# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

01 Jul 2026

## Effectiveness of transcranial direct current stimulation with virtual reality training for balance and fear of falling in people with multiple sclerosis, a randomized control trial

## Protocol summary

**Study aim**

Determining the effectiveness of tDCS stimulation with virtual reality on the postural stability of people with multiple sclerosis.

**Design**

This clinical trial has three intervention groups, sham and control, with parallel, single-blind, and randomized groups, on 36 patients. In this study, simple random method is used

**Settings and conduct**

This study will be conducted at Semnan Neuromuscular Rehabilitation Research Center. In this study, the evaluator does not know the allocation of groups All three groups receive virtual reality training along with tDCS. In one group, tDCS is on and in another group, tDCS is off, and one group receives only virtual reality interventions. The intervention will be implemented for two weeks and 5 days a week

**Participants/Inclusion and exclusion criteria**

Inclusion criteria: 18-60-year-old people with multiple sclerosis who have mild to moderate disability and have a cognitive score higher than 21 in the MMSE test and have no history of falling in the past month. Exclusion criteria: If the participants do not have neurological and orthopedic disorders that affect the performance of the tests and do not have a history of using corticosteroids up to 28 days before the evaluation, based on the medical records and the patient's statements. Also, he does not have any mental problems, attacks or relapses during the last 2 months.

**Intervention groups**

1- Virtual Reality (VR) exercises with active tDCS on the cerebellum area 2- VR intervention along with tDCS sham on the cerebellum 3- VR intervention

**Main outcome variables**

Balance performance; Fear of falling

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20150411021686N4**
Registration date: **2023-12-01, 1402/09/10**
Registration timing: **prospective**

Last update: **2023-12-01, 1402/09/10**
Update count: **0**

**Registration date**

2023-12-01, 1402/09/10

**Registrant information**

**Name**

Zahra Ahmadizadeh

**Name of organization / entity**

Semnan University of Medical Sciences

**Country**

Iran (Islamic Republic of)

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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2024-01-21, 1402/11/01

**Expected recruitment end date**

2026-02-20, 1404/12/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**
Effectiveness of transcranial direct current stimulation with virtual reality training for balance and fear of falling in people with multiple sclerosis, a randomized control trial

**Public title**
The effect of electrical stimulation of the brain with virtual reality on people with multiple sclerosis

**Purpose**
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Having MS as diagnosed by a neurologist No history of falling in the last month according to the reference or family report No addiction according to the client's, family or doctor's report Not having obvious orthopedic, rheumatology, or internal problems that the person complains about (such as back pain, hallux valgus, flat feet, foot ulcers) according to the client's report, the family or the client's doctor, if you cause problems in the implementation of the tests People with mild to moderate disability EDSS=1-5 Age range 18-60 years having cognitive impairment (getting a score higher than 21 in the MMSE test)

**Exclusion criteria:**
Corticosteroid use up to 28 days before evaluation based on medical records and patient statements Having mental problems (according to the patient's file) Having a history of attacks and relapses in the last 2 months (according to the patient's file) Having a history of other neurological diseases (according to the patient's file)

**Age**
From **18 years** old to **60 years** old

**Gender**
Both

**Phase**
N/A

**Groups that have been masked**

- Outcome assessor

**Sample size**
Target sample size: **36**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
In the first stage, patients who meet the inclusion criteria are included in the study. Therefore, our sampling method is convenience sampling at this stage of the method. The randomization method in this research is a web-based block randomization, due to having three groups, blocks of 3 and 6 will be used, and the order of the blocks will be obtained using random numbers on the web, so it can be 36 The participant was randomly assigned to the study. Participants are placed in three control, sham and intervention groups based on the order of entry. The assessor will not know about the random allocation and group allocation of the participants in any of the assessment stages. The number of blocks and how they are executed is done by hiding them inside the envelope.

