

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Sep 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3792 5235

##### Email address

sadeghi@rehab.mui.ac.ir

##### 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**

Isfahan

**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

**Street address**

Sofeh boulevard

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**Web page address**

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

shaghayegh Haghjoo

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research@mui.ac.ir

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http://research.mui.ac.ir/fa/%D9%85%D8%B9%D8%A7%D9%88%D9%86-%D9%BE%DA%98%D9%88%D9%87%D8%B4%DB%8C-%D9%88%D9%81%D9%86%D8%A7%D9%88%D8%B1%DB%8C

**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**

Ebrahim Sadeghi

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Rehabilitation management

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Esfarayan University of Medical Sciences

**Full name of responsible person**

Ebrahim Sadeghi

**Position**

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**Latest degree**

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**Other areas of specialty/work**

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**Person responsible for updating data****Contact****Name of organization / entity**

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**Full name of responsible person**

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**Position**

Associate professor

**Latest degree**

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**Other areas of specialty/work**

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**Email**

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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 shared 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 (forceplate) will be available for researchers who are interested in secondary data analysis.