

**A behaviour-change intervention to reduce sitting time in people with chronic obstructive pulmonary disease: a pilot randomised controlled trial**

**STUDY PROTOCOL**

The proposed study is a prospective, single-blind, randomised controlled trial to determine whether a six-week behaviour-change intervention is effective and feasible in reducing sitting time in people with chronic obstructive pulmonary disease (COPD). The participants will be randomised into two groups:

1. The intervention group, which will receive a six-week behaviour-change intervention that aims to reduce both total sitting time per day and the proportion of daily sitting time accumulated in bouts of longer than 30 minutes, or
2. The control group, which will receive a sham intervention in addition to usual medical care.

Assessments will take place at three time points: prior to randomisation (baseline), at the completion of the behaviour-change intervention (six weeks following randomisation), and at three months following the completion of the behaviour-change intervention (eighteen weeks following randomisation).

**Participant selection**

Participants will be recruited from the waiting lists for pulmonary rehabilitation programs at the following sites:

* Royal Prince Alfred Hospital, Sydney Local Health District
* Prince of Wales Hospital, South Eastern Sydney Local Health District
* Royal North Shore Hospital, Northern Sydney Local Health District
* Hornsby Ku-rin-gai Hospital, Northern Sydney Local Health District
* Ryde Hospital, Northern Sydney Local Health District
* Mona Vale Hospital, Northern Sydney Local Health District
* Manly Hospital, Northern Sydney Local Health District
* Terrey Hills Community Centre, Northern Sydney Local Health District.

**Participant inclusion criteria**

People will be eligible for inclusion if they:

* have a medical diagnosis of COPD (forced expiratory volume in one second / forced vital capacity ratio of < 0.7)
* are clinically stable, defined as no change in medication in the four weeks preceding recruitment
* can mobilise independently with or without a walking aid
* are expected to wait eight weeks or more on the waiting list for a pulmonary rehabilitation program at any of the eight sites listed above.

**Participant exclusion criteria**

People will be excluded if they:

* have participated in a supervised exercise training program within the last six months
* have limited spoken and/or written English which prevents them from participating in the intervention.

**Randomisation**

Participants will be randomised in a concealed manner using a computer-generated random sequence (https://www-users.york.ac.uk/~mb55/guide/minim.htm) to either the intervention or control group. This will be performed by a third person independent of the research team. Randomisation will be stratified according to exercise capacity (6-minute walk distance (6WMD) < 350 metres or ≥350 metres) and whether the participant has completed a pulmonary rehabilitation program in the past (yes or no).

**Primary outcome measures**

Total sitting time and proportion of sitting time accumulated in bouts of longer than 30 minutes: This will be measured using the activPAL3 activity monitor (PAL Technologies Ltd, Glasgow, Scotland, UK), which is a small lightweight sensor attached to the anterior mid-thigh using a waterproof adhesive dressing. This will be worn for seven days, 24 hours a day, at each assessment time point. The activPAL is considered the gold standard method for assessing sedentary time, as it contains an inclinometer that can distinguish between sitting and standing positions, and has demonstrated sensitivity to small changes in walking activity in people with COPD [1]. Time spent standing and walking will also be recorded. All sitting, standing and walking time will be expressed as a percentage of waking hours. Participants will record in a diary any time the activPAL is removed.

Feasibility of the intervention: This will be assessed by evaluating (1) uptake of the intervention (% of eligible participants who enrolled in the study) and retention (% of enrolled participants assessed at the completion of the six-week intervention), (2) compliance with the intervention (total number of intervention sessions completed within the six-week period), and (3) self-reported achievement of weekly goals. Any major or minor adverse events associated with the intervention will also be reported.

**Secondary outcome measures**

Functional exercise capacity: This will be assessed using the 6-minute walk test (6MWT). Two tests will be performed at each assessment time point to account for a learning effect with 30 minutes of rest between tests, and the best result recorded. Heart rate and oxygen saturation will be monitored during the 6MWT using a pulse oximeter. Dyspnoea and rate of perceived exertion will be recorded before and after each 6MWT using a modified 0-10 Borg scale. No studies of clinical populations have yet investigated whether reducing sitting time has any beneficial effects on functional exercise capacity, although it is physiologically unlikely.

Health-related quality of life (HRQoL): This will be assessed using the St George’s Respiratory Questionnaire (SGRQ). The SGRQ provides a total score for HRQoL based on the domains of symptoms, activity limitation, and impact of disease.

