Virtual visual cues to reduce freezing in Parkinson*s disease: an explorative study

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

Summary

ID

NL-OMON45400

Source
ToetsingOnline

Brief title
Virtual visual cueing in Parkinson*s Disease

Condition

- Movement disorders (incl parkinsonism)

Synonym
Freezing of gait in Parkinson's Disease

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Twente
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: Freezing of gait, Parkinson's Disease, Visual cueing

Outcome measures

Primary outcome

The main study parameters are *freezing severity*, *step time variability variability*, *modal footstep latency*, *motor initiation* and *stopping performance *.

The study parameters are contrasted between:

1) Cue responsiveness (during VR foot pedalling and overground walking), and

2) The correlation between freezing during overground walking and VR foot pedalling; both uncued and visually cued, and

3) Participant category (persons with PD-FOG versus healthy controls)

Secondary outcome

Secondary endpoints are: association of freezing during VR pedalling with subjective FOG severity, and user experience with the paradigm.

Other study parameters measured are: age, Hoehn-Yahr-stage, UPDRS part III score, and scores on the mini mental state examination (MMSE) and frontal assessment battery (FAB).

Study description

Background summary

Freezing of gait (FOG) is a particularly disturbing and potentially harmful symptom occurring in a majority of people with Parkinson*s Disease (PD) over

the course of disease. External cues, such as a metronome or bars on the floor, aid in timing and scaling of automatized movement, thereby facilitating initiation and continuation of gait. The mechanism behind visually cued movement has not been fully elucidated. The cerebellar-thalamo-cortical (CTC) network is likely involved in synchronizing movement with an external rhythm, but has not been studied in patients with PD and FOG (PD-FOG). In this study, we aim to validate a paradigm to be used in future neuroimaging studies investigating the neuronal networks underlying visually cued movement. In addition, this behavioural experiment explores whether moving visual cues in a virtual reality (VR) environment can improve motor timing and reduce freezing in persons with PD-FOG.

Study objective

The main objective of this study is to validate a VR foot pedalling paradigm to study visual cueing and freezing of gait in patients with PD-FOG, to allow for its use in future neuroimaging studies. The secondary objective is to assess the influence of virtual visual cues on freezing and motor timing ability in persons with PD and FOG.

Study design

This is an exploratory behavioral study. Experiments are conducted during a single visit to the University of Twente while patients are in their dopaminergic OFF-state (>12 hours after last dopaminergic medication intake). The study visit consists of reception and explanation about the study (15 minutes), overground walking (42 minutes), VR foot pedalling experiment (33 minutes), questionnaires (45 minutes), and an exit interview (15 minutes), totaling to about 2.5 hours in a single visit. During the overground walking test, participants walk along a corridor and are signaled to stop and resume walking in the presence and absence of equally spaced bars on the floor. To increase cognitive load and thereby increase the likelihood of eliciting FOG, the start and stop signals are given as an adjusted auditory Stroop task. During the VR foot pedalling experiment, participants press foot pedals to navigate through a virtual reality (VR) environment. Three different conditions (without visual cues, with transverse bars, and with a staircase displayed in the VR environment) are repeated 12 times per condition, with rests in between blocks. Again, the adjusted auditory Stroop task is applied to increase cognitive load and induce freezing. The questionnaires are used to describe the demographics of the participants. In the exit interview, participants are asked for their feedback on their experience with the VR foot pedalling paradigm. This information is used both to strengthen the interpretation of current results, and to improve future study set-ups with a similar paradigm.

Intervention

Participants perform two tasks in a single visit: an overground walking test and a virtual reality (VR) foot pedalling experiment.

During the overground walking test, participants walk along a corridor and are signaled to stop and resume walking in the presence and absence of equally spaced bars on the floor.

During the VR foot pedalling experiment, participants press foot pedals to navigate through a virtual reality (VR) environment. Three different conditions (without visual cues, with transverse bars, and with a staircase displayed in the VR environment) are repeated 12 times per condition, with rests in between blocks.

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, requiring less participants) 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 overground walking test is minimalized 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. To reduce this risk of falling, a researcher will continuously accompany the participant during walking. The VR foot pedalling experiment is performed lying supine, only requiring foot movements. There are no risks associated with the VR experiment and the burden is considered low. The questionnaires are widely used in medical research and are considered to place little burden on the participants.

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:
* age > 18 years
Participants in the PD-FOG group should additionally meet the following criteria:
* idiopathic Parkinson*s Disease fulfilling the UK Brain Bank criteria
* experiencing freezing of gait minimally twice a day. This is defined as a score of 1 on question 1 *have you experienced freezing of gait in the past month* on the New Freezing of Gait Questionnaire (NFOGQ), and at least one freezing of gait episode has been observed by a parkinsonnet-registered physiotherapist, neurologist or one of our clinical researchers.
Healthy controls are age-matched to the PD-FOG participants in the study.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
* Significant cognitive impairments. This is defined as a score on the mini mental state examination (MMSE) equal to or smaller than 24, or a score on the frontal assessment battery (FAB) of equal to or smaller than 13.
* Comorbidities that cause severe gait impairment (e.g. severe arthrosis or neuropathy)
* Inability to lie supine for the duration of the test period
* Inability to walk 150 meters unaided
* Severe visual impairments preventing the participant from using the virtual reality display

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-07-2018
Enrollment:	35
Type:	Actual

Medical products/devices used

Generic name:	Virtual Reality (VR) Foot Pedal System
Registration:	No

Ethics review

Approved WMO

Date:	23-03-2017
Application type:	First submission
Review commission:	METC Twente (Enschede)

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: 21397
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL60687.044.17
Other	Nog geen NTR nummer toegekend
OMON	NL-OMON21397