Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)

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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

Assisstant Professor

Other areas of specialty/work

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Person responsible for scientific inquiries

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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