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

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

Summary

ID

NL-OMON50616

Source
ToetsingOnline

Brief title
TIM-Holocue

Condition

- Movement disorders (incl parkinsonism)

Synonym
Parkinson's Disease

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: NWO,Michael J. Fox Foundation (Grant ID: 16595)

Intervention

Keyword: Cueing, Freezing of gait, Parkinson's Disease, Walking

Outcome measures

Primary outcome

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 controls and of the Hololens during walking, pre-FOG and FOG episodes for PD patients. Additional main study parameters for the *Holocue efficacy study 1*, *Holocue efficacy study 2* and *technical validation study* are the number and duration of FOG episodes (as annotated by the research assistants, as measured with the Hololens and as predicted by the generic and patient-tailored classification algorithms). Other study parameters include clinical test scores, demographic and clinical parameters, and parameters related to usability and patient friendliness.

Secondary outcome

Clinical test scores, demographic and clinical parameters, and parameters related to usability and patient friendliness

Study description

Background summary

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.

Study 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 control 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 a laboratory setting (Holocue efficacy studies 1 & 2) and in the patient's home environment (Holocue efficacy study 2). Using the data of Holocue efficacy study 2 we will develop a generic classification algorithm to predict FOG from Hololens data (movement and/or environmental data) for assist-as-needed cues at the right time and location, which will be validated in an independent group of PD patients (i.e., technical validation study for accurate and timely FOG prediction). In addition, the generic classification algorithm will be patient-tailored to determine if this improves the prediction of FOG.

Study design

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

Validation study (healthy controls; 1 session; movement laboratory): 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.

Efficacy study 1 (PD patients, movement laboratory, 1 session): 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. All tasks will be performed while wearing the Hololens (collecting movement data of normal walking and during pre-FOG and FOG episodes), with and without the on-demand Holocue functionality to establish its potential efficacy in alleviating FOG episodes once they have occurred. 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). 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. During all sessions, PD patients will wear two shoe-mounted inertial measurement units.

Technical validation study (PD patients, home, 2 sessions): This study includes the external validation of the generic classification algorithm developed using the data of Holocue efficacy study 2 to detected FOG episodes (i.e., timing and accuracy). In addition, the generic classification algorithm will be patient-tailored to determine if this improves the prediction of FOG. We will recruit 12 new patients suffering from FOG using the same criteria of efficacy studies 1 and 2 to obtain truly independent test data for external validation of the generic classification algorithm. This study will be conducted in participants* free-living environments, consisting of two non-standardized supervised walking sessions in and around the participant*s home as part of their daily routine (e.g., doing groceries, visiting friends, leisure walking). Participants will be encouraged to visit freeze-prone locations while wearing the Hololens to collect environmental and movement data. The research assistant will always walk close to the patient for safety reasons. Per 150 minutes visit, we aim for 20-40 minutes of walking. During all sessions, PD patients will wear two shoe-mounted and two trunk-mounted IMUs in order to be able to

cross-validate the classification algorithms.

All trials of Holocue efficacy studies 1 and 2 and the technical validation study will be filmed and will be annotated by two independent reviewers (e.g. FOG episode, walking, voluntary stop) to determine 1) the efficacy of the Holocue application and 2) if FOG episodes can be validly detected and predicted using movement data and/or environment data of the Hololens (for future development of preventive cueing, i.e., to present cues before a FOG episode occurs).

Study burden and risks

The risks of the assessment are minimal. The markerless tracking devices of the Interactive Walkway comprise sensors consisting of an infrared laser transmitter and an infrared camera, which allows for unobtrusive assessment of walking (i.e., no direct contact with the subjects, no potentially harmful radiation, and no cumbersome marker placement). The Hololens, which will be used for presentation of virtual cues to alleviate FOG episodes, allows for unlimited vision of the actual environment. Both systems (i.e., the markerless tracking devices of the Interactive Walkway and the Hololens) are commercially available and have been successfully used in various areas of application and target groups.

Actual measurements will take no longer than 60-150 minutes per session (1 to 3 sessions per participant), including 30 minutes (in total) for clinical testing in PD patients. Walking will be done at a comfortable walking speed. If necessary, PD patients are allowed to use their walking aid. The experimenter can walk along with the patient for assurance or to provide support. Additional rest periods will be offered if necessary. For PD patients, if possible the measurement in the *Technology in Motion* lab will be combined with a regular visit to the outpatient clinic, such that no extra travelling is required. Travel costs to the hospital will be compensated on the basis of public transport (2nd class) or travelled distance by car (¤ 0,19 per km) plus compensation for parking costs. Participants in the Holocue efficacy study 2 and the technical validation study will also receive a VVV voucher of ¤20 and ¤40, respectively.

In summary, the risks of this study are minimal and the burden on the participants is low. On the other hand, the benefits of this study are expected to be great. Holocue addresses one of the most disabling motor symptoms of PD, namely that of FOG, which prevalence increases from about 10% in Hoehn and Yahr stage 1 to more than 90% in the advanced stage 4. By focusing on alleviating and ultimately preventing FOG, Holocue holds the potential to improve treatment beyond current standards of care. It can be particularly helpful for PD patients with FOG in the dopaminergic *ON state* (i.e., often present in atypical parkinsonian disorders and in the late stages of PD), for whom currently no further evidence-based medication is available to alleviate these

disabling motor symptoms.

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

Healthy controls: 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: 18 years or older, male/female, have command of the Dutch language, diagnosed with PD according to the UK PD Brain Bank criteria, experience FOG in the dopaminergic ON state.

Exclusion criteria

Healthy controls: neurological diseases and/or orthopedic 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: additional neurological diseases and/or orthopedic 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.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-02-2019
Enrollment:	74
Type:	Actual

Ethics review

Approved WMO

Date:	03-12-2018
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	01-04-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	03-09-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	02-09-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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: 24506
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL64925.058.18
Other	NL7523
OMON	NL-OMON24506

Study results

Date completed:	14-12-2020
Actual enrolment:	66