

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jun 2026

Behavioral and electrophysiological study of the effectiveness of direct current transcranial stimulation (tDCS) on the improvement of the attention network in tinnitus sufferers

Protocol summary

Study aim

Determining the effectiveness of direct current transcranial stimulation (tDCS) on attention network improvement in patients with tinnitus.

Design

Clinical trial with control group, single blind, randomized, on 30 patients. The rand function of Excel software will be used for randomization.

Settings and conduct

In this research, all people with tinnitus referring to audiology and otolaryngology clinics in Ardabil city will be studied. After completing the tinnitus disability questionnaire with a cut-off point of 58, people enter the next stage of the research. In this stage, after homogenization, they are divided into two experimental and control groups. Both groups are measured with behavioral and electrophysiological tests before the intervention. The experimental group will receive real stimulation and the control group will be blinded with a sham to measure the effect of transcranial stimulation.

Participants/Inclusion and exclusion criteria

Inclusion criteria : Being right-handed Being in the age range of 18-55 years Having tinnitus for six months or more Obtaining a score of 58 or more in the tinnitus disability questionnaire Having normal hearing Having normal or corrected vision Exclusion criteria: Left-handedness or absence of a dominant hand Not being in the age range of 18-55 No tinnitus or tinnitus for less than six months Obtaining 58 points in the tinnitus disability questionnaire

Intervention groups

The intervention in this research is to investigate the effect of transcranial direct current stimulation (tDCS). This treatment method will be offered during 10 sessions and 3 sessions per week. Each session will be for 20 minutes with a current intensity of 2 milliamps for participants in the experimental group and thirty

seconds for the control group (sham).

Main outcome variables

Attention network components

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220625055275N1**

Registration date: **2022-09-15, 1401/06/24**

Registration timing: **retrospective**

Last update: **2022-09-15, 1401/06/24**

Update count: **0**

Registration date

2022-09-15, 1401/06/24

Registrant information

Name

Hamzeh Mahmoudi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-27, 1401/04/06

Expected recruitment end date

2022-08-21, 1401/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Behavioral and electrophysiological study of the effectiveness of direct current transcranial stimulation (tDCS) on the improvement of the attention network in tinnitus sufferers

Public title

The effectiveness of direct current transcranial stimulation (tDCS) on the improvement of the attention network

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Being right-handed Being in the age range of 18-55 years Chronic tinnitus for more than six months Achieve a score of more than 58 in the tinnitus disability questionnaire Having normal hearing , Having normal or corrected vision Complete the consent form to participate in the training program Lack of acute psychological problems (based on the individual's own opinion and the researcher's interview) Lack of a history of obvious neurological and cognitive diseases and head trauma

Exclusion criteria:

Therapeutic intervention with the help of other methods during the research History of seizures, brain tumors, strokes and bleeding Having substance abuse Left-handedness or absence of a dominant hand Not being in the age range of 18-55 No tinnitus or tinnitus for less than six months Obtaining a score less than 58 in the tinnitus disability questionnaire Having a hearing loss Having an uncorrected vision problem

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

To group the subjects, we will do the following steps:
Step 1: We set the values of F and M equal to the number of women and men, respectively (F and M will be at least 15). Step 2: We assign numbers 1 to F to each of the female subjects and numbers 1 to M to the male subjects. Step 3: We execute the command `sample(1:F,7)` in R statistical software. This command will result in 7 people (approximately 50% of the 15 female subjects) being randomly selected. Step 4: We execute

the `sample(1:M,8)` command in R statistical software. This command will result in 8 people (approximately 50% of the 15 male subjects) being randomly selected. Step 5: Men and women whose numbers are extracted in step 3 and step 4 will be included in the experimental group. Step 6: The remaining 8 women and 7 men will be in the control group. Note: It should be noted that if, after this grouping, the age was heterogeneous between the two experimental and control groups, the age variable can be entered as a co-variate in the MANCOVA model.

