Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of Transcranial Direct Current Stimulation(TDCS)on cognitive problems in children and adolescents with attention deficit hyperactivity disorder

Protocol summary

Study aim

Determining the effect of cranial direct current stimulation (TDCS) on the cognitive problems of children and adolescents with attention deficit hyperactivity disorder

Design

A clinical trial with a control group, double-blind, phase 3, on 44 patients. which random number table was used for randomization

Settings and conduct

Children and adolescents with ADHD referred to the clinic are included in the study. After obtaining informed consent, they are divided into intervention and control groups based on the random number table. In the first session, n-back, stroop and digit recall tests are performed for all patients. The intervention group, in addition to drug treatment, is treated for 10 sessions. tDCS is administered with an intensity of 1 milliamperes for 20 minutes, and in the sham control group, tDCS is added as a placebo to drug therapy. In the last session, all children and teenagers will be tested with stroop, n-back and digit span tests.

Participants/Inclusion and exclusion criteria

44 children and adolescents with ADHD, their age is between 7 and 18 years, their IQ is more than 80, and it has been 3 months since their drug treatment, and they have good compliance and cooperation, were included in the study. Exclusion criteria include IQ, having a pacemaker, having a history of ECT and tDCS, having a history of seizures and facial-cranial deformity.

Intervention groups

Intervention group: tDCS sessions with an intensity of 1 mA andal in the left frontal area for 20 minutes and 2-3 sessions per week. Control group: sham tDCS sessions in the same area and the same number of sessions with the same duration as the tDCS group.

Main outcome variables

Investigating the effect of tDCS on cognitive problems including executive functions, working memory and attention in children and adolescents with ADHD

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180723040567N2**
Registration date: **2023-06-04, 1402/03/14**
Registration timing: **retrospective**

Last update: **2023-06-04, 1402/03/14**
Update count: **0**

Registration date

2023-06-04, 1402/03/14

Registrant information

Name

NARGES HOSSEINI

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3700 2310

Email address

hoseinin941@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-06, 1401/09/15

Expected recruitment end date

2023-03-20, 1401/12/29

Actual recruitment start date

2023-02-04, 1401/11/15

Actual recruitment end date
2023-03-20, 1401/12/29
Trial completion date
2023-03-20, 1401/12/29

Scientific title
The effect of Transcranial Direct Current Stimulation(TDCS)on cognitive problems in children and adolescents with attention deficit hyperactivity disorder

Public title
The effect of Transcranial Direct Current Stimulation(TDCS)on cognitive problems in children and adolescents with ADHD
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of ADHD based on DSM-5 criteria aged 7-18 years Normal IQ >=80 Complete consent form by parent or guardian Absence of other psychiatric disorders Cooperation compliance in parent and child-adolescent
Exclusion criteria:
Presence of other medical or psychiatric disorders Having a history of seizures Deformity in the face or skull Having a pacemaker History of receiving ECT History of receiving tDCS
Age
From **7 years** old to **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **44**
Actual sample size reached: **44**
Randomization (investigator's opinion)
Randomized
Randomization description
For the random allocation of cases to two groups A and B according to the number of interventions, blocks of four were considered. By using the sealed envelope site, blocks were created and a random sequence of blocks was created. The sequence created is shown below. created were assigned to the groups. A closed envelope was used to hide the allocation. After entering the plan and signing the consent form, the patients received the envelope and went to the clinic to perform the test. Only the person performing the test of the type of test Done was aware. Block sizes: 4 Actual list length: 44 block identifier, block size, sequence within block, treatment
Blinding (investigator's opinion)
Double blinded
Blinding description
The study is a two-way blind study, the shape of the device, the intensity of the applied current and the duration are the same in both tDCS and sham groups. The patient and their clinical caregiver and the analysts are not aware of what treatment they have undergone and the intervention of tDCS or The sham is applied with the help of the project's associate psychologist
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad University of Medical sciences
Street address
Ghoreishi Department, Daneshgah Ave
City
Mashhad
Province
Razavi Khorasan
Postal code
9175845643
Approval date
2023-02-03, 1401/11/14
Ethics committee reference number
IR.MUMS.MEDICAL.REC.1401.621

Health conditions studied

1

Description of health condition studied
Attention- Deficit Hyperactivity Disorders
ICD-10 code
F90
ICD-10 code description
Attention-deficit hyperactivity disorders

Primary outcomes

1

Description
Working memory problems in children and adolescents with ADHD
Timepoint
Before the first session of tDCS and sham, and after the last session of tDCS and sham
Method of measurement
Forward and reverse digit span test

2

Description
Selective attention problems in children and adolescents with ADHD
Timepoint
Before the first session of tDCS and sham, and after the last session of tDCS and sham
Method of measurement
stroop test

3

Description
Executive function problems in children and adolescents with ADHD
Timepoint
Before the first session of tDCS and sham, and after the last session of tDCS and sham
Method of measurement
n-Back test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: each session of tDCS with an intensity of 1 milliamp and a duration of 20 minutes, 2 to 3 times a week for 5 weeks
Category
Treatment - Devices

2

Description
Control group: Each session of sham tDCS for 20 minutes, 2 to 3 times a week during 5 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Ebne-sina Hospital
Full name of responsible person
Fatemeh Moharary
Street address
Hoorre Ameli Street
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9195983134
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
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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
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Fatemeh Mohareri
Position
Associate Professor
Latest degree
Subspecialist
Other areas of specialty/work
Psychiatrics
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Narges Hosseini

Position
Assistant specialist in child and adolescent psychiatry

Latest degree
Specialist

Other areas of specialty/work
Psychiatrics

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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
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
The total individual participants' data and the results of the study after the deidentification of the individuals are shared.

When the data will become available and for how long
starting in march 2023

To whom data/document is available
All researchers are able to access the study results

Under which criteria data/document could be used
Unidentifiable information is not shared with another organization

From where data/document is obtainable
Unidentifiable information is not available to applicants

What processes are involved for a request to access data/document
Study data is published in the course of the paper and no other personal data is available to applicants

Comments