

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

The effect of vestibular rehabilitation program on the balance performance of people with multiple sclerosis

Protocol summary

Study aim

The effect of vestibular rehabilitation program on the balance performance of people with multiple sclerosis

Design

Clinical trials with control group, with parallel groups, one blind, randomized MS patients who have entered the study are divided into 3 groups using a randomized six-point blocking; receiving vestibular rehabilitation therapy (group A), receiving galvanic vestibular stimulation (group B) and without receiving any vestibular rehabilitation (group C). The sample size was 21 people. According to the probability of falling, 3 groups of 8 people were selected.

Settings and conduct

select individuals to enter the study Pre-interventional studies in all subjects Provide rehabilitation intervention for 6 weeks, 2 sessions per week and 30 minutes each session Post-interventional studies at the end of week 1 to 6 (6 times) in the subjects of the three study groups

Participants/Inclusion and exclusion criteria

Inclusion criteria: Definitive diagnosis of recurrent recurrent MS (RRMS) Individual complaint of dizziness or imbalance Ability to stand without assistance for at least 1 minute Exit criteria: Changing the patient's condition Absence of abnormalities in any of the vestibular function tests

Intervention groups

Group one; vestibular rehabilitation therapy Group two; galvanic vestibular rehabilitation Group three; with no rehabilitation

Main outcome variables

composite score Dizziness handicap inventory score Activities-Specific Balance Confidence Scale score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190222042799N1**

Registration date: **2019-03-05, 1397/12/14**

Registration timing: **prospective**

Last update: **2019-03-05, 1397/12/14**

Update count: **0**

Registration date

2019-03-05, 1397/12/14

Registrant information

Name

Akram Farahani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7719 2366

Email address

ak.farahani@uswr.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-11, 1397/12/20

Expected recruitment end date

2020-03-10, 1398/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of vestibular rehabilitation program on the balance performance of people with multiple sclerosis

Public title

The effect of vestibular rehabilitation in multiple sclerosis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

with Multiple sclerosis Complaint with dizziness or imbalance Ability to stand for at least one minute

Exclusion criteria:

Changing the patient's condition (MS recurrence stage)
Absence of abnormalities in any of the vestibular function tests

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Investigator
- Outcome assessor

Sample size

Target sample size: 24

Randomization (investigator's opinion)

Randomized

Randomization description

Six random blocking

Blinding (investigator's opinion)

Single blinded

Blinding description

The researcher who performs rehabilitation is unaware of the results of rehabilitation until the completion of the study. An outcome evaluator evaluating post-rehabilitation outcomes is unaware of the type of rehabilitation received for the subjects being studied.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of university of social welfare and rehabilitation sciences

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kodakyar Ave., daneshjo Blvd.,Evin

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Postal code

۱۹۸۵۷۱۳۸۳۴

Approval date

2018-05-29, 1397/03/08

Ethics committee reference number

IR.USWR .REC.1397.004

Health conditions studied**1****Description of health condition studied**

Vestibular disorders

ICD-10 code

H81

ICD-10 code description

Disorders of vestibular function

2**Description of health condition studied**

multiple sclerosis

ICD-10 code

G35

ICD-10 code description

Multiple sclerosis

Primary outcomes**1****Description**

composite score in posturography test

Timepoint

At the beginning of the study (before the intervention), weeks 1 to 6 after intervention, and one month After the end of the intervention

Method of measurement

by means of recording device of posturography

2**Description**

dizziness handicap inventory score

Timepoint

At the beginning of the study (before the intervention), weeks 1 to 6 after intervention, and one month After the end of the intervention

Method of measurement

by means of questionnaire completion

3**Description**

Activities-Specific Balance Confidence Scale score

Timepoint

At the beginning of the study (before the intervention), weeks 1 to 6 after intervention, and one month After the end of the intervention

Method of measurement

by means of questionnaire completion

Secondary outcomes

1

Description

Timepoint

Method of measurement

Intervention groups

1

Description

Intervention group: The first intervention group receive vestibular rehabilitation therapy (VRT), the second intervention group receive galvanic vestibular stimulation (GVS).

Category

Rehabilitation

2

Description

Control group: Do not receive any intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Multiple sclerosis society, Rofeydeh hospital

Full name of responsible person

Ali Najafi (Multiple sclerosis society), Azam Moeini (Rofeydeh hospital)

Street address

Multiple sclerosis society: No. 135, Shams Ave., Crossroad Taleghani., Vesal Ave., Enghelab Ave.
Rofeydeh hospital: Nemati Ave., Soleymani Ave., Qheydariyeh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

Mohammadreza Khodaei

Street address

kodakyar Ave., daneshjo Blvd., Evin

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1985713834

Phone

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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

University of social welfare and rehabilitation 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

University of social welfare and rehabilitation sciences

Full name of responsible person

Akram Farahani

Position

student

Latest degree

Master

Other areas of specialty/work

Audiology

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Person responsible for updating data**Contact****Name of organization / entity**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

This study is a PhD thesis and is published in the form of a dissertation.

When the data will become available and for how long

6 months after printing results

To whom data/document is available

Individuals or organizations that are somehow associated with this group of patients.

Under which criteria data/document could be used

Use to help patients recover

From where data/document is obtainable

Person responsible for studying (Akram Farahani)

What processes are involved for a request to access data/document

Formal written request from the relevant organization, consent of Person responsible for studying

Comments