Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effect of Cognitive Rehabilitation with and without Transcranial Alternating Current Stimulation (tACS) on Improving Neurocognitive and Behavioral Performance in Children with Attention Deficit Hyperactivity Disorder (ADHD)

Protocol summary

Study aim

To evaluate the effectiveness of combined cognitive rehabilitation and transcranial alternating current stimulation (tACS) on executive functions (inhibitory control, working memory, cognitive flexibility) and behavioral symptoms in children with ADHD.

Design

Randomized, double-blind, active-controlled, parallel-group trial on 34 children with ADHD. Simple randomization using random number table. Trial phase: not applicable.

Settings and conduct

This study is conducted in 2025 in Mashhad, Iran, at special needs schools and specialized psychiatric clinics. Participants are assessed at three time points (pre-test, post-test, and one-month follow-up). The outcome assessor will be blinded to group allocation.

Participants/Inclusion and exclusion criteria

Children aged 7-12 with definite ADHD diagnosis based on DSM-5-TR structured interview; normal IQ (Raven's test); parent consent and child assent. Exclusion: severe comorbid psychiatric disorders; brain injury or seizure history; intellectual disability; stimulant use within 12 hours before assessment; absence from more than one treatment session.

Intervention groups

Experimental: 10 sessions of computer-based cognitive rehabilitation with active tACS (40 Hz, 1.5 mA, 20 min/session). Active control: 10 sessions of same cognitive rehabilitation with sham stimulation.

Main outcome variables

Primary cognitive outcomes include: inhibitory control (commission errors in Go/No-Go test); working memory (percentage of correct responses in N-Back test); cognitive flexibility (number of completed categories in Wisconsin Card Sorting Test); impulsivity (adjusted score in Balloon Analogue Risk Task). Behavioral outcomes include: executive functions in daily life (total score of BRIEF questionnaire) and core symptoms of disorder (total score of SNAP-IV questionnaire).

General information

Reason for update

Acronym

CRT-tACS-ADHD

IRCT registration information

IRCT registration number: **IRCT20260625069942N1**
Registration date: **2026-07-04, 1405/04/13**
Registration timing: **retrospective**

Last update: **2026-07-04, 1405/04/13**
Update count: **0**

Registration date

2026-07-04, 1405/04/13

Registrant information

Name

Amir Kaviani Arad

Name of organization / entity

Shahid Beheshti University

Country

Iran (Islamic Republic of)

Phone

+98 51 3000 0000

Email address

a.kavei@mail.sbu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-01-20, 1403/11/01

Expected recruitment end date

2025-07-21, 1404/04/30

Actual recruitment start date

2025-04-30, 1404/02/10

Actual recruitment end date

2025-09-11, 1404/06/20

Trial completion date

2025-10-02, 1404/07/10

Scientific title

The Effect of Cognitive Rehabilitation with and without Transcranial Alternating Current Stimulation (tACS) on Improving Neurocognitive and Behavioral Performance in Children with Attention Deficit Hyperactivity Disorder (ADHD)

Public title

Effect of Cognitive Rehabilitation with tACS on ADHD

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Definitive diagnosis of Attention-Deficit/Hyperactivity Disorder based on structured clinical interview according to DSM-5-TR Age range of 7 to 12 years Normal intelligence quotient based on Raven's test Informed consent from parents and verbal assent from child

Exclusion criteria:

Presence of any severe comorbid psychiatric disorder (e.g., psychotic disorder, major depression) History of brain injury or seizure Intellectual disability or mental retardation Use of stimulant medications within 12 hours before assessment or intervention sessions Absence of more than one session from the treatment protocol

Age

From **7 years** old to **12 years** old

Gender

Male

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **37**

Actual sample size reached: **34**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is performed using simple random sampling method with a table of random numbers generated by SPSS software. The unit of randomization is at the individual level. For allocation concealment, sealed opaque envelopes are used so that the random sequence is generated by an individual independent of the principal investigator, and the envelopes are coded accordingly. After initial assessments, the envelope for each participant is opened, and the individual is assigned to either the experimental group (receiving CRT + active tACS) or the active control group (receiving CRT + sham tACS).

Blinding (investigator's opinion)

Double blinded

Blinding description

In this double-blind study, participants (children and their parents) are unaware of the intervention type (active or sham stimulation). The stimulation device is programmed to deliver the sham protocol in a way that is indistinguishable from active stimulation regarding initial sensation (e.g., mild tingling). Additionally, a trained research assistant, who is blinded to group allocation, is responsible for administering all cognitive tests and completing the questionnaires at pre-test, post-test, and follow-up stages. The principal investigator is aware of the group assignment to adjust the stimulation parameters but is not involved in the outcome assessment or data collection process.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Shahid Beheshti University

Street address

Shahid Beheshti University, Presidential Building, Research Deputy, Office of the Research Ethics Committee, Shahid Shahriari Square, Evin, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1983969411

Approval date

2025-06-07, 1404/03/17

Ethics committee reference number

IR.SBU.REC.1404.064

Health conditions studied

1

Description of health condition studied

Attention-Deficit/Hyperactivity Disorder (ADHD)

ICD-10 code

F90.9

ICD-10 code description

Attention-deficit hyperactivity disorder, unspecified type

Primary outcomes

1

Description
Number of commission errors in the Go/No-Go test as an index of inhibitory control
Timepoint
Pre-test, post-test, and one-month follow-up
Method of measurement
Computerized Go/No-Go test

2

Description
Percentage of correct responses in the N-Back test as an index of working memory
Timepoint
Pre-test, post-test, and one-month follow-up
Method of measurement
Computerized N-Back test

3

Description
Number of completed categories in the Wisconsin Card Sorting Test as an index of cognitive flexibility
Timepoint
Pre-test, post-test, and one-month follow-up
Method of measurement
Computerized Wisconsin Card Sorting Test

4

Description
Adjusted score in the Balloon Analogue Risk Task as an index of impulsivity
Timepoint
Pre-test, post-test, and one-month follow-up
Method of measurement
Computerized Balloon Analogue Risk Task

5

Description
Total score of the Behavior Rating Inventory of Executive Function (parent form) as an index of executive function in daily life
Timepoint
Pre-test, post-test, and one-month follow-up
Method of measurement
Behavior Rating Inventory of Executive Function (parent form)

6

Description
Total score of the Swanson, Nolan and Pelham Questionnaire as an index of core symptoms of attention-deficit/hyperactivity disorder
Timepoint
Pre-test, post-test, and one-month follow-up
Method of measurement
Swanson, Nolan and Pelham Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 10 sessions of computer-based cognitive rehabilitation using Aram software with active transcranial alternating current stimulation at 40 Hz frequency, 1.5 mA intensity, for 20 minutes per session are performed. Electrodes are placed in a bipolar montage at Fp2 (anode) and F3 (cathode) according to the international 10-20 system. Each session includes three adaptive rule-based cognitive tasks: Go/No-Go, N-Back, and Wisconsin Card Sorting Test.
Category
Rehabilitation

2

Description
Control group: 10 sessions of computer-based cognitive rehabilitation using Aram software similar to the experimental group with sham (inactive) transcranial alternating current stimulation are performed. The sham protocol is designed to be indistinguishable from active stimulation regarding initial sensation (mild tingling). Electrodes are placed at the same positions as the experimental group (Fp2 and F3), and participants perform the same three cognitive tasks: Go/No-Go, N-Back, and Wisconsin Card Sorting Test in an adaptive and rule-based manner.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Mehr Razavi Specialized Clinic
Full name of responsible person
Amir Kaviani Arad
Street address
Between Vakilabad 13 and 15, Vakilabad Blvd, Mashhad, Razavi Khorasan, Iran
City
Mashhad
Province
Razavi Khorasan
Postal code
9187636456
Phone
+98 51 3841 2345
Email
menelaos.skull@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
The University of Shahid Beheshti
Full name of responsible person
Dr. Seyedeh Mehri Hamidi Sangdehi
Street address
Shahid Shahriari Square, Evin, Shahid Beheshti University, Research Deputy, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1983969411
Phone
+98 21 2243 1587
Email
research@sbu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
The University of Shahid Beheshti
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
The University of Shahid Beheshti
Full name of responsible person
Amir Kaviani Arad
Position
MSc Student in Clinical Psychology
Latest degree
Master
Other areas of specialty/work
Psychology
Street address
Shahid Shahriari Square, Evin, Shahid Beheshti University, Faculty of Psychology and Educational Sciences, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1983969411
Phone
+98 21 29901
Email
a.kavei@mail.sbu.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
The University of Shahid Beheshti
Full name of responsible person
Amir Kaviani Arad
Position
MSc Student in Clinical Psychology
Latest degree
Master
Other areas of specialty/work
Psychology
Street address
Shahid Shahriari Square, Evin, Shahid Beheshti University, Faculty of Psychology and Educational Sciences, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1983969411
Phone
+98 21 29901
Email
menelaos.skull@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
The University of Shahid Beheshti
Full name of responsible person
Amir Kaviani Arad
Position
MSc Student in Clinical Psychology
Latest degree
Master
Other areas of specialty/work
Psychology
Street address
Shahid Shahriari Square, Evin, Shahid Beheshti University, Faculty of Psychology and Educational Sciences, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1983969411
Phone
+98 21 29901
Email

menelaos.skull@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Due to ethical restrictions and lack of written consent from participants for sharing raw data, there is no plan to make individual participant data available.

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

Statistical Analysis Plan
Not applicable

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Full study protocol including title, objectives, methodology, inclusion and exclusion criteria, interventions, outcomes and data analysis methods. This protocol is available as part of the master's thesis in the library of Shahid Beheshti University.

When the data will become available and for how long
Access to the protocol is available from the time of thesis publication (October 2025) indefinitely through the university library and scientific article databases.

To whom data/document is available
All researchers, students, and individuals interested in clinical psychology and cognitive neuroscience.

Under which criteria data/document could be used
For research, educational and systematic review purposes. Commercial use is not permitted.

From where data/document is obtainable
For access to the protocol, refer to the Shahid Beheshti University library or the Iranian thesis database (IranDoc). The principal author (Amir Kaviani Arad) can also be contacted via email at Kaviani.psy@gmail.com.

What processes are involved for a request to access data/document
Requests are submitted via email and will be responded to within 7 working days.

Comments
The protocol is in Persian and contains all complete study information.