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The effects of balance training using the Homebalance instrument in people with multiple sclerosis

Submission date
28/07/2018

Recruitment status
No longer recruiting

Registration date
07/08/2018

Overall study status
Completed

Last Edited
06/09/2023

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
Balance problems are a common symptom of multiple sclerosis (MS), an condition affecting the brain and spinal cord. These balance problems can result in limitations in activity and decreased quality of life for people with MS. While many symptoms of MS are treatable, balance problems cannot be treated with medications as they are too complex. However, a possible treatment option is balance training, which can take different approaches, including supervision by a physical therapist and different exercise tools.
The aim of this study was to look at the effects of a new exercise tool for balance problems called Homebalance in a group of patients with MS.

Who can participate?
Adults with multiple sclerosis and balance problems

What does the study involve?
Participants will be allocated to either the intervention group or the control group.
Participants in the intervention group will be asked to complete 15 minutes of balance training using Homebalance daily for 4 weeks. They will be asked to complete balance-related tests and questionnaires before beginning training (baseline), after 4 weeks of training and 4 weeks after this.
Participants in the control group will be on a waiting list for balance training. This group will also be asked to complete balance-related tests and questionnaires at the baseline and after 4 weeks.

What are the possible benefits and risks of participating?
The possible benefit to participants taking part in this study is the balance training may lead to reduced balance problems. There are no known risks to participants taking part in this study.

Where is the study run from?
MS Centre, Department of Neurology, First Faculty of Medicine and General University Hospital, Prague, Czech Republic

When is the study starting and how long is it expected to run for?
November 2011 to June 2017

Who is funding the study?
1. First Faculty of Medicine Charles University and General University Hospital (Czech Republic)
2. Impuls Endowment (Czech Republic)

Who is the main contact?
Klara Novotna
klara.novotna@vfn.cz

Study website
http://www.homebalance.cz/cz.html

Contact information

Type(s)
Public

Contact name
Miss Klara Novotna

ORCID ID
http://orcid.org/0000-0003-1448-8724

Contact details
MS center, Karlovo nam 32
Prague
Czech Republic
12000

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HomebalanceRS2016

Study information

Scientific Title
Home-based balance training using biofeedback with the Homebalance instrument in people with multiple sclerosis

Study objectives

Regular balance training on daily basis in home based setting using Homebalance instrument can improve balance performance in people with multiple sclerosis

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Committee of the First Faculty of Medicine and General University Hospital in Prague, Czech Republic, 10/11/2011, No. 253172 627912 GAUK

Study design
Interventional single-centre non-randomized study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Home

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to reques a participant information sheet.

Health condition(s) or problem(s) studied
Multiple sclerosis with balance difficulties

Interventions
Participants in the intervention group received individually tailored home-based balance exercise training using Homebalance® for at least 15 minutes each day for 4 weeks. Participants were allowed to sit and rest during the exercise whenever necessary, and the exercise difficulty was tailored to suit each participant's ability and preferences.
Participants on the waiting list for the Homebalance rehabilitation intervention were used as a control group. This group received no intervention.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)

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Primary outcome measure
Balance was assessed at the baseline, after 4 weeks and at the 4 week follow-up (8 weeks after the start of the intervention) using the following:
1. Berg Balance Scale (BBS)
2. Mini-Balance Evaluation Systems Test (Mini-BEST)

Secondary outcome measures
The following were assessed at the baseline, after 4 weeks and at the 4 week follow-up (8 weeks after the start of the intervention):
1. Severity of multiple sclerosis, assessed using the Multiple Sclerosis Functional Composite (MSFC)
2. Gait parameters, assessed using the GAITRite instrument
3. Subjective perceived balance confidence, assessed using the following:
3.1. Activities-specific Balance Confidence Scale (ABC)
3.2. Falls Efficacy Scale (FESI)
4. Subject perceived gait difficulties, assessed using the 12-item MS Walking Scale (MSWS12)

Overall study start date
10/11/2011

Completion date
30/06/2017

Eligibility

Key inclusion criteria
1. Aged 18-60 years old
2. Multiple sclerosis (clinically stable without relapse or worsening in the previous 3 months)
3. Able to walk with or without a walking aid for at least 20 m (EDSS 1-6.5)
4. Able to maintain a standing position for at least 10 minutes
5. Able to perform exercise

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
60 Years

Sex
Both

Target number of participants

40

Total final enrolment
39

Key exclusion criteria
1. Inpatient rehabilitation programme during the previous 3 months
2. Orthopaedic problems or other conditions affecting balance and gait performance
3. Blurred vision
4. Severe cognitive impairment or psychiatric disorders
5. Pregnancy
6. Weight over 150 kg
7. Receiving other physiotherapy targeting balance problems
8. Changes in lifestyle prior to or during the study

Date of first enrolment
01/01/2016

Date of final enrolment
30/03/2017

Locations

Countries of recruitment
Czech Republic

Study participating centre
MS centre, Department of Neurology, First Faculty of Medicine and General University Hospital in Prague
FP, Karlovo nam 32
Prague
Czech Republic
12000

Sponsor information

Organisation
MS centre, Department of Neurology, First Faculty of Medicine and General University Hospital in Prague

Sponsor details
Karlovo nam 32
Prague
Czech Republic
12000

Sponsor type
Hospital/treatment centre

Website
www.homebalance.cz

ROR
https://ror.org/04yg23125

Funder(s)

Funder type
Not defined

Funder Name
Impuls Endowment

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
30/10/2018

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		23/12/2019	06/09/2023	Yes	No