The Impact of Physical Activity on Fatigue and Quality of Life in Lung Cancer Patients

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Abstract:

Background

People with lung cancer have substantial symptom burden and more unmet needs than the general cancer population. Physical activity (PA) has been shown to positively influence quality of life (QOL), fatigue and daily functioning in the treatment of people with breast and colorectal cancers and lung diseases, as well as in palliative settings. A randomised controlled trial (RCT) is needed to determine if lung cancer patients benefit from structured PA intervention. The Physical Activity in Lung Cancer (PAL) trial is designed to evaluate the impact of a 2-month PA intervention on fatigue and QOL in patients with non-resectable lung cancer. Biological mechanisms will also be studied.

Methods/Design

A multi-centre RCT with patients randomised to usual care or a 2-month PA programme, involving supervised PA sessions including a behavioural change component and home-based PA. QOL questionnaires, disease and functional status and body composition will be assessed at baseline, 2, 4 and 6 months. The primary endpoint is comparative levels of fatigue between the 2 arms. Secondary endpoints include: QOL, affective symptoms, dyspnoea, PA behaviour, fitness, functional abilities, hospitalisations, survival, cytokines and insulin-like growth factor.

Discussion:

This study will provide high-level evidence of the effect of PA programmes on cancer-related fatigue and QOL in patients with advanced lung cancer. If positive, the study has the potential to change care for people with cancer using a simple,
inexpensive intervention to improve their QOL and help them maintain independent function for as long as possible.

Trial Registration: Australian New Zealand Clinical Trials Registry No. ACTRN12609000971235

KEY WORDS:
physical activity, exercise, fatigue, quality of life, lung cancer.

Conflict of interest: None of the authors has a conflict of interest to declare.
BACKGROUND

Lung cancer is the leading cause of cancer-related death worldwide. In the United States alone it was estimated there would be 226,160 new lung cancer cases and 160,340 lung cancer deaths in 2012.[1] The majority (60%) of lung cancer patients present with advanced, incurable disease resulting in a median survival of only 9-12 months. In this context, the aim of anti-cancer treatment is to improve or maintain quality of life (QOL) in addition to prolonging survival.

Fatigue is one of the most common and distressing patient-reported symptoms associated with cancer and its treatment.[2-4] People with lung cancer report a higher prevalence and longer duration of cancer-related fatigue, leading to more functional impairment when compared to other cancer patients.[5] There is growing evidence that physical activity can improve fatigue in people with cancer,[6-8] and in those with chronic obstructive pulmonary disease (COPD).[9] However, no study has evaluated the benefits of a lifestyle physical activity programme for people with non-resectable lung cancer. This study will determine if physical activity improves fatigue, in people with non-resectable lung cancer.

In the past five years several large observational studies have reported that physical activity reduces the risk of cancer recurrence, death from cancer, and death from all causes for breast and colon cancer patients.[10-15] These studies have shown consistently that more than 9 metabolic equivalent task (MET) hours/week of physical activity (e.g. walking at a moderate pace for 2.5 hours/week) is associated with improved health outcomes. This is similar to the health guidelines of 150 minutes of moderate intensity physical activity per week or 60 minutes of vigorous physical activity per week. [16]
A burgeoning literature has examined the effects of physical activity on supportive care outcomes in people with cancer including physical fitness, physical function, fatigue and QOL.[7, 17-20] Observed benefits of physical activity include improved cardiovascular and pulmonary function, musculoskeletal strength, maintenance of mobility and independence, and improved psychological well-being and QOL.[8, 21, 22] Systematic reviews and meta-analyses have concluded that physical activity interventions during and after cancer therapies often result in meaningful and reliable improvements in several supportive care outcomes.[7, 8, 18, 19, 21-24] These benefits include observed changes in physiologic measures, objective performance indicators, self-reported functioning and symptoms, psychological well-being and overall QOL. However, these studies did not include people with advanced lung cancer.

