

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 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

##### Street address

kodakyar Ave., daneshjo Blvd.,Evin

##### City

Tehran

##### Province

Tehran

##### 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

#### City

Tehran

#### Province

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#### Postal code

انجمن مالتیپل اسکلرو

#### Phone

+98 21 6695 1187

#### Fax

#### Email

rofeideh.hospital@uswr.ac.ir

## 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

#### City

Tehran

#### Province

Tehran

#### Postal code

1985713834

#### Phone

+98 21 2218 0140

#### Email

Kh.ardakani@uswr.ac.ir

### 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

#### Street address

Nazari Ave., Shohada St., Hengam St., Resalat Sq

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#### Phone

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## Person responsible for scientific inquiries

### Contact

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University of social welfare and rehabilitation sciences

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

University of social welfare and rehabilitation sciences

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**Other areas of specialty/work**

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**Email**

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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**