion • Time: other competing tasks needed to get done, busy schedule • Fatigue • Other competing exercises: preference to walk outside	• Adding exercises to existing home exercise

4.3.4 Participant Informed Future Directions for Research

The suggestions for future directions obtained by the consensus of participants from the focus group are represented in Table 20.

Table 20: Participant Informed Future Directions

Individuals with Lung Cancer	Caregivers
• Starting program sooner after the surgery • Having individual goals at the start of the program • Need for an ongoing / longer duration program • Providing results after the completion of measurements • Partner: adding a support person/ patient partner for those who do not have a caregiver. • Incorporate a nutrition/dietary component with the intervention	• Better promotion/awareness about the program among health care providers • Consider other forms of exercise: e.g. tai chi, aquatic therapy/ swimming • Incorporate programming into care including continuation after cancer treatment (survivorship) • Adding support person volunteer for participants who do not have a caregiver • Extension of program to community locations for improved accessibility • An individualized home exercise program that focuses on the participant's weakness/ area of need

CHAPTER 5: DISCUSSION

This ASSURE pilot study demonstrated that a combined intervention of therapeutic yoga and resistance exercise in a dyadic population is safe and feasible.

5.1 Hypothesis related findings

5.1.1 Hypothesis related to feasibility

A combined intervention of therapeutic yoga and resistance exercise will be feasible and safe for individuals with lung cancer and their caregiver.

The recruitment, adherence and completion rates obtained in the 8-week combined intervention of therapeutic yoga and resistance exercise support the feasibility and safety of resistance exercise and yoga program for individuals with lung cancer and their caregivers. Although a majority of the participants had never taken part in a yoga class or performed resistance exercise; the adherence rates for the intervention were high. Feedback obtained from the focus group suggest that the high adherence was due to the therapeutic yoga approach that used modified postures in sitting or lying on the plinth, and the focus on breathing. The resistance exercise sessions also demonstrated high adherence with a low to moderate intensity exercise approach and modifications made to address symptoms of dyspnea and fatigue. Moreover, various options were available depending on the individual's own strength levels to either use dumbbells, resistance bands or machines to target the specific muscle groups. There were no adverse events while performing the pre and post-intervention testing, yoga and resistance exercises. The lack of adverse events may be due to the screening protocol and monitoring of vital signs prior to sessions.

Moreover, participants were asked to rate their perceived rate of exertion on a modified Borg scale after exercise and were monitored for any abnormal physiological response to exercise.

Initially the eligibility criteria for the ASSURE study was set to include lung cancer individuals with Stage I-III; however, eligibility was expanded to include Stage IV as these patients were subsequently deemed most in need of the intervention. This resulted in a faster recruitment rate. Unfortunately, as the investigators were not present in oncology clinics, data were not collected on the total number of patients seen by the oncologist to inform the eligibility rate. We also did not collect information on the number of survivors taking brochures at the Wellspring location who did not subsequently contact us or participate in the program.

Even though previous studies have demonstrated feasibility for different exercise interventions in various settings[11,24,30,68,69], the ASSURE study is the first to demonstrate feasibility for a combined intervention not only for lung cancer individuals but also for their caregivers. Moreover, past exercise studies have included primarily NSCLC patients. The ASSURE study included individuals with both NSCLC and SCLC, and all stages of lung cancer, with a majority of the sample having advanced stage cancer.

In contrast, previous studies examining yoga as an intervention for lung cancer survivors had recruitment rates ranging from 54% to 74%, and completion rates ranging from 60% to 78%. Moreover, previous exercise studies have reported low recruitment of lung cancer participants ranging from 47% to 77%[45,46,48], and with varying completion rates and adherence rates ranging from 25% to 100% and 73% to 85% respectively.[45,46,48,49,54,68–72]

Consistent with a recent systematic review that concluded that targeted exercise interventions in clinical practice are feasible and safe for advanced cancer[73], we observed only one

minor adverse event (nausea) in the present study. Of note, only one previous study involving a yoga intervention reported having no adverse events in their study.[11,24,30]

5.1.2 Hypothesis related to the preliminary efficacy of outcomes for individuals with lung cancer

A combined intervention of yoga and resistance exercise will show promise in reducing symptoms of dyspnea and fatigue, improve chest expansion, shoulder range of motion, muscular strength, and lung volumes and capacities in individuals with lung cancer.

Dyspnea

A significant difference ($p=0.01$) was found for reported dyspnea for individuals with lung cancer indicating a reduction of self-perceived breathlessness. The improvement could be due to several factors that resulted in increased confidence that exercise would not exacerbate dyspnea such as the focus on breathing and breathing technique, paced exercise under supervision, and the meditation component during yoga classes that promoted relaxation. This suggests that an 8-week intervention twice a week may be of sufficient duration to improve dyspnea, however, due to a lack of follow-up measures, the long-term effects of the intervention on dyspnea could not be determined. While participants with early-stage lung cancer either did not experience dyspnea or experienced only mild dyspnea on exertion, participants with advanced stage cancer experienced larger improvements symptoms of dyspnea, especially related to the distress associated with dyspnea.

Out of three prior studies with a yoga intervention conducted for lung cancer individuals; only one study[11] measured dyspnea on a visual analog scale. To date, there has not been a single study looking at the subjective change in dyspnea after a yoga intervention. The ASSURE study

is unique in its inclusion of a subjective measure of dyspnea. As the dyspnea-12 is a short questionnaire with 12 questions, it could be used clinically to measure changes in dyspnea before and after an exercise session or to measure changes over a period of time. Moreover, as the questionnaire describes the severity of dyspnea based on its physical and emotional components, the scale captures more information than a simple visual analog scale.

Out of the five prior studies that examined the effects of a combination of resistance exercise with breathing and/ or an inspiratory muscle training component; only Brocki et al., Henke et al., and Huang et al., measured dyspnea either during the intervention or before and after the intervention. Huang et al. measured the changes in dyspnea scores using a Borg Dyspnea Index while performing six-minute walk distance as well as the dyspnea score before and after the intervention using an EORTC-QLQ-C30 questionnaire. Huang et al., performed a three-arm RCT comparing a group of individuals with NSCLC receiving one week of high intensity combined inspiratory muscle training and resistance exercise; with a group performing inspiratory muscle training alone. No differences in dyspnea scores were found between the groups.[47] The lack of significance could be due to a shorter duration (one week) and higher intensity of intervention compared to the present study. In addition, as Huang et al. recruited early stage NSCLC prior to surgery, thus any dyspnea experienced may not have been of adequate severity to observe differences from the interventions. The findings of the ASSURE study are consistent with three other surgical studies reported in a meta-analysis by Ni et al., where a significant benefit was found from exercise for dyspnea.[40] The analyses aimed to determine the benefits of exercise intervention before and after lung resection for individuals with NSCLC. The three studies in the meta-analysis had a mean difference of -14.3 in dyspnea score (95% confidence interval=-20.03,-8.58) as

reported on the European Organization for Research and Treatment of Cancer Core Quality of Life Questionnaire (EORTC-QLQ-C30.[40]

The ASSURE study did not measure any outcomes related to exercise capacity such as six-minute walk distance (6MWD) as we were concerned that the test may aggravate symptoms for participants suffering from severe dyspnea on exertion. However, a number of previous reviews have summarized the studies measuring exercise capacity using a 6MWD test.[14,16,40,43,44] It is important to note that all the reviews included only NSCLC individuals whose cancer was resectable surgically. One review summarized 23 trials on feasibility and safety of exercise interventions for different advanced cancers; out of which only one trial measured 6MWD test for advanced lung cancer.[72] Therefore, while conducting tests for exercise capacity in early-stage lung cancer individuals with no or only mild dyspnea may be feasible, little is known about the feasibility of the test in individuals with advanced lung cancer who may present with more symptom burden.

Future studies should: 1) consider including participants based on the presence of dyspnea, 2) conduct a longer follow up period, and 3) assess dyspnea at time points during the intervention period. Screening the individuals with lung cancer using a dyspnea questionnaire and recruiting only those individuals reporting moderate to severe dyspnea should be considered.

Fatigue and Quality of life

The ASSURE study found no significant changes in overall QoL for lung cancer individuals. A recent systematic review of pre- and post-surgically treated NSCLC patients, reported improved HRQOL among four studies after exercise training.[40] Another systematic review reported no significant difference from three RCTs for HRQOL for surgically resected NSCLC survivors.[43] In contrast, Fouladbakhsh et al. showed significant improvement in physical

and mental subscales for QoL scores (SF-36) of NSCLC survivors (Stage I-III) after a yoga intervention.[11] The improvement could be explained by the high adherence obtained to home yoga practice in conjunction with once a week supervised yoga sessions (eight-week). Milbury et al. demonstrated improved mental health aspects of QOL as measured on the SF-36 questionnaire.[24] In the study, the yoga intervention was carried out two to three times/week over the course of five to six weeks during radiation therapy for Stage III NSCLC patients. In contrast, a similar study conducted by the same author[30] with early-stage NSCLC did not demonstrate a significant improvement in QoL scores. Thus, benefit from this type of combined intervention may be better realized by those with advanced stage lung cancer.

A significant benefit was found in the ASSURE study for the fatigue subscale of the FACT-F (Wilcoxon rank sum: $p=0.02$ and paired sample t-test $p=0.04$). A systematic review[19] summarizing studies measuring cancer-related fatigue as an outcome after an exercise intervention for individuals with lung cancer reported that only three out of ten studies showed a significant reduction in fatigue. In the review, however, the included studies generally had small sample sizes and, similar to the present study, were lacking a control or comparison group. Of note, seven studies from the review concluded that exercise was feasible, safe and beneficial for lung cancer-related fatigue.[19]

Lung volumes and capacity/ pulmonary function test

Contrary to the findings of the ASSURE study, Milbury et al.[30] found a significant difference in FEV_1 ($p=0.001$) and FVC ($p=0.03$) after a viniyoga intervention (eight-week, 45 min class/once every week). In the study, spirometry was performed weekly for 14 weeks, at three months and six months. Moreover, the self-reported dyspnea scores measured on a numeric rating scale either remained the same or decreased for some individuals. It is important to note that

Milbury et al. recruited only NSCLC patients with stage I-III, thus excluding those with advanced stage cancer.[30] For the ASSURE study, more than 50% participants had advanced stage lung cancer. Some participants from the ASSURE study were reluctant to perform spirometry, reporting the testing as strenuous, causing discomfort or aggravating their cough. A significant increase in FVC was noted in an RCT after a four-week intervention of combination of resistance, endurance and inspiratory muscle training.[48] Thus, the addition of inspiratory muscle retraining may be needed to achieve an improvement in FEV_1 and FVC.

Muscle Strength:

The key finding of the ASSURE study is that a significant change in muscle strength was achieved for lung cancer survivors with only a single, low-intensity session of resistance exercise per week. Given that yoga practice incorporates postures to strengthen muscles of upper and lower extremity, the volume of training with the combined intervention may have been adequate to induce positive changes in muscle strength. Taking into consideration the symptoms of dyspnea and fatigue experienced by individuals with lung cancer, especially those diagnosed with advanced stage cancer, a higher intensity program may not have been feasible and may have resulted in additional symptom burden. Thus, a lower intensity exercise program performed consistently twice a week may be sufficient to induce an improvement in muscle strength over an eight-week intervention.

