Vibrating socks: a novel cueing intervention to reduce freezing of gait in Parkinson*s disease.

Published: 27-08-2019 Last updated: 04-07-2024

To test the clinical efficacy of vibrating socks, a new tactile cueing device, for the management of FOG in patients with PD.

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

Summary

ID

NL-OMON48143

Source ToetsingOnline

Brief title Vibrating socks for Parkinsons Disease

Condition

• Movement disorders (incl parkinsonism)

Synonym freezing of gait, Parkinson's disease

Research involving Human

Sponsors and support

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

Intervention

Keyword: Freezing of gait, Parkinson's disease, Tactile cueing, Vibrating socks

Outcome measures

Primary outcome

The main study parameter is the percent time of FOG during four different walking tasks.

Secondary outcome

Secondary outcome parameters are the presence of FOG and the spatiotemporal gait parameters as obtained by instrumented gait analysis (Xsens), (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 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.

Study objective

To test the clinical efficacy of vibrating socks, a new tactile cueing device,

for the management of FOG in patients with PD.

Study design

Using a within-subject design, we will test the ability of vibrating socks to provide patients with FOG with cueing to successfully improve gait and alleviate FOG. The study will be performed in two medical centres (Medisch Spectrum Twente and RadboudUMC).

Intervention

The vibrating socks, a new tactile cueing device.

Study burden and risks

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 and a FOG questionnaire will be completed. 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 task will be performed three times, and patients will were a Xsense system for gait analysis. In addition all walking tests will be recorded on video. At the end of each visit, patients* experience is evaluated using a brief questionnaire in order to ensure that the developed device has the potential to be suitable for use in daily life settings.

Short-term skipping of levadopamedication to achieve an OFF status, is a frequently applied and safe strategy within Parkinson research and is safe for patients. Parkinson medication is only symptomatic and it does not affect the underlying disease process. In the OFF status, patients notice an increase in Parkinson's symptoms, this increase is fully reversible on intake of medication. This is not harmful to health and has no long-term effects for the patient.

The potential risks of the investigational product are considered negligible. The low-taxing tests ensure that the risk of the subject falling is no larger during the test than in daily living. The chance of worsening of symptoms is minimal, since the subject is gently stimulated to walk and no movements are forced.

Contacts

Public Medisch Spectrum Twente

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years) Elderly (65 years and older)

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
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research purpose and accompanying instructions.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

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

Medical products/devices used

Generic name:	Vibrating socks
Registration:	No

Ethics review

Approved WMO	
Date:	27-08-2019
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	
Date:	27-01-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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Approved WMO	
Date:	24-12-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 23820 Source: NTR Title:

In other registers

Register CCMO Other ID NL68729.044.19 NL7679