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Effect of a high-intensity tandem bicycle exercise program on clinical severity, functional magnetic resonance imaging and plasma biomarkers in Parkinson's disease: a pilot trial

Submission date
06/02/2018

Recruitment status
No longer recruiting

Registration date
08/02/2018

Overall study status
Completed

Last Edited
18/08/2020

Condition category
Nervous System Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Parkinson's disease is a frequent and progressive condition that causes shaking, difficulty walking and performing fine movements, and many other symptoms. Several drugs are currently available for the treatment of Parkinson's, but their effect is limited, so patients need more and better alternatives. Some studies have found that exercising might be good for people with Parkinson's, especially when it is done at a "forced rate", that is to say, causing the patient to out of their "comfort zone". Using a tandem stationary bicycle is a safe way of exercising for someone with Parkinson's. The aim of this study is to find out whether exercising on a tandem bicycle at a forced rate several times a week has a favourable effect on patients with Parkinson's disease.

Who can participate?
Patients aged 65 or older with Parkinson's disease

What does the study involve?
Participants are asked if they are able to regularly attend three high-intensity exercise sessions, including taking the time, expense, physical dedication and effort represented by this. Those who respond yes are allocated to the intervention group, and those who respond no are allocated to the control group. The control group receive usual care provided by their doctors. Participants in the intervention group receive usual care and also take part in a high-intensity tandem bicycle program: a 30-minute session consisting of a 10-minute warm-up followed by 20 minutes pedalling at 80 revolutions per minute or faster, three times a week over 16 weeks. Both groups are assessed before and after the intervention to measure the severity of their disease, the way their brain functions during movement with an MRI scan, and the blood levels of several markers of Parkinson's disease.

What are the possible benefits and risks of participating?
Possible benefits include improvements in general fitness and well-being, reductions in

Parkinson’s disease symptoms, and improvements in some of the brain processes than have been altered by Parkinson’s disease. The potential risks include muscular aches or minor strains from practicing exercise, and a minor bruise at the site of blood draw.

Where is the study run from?
Fundación Santa Fe de Bogotá (Colombia)

When is the study starting and how long is it expected to run for?
June 2014 to September 2016

Who is funding the study?
1. Fundación Santa Fe de Bogotá (Colombia)
2. Universidad del Rosario (Colombia)
3. Universida de los Andes (Colombia)

Who is the main contact?
Dr Carlos O Mendivil
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
ParkinsonTandem

Study information

Scientific Title
Effect of a high-intensity tandem bicycle exercise program on clinical severity, functional magnetic resonance imaging and plasma biomarkers in Parkinson's disease: a pilot trial

Study objectives
A high-intensity tandem bicycle program may provide benefits on the clinical condition, biochemical markers and functional neuroimaging of patients with Parkinson's disease.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Corporate Committee on Research Ethics (IRB) of Fundación Santa Fe de Bogota, 25/11/2014, ref: CCEI-2342-2014

Study design
Interventional parallel two-arm non-randomized single-center pilot study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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

Interventions
Potential participants from the Hospital's Parkinson's disease clinic were asked if they would be able to regularly attend three high-intensity exercise sessions of the described characteristics, including taking the time, expense, physical dedication and effort represented by this. Those who responded yes were assigned to the intervention group, and those who responded no were assigned to the control group.

After 8 weeks of physical conditioning, participants are allocated to:
1. Intervention group: Usual care plus a high-intensity tandem bicycle program: a 30-minute session consisting of a 10-minute warm-up followed by 20 minutes pedaling at 80 revolutions per minute or faster, three times a week over 16 weeks
2. Control group: Usual care provided by their doctors

Both groups were assessed before and after the intervention for:
1. The severity of their disease
2. The way their brain was functioning during movement with an imaging technique (fMRI)
3. The concentration of several substances that reflect the degree of improvement or deterioration that may be occurring with their Parkinson's

Intervention Type
Behavioural

Primary outcome measure
Disease severity, assessed using the Unified Parkinson's Disease Rating Score (UPDRS) before and right at the end of the 16-week intervention period

Secondary outcome measures
Measured before and right at the end of the 16-week intervention period:
1. Maximal oxygen consumption (VO2 max)
2. Body composition measures: BMI, % body fat, % lean mass, abdominal circumference
3. Cortical activations in functional Magnetic Resonance Imaging (fMRI)
4. Plasma concentrations of Parkinson's disease biomarkers: BDNF, PGDF-BB, Cathepsin-D, NGF, RANTES, ICAM-1

Overall study start date
01/06/2014

Completion date
30/09/2016

Eligibility

Key inclusion criteria
1. Idiopathic PD confirmed by a movement disorder specialist
2. Hoehn & Yahr stage 1 to 3
3. Age 65 or younger
4. Stable dopaminergic therapy
5. A negative exercise stress test

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
14

Total final enrolment
13

Key exclusion criteria
1. Surgery for Parkinson's disease
2. Cancer
3. Musculoskeletal diseases
4. Coronary disease
5. Hyperthyroidism
6. COPD
7. Severe visual problems
8. History of stroke
9. Anemia
10. Use of anticoagulants
11. Use of a pacemaker
12. Use of an insulin pump
13. Mini-mental score below 24

Date of first enrolment
01/04/2015

Date of final enrolment
01/03/2016

Locations

Countries of recruitment
Colombia

Study participating centre
Fundación Santa Fe de Bogotá
Carrera 7 No. 117 – 15
Bogotá
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110111

Sponsor information

Organisation
Fundación Santa Fe de Bogotá

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Sponsor type
Hospital/treatment centre

Website
www.fsfb.org.co/

ROR
https://ror.org/03ezapm74

Organisation
Universidad del Rosario

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Sponsor type
University/education

Website
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Organisation
Universidad de los Andes

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Sponsor type
University/education

Website
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Funder(s)

Funder type
University/education

Funder Name
Universidad de los Andes (University of the Andes)

Funder Name
Fundación Santa Fe de Bogotá (Santa Fe de Bogotá Foundation)

Funder Name
Universidad del Rosario

Alternative Name(s)
University of Rosario, Rosario University, UR

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Colombia

Results and Publications

Publication and dissemination plan
Once it is registered, it will be submitted to an internationally indexed, peer-reviewed journal.

Intention to publish date
01/08/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Carlos O Mendivil (carlosolimpo@gmail.com) and Dr Carolina Segura (carolinasegura2015@gmail.com). Type of data: anonymized primary data including group (intervention or control), demographics, baseline and final values of all study outcomes. When the data will become available: Data are already available and will remain available. By what access criteria data will be shared including with whom: Qualified researchers whose institutional affiliation we can verify. For what types of analyses: Whichever the researchers see fit. Whether consent from participants was obtained: consent was obtained from participants for the sharing of anonymized study data. There are no known ethical or legal restrictions in this concern.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	24/07/2020	18/08/2020	Yes	No