

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

The evaluation of the additive value of performing cognitive task while inducing whole body vibration on balance indices and cognition in multiple sclerosis patients

Protocol summary

Study aim

The evaluation of the additive value of performing cognitive task while inducing whole body vibration on balance indices and cognition in multiple sclerosis patients

Design

This study is a randomized controlled clinical trial with parallel, single blind, randomized block design with Block Randomization. The sample size is 20 patients in each group.

Settings and conduct

This study will be conducted in Shiraz School of Rehabilitation Sciences and the study population will be randomly divided into control (whole body vibration apparatus) and intervention (whole body vibration apparatus at the same time as performing cognitive task) groups. Assessments will be performed by a physiotherapist who is unaware of how the groups are assigned and treatment by another physiotherapist. Data analyser will also be unaware of group assignments. The sample size will be determined after a study as a pilot, considering that there is no similar study. According to the statistics consultant, 20 patients in each group will be taken as a pilot and then the final sample size will be determined

Participants/Inclusion and exclusion criteria

Patients with relapsing-remitting multiple sclerosis in the age range of 20 to 50 years who are able to ambulate at least 100 meters independently without aids or assistance included. Patients with any other musculoskeletal or neurological conditions that limit balance are excluded.

Intervention groups

Intervention group is treated by whole body vibration apparatus at the same time as performing stroop cognitive task. And control group is treated by only whole body vibration apparatus.

Main outcome variables

Static balance; Dynamic balance; Functional balance; Balance confidence; Risk of falling; Cognitive performance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200915048732N1**

Registration date: **2020-12-03, 1399/09/13**

Registration timing: **prospective**

Last update: **2020-12-03, 1399/09/13**

Update count: **0**

Registration date

2020-12-03, 1399/09/13

Registrant information

Name

Mahsa Badpa

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3627 1551

Email address

m_badpa@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-20, 1399/11/01

Expected recruitment end date

2021-07-22, 1400/04/31

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The evaluation of the additive value of performing cognitive task while inducing whole body vibration on balance indices and cognition in multiple sclerosis patients

Public title
The evaluation of the additive value of cognitive task on whole body vibration on balance and cognition in multiple sclerosis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Age range of 20-50 years A definite diagnosis of MS, Relapsing-remitting type, as diagnosed by a neurologist Patients with mild to moderate disability (EDSS = 1-5.5) who are able to stand or ambulate independently. (ambulate at least 100 meters independently without aids or assistance) Literacy Fluent and understandable speech
Exclusion criteria:
 Pregnancy A positive history of having fracture and implant in the knee and hip joints History of epilepsy Malignant tumors Corticosteroid injection 28 days before the intervention Severe osteoporosis Discopathy, Acute protrusion, Spondylolisthesis Severe diabetes Severe wounds and scarring Any musculoskeletal or neurological conditions except MS limiting balance Uncorrected auditory or visual impairment Disorders of the vestibular system at the diagnosis of a specialist Severe mental disorders that lead to impossibility of cooperation of the participant. Using drugs which affecting balance Vertigo History of attacks and relapses during the past 2 months Having experience of vibration during the last 3 months Receive physiotherapy interventions simultaneously or up to 1 month before the start of the research project

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: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants will be assigned to each group by applying Random Allocation software, in a blocking method (size of 4). Group allocation will be defined in a block of four (2 participants in each group) and continue to put all 40

participants into two groups of Intervention and control.

Blinding (investigator's opinion)
Single blinded

Blinding description
Data analyser and the physiotherapist who will measure the outcome measures, will be blinded to the patient's allocation group.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Rehabilitation School of Shiraz University of Medical Sciences, Abiverdi 1 St., Chamran Blvd.

City

Shiraz

Province

Fars

Postal code

33669-71947

Approval date

2020-05-20, 1399/02/31

Ethics committee reference number

IR.SUMS.REHAB.REC.1399.018

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

Static balance

Timepoint

Before and after intervention

Method of measurement

Biodex balance system

2

Description

Dynamic balance

Timepoint

Before and after intervention

Method of measurement

Biodex balance system

3

Description

Functional balance

Timepoint

Before and after intervention

Method of measurement

Mini Balance Evaluation Systems Test (Mini- BESTest)

4

Description

Balance confidence

Timepoint

Before and after intervention

Method of measurement

Activities Specific Balance Confidence scale (ABC)

5

Description

Risk of falling

Timepoint

Before and after intervention

Method of measurement

Biodex balance system

6

Description

Cognitive performance

Timepoint

Before and after intervention

Method of measurement

Montreal Cognitive Assessment Test (MOCA), Symbol Digit Modalities Test (SDMT)

Secondary outcomes

1

Description

Quality of life

Timepoint

Before and after intervention

Method of measurement

Multiple Sclerosis Quality of Life-54 Questionnaire (MSQoL-54)

Intervention groups

1

Description

Intervention group: Patients are treated for 6 weeks, 3 sessions per week, 5 set per session by whole body vibration apparatus at the same time as performing Stroop cognitive task. In this task, congruent and incongruent colored words will be shown to the patients randomly in each trial. In the congruent condition the word and its color are the same and in the incongruent condition the word and its color will be different. For example, the word "blue" will be displayed in a different color; for example, with yellow color letters. Vibration rate in the first 2 weeks 5 set of 30 seconds with 1 minute break between sets, in the second 2 weeks 5 set of 45 seconds with 1 minute break between sets and in the third 2 weeks 5 set of 1 minute with 1 minute break is between sets.

Category

Rehabilitation

2

Description

Control group: This group is treated by only whole body vibration apparatus. Vibration rate is as the same as intervention group.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Rehabilitation Clinic of Shiraz School of Rehabilitation Sciences

Full name of responsible person

Dr. Mohsen Razeghi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Abbas Rezaianzadeh

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Mahsa Badpa

Position

MSc Student of Physical Therapy

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

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Dr. Mohsen Razeghi

Position

Professor

Latest degree

Ph.D.

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