

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jun 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  $\geq 80$  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

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Ghoreishi Department, Daneshgah Ave

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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

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Hoorre Ameli Street

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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

### Contact

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## Person responsible for updating data

### Contact

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Mashhad University of Medical Sciences  
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Assistant specialist in child and adolescent psychiatry  
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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