ISRCTN47046299 https://doi.org/10.1186/ISRCTN47046299

The effects of augmented visual feedback during balance training in Parkinson's disease

Submission date
11/06/2013

Recruitment status
No longer recruiting

Registration date
01/07/2013

Overall study status
Completed

Last Edited
25/08/2015

Condition category
Nervous System Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Parkinson's disease (PD) is a serious disease for which a proper cure is still not available. Symptoms of this disease are trembling or stiff limbs, a general 'slowness of movement' and postural instability. Postural instability means that patients with PD have often trouble to control their posture, for example when they want to stand up from a seat. It is important to develop training protocols that target these specific problems. New technological developments can help us with that. In this research we want to investigate whether it helps when we give the patient extra visual feedback (VF). By VF we mean any type of information about a movement or a movement pattern that is made visible on, for example, a monitor. We know that visual information can often be very helpful in 'guiding' movements in patients with PD, for example during walking. This is also known as 'cueing' . We hope that we can use these same principles for balance training. We think that VF during balance therapy can help PD patients to achieve a proper postural control. However, we do not know if there will be any lasting improvements. If the training does improve balance control, we will look if there are also any changes in brain activity.

Who can participate?
Male and female of all ages with a diagnosis of idiopathic Parkinson's disease (PD).

What does the study involve?
In this study we will look at the benefits of VF training. We do this by randomly allocating 36 patients with PD in two groups. One groups receives normal balance training, the other groups receives VF training. The VF training consists of a number of balance games that can be played on a number of workstations that were developed specifically for this study. The workstations register the patient's own movements. The patient can then score points by being accurate or fast enough. We test all patients before they start training, after the training period ends, and again a few weeks later. During the tests we measure the patient's balance, their brain activity, and ask them about the impact of the disease on their mobility and functioning.

What are the possible benefits and risks of participating?
Physical training interventions for PD patients positively influence mobility and mobility-related problems. The proposed intervention aims in particular at improving balance control. It is also

thought that exercise can reduce feelings of depression. Furthermore, group therapy may promote peer support and social interaction. The treatment does not pose any side effects other than the effects normally associated with exercise, such as mild fatigue or mild muscle soreness.

Where is the study run from?
The study takes place within the VU University medical center and the VU University, Netherlands.

When is the study starting and how long is it expected to run for?
The study started in October 2011 and the duration of the trial will be 18 months. The last participant was recruited in December 2012.

Who is funding the study?
International Parkinson Fonds and the VU University Amsterdam.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
NL33317.029.11

Study information

Scientific Title
Improving Mobility and balance in PArkinson's disease through circuit Class Training: Effects on clinical outcomes, posturography and brain connectivity

Acronym
IMPACT

Study objectives
We hypothesize that training with explicit, augmented visual feedback (VF) of a patient's own movements in a virtual environment is more effective than usual training in improving standing balance performance, with functional reach distance as the primary outcome. We also hypothesize that VF-related changes in balance performance are associated with more pronounced (movement-related changes in) beta synchronization in primary motor areas and corresponding changes in functional connectivity of the entire motor network (including, e.g., pre-motor and supplementary motor areas), which may reflect the learning of novel strategies to control standing balance.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethics Committee (METc) at VU University Medical Centre, 26/09/2011, ref: 2011/150

Study design
Randomised controlled trial of two treatment groups under blinded assessment

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Movement disorders; Parkinson's Disease

Interventions
Patients are allocated to either the experimental or control group.

The intervention will contain ten treatment sessions of 60 minutes each over a period of five weeks. In order to efficiently organize the training, different workstations related to standing balance will be organized in a circuit allowing six patients to train simultaneously. Patients will work in pairs at each workstation and take turns performing the exercise while the other person observes and/or rests. The training paradigm will be applied to both the experimental and the control group.

In the experimental group VF is explicitly integrated in each workstation. Three workstations, consisting of a PC with a wide-screen monitor and movement registration hardware, will be set up in a gym. Patients will be able to interact with balance games that are run on the workstations. Games focus on controlling body position in space, stepping movement, and on performing a sit-to-stand transfer movement.

In the control group workstations will consist of balance exercises that follow the current guidelines for physical therapy in PD. The exercises in both groups will focus on controlling body posture in forward and sideways direction, exploring limits of stability, weight-shifting, sit-to-stand exercises, and dual-task exercises. Which specific workstation will be used for which treatment session will be decided before the start of the training program. Two expert therapists will define training goals, monitor the training intensity during the sessions, and keep time. Throughout the training program, the therapists will monitor individual progress and

progressively adjust personal training goals. If desired, exercise complexity or workload will be increased throughout the sessions.

All training sessions will take place in an outpatient setting of VUmc. All participants will be asked to keep a training and fall log during the duration of the training program. Interventions will be rated by the participants in terms of the perceived exertion over the entire training session. The content of each treatment session will be controlled for type and duration. Warming-up and cooling-down exercises of about 5 minutes will be carried out as a group at the beginning and conclusion of each session, respectively.

Intervention Type
Behavioural

Primary outcome(s)
Functional Reach Test measured at baseline, at six weeks, and at 12 weeks.

Key secondary outcome(s))
Clinical outcome measures
1. Berg Balance Scale
2. Falls Efficacy Scale
3. 10 meter Walk Test
4. Parkinson's Disease Questionnaire
5. Hospital Anxiety and Depression scale
6. Multidimensional Fatigue Inventory

Posturography during quiet stance
1. Variability: COP standard deviation
1.1. anterioposterior direction (SDCOP,x)
1.2. mediolateral direction (SDCOP,y)
2. Local stability: maximum Lyapunov exponent
3. Regularity: sample entropy
4. Number of active control variables: correlation dimension
5. Correlations: scaling exponent

EEG (plus MRI)
1. Source of activity / regions of interest (dipole fits / beamformers)
2. Spectral power changes (in particular motor-related beta- and alpha-power)
3. Intra- / inter-hemispheric synchronization (phase coherence, synchronization likelihood)
4. Topological changes of overall functional connectivity (sensor-based network estimates)

All above outcomes measured at baseline, at six weeks, and at 12 weeks.

Completion date
01/05/2013

Eligibility

Key inclusion criteria
1. A diagnosis of idiopathic Parkinson's disease (PD), mild to moderate stage (i.e. Hoehn & Yahr stages II and III)
2. Able to participate in either of the training programs

3. Written and verbal informed consent.
4. Male and female subjects of all ages

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. The presence of neurological, orthopedic, or cardiopulmonary problems that can impair participation
2. Insufficient cognitive function (Mini Mental State Examination, MMSE < 24)
3. An unstable medication regime
4. Any condition that renders the patient unable to understand or adhere to the protocol such as cognitive, visual, and/or language problems.

Date of first enrolment
01/10/2011

Date of final enrolment
01/12/2012

Locations

Countries of recruitment
Netherlands

Study participating centre
VU University Medical Center
Amsterdam
Netherlands
1007MB

Sponsor information

Organisation
VU University Medical Center (Netherlands)

ROR
https://ror.org/00q6h8f30

Funder(s)

Funder type
University/education

Funder Name
International Parkinson Fund (Internationaal Parkinson Fonds) (Netherlands)

Funder Name
VU University Amsterdam (Netherlands)

Alternative Name(s)
VU University Amsterdam, VU University, VU

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Netherlands

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2014		Yes	No
Protocol article	protocol	04/10/2013		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes