Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effect of sensory retraining technique on paresthesia and balance in patients with multiple sclerosis: a randomized clinical trial

Protocol summary

Study aim

Evaluating the Effect of Sensory Retraining Exercises on Paresthesia, Balance, Tactile Acuity and Quality of Life in Patients with Multiple Sclerosis

Design

A controlled, double group, single blinded (assessor), randomized, phase 3 clinical trial on 30 patients. For randomization permutational randomization method with the number of blocks 5 and block size 6 is used.

Settings and conduct

Individuals in both groups are selected from patients with MS who have been referred to centers under the supervision of SUMS. One group will receive sensory retraining exercises and Gabapentin or pregabalin, and another group will receive only drugs. The assessor and the therapist are not the same person, and in this way, the assessor will be blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age over 18 years, Expanded Disability Status Scale less than 6, patient-reported paresthesia symptoms, score of at least 4 out of 10 in at least one of the symptoms of neuropathy on the visual scale in the legs in the past four weeks, balance disorder, no relapse of MS in at least the past 30 days. Exclusion criteria: Central or peripheral nervous system disorders such as head trauma, stroke, diabetes, Presence of any wounds or swelling at legs, Systemic diseases, pregnancy, lupus, use of tricyclic antidepressant and serotonin and norepinephrine reuptake inhibitors during the study period.

Intervention groups

treatment group: participants receive sensory retraining exercises in addition to the drug pregabalin or gabapentin. control group: participants receive pregabalin or gabapentin.

Main outcome variables

Paresthesia, Balance, Proprioception, 2-point discrimination, Texture of objects, Quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160221026674N7**
Registration date: **2025-11-05, 1404/08/14**
Registration timing: **prospective**

Last update: **2025-11-05, 1404/08/14**
Update count: **0**

Registration date

2025-11-05, 1404/08/14

Registrant information

Name
Marzieh Mohamadi
Name of organization / entity
Shiraz University of Medical Sciences, School of Rehabilitation Sciences
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-11-06, 1404/08/15

Expected recruitment end date

2026-05-05, 1405/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Investigating the effect of sensory retraining technique on paresthesia and balance in patients with multiple sclerosis: a randomized clinical trial

Public title
Investigating the effect of physiotherapy on sensory and balance problems in patients with multiple sclerosis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age over 18 years Diagnosis of MS and confirmation of the diagnosis by a neurologist according to McDonald criteria and the patient's medical reports Extended Disability Status Scale (EDSS) score less than 6 Willing and able to comply with the study requirements Self-reported paresthesia symptoms including tingling, prickling, prickling, burning, crawling (like an insect moving across the skin), itching, partial numbness, and any abnormal sensation; score of at least 4 out of 10 on at least one of the symptoms of neuropathy (numbness, tingling, prickling, and any abnormal sensation) on a visual analogue scale in the legs in the past four weeks Balance Disorder Report: The Mini-Balance Evaluation Systems Test (Mini-BESTest) will be used. Absence of MS relapses for at least the past 30 days (defined as episodes of focal neurological impairment lasting more than 24 hours and without an alternative explanation).

Exclusion criteria:
Central or peripheral nervous system disorders such as head trauma, stroke, diabetes Presence of any wounds or swelling at the treatment site (legs) Systemic diseases Pregnancy lupus Use of Tricyclic antidepressants and Serotonin-norepinephrine reuptake inhibitors family drugs by patients during the study period

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants will be randomly assigned to two groups of 15, intervention (sensory retraining exercises and drug therapy) and control (drug therapy), using a permutation randomization method with number of blocks of 5 and a block size of 6. Randomization will be performed manually by an epidemiologist. Random assignment of samples to groups is done with the ratio of 1:1 and with the help of numbered envelopes. Before performing the initial evaluation of each of the samples, the corresponding envelope is returned by the therapist at the Faculty of Rehabilitation Sciences in Shiraz.

Blinding (investigator's opinion)
Single blinded

Blinding description
The assessor and the therapist are two different people, so the assessor is unaware of which of the two groups each participant is placed in.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences

Street address
Ethics committee, Research and Technology Vice-Chancellor, 7th floor, central building of Shiraz University of Medical Sciences, Zand Street

City
Shiraz

Province
Fars

Postal code
7198754361

Approval date
2025-07-30, 1404/05/08

Ethics committee reference number
IR.SUMS.REHAB.REC.1404.012

Health conditions studied

1

Description of health condition studied
Multiples Sclerosis

ICD-10 code
G35

ICD-10 code description
Multiple sclerosis

Primary outcomes

1

Description
Paresthesia intensity

Timepoint
Before the start of the intervention, immediately after the end of intervention course, 4 weeks after the end of the intervention

Method of measurement
Visual Analog Scale

Secondary outcomes

1

Description
Balance
Timepoint
Before the start of the intervention, immediately after the end of intervention course, 4 weeks after the end of the intervention
Method of measurement
Biodex balance SD

2

Description
Proprioception
Timepoint
Before the start of the intervention, immediately after the end of intervention course, 4 weeks after the end of the intervention
Method of measurement
Body position sense test

3

Description
Two-point discrimination
Timepoint
Before the start of the intervention, immediately after the end of intervention course, 4 weeks after the end of the intervention
Method of measurement
Sliding caliper

4

Description
The texture of objects
Timepoint
Before the start of the intervention, immediately after the end of intervention course, 4 weeks after the end of the intervention
Method of measurement
Testing the texture of objects with customized kit

5

Description
Quality of life
Timepoint
Before the start of the intervention, immediately after the end of intervention course, 4 weeks after the end of the intervention
Method of measurement
Quality of Life questionnaire

Intervention groups

1

Description
Intervention group: Sensory retraining exercises (4 weeks, 3 days a week, 60 minutes each time) with daily use of gabapentin (300 mg/day) or pregabalin (100 mg/day) for 4 weeks. The intervention consists of 4 sensory activities: stimulation of the sense of touch, recognition of the texture of objects, understanding the position of the limbs, and practice of two-point discrimination (ACTOVERCO Pharmaceutical Company).
Category
Treatment - Other

2

Description
Control group: Daily use of gabapentin (300 mg/day) or pregabalin (100 mg/day) for 4 weeks (ACTOVERCO Pharmaceutical Company).
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Clinic of Rehabilitation School, Shiraz University of Medical Sciences
Full name of responsible person
Marzieh mohamadi
Street address
Mehr Building, Shahid Chamran Hospital, Shahid Chamran Boulevard
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Marzieh mohamadi
Position
Assistant professor
Latest degree
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Other areas of specialty/work
Physiotherapy
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Person responsible for updating data

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Other areas of specialty/work
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mohamadm@sums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary

Not applicable

Title and more details about the data/document

Information collection form including primary and secondary outcomes, informed consent form and SPSS file

When the data will become available and for how long

After publication the results of the study

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Only for recording information in scientific databases

From where data/document is obtainable

Correspondence with the project manager by email. mohamadm@sums.ac.ir

What processes are involved for a request to access data/document

Maximum one month after sending the request by email

Comments