A large body of evidence documents the benefits of physical activity as a component of pulmonary and cardiac rehabilitation in similar clinical populations, which demonstrate improved QOL, functional status, and symptom control including dyspnoea in patients with COPD. A Cochrane review of 31 randomised controlled trials in chronic obstructive pulmonary disease patients found those receiving pulmonary rehabilitation had statistically and clinically significant improvements in QOL, including dyspnoea, fatigue and patient control over disease.[9]

Despite the benefits of physical activity, only 20-32% of all cancer survivors report meeting physical activity guidelines.[17, 25-27] A recent study in lung cancer survivors found that 73% did not meet the United States physical activity guidelines, and 51% did not participate in any moderate or vigorous physical activity at all.[28] Lung cancer survivors who met the physical activity guidelines reported significantly better QOL across multiple domains compared to those who did not meet the
This suggests that there are considerable opportunities for improving the physical activity behaviour of lung cancer patients and possibly improving their QOL.

Most physical activity studies have been performed in cancer populations with potentially curative disease, particularly breast and colorectal cancer survivors. By comparison, people with advanced incurable lung cancer are older (median age of 70 years) and more likely to have co-morbidities such as chronic obstructive pulmonary disease and cardiovascular disease. However, physical activity has been found to be beneficial in older cancer patients,[2] and in a palliative population.[20] Cardiopulmonary exercise testing in people with advanced cancer, including lung cancer, has been shown to be safe and feasible, which suggests that most people would be able to follow a programme emphasising moderate intensity physical activity.[30]

The biological mechanisms by which physical activity may modify cancer risk or disease progression, or improve symptom control, include changes in insulin-like growth factor (IGF) levels, immune regulation, sex and metabolic hormone levels, prostaglandin ratio and obesity.[15, 31-34] More specific to lung cancer, physical activity improves pulmonary function and perfusion,[35] and it is hypothesised that physical activity may up-regulate antioxidants and free scavengers to help counteract the effects of cigarette smoke.[36] Physical activity may also decrease the risk of pneumonia and venothrombotic events, thereby improving overall survival and QOL in patients with non-resectable lung cancer. The main candidate mechanisms that will be evaluated in this study are the insulin axis and cytokine levels.

Our aim is to evaluate a physical activity programme in people with non-resectable lung cancer to determine if it improves fatigue and quality of life. Our hypotheses
are that people who undergo the physical activity intervention compared to those who do not, will: 1) report less fatigue; 2) have better health-related quality of life; 3) have improved overall survival; 4) have less decline in their level of physical function over time, and 5) that the reduced fatigue and risk of cancer recurrence occurs through the insulin axis and cytokines mechanisms/pathways.

Methods/Design

This multi-site, randomised controlled trial is being led by the Survivorship Research Group (SuRG) at the University of Sydney, Australia. Funding was obtained from a Young Investigator Award from the Lance Armstrong Foundation. Ethics approval has been obtained from Concord Repatriation General Hospital Human Research Ethics Committee for each participating institution under the New South Wales Health multi-site ethics approval scheme (HREC reference number: 08/CRGH/242). Participants are recruited from lung cancer clinics at 4 Sydney hospitals. Consenting, medically fit people with non-resectable lung cancer, including non-small cell lung cancer (NSCLC) and small cell lung cancer (SCLC) are randomised to usual care or a 2-month physical activity intervention (Figure 1). People with Stage III NSCLC or locally advanced SCLC being treated with curative intent must have completed combination chemo-radiotherapy a minimum of 4 weeks prior to randomisation, and have an incomplete response on staging CT scans. People with metastatic disease being treated palliatively may be receiving chemotherapy, radiotherapy and/or biological agents. All subjects must be medically fit to participate in a physical activity program, as assessed by the Physical Activity Readiness Questionnaire (PAR-Q)[37] and their treating physician. Major exclusion criteria are: Eastern Cooperative Oncology Group (ECOG) performance status ≥3, life expectancy < 6
months or insufficient English fluency to complete the questionnaires. Complete inclusion and exclusion criteria are outlined in Table 1. Randomisation is stratified for disease stage (locally advanced: NSCLC Stage III/ limited SCLC without a complete response to treatment versus metastatic disease: NSCLC Stage IV and extensive SCLC), ECOG performance status (0-1 versus 2), and cancer centre. It is performed by an external academic organisation using an interactive voice response system.

**Intervention**

All participants will have routine follow-up as per local cancer centre practice and receive cancer-specific education materials regarding nutrition (Eat For Health) and exercise (Move Your Body) published by Cancer Council Australia (http://www.cancer.org.au/home.htm) to encourage adoption of a healthy lifestyle.

