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Is a high intensity exercise intervention for people with Parkinson's disease feasible?

Submission date
10/02/2016

Recruitment status
No longer recruiting

Registration date
11/02/2016

Overall study status
Completed

Last Edited
21/03/2016

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
Parkinson's disease (PD) is a long-term medical condition which is caused by the gradual loss of nerve cells (neurons) in a part of the brain called the substantia nigra. These neurons are normally responsible for producing dopamine, a chemical messenger (neurotransmitter) which carries signals around the brain that help to coordinate movement. In people suffering from PD, these neurons gradually die over time, causing the level of dopamine in the brain to gradually fall. As the levels of dopamine become lower, the brain is unable to coordinate movement as effectively, causing abnormal movements such as stiffness, tremor (uncontrollable shaking) and slowness of movement (bradykinesia). These symptoms are treated using medications, the dosage of which is continually increased as the disease progresses (worsens). There is evidence to suggest that exercise programs can help to improve walking ability and balance in people with PD. It has been found however that this does not really work in the long-run, possibly because standard gym equipment is not specifically designed for PD sufferers and their worsening symptoms can make it difficult to use. Another reason may be that PD sufferers may not be able to exercise at an optimal intensity as their disability worsens. The Speedflex system is a new exercise training system which is designed to ensure that anyone can get the maximum benefit from their exercise sessions. Speedflex exercise machines automatically respond to and creates resistance levels based on the how hard a person is working, ensuring that exercise sessions are high-intensity but low impact (easy on the body). The aim of this study is to find out whether it is possible for people with PD to exercise at high-intensity using the Speedflex system, and what the benefits are in terms of fitness and quality of life

Who can participate?
Adults with idiopathic (unknown cause) PD who are physically independent.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in group one begin the high-intensity exercise programme immediately. This involves circuit training using a piece of exercise equipment (the Speedflex system), in three one-hour sessions over a period of six weeks. The Speedflex system is a fixed piece of gym equipment which can be used in a standing or seated position and avoids many of the problems people with PD report (e.g. falls, feeling unsafe) in using convention gym equipment such as treadmills, cross trainers and static bicycles. Those in

group two start the same exercise programme six weeks after group one. Participants in group one complete a number of questionnaires as well as fitness and breathing tests, in order to find out how effective the exercise is at the start of the study and then again after the exercise and six weeks later. Participants in group two complete the same tests and questionnaires at the start of the study, after group one have done their exercise, and again after they have done their exercise and six weeks later.

What are the possible benefits and risks of participating?
Participants may benefit from an improved ability to manage their symptoms and possibly slow down the progression (worsening) of the disease. Risks of taking part are small, however some participants may find the exercise tiring.

Where is the study run from?
North Tyneside General Hospital (UK)

When is the study starting and how long is it expected to run for?
September 2015 to September 2017

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Professor William Gray

Contact information

Type(s)
Scientific

Contact name
Prof William Gray

Contact details
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Additional identifiers

Protocol serial number
20046

Study information

Scientific Title
Can people with Parkinson's disease exercise at high intensity and, if so, what are the benefits? A fe

Study objectives

The aim of this study is to investigate whether it is possible for people with Parkinson's disease (PD) to exercise at high--intensity and, if they can, what are the benefits in terms of fitness and quality of life.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North East - Newcastle & North Tyneside 2 Research Ethics Committee, 05/10/2015, ref: 15/NE /0257

Study design
Single-centre stepped wedge feasibility study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Neurological disorders; Subtopic: Neurological (all Subtopics); Disease: Nervous system disorders, Parkinson's disease

