Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effectiveness of Anodal Transcranial Direct Current Stimulation (tDCS) over the Dorsolateral Prefrontal Cortex (DLPFC) on Executive Functions in Children with Congenital Heart Disease

Protocol summary

Study aim

The primary objective of this study is to determine the efficacy of anodal transcranial direct current stimulation (tDCS) over the left dorsolateral prefrontal cortex (F3) on executive functions (response inhibition, working memory, and cognitive flexibility) in children with congenital heart disease.

Design

This study is a randomized, sham-controlled, double-blind clinical trial involving 40 children with cyanotic congenital heart disease. Participants will be equally assigned to active and sham transcranial direct current stimulation groups. Block randomization will be used, and both participants and outcome assessors will remain blinded to the intervention. Trial phase classification is not applicable.

Settings and conduct

This double-blind, sham-controlled clinical trial at a children's medical center will investigate the effectiveness of 10 sessions of tDCS (area F3) on executive functions in 30 children with congenital heart disease. Participants will be randomly assigned to two intervention groups: real and sham, and will be assessed with cognitive tests at pretest, posttest, and 6-week follow-up. In this study, participants and assessors are unaware of the type of allocation, and sham stimulation (current cut off after 30 seconds) is used in the control group to maintain placebo conditions.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Cyanotic congenital heart disease, right-handedness, and the ability to perform cognitive tasks. Exclusion criteria: Moderate-to-severe cognitive impairment, history of seizures, genetic syndromes, or previous brain stimulation.

Intervention groups

The intervention group will receive 10 sessions of active tDCS over four weeks at 1.5 mA for 20 minutes, with the anode placed over F3 and the cathode over the right shoulder. The control group will receive sham stimulation under identical conditions; the current will be briefly increased and decreased at the beginning of each session and then discontinued.

Main outcome variables

Cognitive flexibility; working memory; sustained attention; response inhibition

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260718070240N1**
Registration date: **2026-08-17, 1405/05/26**
Registration timing: **prospective**

Last update: **2026-08-17, 1405/05/26**
Update count: **0**

Registration date

2026-08-17, 1405/05/26

Registrant information

Name

Yasaman sadat Tabatabaei

Name of organization / entity

Shahid Beheshti University Faculty of Educational science and psychology

Country

Iran (Islamic Republic of)

Phone

+98 21 8841 8743

Email address

y.tabatabaei@mail.sbu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2026-08-23, 1405/06/01
Expected recruitment end date
2026-10-22, 1405/07/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effectiveness of Anodal Transcranial Direct Current Stimulation (tDCS) over the Dorsolateral Prefrontal Cortex (DLPFC) on Executive Functions in Children with Congenital Heart Disease

Public title
Effect of Anodal Transcranial Direct Current Stimulation on Executive Functions in Children with Congenital Heart Disease
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Right-handedness Absence of moderate to severe intellectual disability or cognitive impairment, with sufficient ability to understand the instructions and actively participate in the cognitive tasks, based on clinical interview and parental report No history of neurological complications during or immediately after cardiac surgery, based on the medical records Provision of written informed consent by the parent or legal guardian and assent from the child to participate in the research.
Exclusion criteria:
Receiving any type of brain electrical stimulation (including tDCS) or concurrent psychiatric interventions. History of epilepsy and seizures, or comorbid genetic syndromes such as Down syndrome, Williams syndrome, and DiGeorge syndrome. Changes in the dosage of psychiatric medications within the past month, or the use of medications that affect seizure threshold. Presence of non-removable intracranial or intraoral implants, as well as a history of surgery in the head region.
Age
From **8 years** old to **15 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
After confirmation of eligibility and completion of the baseline assessments, participants will be randomly assigned in a 1:1 ratio to either the active transcranial direct current stimulation group or the sham stimulation control group. Block randomization will be performed using Random Allocation Software
Blinding (investigator's opinion)
Double blinded
Blinding description
Participants will be blinded to whether they receive active or sham transcranial direct current stimulation. The pre-intervention, post-intervention, and six-week follow-up assessments will be conducted by a research colleague who will be unaware of the participants' group allocation. Therefore, both the participants and the outcome assessor will remain blinded throughout the study
Placebo
Used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Shahid Beheshti University
Street address
Shahid Shahriari Square, Evin
City
Tehran
Province
Tehran
Postal code
1983969411
Approval date
2026-05-23, 1405/03/02
Ethics committee reference number
IR.SBU.REC.1405.047

Health conditions studied

1

Description of health condition studied
Congenital Heart Disease (CHD)
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Cognitive flexibility will be assessed using the Intra-Extra

Dimensional Set Shift task (IED) and the Attention Switching Task (AST) of the CANTAB. The main outcome measures will include the adjusted total errors and extra-dimensional shift errors in the IED, as well as switching cost in the AST. Reductions in errors and switching cost at the post-intervention and follow-up assessments compared with baseline will indicate improved cognitive flexibility.