Participants randomised to the physical activity intervention arm receive a 2-month individualised physical activity and behavioural support programme with a Physical Activity Consultant (PAC). The physical activity programme is based on the Theory of Planned Behaviour,[38] and modelled after the successful behaviour change programme developed by the Diabetes Prevention Programme.[39] The goal of the intervention will be to increase the participant’s physical activity over the 2-month intervention by a minimum of 3 MET hours per week compared to baseline. While this may be less than the recommended physical activity guidelines for some participants, those capable of increasing their MET hours further will be encouraged to do so.

The physical activity program will consist of supervised physical activity (30 to 45 minutes duration) and behaviour support sessions (15 to 30 minutes) once a week for
8 weeks, as well as unsupervised home physical activity sessions. The programme will be tailored to the participant’s baseline fitness, performance status and physical activity preferences, and take account of personal facilitators and barriers to physical activity.

Participants will be supplied with a physical activity and behaviour change guidebook titled “Exercising with Lung Cancer” for use throughout the intervention. The structured sessions include physical activity, but the primary focus will be to promote unsupervised physical activity using behaviour lifestyle change principles, such as goal setting, planning, self-monitoring (for which they receive a pedometer and physical activity diary), reinforcement, overcoming barriers, and social support. A full list of behaviour change session titles is outlined in table 2.

**Assessments**

Outcomes will be assessed at baseline (prior to randomisation), 2, 4 and 6 months (Figure 1). Baseline assessments involve a medical history and examination. At all assessments, disease and treatment status will be recorded and subjects will complete patient reported outcome (PRO) questionnaires, a standardised fitness test (6 Minute Walk Test, Senior's Fitness Test, hand grip strength), and donate blood for biomarker analysis. All subjects will wear an Actigraph GT1M accelerometer (Actigraph LLC, Pensacola, FL, USA) on the right hip to objectively determine physical activity for 7 full days prior to each assessment. Survival status will be obtained from the medical records, with follow up until the time of the final analysis.

*Primary and Secondary Endpoints*
The primary endpoint will be the level of self-reported fatigue as assessed by the Functional Assessment of Cancer Therapy - fatigue (FACT-F) subscale. [40, 41] The primary outcome will be a comparison of fatigue in the intervention and control arms at the conclusion of the intervention (i.e. at the 2-month assessment).

Secondary endpoints will include the following Patient Reported Outcomes:

- QOL (European Organisation for Research and Treatment of cancer –Quality of life questionnaire – Core (EORTC-QLQ-C30) and Lung module (LC-13 subscale), [42]
- affective symptoms (General Health Questionnaire 12;[43] Distress Thermometer),[44]
- perceived cognitive function (FACT-Cognition v3),[45]
- sleep quality (Pittsburgh Sleep Quality Index),[46]
- dyspnoea (University of California San Diego Shortness of Breath Questionnaire[47] and
- activities of daily living and instrumental activities of daily living.[48]

Other secondary endpoints relating to physical activity and fitness will include:

- physical activity and sedentary behaviour (Actigraph GT1M accelerometer; Active Australia questionnaire[49], sedentary behaviour questionnaire[50]);
- physical activity attitudes (Social Cognitive Determinants of Exercise questionnaire)[29, 51]
- physical fitness (6 Minute Walk Test, Seniors Fitness Test, hand grip strength);
- pulmonary function (Forced Expiratory Volume in 1 second, Forced Vital Capacity);
- general health, functional and performance status (anthropometric measurements, Colinet co-morbidity score[52], ECOG performance status, admissions to hospital/hospice and survival data); and
- mechanisms and prognostic biomarkers (Glasgow Prognostic Score [C-reactive protein, albumin], selected cytokine levels, insulin-like growth factors).

Table 3 gives an overview of all outcome assessments.

