

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Effectiveness of Trans-Cranial Direct Current Stimulation (TDCS) on Neuropsychological Indices Associated with Social Skills, Theory of Mind, and Emotion Regulation in Children with Autism

#### Protocol summary

##### Study aim

This article deals with the effectiveness of Trans-Cranial Direct Current Stimulation (TDCS) on neuropsychological indices associated with social skills, Theory of Mind, and emotion regulation in children with autism.

##### Design

A randomized, single-blinded, sham controlled clinical trial with a parallel group

##### Settings and conduct

Setting: At Kanian Center in Sanandaj City; Conduct: Receive Electrical Current in 10 Sessions for two Consecutive weeks Blinding: Patients and Families were Unaware of which Group they were in

##### Participants/Inclusion and exclusion criteria

Participants: Children with Autism Diagnosis according to GARZ test; Inclusion criteria: Being more than 6 years old; Families' satisfaction; Exclusion criterion: History of Seizures

##### Intervention groups

The treatment protocol: For the main Group, 10 Sessions of 15-minutes duration, with 1.5 mA electrical stimulation (the anodic or excitatory electrode on left DLFFC point and the cathode electrode on right DLFFC point); For the Control Group, The device is connected, but no flow is received.

##### Main outcome variables

Electrical stimulation by TDCS enhances social skills, Theory of Mind and emotion regulation in autistic children

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191025045234N1**  
Registration date: **2020-01-31, 1398/11/11**

Registration timing: **retrospective**

Last update: **2020-01-31, 1398/11/11**

Update count: **0**

##### Registration date

2020-01-31, 1398/11/11

##### Registrant information

###### Name

Omid Hoseinpanahi

###### Name of organization / entity

Kurdistan university

###### Country

Iran (Islamic Republic of)

###### Phone

+98 87 3316 6494

###### Email address

www.omidhoseinpanahi@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-07-08, 1398/04/17

##### Expected recruitment end date

2019-08-23, 1398/06/01

##### Actual recruitment start date

2019-07-08, 1398/04/17

##### Actual recruitment end date

2019-09-23, 1398/07/01

##### Trial completion date

2019-10-09, 1398/07/17

##### Scientific title

Effectiveness of Trans-Cranial Direct Current Stimulation (TDCS) on Neuropsychological Indices Associated with Social Skills, Theory of Mind, and Emotion Regulation in Children with Autism

**Public title**

Effectiveness of Trans-Cranial Direct Current Stimulation (TDCS) in children with autism

**Purpose**

Health service research

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

Diagnosed with autism according to Garz test Diagnosed with autism according to Autism - Spectrum Quotient

**Exclusion criteria:**

No history of Seizures

**Age**

From **5 years** old to **17 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: **40**

More than 1 sample in each individual

Number of samples in each individual: **40**

Children with Autism Spectrum Disorder

Actual sample size reached: **32**

More than 1 sample in each individual

Actual sample size in each individual: **32**

Children with Autism Spectrum Disorder

**Randomization (investigator's opinion)**

Not randomized

**Randomization description****Blinding (investigator's opinion)**

Single blinded

**Blinding description**

Only patients receiving the intervention were kept blind, in order to determine the true impact of treatment

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

No

**Secondary Ids**

empty

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

Ethics Committee of Kurdistan University

**Street address**

Pasdaran Street

**City**

Sanandaj

**Province**

Kurdistan

**Postal code**

6617715175

**Approval date**

2019-07-06, 1398/04/15

**Ethics committee reference number**

IR.UOK.REC.1389.027

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

Autism

**ICD-10 code**

F84.0

**ICD-10 code description**

Childhood autism

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

Social skills in autistic children

**Timepoint**

Before intervention and after intervention and one month after intervention

**Method of measurement**

Garz test, AQ Autism Assessment Test, Gersham & Elliott Social Skills Test, social skills checklist, Mind Theory Test, emotion regulation checklist

**Secondary outcomes****1****Description**

Improved Garz and AQ scores

**Timepoint**

Before intervention, after intervention and one month after intervention

**Method of measurement**

Garz Test, AQ Autism Assessment Test, Gersham & Eliot Social Skills Test, social skills checklist, Mind Theory Test, emotion regulation checklist, executive functions checklist

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

Intervention Group: The treatment protocol consists of ten 15-minute sessions of 1.5 mA electrical stimulation (anodic or excitation electrodes on Left DLFFC point and cathode electrode on right DLFFC point).

**Category**

Treatment - Devices

**2**

**Description**

Control Group: The device was connected to the patient without transmitting electricity.

**Category**

N/A

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Children 's Rehabilitation Center of Kanian Sanandaj Autism

**Full name of responsible person**

Shahrzad Ghaderi

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Keshavarz Ave.

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shahrzad.ghaderi90@gmail.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

University of Kurdistan

**Full name of responsible person**

Omid Hoseinpanahi

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**Grant name**

NO

**Grant code / Reference number**

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

Yes

**Title of funding source**

University of Kurdistan

**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**

University of Kurdistan

**Full name of responsible person**

Omid Hoseinpanahi

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Occupational Therapy

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**Full name of responsible person**

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**Person responsible for updating data****Contact****Name of organization / entity**

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**Latest degree**

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

**Title and more details about the data/document**

The Results of the Experimental and Control Groups will be Published after Comparison and Statistical Processing

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

After Completing the Statistic Tasks

**To whom data/document is available**

Researchers Working in Academic and Scientific Institutions

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

Use in other Research is Permitted by Reference

**From where data/document is obtainable**

Refer to the Email of a Researcher Named Omid Hossein Panahi

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

After Sending the Email the Information will be Sent After one Month

**Comments**