Neural plasticity in a Virtual reality-Treadmill combined Intervention for enhancing Mobility and reducing falls in Elderly (V-TIME) with Parkinson's Disease

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

Summary

ID

NL-OMON36978

Source
ToetsingOnline

Brief title
V-TIME neural plasticity study

Condition

- Movement disorders (incl parkinsonism)

Synonym
Parkinson's Disease

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud

Source(s) of monetary or material Support: European commission: 7th Framework Program;grant #278169

Intervention

Keyword: Brain imaging, Dual task training, Neural plasticity, Parkinson

Outcome measures

Primary outcome

The main study parameter is the change in blood oxygenation level dependent (ΔBOLD) signal in the bilateral anterior putamen during performance of a dual task containing a lower limb motor task and a cognitive task (pre-training vs. post-training assessment).

Secondary outcome

Secondary study parameters include the change in blood oxygenation level dependent (ΔBOLD) signal in the bilateral caudate nucleus, the anterior cingulate cortex and the prefrontal cortex, during performance of a dual task containing a lower limb motor task and a cognitive task (pre-training vs. post-training assessment). Other secondary study parameters are prefrontal cortex activation (concentration of oxygenated and deoxygenated heamoglobin) during training and more general walking tasks (dual task walking, obstacle negotiation, walking at preferred speed). Also, magnetic resonance imaging will be used to obtain brain oxygenation levels during ankle movements and a cognitive task, resting state functional connectivity, grey matter volume and white matter integrity. Other secondary study parameters are measures of gait, fall frequency, balance and mobility, community ambulation, cognitive functioning, health related quality of life, fear of falling and user

satisfaction of the intervention. A pre-training vs. post training assessment

will be used for all secondary study parameters.

Study description

Background summary

Falls are a major public health concern, especially in patients with Parkinson*s disease. Since gait and balance control are related to cognitive function, fall-prevention should focus on both cognitive and motor aspects. V-TIME is a multi-modal intervention centred around treadmill training, promoting motor control, usual-walking abilities and physical fitness, and addressing cognitive issues that are key to falls. Addition of the virtual reality environment implicitly challenges, teaches, and enhances visual scanning, planning, dual tasking abilities and obstacle negotiation. These additional training goals that aim to enhance the cognitive aspects of mobility have not yet been integrated into common practice and are one of the important added features of the proposed intervention. Recent pilot studies in elderly fallers and patients with Parkinson*s disease showed promising results. This randomized controlled trial aims to confirm these results and to identify neural mechanisms that underlie training effects.

Study objective

The primary objective is to study the effects of 12 weeks of treadmill training with virtual reality on neural plasticity in comparison to the effects of treadmill training without virtual reality.
Secondary objectives are to investigate the role of the prefrontal cortex in treadmill training with and without virtual reality, to determine transfer of training effects to prefrontal cortex activation during more general walking tasks, to relate neural changes to behavioural effects, to compare the effect of different training durations and to investigate long term training effects.

Study design

A prospective, single-blind randomized controlled trial, with 12 weeks of training and four assessments: i.e. pre-training, post-training, at one month follow-up, and six months follow-up period. Two centres will be involved: Radboud University Nijmegen Medical Centre (RUNMC; 50 PD) and Tel Aviv Sourasky Medical Centre (TASMC; 40 PD, for which ethical approval will be obtained at their own site).

Intervention

After consent, participants will be randomized to one of two arms of the study: 1. Treadmill Training with Virtual Reality (TT+VR); 2. Active control comparison of Treadmill Training alone (TT). To ensure comparable representation of men and women, randomization allocation will take place within gender.

Study burden and risks

The outcome of this study may have important consequences for fall prevention in patients with Parkinson*s disease, reducing serious consequences of falling for the patient, but also their family and the society. As falling has an enormous economic burden, a new effective fall prevention intervention could reduce health care costs substantially. Besides, neural mechanisms underneath intervention effects will be identified. This might be used as target for future interventions. The tests consisting of questionnaires, gait and cognition assessment and brain imaging are non-invasive and safe. However, participants may be burdened by the time-investment for the training and measurements, which are time-consuming.

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

Patients are eligible for participation if they meet all of the following inclusion criteria:
- >=2 falls within the 6 months prior to the study
- Age range: 60-85 years
- Diagnosis of PD (UKBB criteria)
- Hoehn and Yahr stage II-III (on medication)
- Stable medication for at least one month and anticipated for the next 6 months
- Able to walk at least 5 minutes unassisted
- Adequate hearing and vision

Exclusion criteria

Patients will be excluded from the study if they meet any of the following criteria:
- Psychiatric co-morbidities (e.g., major depression - DSM IV criteria)
- Clinical diagnosis of dementia (e.g., Alzheimer*s, vascular, etc.)
- History of stroke, traumatic brain injury, brain tumour or other neurological disorders
- Acute lower back or lower extremity pain, musculoskeletal injuries, peripheral neuropathy which restricts gait
- Unstable medical condition including cardiovascular instability in past 6 months
- Unable to comply with training
- Cognitively impaired (< 24 on Mini-Mental State Examination)
- Interfering therapy, or fall clinic visit <1 month ago
- Severe freezing precluding safe participation (>15 on New Freezing of Gait Questionnaire)
- Metal objects or fragments in/on body
- Active implant (e.g. pacemaker, neurostimulator, insulin pump)
- Epilepsy
- Claustrophobia

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-03-2013
Enrollment:	70
Type:	Actual

Ethics review

Approved WMO Date:	18-10-2012
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	18-03-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	29-04-2015
Application type:	Amendment
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

ID: 23705
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL41661.091.12
OMON	NL-OMON23705