The participant adherence rate of 87% to the intervention is another factor that may explain the gains in muscle strength. A previous study by Edvardsen et al. comprising early-stage lung cancer survivors also found significant improvement in muscle strength with a prescription that involved high-intensity endurance and strength training.[71] Another study by Temel et al. included individuals with advanced stage lung cancer who were also prescribed higher intensities of

exercise; however, the study reported a high dropout rate, lower adherence and lower completion rates.[72] Thus, advanced lung cancer survivors may be better served by exercise that is of lower intensity. Although differences exist in intervention variables, similar findings of improvement in muscle strength have been demonstrated in other studies.[46,54,71]

Chest Expansion:

The improvement in chest expansion seen at the level of xiphisternum suggests that participants better chest mobility that may have allowed for improvements in breathing. This finding could be due to learning the proper technique of breathing and use of the diaphragm to breath instead of using accessory muscles of respiration. As lung cancer survivors may avoid chest expansion during respiration due to pain from surgery, it is important to focus attention on restoring chest mobility to improve breathing. This, in turn, may help reduce dyspnea. Further research is needed to explain the possible mechanisms associated with, and the efficacy of interventions to improve chest expansion.

In the ASSURE study, the stage of lung cancer at diagnosis largely influenced the participants' dyspnea and fatigue scores, as well their physical fitness outcomes. The individuals with advanced cancer in the study reported higher levels of dyspnea and fatigue, and were generally less active and more deconditioned at baseline when compared to participants diagnosed with earlier stage disease. A study by Yennurajalingam et al. also found that higher levels of dyspnea were associated with higher levels of fatigue in individuals with advanced lung cancer.[8] The participants with advanced cancer in ASSURE experienced significant reductions in their symptoms of dyspnea and fatigue with a mild to moderate intensity intervention. The mild to moderate intensity of the intervention, however, may not have been adequately challenging for participants who had earlier stage disease and were generally more fit at baseline.

5.1.3 Hypothesis related to the preliminary efficacy of outcomes for caregivers

A combined intervention of yoga and resistance exercise will show promise in improving the QoL, muscular strength and reduce fatigue of caregivers of individuals with lung cancer.

The ASSURE study is one of only a few studies that involved caregiver participation in exercise along with the lung cancer survivor. It is notable that other studies including caregivers used the same outcome measures for both individuals with lung cancer and caregivers.[24,30] The ASSURE study used scales/questionnaires that were more specific to caregivers.

Caregiver oncology QOL questionnaire:

We used a questionnaire specifically designed to measure QoL for caregivers of an oncology population. Although, no significant changes in the QoL of caregivers was observed, , this finding could be due to the small sample size and short duration of the intervention. Also, our sample of caregivers was heterogeneous in terms of caregiver roles, with spouses, friends and other family members taking part in the study. Therefore, many aspects of the questionnaire such as feeling lack of freedom, having financial difficulties, bothered by the feeling of being confined, having a satisfied love life; were not appropriate for all caregivers (non-immediate caregivers or friends). Many of the caregivers (n=5) did not live with the individual with lung cancer. Hence their caregiving role differed from that of caregivers (spouses) living with the survivor (n=4). Moreover, as two caregivers (spouse) living with the individual with lung cancer, dropped out from the study, we only obtained quality of life data on two caregivers post-intervention.

Chalder Fatigue scale:

A significant reduction in caregiver's fatigue was demonstrated by the Wilcoxon Rank Sum test. Caregivers also reported benefits for fatigue in the focus group session, and acute improvements in energy levels both after the yoga class and the resistance exercise sessions. At

present, the lack of literature addressing fatigue, its effects and management strategies for caregivers of individuals with lung cancer; makes it difficult to make any comparisons.

Muscle Strength:

Even though no significant differences in muscle strength were seen after the eight-week intervention for the caregivers, the results from focus group session revealed that the caregivers perceived improvements in their strength. Thus, the mild to moderate intensity of intervention may not have been adequate to induce physiological overload necessary to realize strength benefits. A longer duration and higher intensity exercise prescription may have been needed to realize measurable increases in muscle strength.

5.2 Findings from focus group

5.2.1 Individuals with lung cancer

The findings from the study are reflected by the benefits shared by the individuals with lung cancer at the focus group session. The survivors' perception of improved breathing and energy, and reported benefit of learning the correct breathing technique while exercising, support the reported findings of reduced dyspnea. Participants perceived that yoga resulted in relaxation, while resistance exercise helped to reduce symptoms of fatigue. It can be inferred that the significant findings of this study could be due to a combined effect of the therapeutic yoga and resistance exercise.

Various barriers and facilitators identified by the participants in the present study are similar to those found in a previous systematic review of qualitative and quantitative studies.[31] Similar to the present study, fatigue was the most common barrier to exercise reported in the systematic review. The findings from the review showed that caregivers and relatives provided motivation and encouragement to survivors in the majority of cases.[31] Participating in exercise

with a caregiver was identified as a major facilitator in the present study, both for the individuals with lung cancer and their caregivers. Various facilitators noted in the systematic review such as supervised, moderate intensity exercise with a focus on symptom management, and individualized adaptations were also components of the present study.

5.2.2 Caregivers

The significant findings from the fatigue scale can be related to caregiver's perception of improved energy, focus and reduced stress from both yoga and resistance exercise. A greater benefit for symptoms such as relaxation, improved breathing and concentration were noted after yoga; while the greater benefit for fitness such as improved strength, cardiovascular endurance, body posture and strength were noted after the resistance exercise. The various facilitators noted by caregivers, especially those related to exercise motivation should be taken into consideration when developing future programming for both individuals with lung cancer and their caregivers.

5.3 Limitations

In the ASSURE focus group session, individuals with lung cancer reported improvements in sleep from the intervention; however, was that sleep was not an outcome formally measured in the study. Previous studies with yoga and home-based interventions have measured sleep-related outcomes for individuals with lung cancer or both those with cancer and their caregivers.[11,24,30,70] These studies have demonstrated significant improvements in sleep quality, reduction in sleep disturbance and reduced use of sleep medication. Moreover, a recent review of studies using yoga for cancer-related toxicities showed that seven out of 10 clinical trials reported significant benefits for sleep.[56] Thus, future trials should consider the inclusion of sleep-related outcomes.

5.4 Sample Size Calculation for Future Trial

Based on the point estimates and measures of variability found for the primary outcome of self-reported dyspnea, a future randomized controlled trial would require approximately 23 subjects per group. Assuming a similar completion rate of 77% and a drop-out rate of 20%, an additional 11 participants would be required for a total sample of 114 consisting of 57 individuals with lung cancer and 57 caregivers.

5.5 Summary and Future Directions

A low to moderate intensity combined yoga and resistance exercise intervention is feasible and shows preliminary benefit for individuals with lung cancer and their caregivers. Future studies with a multicenter randomized control design are required to examine the efficacy of the combined yoga and resistance exercise approach.

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APPENDIX

A. Study Brochure

B. Par-Q + Screening Form

C. Karnofsky Performance Status Scale

D. Yoga Intervention

E. Resistance Exercise Intervention

F. Home Exercise Sheet

G. Home Exercise Diary

H. Dyspnoea-12 (D-12) Questionnaire

I. Functional Assessment of Cancer Therapy-Fatigue (Fact-F)

J. Caregiver Oncology Quality of Life Questionnaire (CarGOQOL)

K. Chalder Fatigue Scale

L. Contraindications and Precautions to Exercise Testing and Training

M. Health Research Ethics Board of Alberta (HREBA) Approval

N. Participant Consent Form

O. Focus Group Ethics Approval

P. Focus Group Participant Consent Form

Q. Patient Satisfaction Survey for Individuals with Lung Cancer

R. Patient Satisfaction Survey for Caregiver

S. Focus Group Questions

Appendix A: Study Brochure

How to get to Corbett Hall?

Contact Us:

Cancer Rehabilitation clinic

Telephone: 780-492-6007
Email: frmace@ualberta.ca

Q & A:

How long will I be involved in the program?

You may be in this study for as long as 10 weeks, including the 8-week exercise intervention.

How long will each testing session take?

The testing sessions will take up to 90 minutes to complete.

How many people will take part in the study?

Approximately 20 participants will take part in the study. This will include 10 or more individuals with lung cancer and their caregivers.

Where will the study take place?

The study is taking place in the Cancer Rehabilitation Clinic in Corbett Hall at the University of Alberta: 8205 114th Street, Edmonton.

Yoga and Resistance Exercise for Individuals with Lung Cancer and their Caregivers

ASSURE

INVESTIGATORS:

Principal Investigator:
Dr. Margie McNeely, PhD
Co-Investigators:
Ms. Shreya Rewar, Graduate student.
Dr. Jill Turner, PhD
Dr. Mark Hall, PhD
Dr. Anil Abraham Joy, Medical Oncologist

What does the study involve?

In this study, you and your caregiver will take part in an exercise program involving two different types of exercise training each week.

Each session will start with a gentle warm-up and finish with a cool-down.

The first exercise session of the week will involve resistance exercise training including exercises performed on weight machine, using dumbbells or elastic bands. The chosen exercises will depend on your strength, fitness level and symptoms.

The second exercise session will involve therapeutic yoga that will include a focus on breathing, meditation, and gentle yoga postures and stretches. We will also teach techniques to help you manage shortness of breath when exercising or carrying out day-to-day activities.

A gap of at least one day will be given for rest between the two exercise sessions.

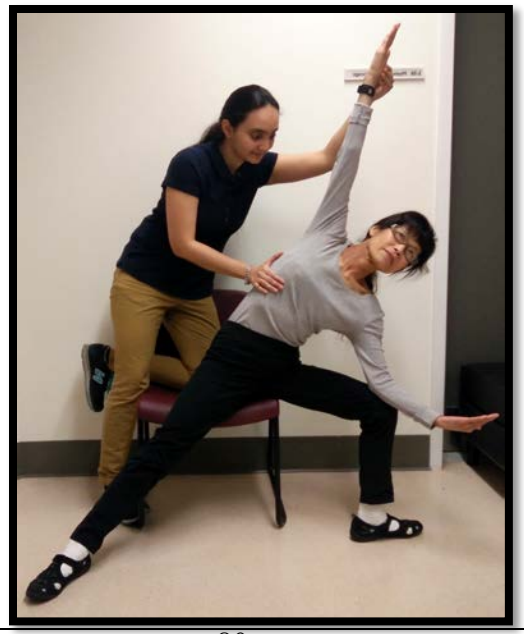
The program will be 8 weeks long. You will be provided with an exercise sheet for light strengthening exercises and gentle yoga to practice at home on at least one additional day of the week.

Who is eligible for the study?

- Individuals diagnosed with any type of primary lung cancer stage I-IV, at any time point during treatment, ≥ 18 years of age, and life expectancy one year or greater.
- A caregiver of the individual with lung cancer can join the study as long as they do not have any serious or uncontrolled health issues.

What are my responsibilities?

- Lung cancer survivors complete all the fitness assessments and study questionnaires and attend sessions; the caregiver completes strength assessment, fatigue, and quality of life questionnaire.