**Blinding (investigator's opinion)**
Single blinded

**Blinding description**
A single-blind , the assessor will be blind to group allocation

**Placebo**
Not used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Research Ethics Committees of Semnan University Of Medical Sciences and Health Services

**Street address**
5 km Damghan Road, school of Rehabilitation

**City**
Semnan

**Province**
Semnan

**Postal code**
35147-99442

**Approval date**
2023-10-30, 1402/08/08

**Ethics committee reference number**
IR.SEMUMS.REC.1402.168

## 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**
Balance

**Timepoint**
before the start of the intervention, after the tenth session of the intervention, and 6 weeks after the end of the intervention

**Method of measurement**
Biodex

**2**

**Description**
fear of falling
**Timepoint**
before the start of the intervention, after the tenth session of the intervention, and 6 weeks after the end of the intervention
**Method of measurement**
Fear of falling questionnaire

## Secondary outcomes

**1**

**Description**
Fatigue
**Timepoint**
Before the start of the intervention, after the tenth session of the intervention, and 6 weeks after the end of the intervention
**Method of measurement**
Fatigue Severity Scale questionnaire

**2**

**Description**
Activity of daily living
**Timepoint**
Before the start of the intervention, after the tenth session of the intervention, and 6 weeks after the end of the intervention
**Method of measurement**
Lawton questionnaire

**3**

**Description**
Postural control
**Timepoint**
Before the start of the intervention, after the tenth session of the intervention, and 6 weeks after the end of the intervention
**Method of measurement**
Force Plate

**4**

**Description**
Functional mobility
**Timepoint**
Before the start of the intervention, after the tenth session of the intervention, and 6 weeks after the end of the intervention
**Method of measurement**
Time Up & Go test

## Intervention groups

**1**

**Description**
Intervention group: receiving virtual reality balance exercises with bright tDCS. To use tDCS, a direct stimulation current will be used by a pair of electrodes (cathode and anode). The current is controlled by an ammeter. Stimulation electrodes are 7x5 cm in size. When using TDCS, a current of 2 mA is applied to the cerebellum for a maximum of 20 minutes. Virtual reality device Visual cues are created by a virtual reality device. A closed loop device is installed on the head. , provides the patient with a virtual tiled floor in a checkerboard arrangement, which dynamically responds to the patient's own movement, much like a real floor, fixed in space.
**Category**
Rehabilitation

**2**

**Description**
Sham control group: received virtual reality balance exercises with tDCS off. This group receives only virtual reality treatment and the silent tDCS device is used for them
**Category**
Other

**3**

**Description**
Control group: Receive only virtual reality balance exercises
**Category**
Other

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Neuromuscular Rehabilitation Research Center
**Full name of responsible person**
Zahra Ahmadizadeh
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Quds Boulevard - next to Nemat Ice Cream - Tabatabai Clinic
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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**

Semnan University of Medical Sciences

**Full name of responsible person**
Dr. Majid Mirmohammadkhani

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Basij Blvd., Central Headquarters of Semnan University of Medical Sciences

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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**
Zahra Ahmadizadeh

**Position**
Assistant Professor

**Latest degree**
Ph.D.

**Other areas of specialty/work**
Occupational Therapy

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## Person responsible for scientific inquiries

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Occupational Therapy

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## Person responsible for updating data

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**Latest degree**
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**Other areas of specialty/work**
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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**

No - There is not a plan to make this available

**Data Dictionary**

Not applicable

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

All data is potentially shareable after de-identifying individuals

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

The access period starts 6 months after the results are published

**To whom data/document is available**

The data of this study will be available only to researchers working in academic and scientific institutions

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

The data of this study will be available for meta-analysis

**From where data/document is obtainable**

Zahra Ahmadizadeh, Mashahir Square, Quds Boulevard, Neuromuscular Rehabilitation Research Center Phone: 00982333654180 Postal Code: 3513138111 ahmadizade.z@gmail.com

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

In order to request the data of this study, it is necessary to send an official written request by e-mail and clearly explain the reason for the request.

**Comments**