

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Feb 2026

### The effects of postural training with cerebellar a-tDCS on balance, static and dynamic postural stability and fear of falling in patients with Multiple Sclerosis

#### Protocol summary

##### Study aim

The effects of postural training with cerebellar a-tDCS on balance, static and dynamic postural stability and fear of falling in patients with Multiple Sclerosis

##### Design

Clinical trials with control group, with parallel groups, Blind two-sided, randomized, without control with placebo, single center trial.

##### Settings and conduct

Neuromuscular Rehabilitation Research Center. Participants are divided into 3 groups. Individuals receive postural training on the biodex balance machine during two weeks and each week during 3 therapeutic sessions (20 minutes).

##### Participants/Inclusion and exclusion criteria

People with MS. Inclusion criteria: 18-40 years; Expanded Disability Status Scale (EDSS) < 4. Exclusion criteria: Severe visual field defect; Severe weakness in limb movement; Other neurological disorders and neurological.

##### Intervention groups

Intervention group 1: According to the protocol, postural exercises are performed on the biodex machine with tDCS of the cerebellum. Intervention group 2: According to the protocol, they perform postural exercises on the biodex machine with unrealistic cerebellar tDCS. Control group: People will only receive postural exercises without receiving any electrical stimulation.

##### Main outcome variables

Fear Of Falling.

#### General information

##### Reason for update

According to the registration of the clinical trial on 2019/08/10, sampling started on 2019/08/23.

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20151228025732N43**

Registration date: **2019-08-10, 1398/05/19**

Registration timing: **prospective**

Last update: **2021-05-11, 1400/02/21**

Update count: **1**

##### Registration date

2019-08-10, 1398/05/19

##### Registrant information

###### Name

Alireza Emadi

###### Name of organization / entity

Semnan University of Medical Sciences, Semnan, Iran

###### Country

Iran (Islamic Republic of)

###### Phone

+98 23 3345 1336

###### Email address

are20935@semums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-08-23, 1398/06/01

##### Expected recruitment end date

2020-01-15, 1398/10/25

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effects of postural training with cerebellar a-tDCS on balance, static and dynamic postural stability and fear of

falling in patients with Multiple Sclerosis

## Public title

The effects of postural training with cerebellar a-tDCS on balance, static and dynamic postural stability and fear of falling in patients with Multiple Sclerosis

## Purpose

Prevention

## Inclusion/Exclusion criteria

### Inclusion criteria:

18-40 years Expanded Disability Status Scale (EDSS) < 4

### Exclusion criteria:

Severe visual field defect Severe weakness in limb movement Other neurologic disorders and neurological

## Age

From **18 years** old to **40 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Participant
- Outcome assessor

## Sample size

Target sample size: **66**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Block randomization; Individual; Random Number Tables. Randomized permutation blocks (block 3). Using Excel software to generate random number tables.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

Study participants and evaluators are unaware of the allocation of study groups.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Semnan University of Medical Sciences

##### Street address

Semnan University of Medical Sciences, Basij Blvd, Semnan

##### City

Semnan

##### Province

Semnan

## Postal code

3514799442

## Approval date

2019-01-15, 1397/10/25

## Ethics committee reference number

IR.SEMUMS.REC.1397.233

## 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

Fear Of Falling

#### Timepoint

Before, after and one month after intervention

#### Method of measurement

Falls Self-Efficacy Scale (FES-I) Questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group 1: According to the protocol, postural exercises are performed on the biodex machine with tDCS of the cerebellum.

#### Category

Diagnosis

### 2

#### Description

Intervention group 2: According to the protocol, they perform postural exercises on the biodex machine with unrealistic cerebellar tDCS.

#### Category

Diagnosis

### 3

#### Description

Control group: People will only receive postural exercises without receiving any electrical stimulation.

#### Category

Diagnosis

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Neuromuscular Rehabilitation Research Center

**Full name of responsible person**

Fatemeh Ehsani

**Street address**

Neuromuscular Rehabilitation Research Center, Qods Blvd, Mashahir Aven.

**City**

Semnan

**Province**

Semnan

**Postal code**

3513138111

**Phone**

+98 23 3365 4180

**Email**

fatemehehsani59@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Semnan University of Medical Sciences

**Full name of responsible person**

Parviz Kokhaei

**Street address**

Semnan University of Medical Sciences, Basij Blvd, Semnan.

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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**

Semnan 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**

Semnan University of Medical Sciences

**Full name of responsible person**

Fatemeh Ehsani

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

**Street address**

Neuromuscular Rehabilitation Research Center, Qods Blvd, Mashahir Aven.

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## Person responsible for scientific inquiries

#### Contact

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**Latest degree**

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**Other areas of specialty/work**

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## Person responsible for updating data

#### Contact

**Name of organization / entity**

Semnan University of Medical Sciences

**Full name of responsible person**

Morteza Ahmadi

**Position**

Student

**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

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

Yes - There is a plan to make this available

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available

**Title and more details about the data/document**

-

**When the data will become available and for how long**

-

**To whom data/document is available**

Only available to scholars working in academic institutions.

**Under which criteria data/document could be used**

In case of relevant studies.

**From where data/document is obtainable**

Fatemeh Ehsani Neuromuscular Rehabilitation Research Center, Ghods Blvd. +98 9191310755

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

-

**Comments**