

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effects of perturbation-based balance training versus traditional balance training on balance and risk of falling in people with multiple sclerosis

Protocol summary

Study aim

Effects of perturbation-based balance training versus traditional balance training on balance and risk of fall in people with multiple sclerosis

Design

Randomized clinical trial with two arm parallel group design of 30 participants, double blinded, and randomized by stratified permuted block method.

Settings and conduct

Thirty patients with Multiple Sclerosis will participate in this study that will be conducted in Musculoskeletal Rehabilitation Research Center, Ahvaz Jundishapur University of Medical Sciences, Iran. Participants will be randomized in perturbation training or traditional balance training (control), and will received intervention 3 times per week (20 minutes in each session) for 4 weeks. Pre and post intervention assessments will be performed by a physical therapist who is blinded to allocation. Also, participants are blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: History of falls in past 3 months; Ability to stand independently; Ability to walk independently at least for 100 meters; MMSE more than 24; EDSS below 5/5 Exclusion criteria: Exacerbation of symptoms in past 3 months; Any musculoskeletal or neurological conditions except MS limiting balance or gait; Receiving treatments to improve balance in past 3 months

Intervention groups

Intervention group: receive walking and balance exercises with perturbation; Control group: receive walking and balance exercises without perturbation; Both group will receive 20-minute individualized (1 trainer to 1 participant) training sessions, 3 times a week for 4 weeks.

Main outcome variables

COP parameters using force plate; Adaptation test; Motor control test; Timed Up and Go; 10 meter walk test; Berg Balance Scale; Activities Specific Balance Confidence scale; Fall Efficacy Scale International; Fall rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140519017752N2**

Registration date: **2018-10-31, 1397/08/09**

Registration timing: **prospective**

Last update: **2018-10-31, 1397/08/09**

Update count: **0**

Registration date

2018-10-31, 1397/08/09

Registrant information

Name

Saeideh Monjezi

Name of organization / entity

Musculoskeletal Rehabilitation Research Center,
Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-22, 1397/09/01

Expected recruitment end date

2020-01-21, 1398/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of perturbation-based balance training versus traditional balance training on balance and risk of falling in people with multiple sclerosis

Public title

Effects of exercises on balance and falls in patients with multiple sclerosis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Inclusion criteria: A definite diagnosis of MS, relapsing-remitting or secondary progressive types, as diagnosed by a neurologist; History of falls in past 3 months; Ability to stand independently; Ability to walk independently at least for 100 meters; Ages between 18-64 years; MMSE more than 24; EDSS below 5/5

Exclusion criteria:

Experiencing an exacerbation of symptoms due to relapse within 3 months of the baseline measurement; Any musculoskeletal or neurological conditions except MS limiting balance or gait; Uncorrected Auditory or visual impairment; Pregnancy; Involving in the other planned treatment; Receiving treatments to improve balance in past 3 months

Exclusion criteria:**Age**

From **18 years** old to **64 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be performed using stratified permuted block method. The unit of randomization will be the individual, and participant will stratified by the age and gender. An statistical software will be used for generating random sequence, and then sealed envelopes will be used to determine the blocks. For allocation concealment, a person who is not a member of research team will perform the randomization.

Blinding (investigator's opinion)

Double blinded

Blinding description

A physiotherapist who has no information about patients' allocation and treatment will perform the assessments. The participants will receive information about their treatment program, but they will not informed if they are in intervention or control group. A statistician who has no information about patients' allocation and treatment will perform the statistical analysis.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ahvaz Jundishapur University of Medical Sciences

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Ground floor, Vice Chancellor for Research and Technology, Ahvaz Jundishapur University of Medical Science

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Approval date

2018-10-22, 1397/07/30

Ethics committee reference number

ethics.research.ac.ir

Health conditions studied**1****Description of health condition studied**

Multiple Sclerosis

ICD-10 code

G35

ICD-10 code description

Multiple sclerosis

Primary outcomes**1****Description**

Static Balance

Timepoint

Before and after intervention (at the end of 4th week)

Method of measurement

Force plate

2**Description**

Ability to adapt to unexpected changes in orientation of the support surface

Timepoint

Before and after intervention (at the end of 4th week)

Method of measurement

"Adaptation test" in Computerized Dynamic Posturography system (Neurocom)

3

Description

Effectiveness of the patient's automatic motor responses to external perturbation

Timepoint

Before and after intervention (at the end of 4th week)

Method of measurement

"Motor Control test" in Computerized Dynamic Posturography system (Neurocom)

4

Description

Dynamic balance

Timepoint

Before and after intervention (at the end of 4th week)

Method of measurement

Time Up and Go Test, 10 meter walk test

5

Description

Functional balance

Timepoint

Before and after intervention (at the end of 4th week)

Method of measurement

Berg balance scale

6

Description

Balance confidence

Timepoint

Before and after intervention (at the end of 4th week)

Method of measurement

Activities Specific Balance Confidence scale

7

Description

Fear of fall

Timepoint

Before and after intervention (at the end of 4th week)

Method of measurement

Fall Efficacy Scale - International

8

Description

Fall rate

Timepoint

Before and after intervention (at the end of 4th week)

Method of measurement

Fall diary

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: receive walking and balance exercises with perturbation; Participants received 20-minute individualized (1 trainer to 1 participant) training sessions, 3 times a week for 4 weeks.

Category

Rehabilitation

2

Description

Control group: receive walking and balance exercises without perturbation; Participants received 20-minute individualized (1 trainer to 1 participant) training sessions, 3 times a week for 4 weeks.

Category

Rehabilitation

Recruitment centers

1

Recruitment center**Name of recruitment center**

Musculoskeletal Rehabilitation Research Center

Full name of responsible person

Zahra Najarzade

Street address

Musculoskeletal Rehabilitation Research Center,
School of Rehabilitation Sciences, Ahvaz Jundishapur
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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Badavi

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Ground floor, Vice Chancellor for Research and
Technology, Ahvaz Jundishapur University of Medical
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ahvaz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Saeideh Monjezi

Position

PhD Candidate

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No detail

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable