Vibrating socks at home for Parkinson’s Disease

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24575

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: NA

Intervention

Outcome measures

Primary outcome

To evaluate the usability of vibrating socks as a home-based cueing device in patients with Parkinson’s disease (PD).

Secondary outcome

To evaluate patient satisfaction about the vibrating socks as a home-based cueing device.
To evaluate the effect of the vibrating socks in the home environment on the physical activity levels of the patients.
To evaluate the effect of the vibrating socks in the home environment on freezing severity measured by the NFOGQ (weekly instead of monthly).
To evaluate the effect of the vibrating socks in the home environment on the occurrence of self-reported falls/near falls by the patients.
To evaluate the long-term effect of the vibrating socks on several gait parameters in the home environment measured by a 3D accelerometer/gyroscope (velocity, step time, step time asymmetry, and cadence), an ECG sensor in combination with the 3D accelerometer/gyroscope (freezing of gait by comparing heart rate with velocity) and smart insoles (step time, step type asymmetry, cadence, and relative durations of the single and double limb support phases).

Study description

Background summary

Rationale: Freezing of gait (FOG) is one of the disabling motor 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 home-based ambulatory device to improve gait in PD. This research concerns a follow-up of the clinical study on the vibrating socks (NL68729.044.19). The vibrating socks will offer tactile cueing in a fixed frequency. We expect prolonged tactile cueing to be feasible in the home environment.

Using a within-subject design, we will measure device usability by the system usability scale. We will include 21 PD patient with a recent history of disabling/regular FOG and who respond well to the vibrating socks in a clinical setting or during a screening test. The study will be performed at the patients' home.

Measurements while wearing the vibrating socks will be conducted for three consecutive weeks ((1) without cueing, (2) with cueing (in which patients can turn cueing manually on/off), (3) follow-up without cueing) at the patients' home, in which they can perform their normal daily living. In addition to the vibrating socks, which contain a 3D accelerometer and gyroscope, patients will also wear an ECG sensor and Smart Insoles to determine gait parameters and heart rate. In the beginning of the first week the motor (MDS-UPDRS part III) and cognitive status (MoCA) will be tested and baseline measurements to determine FOG severity will be performed. In the beginning of the second week patients will perform a task known to elicit freezing (rapid full turns), with and without cueing. This is done to compare the golden standard for freeze detection to accelerometer data combined with heart rate data. Additionally, at the third day of the second week there will be an extra contact moment

to hear if the patient experiences any problems using the device. At the end of every week, four different questionnaires ((1) System Usability Scale (SUS), (2), Patient satisfaction questionnaire, (3) New Freezing of Gait Questionnaire (NFOGQ), (4) 39-item Parkinson's Disease Questionnaire (PDQ-39)) will be filled in by the patient. And at the end of week three the last questionnaire about patient feedback will be filled in.

The primary outcome measure will be device usability measured by the SUS, measured for three consecutive weeks (without cueing, with cueing and follow-up).

Secondary outcome parameters are patient satisfaction will be measured by a patient satisfaction questionnaire on a 5-point Likert scale, measured for three consecutive weeks (without cueing, with cueing and follow-up). Furthermore, the levels of physical activity will be calculated by using the accelerometers of the socks. Additionally, the occurrence of self-reported falls/near falls will be determined. Next, the freezing severity will be determined using the NFOGQ. The NFOGQ is a commonly used questionnaire during clinical assessments of gait in Parkinson's disease patients, for it is notoriously difficult to score FOG in a clinical setting. Lastly, the spatiotemporal gait parameters will be calculated as obtained by the 3D accelerometer and gyroscope, the ECG sensor and smart insoles, including velocity, step time, step time asymmetry, cadence and relative durations of single and double limb support phases.

Study objective

We expect prolonged tactile cueing to be usable in the home environment.

Study design

33 Months

Intervention

Vibrating socks, a new home-based tactile cueing device.

Contacts

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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).
Patients who previously displayed alleviation of gait disturbances when using the vibrating socks in the ongoing study (NL68729.044.19) .
Patients who show or expect a benefit of the vibrating socks during a screening test.

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 the vibration of the socks.
Cognitive impairments that causes the patient to be unable to understand the research purpose and accompanying instructions.
Patients who already use devices that aim to reduce FOG (e.g. Parkinson’s walker). Such devices may interfere with the study results.
Patients who wear compression stockings.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2021
Enrollment:	21
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 52273
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL9280
CCMO	NL76285.100.21
OMON	NL-OMON52273

Study results