Interventions
Participants will be randomly allocated to either group 1 (immediate start intervention) or group 2 (delayed start to intervention), with stratification to ensure groups are broadly matched for age and sex. Randomisation will be done post baseline assessment by a statistician blinded to assessment results and clinical characteristics. Group 1 will exercise in circuits at high-intensity using a piece of exercise equipment (the Speedflex system) which we feel is ideally suited to attaining the maximal exercise capacity of people with PD. The intervention will comprise three, hour-long, exercise sessions per week for 12 weeks. The Speedlflex system is a fixed piece of gym equipment which can be used in a standing or seated position and avoids many of the problems people with PD report (e.g. falls, feeling unsafe) in using convention gym equipment such as treadmills, cross trainers and static bicycles.
During the exercise intervention for group 1, group 2 subjects will have no specific intervention and will be managed by the NHS Trust PD service as clinically indicated. At the end of the group 1 intervention period, all subjects will be re-assessed and group 2 will then start the exercise intervention as for group 1, followed by post exercise intervention. All subjects will be further assessed at 6 weeks post intervention. Thus, group 1 will have 3 assessments (baseline, post-exercise and 6 week follow-up) and group 2 will have 4 assessments (baseline, end of group 1 exercise, post-exercise and 6 week follow-up).

Intervention Type
Other

Primary outcome(s)
Greater than 85% of predicted maximal heart rate achieved during each exercise session in over 50% of patients as determined using a heart rate monitor worn around the chest at baseline, post exercise and 6 weeks for group one, and at baseline, end of group 1 exercise, post-exercise and 6 week follow-up for group two.

Key secondary outcome(s))
Group 1 will have 3 assessments (baseline, post-exercise and 6 week follow-up) and group 2 will have 4 assessments (baseline, end of group 1 exercise, post-exercise and 6 week follow-up).

1. Adverse events (e.g. cardiac events, feeling unwell, slips, trips and falls) are recorded during each exercise session
2. Attendance at sessions is determined using a register at each session
3. Brain derived neurotrophic factor levels (BDNF) are measured using a standard assay of blood samples taken Immediately before the first exercise session, immediately after (5 minutes maximum) first exercise session, immediately before last exercise session, immediately after (5 minutes maximum) last exercise session, at 6-week follow-up assessment. In addition, the delayed start group (group II) will have two extra samples taken at the time of the start and finish of the exercise intervention for group I
4. Cardiac stroke volume is measured using a four-lead Cheetah-NICOM monitor at all assessment point
5. Carer (close family member) quality of life is measured using the validated PDQ-carer assessment at all assessment points
6. Cognitive function is measured using the Montreal Cognitive Assessment (MoCA) at all assessment points.
7. Lung function is determined by measuring forced expiratory volume in 1 second (FEV1) using spirometry at all assessment points
8. Total forced vital capacity is measured using spirometry at all assessment point
9. Gait and balance are measured using the Tinetti scale at all assessment points
10. Physical function is measured using the Barthel Index at all assessment points
11. Quadriceps muscle strength is measured using a hand-held dynamometer at all assessment point
12. Attitudes towards exercise are assessed at baseline and post-intervention via focus group discussions led by a health psychologist
13. Quality of life is measured using the PDQ-39 questionnaire at all assessment points
14. Walking distance is measured using the six minute walk test at all assessment points
15. Maximal oxygen consumption (VO2 max) is measured using a Quark CPET machine manufactured by COSME

Completion date
31/03/2017

Eligibility

Key inclusion criteria
1. Aged 18 years or over
2. Idiopathic Parkinson’s disease by the UK PD Society Brain Bank Criteria
3. Hoehn and Yahr Stage I-III
4. Ability to provide written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Have been enrolled in a study of an exercise intervention in the last 12 months
2. Other forms of Parkinsonism, e.g. drug induced,
3. Significant medical conditions which would preclude cardiac or lung function testing,
4. Significant medical co-morbidity which would preclude exercise or cardiac and lung function testing (e.g. recent blood clot, deep vein thrombosis, pulmonary embolism or myocardial infarction, unstable cardiac or respiratory function, recent major surgery)

Date of first enrolment
15/02/2016

Date of final enrolment
01/05/2016

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
North Tyneside General Hospital
Northumbria Healthcare NHS Foundation Trust
Rake Lane
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United Kingdom
NE29 8NH

Sponsor information

Organisation
Northumbria Healthcare NHS Foundation Trust

ROR
https://ror.org/01gfeyd95

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes