

# 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

**City**

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**Postal code**

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**Phone**

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**Email**

nikpoorg@yahoo.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Gholamali Nikpour

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nikpoorg@yahoo.com

**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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st.A.R.Kargozar@iauamol.ac.ir

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Gholamali Nikpour

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Psychology

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

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**Full name of responsible person**

Alireza Kargozar

**Position**

Masters student

**Latest degree**

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**Other areas of specialty/work**

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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](mailto:nikpoorg@yahoo.com) and also [st.A.R.Kargozar@iauamol.ac.ir](mailto: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**