

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Feb 2026

### The effect of Dynamic Neuromuscular Stabilization on Balance and Balance Confidence in patients with Multiple Sclerosis.

#### Protocol summary

2023-01-01, 1401/10/11

##### Study aim

The effect of dynamic neuromuscular stabilization exercises on balance and balance confidence in patients with multiple sclerosis

##### Design

The study is a clinical trial with a control group, with parallel, double-blind and randomized groups.

##### Settings and conduct

After obtaining an ethics license from the Medical Ethics Committee of Isfahan University of Medical Sciences and also registering the study protocol in the Iranian clinical trial registration system, patients with multiple sclerosis are invited to this study by a neurologist based in Ayatollah Kashani Hospital. The intervention is performed in the physiotherapy ward of Kashani Hospital.

##### Participants/Inclusion and exclusion criteria

Patients (male or female) with multiple sclerosis with EDSS zero to 5.5 who are not in the acute phase of their disease.

##### Intervention groups

The control group performs only conventional treatment according to sources and the intervention group performs dynamic neuromuscular stabilization exercises.

##### Main outcome variables

Balance and Balance Confidence

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200101045970N7**

Registration date: **2023-01-01, 1401/10/11**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-01-01, 1401/10/11**

Update count: **0**

##### Registration date

##### Registrant information

###### Name

Ehsan Ghasemi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 3669 3089

###### Email address

eghasemi@rehab.mui.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

##### Expected recruitment start date

2022-12-22, 1401/10/01

##### Expected recruitment end date

2023-06-20, 1402/03/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of Dynamic Neuromuscular Stabilization on Balance and Balance Confidence in patients with Multiple Sclerosis.

##### Public title

The effect of stabilizing exercises on MS patients

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

###### Inclusion criteria:

At least one year has passed since the diagnosis Age range 15 to 55 years and being in the disease remission period Having a mild to moderate degree of disability

(EDSS = 0-5.5) as determined by your doctor. No recurrence of the disease during the last month No other diseases such as cardiovascular, osteoarthritis, respiratory, skin, cognitive disorders, diabetes and cancer Stability of the patient's vital signs Being able to walk without an aid

**Exclusion criteria:**

Lack of regular participation in training sessions  
Recurrence of the disease during the project Having certain illnesses, such as heart disease, or problems such as fatigue, so that continuing to exercise is detrimental to her. Use of pharmacological agents to control fatigue  
Depressive and sleep disorders that lead to fatigue.  
Participate in an exercise program 8 weeks in past and during treatment Serious balance problems that put a person at risk of falling.

**Age**

From **15 years** old to **55 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **40**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this study, patients are randomly divided into one of two experimental and control groups after examining the inclusion and exclusion criteria. In this study, due to the small number of samples, in consultation with a statistician, it was decided to use the random blocking method. Blocking is usually used to balance the number of samples assigned to each of the groups studied. The statistician used the website <https://www.sealedenvelope.com/simple-randomiser/v1/lists>, Considering that we had 2 groups, they designed 20 two-person blocks. . A person who divides patients into two groups based on this table is unaware of the study.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In this study, because sufficient information about the exercises is given to the participants and it is explained to each of them that they may be randomly placed in one of the two groups, so the participants are not blind. In this study, the evaluator of balance and confidence in balance does not know which group the participant is in, so our evaluator is blind. In addition, the person analyzing the data does not know which person is in which group and only compares the data between the two groups, so they are also blind.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethics committee of Isfahan University of Medical Sciences

**Street address**

Hezar Jerib Ave

**City**

Isfahan

**Province**

Isfahan

**Postal code**

81746-73461

**Approval date**

2022-11-08, 1401/08/17

**Ethics committee reference number**

IR.MUI.NUREMA.REC.1401.100

## 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**

Balance

**Timepoint**

Before the start of treatment, after the end of treatment and 2 months after the end of the last treatment session

**Method of measurement**

Use of Mini BES Test

### 2

**Description**

Balance Confidence

**Timepoint**

Before the start of treatment, after the end of treatment and 2 months after the end of the last treatment session

**Method of measurement**

Use of ABC Scale

## Secondary outcomes

## 1

### Description

Assessment of functional mobility

### Timepoint

Before the start of treatment, after treatment and 2 months after the end of the last treatment session

### Method of measurement

Use of TUG test

## Intervention groups

## 1

### Description

Intervention group: Receive dynamic neuromuscular stabilization exercises. These exercises are performed in different positions that are actually modeled on the positions of the growing baby. Exercises start with simple situations and gradually become more complex. In fact, the exercises start with the supine and then progress to the rolling, sitting, bear and squat-like postures. In each training session, 3 different situations are taught. Each exercise is maintained 3 times for 10 seconds and the patient is given 10 seconds of rest between each. Patients are treated for 4 weeks with a regimen of 3 sessions per week, every other day. The duration of each treatment session is 30 minutes.

### Category

Rehabilitation

## 2

### Description

Control group: Routine balance exercises that include both movement and sensory strategies. Movement strategy includes stabilizing exercises, dual exercises, and ankle balance strategy. Double exercises are generally changed from static to dynamic and walking to make them more advanced. Sensory strategy also tries to strengthen vestibular and sensory-physical information by reducing visual input. Therefore, to achieve this goal, we do some movement phase exercises with closed eyes. Patients are treated for 4 weeks with a regimen of 3 sessions per week, every other day. The duration of each treatment session is 30 minutes.

### Category

Rehabilitation

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

kashani Hospital

#### Full name of responsible person

Ehsan Ghasemi

#### Street address

Street of Ayatollah Kashani

#### City

Isfahan

#### Province

Isfahan

#### Postal code

8183983434

#### Phone

+98 31 3233 0091

#### Email

kashani@mui.ac.ir

#### Web page address

<https://kashani.mui.ac.ir>

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Esfahan University of Medical Sciences

#### Full name of responsible person

Mansour Siavash Dastjerdi

#### Street address

Vice Chancellor for Research and Technology,  
Building No. 4, Isfahan University of Medical Sciences  
and Health Services, Hezar Jerib St.

#### City

Isfahan

#### Province

Isfahan

#### Postal code

81746-73461

#### Phone

+98 31 3668 7898

#### Email

research@mui.ac.ir

#### Web page address

<https://research.mui.ac.ir>

### 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

Ehsan Ghasemi

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

**Street address**

Faculty of Rehabilitation Sciences, Isfahan University of Medical Sciences and Health Services, Hezar Jerib St.

**City**

Isfahan

**Province**

Isfahan

**Postal code**

81746-73461

**Phone**

+98 31 3669 3089

**Email**

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Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Ehsan Ghasemi

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

**Street address**

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**Email**

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Ehsan Ghasemi

**Position**

**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**

Because of confidentiality

**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**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available

**Title and more details about the data/document**

Study protocol, informed consent form and clinical study report

**When the data will become available and for how long**

The study protocol and consent form are now available in the proposal. The clinical study report will be published after the work is completed.

**To whom data/document is available**

All researchers working in scientific institutes can access the proposal.

**Under which criteria data/document could be used**

To be aware of the study conditions and get acquainted with scientific concepts.

**From where data/document is obtainable**

Contact Dr. Ehsan Ghasemi via email or mobile.

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

Immediately after sending the email and receiving the request.

**Comments**