**Statistical analysis**

**Sample size**

A sample size of 106 evaluable participants (53/arm) provides 80% power (two-tailed $\alpha$ 0.05) to detect a difference of 6.9 points (FACT-F subscale range: 0-52) in the primary outcome measure of fatigue between the two treatment arms at 2 months and assuming a standard deviation of 9.[53] This is based on the hypothesis that patients with limited disease will have a greater benefit from the intervention than those with advanced disease. For the advanced cancer strata we estimate a mean difference of 6, which requires 72 patients with advanced disease to obtain 80% power. For the limited disease strata a mean difference of 9 requires 34 patients with limited disease. Using a weighted average of the two groups gives a mean difference of 6.9, requiring a total of 106 patients. Due to the poor prognosis for this patient population we need to increase our enrolment by 30% in the advanced disease group and 20% in the limited disease group to account for attrition. Therefore, in total we will aim to recruit ~140 patients: 98 with advanced disease and 42 with limited disease, giving us power to assess the overall patient group as well as both disease strata separately for the primary endpoint at the 2-month assessment.

**Statistical analyses**
Statistical analyses will be performed on an intention-to-treat basis. Linear mixed models will be used to model all continuous outcomes while accounting for covariance between repeated measures on patients and adjusting for baseline measures, which improves precision of estimation of effects. [54] These models will allow for: 1) comparing patterns of change over time by testing the intervention group by time interaction; and 2) estimating and testing differences between groups at time points of interest via linear contrasts. Mixed models are consistent with the intention-to-treat principle, and are unbiased for data which are missing completely at random and at random. [54, 55]

The effect of blood parameters on fatigue will be considered by using multiple regression at each of the post-intervention time points, adjusting for disease stage (locally advanced vs metastatic) and ECOG performance status (0+1 vs 2), active anti-cancer treatment and intervention. Patterns of change over time in blood parameters will also be investigated with mixed models. Our main hypothesis is that physical activity can alter IGF and cytokine levels. Other biological correlates for evaluation are the relationship between IGF and cytokines, and the association of each with fatigue and survival.

Overall survival is an exploratory endpoint, because the study has limited power to evaluate this. Patients alive at final analysis or who have become lost to follow up will be censored at their last contact date. Overall survival will be described by the Kaplan-Meier method. A stratified log-rank test adjusting for the stratification factors of disease stage (locally advanced vs metastatic) and ECOG performance status (0+1 vs 2) at randomisation will be used to compare overall survival between the two arms. Patterns of missing data will be assessed to consider potential missing data mechanisms. Baseline characteristics of patients lost to follow-up at 2, 4 and 6 months will be compared to patients who completed follow-up to assess patterns of loss to
follow-up, and provide insights into the generalisability of the results.

**Discussion:**

Advanced lung cancer is incurable, and is the leading cause of cancer deaths worldwide. The goal of treatment is to improve QOL, maintain physical function and prolong life. Treatments to date have focused on disease modifying anti-cancer therapies (e.g. chemotherapy or radiation). A focus on the person and their functional status reflects an innovative approach to therapy, maximising their ability to live with mimimal effects of the disease for as long as possible.

A physically active lifestyle improves fatigue and QOL in other cancer populations, particularly in early stage disease, but this type of intervention has not been evaluated in advanced lung cancer, where people are generally older with a higher burden of co-morbid illnesses than other cancer groups. This intervention has the potential to change standard care with a simple, safe, relatively inexpensive treatment that could improve the QOL of people with lung cancer and help them to maintain independent function for as long as possible. This study will determine whether a physical activity programme reduces the number of days participants spend in hospital for symptom control and end of life care. It will obtain unique data about the impact of physical activity on cytokines and the insulin pathway and the influence of each of these biomarkers on prognosis. It will provide preliminary evidence on whether physical activity can impact on survival in people with lung cancer.

One of the greatest challenges to implementation of physical activity programmes has been availability of adequate support and resources to promote and maintain
adherence with physical activity. If a randomised controlled trial demonstrated a significant benefit for people with lung cancer this would not only provide great impetus to patients to increase their physical activity and oncologists to promote it, but provide an evidence base to support a change in policy and practice to ensure patients engage with a physical activity consultant to design and follow-up a personalised physical activity programme. The intervention under study has been designed to ensure it can be offered in a hospital or community setting.

**Conclusions:**
Physical activity has been associated with many health benefits. This study will provide high-level evidence of the effectiveness of physical activity programmes to improve cancer fatigue and QOL in a cancer population with substantial symptom burden and high unmet needs. It will determine the feasibility of delivering exercise programmes in an advanced lung cancer population, and be powered to evaluate whether physical activity improves fatigue and QOL in this patient population. In addition, it will obtain important data about the impact of physical activity on physical function, body composition, mood, perceived cognitive function, dyspnoea, cytokines and the insulin pathway, and their influence on prognosis. The study outcomes have the potential to change standard care, with a non-toxic and inexpensive treatment, which can improve quality of life of people with lung cancer and help them achieve the highest possible level of independent function for as long as possible.[56]
Acknowledgements:

The study has received funding from the Lance Armstrong Foundation / National Lung Cancer Alliance Partnership.