What will my participation involve?

The individual with lung cancer and their caregiver will be required to complete the following:

- Tests to measure your strength, chest expansion, lung volumes, and shoulder range of motion.
- Questionnaires to measure shortness of breath, fatigue, and quality of life.

The testing will be performed before starting of the exercise program and at 8-weeks, after completion of the program.

Parking costs will be covered for all testing and exercise sessions.

Appendix B: PAR-Q+ Screening Form

The Physical Activity Readiness Questionnaire for Everyone

Regular physical activity is fun and healthy, and more people should become more physically active every day of the week. Being more physically active is very safe for MOST people. This questionnaire will tell you whether it is necessary for you to seek further advice from your doctor OR a qualified exercise professional before becoming more physically active.

SECTION 1 - GENERAL HEALTH

	Please read the 7 questions below carefully and answer each one honestly: check YES or NO.	YES	NO
1.	Has your doctor ever said that you have a heart condition OR high blood pressure?	☐	☐
2.	Do you feel pain in your chest at rest, during your daily activities of living, OR when you do physical activity?	☐	☐
3.	Do you lose balance because of dizziness OR have you lost consciousness in the last 12 months? Please answer NO if your dizziness was associated with over-breathing (including during vigorous exercise).	☐	☐
4.	Have you ever been diagnosed with another chronic medical condition (other than heart disease or high blood pressure)?	☐	☐
5.	Are you currently taking prescribed medications for a chronic medical condition?	☐	☐
6.	Do you have a bone or joint problem that could be made worse by becoming more physically active? Please answer NO if you had a joint problem in the past, but it does not limit your current ability to be physically active. For example, knee, ankle, shoulder or other.	☐	☐
7.	Has your doctor ever said that you should only do medically supervised physical activity?	☐	☐

If you answered NO to all of the questions above, you are cleared for physical activity.

Go to Section 3 to sign the form. You do not need to complete Section 2.

- Start becoming much more physically active – start slowly and build up gradually.
- Follow the Canadian Physical Activity Guidelines for your age (www.csep.ca/guidelines).
- You may take part in a health and fitness appraisal.
- If you have any further questions, contact a qualified exercise professional such as a CSEP Certified Exercise Physiologist® (CSEP-CEP) or CSEP Certified Personal Trainer® (CSEP-CPT).
- If you are over the age of 45 yrs. and NOT accustomed to regular vigorous physical activity, please consult a qualified exercise professional (CSEP-CEP) before engaging in maximal effort exercise.

If you answered YES to one or more of the questions above, please GO TO SECTION 2.

Delay becoming more active if:

- You are not feeling well because of a temporary illness such as a cold or fever – wait until you feel better
- You are pregnant – talk to your health care practitioner, your physician, a qualified exercise professional, and/or complete the PARmed-X for Pregnancy before becoming more physically active OR
- Your health changes – please answer the questions on Section 2 of this document and/or talk to your doctor or qualified exercise professional (CSEP-CEP or CSEP-CPT) before continuing with any physical activity programme.

SECTION 2 - CHRONIC MEDICAL CONDITIONS

	Please read the questions below carefully and answer each one honestly: check YES or NO.	YES	NO
1.	Do you have Arthritis, Osteoporosis, or Back Problems?	☐ If yes, answer questions 1a-1c	☐ If no, go to question 2
1a.	Do you have difficulty controlling your condition with medications or other physician-prescribed therapies? (Answer NO if you are not currently taking medications or other treatments)	☐	☐
1b.	Do you have joint problems causing pain, a recent fracture or fracture caused by osteoporosis or cancer, displaced vertebra (e.g., spondylolisthesis), and/ or spondylolysis/pars defect (a crack in the bony ring on the back of the spinal column)?	☐	☐
1c.	Have you had steroid injections or taken steroid tablets regularly for more than 3 months?	☐	☐
2.	Do you have Cancer of any kind?	☐ If yes, answer questions 2a-2b	☐ If no, go to question 3
2a.	Does your cancer diagnosis include any of the following types: lung/bronchogenic, multiple myeloma (cancer of plasma cells), head, and neck?	☐	☐
2b.	Are you currently receiving cancer therapy (such as chemotherapy or radiotherapy)?	☐	☐
3.	Do you have Heart Disease or Cardiovascular Disease? This includes Coronary Artery Disease, High Blood Pressure, Heart Failure, Diagnosed Abnormality of Heart Rhythm	☐ If yes, answer questions 3a-3e	☐ If no, go to question 4
3a.	Do you have difficulty controlling your condition with medications or other physician-prescribed therapies? (Answer NO if you are not currently taking medications or other treatments)	☐	☐
3b.	Do you have an irregular heart beat that requires medical management? (e.g. atrial brillation, premature ventricular contraction)	☐	☐
3c.	Do you have chronic heart failure?	☐	☐
3d.	Do you have a resting blood pressure equal to or greater than 160/90 mmHg with or without medication? (Answer YES if you do not know your resting blood pressure)	☐	☐
3e.	Do you have diagnosed coronary artery (cardiovascular) disease and have not participated in regular physical activity in the last 2 months?	☐	☐
4.	Do you have any Metabolic Conditions? This includes Type 1 Diabetes, Type 2 Diabetes, Pre-Diabetes	☐ If yes, answer questions 4a-4c	☐ If no, go to question 5
4a.	Is your blood sugar often above 13.0 mmol/L? (Answer YES if you are not sure)	☐	☐
4b.	Do you have any signs or symptoms of diabetes complications such as heart or vascular disease and/or complications affecting your eyes, kidneys, and the sensation in your toes and feet?	☐	☐
4c.	Do you have other metabolic conditions (such as thyroid disorders, pregnancy-related diabetes, chronic kidney disease, liver problems)?	☐	☐
5.	Do you have any Mental Health Problems or Learning Difficulties? This includes Alzheimer's, Dementia, Depression, Anxiety Disorder, Eating Disorder, Psychotic Disorder, Intellectual Disability, Down Syndrome)	☐ If yes, answer questions 5a-5b	☐ If no, go to question 6
5a.	Do you have difficulty controlling your condition with medications or other physician-prescribed therapies? (Answer NO if you are not currently taking medications or other treatments)	☐	☐
5b.	Do you also have back problems affecting nerves or muscles?	☐	☐

Please read the questions below carefully and answer each one honestly: check YES or NO.			YES	NO
6.	Do you have a Respiratory Disease? This includes Chronic Obstructive Pulmonary Disease, Asthma, Pulmonary High Blood Pressure		☐ If yes, answer questions 6a-6d	☐ If no, go to question 7
	6a.	Do you have difficulty controlling your condition with medications or other physician-prescribed therapies? (Answer NO if you are not currently taking medications or other treatments)	☐	☐
	6b.	Has your doctor ever said your blood oxygen level is low at rest or during exercise and/or that you require supplemental oxygen therapy?	☐	☐
	6c.	If asthmatic, do you currently have symptoms of chest tightness, wheezing, laboured breathing, consistent cough (more than 2 days/week), or have you used your rescue medication more than twice in the last week?	☐	☐
	6d.	Has your doctor ever said you have high blood pressure in the blood vessels of your lungs?	☐	☐
7.	Do you have a Spinal Cord Injury? This includes Tetraplegia and Paraplegia		☐ If yes, answer questions 7a-7c	☐ If no, go to question 8
	7a.	Do you have difficulty controlling your condition with medications or other physician-prescribed therapies? (Answer NO if you are not currently taking medications or other treatments)	☐	☐
	7b.	Do you commonly exhibit low resting blood pressure significant enough to cause dizziness, light-headedness, and/or fainting?	☐	☐
	7c.	Has your physician indicated that you exhibit sudden bouts of high blood pressure (known as Autonomic Dysreflexia)?	☐	☐
8.	Have you had a Stroke? This includes Transient Ischemic Attack (TIA) or Cerebrovascular Event		☐ If yes, answer questions 8a-c	☐ If no, go to question 9
	8a.	Do you have difficulty controlling your condition with medications or other physician-prescribed therapies? (Answer NO if you are not currently taking medications or other treatments)	☐	☐
	8b.	Do you have any impairment in walking or mobility?	☐	☐
	8c.	Have you experienced a stroke or impairment in nerves or muscles in the past 6 months?	☐	☐
9.	Do you have any other medical condition not listed above or do you live with two chronic conditions?		☐ If yes, answer questions 9a-c	☐ If no, read the advice on page 4
	9a.	Have you experienced a blackout, fainted, or lost consciousness as a result of a head injury within the last 12 months OR have you had a diagnosed concussion within the last 12 months?	☐	☐
	9b.	Do you have a medical condition that is not listed (such as epilepsy, neurological conditions, kidney problems)?	☐	☐
	9c.	Do you currently live with two chronic conditions?	☐	☐

Please proceed to Page 4 for recommendations for your current medical condition and sign this document.

If you answered NO to all of the follow-up questions about your medical condition, you are ready to become more physically active:

- It is advised that you consult a qualified exercise professional (e.g., a CSEP-CEP or CSEP-CPT) to help you develop a safe and effective physical activity plan to meet your health needs.
- You are encouraged to start slowly and build up gradually – 20-60 min. of low- to moderate-intensity exercise, 3-5 days per week including aerobic and muscle strengthening exercises.
- As you progress, you should aim to accumulate 150 minutes or more of moderate-intensity physical activity per week.
- If you are over the age of 45 yrs. and NOT accustomed to regular vigorous physical activity, please consult a qualified exercise professional (CSEP-CEP) before engaging in maximal effort exercise.

If you answered YES to one or more of the follow-up questions about your medical condition:

- You should seek further information from a licensed health care professional before becoming more physically active or engaging in a fitness appraisal and/or visit a or qualified exercise professional (CSEP-CEP) for further information.

Delay becoming more active if:

- You are not feeling well because of a temporary illness such as a cold or fever – wait until you feel better
- You are pregnant - talk to your health care practitioner, your physician, a qualified exercise profesional, and/or complete the PARmed-X for Pregnancy before becoming more physically active OR
- Your health changes - please talk to your doctor or qualified exercise professional (CSEP-CEP) before continuing with any physical activity programme.

SECTION 3 - DECLARATION

- You are encouraged to photocopy the PAR-Q+. You must use the entire questionnaire and NO changes are permitted.
- The Canadian Society for Exercise Physiology, the PAR-Q+ Collaboration, and their agents assume no liability for persons who undertake physical activity. If in doubt after completing the questionnaire, consult your doctor prior to physical activity.
- If you are less than the legal age required for consent or require the assent of a care provider, your parent, guardian or care provider must also sign this form.
- Please read and sign the declaration below:

I, the undersigned, have read, understood to my full satisfaction and completed this questionnaire. I acknowledge that this physical activity clearance is valid for a maximum of 12 months from the date it is completed and becomes invalid if my condition changes. I also acknowledge that a Trustee (such as my employer, community/fitness centre, health care provider, or other designate) may retain a copy of this form for their records. In these instances, the Trustee will be required to adhere to local, national, and international guidelines regarding the storage of personal health information ensuring that they maintain the privacy of the information and do not misuse or wrongfully disclose such information.

