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

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Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23705

Bron
Nationaal Trial Register

Verkorte titel
V-TIME neural plasticity study

Aandoening

Parkinson's Disease

Ondersteuning

Primaire sponsor: Sponsor = European Union (Seventh Framework program number 278169)
Performer = Radboud University Nijmegen Medical Centre
Overige ondersteuning: European Union (Seventh Framework program number 278169)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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).

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type: Interventie onderzoek

Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2013
Aantal proefpersonen:	90
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	27-11-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 36978
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Register	ID
OMON	NL-OMON36978

Resultaten

Samenvatting resultaten
N/A