

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jun 2026

The effect of dynamic neuromuscular stabilization exercises in comparison to core stability exercises on balance, falling and spasticity in people with multiple sclerosis: a double blind randomized control trial

Protocol summary

Study aim

To determine the effect of dynamic neuromuscular stabilization exercises in comparison to core stability exercises on balance, falling and spasticity in people with multiple sclerosis

Design

This study is 2-armed, double-blind RCT compared dynamic neuromuscular stabilization exercise, to core stability exercises in some ambulant individuals with multiple sclerosis. this randomized clinical trial with one to one allocation in two groups (group 1: dynamic neuromuscular stabilization exercise, group 2: core stability exercise). Where the person evaluating the outcome measures is completely blind to the type of exercise each group received. In the case of patients, it is also expected that there will be no difference between the two groups in terms of exercise positions, and duration treatment sessions.

Settings and conduct

The intervention is performed in the patient's house because of COVID-19 pandemic. In this study, both the participants and the assessor are blind.

Participants/Inclusion and exclusion criteria

Participants are included if they have age range between 30 and 50 , Medium disability score between 2 and 5 based on the "Expanded Disability Status Scale", Obtaining a minimum score of 21 from the Mini Mental Scale Examination, Willingness to participate in the study and sign the consent, having at least middle high school graduation to fill out self-declaration questionnaires

Intervention groups

participants in intervention group, will receive "Dynamic neuromuscular stabilization exercise" and in control group, they will receive "core stability exercise" 5 weeks, three sessions per week.

Main outcome variables

The main outcomes are "trunk function" and "balance

score".

General information

Reason for update

Researchers post pilot study realized that the range of disability that is measured by the EDSS should be more limited. Additionally, the interventions are performed in patient's house due to COVID-19 pandemic.

Acronym

IRCT registration information

IRCT registration number: **IRCT20140222016680N5**
Registration date: **2020-04-07, 1399/01/19**
Registration timing: **prospective**

Last update: **2021-11-18, 1400/08/27**

Update count: **3**

Registration date

2020-04-07, 1399/01/19

Registrant information

Name

Shohreh Noorizadeh Dehkordi

Name of organization / entity

Iran University of Medical Sciences, School of Rehabilitation Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2222 7124

Email address

noorizadeh.sh@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-20, 1399/02/01

Expected recruitment end date

2021-10-10, 1400/07/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of dynamic neuromuscular stabilization exercises in comparison to core stability exercises on balance, falling and spasticity in people with multiple sclerosis: a double blind randomized control trial

Public title

The effect of spine stabilizing exercises on balance and falling in people with multiple sclerosis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Having age range between 30 and 50 years Having medium disability rates, between 2 and 5 base on the "Expanded Disability Status Scale" obtaining a minimum score of 21 base on the "Mini Mental Scale Examination" Willingness to participate in the study and sign the consent Having at least middle high school graduation to fill out self-declaration questionnaires

Exclusion criteria:

Suffering from other neurological disorders such as stroke, traumatic brain injury, Ataxia, etc Multiple sclerosis exacerbation during the last month Having apraxia (due to inability to learn and practice the exercises) Severe spasticity (score above 3 based on the "Modified Ashworth Scale") Having a history of major surgery in the lower extremities Explicit postural abnormalities in the spine and lower limbs such as scoliosis and kyphosis Having cardiovascular disease Having uncontrolled diabetes Pregnancy

Age

From **30 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Random blocks (permuted block randomization) with four blocks will be used for randomization. According to the sample size of 66, approximately 17 blocks will be generated using the online site (www.sealedenvelope.com). For concealment in the randomization process, unique code will be used on each

envelope with the type of training specified inside.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, Assessor who evaluates the outcome measures of study will be blind to the allocation of the two treatment groups. Additionally the data also will be evaluated by a person who is blind to the allocation and treatment of groups.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethic committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Hemmat Expressway, Tehran, Iran

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Postal code

۱۴۳۹۶۱۴۵۳۵

Approval date

2020-03-15, 1398/12/25

Ethics committee reference number

IR.IUMS.REC.1398.1358

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**

The Balance score in "Berg Balance Scale"

Timepoint

A day before first treatment session, a day after 15th session (last session) and 3 months after the last session.

Method of measurement

"Berg Balance Scale "

Secondary outcomes

1

Description

The number of falls by asking the patients or their care givers

Timepoint

A day before first treatment session, a day after 15th session (last session) and 3 months after the last session.

Method of measurement

by asking patients: "During last 6 months, how many times have you fallen?"

2

Description

Fear of falling by "Activities-specific Balance Confidence"

Timepoint

A day before first treatment session, a day after 15th session (last session) and 3 months after the last session.

Method of measurement

"Activities-specific Balance Confidence"

3

Description

Patient mobility by the "Multiple Sclerosis Walking Scale-12" and the "Timed Up and Go Test".

Timepoint

A day before first treatment session, a day after 15th session (last session) and 3 months after the last session.

Method of measurement

"Timed Up and Go" and "Multiple Sclerosis Walking Scale-12" and

4

Description

Spasticity score by "Multiple Sclerosis Spasticity Scale-88" and "Modified Ashworth Scale".

Timepoint

A day before first treatment session, a day after 15th session (last session) and 3 months after the last session.

Method of measurement

"Multiple Sclerosis Spasticity Scale-88" and "Modified Ashworth Scale"

5

Description

"sway in the "Biodex balance system"

Timepoint

A day before first treatment session, a day after 15th session (last session) and 3 months after the last session.

Method of measurement

sway in the "Biodex balance system"

6

Description

Trunk function in "Trunk Impairment Scale"

Timepoint

A day before first treatment session, a day after 15th session (last session) and 3 months after the last session.

Method of measurement

"Trunk Impairment Scale"

Intervention groups

1

Description

Intervention group: In this group, Dynamic Neuromuscular Stabilization exercises, will be given in a period of 5 weeks, three sessions per week. During fifteen sessions, progressively 21 exercises are given with focus on improving trunk control in supine, prone, sitting, quadruped and standing positions. Each treatment session, depending on the patient needs to rest, lasts between 60 and 75 minutes. Required equipment are mats, gymnastics ball, chair.

Category

Rehabilitation

2

Description

Control group: Core Stability exercises a period of 5 weeks, will be given in a period of 5 weeks, three sessions per week. During fifteen sessions, progressively 16 exercises are given with focus on improving trunk control in supine, prone, sitting, and standing positions. Each treatment session, depending on the patient needs to rest, lasts between 60 and 75 minutes. Required equipment are mats, gymnastics balls, chair and wall bar.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Neurological physiotherapy Clinic, School of Rehabilitation Sciences, Iran University of Medical sci

Full name of responsible person

Shohreh Noorizadeh Dehkordi

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Sponsors / Funding sources

1

Sponsor

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Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Vice Cancellor for Research of Iran 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
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Full name of responsible person
Shohreh Noorizadeh Dehkordi
Position
Associate Professor
Latest degree

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available