Project CAPARE: Cueing-assisted Personalised Augmented-Reality Exergaming for Parkinson*s rehabilitation

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Ethical review	Approved WMO
Status	Completed
Health condition type	Movement disorders (incl parkinsonism)
Study type	Interventional research previously applied in human subjects

Summary

ID

NL-OMON56729

Source
ToetsingOnline

Brief title
Project CAPARE

Condition

- Movement disorders (incl parkinsonism)

Synonym
Parkinson's disease

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit

Source(s) of monetary or material Support: Europese Unie

Intervention

- Medical device

Keyword: Augmented reality, Gait and balance exercise program, Parkinson's disease

Explanation

N.a.

Outcome measures

Primary outcome

The main study parameters for the data quality study are outcome measures of
gait and balance derived from AR headsets and a validated reference systems.

The main study parameters for the intensity study are intensity of the
gait-and-balance exercises using percentage of maximal heart rate and rating of
perceived exertion.

The main study parameters of the clinical feasibility study to evaluate
home-based gamified cueing-assisted personalized AR gait-and-balance exercises
with Reality DTx® are feasibility (in terms of safety, adherence, performance
and user experience) and effectiveness (in terms of gait-and-balance outcome
measures of standard clinical tests).

Secondary outcome

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Study description

Background summary

Reality DTx® is a potentially effective and clinically feasible medical device with two core modules -movement assistance and movement training- that applies the existing proven principles of sensory cueing and home-based exercise for people with Parkinson*s disease (PD) onto augmented-reality (AR) headsets.

Study objective

The primary objective of this study in people with PD is to examine the clinical feasibility, in terms of safety, adherence, performance and user experience (i.e., patient and physiotherapist), and effectiveness of home-based gamified cueing-assisted personalized AR gait-and-balance exercises with Reality DTx®. In order to achieve this, several (sub)studies will be conducted. First, it will be determined if the AR headset data can be used to reliably and validly calculate outcomes of clinical tests and exergames for remote monitoring of gait-and-balance outcomes and to personalize exergame content (data quality study). Subsequently, the intensity of the AR gait-and-balance exercises of Reality DTx® will systematically be evaluated (intensity study). Finally, a clinical feasibility study will be conducted to test the cueing protocol and assess the feasibility and effectiveness in a clinical setting of home-based gamified cueing-assisted personalized AR gait-and-balance exercises with Reality DTx®.

Study design

This study is a clinical feasibility study with two substudies, namely a data quality study and an intensity study. The substudies will be performed first to be able to better interpret the results of the clinical feasibility study.

To validate gamified gait-and-balance monitoring outcomes (data quality study), 1 session in the laboratory will be performed.

To systematically evaluate the intensity of the gait-and-balance exercises (intensity study), 1-2 home visits will be performed depending on the fitness level of the participant.

The clinical feasibility study is a concealed two-arm Randomized Controlled Trial and consists of three in-clinic assessments. After a baseline assessment of standard clinical tests, participants will start with an 6-week usual care control period. After 6 weeks, participants undergo the midterm assessments. Then, participants will start with the 8-week Reality DTx® intervention and will receive a final assessment hereafter. A predefined two-armed block-randomisation will determine which participants will be allocated to the control group and which participants will be allocated to the intervention group.

Intervention

Reality DTx®, a class I CE marked medical device, is a software application for AR headsets, such as HoloLens 2 and Magic Leap 2. The intended use of the Reality DTx® software is to provide visual and auditory cues to assist walking and modify gait and to provide gamified AR exercise programs for the therapeutic treatment of gait and balance in PD.

Study burden and risks

The risks of this study are minimal and the burden on the participants is low to medium considering the clinical assessments and daily exercise and likely outweighs the benefits associated with physical activity promotion in people with PD in general, such as slowing down the progression of motor symptoms, and boosting their gait-and-balance skills through the offered home-based gamified AR exercises program as an addition to usual care.

Contacts

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Trial sites

Trial sites in the Netherlands

Vrije Universiteit
Target size: 130

Listed location countries

Netherlands

Eligibility criteria

Age

Elderly (65 years and older)
Adults (18-64 years)

Inclusion criteria

- 21 years or older
- Have command of the Dutch language
- Diagnosed with PD according to the UK PD Brain Bank criteria (stages 1-3 on the Hoehn and Yahr scale)
Additionally for persons with PD in the clinical feasibility study a person must experience:
- Bothersome gait or balance impairments (i.e., negatively affecting their ability to perform their usual daily activities)

Exclusion criteria

- Inability to comply with the protocol, i.e. additional neurological diseases and/or orthopaedic problems seriously interfering with gait function, insufficient physical capacity (e.g., frequent faller) or severe cognitive impairments (as observed by the researcher or clinician)
- Severe visual or hearing impairments (after corrective aids)
- Inability to walk independently for 30 minutes (in bouts of 5-10 minutes)
- Severe visual hallucinations or illusions
Additionally for persons with PD in the clinical feasibility study:
- No stable dosage of medication

Study design

Design

Study phase:	N/A
Study type:	Interventional research previously applied in human subjects
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	No intervention
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	07-05-2024
Enrollment:	130
Duration:	3 months (per patient)
Type:	Actual

Medical products/devices used

Product type:	Medical device
Generic name:	Reality DTx
Registration:	Yes - CE intended use

IPD sharing statement

Plan to share IPD: Undecided

Plan description
N.a.

Ethics review

Approved WMO

Date:	18-04-2024
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Not approved

Date:	17-01-2025
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date:	12-02-2025
Application type:	Amendment
Review commission:	MEC-U

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	NL86191.100.24
Research portal	NL-005736