Timepoint

Measurements will be conducted at three time points: pre-test before the intervention, post-test immediately after completion of the intervention, and a one-month follow-up after completion of the intervention.

Method of measurement

Cognitive flexibility will be measured using the Intra-Extra Dimensional Set Shift task and the Attention Switching Task from the Cambridge Neuropsychological Test Automated Battery.

2

Description

Working memory will be assessed using the Spatial Span task (SSP) and the Spatial Working Memory task (SWM) of the CANTAB. Spatial span in the SSP will be used as an indicator of visuospatial short-term memory capacity, and between-search errors in the SWM will be used as an indicator of spatial working-memory performance. An increase in spatial span and a reduction in between-search errors at the post-intervention and follow-up assessments compared with baseline will indicate improved working memory.

Timepoint

Measurements will be conducted at three time points: pre-test before the intervention, post-test immediately after completion of the intervention, and a one-month follow-up after completion of the intervention.

Method of measurement

Working memory will be measured using the Spatial Span task and the Spatial Working Memory task from the Cambridge Neuropsychological Test Automated Battery.

3

Description

Sustained attention will be assessed using the Rapid Visual Information Processing task (RVP) of the CANTAB. The A′ score will be used as an indicator of sensitivity to target stimuli, and mean response latency will be used as an indicator of response speed. An increase in the A′ score and a reduction in response latency at the post-intervention and follow-up assessments compared with baseline will indicate improved sustained attention.

Timepoint

Measurements will be conducted at three time points: pre-test before the intervention, post-test immediately after completion of the intervention, and a one-month follow-up after completion of the intervention.

Method of measurement

Sustained attention will be measured using the Rapid Visual Information Processing task from the Cambridge Neuropsychological Test Automated Battery.

4

Description

Response inhibition will be assessed using the Affective Go/No-Go task (AGN) and the Stop Signal Task (SST) of the CANTAB. Total commission errors in the AGN and Stop-Signal Reaction Time in the SST will be considered the main indicators of response-inhibition performance. Reductions in commission errors and Stop-Signal Reaction Time at the post-intervention and follow-up assessments compared with baseline will indicate improved response inhibition.

Timepoint

Measurements will be conducted at three time points: pre-test before the intervention, post-test immediately after completion of the intervention, and a one-month follow-up after completion of the intervention.

Method of measurement

Response inhibition will be measured using the Affective Go/No-Go task and the Stop Signal Task from the Cambridge Neuropsychological Test Automated Battery.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Participants in this group will receive active transcranial direct current stimulation using the NeuroStim 2 device manufactured by Medina Teb Company. Stimulation will be administered at a current intensity of 1.5 milliamperes for 20 minutes per session, using 5 × 5-centimeter electrodes. The anode will be placed over the F3 position, corresponding to the left dorsolateral prefrontal cortex, and the cathode will be placed over the right shoulder. The intervention will consist of 10 sessions over a four-week period, with three sessions per week and an interval of at least one day between sessions. Before stimulation, the electrode placement sites will be prepared and electrode impedance will be checked. All sessions will be administered by trained personnel in accordance with relevant safety considerations.

Category

Treatment - Devices

2

Description

Control group: Control group: Participants in this group will receive sham transcranial direct current stimulation using the NeuroStim 2 device manufactured by Medina Teb Company. The 5 × 5-centimeter electrodes will be positioned in the same manner as in the intervention group, with the anode placed over the F3 position, corresponding to the left dorsolateral prefrontal cortex, and the cathode placed over the right shoulder. At the beginning of each session, the current intensity will be gradually increased to 1.5 milliamperes over

approximately 30 seconds to produce an initial tingling sensation similar to active stimulation. The current will then be gradually reduced over approximately 30 seconds, and no effective current will be delivered during the remainder of the session. The duration of attendance, preparation procedures, electrode placement, and impedance monitoring will be identical to those of the intervention group. Sham stimulation will be administered in 10 sessions over a four-week period, with three sessions per week and an interval of at least one day between sessions. After completion of all study assessments, participants in the control group will be offered five free sessions of active stimulation for ethical considerations.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Cardiovascular Research Center affiliated with Tehran University of Medical Sciences

Full name of responsible person

Yasaman Sadat Tabatabaei

Street address

Unit 4, 2nd Floor, No. 142, Nosrat Street, North Jamalzadeh Street, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

۱۴۱۹۸۵۳۵۵۶

Phone

+98 912 062 7758

Email

y.tabatabaei@mail.sbu.ac.ir

2

Recruitment center

Name of recruitment center

Children's Medical Center Hospital

Full name of responsible person

Yasaman Sadat Tabatabaei

Street address

No. 62, Dr. Mohammad Gharib St., End of Keshavarz Blvd., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1419733151

Phone

+98 21 6147 9999

Email

cmcpr@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University

Full name of responsible person

Seyedeh Mehri Hamidi Sangdehi

Street address

Shahid Beheshti University, Shahid Shahriari Square, Evin, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1983969411

Phone

+98 21 2990 5317

Email

m_hamidi@sbu.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

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

Faculty of Psychology and Educational Sciences, Shahid Beheshti University

Full name of responsible person

Yasaman Sadat Tabatabaei

Position

Master’s Student and Researcher

Latest degree

Bachelor

Other areas of specialty/work

Psychology

Street address

Shahid Shahriari Square, Evin, Tehran

City

Tehran

Province

Tehran

Postal code

1983969411

Phone

+98 21 8841 8743

Email

yasamantabatabaei79@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Faculty of Psychology and Educational Sciences, Shahid Beheshti University

Full name of responsible person

Yasaman Sadat Tabatabaei

Position

Master’s Student and Researcher

Latest degree

Bachelor

Other areas of specialty/work

Psychology

Street address

Shahid Shahriari Square, Evin, Tehran

City

Tehran

Province

Tehran

Postal code

1983969411

Phone

+98 21 8841 8743

Email

yasamantabatabaei79@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Faculty of Psychology and Educational Sciences, Shahid Beheshti University

Full name of responsible person

Yasaman Sadat Tabatabaei

Position

Master’s Student and Researcher

Latest degree

Bachelor

Other areas of specialty/work

Psychology

Street address

Shahid Shahriari Square, Evin, Tehran

City

Tehran

Province

Tehran

Postal code

1983969411

Phone

+98 21 8841 8743

Email

yasamantabatabaei79@gmail.com

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

Not applicable

Title and more details about the data/document

De-identified individual participant data and related study documents. After publication of the main study results, de-identified participant-level data on demographic and clinical characteristics, group allocation, executive function outcomes, and adverse events, together with the study protocol and data collection forms, may be shared with qualified researchers upon reasonable request and after approval by the principal investigator and compliance with the relevant ethics requirements. No direct identifiers or information that could reasonably permit identification of participants will be shared.

When the data will become available and for how long

Access to the research data and related documents will begin six months after the publication of the main study results and will remain available indefinitely.

To whom data/document is available

Qualified researchers affiliated with recognized universities, scientific and research institutions, or healthcare centers may submit a request to access the study data or related documents. Access will be granted upon submission of a written request, a valid research proposal, ethics committee approval, and a signed data confidentiality agreement. Researchers employed in industry may apply only if they are formally collaborating with a recognized academic or research institution and meet the aforementioned requirements.

Under which criteria data/document could be used

The research data and related documents may only be used for scientific and research purposes, including statistical analyses, secondary data analyses, and validation of the study findings. The provided data will be shared in a de-identified format, and any commercial use, transfer of data to third parties, or attempts to re-identify participants will be prohibited. Data access will be subject to submission of a formal request, a description of the intended purpose and analysis methods, verification of the applicant’s scientific qualifications, ethical approval when required, and agreement to maintain confidentiality and ensure responsible use of the data.

From where data/document is obtainable

Applicants seeking access to the research data or related documents should first submit a formal request by email

to Ms. Yasaman Sadat Tabatabaei, the principal researcher, at y.tabatabaei@mail.sbu.ac.ir. The request should include the applicant's full details, academic or institutional affiliation, the intended purpose of data use, a brief description of the proposed research, and the planned analytical methods. When necessary, requests will be reviewed in coordination with the study supervisors, Dr. Vahid Sadeghi Firoozabadi and Dr. Vahid Nejati, and the study advisor, Dr. Ehsan Aghaei Moghadam. Institutional inquiries concerning clinical data or study documents may also be directed to the Heart Research Center affiliated with Tehran University of Medical Sciences. Data or documents will be provided only after approval of the request, compliance with ethical requirements, and completion of a confidentiality agreement.

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

Applicants must submit a formal request by email to the principal researcher. The request should include the applicant's identity and institutional affiliation, the intended purpose of using the data or documents, a brief description of the proposed research, the planned analytical methods, and ethics committee approval when required. Receipt of the request will be acknowledged within a maximum of five working days. The request will then be reviewed for scientific merit, ethical compliance, feasibility, and consistency with the participants' informed consent. This review will be conducted by the principal researcher and, when necessary, in coordination with the study supervisors and the relevant research center. The review process will normally take between 10 and 15 working days. Following preliminary approval, the applicant will be required to sign a confidentiality and responsible data-use agreement and provide any additional documents, if necessary. Once all requirements have been fulfilled, the approved de-identified data or study documents will be securely provided within a maximum of 10 working days. Overall, when the request and supporting documents are complete, the process is expected to take approximately three to six weeks. Incomplete requests or applications requiring additional ethical or institutional review may take longer

Comments