

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### A Comparative Study of the Effect of Reactive and Proactive Exercises on Balance and Balance Confidence in Multiple Sclerosis Patients : A Randomized Clinical Trial

#### Protocol summary

##### Study aim

Comparative study of the effect of reactive and proactive exercises on balance and confidence in the balance of patients with multiple sclerosis

##### Design

In this double-blind trial study, 51 people were randomly assigned to control and experimental groups.

##### Settings and conduct

This study is performed in the physiotherapy ward of Kashani Hospital in Isfahan on patients with multiple sclerosis.

##### Participants/Inclusion and exclusion criteria

Patients (male or female) with multiple sclerosis with a disability degree of 5.3 to 5.5 who are not in the acute phase of their disease.

##### Intervention groups

All patients receive conventional evidence-based treatment for multiple sclerosis rehabilitation. The control group performs only conventional therapy and the two intervention groups, depending on the type of group, perform special balance exercises (reactive and proactive) in addition to conventional therapy.

##### Main outcome variables

Evaluations include assessing the degree of balance and confidence in balance in patients with multiple sclerosis .The number of patient falls per week is also recorded.

#### General information

##### Reason for update

##### Acronym

MS

##### IRCT registration information

IRCT registration number: **IRCT20200101045970N8**

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

Registration timing: **prospective**

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

Update count: **0**

##### Registration date

2023-01-01, 1401/10/11

##### 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

2023-01-21, 1401/11/01

##### Expected recruitment end date

2023-07-21, 1402/04/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

A Comparative Study of the Effect of Reactive and Proactive Exercises on Balance and Balance Confidence in Multiple Sclerosis Patients : A Randomized Clinical Trial

##### Public title

The effect of exercise therapy on balance in patients with multiple sclerosis

##### Purpose

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**  
 Diagnosis of MS by a specialist doctor Age range from 20 to 50 years and being in the remission period At least one year has passed since the diagnosis of the disease having a mild to moderate degree of disability (EDSS=3.5-5.5) determined by a specialist doctor. Being able to stand without assistance for at least 3 minutes

**Exclusion criteria:**  
 Lack of regular participation in training sessions  
 Recurrence of the disease during the plan and six months before  
 Excessive fatigue so that it is harmful for her to continue training. Biomechanical or neurological disease or any specific disease in the expert's opinion that affects balance. Participation in a specific exercise program in the 3 months before and during treatment  
 Suffering from other diseases such as cardiovascular, arthritis, respiratory, diabetes, cancer and vestibular system disorders according to the opinion of the relevant expert. A deformity in the lower limb that creates a risk of falling for the person. Use of medicinal agents to control fatigue and sedatives that affect balance. Cognitive disorders and depression and sleep that lead to fatigue.

**Age**  
 From **20 years** old to **50 years** old

**Gender**  
 Both

**Phase**  
 N/A

**Groups that have been masked**

- Outcome assessor
- Data analyser

**Sample size**  
 Target sample size: **51**

**Randomization (investigator's opinion)**  
 Randomized

**Randomization description**  
 In this study, patients are randomly divided into one of three reactive, proactive 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 3 groups, they designed 17 two-person blocks. . A person who divides patients into three 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 three 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 three 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 Jrib

##### City

Isfahan

##### Province

Isfahan

##### Postal code

81746-73461

#### Approval date

2022-12-28, 1401/10/07

#### Ethics committee reference number

IR.MUI.NUREMA.REC.1401.128

## 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 1 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 1 months after the end of the last treatment session

### Method of measurement

Use of ABC Scale

## Secondary outcomes

### 1

#### Description

Number of falls per week

#### Timepoint

Before the start of treatment, after the end of treatment and 1 months after the end of the last treatment session

#### Method of measurement

questionnaire

## Intervention groups

### 1

#### Description

Intervention group: Reactive exercises + conventional exercises. The duration of each treatment session for the intervention group is 60 minutes. 5 minutes of warm-up, 25 minutes of common balance exercises, 25 minutes of relevant balance exercises (reactive) and 5 minutes of cooling down.

#### Category

Rehabilitation

### 2

#### Description

Intervention group: Proactive exercises + conventional exercises. The duration of each treatment session for the intervention group is 60 minutes. 5 minutes of warm-up, 25 minutes of common balance exercises, 25 minutes of relevant balance exercises (Proactive) and 5 minutes of cooling down.

#### Category

Rehabilitation

### 3

#### Description

Control group: Conventional exercises. 5 minutes of warm up, 25 minutes of common balance exercises and 5 minutes of cool down.

#### 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

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##### Province

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##### 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.

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**Postal code**

81746-73461

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**Email**

eghasemi@rehab.mui.ac.ir

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

Esfahan University of Medical Sciences

**Full name of responsible person**

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**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

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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**

assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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**Email**

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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**

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**