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Can exercise improve heart and lung function in people with Parkinson's? The EXoCARP study.

Submission date
15/03/2019

Recruitment status
No longer recruiting

Registration date
18/03/2019

Overall study status
Completed

Last Edited
07/07/2023

Condition category
Nervous System Diseases

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Difficulties with breathing, known as respiratory impairment, are considered to be the main cause of complications and mortality in Parkinson's. Although there is evidence of respiratory impairment in the earlier stages of the disease, these symptoms do not generally appear as problems until the end-stage. Taking part in regular exercise that increases the heart and breathing rate, known as aerobic exercise, has been shown to improve respiratory function in people with respiratory disease such as asthma, and in healthy people. However, the effects of aerobic exercise training on respiratory function in people with Parkinson's have not been investigated. If increasing the amount of regular aerobic exercise improves respiratory function in the early to middle stages of the disease, it might be possible to decrease or delay respiratory impairment in the later stages. In turn, this might reduce complications due to respiratory impairment and improve quality of life for people with Parkinson's. Furthermore, engaging more in regular aerobic exercise might have additional benefits for people with Parkinson's, improving other symptoms that are not related to movement such as memory, mood, and independence in daily living. This might ultimately reduce long-term health and social care costs for people with Parkinson's. Before this can be tested in a clinical trial, the feasibility of running a clinical trial, and the acceptability of the exercise programme, need to be tested. Thus, this pilot study will determine the feasibility of a subsequent clinical trial investigating the effectiveness of an eight-week programme of increased aerobic exercise compared to usual physical activity to improve respiratory function in people with Parkinson's.

Who can participate?
Male and female adults (aged 18 years or over) with a diagnosis of Parkinson's who are able to walk independently without assistance for at least 10metres, and able to understand information and follow the instructions given in English language. People with existing chronic lung disease, or significant or unstable heart disease, or who are smokers, or who have any other condition or disorder that prevents them from taking part in increased physical activity, or who are unable to provide informed consent to take part, will not be eligible to take part.

What does the study involve?
Volunteers will be given full information about the study asked to attend an appointment at Keele University, where they will be asked to sign a consent form and complete a health

screening questionnaire to make sure that they are eligible to take part. Those who are eligible with then be asked to complete five short questionnaires about mood, memory, independence in daily life, quality of life, and non-movement problems in Parkinson's.

Participants will then complete a series of baseline breathing tests and an exercise test, which will be used to work out the intensity of their individual exercise programme. The breathing tests involve breathing in and out into a piece of equipment that will record how hard they can breathe out. The exercise test will involve sitting on an exercise bicycle, with a member of the research team to help them get on and off if needed. The participant will then be asked to pedal, gradually increasing at a steady rate, until they get tired and want to stop, without exceeding a pre-set heart rate (no more than 70% of their maximum heart rate; for example a maximum of 105 beats per minute for someone aged 70). During this sub-maximal exercise test, participants will wear a heart rate monitor around the chest to monitor the number of heart beats per minute (heart rate). The heart rate and blood pressure will be recorded before and after the exercise test.

Following completion of these tests, participants will be randomly assigned to either: undertake an 8-week community-based sub-maximal aerobic exercise programme e.g. community walking, cycling, treadmill walking (the type of exercise can be chosen by the participant according to preference) for 30 minutes, three times per week; or to continue with their usual level of physical activity for 8 weeks. Those assigned to the aerobic exercise intervention will identify the type of exercise they would prefer to do, through discussion with the researcher, who will offer instruction, advice and support on how to regulate and monitor the amount of exercise they will do, and how to build this into their day, 3 days a week, for 8 weeks.

During the 8-weeks intervention period of the trial, all participants will be asked to wear an activity monitor on a strap around their waist, to record when any physical activity has been undertaken, and for how long. The activity monitor will record heart rate, and exercise 'counts', for example the number of steps taken during a walk. Participants will also be asked to complete a daily record of their physical exercise.

After 8 weeks, all participants will be asked to attend a further appointment at Keele University, where the breathing and exercise tests and the five questionnaires will be repeated; the questionnaire about usual exercise activity will not be repeated. At a final 12 week, appointment at Keele University, the breathing and exercise tests will be repeated once more, but the questionnaires will not be repeated.

What are the possible benefits and risks of participating?
The possible benefits of participating include an improvement in breathing and exercise tolerance, and improvement in general well-being, independence in daily living, mood and memory. Potential risks of participating in any exercise include development of symptoms of heart disease. However, these are not anticipated as people with heart disease will not be eligible to take part in the study. Other potential risks of taking part in regular exercise include fatigue, muscle soreness, and breathlessness. However, these are usually short-term and are normal responses to exercise.

Where is the study run from?
The study is being run from the School of Health and Rehabilitation at Keele University. We will be recruiting people with Parkinson's through Parkinson's UK and other support groups in Staffordshire and Cheshire.

When is the study starting and how long is it expected to run for?
We plan to start recruiting to the study in March 2019, and anticipate the study will run until September 2020.

