INFORMATION SHEET

Study Title: Aerobic exercise to improve cardiopulmonary function in people with Parkinson's: a mixed method pilot study.

Invitation

You are being invited to consider taking part in the research study "Aerobic exercise to improve cardiopulmonary function in people with Parkinson's: a mixed method pilot study." This project is being undertaken by Aseel Aburub, a PhD student at Keele University, supervised by Dr. Sue Hunter, Sean Ledger, Professor Nicola Edelstyn and Professor Julius Sim.

Before you decide whether or not you wish to take part, it is important for you to understand why this research is being done and what it will involve. Please take time to read this information carefully and discuss it with friends and relatives if you wish. Ask us if there is anything that is unclear or if you would like more information.

Aims of the Research

Respiratory impairment (difficulty with breathing to full capacity and keeping the chest clear of infection) is considered to cause complications in the later stages of Parkinson's. Although there is evidence of respiratory impairment in the early stages of the disease, these symptoms do not appear until the end-stage. Aerobic exercise has been shown to improve respiratory function in asthmatic patients and in healthy people, but effects of aerobic training on respiratory function in people with Parkinson's have not been investigated. If aerobic exercise could decrease or delay respiratory impairment in Parkinson's, this might reduce respiratory complications, improve quality of life, and reduce treatment costs. Thus, this study will investigate the effects of an eight-week program of aerobic exercise, such as walking at a faster pace for 30 minutes, on respiratory function in people with Parkinson's.

Why have I been invited?

You have been invited to take part because you are a member of a Parkinson's support group. Permission has been granted from your group lead for me to approach all members to invite them to take part in this study, which will recruit up to 50 people with Parkinson's.

Do I have to take part?

You are free to decide whether you wish to take part or not. If you do decide to take part, you will be asked to sign a consent form. You will be given a copy of this participant information sheet and your signed consent form to keep. You are free to withdraw from this study at any time and without giving reasons. If you decide to withdraw from the study, we will destroy securely any documentation that contains personal identifiable information, but we will need to use other data collected up to the point of your withdrawal. For example, if you want to withdraw after week 4, all data collected up to and including week 4 will be used in our analysis. If you choose to withdraw after the focus group has been

completed, we will still use all the data from the focus group in our analysis. However, you would be able to withdraw your consent, in writing and within one week of completing the focus group, to the use of your quotations in any written or verbal presentation of the findings of this study. You are free to withdraw from the study at any time and this will not affect your continuing medical care.

What will happen if I take part?

If you would like to take part, we will arrange a suitable time for you to attend an appointment at Keele University for your assessment. You will be asked to sign a written consent form indicating that you are happy to take part in the study. We will collect some information about you, including name, gender, age, height, weight, and medical history; and you will then be asked to complete the following tests:

- A breathing (lung function) test (which will be conducted on three occasions during the trial, at weeks 0, 8 and 12):
  You will be asked to do a lung function test by using a noseclip and mouthpiece that is connected to a device; this is called spirometry. You will be asked to simply breath in and out quickly, and the device will record the amount of air you breath in and out, and the force of your breathing. This test will take approximately 30 minutes.

- A submaximal exercise test (which will be conducted on three occasions during the trial, at weeks 0, 8 and 12):
  You will perform an exercise test on a static bike (cycle ergometer). The exercise intensity will begin at a low level and will be advanced in stages, depending on your fitness level, depending on your age and weight. The test can be stopped at any time if we observe or you report any signs of fatigue or any type of discomfort. However, these symptoms are not anticipated and are considered to be unlikely. Blood pressure, heart rate, breathing rate and the amount of oxygen that you consume will be measured during the test. The test may take approximately 8-15 minutes to be completed. Before the test you will be asked to have a rest for 30 minutes. Thus, we allocate one hour for this test to be done.

- Completion of questionnaires.
  As part of the assessment you will be asked to complete six short questionnaires about your general physical functionality, memory, sleep and general health perception. It should take no more than a total of 30 minutes to complete them all.

