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

City
Tehran

Province
Tehran

Postal code
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
Street address
Rehab Faculty, Damavan Str, Immam Hossein Square
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http://rehab.sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Sedigheh Naimi
Street address
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Phone
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Email
tavan2020@yahoo.com
Web page address
http://rehab.sbmu.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
Minoo KhalkhaliZavieh
Position
دانشیار فیزیوتراپی
Latest degree
Ph.D.
Other areas of specialty/work
Physiotherapy
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Damavand street, across from Buali hospital, Tehran, Iran. SBMU School of Rehabilitation Sciences.
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Person responsible for updating data

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Position
Associate Professor of Physiotherapy

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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
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