Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effectiveness of transcranial direct current stimulation (tDCS) on attention and balance in patients with stroke patients under dual-task conditions

Protocol summary

Study aim

to investigate the effects of different transcranial direct current stimulation (tDCS) conditions, including stimulation over Dorsal Lateral PreFrontal Cortex (DLPFC), Primary motor cortex (M1), simultaneous DLPFC–M1, and sham stimulation, on attention and balance in stroke patients under dual-task conditions.

Design

This is a randomized, double-blind, crossover clinical trial with four stimulation conditions and a total sample of 32 patients with chronic stroke. Randomization will be performed using a counterbalanced design.

Settings and conduct

tDCS will be delivered using the Neurostim2 device (Medina Teb, Iran) with a current intensity of 2 mA for 20 minutes. The electrode montage will be identical across all conditions to maintain participant blinding. The study will be conducted at the School of Rehabilitation Sciences, Isfahan University of Medical Sciences, Musculoskeletal Research Center.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Participants with chronic stroke; independent walking ability and sufficient alertness; MMSE ≥25; informed consent; Exclusion criteria: No history of uncontrolled seizures or severe neurological/psychiatric disorders; use of drugs affecting neural excitability; metal implants or electronic devices in the head; current or past substance or alcohol abuse; severe or uncontrolled cardiac disease.

Intervention groups

Four stimulation conditions in a crossover design: (1) Active stimulation over DLPFC; (2) Active stimulation over M1; (3) Simultaneous active stimulation over DLPFC and M1; (4) Sham stimulation.

Main outcome variables

Sustained attention (assessed by the Visual Continuous Performance Test – CPT); balance under single- and dual-task conditions (assessed by the Timed Up and Go – TUG test, single and dual task).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251020067695N1**
Registration date: **2025-10-24, 1404/08/02**
Registration timing: **prospective**

Last update: **2025-10-24, 1404/08/02**
Update count: **0**

Registration date

2025-10-24, 1404/08/02

Registrant information

Name

Ali Sattari Dehkordi

Name of organization / entity

The Institute for Cognitive Science Studies (ICSS)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-11-26, 1404/09/05

Expected recruitment end date

2026-03-06, 1404/12/15

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effectiveness of transcranial direct current stimulation (tDCS) on attention and balance in patients with stroke patients under dual-task conditions

Public title
Effect of direct current brain stimulation on attention and balance in stroke patients
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosed ischemic or hemorrhagic stroke confirmed by a neurologist and at least six months post-stroke Ability to walk independently for at least 9 meters without assistance or cane Ability to press the space key using the unaffected upper limb No severe visual or auditory impairments Mini-Mental State Examination (MMSE) score of 25 or higher Stability of routine pharmacological and rehabilitation treatments during the study period (without any change in the standard care of patients) Providing informed consent personally or through family representative
Exclusion criteria:
History or presence of uncontrolled seizures or epilepsy Presence of active neurological or psychiatric disorders (e.g., Parkinson’s disease, multiple sclerosis, schizophrenia, bipolar disorder, major depression) Use of medications affecting neural excitability such as benzodiazepines or antiepileptic drugs Presence of metallic implants in the skull or electronic devices such as pacemakers Intolerance to electrical stimulation or occurrence of severe adverse effects during the first session Current or significant history of substance or alcohol abuse Severe or uncontrolled cardiac diseases Skin or skull abnormalities at electrode placement sites Absence from more than one intervention session Occurrence of balance disturbances in three or more trials (e.g., loss of balance requiring assistance or early termination for safety reasons) Recurrent stroke during the intervention period Withdrawal from participation during the study
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **32**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants are randomly assigned to one of four tDCS conditions (DLPFC, M1, DLPFC+M1, Sham) using a four-by-four Latin square design. For each participant, a random number between 1 and 8 is generated; numbers 1 and 2 correspond to Sequence 1, 3 and 4 to Sequence 2, 5 and 6 to Sequence 3, and 7 and 8 to Sequence 4. If a sequence reaches its capacity, the selection range is adjusted according to the remaining sequences. Randomization unit: individual Randomization tool: Google Randomizer Allocation concealment: The codes and sequences are managed by a person independent of the principal investigator, who sets up the tDCS device. The principal investigator remains unaware of the stimulation type until the end of data collection.
Blinding (investigator's opinion)
Double blinded
Blinding description
All participants are blinded to the type of tDCS stimulation they receive. Group allocation and session coding are performed by an independent person. The principal investigator and outcome assessors remain unaware of the stimulation type until data collection is completed, and are therefore blinded during this period. After data collection is completed and the codes are unblinded, the principal investigator has access to analyze the data. This procedure ensures a double-blind study, preventing prior knowledge of the stimulation type from affecting participants or outcome assessors.
Placebo
Used
Assignment
Crossover
Other design features
Each participant will undergo four separate sessions, with a wash-out period of 7±2 days between sessions to prevent carryover effects. The order of tDCS conditions for each participant is randomized and counterbalanced. The tDCS device appears identical in all conditions to maintain participant blinding. Outcome assessors and the principal investigator remain blinded to the stimulation type until data collection is complete, and data analysis is performed after unblinding.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Institute for cognitive science studies
Street address
Ministry of Health and Medical Education, Block A, 13th Floor, Central Headquarters, Simaye Iran Street, Between Flammak Jonoubi and Zarafshan, Qods Town
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Approval date
2025-10-19, 1404/07/27
Ethics committee reference number
IR.UT.IRICSS.REC.1404.039

