Vibrating socks for Parkinson’s Disease

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23820

Source
Nationaal Trial Register

Brief title
TBA

Health condition

Parkinson's disease

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: Michael J. Fox Foundation

Intervention

Outcome measures

Primary outcome

The presence and percent time of FOG (total FOG duration divided by the total walking duration). The presence and percent time of FOG will be determined via offline visual analysis of the videos by experienced raters.

Secondary outcome

Spatiotemporal gait parameters as obtained by instrumented gait analysis (Xsense),

including velocity, step length, cadence and relative durations of the single and double limb support phases). In addition, patients' experience will be evaluated using standardized questionnaires.

Study description

Background summary

Freezing of gait (FOG) is one of the most disabling symptoms of Parkinson's disease (PD). Non-pharmacological approaches, including external cueing, are generating growing interest. However, it remains difficult to translate such cueing strategies into an efficient ambulatory device that is effective, but at the same time socially acceptable (i.e. 'invisible' to outsiders). In this regard, tactile cueing holds great promise. Here, we propose rhythmically vibrating socks as a new ambulatory device to improve gait and alleviate FOG in PD. The vibrating socks can offer tactile cueing in an open-loop (fixed frequency) or closed-loop manner (vibration is activated when 80% of body weight is placed on the sock. We expect both types of tactile cueing to be feasible and effective, with tactile cueing being preferential over auditory cueing.

Using a within-subject design, we will test the ability of vibrating socks, a new tactile cueing device for the management of FOG in patients with PD. We will include 40 PD patients with a recent history of disabling/regular FOG in two medical centres (Medisch Spectrum Twente and Radboud UMC).

Measurements will be conducted during two separate mornings (max. 4 hours per session), one while ON dopaminergic medication and one while OFF dopaminergic medication (>12 hours after intake of the last dose of medication). During both sessions motor (MDS-UPDRS part III) and cognitive status (FAB and MMSE) will be tested. Additionally, patients will perform four different walking tasks ((1) walking at preferred speed for 10 m, (2) turning while walking, (3) gait trajectory with narrow passages, (4) rapid full turns) in four different conditions ((1) tactile cueing in a closed-loop manner; (2) tactile cueing in an open-loop manner; (3) auditory cueing; or (4) no cueing). Each walking test will be performed three times, and recorded on video.

Primary outcome measure will be the presence and percent time of FOG (total FOG duration divided by the total walking duration). The presence and percent time of FOG will be determined via offline visual analysis of the videos by experienced raters.

Secondary outcome parameters are the spatiotemporal gait parameters as obtained by instrumented gait analysis (Xsense), including velocity, step length, cadence and relative durations of the single and double limb support phases). In addition, patients' experience will be evaluated using standardized questionnaires.

All outcome parameters will be compared between the four conditions (tactile closed loop cuing, tactile open loop cueing, auditory cueing and no cueing).

Study objective

We expect both types of tactile cueing (open- and closed loop) to be feasible and effective, with tactile cueing being preferential over auditory cueing.

Study design

24 months

Intervention

Vibrating socks, a new tactile cueing device

Contacts

Public
Medisch Spectrum Twente
Marleen C. Tjepkema-Cloostermans

+31 53 487 2850
Scientific
Medisch Spectrum Twente
Marleen C. Tjepkema-Cloostermans

+31 53 487 2850

Eligibility criteria

Inclusion criteria

Idiopathic Parkinson’s disease.
Recent history of disabling/regular freezing of gait (defined as presence of FOG several times a day in the past month and lasting longer than 1 second and verified objectively by an experienced neurologist).

Exclusion criteria

Gait impairments as a result of any other factor than Parkinson’s disease.
Sensory impairments (e.g. due to polyneuropathy) hampering patients to perceive vibration

of the socks.
Cognitive impairments that causes the patient to be unable to understand the research purpose and accompanying instructions.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	N/A: single arm study
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-02-2020
Enrollment:	40
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	17-04-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 48143
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7679
CCMO	NL68729.044.19
OMON	NL-OMON48143

Study results