The Park-in-Shape study: a randomized controlled trial evaluating the effects of exercise on motor and non-motor symptoms in Parkinson*s disease.

Published: 07-05-2014
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Objectives: To evaluate whether aerobic exercise leads to clinically relevant improvements in 1) motor and 2) non-motor symptoms as well as quality of life and physical fitness.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Movement disorders (incl parkinsonism)
Study type	Interventional

Summary

ID

NL-OMON44535

Source
ToetsingOnline

Brief title
Exercise and Parkinson: The Park-in-Shape study

Condition

- Movement disorders (incl parkinsonism)

Synonym
hyokinetic-rigid syndrome, Parkinson's disease

Research involving
Human

Sponsors and support

Primary sponsor: Neurologie
Source(s) of monetary or material Support: ZonMW,Moller stichting

Intervention

Keyword: Exercise, Parkinson's disease, Randomized controlled trial, Symptoms

Outcome measures

Primary outcome

The primary outcome will be the UPDRS-MDS motor scale in OFF after 6 months.

Secondary outcome

The secondary outcomes will be the UPDRS-MDS motor scale in ON state after 6

months, and other motor and non-motor symptoms after 6 months, physical fitness

(VO2max, 6MWT) and quality of life after 6 months and adherence rate.

Study description

Background summary

PD patients are often physically inactive. A sedentary lifestyle is associated with co-morbid complications, whereas exciting new reports suggest that exercise might have the potential to suppress motor symptoms.
Hypothesis: We hypothesize that intensive aerobic exercise in sedentary PD patients results in clinically relevant improvements of several disease-related symptoms.

Study objective

Objectives: To evaluate whether aerobic exercise leads to clinically relevant improvements in 1) motor and 2) non-motor symptoms as well as quality of life and physical fitness.

Study design

phase 2, double-blind, randomized controlled trial

Intervention

Patients will be randomized to (a) cycling on a stationary home trainer, combined with virtual reality and gaming elements (exergaming group, n=65); or

(b) stretching exercises without aerobic component (active control group, n=65)

Study burden and risks

The baseline and follow up assessments will be performed at the Radboudumc and will last approximately 5 hours (including 1 hour lunch break and a 15 min coffee break). Almost all tests will be performed in the OFF stage of dopaminergic medication, except for the maximal aerobic exercise test and the UDPRS motor score that will be performed in both ON and OFF stage. Patients will be thoroughly screened for cardiovascular risks before performing a maximal aerobic exercise test and when considered harbouring a high cardiovascular risk or when experiencing any exercise intolerance during the test patients will be excluded to minimize the risk of an adverse event.
All subjects will perform a form of exercise at home for at least three times a week for six months. The control subject will perform stretching exercises which will be explained to them through an explanatory video*s and/or photo*s and one home visit by a trained physiotherapist. The subjects in the intervention group will cycle on a stationary bicycle for 30-45 minutes on a target heart range (determined during the maximal exercise test). The home trainer was chosen because it is a safe intervention (reduces risk of falls).
The bicycle will be placed at the patients home by the supplier and a member of the research team will explain the exercise program. During the exercise a visual feedback on their heart rate is provided that informs the patient whether he/she is exercising in their prescribed heart rate zone. Data from the bicycle is sent automatically to the researches after each training session allowing the researchers to monitor the results and adjust settings when needed. Additionally all patients will be supplied with a motivational App that stimulates and reminds them to exercise, shows their achievements and provides additional support by allowing them to invite their family and friends to follow their achievements.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1) Idiopathic Parkinson*s disease, according to the UK Brain Bank criteria, diagnosed by a neurologist
2) H&Y stage *2 tested in OFF
3) Age 30-75 years
4) Sedentary lifestyle (insufficient aerobic physical activity, as defined by the current American College of Sports Medicine (ACSM) recommendations for older adults).
5) Both medicated and unmedicated patients are eligible, if they:
* Receive a stable dopaminergic medication dose (both levo-dopa and/or a dopamine agonist are allowed) for one month before the study
* Are umedicated and deemed unlikely to start treatment within the next month by their treating neurologist

Exclusion criteria

1) Use of beta-blockers
2) Use of anti-psychotics
3) Inability to cycle or perform stretching exercises due to (other) neurologic or orthopedic co-morbidities
4) Inability to fill out questionnaires or perform a computer task (i.e due to poor vision, inability to read Dutch (illiteracy or foreign language)
5) Psychiatric diseases, including major depressive disorder, severe or moderate depressive episode or any form of psychosis, diagnosed by a psychiatrist in the last year.
6) No internet at home
7) MMSE <24
8) Contra-indications for aerobic exercise including diagnosed cardiac diseases (for instance

but not exclusive: unstable angina, heart block, arrhythmia*s, uncontrolled hypertension), diagnosed but poorly controlled diabetes mellitus or pulmonary diseases (e.g. but not exclusive COPD, exertional asthma, pulmonary emphysema).
9) Unavailable for more than 10% (approximately 2.5 weeks) of the 6 months

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-02-2015
Enrollment:	130
Type:	Actual

Ethics review

Approved WMO Date:	07-05-2014
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	24-07-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	

Date:	23-12-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	04-06-2015
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	26-04-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	20-03-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 26339
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL47747.091.14
OMON	NL-OMON26339

Study results

Date completed:	25-05-2018
Actual enrolment:	130

Summary results
Trial is onging in other countries