NAME _____ DATE _____

SIGNATURE _____WITNESS _____

SIGNATURE OF PARENT/GUARDIAN/CARE PROVIDER _____

For more information, please contact:
Canadian Society for Exercise Physiology
www.csep.ca

KEY REFERENCES
1. Jamnik VJ, Warburton DER, Makarski J, McKenzie DC, Shephard RJ, Stone J, and Gledhill N. Enhancing the eectiveness of clearance for physical activity participation; background and overall process. APNM 36(S1):S3-S13, 2011.
2. Warburton DER, Gledhill N, Jamnik VK, Bredin SSD, McKenzie DC, Stone J, Charlesworth S, and Shephard RJ. Evidence-based risk assessment and recommendations for physical activity clearance; Consensus Document. APNM 36(S1):S266-s298, 2011.

The PAR-Q+ was created using the evidence-based AGREE process (1) by the PAR-Q+Collaboration chaired by Dr. Darren E. R. Warburton with Dr. Norman Gledhill, Dr. Veronica Jamnik, and Dr. Donald C. McKenzie (2). Production of this document has been made possible through financial contributions from the Public Health Agency of Canada and the BC Ministry of Health Services. The views expressed herein do not necessarily represent the views of the Public Health Agency of Canada or BC Ministry of Health Services.

CSEP approved Sept 12 2011 version

Appendix C: Karnofsky Performance Status Scale

The Karnofsky Performance Scale Index allows patients to be classified as to their functional impairment. This can be used to compare effectiveness of different therapies and to assess the prognosis in individual patients. The lower the Karnofsky score, the worse the survival for most serious illnesses.

KARNOFSKY PERFORMANCE STATUS SCALE DEFINITIONS RATING (%) CRITERIA

Able to carry on normal activity and to work; no special care needed.	100	Normal no complaints; no evidence of disease.
	90	Able to carry on normal activity; minor signs or symptoms of disease.
	80	Normal activity with effort; some signs or symptoms of disease.
Unable to work; able to live at home and care for most personal needs; varying amount of assistance needed.	70	Cares for self; unable to carry on normal activity or to do active work.
	60	Requires occasional assistance, but is able to care for most of his personal needs.
	50	Requires considerable assistance and frequent medical care.
Unable to care for self; requires equivalent of institutional or hospital care; disease may be progressing rapidly.	40	Disabled; requires special care and assistance.
	30	Severely disabled; hospital admission is indicated although death not imminent.
	20	Very sick; hospital admission necessary; active supportive treatment necessary.
	10	Moribund; fatal processes progressing rapidly.
	0	Dead

References:
Crooks, V, Waller S, et al. The use of the Karnofsky Performance Scale in determining outcomes and risk in geriatric outpatients. J Gerontol. 1991; 46: M139-M144.
de Haan R, Aaronson A, et al. Measuring quality of life in stroke. Stroke. 1993; 24:320- 327.
Hollen PJ, Gralla RJ, et al. Measurement of quality of life in patients with lung cancer in multicenter trials of new therapies. Cancer. 1994; 73: 2087-2098.
O'Toole DM, Golden AM. Evaluating cancer patients for rehabilitation potential. West J Med. 1991; 155:384-387.
Oxford Textbook of Palliative Medicine, Oxford University Press. 1993;109.

Appendix D: Yoga Intervention

	WEEK 1-2	WEEK 3-4	WEEK 5-6	WEEK 7-8
Physical Principles	• Postural and breath awareness	• Stretch, lengthen and breath into the improved posture	• Managing breathlessness with yoga	• Strengthen and restore
Mental Focus	• Self-observation • Being present physically and mentally together in the room	• Self-acceptance and trust yourself • Connect with oneself	• Connect with your caregiver	• Connecting the body, mind and soul through breath • Integrating lessons learned from the class into one's life.
Yoga	• 4-part breath awareness: 10 mins • Pursed Lip Breath: 5-10 min • Samasthiti posture/Mountain pose: 5 min • Urdhva Hastasana/Upward Salute: 5 min • Bharadvajasana on chair/twist: 5 min • Trikonasana/ Triangle Pose: 5 min • Shavasana/corpse pose: 10 min • Mindfulness and focused attention through guided meditation: 10 min • Body Scan Meditation: 10 min	• Slow Abdominal Breathing: 5-10 min • Gomukhasana/ Cow pose: 5 min • Uttanasana/forward bend: 5 min • Vimanasana/ airplane pose: 5 min •Balance pose: 5 min • Virabhadrasana 1 and 2/ Warrior 1 and 2: 5 min • Utkatasana/ Squat: 5 min • Compassion based meditation: 10 min • Anapana Breath Meditation: 10 min	• Alternative nostril breathing: 5-10 min • Back bend pose with caregiver: 5 min • Back rotations with caregiver: 5 min • Lateral bend with caregiver: 5 min • Virabhadrasana 3/Warrior 3: 5 min • Mindfulness activities: 10 min • Marjariasa Na and Bitilasana/Cat and cow pose: 5 min • Shavasana/ corpse pose: 5 min • Meditation holding hands: 10 min	• 24x7 Breath awareness when awake • Dandasana/staff pose: 5 min • Garudasana/eagle arms: 5 min • Plank pose: 5 min • Urdhava Baddhanguliyasana/ Upward Bound fingers pose: 5 min • Ustrasana/ camel pose on chair: 5 min • Shavasana:5 min • Heart centered Meditation: 10 min
Benefits	• Improves self-awareness of breath, posture and mood. • Relaxation promotes the parasympathetic nervous system which helps in reduction of dyspnea	• Improved sleep and energy levels • Improves lung expansion • Improvement in self-confidence and motivation	• Reduction in dyspnea • Improved caregiver distress and bonding with the patient at the end of the session.	• Improved overall symptoms • Improved exercise self-efficacy

Appendix E: Resistance Exercise Intervention

RESISTANCE EXERCISE PROTOCOL

- The progressive resistance exercise training would be carried out once a week for both the individuals with lung cancer and their caregivers.
- All the sessions will be recorded in log books
- The caregivers and individuals with lung cancer will have the same exercise program and may represent a low-intensity exercise program for caregivers. The caregivers will progress easily and quickly through the program as compared to the lung cancer participants.

Prescription:

- The initial prescription will be based on the percentage of the 1RM performed at the baseline testing.
- Progression will be made on the basis of the rating of the Modified Borg Scale for Perceived Dyspnea at the end of the resistance exercise session.

Frequency, duration, and intensity:

WEEKS	FREQUENCY	REPETITIONS	SETS	INTENSITY (% OF 1RM)
0-1	1	8-10 or to tolerance	1	40% of 1 RM
2	1	10-12 or to tolerance	2	40% of 1 RM
3-4	1	8-10 or to tolerance	2	50% of 1 RM
5-6	1	10-12 or to tolerance	2	50% of 1 RM
7-8	1	8-10 or to tolerance	2	60% of 1 RM

Note: The resistance exercise will be followed by a one day break and a yoga class on the non-consecutive day.

The participants will be given pamphlets for core resistance exercises which can be performed safely and easily at home to maintain the benefits gained from the exercise.

Program components	Program details
Purpose	Improve muscle strength of upper extremity, scapular, and lower extremity muscles.
Warm up	Options: • Shoulder range of motion exercise with breath regulation • Low-intensity aerobic exercise

Muscle groups to be strengthened	• Rhomboids (scapular retraction) • Levator scapula (scapular elevation) • Biceps (elbow flexion) • Triceps (elbow extension) • Infraspinatus, posterior deltoid (external rotation) • Middle deltoid, supraspinatus and subscapularis (abduction in the plane of the scapula) • Quadriceps (leg extension) • Hamstrings (leg flexion) • Gluteal muscle group (hip extension and abduction)
Intensity	RPE: no greater than 13 on the Modified Borg Scale for dyspnea
Repetitions	10-15: progress to maximum of 20 repetitions initially when performing only one set
Sets	progress from 1 set to 2 sets
Rest	2-3 minutes of rest between exercise stations and up to 5 mins between sets
Concentric and eccentric tempo	2-4 seconds (exhaling) and 4 seconds (inhaling)
Total set duration	Total 20-30 minutes/set for 12 repetitions each.
Stretching	• Pectoralis major and minor • Triceps and biceps • Quadriceps and hamstrings • Calf muscles: gastrocnemius and soleus
Reduce workload	• Excessive fatigue post-exercise • Muscle soreness> 48 hours • Exacerbation of dyspnea and increase in pain
Terminate repetitions	Poor posture, compensating with another muscle group than the ones targeted, dyspnea and coughing, pain

Appendix F: Home Exercise Sheet

HOME EXERCISE PROGRAM:

1 Plank:

In a prone position with your arms in front of your head and your elbows in line with yourshoulders, lift yourself up and maintain the position on your elbows and the tip of your toes. Squeeze your buttocks to prevent your back from arching.

You could also modify it on a wall or a stable elevated place like a table or kitchen top. You could either keep the elbows bent as shown in first figure or keep it straight.

2. Push ups:

Place hands shoulder width apart on wall or table or floor. Slightly squeeze the shoulder blades together to stabilize them and bend the elbows to lower yourself toward the wall/ table/ floor. Extend the elbows to push yourself off. Keep the back straight, heels on the ground and head in line with the spine.
Repeat.

3. Sit to Stand:

Sit on a chair that has been placed against a wall to prevent it from moving.
Fold your arms across your chest.
With your feet slightly apart, lean forward so your shoulders are over your feet and stand up fully.
Slowly return to sitting.

4. Abdominal and Costal breathing:

In a seated position, with your back well supported, one hand on your abdomen.
In a sitting position, with your back well supported, hands resting on each side of your chest wall. In both position: Breathe in at the count 1-3 in your mind; breathe out at count of 1-5 in your mind. Repeat.

HOME EXERCISE PROGRAM:

5. Sit down with a straight back.
Slowly breathe in with your nose while you lift your arms overhead.
Slowly exhale with your mouth as you lower the arms.
Repeat.

6. Sit down with the hands behind the nape.
Slowly inhale as you pull the elbows back.
Exhale slowly as you bring the elbows together in front.
Repeat.

7. Stand up with with your arms relaxed on your side.
Rotate your arms so your thumbs are pointing backward to open the chest.
Squeeze the shoulder blades together, keep your chin tucked and hold this position for few seconds. Relax and Repeat.

8. Stand with your back against the wall, feet hip width apart and about a foot away from the wall, knees slightly bent.
Start by lifting up through your breastbone drawing your shoulders back against the wall, opening up through the front of the shoulders. Keep your lower rib cage relaxed and down.
Nod your chin slightly, sliding the back of your head up the wall to bring the neck to neutral, the plane of the face parallel to the wall.
Hold this position but do not do this rigidly.
Relax and then repeat.

SMELL THE ROSES, BLOW THE CANDLES!

Appendix G: Home Exercise Diary

Participant Exercise Diary

When filling out your diary, please keep in mind the following:

- Only count exercise session at least **10 minutes or longer** in duration.
- Only count exercise done in your free time *(not work or housework)*.
- Only record exercise of moderate or strenuous intensity *(RPE 11 and up)*.
- State your fatigue level post exercise *(0 = No fatigue and 10 = Severe fatigue, rest/nap needed)*.

WEEK	Exercise Type	Duration	Intensity	Fatigue Level	Pain/Other
Example	***Circuit training***	***60 min***	***12***	***4***	***no***
1					
2					
3					

RPE SCALE

6	
7	**Very, very light**
8	
9	**Very light**
10	
11	**Fairly light**
12	
13	**Somewhat hard**
14	
15	**Hard**
16	
17	**Very hard**
18	
19	**Very, very hard**
20	

Participant Exercise Diary

WEEK	Exercise Type	Duration	Intensity	Fatigue Level	Pain/Other
4					
5					
6					
7					

Participant Exercise Diary

8					

Congratulations on completing the exercise program and thanks for exercising with us!

Please feel to provide any comments, suggestions, or feedback that you may have about the program:

Appendix H: Dyspnea-12 (D-12) Questionnaire

DYSPNOEA-12 QUESTIONNAIRE

Item	None	Mild	Moderate	Severe
1. My breath does not go in all the way				
2. My breathing requires more work				
3. I feel short of breath				
4. I have difficulty catching my breath				
5. I cannot get enough air				
6. My breathing is uncomfortable				
7. My breathing is exhausting				
8. My breathing makes me feel depressed				
9. My breathing makes me feel miserable				
10. My breathing is distressing				
11. My breathing makes me agitated				
12. My breathing is irritating				

Number of items missing	Calculation to account for missing items	Dyspnoea-12 score calculation
1	36 ÷ 33 = 1.09	1.1 x total Dyspnoea-12 score
2	36 ÷ 30 = 1.2	1.2 x total Dyspnoea-12 score
3	36 ÷ 27 = 1.3	1.3 x total Dyspnoea-12 score

Appendix I: Functional Assessment of Cancer Therapy-Fatigue (FACT-F)

FACIT-F (Version 4)

Below is a list of statements that other people with your illness have said are important**. Please circle or mark one number per line to indicate your response as it applies to the <u>past 7 days</u>.**

	PHYSICAL WELL-BEING	**Not at all**	**A little bit**	**Some-what**	**Quite a bit**	**Very much**
GP1	I have a lack of energy	0	1	2	3	4
GP2	I have nausea	0	1	2	3	4
GP3	Because of my physical condition, I have trouble meeting the needs of my family	0	1	2	3	4
GP4	I have pain	0	1	2	3	4
GP5	I am bothered by side effects of treatment	0	1	2	3	4
GP6	I feel ill	0	1	2	3	4
GP7	I am forced to spend time in bed	0	1	2	3	4

	SOCIAL/FAMILY WELL-BEING	**Not at all**	**A little bit**	**Some-what**	**Quite a bit**	**Very much**
GS1	I feel close to my friends	0	1	2	3	4
GS2	I get emotional support from my family	0	1	2	3	4
GS3	I get support from my friends	0	1	2	3	4
GS4	My family has accepted my illness	0	1	2	3	4
GS5	I am satisfied with family communication about my illness	0	1	2	3	4
GS6	I feel close to my partner (or the person who is my main support)	0	1	2	3	4
Q1	*Regardless of your current level of sexual activity, please answer the following question. If you prefer not to answer it, please mark this box* ☐ *and go to the next section.*					
GS7	I am satisfied with my sex life	0	1	2	3	4

FACIT-F (Version 4)

Please circle or mark one number per line to indicate your response as it applies to the <u>past 7 days</u>.

	EMOTIONAL WELL-BEING	**Not at all**	**A little bit**	**Some-what**	**Quite a bit**	**Very much**
GE1	I feel sad	0	1	2	3	4
GE2	I am satisfied with how I am coping with my illness	0	1	2	3	4
GE3	I am losing hope in the fight against my illness	0	1	2	3	4
GE4	I feel nervous	0	1	2	3	4
GE5	I worry about dying	0	1	2	3	4
GE6	I worry that my condition will get worse	0	1	2	3	4

	FUNCTIONAL WELL-BEING	**Not at all**	**A little bit**	**Some-what**	**Quite a bit**	**Very much**
GF1	I am able to work (include work at home)	0	1	2	3	4
GF2	My work (include work at home) is fulfilling	0	1	2	3	4
GF3	I am able to enjoy life	0	1	2	3	4
GF4	I have accepted my illness	0	1	2	3	4
GF5	I am sleeping well	0	1	2	3	4
GF6	I am enjoying the things I usually do for fun	0	1	2	3	4
GF7	I am content with the quality of my life right now	0	1	2	3	4

FACIT-F (Version 4)

Please circle or mark one number per line to indicate your response as it applies to the past 7 days.

	ADDITIONAL CONCERNS	Not at all	A little bit	Some-what	Quite a bit	Very much
HI7	I feel fatigued	0	1	2	3	4
HI12	I feel weak all over	0	1	2	3	4
An1	I feel listless ("washed out")	0	1	2	3	4
An2	I feel tired	0	1	2	3	4
An3	I have trouble starting things because I am tired	0	1	2	3	4
An4	I have trouble finishing things because I am tired	0	1	2	3	4
An5	I have energy	0	1	2	3	4
An7	I am able to do my usual activities	0	1	2	3	4
An8	I need to sleep during the day	0	1	2	3	4
An12	I am too tired to eat	0	1	2	3	4
An14	I need help doing my usual activities	0	1	2	3	4
An15	I am frustrated by being too tired to do the things I want to do	0	1	2	3	4
An16	I have to limit my social activity because I am tired	0	1	2	3	4

Appendix J: Caregiver Oncology Quality of Life Questionnaire (CarGOQOL)

CAREGIVER QUALITY OF LIFE QUESTIONNAIRE

Answer each question by checking the case that comes closest to what you thought or felt **during the last four weeks.** Some of the questions concern your private life. These questions are necessary to evaluate every aspect of your quality of life. However, if you do not know how to respond to a question or if a question does not concern you, skip to the next question.

	During the last four weeks, in connection with the person you help, have you …	Never Not at all	Rarely A little	Sometimes Moderately	Often A lot	Always Enormously
1	Been worried, anxious?	❑	❑	❑	❑	❑
2	Been sad, depressed?	❑	❑	❑	❑	❑
3	Been emotionally tired, worn out?	❑	❑	❑	❑	❑
4	Been stressed?	❑	❑	❑	❑	❑
5	Felt a lack of freedom?	❑	❑	❑	❑	❑
6	Been bothered by the feeling of being confined?	❑	❑	❑	❑	❑
7	Been bothered by the fact that your life was entirely devoted to the care recipient?	❑	❑	❑	❑	❑
8	Been embarrassed to be the only person to provide assistance?	❑	❑	❑	❑	❑
9	Been satisfied with information given by health care providers (doctors, nurses…)?	❑	❑	❑	❑	❑

10	Been reassured by the health care providers (doctors, nurses…)?	❑	❑	❑	❑	❑

During the last four weeks, in connection with the person you help, have you …		Never Not at all	Rarely A little	Sometimes Moderately	Often A lot	Always Enormously
11	Felt that your role as caregiver was recognized by health care providers (doctors, nurses…)?	❑	❑	❑	❑	❑
12	Had financial difficulties (lodging, transportation…)?	❑	❑	❑	❑	❑
13	Had other difficulties (lodging, transportation…)?	❑	❑	❑	❑	❑
14	Encountered difficulties in the administrative process (health insurance paperwork and other paperwork related to the cancer illness?	❑	❑	❑	❑	❑
15	Experienced feelings of guilt?	❑	❑	❑	❑	❑
16	Been bothered by a feeling of helplessness against disease?	❑	❑	❑	❑	❑
17	Felt a feeling of injustice, anger, or rebellion?	❑	❑	❑	❑	❑
18	Had sleeping difficulties?	❑	❑	❑	❑	❑
19	Had problems with your appetite?	❑	❑	❑	❑	❑

20	Been physically tired, worn out?	❑	❑	❑	❑	❑
21	Had the impression that your health was fragile?	❑	❑	❑	❑	❑
During the last four weeks, in connection with the person you help, have you …		Never Not at all	Rarely A little	Sometimes Moderately	Often A lot	Always Enormously
22	Felt you made a difference for the person you are helping?	❑	❑	❑	❑	❑
23	Felt useful?	❑	❑	❑	❑	❑
24	Could rest, relax?	❑	❑	❑	❑	❑
25	Could take care of yourself, pay attention to your own health?	❑	❑	❑	❑	❑
26	Been assisted, supported, understood by your family?	❑	❑	❑	❑	❑
27	Been assisted, supported, understood by your friends?	❑	❑	❑	❑	❑
28	Had difficulties in your intimate, emotional life?	❑	❑	❑	❑	❑
29	Had a satisfying love and sexual life?	❑	❑	❑	❑	❑

Appendix K: Chalder Fatigue Scale

chalder fatigue scale

name: _____ date: _____

We would like to know more about any problems you have had with feeling tired, weak or lacking in energy in the last month. Please answer ALL the questions by ticking the answer which applies to you most closely. If you have been feeling tired for a long while, then compare yourself to how you felt when you were last well. Please tick only one box per line.

	less than usual	***no more than usual***	***more than usual***	***much more than usual***
do you have problems with tiredness?				
do you need to rest more?				
do you feel sleepy or drowsy?				
do you have problems starting things?				
do you lack energy?				
do you have less strength in your muscles?				
do you feel weak?				
do you have difficulties concentrating?				
do you make slips of the tongue when speaking?				
do you find it more difficult to find the right word?				
	better than usual	***no worse than usual***	***worse than usual***	***much worse than usual***
how is your memory?				

This scale can be scored "bimodally" with columns representing 0, 0, 1 & 1 and a range from 0 to 11 with a total of 4 or more qualifying for "caseness". Alternatively it can be scored in "Likert" style 0, 1, 2 & 3 with a range from 0 to 33. Mean "bimodal" score for CFS sufferers was 9.14 (SD 2.73) and for a community sample 3.27 (SD 3.21). Mean "Likert" score was 24.4 (SD 5.8) and 14.2 (SD 4.6).

total (0-33) =

Appendix L: Contraindications and Precautions to Exercise Testing and Training

	Contraindications to Exercise testing and training	Precautions requiring modification and/or physician approval
Factors related to Cancer Treatment	• No exercise on the days of intravenous chemotherapy within 24 hours of treatment • No exercise prior to blood draw • Severe tissue reaction to Radiation Therapy	• Caution if on treatments that affect lung and/or heart: recommend medically supervised exercise testing and training • Mouth sores/ulcerations: avoid mouthpieces for maximal testing. • Use a face mask
Musculoskeletal	• Bone, back or joint pain of recent origin • Unusual muscular weakness • Severe Cachexia • Unusual/extreme fatigue • Poor functional status: avoid exercise testing if Karnofsky performance score <60%	• Any pain or cramping: investigate • Osteopenia: avoid high impact exercise if risk of fracture • Steroid-induced myopathy • Cachexia: multidisciplinary approach to exercise • Mild to moderate fatigue: closely monitor response to exercise
Cardiovascular	• Chest pain • Resting pulse >100/min or 50/min • Resting blood pressure >145 mm Hg systolic and 95 mm Hg Diastolic • Irregular pulse • Swelling of ankles	• If on blood pressure medication that controls heart rate, target HR may not be attainable, do no overexert
Pulmonary	• Severe dyspnea • Cough, wheezing • Chest pain increased by deep breath	• Mild to moderate dyspnea: avoid maximal tests

Appendix M: Health Research Ethics Board of Alberta (HREBA) Approval

Health Research Ethics Board of Alberta
Cancer Committee
1500, 10104 - 103 Avenue NW
Edmonton, Alberta, T5J 4A7
Telephone: (780) 423-5727
Fax: (780) 429-3509
Email: cancer@hreba.ca

Modification of Ethics Approval

This is to acknowledge that the modification to the research indicated below has been reviewed and on behalf of the Health Research Ethics Board of Alberta (HREBA) – Cancer Committee (CC), I am pleased to advise that approval has been granted.