Domain- and behaviour-specific sitting time: This will be measured using the Sedentary Behaviour Questionnaire (SBQ). In this questionnaire, participants report how much time they spend sitting during nine different activities (e.g., watching TV, reading, transport) on a typical weekday and on a typical weekend day. The SBQ has demonstrated good test-retest reliability (ICC 0.51-0.93) and has been validated against objective measures of sitting time in healthy and overweight adults [2]. The SBQ will also be used to inform goal setting during the intervention period.

Patient activation: This will be measured using the Patient Activation Measure (PAM). “Patient activation” refers to a person’s knowledge, skills and confidence in managing their own health. The PAM assigns participants a score between 0-100, which corresponds to one of four activation levels. Patients with higher levels of activation are more likely to engage in positive health behaviours, manage their health more effectively and have better clinical outcomes; conversely, participants with low levels of activation tend to be passive and feel overwhelmed by managing their own health. The PAM has been tested extensively across different health conditions and demographic groups, and has been shown to be a consistent and accurate way of measuring changes in activation over time [3]. The PAM will be used to assess the impact of the behaviour-change intervention on participants’ capabilities and sense of empowerment to manage their own health.

Anxiety and depression: This will be assessed using the Hospital Anxiety and Depression Scale (HADS). The HADS has been shown to be a valid and reliable tool for detecting states of anxiety and depression in outpatient settings [4], and is regularly used in people with COPD.

Participant satisfaction and burden: This will be assessed using a study-specific questionnaire at the completion of the behaviour-change intervention, and will consist of a series of 5-point Likert scales and open-ended items. Semi-structured interviews will also be conducted to obtain qualitative data on participants’ experiences of the behaviour-change intervention. Interview questions will explore the impact of the intervention on beliefs and attitudes towards sitting time and on self-rated health, as well as barriers and facilitators to reducing sitting time. The interviews will be conducted in participants’ homes within one month of completion of the behaviour-change intervention by a third person independent of the research team. Each interview will be audiotaped and will take 30-45 minutes to complete.

**The behaviour-change intervention**

The behaviour-change intervention has been informed by the health belief model, which suggests that an individual is most likely to undertake a recommended preventative health action if they perceive a threat to their health, are simultaneously cued to action, and the perceived benefits of the health action outweigh the perceived barriers and costs [5].

In order to meet the target behaviours of (1) “Replace sitting with standing when possible”, and (2) “Stand up and move for two minutes after 30 minutes of unbroken sitting”, the stage of readiness for change of each participant will be assessed (pre-contemplation, contemplation, preparation, action or maintenance). The COM-B model and the Behaviour Change Wheel will then be used as a framework to employ appropriate behaviour change techniques to facilitate movement through the stages of change [6]. These include:

1. Education regarding the health risks associated with too much sitting, and how these risks can be reduced by replacing sitting with light intensity physical activity (e.g., standing).
2. Guided goal setting to reduce total sitting time and break up bouts of prolonged sitting. The aim is to implement one goal per week and progress that goal over the intervention period, so that by the final week participants will have integrated six goals into their day to reduce sitting time. Action planning and problem solving will be used to specify when, where and how participants will reduce their sitting time (e.g., Week 1: “I am going to stand up each time I finish one chapter of a book”, Week 2: “I am going to stand up while I prepare food for dinner” + Week 1 goal).
3. Motivational interviewing techniques. This will involve positive reinforcement, addressing any maladaptive beliefs participants may have about their disease or about sitting, using recollections of previous success with reducing sitting time to inform new goals, and acknowledging any difficulties they may have and redirecting them towards a solution.
4. Use of the Jawbone UP3 device to provide feedback about inactivity. The Jawbone UP3 (Jawbone, SF, USA) is a commercially available accelerometer worn on the wrist that is able to track and quantify periods of inactivity (referred to as “idle time” by the device). Participants will be asked to wear the Jawbone throughout the duration of the intervention. During face-to-face sessions, participants will be shown their activity data from the Jawbone and asked to reflect on periods of “idle time” ≥ 30 minutes. This feedback will then be used to inform subsequent goal setting. The Jawbone also has a vibrating alert function and will be programmed to vibrate after 30 minutes of sustained inactivity. This real-time feedback aims to remind participants to move if they accumulate 30 minutes of sustained inactivity.
5. Use of a workbook to record weekly goals and action plans. This workbook will also contain a simple daily checklist that participants can use to self-monitor their goals (e.g., “Today, did you achieve your goal of standing up while ironing the clothes? Yes/No. If not, what was stopping you?”). Self-reported achievement of goals will be interpreted from this checklist.

