Augmented Reality cues to reduce Freezing of Gait during turning in persons with Parkinson*s disease

Published: 15-08-2018
Last updated: 15-05-2024

The primary objective of this study is to investigate the effect of visual turning-cues presented in augmented reality on the severity of freezing of gait evoked during turning in patients with Parkinson*s disease. This effect is compared to that of...

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

Summary

ID

NL-OMON46306

Source
ToetsingOnline

Brief title
Augmented reality turning-cues 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 endpoint is FOG severity, as defined by the parameters: fraction of time spent with freezing; number of freezing episodes; duration of freezing. The occurrence of FOG is determined by evaluation of the video recordings by two independent trained raters. The FOG severity will be compared amongst the different cueing conditions.

Secondary outcome

A secondary endpoint is quantification of the turns with parameters of interest: lateral weight shifting; turn duration; cadence; step time; step height; footstep latency; motor initiation and stopping performance. Another secondary endpoint is the association of FOG severity parameters obtained from the video recordings, with FOG detection parameters calculated using data from the accelerometers.

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 the disease. FOG symptoms are predominantly evoked by turning around and remain difficult to treat with pharmacological management and/or surgical treatment.
External cues, such as auditory, tactile or visual stimuli, aid in scaling and timing of automatized movement. Cueing is thought to enforce goal directed movement and to increase attention to gait.

There is preliminary evidence that visual cueing is effective for preventing FOG during turning. Visual cues might be more effective than auditory cues in reducing FOG. However, few studies investigated the effect of visual cueing during turning. Comparative studies investigating the effect of auditory and visual cues on FOG are scarce, and specifically for an effect during turning not available.
In the current study we use the Microsoft HoloLens, a commercially available brand of smart glasses, to present cues to investigate the feasibility of visual cueing in augmented reality aiding in turning around. We compare 4 cueing conditions (visual cues; auditory cues; a combination of visual and auditory cues; and no cues) to determine optimal ambulant management of freezing symptoms.

Study objective

The primary objective of this study is to investigate the effect of visual turning-cues presented in augmented reality on the severity of freezing of gait evoked during turning in patients with Parkinson*s disease. This effect is compared to that of conventional auditory cueing strategies; that of a combination of visual and auditory cueing; and lastly, to a control condition without cueing.
A secondary objective of this study is to investigate the effect of visual cues in augmented reality on different gait parameters such as lateral weight shifting, turn duration, cadence, step time, step height, footstep latency, motor initiation and stopping performance.
Another secondary objective of this study is to investigate the feasibility of using accelerometers for ambulant FOG detection.

Study design

This is an explorative behavioral study. All procedures are non-invasive. The experiments require a single 2,5 to 3-hour visit to our laboratory in Enschede. This visit includes a 45 minutes session for questionnaires; 30 minutes practice and preparation session; ca. 70 minutes of turning tasks (including breaks); and an exit interview, lasting around 15 minutes. The questionnaires are relevant for obtaining clinical characteristics of the patients and to check whether participants comply with the inclusion criteria. The purpose of the practice session is to get the subjects acquainted with the HoloLens cueing system. The turning tasks are performed to obtain measurements related to FOG severity and response to the visual cues in AR.
The turning experiments are split in two sessions, consisting of 4 blocks each. In each block, lasting maximally 4.5 minutes, the subject performs 15 trials. In every trial, the participant is required to make 180-degree turns *on the spot*. There will be a different cueing condition per block: participants will receive either auditory cues; visual cues in AR; both auditory and visual cues; or no cues. Within each block, the cueing condition is held constant. The order

of the blocks within each session (i.e. the order of the different cueing conditions) will be pseudo-randomized to control for the influence of training or tiredness.

Intervention

The HoloLens cueing system provides visual and auditory external cues to aid the participant during turning around. The visual and auditory cues will be displayed by the Microsoft HoloLens, using an application that we developed for this purpose.

Study burden and risks

All procedures are non-invasive. Experiments are conducted while participants are in the *end of dose* * state, i.e. at the end of their regular dopaminergic medication cycle. This requires the participant to delay (but not skip) normal intake of medication and is expected to increase PD symptoms and FOG severity. This increases the power of the study, thereby reducing the number of participants to be tested. Furthermore, the end-of-dose state is most representative of the dopaminergic state in which persons with PD-FOG experience the most FOG in daily life. The increase of PD symptoms and FOG severity is completely reversible upon medication intake after the experiments. Studies in the *end of dose* * state are common in PD research and do not pose a risk to participants. Physical tiredness which might occur during the turning sessions 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 and during the turning tasks. There are no risks associated with the use of smart glasses and presentation of AR reality stimuli, 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

Public
Universiteit Twente

Drienerlolaan 5
Enschede 7522NB
NL
Scientific
Universiteit Twente

Drienerlolaan 5
Enschede 7522NB
NL

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
* Diagnosed with idiopathic Parkinson*s disease according to the UK Brain Bank Criteria [29]
* Written informed consent
* Presence of FOG (defined as a score of 1 on question 1 from the NFOGQ[30]: *have you ever experienced FOG in the past month?*)
* Disabling/regular FOG (defined as a score of 3 *Very often, more than one time a day* on question 2 from the NFOGQ: *How often do you experience FOG?*)
* Normal or corrected to normal vision.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
* Comorbidities that cause severe gait impairment (e.g. severe arthrosis or neuropathy)
* Comorbidities that cause severe vision impairment (e.g. severe maculopathy)
* Severe cognitive impairments (MMSE <24) or or a score on the frontal assessment battery (FAB) of equal to or smaller than 13.
* Inability to perform a 180 degree turn around the axis unaided (e.g.: without the help of a walking aid or the direct help of a person).
* Severe uncorrected bilateral hearing impairment, preventing the participant to hear the metronome.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-11-2018
Enrollment:	16
Type:	Actual

Medical products/devices used

Generic name:	Cues via smart glasses
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO

Date:	15-08-2018
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: 27339
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL66241.044.18
OMON	NL-OMON27339