Ethics ID:	HREBA.CC-17-0049_MOD1
Principal Investigator:	Margaret McNeely
Co-Investigator(s):	Anil Abraham Joy Jill Turner
Student Co-Investigator(s):	Shreya Rewar
Study Title:	Feasibility and preliminary efficacy of a combined therapeutic yoga and resistance exercise intervention for individuals with lung cancer and their caregivers.
Sponsor (if applicable):	

Effective: 14/04/2017 **Expires:** 13/04/2018

Reviewed and approved by delegated review on 16 May 2017

The following documents have been approved:

- ASSURE Study Brochure, 9-May-17, May 10, 2017
- Protocol Version May 9, 2017, 9-May-17, May 10, 2017

This Committee is constituted and operates in accordance with the Alberta Health Information Act (HIA), the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2), Good Clinical Practice (GCP) Guidelines of the International Conference on Harmonization (ICH), Health Canada's *Food and Drug Regulations* (FDR), Part C, Division 5 and is registered with the U.S. Department of Health and Human Services (HHS), Office for Human Research Protections (OHRP), IRB # 00009687.

Members of the HREBA-CC who are named as principal investigators or co-investigators in this research do not participate in discussions related to, nor vote on, such studies when they are presented to the Committee. The membership of this Committee is listed at www.hreba.ca.

Please note that the approval of this modification does not change the effective or expiry dates of this study as indicated above.

Please accept the Committee's best wishes for success in your research.

Approved on behalf of CC by, **Date:**

Raul Urtasun , HREBA-CC May 17, 2017

Note: This correspondence includes an electronic signature (validation and approval via an online system).

Appendix N: Participant Consent Form

Informed Consent Form for Participation in a Research Study

Feasibility and preliminary efficacy of a combined therapeutic yoga and resistance exercise intervention for individuals with lung cancer and their caregivers

(A study examining a therapeutic yoga and resistance exercise program for individuals with lung cancer and their caregivers "ASSURE")

Protocol ID: HREBA-CC: 17-0049

Principal Investigator: Dr. Margaret McNeely, PT, PhD
Department of Physical Therapy/ Department of Oncology
University of Alberta & Cross Cancer Institute
Phone: 780-248-1531

Sponsor/Funder(s): University of Alberta

Emergency Contact Number (24 hours / 7 days a week):
Cross Cancer Institute Telephone Triage Nurse:
780-432-8919 or 1-877-707-4848 (toll free)

You are being invited to participate in this research study because you have indicated that you are interested in taking part in an exercise program for individuals with lung cancer and their caregivers. This consent form provides detailed information about the study to assist you with making an informed decision. Please read this document carefully and ask any questions you may have. All questions should be answered to your satisfaction before you decide whether to participate.

The study staff will tell you about timelines for making your decision. You may find it helpful to discuss the study with family and friends so that you can make the best possible decision within the given timelines.

Taking part in this study is voluntary. You may choose not to take part or, if you choose to participate, you may leave the study at any time without giving a reason. Deciding not to take part or deciding to leave the study will not result in any penalty or any loss of medical or health-related benefits to which you are entitled.

The principal investigator, who is one of the researchers, or the site project coordinator will discuss this study with you and will answer any questions you may have. If you do consent to participate in this study, you will need to sign and date this consent form. You will receive a copy of the signed form.

WHAT IS THE BACKGROUND INFORMATION FOR THIS STUDY?

Lung cancer is one of the most common types of cancer in Canada. Pain, shortness of breath, fatigue, weight loss and anxiety are common symptoms associated with the disease, and fear of worsening these symptoms is often reported as a barrier to taking part in cancer rehabilitation and exercise programs. As the course of lung cancer and its treatment can be difficult, the caregivers responsible for providing care may have less time to care for themselves and their own health. In this study, lung cancer survivors and their caregivers will be asked to take part in a specialized therapeutic exercise rehabilitation program that aims to address these issues. The study will assess whether survivors and their caregivers are willing and able to take part in this type of exercise rehabilitation program that includes both therapeutic yoga and resistance exercise, and if there are any potential benefits in terms of symptoms and quality of life outcomes.

The Health Research Ethics Board of Alberta – Cancer Committee (HREBA-CC), which oversees the ethical acceptability of research involving humans, has reviewed and granted ethics approval for this study.

WHY IS THIS STUDY BEING DONE?

The purpose of the study is to determine whether lung cancer survivors and their caregivers are willing and able to take part in a combined therapeutic yoga and resistance exercise intervention for individuals with lung cancer and their caregivers. The program is called the yogA and reSiStance exercise for lUng canceR and carEgivers (Assure) program. Our aim is to help you to feel more confident in taking part in exercise by providing you with a personalized program and by ensuring you are not short of breath when exercising. We want to see whether individuals with lung cancer and their caregivers are interested in participating in a program, able to attend the intervention sessions and complete the program. We also plan to study the effects of therapeutic yoga and resistance exercise on fitness and symptom outcomes for individuals with lung cancer and their caregivers.

WHAT ARE OTHER OPTIONS IF I DECIDE NOT TO PARTICIPATE IN THIS STUDY?

You do not have to take part in this study in order to receive continued medical care. You may choose not to participate in this study. Your healthcare provider will discuss lifestyle recommendations with you. Right now, the usual treatment at the Cross Cancer Institute is to receive counseling on the value of physical activity and healthy living after the completion of cancer treatments.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

About 20 participants including 10 individuals with lung cancer and 10 caregivers from Edmonton and area will be involved in this study. We plan to enroll about 20 people at the Cross Cancer Institute.

WHAT WILL HAPPEN DURING THIS STUDY?

STUDY INTERVENTION
If you agree to take part in this study, you will undergo screening and fitness testing prior to

taking part in the exercise program. The program will take place at Cancer Rehabilitation Clinic at the Faculty of Rehabilitation Medicine, University of Alberta. You will take part in a twice-weekly exercise program for an 8-week period. The fitness testing will be done before and after the 8-week program. The testing will include questionnaires and physical measurements. The therapeutic yoga and resistance exercise program will be tailored to your fitness level and designed to address your personal fitness or lifestyle goals.

STUDY PROCEDURES

Established Procedures

The following established procedures will be done as part of this study. Some of these procedures may be done as part of your standard care, in which case the results may be used. Some may be done more frequently than if you were not taking part in this study. Some of these procedures may be done solely for the purpose of the study. If the results show that you are not able to continue participating in the study, the principal investigator will let you know.

Tests for both lung cancer survivors and caregivers:

- Musculoskeletal fitness measurement: We will measure your upper and lower body strength (one repetition maximum/1RM test) on a bench press, seated row, and leg press machine which will take 5-10 minutes to complete. This measurement will be taken for both the individuals with lung cancer and their caregivers.

Tests for lung cancer survivors:

- Body composition measurement: We will measure your height and body weight. These measurements take 2-3 minutes to complete.

- Vitals: We will measure your heart rate, blood pressure and oxygen level before and after the intervention. It will take 2-3 minutes to complete.

- Lung volumes and capacities measurement: We will perform a pulmonary function test using an instrument called spirometer. This is a simple test where you have to blow air into and out through a mouthpiece. It will take about 5-10 minutes to complete.

- Chest Expansion: We will measure the expansion of your chest using a tape while you inhale and exhale. It will take about 1 minute to complete

- Shoulder range of motion: We will perform it in a seated position using an instrument called goniometer. You will be asked to raise your arm above the head in two directions as far as you can reach. It will take about 2-3 minutes to complete.

Questionnaires for lung cancer survivors:

You will be provided with a questionnaire package at the start of the study and after 8-weeks.

- Dyspnea-12: The questionnaire asks you to respond to your general perception of your current state of dyspnea on a 12-item scale. It will take about 5 minutes to complete.

- The functional assessment of chronic illness therapy (FACIT-F): It is a questionnaire to assess the extent of any fatigue you experience. It will take 5 minutes to complete.

Questionnaires for caregivers:

- Caregiver Oncology Quality of Life questionnaire CarGOQoL: This is a 29-item questionnaire that assesses quality of life. It will take about 10 minutes to complete.

- Chalder Fatigue Scale: an 11-item questionnaire that will ask you about your energy levels and any tiredness you may be experiencing. It will take approximately 3-5 minutes to complete.

The information you provide is for research purposes only and will remain strictly confidential. Some of the questions are personal; you may choose not to answer them.

Even though you may have provided information on a questionnaire, these responses will not be reviewed by individuals not involved in this study, e.g., your health care practitioner/team. If you would like them to know this information, please bring this to their attention.

Participant Diaries

You will be asked to keep a diary of your daily physical activity during the 8-week exercise program. This will include recording the type of physical activity, the duration and intensity of each session and any symptoms before or after each session. You will be asked to return the diary at your 8-week follow-up test or to submit an electronic copy to the researchers.

WHAT ARE THE POTENTIAL SIDE EFFECTS FROM PARTICIPATING IN THIS STUDY?

You may experience side effects from participating in this study. Some side effects are known and are listed below, but there may be side effects that are not expected. You should discuss these with the principal investigator or project coordinator. The risks and side-effects of the standard or usual treatment will be explained to you as part of your standard care. These risks are not included in this consent form.

The main side effect from exercise testing and training is secondary muscle soreness. You may notice that your muscles are sore for a couple of days after the testing session and during the first week or so of the exercise program. We expect that these symptoms will get better as you get used to the exercise. As well, the exercise program will be personalized to you to minimize any excessive soreness and modified as needed if you experience any soreness or fatigue from your exercise sessions.

Every medical treatment including the standard treatment has side effects, which your doctor will explain to you. It is important that you know and understand the possible side effects of the treatments given in this study. The main risk associated with exercise is musculoskeletal injury (injury to the muscles, tendons, joints or bones). Your exercise sessions will be supervised and

your program designed to minimize this risk by slowly increasing the amount and intensity of your exercise over time.

There is also a very small risk of heart issues (such as chest pain, irregular heart rate, heart attack) should you exercise too intensively. To avoid any risks associated with exercise, you will be screened to ensure it is safe and appropriate for you to take part in the exercise program. As well, the chosen exercises will be of a low intensity level to minimize the stress on the heart and body and we will monitor your vital signs (e.g., heart rate, blood pressure, breathing) during the exercise testing and when you exercise at the clinic. If any concerns are identified at any time, you will be referred back to your doctor for further evaluation. If any issues develop during the study period, your exercise sessions may be held or discontinued.