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An equipment grant was received from the Sydney Cancer Centre Foundation for purchase of gymnasium equipment for use by trial participants.
Figure 1: Study flowchart

- **Diagnosis of incurable lung cancer**
- **Study registration**
  Baseline assessment (0 month)
- **Randomisation**
  Stratified by disease stage, performance status & centre
- **Arm 1 Intervention**
  General health education materials + 8 week physical activity program
- **Arm 2 Control**
  General health education materials
- **Follow-up 2, 4, 6 months**
  PRO, physical fitness & function
- **Survival follow-up**
  To death or 3 years post-intervention

PRO = patient reported outcomes
Table 1: Study inclusion and exclusion criteria:

<table>
<thead>
<tr>
<th>Inclusion criteria</th>
<th>Exclusion criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnosis of invasive lung cancer (NSCLC or SCLC) that, in the opinion of the oncology team, is non-resectable and non-curable</td>
<td>European Co-operative Oncology Group (ECOG) Performance Status of &gt; 3.</td>
</tr>
<tr>
<td>People with Stage III NSCLC or limited SCLC who have evidence of residual disease and have completed treatment with chemotherapy and or radiotherapy a minimum of 4 weeks prior to commencing the study</td>
<td>Pre-existing significant co-morbid conditions precluding participation in a physical activity programme, as determined by the investigator.</td>
</tr>
<tr>
<td>People with advanced disease being treated palliatively may be receiving chemotherapy, biological agents and/or best supportive care.</td>
<td>Insufficient English fluency to complete the questionnaires.</td>
</tr>
<tr>
<td>Aged at least 18 years.</td>
<td>Life expectancy of &lt; 6 months.</td>
</tr>
<tr>
<td>Medically fit to participate in a physical activity programme, as determined by their oncologist.</td>
<td>Inability to complete the baseline exercise test (6 Minute Walk) done prior to randomisation.</td>
</tr>
<tr>
<td>Ability (i.e. sufficiently fluent) and willingness to complete the patient-reported outcome questionnaires, physical activity questionnaires and logs in English.</td>
<td></td>
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<tr>
<td>Give written informed consent.</td>
<td></td>
</tr>
<tr>
<td>Completion of the 3 Questionnaire assessment within 14 days of registration.</td>
<td></td>
</tr>
<tr>
<td>Completion of the Physical Activity Readiness Questionnaire within 14 days of registration</td>
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</tbody>
</table>

NSCLC = Non-small cell lung cancer  
SCLC = Small cell lung cancer
Table 2: Behaviour change sessions

<table>
<thead>
<tr>
<th>Session*</th>
<th>Session focus</th>
</tr>
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<tbody>
<tr>
<td>1</td>
<td>goal setting and planning</td>
</tr>
<tr>
<td>2</td>
<td>key benefits of physical activity</td>
</tr>
<tr>
<td>3</td>
<td>strategies for making physical activity fun and enjoyable</td>
</tr>
<tr>
<td>4</td>
<td>overcoming barriers</td>
</tr>
<tr>
<td>5</td>
<td>securing social support from family and friends</td>
</tr>
<tr>
<td>6</td>
<td>time management</td>
</tr>
<tr>
<td>7</td>
<td>self-monitoring</td>
</tr>
<tr>
<td>8</td>
<td>stimulus control and self-reinforcement</td>
</tr>
</tbody>
</table>

* Order of behaviour change session delivery can be tailored to suit the most pressing educational and behavioural needs of participants.
Table 3: Assessments

