Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

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

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

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Name of organization / entity

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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 sufferes

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 an 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
Street address
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

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Sponsors / Funding sources

1

Sponsor
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
I 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

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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