Augmented reality turning-cues in Parkinson’s Disease

No registrations found.

Ethical review	Not applicable
Status	Other
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON27339

Source
NTR

Health condition

Freezing of gait, Parkinson's disease, turning problems

ziekte van Parkinson, bevriezen van lopen, problemen met omdraaien

Sponsors and support

Primary sponsor: University of Twente, Enschede
Source(s) of monetary or material Support: self financing

Intervention

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 parameters obtained from the video recordings, with FOG detection parameters calculated using data from the accelerometers.

Study description

Background summary

Background: 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. The use of external cues, such as auditory, tactile or visual stimuli, have shown to be a valuable strategy to prevent or overcome freezing. There is preliminary evidence that visual cueing is effective for preventing FOG during turning, and in terms of effectiveness, visual cues might be favorable over auditory cues. However, the feasibility of mobile visual cueing, and the benefit compared to auditory cueing needs to be investigated further.

In the current study we use smart glasses to present interactive visual cues in augmented reality, aimed at reducing freezing of gait during 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 design: This is an explorative behavioral study aimed at investigating the feasibility of using visual cueing in AR for alleviating FOG symptoms during turning in persons with PD. All procedures are non-invasive. The experiments require a single 2,5-3 hour visit to our laboratory in Enschede.

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.

Study population: 16 subjects that are diagnosed with Parkinson’s disease and experience regular freezing of gait (i.e. on average, more than once per day). Subjects must be able to walk without walking aid, must have normal or corrected to normal vision and must have no cognitive.

Main study parameters/endpoints: 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.

Study objective

Visual cues, presented in augmented reality can reduce the severity of freezing of gait evoked during turning in patients with Parkinson’s disease. This reduction is significantly stronger for visual cues than for conventional auditory cues, as well as for a control condition without cueing.

Study design

not applicable

Intervention

A comparison will be made amongst 4 cueing conditions:

Visual cueing: Using a Microsoft HoloLens, a brand of smartglasses, there are cues displayed on top of the real environment. The cues will reflect the turn-progress and balance of the participant using data from accelerometers and pressure insoles. The cues will be automatically turned off after turn completion (180 degrees).

Auditory cueing: A high-pitch high-frequency metronome will sound, assisting the participant during the turning movement. Turn progression will be registered using data from the Xsens sensors: after turning 180-degrees, the turn is completed and the cueing will stop automatically.

Combined cueing: A combination of the described auditory and visual cues will appear and will be automatically turned off after turn completion.

No cueing: the participant is wearing the HoloLens but does not receive any cues.

Contacts

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Eligibility criteria

Inclusion criteria

• Age > 18 years

• Diagnosed with idiopathic Parkinson’s disease according to the UK Brain Bank Criteria

• 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

• 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).

Study design

Design

Study type:	Observational non invasive
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	01-06-2018
Enrollment:	16
Type:	Unknown

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 46306
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7049
NTR-old	NTR7254
CCMO	NL66241.044.18
OMON	NL-OMON46306

Study results