<table>
<thead>
<tr>
<th>Investigations</th>
<th>Timing</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>History and Physical Exam including:</strong></td>
<td>0, 2, 4, 6 months</td>
</tr>
<tr>
<td>• Height (baseline only)</td>
<td></td>
</tr>
<tr>
<td>• Weight and Body Mass Index (BMI)</td>
<td></td>
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<tr>
<td>• Blood Pressure and Heart Rate</td>
<td></td>
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<tr>
<td>• Oxygen saturation (SaO2) (on room air)</td>
<td></td>
</tr>
<tr>
<td>• Concomitant medications (any changes to baseline meds)</td>
<td></td>
</tr>
<tr>
<td>• Colinet Co-morbidity Score</td>
<td></td>
</tr>
<tr>
<td>• Eastern Cooperative Oncology Group Performance Status (ECOG PS)</td>
<td></td>
</tr>
<tr>
<td>• Disease status</td>
<td></td>
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<tr>
<td>• Current treatments</td>
<td></td>
</tr>
<tr>
<td><strong>Fitness Testing</strong></td>
<td>0, 2, 4, 6 months</td>
</tr>
<tr>
<td>• 6-minute walk test (6MWT)</td>
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<tr>
<td>• Senior’s Fitness Test</td>
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<tr>
<td>• Hand grip strength</td>
<td></td>
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<tr>
<td><strong>Pulmonary Function</strong></td>
<td>0, 2, 4, 6 months</td>
</tr>
<tr>
<td>• Forced Expiratory Volume at 1 second (FEV₁)</td>
<td></td>
</tr>
<tr>
<td>• Forced Vital Capacity (FVC)</td>
<td></td>
</tr>
<tr>
<td><strong>Adverse Events</strong></td>
<td>0, 2, 4, 6 months</td>
</tr>
<tr>
<td>• Adverse events will be recorded and graded using National Cancer Institute</td>
<td></td>
</tr>
<tr>
<td>Common Terminology Criteria for Adverse Events Version 3.0 (NCI CTCAE v3.0)</td>
<td></td>
</tr>
<tr>
<td><strong>Patient Reported Outcomes</strong></td>
<td>0, 2, 4, 6 months</td>
</tr>
<tr>
<td>• Functional Assessment of Cancer Therapy - Fatigue (FACT-F subscale)</td>
<td></td>
</tr>
<tr>
<td>• Quality of Life (QOL) European Organisation for Research and Treatment of</td>
<td></td>
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<tr>
<td>Cancer – Quality of life questionnaire – Core (EORTC-QLQ-C30) and Lung module</td>
<td></td>
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<tr>
<td>(LC-13 subscale)</td>
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<tr>
<td>• Depression and Anxiety (General Health Questionnaire - GHQ12)</td>
<td></td>
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<tr>
<td>• Sleep Quality (Pittsburgh Sleep Quality Index - PSQI)</td>
<td></td>
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<tr>
<td>• Cognitive Function (Functional Assessment of Cancer Therapy – Cognitive</td>
<td></td>
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<tr>
<td>scale - FACT-COG v3)</td>
<td></td>
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<tr>
<td>• Distress (Distress Thermometer)</td>
<td></td>
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<tr>
<td>• Dyspnoea (The University of California, San Diego Shortness of Breath</td>
<td></td>
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<tr>
<td>Questionnaire - SOBQ</td>
<td></td>
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<tr>
<td>• Activities of Daily living (ADLs) and Independent Activities of Daily</td>
<td></td>
</tr>
<tr>
<td>Living (IADLs)</td>
<td></td>
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<tr>
<td>• Sedentary time (Sitting Questionnaire)</td>
<td></td>
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<tr>
<td>• Physical activity attitudes (Social Cognitive Determinants of Exercise</td>
<td></td>
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<tr>
<td>questionnaire)</td>
<td></td>
</tr>
<tr>
<td><strong>Physical Activity Behaviour/Adherence</strong></td>
<td>0, 2, 4, 6 months</td>
</tr>
<tr>
<td>• Physical activity participation (Active Australia)</td>
<td></td>
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<tr>
<td>• Accelerometer - for one week prior to each assessment</td>
<td></td>
</tr>
<tr>
<td><strong>Other Investigations</strong></td>
<td>0, 2, 4, 6 months</td>
</tr>
<tr>
<td>• Fasting Serum/plasma collection for correlative studies and optional</td>
<td></td>
</tr>
<tr>
<td>banking</td>
<td></td>
</tr>
<tr>
<td>Glasgow Prognostic score: Full blood count (FBC), Albumin, C-reactive protein (CRP)</td>
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</table>
References:


