Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
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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, approximately17 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. Aditionally 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
City
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Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
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
Name of organization / entity
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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
Iran University of Medical Sciences
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Shohreh Noorizadeh Dehkordi
Position
Associate Professor
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Other areas of specialty/work
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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