Prediction of Freezing of Gait and evaluation of the Parkinson's Vibrating Socks during daily-life activities in a house-like environment for people with Parkinson's disease.

Published: 12-11-2024
Last updated: 18-01-2025

To develop a FOG prediction algorithm under free-living conditions, and to test evaluate the use of the Parkinson*s Vibrating socks under the same conditions

Ethical review	Approved WMO
Status	Pending
Health condition type	Movement disorders (incl parkinsonism)
Study type	Observational non invasive

Summary

ID

NL-OMON57149

Source
ToetsingOnline

Brief title
Parkinson's Vibrating Socks

Condition

- Movement disorders (incl parkinsonism)

Synonym
Freezing of Gait in Parkinson's Disease

Research involving
Human

Sponsors and support

Primary sponsor: University of Twente
Source(s) of monetary or material Support: Interreg european project

Intervention

Keyword: Cueing devices, Freezing of Gait, Parkinson's disease

Outcome measures

Primary outcome

Primary objective:

• To create and evaluate a FOG prediction algorithm using IMU sensors, physiological sensors, and a wearable camera in a house-like environment.

• To quantitatively and qualitatively evaluate the use of Parkinson*s vibrating socks in a house-like environment.

Primary study parameters:

Study parameters to answer the first study's main objective will be collected by the 15 movement sensors attached to different body positions (collecting body position, body acceleration, and body rate of rotation), one smartwatch with GSR and PPG sensors, one wearable ECG sensor and one wearable GSR sensor for monitoring the stress levels, and one eye tracker to retrieve the pupil diameters and the point of fixation of the subject in the environment in front of him/her, and eHealth house*s cameras (for labeling purposes). The primary endpoint will then be the prediction model.

Study parameters to answer the second study's main objective will be the same as the first study*s main objective, adding the questionnaires that the participants will fill out at the end of the day about the Parkinson*s Vibrating Socks.

Secondary outcome

Secondary objective:

• To investigate how stress levels change before FOG.

• To investigate how the environment influences FOG.

• To investigate if there is any correlation between abnormal posture and the onset of FOG.

• To assess the effectiveness of monitoring skin conductance and heart rate by using a smartwatch on the wrist, compared to standard ECG and Skin conductance measures.

Secondary study parameters:

The study*s secondary objective will be answered using the same outcome parameters as the first objective, except for the questionnaires about the usability of the investigated device.

Study description

Background summary

Freezing of Gait (FOG) is one of the most bothersome gait difficulty experienced by people with Parkinson*s disease (PD). Cueing systems can be

promising in reducing the number of freezing episodes. Cues can be auditory, visual, or tactile stimuli. Developing a minimally invasive tactile system (Parkinson*s Vibrating Socks) could overcome the usability limits of both visual and auditory cues. Cues can be provided in two different ways: continuously or *on-demand*. *On-demand* cueing can prevent cue dependency and fatigue, and maintain more effectiveness over time. To provide *on-demand* cues, it*s important to predict freezing before it happens.

Study objective

To develop a FOG prediction algorithm under free-living conditions, and to test evaluate the use of the Parkinson*s Vibrating socks under the same conditions

Study design

Data will be collected at the University of Twente (eHealth house) for one day. All participants will be asked to skip their morning levodopa intake on the day of the visit. By doing so, in the morning, participants will be acquired in a clinically defined OFF state in which FOG happens more often. If they do not want to participate under this condition, they will be invited following their regular levodopa intake in the morning (ON state), as the main objective of the data collection is to collect as many FOG events as possible, without regard to the medication condition. Upon arrival, participants will be instrumented with different wearable motion and physiological (e.g. ECG) sensors on their bodies. Next, participants will proceed to a laboratory with a home-like environment (the eHealth house). During the first part of the visit (in OFF state), participants will perform activities resembling their morning routine (semi-free-living condition). After that, participants will be asked to follow a trail inside the house (semi-controlled condition).
In the afternoon, in ON state, participants will follow the same trail in 3 different conditions: without any cueing system, and wearing the Parkinson*s Vibrating socks, activated in two different conditions: continuous cueing and on-demand cueing (simulated). Lastly, questionnaires regarding the usability of the socks will be presented to the participants. The entire study visit will be registered by video (gold standard to FOG detection). The study visit is expected to last no more than 7 hours (including at least 1.5-hour break), with less than 2 hours in the OFF state.

Study burden and risks

All procedures are non-invasive. The study visit will begin at an OFF status because FOG happens more predominantly when participants are without medication (if the participants will accept this condition). The study visit is expected to last no more than 7 hours in total, with less than 2 hours in OFF state. In OFF condition, there is a small risk of participants feeling overwhelmed or, for instance, experiencing a fall episode. To diminish the risk, we have

minimized the activities performed in an OFF state. In addition, participants will be advised to take about 1.5-hour break between the morning and the afternoon sessions. Moreover, 5-minute breaks will be present between two consecutive phases in the afternoon. Finally, to ensure safety and efficiency, the assessments will be performed by a trained researcher. In any case, if the participant wishes so, the study visit can be stopped or canceled at any time. Participants are not expected to directly benefit from the study. However, under their request, clinical and technical data collected during the study can be made available to them.

Contacts

Public
University of Twente

Drienerlolaan 5
Enschede 7522 NB
NL
Scientific
University of Twente

Drienerlolaan 5
Enschede 7522 NB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Diagnosis of Parkinson*s disease;

2. Use of Parkinson*s disease medications, and/or usage of advanced therapies such as Deep Brain Stimulation that can be deactivated;
3. 18 years or older;
4. At least 3 Freezing of gait episodes of any type experienced daily (on average)
5. Able to provide informed consent.
6. Able to understand verbal instructions.

Exclusion criteria

1. Incapacitating dyskinesia or dystonia;
2. Comorbidities that cause severe gait impairment (e.g. severe arthrosis or neuropathy);
3. Constant use of any gait aid.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	02-09-2024
Enrollment:	30
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	12-11-2024
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL86905.091.24