

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

Comparison the effect of unihemispheric concurrent dual-Site transcranial direct Current stimulation of primary motor and dorsolateral prefrontal cortices with stimulation of primary motor cortex on postural control of older adult with and without cognitive task

Protocol summary

Study aim

Comparison the effect of concurrent dual-Site of cortex with stimulation of M1 and sham method on postural control and balance of older adult with and without cognitive task

Design

Cross over randomized control trial with single blind on 27 healthy elderly participants. randomization with randomized envelopes.

Settings and conduct

In light of increase in elderly population and decrease of balance in this population due to decrease of cognitive-motor function the risk of falling increase for them. This study will be conducted in biomechanics laboratory of rehabilitation faculty of shahid beheshty medical university. All of participants will receive 3 intervention sessions that containing one session of sham stimulation , one session of M1-DLPFC stimulation and one session of M1 stimulation. Participants will be unaware of intervention they receive.

Participants/Inclusion and exclusion criteria

Healthy participants with 65 to 74 age range without hospital stay at recent 6 month or serious musculoskeletal or neurologic diseases or surgery history.

Intervention groups

This cross over study will be conducted three sessions that all participants will receive sham, M1 and M1-dorsolateral prefrontal cortex(DLPFC) stimulation with random order.

Main outcome variables

Displacement and velocity of center of pressure in(antero posterior ,mediolateral) and total distance and velocity of center of pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220216054035N1**

Registration date: **2022-09-24, 1401/07/02**

Registration timing: **prospective**

Last update: **2022-09-24, 1401/07/02**

Update count: **0**

Registration date

2022-09-24, 1401/07/02

Registrant information

Name

Monire Alem

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 17 3327 5887

Email address

monireaalem@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-12, 1401/07/20

Expected recruitment end date

2023-01-20, 1401/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of unihemispheric concurrent dual-Site transcranial direct Current stimulation of primary motor and dorsolateral prefrontal cortices with stimulation of primary motor cortex on postural control of older adult with and without cognitive task

Public title

Comparison the effect of unihemispheric concurrent dual-Site transcranial direct Current stimulation of primary motor and dorsolateral prefrontal cortices with stimulation of primary motor cortex on postural control of older adult with and without cognitive task

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Healthy elderly with age between 65-74 years old Ability to stand without assistive device Right handed (according to edinburgh Handeness,old field 1917) Educated enough because our study contain cognitive components

Exclusion criteria:

Any cardiovascular , neurological (like Parkinson, Alzheimer) , musculoskeletal diseases, surgery history , brain tumor, peripheral neuropathy, any visual or auditory defects that isn't managed, vertigo, any vestibular problems, any metal implant in brain Hospital stay in recent 6 month Using any drug that effect central nervous system Inability to stand or walk without help Any condition that cause abnormality in physical activity

Age

From **65 years** old to **74 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **27**

Randomization (investigator's opinion)

Randomized

Randomization description

Assessment of static balance is simple randomization. First chose from two sealed envelopes that decide their standing that will be with or without cognitive activity then intervention is on simple randomization thus choosing their intervention method than chose from three envelopes that contain one of three interventions include sham, primary motor cortex (M1) stimulation and, M1-dorsolateral prefrontal cortex (DLPFC) stimulation.After intervention assessment of static balance is simple randomization.

Blinding (investigator's opinion)

Single blinded

Blinding description

We will explain about intervention to participants but they will not aware what type of intervention they will

receive in each session.

Placebo

Used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of shahid beheshti university of medical university

Street address

7th Floor, Bldg No.2 SBUM, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran

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1985717443

Approval date

2021-11-07, 1400/08/16

Ethics committee reference number

IR.SBMU.RETECH.REC.1400.498

Health conditions studied

1

Description of health condition studied

Elderly stability

ICD-10 code

R54

ICD-10 code description

Age-related physical debility

Primary outcomes

1

Description

Anteroposterior displacement of center of pressure in stance without cognitive task

Timepoint

Every session before and after intervention

Method of measurement

Force plate

2

Description

Mediolateral displacement of center of pressure in stance without cognitive task

Timepoint

Every session before and after intervention

Method of measurement

Force plate

3

Description

Total displacement of center of pressure in stance without cognitive task

Timepoint

Every session before and after intervention

Method of measurement

Force plate

4

Description

Total velocity of displacement of center of pressure in stance without cognitive task

Timepoint

Every session before and after intervention

Method of measurement

Force plate

5

Description

Mediolateral velocity of displacement of center of pressure in stance without cognitive task

Timepoint

Every session before and after intervention

Method of measurement

Force plate

6

Description

Anteroposterior velocity of displacement of center of pressure in stance without cognitive task

Timepoint

Every session before and after intervention

Method of measurement

Force plate

7

Description

Anteroposterior velocity of displacement of center of pressure in stance with cognitive task

Timepoint

Every session before and after intervention

Method of measurement

Force plate

8

Description

Mediolateral velocity of displacement of center of pressure in stance with cognitive task

Timepoint

Every session before and after intervention

Method of measurement

Force plate

9

Description

Total velocity of displacement of center of pressure in stance with cognitive task

Timepoint

Every session before and after intervention

Method of measurement

Force plate

10

Description

Total displacement of center of pressure in stance with cognitive task

Timepoint

Every session before and after intervention

Method of measurement

Force plate

11

Description

Mediolateral displacement of center of pressure in stance with cognitive task

Timepoint

Every session before and after intervention

Method of measurement

Force plate

12

Description

Anteroposterior displacement of center of pressure in stance with cognitive task

Timepoint

Every session before and after intervention

Method of measurement

Force plate

Secondary outcomes

empty

Intervention groups

1

Description

Control group: electrode will be like M1 stimulation but device would be off after 60 seconds. 60 second is a reliable stimulation for sham due to the fact that transcranial direct current stimulation(tDCS) effect will be forgotten after one minute.

Category

Placebo

2

Description

Intervention group: M1 stimulation , using one tDCS device anode electrode would be placed at M1 and cathode would be placed at supraorbital region.

Category

Rehabilitation

3**Description**

Intervention group: concurrent dual-Site of M1-DLPFC, 2 tDCS devices will be used. in left hemisphere anode electrode of one device would be placed at M1 and on the other side anode electrode would be placed at DLPFC and cathode electrode for both devices would be placed at opposite side supraorbital region.

Category

Rehabilitation

Recruitment centers**1****Recruitment center****Name of recruitment center**

Rehabilitation Faculty of SBMU

Full name of responsible person

Monire alem

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Rehab Faculty, Damavan Str, Immam Hossein Square

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Web page address<http://rehab.sbm.ac.ir>**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Sedigheh Naimi

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Web page address<http://rehab.sbm.ac.ir>**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mino KhalkhaliZavieh

Position

دانشیار فیزیوتراپی

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

Damavand street, across from Buali hospital, Tehran, Iran. SBMU School of Rehabilitation Sciences.

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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Position

Associate Professor of Physiotherapy

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Minoo KhalkhaliZavieh

Position

Associate Professor of Physiotherapy

Latest degree

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Other areas of specialty/work

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Email

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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All of this study data could be shared after making it
unrecognizable.

When the data will become available and for how long

Data would be shared one month after publication.

To whom data/document is available

This data only assessable for academic researchers.

Under which criteria data/document could be used

There is no specific qualification for using this study data.

From where data/document is obtainable

To receive this study data please contact Dr.Minoo
KhalkhaliZavieh. phone:+98 21 2057 7754
email:minoo_kh@yahoo.comaddress: Damavand street,
across from Buali hospital, Tehran, Iran. SBMU School of
Rehabilitation Sciences.

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

Only a request letter would be enough for receiving data.

Comments