After these tests, you will be randomly allocated to one of two groups: one group will be given an 8-week exercise program to do at home for 30 minutes three times per week, on top of your usual activities; the other group will just continue with their usual activities. Participants in both groups will be asked to wear a physical activity monitor. You will be given devices that record your physical activity level. You will be asked to wear it around your waist during the day except for swimming or showering. Those allocated to the 'usual care' group will be asked to simply undertake their usual level of physical activity for the duration of the trial, and not to engage in any new activity. At the end of a 12 week period, those who have received the exercise programme will be asked to participate in a discussion (focus group) to discuss any feedback they have about the study. The discussion will be audio recorded. In preparing the data from the process evaluation for analysis, all the audio tapes will be transcribed in full into text.

What are the benefits (if any) of taking part?

The results obtained from the tests may help in quantifying your exercise capacity and may be helpful in evaluating what type of physical activities are appropriate and safe for you. Participating in this pilot study will help us to find out whether the exercise programme improves fitness and function, is an acceptable programme that people with Parkinson's can do at home, and will help us to plan a larger trial.

What are the risks (if any) of taking part?

In certain exceptional circumstances, e.g. under intensive aerobic exercise, some people experience abnormal changes to blood pressure, fainting, angina, and in rare instances heart attack or stroke. However, in this study, the intensity of the aerobic exercise will be restricted and limited and participants will not be exercising at an intensive aerobic level; the exercise test will be at a sub-maximal level only. The level of exercise intensity will be closely monitored throughout and will be limited by the calculated 70% of maximum age-related heart rate. For example, for a 50-year-old person, the estimated maximum age-related heart rate would be calculated as 220 – 50 years = 170 beats per minute (bpm), and 70% of that would be 170 x 0.70 = 119 beats per minute. Similarly, for an 80-year-old person, the estimated 70% maximum heart rate would be (220 – 80) x 0.70 = 98 beats per minute. So, a 50 year old participant in this study would not exercise to a point at which heart rate exceeds 119 bpm, and an 80 year old would not exercise to a point at which heart rate exceeds 98 bpm. The exercise intensity would be monitored so that these heart rates (according to age) were not exceeded throughout the test. It is worthy of note that the average adult resting heart rate is around 70 beats per minute, e.g. when sitting in a chair.

The exercise test will be completed under the supervision of an appropriately qualified and experienced physiotherapist with expertise in exercise testing, and registered with the UK Health and Care Professions Council (HCPC).

How will information about me be used?

All personal information collected about you will be treated as confidential and privileged, and we will only collect information about you that we need to analyse the results of the study. The information and data will be used for statistical analysis or scientific purposes with your right of privacy maintained. For example, we will want to calculate the average age and the male:female ratio of people in the study. Your height and weight will be used to help us to interpret the data from the exercise, breathing and walking tests.

Who will have access to information about me?

We would like to reassure you that your personal information would be kept strictly confidential, and will only be accessible to members of the research team involved in the collection and processing / analysis of that data. No personal identifying information will appear in our published results according to Keele University confidentiality guidelines.

Who is funding and organising the research?

This research is not being funded externally and is part of Aseel Aburub's PhD studies, organised and overseen by Keele University.

What if there is a problem?

If you have a concern about any aspect of this study, you may wish to speak to the researchers who will do their best to answer your questions. You should contact *Aseel Aburub* in the first instance, or, alternatively, you may want to contact the project lead supervisor, *Dr Sue Hunter* (see contact details at the end of this page).

If you remain unhappy about the research and/or wish to raise a complaint about any aspect of the way that you have been approached or treated during the course of the study, please write to [name to be inserted when confirmed] who is the University's contact for complaints regarding research at the following address:-

[name to be inserted when confirmed] Research Governance Officer

Directorate of Engagement and Partnerships
IC2 Building
Keele University
ST5 5NH
E-mail: [*to be confirmed*]
Tel: 01782 733306

Contact for further information

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