Improving mobility and balance in Parkinson*s disease through circuit class training:
Effects on clinical outcomes, posturography and brain connectivity

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Primary objective is to investigate whether a VF-based balance training program leads to improved balance control in PD patients and how posturographic outcomes are associated with changes in clinical outcome measures.Secondary objective is to...

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

Summary

ID

NL-OMON36463

Source
ToetsingOnline

Brief title
IMPACT

Condition

- Movement disorders (incl parkinsonism)

Synonym
Parkinson's disease; Parkinson's

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Internationaal Parkinson Fonds

Intervention

Keyword: balance training, Parkinson's disease, postural control, rehabilitation

Outcome measures

Primary outcome

Functional Reach Test

Secondary outcome

Clinical outcome measures

* Berg Balance Scale

* Falls Efficacy Scale

* 10 meter Walk Test

* Parkinson*s Disease Questionnaire

* Hospital Anxiety and Depression scale

* Multidimensional Fatigue Inventory

Posturography during quiet stance

* Variability: COP standard deviation

a. anterioposterior direction (SDCOP,x)

b. mediolateral direction (SDCOP,y)

* Local stability: maximum Lyapunov exponent

* Regularity: sample entropy

* Number of active control variables: correlation dimension

* Correlations: scaling exponent

EEG (plus MRI)

* Source of activity / regions of interest (dipole fits / beamformers)

* Spectral power changes (in particular motor-related beta- and alpha-power)

* Intra- / inter-hemispheric synchronization (phase coherence, synchronization likelihood)

* Topological changes of overall functional connectivity (sensor-based network estimates)

Study description

Background summary

Parkinson*s disease (PD) is a progressive neurodegenerative disease, for which curative treatments are lacking. Clinical motor symptoms of PD include tremor, rigidity, bradykinesia and postural instability. These symptoms lead to impaired mobility affecting activities of daily living and quality of life.
There is growing evidence that physical training interventions such as exercise training and physical therapy can positively influence mobility and mobility-related problems such as falls (De Goede, Keus, Kwakkel, & Wagenaar, 2001; Hirsch & Farley, 2009; Kwakkel, De Goede, & Van Wegen, 2007). Positive effects of training on postural con-trol have been suggested in a number of studies (Goodwin, Richards, R. S. Taylor, A. H. Tay-lor, & Campbell, 2008) but results are yet moderate at best. Although recent animal studies have suggested that physical exercise in PD may yield beneficial dopaminergic changes by promoting adaptive neuroplasticity (Hirsch & Farley, 2009; 2009; Yoon et al., 2007), it is unknown if improvements in motor tasks (such as standing balance) are in fact due to a restitution of function using existing dopaminergic pathways or due to substitution of function by means of compensation strategies using non-dopaminergic pathways. It is hence of great relevance to develop training protocols that target the more specific needs of PD patients. Unfortunately, human studies on the relationship between functional improvements and exercise-induced plasticity are still lacking.
Providing additional visual feedback during quiet stance offers a promising new perspective for balance therapy as it prompts PD patients directly to achieve

proper postural control. However, to what extent motor training with visual feedback yields lasting improvements is yet unknown. If the training does affect balance control, we ask whether this is manifested in the accompanying neural activity in the central nervous system, in particular in the cortex. Quiet stance paradigms provide convenient ways to study feedback-based balance control given the relative ease and safety with which such tasks can be recorded in older healthy adults and in patients. In the current study we will use a quiet stance paradigm to test to what degree postural control and thus balance is modulated with specific balance-oriented exercise training, i.e. a circuit class training using balance workstations. We will quantify effects through selected posturographic outcome measures, like the variability of the center-of-pressure (COP) and correlate these with clinical balance assessments and changes in brain dynamics (EEG). With the current study we aim to typify the relationships between outcome measures from clinical questionnaires, posturography, and clinical neurophysiology.

Study objective

Primary objective is to investigate whether a VF-based balance training program leads to improved balance control in PD patients and how posturographic outcomes are associated with changes in clinical outcome measures.

Secondary objective is to investigate the effects of a balance training program on patterns of functional cortical connectivity as determined by EEG.

Study design

This study is a randomized clinical trial (RCT) comparing two treatment groups under blinded assessment.

Patients will be recruited from the Neurology Department and from patient databases of the Department of Physical Therapy of the VU University Medical Center. Patients who are likely to meet the criteria for inclusion will be asked to participate in the RCT. They will randomly be assigned to either the experimental or conventional exercise circuit class training. Groups convene during 60-minute group sessions, two times a week for six weeks. Patients will fill in questionnaires and undergo clinimetric assessments, EEG recordings, and posturography prior to, after, and 6 weeks after completion of the training program. An MRI scan will also be obtained to substan-tiate off-line source localization of the EEG signals. All training sessions will take place at the VU University Medical Center outpatient center. Assessments will take place at the VU University Medical Center outpatient center as well as at the VU University, Faculty of Human Movement Sciences.

Intervention

Patients will be assigned to one of two balance training groups and will convene in groups (~6 patients per session) during twice-weekly training sessions of one hour, for six weeks. Two types of balance training will be administered, one focusing on restitution of function using a set of conventional repetitive balance exercises, the other focusing on substitution of function by using several visual feedback techniques.

Study burden and risks

Patients take part in a training program two times a week during six weeks. Before, after, and 6 weeks after completion of the training program assessments will be performed (75 min). In addition one MRI scan will be obtained for each patient (30-60 minutes). Participation in this study will involve minimal risk.

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

1. Patient is diagnosed with Parkinson's Disease, stages II-III on the Hoehn and Yahr scale, and able to participate in all forms of therapy.
2. Patient*s medication is stable and remains unchanged during the study period.
3. Sufficient cognitive function (Mini Mental State Examination > 24)

Exclusion criteria

1. Presence of (other) neurological, orthopedic, or cardiopulmonary problems that can impair participation.
2. Any conditions that render the patient unable to understand or adhere to the protocol such as cognitive, visual, and/or language problems.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-11-2011
Enrollment:	36
Type:	Actual

Ethics review

Approved WMO

Date:	26-09-2011
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL33317.029.11