# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

21 Oct 2026

## The effects of postural trainingwith 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 trainingwith 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 neurologic 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)

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+98 23 3345 1336

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**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 trainingwith 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 trainingwith 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.

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Semnan

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## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**
Semnan University of Medical Sciences

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Parviz Kokhaei

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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

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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**