

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

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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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

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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 updating data

Contact

Name of organization / entity
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Full name of responsible person
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Assistant specialist in child and adolescent psychiatry
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Specialist
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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