Vibrating socks as a home-based tactile cueing device for Parkinson's disease.

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To evaluate the usability of vibrating socks as a home-based tactile cueing device in PD.

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

Summary

ID

NL-OMON52273

Source
ToetsingOnline

Brief title
Vibrating socks at home

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: Medisch Spectrum Twente

Intervention

Keyword: Freezing of gait, Home-based, Parkinson's disease, Tactile cueing, Usability, Vibrating socks

Outcome measures

Primary outcome

The main study parameter is the device usability measured by the system usability scale.

Secondary outcome

- To evaluate patient satisfaction about the vibrating socks as a home-based cueing device measured by a patient satisfaction questionnaire on a 5-point Likert scale.

- To evaluate the effect of the vibrating socks in the home environment on the physical activity levels of the patient measured by the built-in accelerometer of the socks.

- 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 long-term effect of the vibrating socks on several gait parameters in the home environment measured by a 3D accelerometer (velocity, step time, step time asymmetry, and cadence).

Study description

Background summary

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 vibrating socks to be usable as a cueing device for applying prolonged tactile cueing in the home environment.

Study objective

To evaluate the usability of vibrating socks as a home-based tactile cueing device in PD.

Study design

Using a within-subject design, we will measure device usability by the system usability scale. The study will be performed at the patients* home.

Intervention

The vibrating socks, a new home-based tactile cueing device.

Study burden and risks

Measurements while wearing the vibrating socks will be conducted for two consecutive weeks (week A without cueing and week B with cueing (in which patients can turn cueing manually on/off)) at the patients* home, in which they can perform their normal daily living. The order of starting with week A or week B, will be balanced between patients.
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 week A will the socks be turned on, however no cueing will be given. At the third day of this week there will be a contact moment to hear if the patient experiences any problems using the device. At the end of the week the NFOGQ en PDQ-39 will be filled in.

In week B the socks will be in cueing mode. At the third day of this week there will be a contact moment to hear if the patient experiences any problems using the device. At the end of the week the NFOGQ, PDQ-39 and SUS will be filled in. The participant will then also 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.

At the end of the measurement period participants will fill in the patient satisfaction questionnaire and the patient feedback questionnaire.
The potential risks of the investigational product are considered negligible.
The chance of worsening of symptoms is minimal, since the subject is gently stimulated to walk and no movements are forced.

Contacts

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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).
Patients who previously displayed alleviation of gait disturbances when using

the vibrating socks tested 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 vibration of the socks.
Cognitive impairments that cause 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) and cannot participate without using these devices. Such devices may interfere with the study results.
Patients who wear compression stockings.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	28-06-2021
Enrollment:	21
Type:	Actual

Medical products/devices used

Generic name:	Vibrating socks
Registration:	No

Ethics review

Approved WMO Date:	24-03-2021
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	03-06-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	12-07-2022
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: 24575
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL76285.100.21
OMON	NL-OMON24575