

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of postural training with 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 effect of postural training with 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. Using sequences of random numbers method, participants were randomly divided into two groups. Group I receive 20 minutes a-tDCS over the cerebellum region during two-week postural training and Group II receive two-week postural training with sham tDCS (mounted TDCS electrodes over the cerebellum region without any TDCS currents for 2 minutes). Postural training will be performed on Byodex Balance System (BBS) for 20 minutes following 3 sessions in each week for two-week. The participants with 60-80 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 BBS platform for 30 seconds, 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 and after interventions, the falling sensation, stability indices and balance will be assessed by fall risk assessment tool, BBS and Berg balance scale, respectively. Both participants in each group and assessors were blinded to the experimental conditions and interventions (active or sham a-tDCS). Accordingly, the study will be double blind.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017022521294N5**  
Registration date: **2017-05-01, 1396/02/11**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-05-01, 1396/02/11

##### 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

2017-04-01, 1396/01/12

##### Expected recruitment end date

2017-09-01, 1396/06/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

## Trial completion date

empty

## Scientific title

The effect of postural training with 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 effect of postural training with 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 60-80 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

2017-03-20, 1395/12/30

## Ethics committee reference number

226 IR.SEMUMS.REC.1395

## Health conditions studied

### 1

#### Description of health condition studied

The effect of Postural training with 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 and dynamic stability indices

#### Timepoint

Before and after receiving after intervention

#### Method of measurement

Byodex Balance System

## Secondary outcomes

### 1

#### Description

Balance

#### Timepoint

Before and after receiving intervention

#### Method of measurement

Berg balance scale

### 2

#### Description

Falling sensation

#### Timepoint

Before and after receiving intervention

#### Method of measurement

Fall risk assessment tool

## Intervention groups

### 1

#### Description

Intervention group: Before and after two-week postural training with a-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. Postural training with tDCS intervention will be performed for 3 sessions in each week for two-week.

**Category**

Rehabilitation

**2****Description**

Control group: Before and after postural training with 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. Postural training will be performed for 20 minutes and 3 sessions in each week for two-week.

**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, Semnan Semnan

**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

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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*