

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jul 2026

### Effectiveness of transcranial direct current stimulation on attention to eyes compared with other facial features in children with autism spectrum by eye-tracker

#### Protocol summary

##### Study aim

Effectiveness of tDCS on attention to eyes compared with other facial features in children with high-function autism by eye-tracker

##### Design

Two parallel group randomised trial with blinded postoperative care and outcome assessment, 24 samples and changes is evaluated by a eye tracker (tobiiprox2-60hz)

##### Settings and conduct

The present study will be performed in Shohada -Tajrish Hospital for initial diagnosis and evaluation, the desired variables are evaluated by software (tobiiprox2-60hz) in the eye tracker by aware tester. It should be noted that both the evaluator and the patients are unaware of the research (double blind). The tDCS will place the anode electrode on the left Dorso latral pre forntal and the cathode on the right shoulder for 5 sessions for 20 minutes receive a current of 2 mA. For the control group, the electrode is placed in the same way and turn on sham.

##### Participants/Inclusion and exclusion criteria

Mild disorder according to (ASSQ) score higher than 88  
Age range 15 -7 years Having verbal intelligence above 80  
No physical and neurological disease  
There is no metal implant in the body  
Absence of infection and inflammation inside the brain  
In case of seizures, it is excluded from the study

##### Intervention groups

The intervention includes patients with autism who will receive a tDCS intervention for 5 sessions for 20 minutes at the anode electrode on the left DLPF and the cathode on the right shoulder and a current of 2 mA. The control includes patients with autism who will receive a sham tDCS intervention for 5 sessions for 20 minutes at the anode electrode on the left DLPF and the cathode on the right shoulder

#### Main outcome variables

The total number of fixation eye and the duration of the fixation time done on the eye

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20211116053071N1**

Registration date: **2021-12-21, 1400/09/30**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-12-21, 1400/09/30**

Update count: **0**

##### Registration date

2021-12-21, 1400/09/30

##### Registrant information

##### Name

ashkan Irani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2272 4208

##### Email address

irani.ot@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-08-23, 1400/06/01

##### Expected recruitment end date

2022-01-21, 1400/11/01

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Effectiveness of transcranial direct current stimulation on attention to eyes compared with other facial features in children with autism spectrum by eye-tracker

**Public title**

effectiveness of tDCS on attention to eyes in children with autism spectrum

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Diagnosis of high-functioning autism by a pediatric psychiatrist based on criteria DSM-V and confirmation of diagnosis using interview Kiddie-SADS Mild disorder according to the Autism spectrum Disorders Screening Questionnaire (ASSQ) Age range 15 -7 years Having normal or corrected visual acuity with glasses (with the approval of an optometrist) Lack of physical and neurological disease Discontinue the drug 72 hours before the intervention under the supervision of a physician Absence of metal implants in vivo

**Exclusion criteria:**

Suffering from neurological and neuropsychological diseases during the study At any stage of the study that the subject was not willing to continue to cooperate, can be excluded from the study

**Age**

From **7 years** old to **15 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **24**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Using simple randomization, each new person who enters the study uses the table of random numbers if the odd number is entered into the control group and if the even number is entered into the test group, and this is done until both groups are completed. continues . And except for the main researcher, persons will not know which group of study they have entered.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Participants are evaluated by a eye tracker, it should be noted that they are evaluated by a person familiar with the eye tracker and uninformed to research. but tDCS is placed on the skull in the same way in both the

experimental group and the control group, but in the control group, tDCS is turned on as a sham, which is turned off after the device is turned on after the initial burning sensation.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

vice-chancellor in Research Affair-Shhid Beheshti University of MedicalSciences

**Street address**

shariaty street , tajrish squarer, shohadai Tajrish hospital

**City**

tehran

**Province**

Tehran

**Postal code**

1989934148

**Approval date**

2021-10-31, 1400/08/09

**Ethics committee reference number**

IR.SBMU.RETECH.REC.1400.500

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

autism spectrum disorder

**ICD-10 code**

F84.0

**ICD-10 code description**

Autistic disorder

**Primary outcomes****1****Description**

1- Total number eye fixation done

**Timepoint**

The first session before interval and the after fifth session with an interval of five days

**Method of measurement**

by Eye Tracker

**2****Description**

Number of first fixation done

#### **Timepoint**

The first session before interval and the after fifth session with an interval of five days

#### **Method of measurement**

by Eye Tracker

### **3**

#### **Description**

duration time of the first fixation

#### **Timepoint**

The first session before interval and the after fifth session with an interval of five days

#### **Method of measurement**

by Eye Tracker

### **4**

#### **Description**

duration time of the first fixation to eye

#### **Timepoint**

The first session before interval and the after fifth session with an interval of five days

#### **Method of measurement**

by Eye Tracker

## **Secondary outcomes**

empty

## **Intervention groups**

### **1**

#### **Description**

Intervention group: Using direct electrical stimulation by a tDCS-aware tester for 5 sessions for 20 minutes and five sessions per week, the anode electrode will be placed on the left DLFP and the cathode on the right shoulder through pads impregnated with physiological serum (1% NaCl) And will receive a current of 2 mA. The electrodes are placed according to the 10-20 system

#### **Category**

Rehabilitation

### **2**

#### **Description**

Control group: Using direct electrical stimulation by a tDCS-aware tester for 5 sessions for 20 minutes and five sessions per week, the anode electrode will be placed on the left DLFP and the cathode on the right shoulder through pads impregnated with physiological serum (1% NaCl) And will receive a current of 2 mA. The electrodes are placed according to the 10-20 system but the device turns on like a sham and turns off after a minute

#### **Category**

Rehabilitation

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Shohadai Tajrish Hospital Department of Physical Medicine

##### **Full name of responsible person**

Ashkan Irani

##### **Street address**

Shariaty street,Tajrish squeeer

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##### **Phone**

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##### **Email**

Ashkan2579@yahoo.com

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

##### **Name of organization / entity**

Shahid Beheshti University of Medical Sciences

##### **Full name of responsible person**

دکتر رایگانی

##### **Street address**

shariaty,tajrish

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##### **Email**

Pr\_shohada@sbm.ac.ir

#### **Grant name**

#### **Grant code / Reference number**

#### **Is the source of funding the same sponsor organization/entity?**

Yes

#### **Title of funding source**

Shahid Beheshti University of Medical Sciences

#### **Proportion provided by this source**

80

#### **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**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Ashkan Irani

**Position**

In charge of the neurosurgery department

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Neuroscience

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

masood raigani

**Position**

professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Physical Medicine

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

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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 data will be published in such a way that the names of the people are not known and the people or data will be mentioned by the code

**When the data will become available and for how long**

after publish article

**To whom data/document is available**

researcher in univercity

**Under which criteria data/document could be used**

for new research or meta analysis

**From where data/document is obtainable**

dr Ashkan Irani emai: ashkan2579@yahoo.com

**What processes are involved for a request to access data/document**

After submitting the application and sending the proposal, it will be made available to the applicant by presenting it in the council of the Physical Medicine Research Center, after agreeing and fulfilling the necessary obligations to preserve and use the information only for the agreed research.

**Comments**