Explorative study: serious games rehabilitation programme to manage gait and balance disorders in patients with Parkinson's disease

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON46570

Source
ToetsingOnline

Brief title
Serious game gait and balance rehabilitation in Parkinson's

Condition

- Other condition

Synonym
gait and balance problems, parkinson's disease

Health condition

neurologische aandoeningen

Research involving

Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: EuroStars

Intervention

Keyword: balance disorders, gait problems, Parkinson, serious game

Outcome measures

Primary outcome

The primary outcome of this study will difference between groups on the Timed Up & Go test score at week 6 measured in ON medication state. Timed Up & Go test will be videotaped and rated by a blinded investigator.

Secondary outcome

Secondary outcomes include motor and non-motor symptoms, gait and balance disorders, cognitive functioning, depression and anxiety, organisational and economic impact, patient and professional experience, safety, tolerance, feasibility, and neurophysiological gait and balance parameters.

The addition of the 18 week follow up assessment (as secondary endpoint) provides us information about the course of the effect and whether it persists in either those who continue and stop playing the game and the attractiveness of the game.

Study description

Background summary

Parkinson*s disease (PD) is a neurodegenerative disorder with many motor- and non-motor symptoms. People with Parkinson (PwP) fall frequently during the course of the disease. This can have tremendous and serious consequences, like an increase in disability, reduced quality of life and hospital admission. Rehabilitation in PD has been shown to play an important role in the reduction falls and fall risk. Recent technological advances make it possible to introduce individualized, home-based exercise in virtual reality games specifically designed for PwP, including fallers. Preliminary evidence in a small pilot study with 10 people showed good acceptability and feasibility of a serious game with a 'Toap Run' developed for PD, with potential benefits on falls and freezing of gait.

Study objective

The primary objective is to evaluate the efficacy of the serious game *Toap Run* on gait and balance outcomes in patients with PD. Secondary objectives include assessing the effects of the game on disease symptoms, spatiotemporal gait parameter and quality of life. Moreover, the impact of this program on health economics will be also evaluated.

Study design

We will perform an explorative single - blind randomised controlled trial with active control arm. Patients (n=25) will be included in France (Brain and Spine Institute- we will ask for local ethical approval) and The Netherlands (Radboudumc, n=25). Patients will be equally allocated to 2 parallel groups either receiving balance training using the serious game *Toap Run* or to a active control control group for 6 weeks. Measurements will be performed at three timepoints by a blinded rater.

Intervention

Patients will be randomized to receive either rehabilitation with serious game *Toap Run* on the Kinect TM® system (intervention) (n=12 or 13) or similar game performed with the keyboard of the computer (active control group)) (n=12 or 13). Toap Run will be personalised for the subjects using a Kinect via a brief in-game gait and balance test. For subjects without Kinect (for example controls), the difficulty level will be raised in accordance with a standard training protocol.

Study burden and risks

Subjects are assessed at three moments: baseline, week 6 and week 18 (follow-up). This assessment takes about 4 hours each time to complete. They are required to keep a fall journal, which may cost a minute a day to fill out. All of the intervention and control group subjects are required to play the game

for at least 6 weeks in a row for at least 2:15 hours a week. We may encounter two types of risks: physical injury and/or gaming addiction. The possible benefits for participants are improvements in gait and balance functions, as well as improvements in quality of life. The total burden will be about 30 hours, plus the additional play time after the first follow-up assessment.

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

- Diagnosis of probable PD according to the UK Brain Bank Criteria
- Age of >18 years old.
- UPDRS-MDS part II: walking and balance (item 2.12) score >= of 1 and/or Freezing (2.13 item) score of >=1 at screening visit during assessed in *on* medication state
- Relatively stable dopaminergic medication (and relatively stable stimulation parameters in

case of a neurostimulator) within last 30 days, or the change in medication does not influence moving (LED change of less than 50% increase or decrease).
- Properly controlled other medical conditions and/or lack of interference with the research protocol.
- Must have access to internet via a computer/laptop at home.

Exclusion criteria

- Advanced Parkinson*s disease defined as stage 5 according to Hoehn and Yahr (inability to stand up or walk alone).
- Mild Cognitive Impairment or dementia (MMSE < 24).
- Impulse control disorders defined as score >1(inclusively) in item 1.6 of part I MDS-UPDRS.
- Participation in other research study.
- Physical limitation such as incapacitation.
- Severe auditory or visual deficits.
- Computer/laptop does not comply to minimum system requirements of the serious game.

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-10-2019
Enrollment:	25
Type:	Actual

Ethics review

Approved WMO Date:	02-08-2018
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL64775.091.18