Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the effectiveness of Transcranial Direct Current Brain Stimulation (tDCS) and computer-based cognitive rehabilitation on improving executive functions, cognitive emotion regulation and impulsivity in children with attention deficit/ hyperactivity disorder

Protocol summary

Study aim

Comparison of the effectiveness of Transcranial Direct Current Brain Stimulation (tDCS) and computer-based cognitive rehabilitation on improving executive functions, cognitive emotion regulation and impulsivity in children with attention deficit/ hyperactivity disorder

Design

The current research has parallel groups (3 groups): two experimental groups and one control group. A blinded and randomized strain. After preparing the list of children suffering from attention deficit hyperactivity disorder, 60 people will be selected by simple random (lottery list) and two blind strains and will be divided into the desired groups by a simple sorting method (through the preparation of lottery list).

Settings and conduct

The current research will be conducted in Fatemi hospital in Ardabil city in the department of psychiatry. The implementation will be done by someone other than the researcher who is familiar and expert in the field of cognitive rehabilitation. The participants in the research are not aware of the assignment in the groups and they are also unaware of the names and research results of the other groups.

Participants/Inclusion and exclusion criteria

Entry conditions: having attention deficit/hyperactivity disorder; informed consent of parents and children to participate in the research and not having other psychiatric disorders Conditions of non-entry: low intelligence score

Intervention groups

First Intervention Group: They will receive electrical stimulation of the brain. Second Intervention Group: They will receive computer cognitive rehabilitation. A control group: They will not receive an intervention.

Main outcome variables

executive functions; cognitive emotion regulation; impulsivity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220911055936N1**
Registration date: **2022-10-02, 1401/07/10**
Registration timing: **registered_while_recruiting**

Last update: **2022-10-02, 1401/07/10**
Update count: **0**

Registration date

2022-10-02, 1401/07/10

Registrant information

Name

sara Taghizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 45 3325 7563

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-22, 1401/06/31

Expected recruitment end date

2022-11-21, 1401/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of Transcranial Direct Current Brain Stimulation (tDCS) and computer-based cognitive rehabilitation on improving executive functions, cognitive emotion regulation and impulsivity in children with attention deficit/ hyperactivity disorder

Public title

Comparison of the effectiveness of Transcranial Direct Current Brain Stimulation (tDCS) and computer-based cognitive rehabilitation on children with attention deficit/ hyperactivity disorder

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

having attention deficit/hyperactivity disorder informed consent of parents and children to participate in the research not having other psychiatric disorders

Exclusion criteria:

Obtaining low intelligence score on Raven's intelligence test

Age

From **7 years** old to **13 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

After preparing a list of children with attention deficit/ hyperactivity disorder, 60 of these children will be selected as a simple random sampling method (random listing and selection of people in lottery) and again by simple random method (preparation Lottery list and selection of people as lottery) will be planted in two experimental groups and one control group (each containing 20 people(

Blinding (investigator's opinion)

Single blinded

Blinding description

The participants in the research will not know about the other experimental groups, the method of intervention, the results, and also the names of the participants. The test groups will be present at the performance site at completely different times

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mohaghegh Ardabili University

Street address

Mohaghegh Ardabili University, Daneshghah Ave

City

Ardabil

Province

Ardabil

Postal code

5613974887

Approval date

2022-09-03, 1401/06/12

Ethics committee reference number

IR.UMA.REC.1401.044

Health conditions studied

1

Description of health condition studied

Attention Deficit/ Hyperactivity Disorder

ICD-10 code

F90.0

ICD-10 code description

Attention-deficit hyperactivity disorder, predominantly inattentive type

Primary outcomes

1

Description

Executive Functions

Timepoint

Conducting electrical brain stimulation (tDCS) once a week for 10 sessions, for the first experimental group. Implementation of the computerized cognitive rehabilitation package twice a week for 10 sessions, for the second experimental group. Conducting the pre-test and post-test before and after the end of the intervention sessions (one week before and after the start and end of the intervention)

Method of measurement

1- N-Back working memory test (to measure working memory) 2- Stroop color word test (to measure inhibition)

2

Description

Cognitive Emotion Regulation

Timepoint
Conducting electrical brain stimulation (tDCS) once a week for 10 sessions, for the first experimental group. Implementation of the computerized cognitive rehabilitation package twice a week for 10 sessions, for the second experimental group. Conducting the pre-test and post-test before and after the end of the intervention sessions (one week before and after the start and end of the intervention)
Method of measurement
cognitive emotion regulation questionnaire (to measure cognitive emotion regulation)

3

Description
Impulsivity
Timepoint
Conducting electrical brain stimulation (tDCS) once a week for 10 sessions, for the first experimental group. Implementation of the computerized cognitive rehabilitation package twice a week for 10 sessions, for the second experimental group. Conducting the pre-test and post-test before and after the end of the intervention sessions (one week before and after the start and end of the intervention)
Method of measurement
Balloon risk test (to measure impulsivity)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention Group One: Electrical Stimulation of the Brain (TDCS): In this group, which includes 20 subjects, the brain's electrical stimulation will be performed for 10 20 -minute current with 2 mAh for subjects
Category
Rehabilitation

2

Description
Second Intervention Group: Computer Cognitive Rehabilitation: In this group, which includes 20 subjects, participants will receive Captain Log Rehabilitation Package 10 times for 60 minutes
Category
Rehabilitation

3

Description
Control Group: In this group, which includes 20 subjects, people will not receive any study interventions and will only be taken pre -test and post -test
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Fatemi hospital
Full name of responsible person
Sara Tghizadeh
Street address
No. 19, behind Alavi Hospital, Saheli Ave, Ibrahim Abad Blvd
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
دانشگاه محقق اردبیلی
Full name of responsible person
Mohammad Narimani
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Mohaghegh Ardabili University, Daneshgah Ave
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+98 45 3150 5625
Email
narimani@uma.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
دانشگاه محقق اردبیلی
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
Mohaghegh Ardabili University.
Full name of responsible person
Sara Taghizadeh
Position
PhD student
Latest degree
Master
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
No - There is not 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
No - There is not a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
There is no data release plan. But this will be done if necessary
When the data will become available and for how long
There is no data release plan. But this will be done if necessary
To whom data/document is available
It will be available for researchers in academic and scientific institutions
Under which criteria data/document could be used
The final results will be provided to the applicants
From where data/document is obtainable
To receive documents, they can refer to the author's email address sara.taghizadeh1370@gmail.com
What processes are involved for a request to access data/document
After sending the email and request, the answer will be given in about a month
Comments