Vibrating socks at home for Parkinson’s Disease

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

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24575

Bron
Nationaal Trial Register

Verkorte titel
TBA

Aandoening

Parkinson's disease

Ondersteuning

Primaire sponsor: Medisch Spectrum Twente
Overige ondersteuning: NA

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

33 Months

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-03-2021
Aantal proefpersonen:	21
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing
Soort: Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 52273
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten