Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effectiveness of balance exercises on the textured surface on somatosensory, balance and Spatio-temporal parameters of gait in patients with relapsing-remitting multiple sclerosis: A parallel-groups clinical study

Protocol summary

Study aim
The effect of balance exercises on textured surface on somatosensory, balance and spatial-temporal parameters of gait in people with multiple sclerosis

Design
A clinical trial with a control group, with parallel groups, double-blind, randomized by block randomization method, on 30 patients. A random number table will be used for randomization.

Settings and conduct
Location: Isfahan Exercises: intervention group:Balance exercises and simultaneous sensory stimulation control group:balance exercises . Trend: Obtaining patients 'consent and collecting demographic information, measuring and recording study variables in two experimental and control groups before and after exercise therapy intervention. Intervention program: 12 hours of therapy based on improving balance (6 weeks, one-hour 2 sessions per week). Blinding participants, evaluating and analyzing data

Participants/Inclusion and exclusion criteria
Inclusion criteria: Diagnosis of a neurologist Weakness in somatosensory function based on sensory evaluation EDSS score 2 to 5.5 (for the ability to perform or complete gait tests according to previous studies) The ability to walk a distance of 25 feet with or without assistive device Ability to stand independently for 2 minutes Exclusion criteria: The underlying illnesses Receive corticosteroid treatment one month before the study Uncorrected visual disorders Exacerbation of symptoms Changes in medications during the study Attack 30 days before the start of the study or during the study

Intervention groups
The intervention group will receive balance exercises and sensory stimulation simultaneously(standing on a textured mat.) and the control group will receive balance exercises.

Main outcome variables
Fatigue, pain, spasticity, ataxia, muscle strength, sensory, static and dynamic balance, spatio-temporal parameters of walking

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150210021034N10**
Registration date: **2021-03-30, 1400/01/10**
Registration timing: **prospective**

Last update: **2021-03-30, 1400/01/10**
Update count: **0**

Registration date
2021-03-30, 1400/01/10

Registrant information

Name
Ebrahim Sadeghi-Demneh

Name of organization / entity
Isfahan University of Medical Sciences

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-04-21, 1400/02/01
Expected recruitment end date
2021-10-22, 1400/07/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effectiveness of balance exercises on the textured surface on somatosensory, balance and Spatio-temporal parameters of gait in patients with relapsing-remitting multiple sclerosis: A parallel-groups clinical study

Public title
The effectiveness of balance-sensory exercises on motor function in patients with MS
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of a neurologist Weakness in somatosensory function based on sensory evaluation EDSS score 2 to 5.5 (for the ability to perform or complete gait tests according to previous studies) The ability to walk a distance of 25 feet with or without assistive device Ability to stand independently for 2 minutes
Exclusion criteria:
The underlying illnesses (such as diabetes and epilepsy) or any problems with neuro-musculoskeletal system other than multiple sclerosis (eg, history of surgery, fracture) disrupts the balance and sensory status Receive corticosteroid treatment one month before the study Uncorrected visual disorders Exacerbation of symptoms Changes in medications during the study Attack 30 days before the start of the study or during the study
Age
No age limit
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
The samples will be divided into two groups using the blocked randomization method. The choice of this randomization method is according to the sample size of the present study (less than 100 people) to ensure an equal number of people in each group. Randomization unit: individual Randomization tool: Random number table In order to hide random allocation, opaque envelopes sealed and sealed with random sequence are used: In this method, first a random sequence is created using the mentioned method, then based on the sample size of the research, a number of envelopes with aluminum foil (foil) are used. The contents of the envelopes are prepared and each of the random sequences created is recorded on a card and the cards are placed inside the envelopes in the order of placement. In order to maintain a random sequence, the envelopes are numbered in the same way on the outer surface. Finally, the lid of the letter envelopes is glued and placed in a box, respectively. It becomes obvious. Execution of the random allocation process: One person will create a random sequence, the other person will examine the participants in terms of entry and exit criteria for the study and will register them in the study and the third person will participate in the study.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, participants are informed that they are in two groups with different programs, but they are not aware that they are in the intervention or control group. The outcome assessor and data analyst are also unaware of the allocation of groups.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethic's committee of Isfahan University of Medical Sciences, Isfahan, Iran
Street address
Hezar Jerib St.
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2021-03-03, 1399/12/13
Ethics committee reference number
IR.MUI.RESEARCH.REC.1399.764

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 the intervention, a week after the intervention

Method of measurement

Participants are asked to stand quiet on the force-plate while put the feet together and keep the arms relaxed beside the body. The center of pressure is recorded during 60 second of standing.

2

Description

dynamic balance

Timepoint

Before the intervention, a week after the intervention

Method of measurement

Timed up and go test: Participants sit on a chair to start the test They are asked to walk with maximum speed during test. They rise with a "go" signal and walk until reach a line at 3 meters distance from the chair then turn and walk back to the chair and sit on it. The time is recorded using a stopwatch.

3

Description

Spatial-temporal parameters of gait

Timepoint

Before the intervention, a week after the intervention

Method of measurement

Walking of participant will be recorded using a motion capture system then parameters of the "gait symmetry" calculated and reported using a Visual 3D software.

4

Description

somatosensory(sense of joint position)

Timepoint

Before the intervention, a week after the intervention

Method of measurement

Ankle proprioception was measured using perception of the inclination whilst participants stood over an adjustable slope box with closed eyes.

Secondary outcomes

1

Description

fatigue

Timepoint

Before the intervention, a week after the intervention

Method of measurement

The level of fatigue will be measured using "Fatigue severity scale"

2

Description

pain

Timepoint

Before the intervention, a week after the intervention

Method of measurement

The participants' pain will be quantified using "Visual analog scale".

3

Description

spasticity

Timepoint

Before the intervention, a week after the intervention

Method of measurement

Muscle spasticity will be measured using "Modified Ashworth scale".

Intervention groups

1

Description

Intervention group: Number: 15 people with multiple sclerosis- Intervention program: Performing balance exercises according to Canadian guidelines Physical activity of adults with multiple sclerosis on a textured surface (material: rubber - 6 mm thick, area 1 in 1.5 m with dentin tissue 3 mm thick And the distance between the dentin 2.5 mm) Duration: 6 weeks (2 one-hour sessions per week).

Category

Rehabilitation

2

Description

Control group: Number: 15 people with multiple sclerosis- Intervention program: Performing balance exercises according to Canadian guidelines Physical activity of adults with multiple sclerosis on a tissue-free surface (material: rubber - 6 mm thick, area 1 in 1.5 meters with a tissue-free surface) - Duration: 6 weeks (2 one-hour sessions per week).

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital, Isfahan, Iran

Full name of responsible person
Masoud Etemadifar
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Sponsors / Funding sources

1

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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
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
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Position
Associate professor
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is 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
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
The study data (excluding the personal details) can be shred with other researchers or systematic reviewers.
When the data will become available and for how long
Data will be shared once findings are come up or summary date is published.
To whom data/document is available
Data will be shared personally and for academic purposes only.
Under which criteria data/document could be used
Data will be shared for teaching or research. Dr Sadeghi (correspondence) will review the requests.
From where data/document is obtainable
People can sent their request to the correspondence and obtain the data.
What processes are involved for a request to access data/document
Request can be sent through an email (sadeghi@rehab.mui.ac.ir).
Comments
The kinematic and kinetic information of the gait and data for static balance (forcepate) will be available for researchers who are interested in secondary data analysis.