

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

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21397

Source

Nationaal Trial Register

Brief title

-

Health condition

Parkinson's Disease; Freezing of Gait; ziekte van Parkinson; Bevriezen van lopen

Sponsors and support

Primary sponsor: University of Twente

Source(s) of monetary or material Support: ZonMW

Intervention

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.

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

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 design

Experiments are conducted during a single visit to the University of Twente.

Intervention

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.

Contacts

Public

Sabine Janssen
[default]
The Netherlands

Scientific

Sabine Janssen
[default]
The Netherlands

Eligibility criteria

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.

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 (30)) equal to or smaller than 14, or a score on the frontal assessment battery (FAB(31)) 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:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-04-2017
Enrollment:	35
Type:	Anticipated

Ethics review

Positive opinion	
Date:	16-02-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 45400

Bron: ToetsingOnline

Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6229
NTR-old	NTR6409
CCMO	NL60687.044.17
OMON	NL-OMON45400

Study results