Health conditions studied

1

Description of health condition studied
stroke
ICD-10 code
G46
ICD-10 code description
Vascular syndromes of brain in cerebrovascular diseases

Primary outcomes

1

Description
Sustained attention
Timepoint
Before and after each stimulation session (4 sessions per participant); the interval between sessions is 7±2 days to allow washout of previous stimulation effects
Method of measurement
Visual Continuous Performance Test (CPT) with 150 visual stimuli, including 30 target stimuli; outcome measures: number of correct responses, omission errors, commission errors, and reaction time

Secondary outcomes

1

Description
Balance in single-task condition
Timepoint
Before and after each stimulation session (4 sessions); interval between sessions is 7±2 days (washout period)
Method of measurement
Timed Up and Go (TUG) single-task test; measuring time to complete 3-meter path, number of responses, number of errors, and percentage of correct responses

2

Description
Balance in dual-task condition (walking with serial subtraction)
Timepoint
Before and after each stimulation session (4 sessions); interval between sessions is 7±2 days (washout period)
Method of measurement
TUG with serial subtraction from a randomly selected three-digit number between 400 and 500; measuring time to complete the path, number of correct responses, and only the first calculation error in each walking trial is recorded as an error. Subsequent consecutive errors arising from the same initial mistake within the same trial are not counted. Errors in a new trial or independent errors are recorded separately.

Intervention groups

1

Description
Intervention group 1: DLPFC stimulation; the anodal electrode is placed at F3 (left dorsolateral prefrontal cortex) and the cathode at AF8 (right supraorbital area). The M1 region receives sham stimulation, so only DLPFC is actually stimulated. The current intensity is 2 mA for 20 minutes, with gradual ramp-up and ramp-down over 30 seconds at the beginning and end of stimulation.
Category
Treatment - Devices

2

Description
Intervention group 2: M1 stimulation; the anodal electrode is symmetrically placed at Cz (lower limb motor area) and the cathode on the left shoulder (extracephalic). The DLPFC region receives sham stimulation, so only M1 is actually stimulated. Current intensity is 2 mA for 20 minutes, with gradual ramp-up and ramp-down over 30 seconds at the start and end.
Category
Treatment - Devices

3

Description
Intervention group 3: Simultaneous DLPFC and M1 stimulation; two anodal electrodes are placed simultaneously at F3 and Cz, and the cathodes at AF8 and left shoulder, respectively. Real stimulation is applied concurrently to both regions. The current intensity is 2 mA for 20 minutes, with gradual ramp-up and ramp-down over 30 seconds at the beginning and end.
Category
Treatment - Devices

4

Description
Control group: Sham stimulation; the montage similar to the combined stimulation is applied, but the current is gradually ramped up for 30 seconds and then ramped down. This method allows the participant to feel initial stimulation without receiving real stimulation. The appearance and number of electrodes remain the same across all sessions to maintain blinding.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
Musculoskeletal Research Center

Full name of responsible person
Dr. Ebrahim Sadeghi Damneh

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Sponsors / Funding sources

1

Sponsor

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Grant name

Grant code / Reference number

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

Title of funding source
The Institute for Cognitive Science Studies (ICSS)

Proportion provided by this source
100

Public or private sector
Private

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
The Institute for Cognitive Science Studies (ICSS)

Full name of responsible person
Ali Sattari Dehkordi

Position
Master’s Student

Latest degree
Bachelor

Other areas of specialty/work
Master’s Student in Cognitive Science – Cognitive Rehabilitation

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
Individual participant data have not yet been collected. After the completion of the study, all data will be shared following anonymization of participants. Shared data will include all primary and secondary outcomes.

When the data will become available and for how long
Access will begin six months after publication of the study results and will be available for a period of five years.

To whom data/document is available
Researchers affiliated with academic and research institutions who submit a valid research proposal will be granted access.

Under which criteria data/document could be used
Data may only be used for research and analytical purposes; commercial use or publication without proper citation is prohibited. All analyses must be conducted in accordance with the submitted research proposal.

From where data/document is obtainable
Requests should be directed to the principal investigator, Dr. Peyman Hassani Abhariyan, and also the primary researcher, Ali Sattari Dehkordi, via email [emails] or by postal mail to the Cognitive Sciences Higher Education Institute. ایمیل‌ها: abharian1972@yahoo.com alisattari2090@gmail.com research@icss.ac.ir

What processes are involved for a request to access data/document
The applicant submits a request along with a research proposal; after review and approval by the ethics committee and the principal investigator, anonymized data files will be provided. The process typically takes 6 to 8 weeks.

Comments
Any changes to the timing or conditions of data access will be communicated following agreement with the principal investigator and the ethics committee.