

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

**INFORMATION FOR PARTICIPANTS**

**Introduction**

You are invited to take part in a research study which will investigate whether a six-week behaviour-change program is effective and feasible in reducing sitting time in people with chronic obstructive pulmonary disease (COPD). Too much sitting, especially long unbroken periods of sitting, is associated with a greater risk of mortality, hospitalisation for an acute exacerbation, diabetes, cardiovascular disease and weight gain. However, the most effective way to reduce sitting time in people with COPD is unknown. This study aims to determine whether a six-week behaviour-change program can reduce total daily sitting time and minimise long periods of unbroken sitting in people with COPD.

The study is being conducted as part of the requirements for a Doctor of Philosophy (Health Sciences) degree at the University of Sydney. The researchers are:

<Insert investigator>

**Study procedures**

You have been invited to take part in this study because you have a diagnosis of COPD and you are on the waiting list for pulmonary rehabilitation at <Insert institution>.

If you agree to participate in this study, you will be asked to sign the Participant Consent Form. You will then be randomly placed into either the intervention group (Group 1) or into a group for comparison (Group 2). There is an equal chance that you will be placed either group.

If you are in the intervention group (Group 1), you will be asked to participate in a six-week behaviour-change program. The program involves working with an investigator from the study to set six personal goals to reduce your sitting time and break up long periods of sitting in your daily life. You will be required to write down your goals in a workbook, and use a checklist to record whether or not you achieved your goals for the day. An investigator from the study will contact you once a week to provide you with support and feedback, and assist you with any difficulties you may be having. On three occasions, the investigator will visit you in your home; on the other three occasions, the investigator will call you on the phone. When the investigator visits you in your home, you will be asked to fill out a series of questionnaires that take a total of 10 minutes to complete. These questionnaires will assess your readiness to change your behaviour, the different motivating factors you may have to reduce your sitting time, and your confidence in your ability to reduce your sitting time.

During the six-week program you will also be asked to wear a bracelet style activity monitor. The bracelet style activity monitor will record how much time you spend sitting and will vibrate if you have been sitting for longer than 30 minutes to remind you to stand up and move. You should remove the bracelet style activity monitor when showering and when you go to sleep at night. The bracelet style activity monitor is the size and shape of a bracelet and should not cause any discomfort, but can be removed if any discomfort occurs.

If you are in the group for comparison (Group 2), you will not participate in the six-week behaviour-change program. An investigator from the study will call you on the phone once a week to monitor any changes in your health status over the six-week period.

You will be asked to complete a number of tests on three different occasions: before you are placed into either the intervention group or the control group, at completion of the behaviour-change program at six weeks, and finally at the end of study at three months. The testing will be held at <Insert institution> and will take approximately one hour.

The following measures will be taken:

1. Sitting, standing and walking time. You will be asked to wear a device called the activPAL. This device is attached to the front of your thigh with an adhesive dressing and will need to be worn for seven consecutive days, 24 hours a day. The device should not cause any discomfort. You may remove the activPAL device for showering or if any discomfort occurs.
2. Exercise capacity. You will be asked to complete two 6-minute walk tests, with a 30-minute rest period between tests. The aim of the test is to walk as fast and as far as you can for six minutes around an indoor track. Your heart rate, oxygen saturation, and levels of breathlessness and exertion will be monitored during the test.
3. Quality of life. You will be asked to fill in a questionnaire about the impact of COPD on your life. It will take about 15 minutes to do and will be completed during the rest period between the 6-minute walk tests.
4. Self-reported sitting time. You will be asked to fill in a questionnaire about the amount of time you spend sitting during different activities (e.g., watching TV, reading). It will take about five minutes to do and will be completed during the rest period between the 6-minute walk tests.
5. Patient activation. You will be asked to fill in a questionnaire about your confidence and ability to manage your own health. It will take about five minutes to do and will be completed during the rest period between the 6-minute walk tests.
6. Anxiety and depression. You will be asked to fill in a questionnaire about your emotional state. It will take about five minutes to do and will be completed during the rest period between the 6-minute walk tests.
7. Satisfaction with the behaviour-change program. If you are in the intervention group, you will be asked to fill in a survey about your satisfaction with the behaviour-change program. It will take about 15 minutes to do and will only be completed at the end of study. You may also be asked to complete an interview about your experiences of the behaviour-change program, and some of the barriers you faced in reducing your sitting time. The interview will be conducted in your home within one month of completing the behaviour-change program by a third person outside of the research team. The interview will be audiotaped and will take about 30-45 minutes to do.

Once the second set of measures has been taken, you will be able to commence a pulmonary rehabilitation program at <Insert institution> when there is a place available.

You will then be followed up for another three months, where you will complete the third set of measures and complete your participation in the study.

**Risks**

We do not expect there to be any risks from participating in the behaviour-change intervention. None of the devices used in this study should cause you any discomfort. There is a small possibility of an adverse reaction during the 6-minute walk tests, but it is extremely unlikely that any unforeseen cardiac events would occur. Your heart rate and oxygen saturation will be monitored continuously during the tests, and the tests will be terminated if it is found to be unsafe or if you request it.

**Benefits**

While we intend that this research study furthers medical knowledge and may improve treatment of COPD in the future, it may not be of direct benefit to you.

**Compensation for injuries or complications**

If you suffer any injuries or complications as a result of this study, you should contact Ms Sonia Cheng as soon as possible, who will assist you in arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

In addition, you may have a right to take legal action to obtain compensation for any injuries or complications resulting from the study. Compensation may be available if your injury or complication is sufficiently serious and is caused by the equipment or by the negligence of an investigator involved in the study. You do not give up any legal rights to compensation by participating in this study.

**Voluntary Participation**

Taking part in this study is completely voluntary. You do not have to take part in it. If you do take part, you can withdraw at any time without having to give a reason. If you decide not to take part in the study, you will remain on the waiting list for a pulmonary rehabilitation program at <Insert institution> and will be contacted when there is a place available. Whatever your decision, please be assured that it will not affect your medical treatment, your relationship with the staff who are caring for you, or your position on the waiting list for pulmonary rehabilitation.

**Confidentiality**

All the information collected from you for the study will be treated confidentially, and only the researchers named above will have access to it. The study results may be presented at a conference or in a scientific publication, but individual participants will not be identifiable in such a presentation.

**Further Information**

When you have read this information, Ms Sonia Cheng will discuss it with you further and answer any questions you may have. If you would like to know more at any stage, please feel free to contact her on 0402 572 611. This information sheet is for you to keep.

**Ethics Approval and Complaints**

This study has been approved by the Ethics Review Committee (RPAH Zone) of the Sydney Local Health District. Any person with concerns or complaints about the conduct of this study should contact the Executive Officer on 02 9515 6766 and quote protocol number X16-0305.