Cue X: a gamified gait-and-balance exercise program for augmented-reality glasses to improve Parkinsonian gait

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

Summary

ID

NL-OMON51602

Source
ToetsingOnline

Brief title
Cue X

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: Eureka Eurostars en Strolll;Ltd,Strolll, Ltd

Intervention

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

Outcome measures

Primary outcome

The main study parameters to evaluate clinical feasibility of home-based gamified AR gait-and-balance exercises with Cue X are usability (e.g., system usability scale), safety (e.g., adverse events, side effects), adherence (e.g., compliance to the prescribed exercises, withdrawal, hours exercising, number of days exercising minimally 30 min), and patient-reported experience measures and patient-reported outcome measures (e.g., perceived effectiveness through Likert scale reporting, quality of life questionnaire).

The main study parameters to evaluate the potential effect of the Cue X gamified AR gait-and-balance exercise program are gait-and-balance outcome measures from standard clinical tests as well as from laboratory based Interactive Walkway gait-and-balance tests.

Secondary outcome

Secondary study parameters to evaluate the potential effect of the Cue X gamified AR gait-and-balance exercise program are gait-and-balance outcome measures.

For the secondary objectives 1 (gait-modifying ability) and 2 (data quality), study parameters are spatiotemporal gait parameters (speed, cadence, step length, step time) derived from Interactive Walkway and AR headsets during the

8-meter walking test (with or without visual/auditory cues) and standard

clinical tests of gait and balance derived from AR headsets and stopwatch

scores.

Study description

Background summary

Cue X is a new product 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 clinical feasibility study in people with PD is to evaluate the feasibility and potential efficacy of home-based gamified AR gait-and-balance exercises with Cue X. Secondary objectives of this study are to validate the gait-modifying effects of Cue X AR cueing and to quantify the test-retest reliability and concurrent validity of (clinical) outcome measures of gait and balance, as derived from AR headset data.

With these primary and secondary objectives, the study will give insight into 1) the feasibility and potential efficacy of Cue X for home-based gamified AR gait-and-balance exercises, 2) the most effective type of AR cueing and 3) the best parameters for feedback, reporting and sample-size calculations for a subsequent effect study with Cue X. Furthermore, the study will inform about the best AR headset for these purposes.

Study design

(Single-arm) clinical feasibility study

The study consists of four visits to the gait laboratory, one home visit. In between laboratory visits 2 and 4, participants will use Cue X to train their gait and balance with gamified AR gait-and-balance exercises in their own home environment as intervention above usual care. The exercise content will be evaluated on a weekly basis, as well as safety and usability.

Intervention

Cue X, 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 Cue X software is to provide visual and auditory cues to assist walking and modify gait and to provide gamified AR exercise programs to improve 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 laboratory visits 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)
Elderly (65 years and older)

Inclusion criteria

- 18 years or older
- Have command of the Dutch language
- Diagnosed with Parkinson's disease according to the UK PD Brain Bank criteria (stages 2-4 on the Hoehn and Yahr scale)
- 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 or cognitive/communicative inability (as observed by the researcher or clinician) to understand instructions and participate in the tests
- (Severe) visual or hearing impairments (after corrective aids)
- (Severe) visual hallucinations or illusions
- Inability to walk independently for 30 minutes
- No stable dosage of medication

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	13-12-2022
Enrollment:	30

Type:	Actual

Medical products/devices used

Generic name:	Cue X
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	21-11-2022
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Not approved Date:	15-12-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	02-01-2024
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
ClinicalTrials.gov	NCT05605249
CCMO	NL82441.100.22