Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effectiveness of a multidimensional intervention (transcranial direct current stimulation and skill-based cognitive-behavioral intervention) on response inhibition and attentional bias to threat in children with oppositional defiant disorder

Protocol summary

Study aim
To determine the effectiveness of a multidimensional intervention including non-invasive brain electrical stimulation (tDCS) and cognitive-behavioral skill-based intervention (CBT) on response inhibition and attention bias to threat in children with oppositional defiant disorder (ODD).

Design
This study employed a quasi-experimental pretest-posttest design with a control group. Participants were randomly assigned to three groups (two experimental and one control).

Settings and conduct
The study was conducted in psychological clinics and counseling centers in Tehran. All interventions and assessments were implemented by the researcher under the supervision of the academic advisor.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Clinical diagnosis of Oppositional Defiant Disorder (ODD) based on DSM-5 by a psychologist or psychiatrist Written informed consent from parents Ability to participate in therapy sessions and computer-based tasks Absence of severe comorbid disorders such as autism spectrum disorder or intellectual disability Exclusion Criteria: Absence from more than two therapy sessions Lack of cooperation during tests or exercises Emergence of new psychological symptoms requiring independent intervention Withdrawal from participation by the child or parents

Intervention groups
Experimental Group 1: Received transcranial Direct Current Stimulation (tDCS) for nine 20-minute sessions over three weeks. Experimental Group 2: Received cognitive-behavioral skill-based intervention (CBT) in nine 70-minute weekly sessions. Control Group: Did not receive any intervention during the study period.

Main outcome variables
Response Inhibition: Scores obtained from the Stroop test (number of errors, correct responses, and reaction time). Attention Bias to Threat: Scores obtained from the Dot-Probe Task.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250928067398N1**
Registration date: **2025-10-01, 1404/07/09**
Registration timing: **prospective**

Last update: **2025-10-01, 1404/07/09**
Update count: **0**

Registration date
2025-10-01, 1404/07/09

Registrant information

Name
Elnaz Nazer

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date

2025-10-06, 1404/07/14

Expected recruitment end date

2025-10-12, 1404/07/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of a multidimensional intervention (transcranial direct current stimulation and skill-based cognitive-behavioral intervention) on response inhibition and attentional bias to threat in children with oppositional defiant disorder

Public title

Investigating the effects of two different treatments on attention and behavior control in defiant children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of oppositional defiant disorder (ODD) by a psychiatrist or clinical psychologist based on DSM-5 criteria Written informed consent from parents for child participation Ability to attend intervention sessions and complete the required tasks Absence of severe comorbid disorders such as autism spectrum disorder or intellectual disability No regular use of psychiatric medications during the past three months

Exclusion criteria:

Neurological disorders or epilepsy interfering with tDCS intervention Any medical contraindication for receiving transcranial direct current stimulation

Age

From **8 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: Simple randomization Unit of randomization: Individual Randomization tool: SPSS software (random number generation) Sequence generation: Participants allocated equally across groups based on random numbers generated Block/stratified randomization: Not applied (small sample, homogeneous population)

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Tehran Islamic Azad University Of Medical Sciences

Street address

Central Administrative Building, Islamic Azad University of Medical Sciences – Tehran No. 16 West, Gol Yakh Gharbi St., Ayeneh Blvd., Shahid Pabarja St., Gholhak Crossroad, Shariati St., Tehran, Iran

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Province

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Postal code

1949635881

Approval date

2025-09-22, 1404/06/31

Ethics committee reference number

IR.IAU.TMU.REC.1404.327

Health conditions studied

1

Description of health condition studied

Oppositional Defiant Disorder (ODD)

ICD-10 code

F91.3

ICD-10 code description

Oppositional defiant disorder

Primary outcomes

1

Description

Response Inhibition:This variable assesses participants' ability to inhibit impulsive responses and control behavioral reactions. It is evaluated using the computerized Stroop Color-Word Test. The main indicators are the number of correct responses, number of errors, and reaction time (in milliseconds). Decreased reaction time and error rate, along with increased accuracy, indicate improvement in response inhibition.

Timepoint

Pre-test (before intervention) and Post-test (after completion of intervention sessions).

Method of measurement

Response inhibition is measured using the computerized Stroop Color-Word Task. The stimuli consist of congruent and incongruent color-word pairs, and participants must

identify the color of the word while ignoring its meaning. Reaction time (in milliseconds) and accuracy of responses are recorded as the main indicators.

