Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparing the effect of transcranial direct current stimulation (tDCS) with and without cognitive rehabilitation based on computerized task and occupational performance on executive functions in children with autism spectrum disorder aged 8-14 years

Protocol summary

Study aim

The aim of this study is to compare the effect of transcranial direct current stimulation (tDCS) with and without cognitive rehabilitation based on computer tasks and occupational performance on executive function skills of children with autism spectrum disorder (ASD) aged 8-14 years in terms of behavioral characteristics and performance.

Design

This study is a clinical trial with a control group and single-blind with a follow-up phase. Participants will convenience sampling in four groups: tDCS, tDCS with computer-based cognitive rehabilitation, tDCs with occupation-based cognitive rehabilitation, and control group receiving routine cognitive training therapy. They will be evaluated before and after the mentioned interventions and will be followed up one month later.

Settings and conduct

The rehabilitation clinics of Tehran

Participants/Inclusion and exclusion criteria

diagnosis of ASD level 1 age 8-14 years not receiving tDCS since last year not receiving drug since two weeks ago

Intervention groups

In this study, there are 4 groups: one group receives only tDCS, the second group receives tDCS with cognitive rehabilitation in the form of computer tasks, the third group receives tDCS with cognitive rehabilitation focused on occupational performance, and the fourth group as control, receives common cognitive educational interventions.

Main outcome variables

The outcomes of the present study are executive functions in terms of behavioral characteristics and performance.

General information

Reason for update

Acronym

transcranial direct current stimulation (tDCS); autism spectrum disorder (ASD)

IRCT registration information

IRCT registration number: **IRCT20150223021208N2**
Registration date: **2020-11-20, 1399/08/30**
Registration timing: **prospective**

Last update: **2020-11-20, 1399/08/30**
Update count: **0**

Registration date

2020-11-20, 1399/08/30

Registrant information

Name

Samauneh Karamali Esmaeili

Name of organization / entity

Iran Univercity of Medical Sciences- School of Rehabilitation Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-21, 1399/10/01

Expected recruitment end date

2021-03-18, 1399/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of transcranial direct current stimulation (tDCS) with and without cognitive rehabilitation based on computerized task and occupational performance on executive functions in children with autism spectrum disorder aged 8-14 years

Public title

Comparing the effect of transcranial direct current stimulation (tDCS) with cognitive rehabilitation in autism

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Children aged 8-14 years with a diagnosis of level 1 autism spectrum disorder based on the diagnosis of a child psychiatrist and assessment by the GARS If receive medication, at least two weeks have been passed since the start of the drug

Exclusion criteria:

comorbid neurological disorder receiving the tDCS during the previous year

Age

From **8 years** old to **14 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, a comparison of 4 groups is considered that the participants in each group are not aware of the other groups and the place of the treatment they receive in the study (is it intervention or control?!). The therapists who provide interventions are not aware of the main purpose of the study and the existence of four groups with different interventions. Data analysis is performed by a person who has no contact with the participants, assessors and therapists

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iran University of Medical Sciences

Street address

Shahid hemmat highway

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Approval date

2019-04-07, 1398/01/18

Ethics committee reference number

IR.IUMS.REC.1398.141

Health conditions studied

1

Description of health condition studied

Autism spectrum disorder

ICD-10 code

F84.0

ICD-10 code description

Autistic disorder

Primary outcomes

1

Description

executive function

Timepoint

before, after, and 1 month after the intervention (follow-up)

Method of measurement

Behavior Rating Inventory of Executive Function (BRIEF)- Wisconsin Card Sorting Test (WCST)- Tower of London (ToL)- Stroop test

2

Description

occupational performance

Timepoint

before, after, and 1 month after the intervention (follow-up)

Method of measurement

Canadian Occupational Performance Measure (COPM)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: twelve sessions of tDCS with electrode size 25 CM2 and 1 mA intensity in the left dorsolateral prefrontal cortex region (F3), which is determined according to the international classification system 10-20, for 20 minutes every week for 3 weeks (Four sessions per week) will provide; the reference electrode is placed on F4. Thirty seconds after starting current stimulation gradually reaches 1 mA and the final 30 seconds of current stimulation gradually decreases from 1 mA to zero.

Category
Treatment - Devices

2

Description
Intervention group 2: tDCS with computerized cognitive rehabilitation- tDCS is described in the first intervention. When receiving tDCS, the child will simultaneously perform computerized tasks for 12 sessions of 20 minutes. These tasks are in the form of computerized games to strengthen working memory, attention and concentration, problem solving, planning, inhibition and other executive function skills.

Category
Rehabilitation

3

Description
Intervention group 3: tDCS with occupation-based cognitive rehabilitation- tDCS is described in the first intervention. occupational cognitive rehabilitation in this study included 12 sessions of cognitive rehabilitation, two sessions per week, each session lasting 60 minutes; The first 30 minutes of each occupational cognitive rehabilitation program session will include meaningful and purposeful activities and games to improve executive functions, and the second 30 minutes of these sessions will focus on teaching the occupations that each child's parents determine in interviewing the Canadian Occupational Performance Measure (COPM) and prioritize the child's problems in doing daily activities by stating their perceptions about child's performance and their satisfaction.

Category
Rehabilitation

4

Description
Control group: traditional cognitive training interventions- intervention through training strengthens the executive function components such as working memory, attention and concentration, problem solving, planning, and inhibition using educational equipment and pen and paper tasks. Children in this group will receive 12 training sessions for 6 weeks (two sessions per week), 1 hour per session.

Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Iranian Autism charity Association
Full name of responsible person
Dr saeedeh saleh-ghaffari
Street address
No. 8, East Laleh Boulevard, After Hemmat Bridge, South Sattari highway, Tehran
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2

Recruitment center
Name of recruitment center
Arman-Shayan clinic
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Arman Shayan Clinic, Behnam St, Ayatollah Kashani Blvd, Sadeghieh 2nd Square, Tehran
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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
Iran 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
Iran University of Medical Sciences

Full name of responsible person
Dr Samaneh Karamali Esmaili

Position
Assisstant professor

Latest degree
Ph.D.

Other areas of specialty/work
Occupational Therapy

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Tehran

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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

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

Informed consent form: the word file can be made available. Clinical study report: will be published in several articles.

When the data will become available and for how long

Informed consent form: After publishing the last paper Clinical study report: After publication (if the article would not be free, if people email us a request and state the purpose of using the article, we will provide the full-text of article.)

To whom data/document is available

Informed consent form: Academic researchers Clinical study report: everyone who is interested to the topic.

Under which criteria data/document could be used

Informed consent form: The users should announce the purpose of using the informed consent form. Clinical study report: for clinical and research uses

From where data/document is obtainable

Informed consent form: Send us an e-mail Clinical study report: Search databases or send us an email.

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

Informed consent form: After sending the email and announcing the purpose of using the consent form or the clinical study report, it will be sent to them within a week.

Comments