

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 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

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8183983434

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kashani@mui.ac.ir

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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.

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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

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

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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

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Other areas of specialty/work

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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

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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