2

Description

Attention Bias to Threat:This variable measures participants' tendency to allocate attention toward threatening stimuli. It is assessed using the Dot-Probe Task involving pairs of emotional (angry, fearful, disgusted) and neutral facial images. Reaction time to the location of the probe appearing after the image pair is recorded. Reduced reaction time to threatening stimuli indicates decreased attention bias to threat.

Timepoint

Pre-test (before intervention) and Post-test (after completion of intervention sessions).

Method of measurement

Attention bias to threat is measured using the Dot-Probe Task. Participants view pairs of emotional (threat-related) and neutral faces and respond to the location of a probe appearing immediately after. The difference in reaction times between threat and neutral stimuli is calculated as the index of attention bias.

Secondary outcomes

1

Description

The mean reaction time and accuracy rate of participants in the congruent and incongruent conditions of the Stroop task are measured separately. Reduced reaction time and increased accuracy in both conditions indicate improvement in cognitive processing and attentional control.

Timepoint

Pre-test (before intervention) and Post-test (after completion of intervention sessions).

Method of measurement

This variable is recorded using a computerized Stroop task software, calculating reaction time (in milliseconds) and response accuracy separately for congruent and incongruent conditions.

2

Description

The severity of Oppositional Defiant Disorder (ODD) symptoms in participants is assessed using the Child Behavior Checklist (CBCL) or the ODD subscale. Lower post-test scores compared to pre-test scores indicate a reduction in oppositional and defiant behaviors.

Timepoint

Pre-test and Post-test.

Method of measurement

The measurement tool is the Child Behavior Checklist (CBCL) completed by parents. The ODD subscale score is used as the indicator of disorder severity.

3

Description

Participants' ability to regulate their emotions is assessed using the Emotion Regulation Checklist (ERC). Higher ERC scores indicate improved ability to manage and modulate emotional responses.

Timepoint

Pre-test and Post-test.

Method of measurement

The ERC questionnaire is completed by parents and includes subscales of emotion regulation and emotional lability. The total average score is calculated for analysis.

Intervention groups

1

Description

Intervention group: Intervention Group 1 (Transcranial Direct Current Stimulation – tDCS):Participants in this group received nine sessions of transcranial direct current stimulation (tDCS), three sessions per week for three consecutive weeks. Each session lasted approximately 20 minutes. A 2 mA direct current was applied using saline-soaked sponge electrodes with anodal placement over the left DLPFC and cathodal over the right DLPFC. The device used was CE certified and approved by the Ministry of Health.

Category

Treatment - Devices

2

Description

Intervention group: Intervention Group 2 (Cognitive-Behavioral Skill-Based Intervention – CBT):Participants attended nine weekly training sessions (each lasting about 70 minutes). The sessions included emotional regulation, anger management, effective communication, and problem-solving skills. The intervention was delivered by the researcher under supervisor supervision using standard cognitive-behavioral techniques.

Category

Behavior

3

Description

Control group: Participants in this group did not receive any intervention during the study period. They only participated in the pre-test and post-test assessments. After the completion of the study, optional educational sessions were provided to the control group to ensure ethical considerations.

Category

Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Neda Awareness to Peace Psychological Clinic
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
Tehran University of Medical Sciences
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
Tehran University of Medical Sciences
Full name of responsible person
Elnaz Nazer
Position
Student
Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Since the individual participant data are confidential and specific to a master's thesis, public sharing is not recommended.

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
No - There is not 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
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
The individual participant data of this study are confidential and will be used only for scientific analysis within the framework of a master's thesis. No individual data will be publicly shared; however, the summarized results will be published as a scientific paper.

When the data will become available and for how long
The study data will be archived for five years after the completion of statistical analysis and thesis defense. Access will be granted only upon formal request by the university or the ethics committee.

To whom data/document is available
Only the principal investigator, the academic supervisor, and, if required, the Ethics Committee of Islamic Azad University of Medical Sciences, Tehran Branch, will have access to the data.

Under which criteria data/document could be used
The data may only be used for research purposes within the university's approved framework. Any secondary use requires formal approval from the university's Ethics Committee.

From where data/document is obtainable
Requests should be addressed to the principal investigator (Ms. Elnaz Nazer) through the Faculty of Medicine, Islamic Azad University of Medical Sciences, Tehran.

What processes are involved for a request to access data/document
Requests will be reviewed, and upon approval by the supervisor and the Ethics Committee, anonymized and summarized data may be provided to the applicant if necessary.

Comments
The collected data are solely intended for academic and educational purposes of the thesis. Public dissemination of raw data would conflict with the confidentiality principles of participants.