Who is funding the study?
The study is being undertaken by a PhD student at Keele University

Who is the main contact?
Dr Sue Hunter, Senior Lecturer, School of Health and Rehabilitation, Keele University, Keele, Staffordshire, ST5 5BG. Email address: s.m.hunter@keele.ac.uk

Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Version 0.2, 05/02/2019

Study information

Scientific Title
Aerobic exercise to improve cardiopulmonary function in people with Parkinson's: a mixed-methods pilot study

Acronym
EXoCARP

Study objectives

Is it feasible to deliver an 8-week community-based aerobic exercise intervention for people with Parkinson's in a trial, with sufficient numbers of participants recruited from community groups?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 07/03/2019, Faculty of Medicine and Health Sciences Research Ethics Committee (FREC) (School of Medicine, Keele University, Staffs, ST5 6JQ; 01782 734673; k.m.adams@keele.ac.uk) ref: MH-180006; MHFI-0003

Study design
Randomised controlled trial (pilot)

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Parkinson's disease

Interventions
Participants will be randomised (stratified according to Hoehn & Yahr stage 1-3) to either a) an 8-week community based participant-led sub-maximal aerobic exercise programme e.g. community walking, cycling, for 30 minutes three times per week; or b) usual care / physical activity (control).
Participants will record on a daily diary sheet the time they have spent exercising and the type of exercise they have done. This diary sheet will be returned to the research team when the participant returns for outcome measurements at week 8. Further, all participants will wear an activity monitor around their waist for the 8 weeks of the intervention, which will collect data about the amount of activity undertaken each day. This will be returned to the research team and the data will be downloaded from the monitor for analysis.

Intervention Type
Other

Primary outcome(s)
1. Recruitment, refusal and attrition rates.
2. Measures of pulmonary function: Lung volumes using spirometry - recorded at baseline (week 0), post-intervention (week 8) and at follow-up (week 12)
2.1 Forced expiratory volume in one second (FEV1) (the maximum amount of air that a person can forcibly breath out in one second).
2.2 Forced vital capacity (FVC) (the amount of air that can be forcibly exhaled from the lungs after taking the deepest breath possible).
2.3 Ratio of FEV1/FVC to identify any airflow limitation compared to established normative values.
3. Cardiovascular response to sub-maximal exercise, measured by cycle cardiopulmonary exercise test (CPET) recorded at baseline (week 0), post-intervention (week 8) and at follow-up

(week 12):
3.1 Predicted peak oxygen uptake (VO2peak %pred) to identify the predicted maximum amount of oxygen a person can utilise during exercise, a measure of cardiorespiratory fitness.
3.2 Heart rate (HR) during the CPET.
3.3 Blood pressure (systolic (SBP) and diastolic (DBP)).
3.4 Maximum workload (power of the cycle) achieved.
3.5 Test duration (how many minutes of exercise could the participant manage before stopping).

Key secondary outcome(s))
1. Objective measure of daily physical activity levels, by using a physical activity monitor (ActiGraph; Pensacola, FL) - recorded post-intervention (week 8)
1.1 Level of physical activity while walking measured by counts (count is the unit of movement in accelerometer in the three axes X, Y and Z) per minute.
1.2 Metabolic equivalents (METs) spent while walking (metabolic equivalent is a physiological measure expressing the energy cost of physical activities and is defined as the ratio of metabolic rate (and therefore the rate of energy consumption) during a specific physical activity), as a measure of intensity of exercise. METs=calories/(weight x time).
1.3 Steps/minute.
1.4 METs spent in different daily activities during the study period.
1.5 The activity monitors will be programmed only to detect physical activity measures, and will not record any GPS or location date.
1.6 In addition to the actigraph, an exercise diary will be provided for participants to record the duration and type of the additional aerobic exercise they have undertaken each day
2. Quality of life: Parkinson's quality of life questionnaire (PDQ-39) - recorded at weeks 0 and 8.
3. Depression: The Geriatric Depression Screening Questionnaire - recorded at weeks 0 and 8.
4. Independence in activities of daily living: Barthel Index - recorded at weeks 0 and 8.
5. Non-motor symptoms: Parkinson's non-motor symptoms questionnaire - recorded at weeks 0 and 8.
6. Memory: Prospective-Retrospective Memory Questionnaire - recorded at weeks 0 and 8

Completion date
01/01/2021

Eligibility

Key inclusion criteria
1. Adults (male and female) aged over 18 years old, diagnosed with Parkinson's according to the UK Brain Bank Criteria.
2. Disease severity classified between I-III according to the Hoehn and Yahr scale. Patients with I-III scores on Hoehn and Yahr are able to walk independently without assistance. Participants will be requested to do a sub-maximal CPET, therefore they need to be walking independently.
3. Ability to stand and walk for at least 10 meters without assistance.
4. Ability to understand instructions, with Mini-Mental State Examination score (MMSE) ≥24 (scores <24 reflect cognitive impairment).

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
21

Key exclusion criteria
1. Pre-existing diagnosis of lung disease, e.g. chronic obstructive pulmonary disease (COPD), asthma, bronchiectasis, emphysema, lung cancer.
2. Current smoker.
3. Participants with a history of heart disease that would present a risk of adverse cardiac event in response to the sub-maximal exercise tests (in accordance with the American Heart Association/ American College of Sport Medicine guidelines) as identified using the American Heart Association/ American College of Sport Medicine (AHA/ACSM) Health/Fitness Facility Pre-Participation Questionnaire.
4. Any other previously diagnosed musculoskeletal or neurological disorder that may prevent participation in physical activity.
5. Inability to understand English language (for the purpose of understanding instructions and information related to the study, as no interpreter is available).
6. Participants are required to sign a consent form, understand the instructions of the tests, the interventions and answer questionnaires. Thus, participants will be excluded from the study if they have dementia (as indicated by a MMSE score <24), or any other neurological or psychiatric disorder that would mean participants were unable to provide written informed consent.

Date of first enrolment
18/03/2019

Date of final enrolment
30/06/2020

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
School of Health and Rehabilitation
Keele University
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Sponsor information

Organisation
Keele University

ROR
https://ror.org/00340yn33

Funder(s)

Funder type
University/education

Funder Name
Keele University

Alternative Name(s)
La Universidad de Keele

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date