Freezing of Gait prediction in daily life

Published: 03-12-2019
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Objective: to develop a FOG detection and prediction algorithm under free-living conditions.

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

Summary

ID

NL-OMON48011

Source
ToetsingOnline

Brief title
FOG@Home

Condition

- Movement disorders (incl parkinsonism)

Synonym
paralysis agitans; shaking palsy

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universiteit Nijmegen
Source(s) of monetary or material Support: EFRO project

Intervention

Keyword: Daily life, Freezing of Gait, Parkinson's disease, Wearable Sensors

Outcome measures

Primary outcome

Machine learning and deep learning techniques will be applied to outcomes derived from clinical assessments, wearable motion sensors (e.g. gait related: abnormal gait classification, gait cadence, gait velocity, freezing index, number of FOG episodes, percentage time spent on FOG, heart rate variability, and skin conductivity), and video (presence of FOG) in order to create an algorithm aiming at predicting an upcoming FOG episode and detecting an existing FOG episode. Afterwards, ensemble technique will be applied to combine the results from multiple different algorithms or parameters into a single result. This step will increase algorithm precision. The same techniques will be applied to data collected during the follow-up, in order to develop an algorithm robust predicting an upcoming FOG episode and detecting an existing FOG episode under free-living circumstances.

Secondary outcome

To investigate the influence of different sensor types, sensor number, and sensor locations on the performance of a FOG detection and prediction algorithm performance we will create different prediction algorithms using data from clinical assessments (see table 1) and data from wearable sensors collected in different numbers and sensor location. Models will be created using Machine learning and/or Deep learning approaches. Machine learning algorithms build a mathematical model based on sample data, here outcomes extracted from the sensors and clinical assessments, in order to make predictions or decisions

without being explicitly programmed to perform the task. Self-reported FOG, falls and balance problems, extracted from the smartphone application, will increase model performance. Afterwards, model performance measures from models including data from all sensors versus data from sensor from one location only, as well as models from semi-free-living condition versus free-living conditions will be compared in order to stablish the best model.

Next, we will apply the model created using data from study visit 1 (see paragraph 10.1) to the data collected in study visit 2. We will then compare the performance measures of each model and determine whether the model is robust for a population that shows changes over time (i.e. the test-retest reliability of the algorithm for prediction FOG episodes).

Finally, we will correlate balance-related outcomes (see table 1) to gait variability measures (i.e. stride time, stride length, gait cadence, and gait velocity). To achieve that we will apply extract from the raw sensor data outcomes such as: level of chaos in the signal (maximal Lyapunov exponent), stride time variability, stride length variability, and time in double stance.

To increase reliability, all outcomes will be averages over a 3-days period.

Those outcomes will them be used to detect a change on balance against clinical measurements (collected in study-visit 1 and 2) and patients* self-reports collected during the 7-days study follow-up.

Study description

Background summary

Freezing of Gait (FOG) is the most bothersome gait difficulty experienced by people with Parkinson*s disease (PD). FOG is assessed by visual gait analysis during clinical consultations. However, the episodic character of FOG makes it difficult to accurately assess the severity of FOG. Therefore, reliable detection of FOG outside hospital environments would enhance care for this disabling symptom.

Study objective

Objective: to develop a FOG detection and prediction algorithm under free-living conditions.

Study design

Observational longitudinal cohort study.

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: All procedures are non-invasive. The study visit will begin at an OFF status because FOG happens more predominantly when participants are without medication. The study visit is expected to last no more than 5 hours in total, with 2.0 hours in OFF state. There is a small risk of participants feeling overwhelmed or, for instance, experiencing a fall episode. To diminish the risk, we have minimized the number of assessments in an OFF state. In addition, participants will be advised to take a 40 minutes break. Finally, to ensure safety and efficiency, the assessments will be performed by a trained and experienced physiotherapist. In any case, if the participant wishes so, the assessment can be stopped or cancelled 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. Once in their possession, participants may share the data with any health professional or family member if they wish to.

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

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
1. Self-reported diagnosis of Parkinson*s disease;
2. Use of levodopa or other Parkinson*s disease medication;
3. 18 years or older;
4. Freezing of gait episodes experienced on a daily basis (New freezing of gait questionnaire answer to question 2 * *How frequently do you experience freezing episodes?* * * Very often, more than once a day);
5. No cognitive or psychiatric impairment as judged by the researcher;
6. Possession of a smartphone with suitable Android operating system;
7. Able to provide informed consent.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

1. Incapacitating dyskinesias or dystonia;
2. Comorbidities that cause severe gait impairment (e.g. severe arthrosis or neuropathy);
3. Usage of advance therapies such as Deep Brain Stimulation;
4. Freezing of gait episodes exclusively in ON period (because this is thought to have a different pathophysiologic mechanism than the more regular version of

FOG which occurs predominantly during OFF).

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	19-04-2021
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	03-12-2019
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	13-05-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	24-02-2022
Application type:	Amendment
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	NL71352.091.19