

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 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

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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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of Kurdistan

Full name of responsible person

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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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Position

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Other areas of specialty/work

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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