

Visual cues via smart glasses to reduce freezing of gait in Parkinson*s disease*

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

Summary

ID

NL-OMON42372

Source

ToetsingOnline

Brief title

smart glasses to reduce freezing of gait

Condition

- Movement disorders (incl parkinsonism)

Synonym

freezing of gait in Parkinson's disease

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum

Source(s) of monetary or material Support: fonds NutsOhra

Intervention

Keyword: freezing of gait, Parkinson' disease, smart glasses

Outcome measures

Primary outcome

Walking tasks will be video-taped and rated for the presence of FOG by two experienced raters.

Secondary outcome

In addition, participants will wear some accelerometers on their body (XSens), using which we can calculate gait parameters such as step length.

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. External cueing, i.e. providing external sensory stimuli during gait and gait-related activities, is a good option to non-invasively provide alleviation of FOG. Unfortunately, the positive impact of external cueing therapy in a laboratory setting does not necessarily generalize to uncued living activities. Since patients experience difficulties generalizing the skills taught in the clinic or in a home training program to uncued situations, permanent cueing devices may be essential to follow-up and maintain the progresses achieved. Recent advances in mobile technology have made it possible to widely provide cueing therapy through smart glasses. We have developed a cueing application (app) for smart glasses platforms that can guide gait in PD-patients. In a pilot study in which 10 PD-patients with FOG were included, our initial observations show that the rhythmic visual and auditory cues applied via smart glasses decreased the number and duration of FOG episodes compared to walking tasks without smart glasses, when tested in a laboratory setting. Patients were enthusiastic about the rhythmic visual cues provided by smart glasses, but also asked for visual cues in the form of imaginary lines on the floor. We have further developed our cueing application, and are now able to display visual lines on the floor. In the coming study in our movement laboratory at the University of Twente, we would like to evaluate the effect of visual cues in the form of visual lines on

the floor on the occurrence and duration of FOG in patients with Parkinson's disease.

Study objective

The main objective of this study is to assess the effect of visual cues (provided by smart glasses) in the form of visual lines on the floor on walking performance and occurrence of FOG in comparison to walking without visual cues and walking with conservative rhythmic cues (such as metronome). To this purpose, participants will come once to our movement laboratory at the University of Twente. Patients will be asked to perform a series of walking tasks, with and without cues (lines on the floor provided by smartglasses and conservative rhythmic cues). Walking tasks will be video-taped and rated for the presence of FOG. In addition, participants will wear some accelerometers on their body (XSens), using which we can calculate gait parameters such as step length.

Study design

This is an explorative study aiming to test the functional efficacy of visual cueing by smart glasses on FOG in patients with Parkinson's disease. Participants will come once to our movement laboratory at the University Twente. Patients will be asked to perform a series of walking tasks, with and without cues provided by smart glasses and with conservative rhythmic cues

Intervention

Visual cues will be provided via smart glasses.

Study burden and risks

Patients with FOG are subject to falls. We do not expect that walking with smart glasses aggravates the risk of falls. During the walking tasks, one of the researchers will walk with the patient, so the patient cannot fall. 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 (Hughes et al. , 1992).
- 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).
- Patients need to use conservative cues in daily life.

Exclusion criteria

- Presence of stroke in history or a psychiatric disease.
- Severe visual impairments.
- Severe co-morbidity (such as orthopedic problems) limiting ambulation.
- Severe cognitive impairments (MMSE<24).

Study design

Design

Study type:	Interventional
Intervention model:	Other
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	28-01-2016
Enrollment:	24
Type:	Actual

Medical products/devices used

Generic name:	cues provided by smart glasses (Epson Moverio BT-200)
Registration:	Yes - CE intended use

Ethics review

Approved WMO	
Date:	19-11-2015
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

No registrations found.

In other registers

Register ID

CCMO NL54149.044.15

Other we hebben onze studie aangemeld bij trialsregister.nl; een nummer hebben we nog niet ontvangen.