EEG signals predicting freezing of gait in Parkinson patients

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

Summary

ID

NL-OMON47712

Source
ToetsingOnline

Brief title
FOG Prediction

Condition

- Movement disorders (incl parkinsonism)

Synonym
Freezing of gait in Parkinson's Disease

Research involving
Human

Sponsors and support

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

Intervention

Keyword: EEG data analysis, Freezing of Gait, Parkinson's Disease

Outcome measures

Primary outcome

The following study parameters will be collected during the 1st and 2nd

experiments. Both experiments will be video-taped and rated for the presence of

FOG. The videos only can be accessed by researchers.

o 64- and 32-channel EEG data will be acquired by ActiCap and TMSi EEG system

from participants in both two experiments, respectively;

o Gait parameters such as cadence will be calculated from 4 accelerometers on

lower body of participants (TMSi, 4 sensors = 2 above ankles, 2 above knees);

o Gait parameters related to the gait of upper body will be calculated

from 2 accelerometers and 2 EMG sensors (TMSi) above metacarpophalangeal joints

and forearms of participants, respectively ;

o ECG data measured (TMSi);

o Vertical forces of foot acquired by TMSi Footswitches.

Secondary outcome

no applicable

Study description

Background summary

Freezing of gait (FOG) is a common and debilitating phenomenon in Parkinson*s disease (PD). FOG is defined as a brief, episodic absence or marked reduction of forward progression of the feet despite the intention to walk. Recent technological advances have improved the ability to provide compensation

strategies in daily life situations. Examples include wearable minicomputers in the form of smart glasses that can provide rhythmic visual cueing or augmented visual cues on top of the patient*s visual field. The feasibility of these technological advances would further improve, if these cueing-strategies could be applied in an on-demand manner (i.e. cueing only occurs when FOG is detected, and preferably predicted). Hence, there is a need to introduce a real-time system for FOG prediction and detection to automatically activate external cues.

Study objective

The main objectives of this study are to acquire EEG, ECG and motion data from 15 PD patients with FOG for the algorithm development to online detect and predict FOG, and test the performance of developed algorithm in 15 PD patients with FOG. We will perform two separate experiments. In the first (1st) experiment, we will provoke FOG during stepping movements in place. Using these data, we will develop an algorithm to detect and predict FOG. In the second (2nd) experiment, we will test the developed algorithm during several walking tasks.

Study design

We will perform two separate experiments. In the first experiment, we will provoke FOG during stepping movements in place. Using these data, we will develop an algorithm to detect and predict FOG. In the second experiment, we will test the developed algorithm during several walking tasks. All procedures of this study are non-invasive. In both experiments, 15 PD patients with FOG will be included. All participants are tested at their *off* medication state, following an overnight withdrawal (> 12 hours after intake) of anti-Parkinson medication. The participants attending the 1st experiment (in-place movement) will be asked whether would be willing to continue the 2nd experiment (daily life movement). A new participant will be recruited if the participant does not want to participate in the 2nd experiment.

The 1st experiment consists of the following parts: reception and explanation about the study (15 minutes), questionnaires (45 minutes), system preparation of EEG, motion sensors, ECG and footswitches equipment (50 minutes), movement-in-place tasks (approximately 70 minutes, including several breaks). The movement-in-place tasks are composed of 3 conditions: normal (at self-selected speed) stepping in place, normal turning (a 180-degree turn) in place, rapid turning (a 180-degree turn) in place. Every condition lasts 2 minutes. A single visit for 1st experiment takes approximately 3 hours.

The 2nd experiment consists of the following parts: reception and explanation about the study (15 minutes), questionnaires (45 minutes), system preparation of EEG, motion sensors and ECG equipment (40 minutes), movement tasks (80

minutes including several breaks). The movement tasks include rapid-turning in place with or without dual tasks (Adjusted Auditory Stroop task, AAS task), walking at a normal speed on a 8-meter trajectory including executing several turns and walking through doorways, walking on the same trajectory at a rapid speed with dual tasks (AAS task), and walking on the same trajectory at a normal speed with dual tasks (AAS task and using a walking tray with a cup of water). Every condition lasts 1 or 1.5 minutes. A single visit for 2nd experiment takes approximately 3 hours.

Study burden and risks

All procedures are non-invasive. Experiments are conducted while participants are in their 'off' state (>12 hours after last intake of dopaminergic medication). This is expected to cause more FOG (increasing the power of the study) and an increase of PD symptoms which will resolve upon medication intake after the experiments. Studies in the 'off' state are common in PD research and do not pose a risk to participants. Physical tiredness which might occur during the in-place movement and walking tasks is minimized by allowing participants to rest as often and long as needed. Persons with PD, and especially those with FOG, are, due to the nature of their disease, at risk for falling. We do not expect that walking with the portable EEG cap nor ECG equipment aggravates the risk of falls. During the walking tasks, one of the researchers will walk with the patient, to prevent the patient from falling. This study is therefore not dangerous and poses no risk to the patients.

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

* Men/women of age > 18 years with idiopathic Parkinson*s disease, as diagnosed by the UK Brain Bank Criteria.
* Written informed consent.
* Presence of FOG (defined as a score of 1 on question 1 "Have you experienced FOG in the past month" from the NFOGQ).
* Disabling/regular FOG (defined as a score of 3 "Very often, more than one time a day" on question 2 "How often do you experience FOG" from the NFOGQ).

Exclusion criteria

* Comorbidities that cause severe gait impairment (e.g. severe arthrosis or neuropathy).
* Severe cognitive impairments (MMSE<24).
* Inability to walk 150 meters unaided.
* Bald (entirely) participants

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-11-2017
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO Date:	04-05-2017
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	02-08-2018
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	NL60942.091.17