Blinding (investigator's opinion)

Single blinded

Blinding description

In each clinical trial design, three groups can influence the results of the study. Experiments, researcher, evaluator or analyst. In this study, by randomly selecting participants in two experimental and control groups and applying independent variables to both groups, which are in one sham and play the role of placebo. Also, the analyst is not aware of the sham of the intervention in the group and they become practically blind

Placebo

Used

Assignment

Factorial

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committees of university of Tabriz

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29 Bahman Boulevard, Tabriz University, Central Library and University Document Center, Tabriz

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Approval date

2022-07-31, 1401/05/09

Ethics committee reference number

IR.TABRIZU.REC.1401.029

Health conditions studied**1****Description of health condition studied**

Attention network

ICD-10 code**ICD-10 code description**

Primary outcomes

1

Description

Attention network alerting component: in the behavioral test, a cross (+) is displayed in the center of the screen, with flankers in the form of congruent (<<<<<) or incongruent (>>>><>>>) above or below it appear. Participants are required to focus on the cross during the test period and when the flankers appear, with high speed and accuracy in the direction of the central arrow using the mouse (the left mouse key for when the central arrow tip is to the left and the key the right side of the mouse when the tip of the central arrow is to the right). The alert component is obtained from the fraction of the reaction time and the number of errors of the central sign from the alarm without a sign.

Timepoint

After randomization into two experimental and control groups, the pre-test is performed, then the intervention is carried out in 10 sessions and transcranial stimulation is applied in 3 sessions every week for 20 beats, then the post-test is performed.

Method of measurement

Attention network test, quantitative electroencephalography

2

Description

Orientation component of the attention network: the orientation component is obtained from the fraction of the reaction time and the number of spatial cue errors from the central cue.

Timepoint

After randomization into two experimental and control groups, the pre-test is performed, then the intervention is carried out in 10 sessions and transcranial stimulation is applied in 3 sessions every week for 20 beats, then the post-test is performed.

Method of measurement

Attention network test, quantitative electroencephalography

3

Description

Executive component of attention network: The executive control component is obtained from the fraction of the reaction time and the number of errors of the incongruent arrows from the congruent ones

Timepoint

After randomization into two experimental and control groups, the pre-test is performed, then the intervention is carried out in 10 sessions and transcranial stimulation is applied in 3 sessions every week for 20 beats, then the post-test is performed.

Method of measurement

Attention network test, quantitative electroencephalography

4

Description

The absolute power of the alpha wave in the frontal region

Timepoint

After randomization into two experimental and control groups, the pre-test is performed, then the intervention is carried out in 10 sessions and transcranial stimulation is applied in 3 sessions every week for 20 beats, then the post-test is performed.

Method of measurement

Quantitative electroencephalography

Secondary outcomes

1

Description

Improvement of attention after intervention based on Tinnitus Disability Questionnaire score

Timepoint

Before and after intervention sessions

Method of measurement

25-question tinnitus disability questionnaire

Intervention groups

1

Description

Intervention group: Transcranial direct current stimulation (tDCS) in this study, this treatment method will be provided during 10 sessions and 3 sessions per week. In each session for 20 minutes, the current intensity of 2 mA will be applied to the participants in the experimental group.

Category

Treatment - Other

2

Description

Control group: Control group: transcranial direct current stimulation (tDCS) in this study, this treatment method will be provided during 10 sessions and 3 sessions per week. In each session, for 30 seconds, the current intensity of 2 mA will be applied to the control (sham) group. Control group: transcranial direct current stimulation (tDCS) in this study, this treatment method will be provided during 10 sessions and 3 sessions per week. In each session, for 30 seconds, the current intensity of 2 mA will be applied to the control (sham) group.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Nyusha audiology clinic

Full name of responsible person

Hamzeh Mahmoudi

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding sourceI have no sponsorship or financial prohibition from an
institution or organization**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**

Other

Person responsible for general inquiries**Contact****Name of organization / entity**

The University of Tabriz

Full name of responsible person

Dr. Mansour Bayrami

Position

Professor

Latest degree

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Other areas of specialty/work

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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

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

Statistical Analysis Plan

Not applicable

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

Not applicable