The behaviour-change intervention will be administered by one of the principal investigators and will consist of six weekly sessions. In Weeks 1, 3 and 6, participants will receive a one on one, face-to-face session of one-hour duration in their own home. In the other three weeks of the intervention, participants will receive supportive phone calls of up to 30 minutes. The “GROW” model will be applied to each session to ensure that the intervention is delivered consistently across participants. The “GROW” model is a standardised, solution-focused framework for conversations regarding behaviour change commonly used in health coaching interventions [7]. In the face-to-face sessions, participants will also complete the following questionnaires:

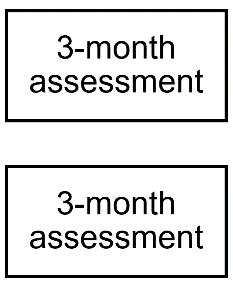
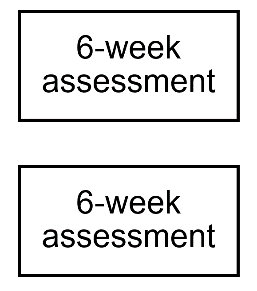
1. Stage of readiness for change assessment tool
2. Perceived Competence Scale, which assesses participants’ confidence in their ability to achieve the target behaviour, and
3. Treatment Self-Regulation Questionnaire, which assesses different motivators for the behaviour change.

The questionnaires have been adapted for this study to assist the principal investigator in monitoring participants’ movement through the stages of change and subsequently tailor the intervention to meet the individual needs and progress of each participant.

A safety protocol will be implemented to ensure the safety of the principal investigator when conducting face-to-face sessions in the participants’ own homes. A risk assessment will be performed over the phone prior to the initial face-to-face session, which consists of a checklist to evaluate the safety of the residence, the geographical location of the residence, and details about the participant and other residents in the home. If actual or potential risks are identified during this assessment, risk management strategies will be developed and documented. The principal investigator will also be required make mobile phone contact with another investigator from the study before entering the participant’s home, and again on exit.

**The sham intervention**

In order to provide similar levels of attention to the intervention and control groups, participants in the control group will be given a sham intervention in addition to usual care. The sham intervention will consist of weekly “sham” phone calls during the six-week intervention period. During these phone calls, the principal investigator will only confirm that the participant’s condition has not changed over the intervention period. No instructions regarding sitting time or exercise will be given, and participants will be directed to contact their local GP if they have any health issues.

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Weeks following randomisation:

1 2 3 4 5 6

**Figure 1.** Study flow diagram.

☺ = Face-to-face session; 🕿 = Phone session.

**Sample size calculation**

A total of 50 participants (25 per group) will be required to detect a between-group difference in sitting time of 90 minutes per day (α = 0.05, 80% power). The aim is to recruit 56 participants (28 per group) based on a 10% loss to follow-up. These sample size calculations are based on data from the “Small Steps” study, which used a behaviour-change intervention to reduce sitting time in healthy older adults [8]. The “Small Steps” study suggested that a reduction in sitting time of at least 90 minutes per day would be a meaningful change (moderate effect size of 0.53) based on a mean sedentary time of 534 ± 114 minutes per day.

**Data analysis**

All analyses will be performed using SPSS (Version 22 for Windows, IBM, USA). Intention-to-treat analysis will be conducted, and a p-value of < 0.05 considered significant. Analysis of covariance (ANCOVA) will be used to calculate between-group comparisons of (1) total sitting time and (2) proportion of sitting time accumulated in bouts of longer than 30 minutes after adjusting for pre-intervention values. Uncertainty about the size of the mean differences between groups will be quantified with 95% confidence intervals. Within-group comparisons will be examined using paired t-tests and described as mean differences with 95% confidence intervals. Functional exercise capacity, HRQoL, patient activation, and anxiety and depression will be analysed similarly.

Domain- and behaviour-specific sitting time according to the SBQ will be analysed descriptively. Feasibility measures will also be analysed descriptively. Uptake/retention of the intervention and participant compliance will be calculated as percentages. Adverse events will be categorised as “major” or “minor” events.

Qualitative data from the semi-structured interviews will be collected from participants in the intervention group until saturation is achieved [9]. De-identified interview transcripts will be examined using line-by-line iterative thematic analysis, and quotations extracted from the transcripts to provide supporting data for each theme [10].

**References**

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