If you have any side effects, you should call the principal investigator or study coordinator in charge of the study. The telephone numbers are on the last page of this form.

WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?

Participation in this study may or may not be of personal benefit to you. Possible benefits include improved physical fitness, better energy and improved overall quality of life. However, based on the results of the study, it is hoped that in the long-term patient care can be improved.

WHAT ARE MY RESPONSIBILITIES AS A STUDY PARTICIPANT?

If you choose to participate in this study, you will be expected to:

- Tell the study coordinator about your current medical conditions;
- Tell the study coordinator about all prescription and non-prescription medications and supplements, including vitamins and herbals, that you may be taking. This is for your safety as these may affect your ability to exercise;
- Tell the study coordinator if you are thinking about participating in another research study;
- Attend all scheduled study visits, undergo all the procedures described above and complete the questionnaires.
- Inform the study coordinator of any injuries, side effects or health problems that you may be experiencing

HOW LONG WILL I BE PARTICIPATING IN THIS STUDY?

The study exercise program will last for about 8 weeks. You will be asked to come to the Cancer Rehabilitation Clinic in Corbett Hall at the University of Alberta for pre-and post-intervention tests that will take about an hour and a half to complete.

CAN I CHOOSE TO LEAVE THIS STUDY EARLY?

You can choose to end your participation in this research (called early withdrawal) at any time without having to provide a reason. If you choose to withdraw early from the study without finishing the intervention, procedure, or follow-up, you are encouraged to contact the principal investigator or study coordinator. If you decide to stop participating in the study, we encourage you to talk to your doctor first. You may be asked questions about your experience with the study intervention.

You may withdraw your permission to use information that was collected about you for this study at any time by letting the study coordinator know. However, this would also mean that you withdraw from the study. Information that was recorded before you withdrew will be used by the researchers for the purposes of the study, but no additional information will be collected or sent to the sponsor after you withdraw your permission.

CAN MY PARTICIPATION IN THIS STUDY END EARLY?

In discussion with you, your doctor at the Cross Cancer Institute, either at his/her own initiative or at the request of the sponsor of this study, may withdraw you from the study at any time if it is in your best interests. The principal investigator may stop your participation in the study early, and without your consent, for reasons such as:

- You are unable to tolerate the exercise.
- You sustain an injury as a result of participation.
- You experience an adverse effect during or after exercising.
- Your doctor no longer feels this is the best treatment for you.
- The sponsor decides to stop the study;

If this happens, it may mean that you would not receive the study intervention for the full period described in this consent form. If you are removed from the study, the principal investigator will discuss the reasons with you and plans will be made for your continued care outside of the study.

HOW WILL MY PERSONAL INFORMATION BE KEPT CONFIDENTIAL?

If you decide to participate in this study, the principal investigator and study staff will only collect the information they need for this study.

Records identifying you, including information collect from your medical files/records, such as your Electronic Medical Records (EMR), Netcare, charts, etc., will be kept confidential to the extent permitted by the applicable laws, will not be disclosed or made publicly available, except as described in this consent document.

Authorized representatives of the following organizations may look at your identifiable medical/clinical study records at the site where these records are held for quality assurance purposes and/or to verify that the information collected for the study is correct and follows proper laws and guidelines:

- The Health Research Ethics Board of Alberta – Cancer Committee, which oversees the ethical conduct of this study
- Members of the Regulatory/Audit team at the Cross Cancer Institute, for quality assurance purposes

Authorized representatives of the above organizations may **receive** information related to the study from your medical/clinical study records that will be kept confidential in a secure location and may be used in current or future relevant health research. Your name or other information that may identify you will not be provided (i.e., the information will be de-identified). The records received by these organizations will be coded with a number. The key that indicates what

number you have been assigned will be kept secure by the researchers directly involved with your study and will not be released. To protect your identity, the information that will be on your assessment forms and questionnaires will be limited to your study ID and initials.

Any disclosure of your identifiable health information will be done in accordance with federal and provincial laws including the Alberta Health Information Act (HIA). The organizations listed above are required to have organizational policies and procedures to protect the information they see or receive about you, except where disclosure may be required by law. The principal investigator will ensure that any personal health information collected for this study is kept in a secure and confidential AHS facility as also required by law.

If the results of this study are published, your identity will remain confidential. It is expected that the information collected during the study will be used in analyses and will be published and/or presented to the scientific community at meetings and in journals, but your identity will remain confidential. It is expected that the study results will be published as soon as possible after completion. This information may also be used as part of a submission to regulatory authorities around the world to support the approval of this intervention.

Even though the likelihood that someone may identify you from the study data is very small, it can never be completely eliminated. Every effort will be made to keep your identifiable information confidential, and to follow the ethical and legal rules about collecting, using and disclosing this information.

Data collected will be kept in a locked filing cabinet in the Cancer Rehabilitation Clinic at the University of Alberta and data will only be used for research purposes.

Studies involving humans sometimes collect information on race and ethnicity as well as other characteristics of individuals because these characteristics may influence how people respond to different interventions. Providing information on your race or ethnic origin is voluntary.

While the study team will take precautions to protect your confidentiality we cannot guarantee that other members of the focus group will respect your privacy or keep the discussions of the group confidential.

WILL MY HEALTHCARE PROVIDER(S) BE INFORMED OF MY PARTICIPATION IN THIS STUDY?

Your family doctor/health care provider will be informed that you are taking part in a study so that you can be provided with appropriate medical care. If you do not want your family doctor/health care provider to be informed, please discuss with your study team to find out your options.

WILL THERE BE ANY COSTS INVOLVED WITH PARTICIPATING IN THIS STUDY?

You will not have to pay for the exercise program you receive in this study. We will provide a parking pass to cover your parking costs at the University of Alberta when you come for any tests or procedures associated with the study. Costs associated with attending the 8-week

exercise program at Cancer Rehab Clinic will be covered. There may be additional costs to you for taking part in this study such as:

- transportation
- meals
- babysitting, etc.

Possible Costs After the Study is Complete

You may not be able to receive the study intervention after your participation in the study is completed. There are several possible reasons for this, some of which are:

- Your caregivers may not feel it is the best option for you;
- You may decide it is too expensive and insurance coverage may not be available;
- The intervention may not be available free of charge.

The principal investigator will discuss these options with you.

WILL I BE COMPENSATED FOR PARTICIPATING IN THIS STUDY?

You will not be paid for taking part in this study. However in the case of research-related side effects or injury, as a direct result of participating in this research, you will receive all medical treatments or services recommended by your doctors.

Although no funds have been set aside to compensate you in the event of injury or illness related to the study treatment or procedures, you do not give up any of your legal rights for compensation by signing this form.

WHAT ARE MY RIGHTS AS A PARTICIPANT IN THIS STUDY?

You will be told, in a timely manner, about new information that may be relevant to your willingness to stay in this study. You have the right to be informed of the results of this study once the entire study is complete. If you would like to be informed of these results, please contact the principal investigator.

The results of this study will be available on a clinical registry; refer to the section titled “Where can I find online information about this study?”. Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected.

By signing this form you do not give up any of your legal rights against the hospital, investigators, sponsor, involved institutions for compensation or their agents, nor does this form relieve these parties from their legal and professional responsibilities.

IS THERE CONFLICT OF INTEREST RELATED TO THIS STUDY?

There are no conflicts of interest declared between the principal investigator and sponsor of this study.

WHAT IF RESEARCHERS DISCOVER SOMETHING ABOUT ME AS A RESEARCH

PARTICIPANT?

During the study, the researchers may learn something about you that they didn't expect. For example, the researchers may find out that you have another medical condition.

If any clinically important information about your health is obtained as a result of your participation in this study, you will be given the opportunity at that time to decide whether you wish to be made aware of that information.

WHERE CAN i FIND ONLINE INFORMATION ABOUT THIS STUDY?

A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

The study registration number to use this website is: NCT 03084692

WHO DO I CONTACT FOR QUESTIONS?

If you have questions about taking part in this study, or if you suffer a research-related injury, you should talk to the project coordinatior or principal investigator. These person(s) are :

Shreya Rewar, MSc (Project Coordinator)	780-492-6007
Name	Telephone
Dr. Margaret McNeely, PT, PhD	780-248-1531
Name	Telephone

Dr. Margaret McNeely can also be paged through the Cross Cancer Institute Switchboard at 780-432-8771

If you have questions about your rights as a participant or about ethical issues related to this study and you would like to talk to someone who is not involved in the conduct of the study, please contact the Office of the Health Research Ethics Board of Alberta – Cancer Committee at:

Telephone: 780-423-5727 Toll Free: 1-877-423-5727

SIGNATURES

Part 1 - to be completed by the potential participant.

	Yes	No
Do you understand that you have been asked to take part in a research study?	☐	☐
Do you understand why this study is being done?	☐	☐
Do you understand the potential benefits of taking part in this study?	☐	☐
Do you understand the risks of taking part in this study?	☐	☐
Do you understand what you will be asked to do should you decide to take part in this study?	☐	☐
Do you understand the alternatives to participating in this study?	☐	☐
Do you understand that you are free to leave the study at any time, without out having to give reason and without affecting your future health care?	☐	☐
Do you understand who will see your records, including health information that identifies you?	☐	☐
Do you understand that by signing this consent form you are giving us permission to access your health information if applicable?	☐	☐
Do you understand that by signing this consent form that you do not give up any of your legal rights?	☐	☐
Do you understand that your family doctor/health care provider may be informed of your participation in this study?	☐	☐
Have you had enough opportunity to ask questions and discuss this study?	☐	☐

By signing this form I agree, or *allow the person I am responsible for*, to participate in this study.

Signature of Participant /*Substitute Decision-Maker*	PRINTED NAME	Date

(As a Substitute Decision-Maker, you are being asked to provide informed consent on behalf of a person who is unable to provide consent for him/herself. If the participant gains the capacity to consent for him/herself, your consent for them will end.)

Part 2 - to be completed by the principal investigator or designee who conducted the informed consent discussion. Only compete this section if the potential participant has **agreed** to participate.

I believe that the person signing this form understands what is involved in the study and has freely decided to participate.

Signature of Person Conducting the Consent Discussion	PRINTED NAME	Date

Part 3 - to be completed only if the participant is unable to read or requires assistance of an oral translator/interpreter.

- The informed consent form was accurately explained to, and apparently understood by the participant*/substitute decision maker.*
- Informed consent was freely given by *or on behalf of* the participant.

Signature of Impartial Witness/Interpreter	PRINTED NAME	Date

******You will be given a copy of this signed and dated consent form prior to participating in this study.******

Appendix O: Focus Group Ethics Approval

Health Research Ethics Board of Alberta
Cancer Committee
1500, 10104 - 103 Avenue NW
Edmonton, Alberta, T5J 0H8
Telephone: (780) 423-5727
Fax: (780) 429-3509
Email: cancer@hreba.ca

Modification of Ethics Approval

This is to acknowledge that the modification to the research indicated below has been reviewed and on behalf of the Health Research Ethics Board of Alberta (HREBA) – Cancer Committee (CC), I am pleased to advise that approval has been granted.

Ethics ID:	HREBA.CC-17-0049_MOD2
Principal Investigator:	Margaret McNeely
Co-Investigator(s):	Anil Abraham Joy Jill Turner
Student Co-Investigator(s):	Shreya Rewar
Study Title:	Feasibility and preliminary efficacy of a combined therapeutic yoga and resistance exercise intervention for individuals with lung cancer and their caregivers.
Sponsor:	University of Alberta Physiotherapy Foundation of Canada

Effective: 4/14/2017 **Expires:** 4/13/2018

Reviewed and approved by delegated review on 26 February 2018.

The following documents have been approved:

- Consent Addendum, February 18, 2018, February 23, 2018
- Participant Program Satisfaction Questionnaire, February 18, 2018, February 23, 2018
- Caregiver Program Satisfaction Questionnaire, February 18, 2018, February 23, 2018
- Revised Protocol Feb 18, 2018 Clean Version, February 18, 2018, February 23, 2018

This Committee is constituted and operates in accordance with the Alberta Health Information Act (HIA), the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2), Good Clinical Practice (GCP) Guidelines of the International Conference on Harmonization (ICH), Health Canada's *Food and Drug Regulations* (FDR), Part C, Division 5 and is registered with the U.S. Department of Health and Human Services (HHS), Office for Human Research Protections (OHRP), IRB # 00009687.

Members of the HREBA-CC who are named as principal investigators or co-investigators in this research do not participate in discussions related to, nor vote on, such studies when they are presented to the Committee. The membership of this Committee is listed at www.hreba.ca.

Please note that the approval of this modification does not change the effective or expiry dates of this study as

indicated above.

Please accept the Committee's best wishes for success in your research.

Approved on behalf of CC by,	**Date:**
Raul Urtasun , HREBA-CC	Wednesday, February 28, 2018

Note: This correspondence includes an electronic signature (validation and approval via an online system).

Appendix P: Focus Group Participant Consent Form

ADDENDUM TO

PARTICIPANT INFORMATION & CONSENT

Title of Program: Feasibility and preliminary efficacy of a combined therapeutic yoga and resistance exercise intervention for individuals with lung cancer and their caregivers (ASSURE Study)

Principal Investigator: Margaret McNeely, PT, PhD

Research/Study Coordinator: Shreya Rewar, BPT

Before beginning this program, you signed an Information & Consent Form describing the program and your rights as a participant. At that time, we explained that we would tell you about any changes to the program. We have added two optional components to the outcomes associated with the program. After discussing this new information with the coordinators, if you would like to take part in either of these optional components of the program, please sign this Consent Form Addendum. Other information from the original consent that you signed at the beginning of the program still applies.

Optional components (one time only):

- You will have the option to complete an anonymous survey that asks you about your satisfaction with participating in the ASSURE study. This questionnaire will take around 20 minutes to complete.
- Post-program Group Discussion: After finishing the program, you will have the option to take part in a group discussion session. The information being collected will help us to better understand the benefits of the study, and allow us to plan future lung cancer-specific exercise research and programming. This one-time group discussion session will take about 90 minutes. All information collected in the group session will be confidential.

ADDENDUM TO CONSENT FORM

Title of Study: Feasibility and preliminary efficacy of a combined therapeutic yoga and resistance exercise intervention for individuals with lung cancer and their caregivers.

Principal Investigator: Margaret McNeely, PT, PhD 780-248-1531

Research/Study Coordinator: Shreya Rewar, BPT 780-492-6007

I have read all of the new information in this addendum concerning the study I am currently participating in.

I have been given the opportunity to discuss the information contained in this addendum. All of my questions have been answered to my satisfaction.

This signature on this Information & Consent Form Addendum means that I agree to complete one or both of the optional components. I understand that I remain free to withdraw at any time.

Signature of Participant	Name (Printed)	Date

Signature of Person Obtaining Consent	Name (Printed)	Date

A SIGNED COPY OF THIS ADDENDUM MUST BE GIVEN TO THE RESEARCH PARTICIPANT

Appendix Q: Participant Satisfaction Survey for Individuals with Lung Cancer

ASSURE PARTICIPANT SATISFACTION SURVEY

Please answer the following questions regarding the ASSURE program and the staff. Please select the answer that best describes how you feel.

	Very much	**Quite a bit**	**Somewhat**	**Little bit**	**Not at all**
The Assure program helped me to meet my health and wellness goals.	5	4	3	2	1
The Assure program helped me to manage the symptoms related to my cancer and/or treatments	5	4	3	2	1
The Assure program helped me to increase my knowledge related to the benefits of physical activities	5	4	3	2	1
The staff made me feel comfortable	5	4	3	2	1
The staff were knowledgeable and informative	5	4	3	2	1
The staff were supportive and cared about my personal health and wellbeing	5	4	3	2	1
The staff made an effort to teach me about my health and wellness	5	4	3	2	1
The program staff worked with me to ensure the yoga and exercise were appropriate for my level of fitness and my symptoms	5	4	3	2	1

Overall the service that you received from the staff was:	Excellent 5	Above average 4	Average 3	Below average 2	Poor 1

The following questions ask you how you feel about the ASSURE program. Please read carefully and select the answer that best represents your feeling.

	Very Much	Quite a bit	Somewhat	A little bit	Not at all
How beneficial was the overall exercise program?	5	4	3	2	1
How beneficial was the yoga class?	5	4	3	2	1
How beneficial was the resistance exercise component?	5	4	3	2	1
How beneficial was the home exercise component?	5	4	3	2	1
How enjoyable was the exercise program?	5	4	3	2	1
How supportive were your family/ friends of the exercise program?	5	4	3	2	1
How motivated were you to do the exercise program?	5	4	3	2	1
How difficult was it for you to do the exercise program?	5	4	3	2	1
How beneficial was it to exercise with a support person (caregiver/ spouse/friend/ family member)	5	4	3	2	1

Now that you have completed the 8-week therapeutic yoga and exercise program, the following questions ask you about your plans to continue yoga, resistance exercise or home exercise. Please select the answer that best represents what you feel.

	Very Much	Quite a bit	Somewhat	A little bit	Not at all
How beneficial do you think it will be for you to continue exercising?	5	4	3	2	1
How enjoyable do you think it will be for you to continue exercising?	5	4	3	2	1
How supportive do you think friends/family will be if you try to continue exercising?	5	4	3	2	1
How motivated are you to continue exercising?	5	4	3	2	1
How difficult do you think it will be for you to continue exercising?	5	4	3	2	1
How confident are you to continue exercising on your own?	5	4	3	2	1

How much of a burden was it for you to complete the following?

	Not at all	A little bit	Somewhat	Quite a bit	Very much
The muscular strength, chest expansion, spirometry, range of motion testing.	1	2	3	4	5
The questionnaires	1	2	3	4	5
The yoga class	1	2	3	4	5
The resistance exercise sessions	1	2	3	4	5
Travelling to and from the exercise facility	1	2	3	4	5

Looking back, how do you feel about your participation in the exercise program?

	Not at all	A little bit	Somewhat	Quite a bit	Very much
It was rewarding	1	2	3	4	5
It was a waste of my time	1	2	3	4	5
It will be useful for research helping others	1	2	3	4	5
It was useful for me personally	1	2	3	4	5

Please provide us with any additional information regarding the ASSURE program that you feel is important for us to know, but may not have been covered in the questions above. (e.g. additional strengths or weaknesses of the program, specific benefits or negative aspects you experiences, etc.)

Appendix R: Participant Satisfaction Survey for Caregivers

ASSURE PARTICIPANT SATISFACTION SURVEY (caregivers)

Please answer the following questions regarding the ASSURE program and the staff. Please select the answer that best describes how you feel.

	Very much	**Quite a bit**	**Somewhat**	**Little bit**	**Not at all**
The Assure program helped me to meet my health and wellness goals.	5	4	3	2	1
The Assure program helped me to increase my knowledge related to the benefits of physical activities	5	4	3	2	1
The staff made me feel comfortable	5	4	3	2	1
The staff were knowledgeable and informative	5	4	3	2	1
The staff made an effort to teach me about my health and wellness	5	4	3	2	1
The program staff worked with me to ensure the yoga and exercise were appropriate for my level of fitness and my symptoms	5	4	3	2	1

Overall the service that you received from the staff was:	Excellent 5	Above average 4	Average 3	Below average 2	Poor 1

The following questions ask you how you feel about the ASSURE program. Please read carefully and select the answer that best represents your feeling.

	Very Much	Quite a bit	Somewhat	A little bit	Not at all
How beneficial was the overall exercise program?	5	4	3	2	1
How beneficial was the yoga class?	5	4	3	2	1
How beneficial was the resistance exercise component?	5	4	3	2	1
How beneficial was the home exercise component?	5	4	3	2	1
How enjoyable was the overall ASSURE program?	5	4	3	2	1
How motivated were you to do the ASSURE program?	5	4	3	2	1
How difficult was it for you to do the ASSURE program?	5	4	3	2	1
How beneficial was it to exercise with your spouse/family member/ friend?	5	4	3	2	1

Now that you have completed the 8-week therapeutic yoga and exercise program, the following questions ask you about your plans to continue yoga, resistance exercise or home exercise. Please select the answer that best represents what you feel.

	Very Much	Quite a bit	Somewhat	A little bit	Not at all
How beneficial do you think it will be for you to continue exercising?	5	4	3	2	1
How enjoyable do you think it will be for you to continue exercising?	5	4	3	2	1
How motivated are you to continue exercising?	5	4	3	2	1
How difficult do you think it will be for you to continue exercising?	5	4	3	2	1
How confident are you to continue exercising on your own?	5	4	3	2	1

How much of a burden was it for you to complete the following?

	Not at all	A little bit	Somewhat	Quite a bit	Very much
The muscular strength measurements	1	2	3	4	5
The questionnaires	1	2	3	4	5
The yoga class	1	2	3	4	5
The resistance exercise sessions	1	2	3	4	5
Travelling to and from the exercise facility	1	2	3	4	5

Looking back, how do you feel about your participation in the exercise program?

	Not at all	A little bit	Somewhat	Quite a bit	Very much
It was rewarding	1	2	3	4	5
It was a waste of my time	1	2	3	4	5
It will be useful for research helping others	1	2	3	4	5
It was useful for me personally	1	2	3	4	5

In context of the person you supported in ASSURE:

The Assure program helped your spouse/family member/ friend manage the side effects and symptoms related to cancer and/or treatments	5	4	3	2	1
The Assure program strengthen the bond with your spouse/family/friend?	5	4	3	2	1

Please feel free to provide us with any additional information regarding the ASSURE program that you feel is important for us to know, but may not have been covered in the questions above. (E.g. additional strengths or weaknesses of the program, specific benefits or negative aspects you experiences, etc.)

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Appendix S: Focus Group Questions

Questions for Individuals with lung cancer:

1. What were the Barriers (difficult) and Facilitators (easy) to exercise?
2. What was the value of the home exercise component? Would you recommend the program to others with lung cancer and what would you say?
3. What would be your future recommendations to make the study better for participants? If we were to offer a program then what should it look like?

Questions for caregivers:

1. What were the benefits for your friend/ family to participate in the program and what was the benefit for yourself?
2. What were the barriers and facilitators to yoga, resistance exercise and home exercise?
3. Would you recommend this program to other caregivers? If we were to offer a program then what should it look like?