STEPWISE Parkinson: A smartphone based, titrated exercise solution for patients with Parkinson*s disease in daily life - pilot study

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON49229

Source
ToetsingOnline

Brief title
STEPWISE Parkinson - pilot study

Condition

- Other condition

Synonym
Parkinson's disease

Health condition

bewegingsstoornis, ziekte van Parkinson

Research involving

Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Locomotion, Motivation, Parkinson disease, Physical Activity

Outcome measures

Primary outcome

The main study parameter will be change in number of steps from baseline to

follow-up (after four weeks), measured with the patients* own smartphone

Secondary outcome

Secondary outcomes will be usability and enjoyment of the application and

different measures of physical fitness, motor- and non-motor functioning.

Study description

Background summary

Exercise affords health benefits for patients with Parkinson*s disease (PD), but implementing exercise in daily life remains challenging. We recently showed that PD patients can adhere to a 6 month high-intensity exercise training program on a stationary bicycle at home and found a higher aerobic capacity and improved motor symptoms after the training program. However, such a training program is not very scalable. We take an important step forward by developing and studying an innovative and fully decentralized smartphone-based program to increase long-term physical activity in patients with PD in daily life.

Study objective

The aim of this pilot study is to investigate whether the developed smartphone app can increase physical activity in PD patients for a short period of time (one month). The secondary aim is to study the usability and enjoyment of the app and the potential effects of an increase in physical activity on physical

fitness, motor- and non-motor functioning.

Study design

Pilot double-blind controlled intervention study.

Intervention

Patients will be randomized into one of three groups. All groups will be encouraged to increase their physical activity level, measured in step counts on the patients* own smartphone with a different percentage: (a) an increase in step count of 10% (active control group, N = 10), (b) in increase in step count of 50% (experimental group 1, N = 10), or (c) an increase in step count of 100% (experimental group 2, N = 10), compared to their baseline level.

Study burden and risks

The motivational application is non-invasive and the risks associated with participation in this project is negligible. Patients with PD will use the application at home for a time period of four weeks. The interventional groups will be encouraged to become substantially more active (ie. Take 50% or 100% more steps than at baseline) and one group will be encouraged to only slightly increase their physical activity level (ie. Take 10% more steps than at baseline). At baseline and after four weeks, PD patients will visit the Radboud University Medical Centre for measurements and PD patients and their caregivers will fill in a questionnaire and will be interviewed by telephone. This will take approximately 3-4 hours. All tests will be performed in the medication on state. Travel expenses will be reimbursed.

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 PD
2) Hoehn and Yahr 1-3
3) able to understand the Dutch language
4) able to walk independently
5) less than 30 minutes of outdoor and/or sports activities per day (LASA Physical Activity Questionnaire (LAPAQ))
6) takes less than 7.000 steps/day during 1-week baseline

Exclusion criteria

1) weekly falls in the previous 3 months
3) medical conditions that hamper mobility
4) living in a nursing home
5) cognitive impairments that hamper use of the motivational app on the smartphone (Montreal Cognitive Assessment <26)
6) not in the possession of a suitable smartphone (Iphone or Android)

Study design

Design

Study phase:	2
Study type:	Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-11-2020
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	08-09-2020
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	08-02-2021
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

No registrations found.

In other registers

Register	ID
CCMO	NL74352.091.20