Slow-SPEED-NL: Slowing Parkinson's Early through Exercise Dosage-Netherlands

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

Summary

ID

NL-OMON55989

Source
ToetsingOnline

Brief title
Slow-SPEED-NL

Condition

- Movement disorders (incl parkinsonism)

Synonym
Parkinson's disease

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Motivation, Parkinson's Disease, Physical acitivity, Prevention

Outcome measures

Primary outcome

The main study parameter is the longitudinal change (from baseline to 2-year follow-up) in number of steps between the treatment- and active control arm, measured with the participants* smartphone and smartwatch.

Secondary outcome

Secondary outcomes will be longitudinal change in measures of physical fitness, prodromal motor and non-motor features of PD, biological mediators for prodromal disease progression (blood: neuroinflammation, neurodegeneration, pathological protein spread, growth factors and ageing mechanisms, brain imaging markers of global and region-specific atrophy and neuroplasticity). Furthermore, we will assess completeness of remote digital biomarker assessments in both groups combined and feasibility. We will explore the incidence of clinically manifest PD in both treatment arms, acknowledging that only few participants may reach this endpoint during this 2-year study. Finally, we will conduct sensitivity analyses on gene specific mutations.

Study description

Background summary

Disease-slowing interventions have been ineffective in clinically manifest Parkinson*s disease (PD), when pathology is already advanced, but could succeed in prodromal PD, when pathology is limited. People with an isolated Rapid Eye Movement (REM) sleep Behaviour Disorder People (iRBD) have a high risk to

develop clinically manifest PD or a related neurodegenerative disease and are therefore considered to have probable prodromal PD. Here, we will study the effect of physical activity on the prodromal course of Parkinson's disease.

Study objective

The primary objective is to determine the feasibility of a remote intervention study to promote physical activity in people with iRBD. The secondary objectives are to determine the longitudinal effect of an exercise intervention in people with iRBD on digital, brain imaging and blood-based biomarkers of physical fitness and prodromal PD.

Study design

Double-blind randomized controlled trial.

Intervention

Participants will be randomized into one of two groups. Both groups will be encouraged to gradually increase the volume and intensity of their physical activities. Volume will be measured with a smartphone and smartwatch as change in step count relative to their own baseline step count (<7000). Intensity will be measured as change in the amount of minutes in which > 64% heart rate of their maximum heart rate is exerted relative to their own baseline count. The target step count and intensity will be a large relative increase (by 100%) for the intervention group (N=55). The active control group will get a target step count and intensity with a small relative increase (by 10%) (N=55). Treatment will be administered remotely using a gamified enhanced app.

Study burden and risks

The load on participants consists of the time spent on this project and two research visits. The motivational smartphone application is non-invasive and the risks associated with participation in this project are negligible. The research visits will take place at baseline and after the intervention period (2 years), consisting of physical examination, questionnaires, blood drawing assessments at Radboudumc (once 6 ml; further six samples of total 53ml at each assessment) and magnetic resonance brain imaging assessments at Donders Brain Imaging Institute. The total time per visit is estimated to be 3 hours. Travel expenses will be reimbursed. All other outcomes will be assessed remotely using the participants* smartphone, a dedicated study smartwatch and digital questionnaires. This involves passive monitoring of cardiorespiratory and prodromal measures, as well as active assessments of prodromal motor features (every 6 weeks) using the Roche PD mobile application v2. All measurements are minimally burdensome and without nuclear radiation. Individual participants do not directly benefit from participation, with the possible exception of

cardiovascular health benefits that may arise from increasing their physical activity level. Disclosing information regarding the risk of developing PD may cause distress. Only participants who are aware of this risk or wish to be informed about risks related to iRBD will be included.

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) previously diagnosed with iRBD meeting the following criteria according to the International Classification of Sleep Disorders (ICSD-3)59. Criteria A-D must be met:
a. Repeated episodes of sleep related vocalization and/or complex motor behaviours
b. These behaviours are documented by polysomnography to occur during REM sleep

or, based on clinical history of dream enactment, are presumed to occur during REM sleep
c. Polysomnographic recording demonstrates REM sleep without atonia (RWA)
d. The disturbance is not explained more clearly by another sleep disorder, mental disorder, medication, or substance use (the usage of beta-blockers or anti-depressant as possible luxating factor is not excluded)
2) Aged 50 years or older
3) able to understand the Dutch language;
4) being able to walk independently inside the home without the use of a walking aid.
5) equal to or less than 120 minutes of sports/outdoor activities per day (question 5-28 LASA Physical Activity Questionnaire (LAPAQ))
6) less than an average 7,000 steps/day during the 4-week eligibility and baseline period
7) In possession of a suitable smartphone (screen size minimum 4.6 inch), (Android version 9 or iOS version 15 or newer)

Exclusion criteria

1) clinically diagnosed or self-reported diagnosis neurodegenerative disease;
2) self-reported weekly falls in the previous 3 months;
3) dexterity problems or cognitive impairments hampering smartphone use;
4) if they do not wish to be informed about an increased risk of developing diseases associated with iRBD
5) if individual is not community dwelling

Regarding the MRI brain-imaging:
6) history of epilepsy, structural brain abnormalities (i.e. stroke, traumatic defects, large
archnoid cysts) or brain surgery
7) claustrophobia
8) implanted electrical devices (i.e. pacemaker, DBS, neurostimulator)
9) metal implants (such as prosthetics, ossicle prosthesis, metal plates or other non-removable metal part)
10) pregnancy
11) any other exclusion as per Donders Centre for Cognitive Neuroimaging MRI screening form

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:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	21-02-2024
Enrollment:	110
Type:	Actual

Ethics review

Approved WMO Date:	25-09-2023
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	19-12-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	30-04-2024
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	NL84072.091.23