Technology in Motion (TIM) - Project Holocue: Towards on-demand and assist-as-needed patient-tailored cues to alleviate and prevent freezing of gait

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24506

Source
NTR

Brief title
TBA

Health condition

Parkinson's disease

Sponsors and support

Primary sponsor: LUMC
Source(s) of monetary or material Support: The Michael J. Fox Foundation for Parkinson's Research (Grant ID: 16595)

Intervention

Outcome measures

Primary outcome

The main study parameters are spatiotemporal gait parameters (e.g., walking speed, cadence, step length, step time) calculated from the walking data of the HoloLens and a reference motion capture system for healthy subjects and PD patients and of the HoloLens during walking, pre-FOG and FOG episodes for PD patients. Additional main study parameters for the ‘Holocue efficacy study 1’ and ‘Holocue efficacy study 2’ are the number and duration of FOG episodes (as annotated by the research assistants, as measured with the Hololens and as predicted by the classification algorithm).

Secondary outcome

Secondary study parameters include clinical test scores, demographic and clinical parameters, and parameters related to usability and patient friendliness.

Study description

Background summary

Rationale
Freezing of gait (FOG) is one of the most disabling motor symptoms of Parkinson’s disease (PD) and a major cause of falls with a debilitating impact on quality of life. There is a general consensus among clinicians that cues can be an effective therapeutic to help alleviate FOG episodes once they have occurred. Whereas recent studies suggest that 3D cues may be more effective than 2D cues, patients’ responses to specific cueing modalities vary strongly, calling for an individually tailored approach for presenting the right type(s) of cues. With Holocue, we therefore aim to alleviate FOG by presenting patient-tailored cues on demand, such as horizontal bars to step over. We have built the Holocue application for Microsoft HoloLens, an untethered non-occluding mixed-reality headset with a holographic display unit through which 3D holograms can be displayed in one’s own environment. By focusing on alleviating FOG, Holocue holds the potential to improve treatment beyond current standards of care. It may be particularly helpful for PD patients with FOG in the dopaminergic ‘ON state’, for whom currently no further evidence-based medication is available to alleviate these disabling motor symptoms.

Objective
The primary objective of this study is to explore the potential efficacy of the Holocue application for alleviating FOG episodes through on-demand cue activation. In order to achieve this, walking data obtained from the HoloLens will first be validated against walking data obtained from a reference motion capture system in healthy subjects (HoloLens validation study). Subsequently, the usability and acceptability of the Holocue application will be examined in PD patients with FOG in the dopaminergic ‘ON state’ in the ‘Technology in Motion’ lab at the Leiden University Medical Center (LUMC) (Holocue efficacy study 1; Holocue efficacy study 2 [improvements implemented]) and in the patient’s home environments (Holocue efficacy study 2). We will also try to predict FOG from Holocue data (movement and/or environmental data collected during the Holocue efficacy studies) for

assist-as-needed cues at the right time and location.

Study design
Observational, cross-sectional study in which walking data is collected in healthy subjects and PD patients.

Study population
23 healthy adults will participate in the HoloLens validation study. 15 PD patients who experience FOG in the dopaminergic 'ON state' will participate in the Holocue efficacy study 1 (of which at least 5 patients with deep brain stimulation). 24 PD patients with FOG in the dopaminergic 'ON state' will participate in the Holocue efficacy study 2. Patients can participate in both studies.

Methods
Validation study (healthy subjects, movement laboratory, 1 session): Overground walking data of the HoloLens will be systematically collected and validated against the Interactive Walkway, a reference motion capture system. Subjects will walk over the 8 m-walkway at different imposed step lengths, walking speeds and cadences by means of presented visual context or auditory cues. Total measuring time (including instructions and practice) will be approximately 60 min.
Holocue efficacy study 1 (PD patients, movement laboratory, 1 session): First, patients' gait will concurrently be assessed with the IWW and the HoloLens to validate walking data of the Hololens in PD patients. Participants will walk at a self-selected comfortable walking speed, as well as at faster and slower speeds (three repetitions each). Next, the potential efficacy for alleviating FOG episodes through on- demand cue activation will be examined. To this end, the Interactive Walkway will be used to elicit FOG by means of suddenly projecting visual obstacles, stop-and-go cues and narrow turning indicators on the 8 m-walkway, all with and without cognitive dual tasking to vary the likelihood of FOG occurrences. FOG will also be assessed in real-world situations in and around the lab that are known to elicit freezing (e.g., turning, walking through narrow passages). Patients will complete all tasks under three conditions (Holocue, HoloLens without Holocue, Control without HoloLens). The two control conditions are important to establish the potential efficacy of Holocue in alleviating FOG episodes once they have occurred (Holocue vs. HoloLens without Holocue) relative to the potential effects of wearing an unfamiliar device (HoloLens without Holocue vs. Control without HoloLens). Total measuring time (including instructions and practice) is approximately 90 min.
Holocue efficacy study 2 (PD patients, movement laboratory/home, 3 sessions): Session 1 is a home-based session supervised by a research assistant. Patients will walk in their own home environment, indoors and outdoors, and are encouraged to visit 'freeze prone' locations. Patients will walk these routes with and without wearing the HoloLens (without Holocue functionality). Session 2 is a laboratory session, during which patients will be accustomed to the Holocue application and trained in selecting and activating cues, and during which the potential efficacy for alleviating FOG will be explored in the laboratory setting (three conditions: Holocue, HoloLens without Holocue, Control without HoloLens; NB: improvements implemented based on Holocue efficacy study 1). Session 3 is again a home-based session. Patients will walk similar routes in and around their house as in session 1, supervised by the research assistant, while wearing the HoloLens with and without the Holocue on-demand

application.

Study objective

It is expected that the HoloLens can obtain reliable walking data and that the Holocue application will be found useful by PD patients in alleviating FOG, both in the laboratory and in the home environment.

Study design

HoloLens validation study: one session, movement laboratory LUMC
Holocue efficacy study 1: one session, movement laboratory LUMC
Holocue efficacy study 2: three sessions, each session one week apart, movement laboratory LUMC/home

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Eligibility criteria

Inclusion criteria

Healthy subjects (n = 23)
- 18 years or older
- male/female
- have command of the Dutch language
- normal gait function
- normal cognitive function (MoCA score ≥ 26)
- normal or corrected to normal vision

PD patients (n = 39)

- 18 years or older
- male/female
- have command of the Dutch language
- registered at the LUMC
- diagnosed with PD according to the UK PD Brain Bank criteria
- experience FOG in the dopaminergic ‘ON state’

Exclusion criteria

Healthy subjects (n = 23)
- neurological diseases and/or orthopaedic problems interfering with gait function
- inability to comply with the protocol, i.e. insufficient general fitness or cognitive/communicative inability to understand instructions and participate in the measurement

PD patients (n = 39)
- additional neurological diseases and/or orthopaedic problems seriously interfering with gait function
- inability to comply with the protocol, i.e. insufficient general fitness or cognitive/communicative inability to understand instructions and participate in the measurement
- inability to walk independently, visual hallucinations or illusions

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-02-2019
Enrollment:	62

Type: Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion
Date: 14-02-2019

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 50616
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7523
CCMO	NL64925.058.18
OMON	NL-OMON50616

Study results