

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 2026

### The immediate and long-term effect of cerebellar anodal trans-cranial direct current stimulation (a-tDCS) on balance, static and dynamic postural stability in older adults with a high risk for falling

#### Protocol summary

##### Summary

The purpose of the present study was to investigate the immediate and long-term effect of cerebellar anodal trans-cranial direct current stimulation (a-tDCS) on balance and postural stability in older adults with high risk for falling. This study has clinical trial design. Participants will be randomly allocated in two groups included; Group I who received 20 minutes a-tDCS over the cerebellum region and Group II who served as placebo group (mounted TDCS electrodes over the cerebellum region without any TDCS currents for 2 minutes). The participants with 60-75 years and high risk for falling will be included. Participants who have history of neurological diseases or musculoskeletal disorders, severe perceptual and memorial problems, brain diseases, visual and auditory problems, lower extremity pathology and range of motion limitation will be excluded. All participants will be asked to stand on each static and dynamic level of Byodex Balance System (BBS) platform for 30-second, before and after receiving a-tDSC treatment. Accordingly, the anterior/posterior, medial/lateral and overall stability indices will be analyzed before and after a-tDCS treatment. In addition, before, after intervention and for one-week following, the falling sensation, stability indices and balance will be assessed by fall risk assessment tool, BBS and Berg balance scale, respectively.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016101021294N4**  
Registration date: **2017-02-10, 1395/11/22**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-02-10, 1395/11/22

##### Registrant information

###### Name

Fatemeh Ehsani

###### Name of organization / entity

Semnan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 23 3365 4180

###### Email address

f.ehsani@semums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice Chancellor for research of Semnan University of Medical Sciences

##### Expected recruitment start date

2016-12-31, 1395/10/11

##### Expected recruitment end date

2017-05-31, 1396/03/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The immediate and long-term effect of cerebellar anodal trans-cranial direct current stimulation (a-tDCS) on balance, static and dynamic postural stability in older adults with a high risk for falling

##### Public title

The immediate and long-term effect of cerebellar anodal trans-cranial direct current stimulation (a-tDCS) on balance, static and dynamic postural stability in older adults with a high risk for falling

#### **Purpose**

Treatment

#### **Inclusion/Exclusion criteria**

Inclusion criteria: Participants who have 60-75 years old and older adults who are prone to falling based on fall risk assessment tool or having falling history during 6 last month will be concluded. Exclusion criteria: Adults were no high risk for falling; Adults with severe perceptual and memory problems evidenced by Mini Mental Status Examination (MMSE) scores of less than 21; having neurological disease, especially Parkinson and Alzheimer's; having visual or auditory problems; having lower extremity pathology and range of motion limitations will be excluded from the study.

#### **Age**

From **60 years** old to **80 years** old

#### **Gender**

Both

#### **Phase**

N/A

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **30**

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

Randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Double blinded

#### **Blinding description**

#### **Placebo**

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 science

###### **Street address**

5 kilometer in Damghan Road, Semnan, Iran

###### **City**

Semnan

###### **Postal code**

##### **Approval date**

2016-08-10, 1395/05/20

##### **Ethics committee reference number**

IR.Semums.REC.1395.159

### **Health conditions studied**

#### **1**

##### **Description of health condition studied**

Immediate and long-term effect of cerebellar anodal trans-cranial direct current stimulation on balance and psotural stability older adults with high risk for falling

##### **ICD-10 code**

##### **ICD-10 code description**

### **Primary outcomes**

#### **1**

##### **Description**

Static stability indices

##### **Timepoint**

Before receiving TDCS intervention, immediate and one-week after interventionafter

##### **Method of measurement**

Byodex Balance System

### **Secondary outcomes**

#### **1**

##### **Description**

Dynamic postural indices

##### **Timepoint**

Before and after receiving TDCS, after one-week receiving TDCS

##### **Method of measurement**

Byodex Balance System

#### **2**

##### **Description**

Falling sensation

##### **Timepoint**

Before and after receiving TDCS, after one-week receiving TDCS

##### **Method of measurement**

Fall risk assessment tool

#### **3**

##### **Description**

Balance

##### **Timepoint**

Before and after receiving TDCS, after one-week receiving TDCS

##### **Method of measurement**

Berg balance scale

### **Intervention groups**

#### **1**

##### **Description**

Intervention group: Before and after receiving TDCS intervention, the participants will be asked to stand on

static and dynamic levels of Byodex Balance System for 30-second. In TDCS intervention, anodal and cathodal electrodes will be positioned on cerebellum and ipsi-lateral deltoid muscle, respectively. Stimulation will be used with 2 Mili Ampere intensity for 20-minute.

**Category**

Rehabilitation

**2**

**Description**

Control group: Before and after receiving sham-TDCS intervention, the participants will be asked to stand on static and dynamic levels of Byodex Balance System for 30-second. In sham-TDCS intervention, anodal and cathodal electrodes will be positioned on cerebellum and ipsi-lateral deltoid muscle, respectively. Stimulation will be used with 2 Mili Ampere intensity for 2-minute.

**Category**

Placebo

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Neuromuscular Rehabilitation Research Center

**Full name of responsible person**

Fatemeh Ehsani

**Street address**

Blvd. Ghods, Mashahir Square, Semnan

**City**

Semnan

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Vice Chancellor for research of Semnan University of Medical Sciences

**Full name of responsible person**

Ali Rashidipoor

**Street address**

Vice Chancellor for research of Semnan University of Medical Sciences, Blvd. Basig

**City**

Semnan

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice Chancellor for research of Semnan University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

empty

**Domestic or foreign origin**

empty

**Category of foreign source of funding**

empty

**Country of origin**

**Type of organization providing the funding**

empty

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Neuromuscular Rehabilitation Research Center

**Full name of responsible person**

Fatemeh Ehsani

**Position**

Assistant Professor

**Other areas of specialty/work**

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**Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*