

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

<b>Submission date</b> 28/07/2018	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 07/08/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 06/09/2023	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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 request 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)**

### **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**

**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?
<a href="#">Results article</a>		23/12/2019	06/09/2023	Yes	No