

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Investigating the effectiveness of transcranial direct electrical stimulation cognitive functions in children with attention deficit hyperactivity disorder

Protocol summary

Study aim

Determining the effect of transcranial direct electrical stimulation on cognitive function in children with attention deficit hyperactivity disorder

Design

Clinical trial with control group with two groups only without blinding randomized on 37 patients. Randomized by a table of random numbers

Settings and conduct

This study will be conducted as a clinical trial in 22 Bahman clinic in 2023. Each of the members of the two groups will be individually pre-tested using the Swanson-Nolan and Pelham questionnaire, the audio-visual continuous assessment software (IVA-2). The method of applying stimulation in tDCS will be in such a way that the sponge pad, which is actually the covering of the electrodes, will be soaked with 3% sodium chloride and the electrodes will be placed inside it. Anode tDCS stimulation with an intensity of 2 mA for 21 minutes and in ten sessions will be performed on the experimental group. One group received standard treatment and the other group received tDCS in addition to standard treatment, and the post-test will be performed on all participants.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Children under 12 years old 3- Willingness to study Conditions of non-entry of participants: 1- Unwillingness to participate in the study 2-Suffering from another psychiatric disorder 3- The presence of metal parts in the body 4- Seizure history

Intervention groups

This study will be conducted as a clinical trial on children with attention deficit hyperactivity disorder. One group will receive the standard treatment and one group will receive the tDCS method in addition to the standard treatment

Main outcome variables

Short term memory; Visual and spatial skills; Executive functions; Attention and concentration; Language; Awareness of time and place; Direct electrical stimulation

General information

Reason for update

Changing the sample size.

Acronym

IRCT registration information

IRCT registration number: **IRCT20231030059908N1**

Registration date: **2023-11-21, 1402/08/30**

Registration timing: **registered_while_recruiting**

Last update: **2025-02-22, 1403/12/04**

Update count: **1**

Registration date

2023-11-21, 1402/08/30

Registrant information

Name

Fateme Mollazade

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 5523 4944

Email address

f.mollazade1159@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-01, 1402/09/10

Expected recruitment end date

2024-05-30, 1403/03/10

Actual recruitment start date

2023-09-23, 1402/07/01

Actual recruitment end date

2025-01-18, 1403/10/29

Trial completion date

2025-01-18, 1403/10/29

Scientific title

Investigating the effectiveness of transcranial direct electrical stimulation cognitive functions in children with attention deficit hyperactivity disorder

Public title

Investigation the Effect of transcranial Direct Current Stimulation (TDCS) in attention-deficit, hyperactivity disorder (ADHD)

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

ADHD

Exclusion criteria:

Unwilling to participate in the study Having another psychiatric disorder The presence of metal grafts in the body History of seizures

Age

From **6 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **64**

Actual sample size reached: **34**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization is using a table of random numbers that are selected through a random number computer.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Mashhad Azad University of

Medical Sciences

Street address

No14, Emam khomeini Ave, Mashhad Town.

City

Mashhad

Province

Razavi Khorasan

Postal code

9187147578

Approval date

2023-07-19, 1402/04/28

Ethics committee reference number

IR.IAU.MSHD.REC.1402.045

Health conditions studied**1****Description of health condition studied**

ADHD

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

The score of Swanson-Nolan and Pelham questionnaire (SNAP_4)

Timepoint

The beginning of the study 30 days after the start of the study

Method of measurement

Swanson-Nolan and Pelham questionnaire

2**Description**

Cognitive assessment

Timepoint

The first day before the start, the tenth day.

Method of measurement

IVA-2 cognitive assessment software

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: receiving transcranial direct stimulation for 21 minutes in 10 sessions

Category

Treatment - Devices

2**Description**

Intervention group: In addition to the standard treatment, the new treatment receives transcranial direct electrical stimulation

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

22Bahman hospital clinic.

Full name of responsible person

Mansoure Mirzadeh

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Kuhsangi complex, No8, Alale Ave, pirouzi2/1 Blv.
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr.Touraj Zandbaf

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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

Islamic Azad University

Proportion provided by this source

100

Public or private sector

Private

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

Islamic Azad University

Full name of responsible person

Fateme Mollazade

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Psychiatrics

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Person responsible for updating data

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Fateme Mollazade

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Other areas of specialty/work

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Fax**Email**

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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