

# “Exercise and Parkinson”: The Park-in-Shape study

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON26339

### Source

Nationaal Trial Register

### Health condition

Parkinson's disease - Ziekte van Parkinson  
Exercise - Bewegen

## Sponsors and support

**Primary sponsor:** Radboud university medical center Nijmegen, department of neurology

**Source(s) of monetary or material Support:** ZonMw and a private foundation

## Intervention

## Outcome measures

### Primary outcome

UPDRS-motor score after six months

### Secondary outcome

Other motor and non-motor symptoms, quality of life, physical fitness after 6 months

## Study description

### Study objective

We hypothesize that intensive aerobic exercise in sedentary PD patients results in clinically relevant improvements of several disease-related symptoms.

### Study design

Assessments at baseline and after 6 months

### Intervention

Aerobic exercise, exergaming; 3-5x/wk for 6 months

## Contacts

### Public

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### Scientific

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## Eligibility criteria

### Inclusion criteria

1) Idiopathic Parkinson's disease, according to the UK Brain Bank criteria, diagnosed by a neurologist

2) H&Y stage  $\leq 2$

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<sup>23</sup>).

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 unmedicated 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 type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

## Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2014
Enrollment:	130
Type:	Actual

## Ethics review

Positive opinion	
Date:	14-08-2014
Application type:	First submission

## Study registrations

### Followed up by the following (possibly more current) registration

ID: 44535  
Bron: ToetsingOnline  
Titel:

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

No registrations found.

## In other registers

Register	ID
NTR-new	NL4575

**Register**

NTR-old

CCMO

OMON

**ID**

NTR4743

NL47747.091.14

NL-OMON44535

**Study results**