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

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

# 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: European Media and Immersion Lab (EMIL),Strolll Limited

#### Intervention

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

#### **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

# **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**

# **Listed location countries**

Netherlands

# **Eligibility criteria**

Age 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 type:InterventionalIntervention model:OtherAllocation:Randomized controlled trialMasking:Open (masking not used)

Primary purpose: Treatment

### Recruitment

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NL	
Recruitment status:	Recruiting
Start date (anticipated):	07-05-2024

Enrollment:	130
Туре:	Actual

### Medical products/devices used

Generic name:	Reality DTx
Registration:	Yes - CE intended use

# **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)

# **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
Other	86191
ССМО	NL86191.100.24