Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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Omid Hoseinpanahi

Name of organization / entity
Kurdestan university

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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
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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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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