Vibrating socks for Parkinson’s Disease

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Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23820

Bron
Nationaal Trial Register

Verkorte titel
TBA

Aandoening

Parkinson's disease

Ondersteuning

Primaire sponsor: Medisch Spectrum Twente
Overige ondersteuning: Michael J. Fox Foundation

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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).

Doel van het onderzoek

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

Onderzoeksopzet

24 months

Onderzoeksproduct en/of interventie

Vibrating socks, a new 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).

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 vibration

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

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	14-02-2020
Aantal proefpersonen:	40
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	17-04-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 48143
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten