

**Participant Information Sheet**

|  |  |  |  |
| --- | --- | --- | --- |
| Study title: | Physical activity and text messaging to improve exercise capacity in obstructive sleep apnoea (OSA). | | |
| Locality: | **Dunedin** | Ethics committee ref.: | **17/STH/105** |
| Lead investigator: | **Dr Margot Skinner** | Contact phone number: | **03 479 7466** |

You are invited to take part in a study that involves physical activity and use of text messaging to improve exercise levels in adults with obstructive sleep apnoea (OSA). If you do not want to take part, you don’t have to give a reason, and it will not affect the care you receive. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

This Participant Information Sheet sets out why we are doing the study, what you would need to do, what the benefits and risks to you might be, and what will happen after the study ends. We will go through this information with you and answer any questions you may have. You do not have to decide today if you wish to be involved in this research. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers.

If you agree to take part in this study, we will ask you to sign the Consent Form on the last page of this document. We will give you a copy of both the Participant Information Sheet and the Consent Form to keep.

This document is 6 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

What is the purpose of the study?

Our study looks at different ways of supporting people with OSA to be more active. This will involve exercising in a group, or doing individual exercise, with or without text messaging for support. There have not been any studies on this in adults with your condition.

At present, adults diagnosed with OSA in our region are referred back to their GPs when they do not meet criteria for treatment. We think that a physical activity programme may provide health benefits to this group as well as to others who do meet the level for treatment. If you agree to be involved in this study, we will place you into one of the three groups at random, which involves either text messages for support, or a physical activity programme run by a physiotherapist, or both. The random selection ensures that there are no known differences between the groups. We will provide you with an individual activity programme suitable for your level of health and physical activity. So that they do not influence any results, the physiotherapist running the physical activity classes will not know whether people are getting text messages for support or not.

This study is funded through the School of Physiotherapy at the University of Otago. The primary investigator is Dr Margot Skinner, who is based at the School of Physiotherapy, and can be contacted on (03) 479 7466 or [margot.skinner@otago.ac.nz](mailto:margot.skinner@otago.ac.nz) to answer questions you may have before you decide whether to join the study.

**If you decide you wish to be involved in the study, please contact Marina Moss, the Clinical Research Administrator at the School of Physiotherapy on (03) 479 4979 to arrange an appointment.**

What will my participation in the study involve?

You have been chosen for this study as you have signs of OSA, including feeling tired on first waking and/or feeling sleepy during the day. Being in the study will mean that you have group activity for 12-weeks and/or support from a physiotherapist in the form of text messages to help you keep active. If you choose to be in the study but the overnight sleep test shows you do not have OSA, you will no longer be included in the study. However, you could still join the physical activity class if you have a referral from your GP.

At the start of the study, you will meet with the researcher for about 90 minutes. At this meeting, you will be asked to fill in six short questionnaires and some measurements will be taken: these include height, weight, blood pressure, heart rate, oxygen levels, neck size, waist size, grip strength and the distance you can walk in six minutes. Some of the questionnaires include sensitive information. You will fill in all the questionnaires, without the help of the researcher, and the questionnaires will have a number code on them, instead of your name. Before you leave, you will be given a small device (the size of a man’s watch) to wear on your wrist. This is to monitor your activity levels for seven days and nights. It must be removed when showering or swimming.

After the first meeting, if you are in one of the groups involving group physical activity, we will ask you to attend a class at the Unipol gym for an hour a week. The entrance is on Anzac Avenue, next to the Plaza Café, at the Forsyth Barr Stadium.

Each person in the study will attend two follow-up meetings, each lasting about 90 minutes, where the same questionnaires and measurements will be repeated. These will be at 12 weeks, and 24 weeks after the first meeting. You will also be asked to fill in just the questionnaires at 6 weeks and this can be done at home.

After completion of the study, we are interested in getting feedback from participants about their involvement, and the acceptability of the exercise programme and/or text messages. This would involve a single phone interview lasting no more than 30 minutes. Participants will only be given the opportunity to be interviewed if they wish to be so.

What are the possible benefits and risks of this study?

We will provide you with a personal activity plan based on the findings from the first meeting and advice on how to get started with exercise and how to monitor yourself to work at the right level of effort and comfort. The physical activity class will be run by a physiotherapist who is used to helping people who may have been physically inactive. The benefits of the study may include an increase in your activity levels and some positive changes in your health. You will receive a contact phone number at the start of the study, should you wish to seek advice at any time during the research. We will also inform your GP that you are involved in the study if you agree to let us do so. There is a small degree of risk involved in starting physical activity if you have not done much before. The risk is small, such as slight muscle soreness, but the benefits of starting to do some activity outweigh the risks.

Who pays for the study?

Being in the study will not cost you anything. There will be no charge for going to the classes if you are a participant in the study.

What if something goes wrong?

If you were injured during the exercise group in this study, which is unlikely, you would be eligible for compensation from ACC just as you would be if you were injured in an accident at work or at home. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery. Here is the link for further details: [*http://www.acc.co.nz/PRD\_EXT\_CSMP/groups/external\_claims\_care/documents/form/wcm2\_020603.pdf*](http://www.acc.co.nz/PRD_EXT_CSMP/groups/external_claims_care/documents/form/wcm2_020603.pdf)

If you have private health or life insurance, you may wish to check with your insurer that taking part in this study will not affect your cover.

What are my rights?

You are free to decide not to be in this study and, if you do choose to be involved, you may withdraw at any time and without any disadvantage to yourself. You have a right to access information collected about you as part of the study. Any new information that emerges during the study that might impact your health, either positively or negatively, will be made available to you. Data obtained will remain anonymous using the code numbers for the data sets, so no-one can be identified. The data will remain confidential to the researchers involved throughout.

What happens after the study or if I change my mind?

Following completion of the study, the group physical activity class will be available to anyone who wishes to continue; there is a gold coin donation system in place for each session.

Study data will be available to the research team and a research assistant. Names will not be used on any records.  Any printed records will be stored in a locked filing cabinet and all data on the computer will be password protected. Any raw data on which the results of the project depend will be stored securely for at least ten years in a locked filing cabinet. Since we may publish the results of the study in a journal that requires the public storage of data, data storage may be changed to public storage in the future, with the data remaining anonymous.

Once finished, the main findings of the study will be available to anyone who was involved, in electronic or printed form. This will be available in December 2020. The study findings will be presented at local, national, and international conferences, and article/s published in a relevant scientific journal.

Who do I contact for more information or if I have concerns?

If you have any questions, concerns, or complaints about the study at any stage, you can contact:

Dr Margot Skinner, Principal Investigator School of Physiotherapy

Phone: (03) 479 7466

Email: [margot.skinner@otago.ac.nz](mailto:margot.skinner@otago.ac.nz)

If you want to talk to someone who isn’t involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050

Dunedin: (03) 479 0265  
Invercargill: (03) 214 0415  
Fax: 0800 2 SUPPORT (0800 2787 7678)

Email: [advocacy@hdc.org.nz](mailto:advocacy@hdc.org.nz)

For Māori health support please contact the number above and ask for the Māori advocate.

You can also contact the Health and Disability Ethics Committee (HDEC) that approved this study on:

Phone: 0800 4 ETHICS

Email: hdecs@moh.govt.nz

|  |  |
| --- | --- |
| **Consent Form** |  |

**If you need an INTERPRETER, please tell us.**

**Please tick to indicate you consent to the following** *(Add or delete as appropriate)*

|  |  |  |
| --- | --- | --- |
| I have read, or have had read to me in my first language, and I understand the Participant Information Sheet. | Yes 🞏 | No 🞏 |
| I have been given sufficient time to consider whether or not to participate in this study. | Yes 🞏 | No 🞏 |
| I have had the opportunity to use a legal representative, whanau/ family support or a friend to help me ask questions and understand the study. | Yes 🞏 | No 🞏 |
| I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet. | Yes 🞏 | No 🞏 |
| I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my medical care. | Yes 🞏 | No 🞏 |
| I consent to the research staff collecting and processing my information, including information about my health. | Yes 🞏 | No 🞏 |
| If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed. | Yes 🞏 | No 🞏 |
| I consent to my GP and/or Consultant at the OSA Clinic being informed about my participation in the study and of any significant abnormal results obtained during the study. | Yes 🞏 | No 🞏 |
| I agree to an approved auditor appointed by the New Zealand Health and Disability Ethic Committees, or any relevant regulatory authority or their approved representative reviewing my relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study. | Yes 🞏 | No 🞏 |
| I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study. | Yes 🞏 | No 🞏 |
| I understand the compensation provisions in case of injury during the study. | Yes 🞏 | No 🞏 |
| I know who to contact if I have any questions about the study in general. | Yes 🞏 | No 🞏 |
| I understand my responsibilities as a study participant. | Yes 🞏 | No 🞏 |
| I wish to receive a summary of the results from the study. | Yes 🞏 | No 🞏 |
| I wish to provide feedback following completion of the study in the form of a single interview. | Yes 🞏 | No 🞏 |

**Declaration by participant:**

I hereby consent to take part in this study.

|  |  |
| --- | --- |
| Participant’s name: | |
| Signature: | Date: |

**Declaration by member of research team:**

I have given a verbal explanation of the research project to the participant, and have answered the participant’s questions about it.

I believe that the participant understands the study and has given informed consent to participate.

|  |  |
| --- | --- |
| Researcher’s name: | |
| Signature: | Date: |