Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 ssessments 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

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

City
Ahvaz

Province
Khouzestan

Postal code
6135715794

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 University of Medical Sciences, Ahvaz, Iran
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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 Science
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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