

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

Comparison of the effectiveness Transcranial Direct Current Stimulation with cognitive-behavior therapy on the test anxiety of first and second period of time high school students in Baladeh region

Protocol summary

Study aim

Determining the effectiveness Transcranial Direct Current Stimulation with cognitive-behavior therapy on the test anxiety of first and second period of time high school students

Design

Two arm parallel group randomized trial with a control group was performed on 45 high school students. Random number table was used for randomization.

Settings and conduct

The 45 students participating in the study will be randomly divided into three groups. Before and after the interventions in different groups, the level of students' test anxiety will be measured using the Friedman test anxiety questionnaire and statistical data will be collected.

Participants/Inclusion and exclusion criteria

participants: The first and second period of time high school students in Baladeh region inclusion criteria: Written consent to participate in the research, Iranian nationality, living in Baladeh region, study in the first or second period of high school, nothing mental health problems leading to hospitalization of the student, not to be absent in cognitive-behavioral training sessions of test anxiety more than 4 sessions, observance of the rules of cognitive-behavioral training sessions of test anxiety

Intervention groups

Transcranial Direct Current Stimulation group: It is an instruction that is performed during 10 sessions and each session for 20 minutes and in a one-month interval by direct and weak electric current with the intensity of 2 mA stimulated by nerves through two electrodes located on their skulls. Cognitive-behavioral therapy group: In the present study, cognitive-behavioral therapy means training that is performed as a group for 8 sessions, during 8 weeks and each treatment session lasts 60

minutes. Control group: No intervention was performed in the students of the control group.

Main outcome variables

Reduce test anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190817044550N3**

Registration date: **2020-09-13, 1399/06/23**

Registration timing: **prospective**

Last update: **2020-09-13, 1399/06/23**

Update count: **0**

Registration date

2020-09-13, 1399/06/23

Registrant information

Name

Mohammad Hoseini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8950 2504

Email address

meditorha@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-21, 1399/10/01

Expected recruitment end date

2021-03-05, 1399/12/15

Actual recruitment start date

empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effectiveness Transcranial Direct Current Stimulation with cognitive-behavior therapy on the test anxiety of first and second period of time high school students in Baladeh region

Public title
Evaluation the effect of Transcranial Direct Current Stimulation and cognitive-behavior therapy on the test anxiety of high school students

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Having the written consent to participate in the research Iranian nationality Living in Baladeh region Study in the first or second period of high school No mental health problems leading to hospitalization of the student Not to be absent in cognitive-behavioral training sessions of test anxiety more than 4 sessions Observance of the rules of cognitive-behavioral training sessions of test anxiety Age between 11 and 18 years old

Exclusion criteria:
Reluctance to collaborate in the study Having mental health problems while studying Absence from cognitive-behavioral training sessions test anxiety more than 4 sessions

Age
From **11 years** old to **17 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
We used the permuted block randomization method, and these blocks were randomly designed in Excel software, and then groups equal to the allocation of a as the intervention group and b as the control group were performed.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Biomedical Research Ethics Committee, Islamic Azad University - Babol Branch

Street address

Babol Islamic Azad University, Three kilometers of Ghaemshahr Rd, Babol town, Mazandaran Province, Iran

City

Babol

Province

Mazandaran

Postal code

3738147471

Approval date

2020-08-26, 1399/06/05

Ethics committee reference number

IR.IAU.BABOL.REC.1399.028

Health conditions studied

1

Description of health condition studied

Test anxiety

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Friedman Test Anxiety Score

Timepoint

Before and after the intervention

Method of measurement

Using Friedman test Anxiety Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

First Intervention group: transcranial stimulation of the brain with direct current is an instruction that was performed during 10 sessions and each session for 20 minutes and in a one-month interval (with an interval of two days between sessions) by direct and weak electric current with the intensity of 2 mA stimulated by nerves

through two electrodes located on their skulls.

Category

Behavior

2

Description

Second Intervention group: cognitive-behavioral therapy means training that is performed as a group for 8 sessions, during 8 weeks and each treatment session lasts 60 minutes.

Category

Behavior

3

Description

Control group: No intervention was performed in the students of the control group.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Babol Islamic Azad University

Full name of responsible person

Gholamali Nikpour

Street address

Babol Islamic Azad University, Three kilometers of Ghaemshahr Rd, Babol town, Mazandaran Province, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Gholamali Nikpour

Street address

Babol Islamic Azad University, Three kilometers of Ghaemshahr Rd, Babol town, Mazandaran Province, Iran

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Email

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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

Islamic Azad University

Proportion provided by this source

100

Public or private sector

Private

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

Islamic Azad University

Full name of responsible person

Alireza Kargozar

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Psychology

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Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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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

The data obtained from this project will eventually be reported as standard and general, and reporting personal information by individuals does not seem necessary.

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Demographic information and information about the main outcome of this project can be shared.

When the data will become available and for how long

Start of access period 1 year after printing the results

To whom data/document is available

The data of this project can be shared by all aspiring researchers working in academic and scientific institutes.

Under which criteria data/document could be used

Appropriate scientific use of the data of this study in order to improve the quality of similar studies is unimpeded.

From where data/document is obtainable

The data of the present research is possible by announcing the request via email nikpoorg@yahoo.com and also st.A.R.Kargozar@iauamol.ac.ir.

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

After confirming the eligibility of the person requesting the information, the data will be sent as soon as possible via the above emails.

Comments