Training the brain with virtual reality treadmill training to enhance mobility and reduce falls in elderly with Parkinson's Disease.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23705

Source
Nationaal Trial Register

Brief title
V-TIME neural plasticity study

Health condition

Parkinson's Disease

Sponsors and support

Primary sponsor: Sponsor = European Union (Seventh Framework program number 278169)
Performer = Radboud University Nijmegen Medical Centre
Source(s) of monetary or material Support: European Union (Seventh Framework program number 278169)

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Secondary study parameters include the change in blood oxygenation level dependent (BOLD) 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 (fMRI, 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 (functional near infrared spectroscopy fNIRS; 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

In this trial, which is part of the Seventh Framework program V-TIME, neural correlates of plasticity of the V-TIME fall prevention intervention are investigated.

Study objective

Previous work showed that a shift in functional connectivity from the posterior to the anterior putamen can be seen in PD patients (Helmich et al. 2010). Thus, PD patients probably use their anterior putamen for both cognitive and simple motor tasks. In healthy persons, cognitive tasks mostly rely on the anterior putamen whereas simple motor tasks mostly rely on the posterior putamen. We hypothesize that a bottleneck in the anterior putamen causes reduced dual task performance in PD patients. Through the VR training, we expect to see compensation for this bottleneck in other brain regions. Thus, we hypothesise that treadmill training with VR will cause a partial shift of cognitive control from the anterior putamen towards other brain regions such as the anterior cingulated cortex, the nucleus caudatus and

the prefrontal cortex.

Study design

Pre assessment (all outcome measures), intermediate assessments after 4 weeks (physical and mental functioning) and 6 weeks (physical and mental functioning and fNIRS) of training, post assessment (all outcome measures), 1 and 6 month follow up assessments (all outcome measures besides (f)MRI and fNIRS).

Intervention

At RUNMC (Nijmegen) 50 patients with PD will be randomized into one of these two groups:

1. Treadmill Training with Virtual Reality (TT+VR) for 12 weeks, three times per week;

2. Active control comparison of Treadmill Training alone (TT), 12 weeks, three times per week.

At TASMC (Tel Aviv) 40 patients with PD will be randomized into one of these two groups:

1. Treadmill Training with Virtual Reality (TT+VR) for 6 weeks, three times per week;

2. Active control comparison of Treadmill Training alone (TT), 6 weeks, three times per week.

Contacts

Public
Radboud University Nijmegen Medical Centre
Department of Geriatric Medicine, 925
PO box 9101
Freek Nieuwhof
Nijmegen 6500 HB
The Netherlands
+31 (0)24 3617853
Scientific
Radboud University Nijmegen Medical Centre
Department of Geriatric Medicine, 925
PO box 9101
Freek Nieuwhof
Nijmegen 6500 HB
The Netherlands
+31 (0)24 3617853

Eligibility criteria

Inclusion criteria

1. At least 2 falls within the 6 months prior to the study;

2. Age range: 60-85 years;

3. Diagnosis of PD (UK Parkinson's Disease Society Brain Bank: UKBB);

4. Hoehn and Yahr stage II-III (on medication);

5. Stable medication for at least one month and anticipated for the next 6 months;

6. Able to walk at least 5 minutes unassisted;

7. Adequate hearing and vision.

Exclusion criteria

1. Psychiatric co-morbidities (e.g., major depression - Diagnostic and Statistical Manual of Mental Disorders (DSM) IV criteria);

2. Clinical diagnosis of dementia (e.g., Alzheimer's, vascular, etc.);

3. History of stroke, traumatic brain injury, brain tumour or other neurological disorders;

4. Acute lower back or lower extremity pain, musculoskeletal injuries, peripheral neuropathy which restricts gait;

5. Unstable medical condition including cardiovascular instability in past 6 months;

6. Unable to comply with training;

7. Cognitively impaired (< 24 on Mini-Mental State Examination);

8. Interfering therapy, or fall clinic visit <1 months ago;

9. Severe freezing precluding safe participation (>15 on New Freezing of Gait Questionnaire);

10. Metal objects or fragments in/on body;

11. Active implant (e.g. pacemaker, neurostimulator, insulin pump);

12. Epilepsy;

13. Claustrophobia.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2013
Enrollment:	90
Type:	Anticipated

Ethics review

Positive opinion

Date:	27-11-2012
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 36978
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL3488
NTR-old	NTR3723
CCMO	NL41661.091.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON36978

Study results

Summary results
N/A