Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effect of multi-site transcranial electrical stimulation (tES) with different methods on psychophysical, psychological and electroencephalographic (EEG) indicators in people with chronic tinnitus

Protocol summary

Study aim

Investigating and comparing the effect of different multi-site transcranial electrical stimulation methods on psychophysical, psychological and electroencephalographic indicators of tinnitus in people with chronic tinnitus.

Design

The present study is an intervention in the form of a randomized clinical trial with a parallel and single blind design. 40 people participated in the study in the form of four separate groups receiving multi-site electrical stimulation including: tDCS-tRNS group, tRNS group, tRNS+DC offset group and sham group.

Settings and conduct

After completing the informed consent form and performing basic assessments (before stimulation), people in each group will receive the desired electrical stimulation in 8 sessions. After the end of the sessions and three months after that, all people will be evaluated again. This study is conducted in Tehran University of Medical Sciences.

Participants/Inclusion and exclusion criteria

Conditions of entry: age range from 18 to 60 years, at least six months of non-pulsatile tinnitus perception, Normal or almost normal hearing status and having of the necessary ability to perform the tests Conditions of non-entry: not understanding polyphonic tinnitus, and not suffering from ear, nose and throat diseases, chronic neurological diseases and psychiatric disorders

Intervention groups

The intervention groups include three experimental groups and one control group. People in the experimental groups received three different types of multi-site electrical stimulation, and in the control group, participants received sham stimulation.

Main outcome variables

Tinnitus psychophysical loudness; Tinnitus loudness and annoyance; The degree of tinnitus handicap; The degree of negative effects of tinnitus; Satisfaction with quality of life; Severity of depression and anxiety; Absolute and relative power of EEG frequency bands; Current source density

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220901055849N1**
Registration date: **2022-09-06, 1401/06/15**
Registration timing: **prospective**

Last update: **2022-09-06, 1401/06/15**
Update count: **0**

Registration date

2022-09-06, 1401/06/15

Registrant information

Name

Sahand Nazeri

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-21, 1401/11/01

Expected recruitment end date

2024-04-20, 1403/02/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of multi-site transcranial electrical stimulation (tES) with different methods on psychophysical, psychological and electroencephalographic (EEG) indicators in people with chronic tinnitus

Public title
Investigating the effect of multi-site transcranial electrical stimulation in the treatment of chronic tinnitus
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age range from 18 to 60 years At least six months of persistent non-pulsatile tinnitus perception Normal hearing thresholds (below 25 dB HL) at frequencies from 250 to 2000 Hz and hearing thresholds below 40 dB HL at frequencies above 2000 Hz The normal state of the outer and middle ear (normal otoscopy and obtaining a type A tympanogram with a static compliance between 0.3 and 1.6) Passing at least six months since receiving transcranial electrical or magnetic stimulation (regardless of the purpose of stimulation and the stimulation protocol used) Having the necessary abilities to perform the tests
Exclusion criteria:
Perceiving polyphonic tinnitus Observing a conductive component (Air-Bone Gap ≥ 15 dB HL) in the audiogram Formal music training Having diseases of the ear, nose and throat The existence of obvious cognitive disorders and mental disability Suffering from chronic neurological diseases Suffering from chronic psychiatric disorders A history of alcohol and drug abuse or addiction Taking drugs that affect the function of the central nervous system A history of severe head trauma or surgery related to the central nervous system in the head and neck area Receiving other conventional treatment methods for tinnitus in at least the last six months Using a heart pacemaker or implantable electrodes in the head and neck area Pregnancy
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Each of the eligible people, randomly and using the minimization method, are allocated in one of the four groups receiving multi-site electrical stimulation. QMinim program (web version of MinimPy software) is used to carry out the process of random allocation using the minimization method. In the minimization method, the first person randomly enters one of the four groups with equal probability. From the second person onwards, participants enter groups with unequal probability (in favor of the group that has the least balance with other groups in terms of the desired variables). This process is done in such a way, that by allocating each participant, the most possible balance is achieved in the distribution of the desired variables among the groups, and at the same time, the number of people in each group is as equal as possible. In this study, the basic probability of each person being in a group with the least balance (compared to other groups) is 85%.
Blinding (investigator's opinion)
Single blinded
Blinding description
The participants have no information about the group to which they have been assigned. But the researcher has all the necessary information to carry out the study.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of School of Nursing and Midwifery & Rehabilitation - Tehran University o
Street address
Central Organization of Tehran University of Medical Sciences, At the corner of Qods St., Keshavarz Blvd.
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Tehran
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Approval date
2022-08-31, 1401/06/09
Ethics committee reference number
IR.TUMS.FNM.REC.1401.071

Health conditions studied

1

Description of health condition studied
Tinnitus

ICD-10 code
H93.1
ICD-10 code description
Tinnitus

Primary outcomes

1

Description
Tinnitus psychophysical loudness
Timepoint
Before, after and three months after the electrical stimulation sessions
Method of measurement
Loudness matching

2

Description
Tinnitus loudness
Timepoint
Before, after and three months after the electrical stimulation sessions
Method of measurement
Visual Analogue Scale (VAS)

3

Description
Tinnitus annoyance
Timepoint
Before, after and three months after the electrical stimulation sessions
Method of measurement
Visual Analogue Scale (VAS)

4

Description
The degree of tinnitus handicap
Timepoint
Before, after and three months after the electrical stimulation sessions
Method of measurement
Tinnitus Handicap Inventory (THI)

5

Description
The degree of negative effects of tinnitus
Timepoint
Before, after and three months after the electrical stimulation sessions
Method of measurement
Tinnitus Functional Index (TFI)

6

Description
Satisfaction with quality of life
Timepoint
Before, after and three months after the electrical stimulation sessions
Method of measurement
SF-36 Questionnaire

7

Description
Severity of depression
Timepoint
Before, after and three months after the electrical stimulation sessions
Method of measurement
Beck Depression Inventory-Second Edition (BDI-II)

8

Description
Severity of anxiety
Timepoint
Before, after and three months after the electrical stimulation sessions
Method of measurement
Beck Anxiety Inventory (BAI)

9

Description
Absolute power of EEG frequency bands
Timepoint
Before, after and three months after the electrical stimulation sessions
Method of measurement
EEGLAB software

10

Description
Relative power of EEG frequency bands
Timepoint
Before, after and three months after the electrical stimulation sessions
Method of measurement
EEGLAB software

11

Description
Current source density
Timepoint
Before, after and three months after the electrical stimulation sessions
Method of measurement
sLORETA software

Secondary outcomes

1

Description
Tinnitus pitch
Timepoint
Before, after and three months after the electrical stimulation sessions

Method of measurement
Pitch matching

Intervention groups

1

Description
First intervention group: In this group, the tDCS-tRNS method is used to provide multi-site electrical stimulation. In each session, first, tDCS stimulation with a current intensity of 2 mA is presented to the DLPFC area, and then, low frequency tRNS stimulation (0.1-100 Hz) with an intensity of 2 mA is presented to the auditory cortex area. Each person receives multi-site electrical stimulation in 8 sessions and in a period of 4 weeks. The total duration of providing multi-site electrical stimulation in each session is 30 minutes, which is divided into two consecutive 15-minute stimulations presented to separate areas in the cortex (multi-site presentation).
Category
Treatment - Devices

2

Description
Second intervention group: In this group, the tRNS method is used to provide multi-site electrical stimulation. In each session, high-frequency tRNS stimulation (100-640 Hz) was first delivered to the DLPFC region, followed by low-frequency tRNS stimulation to the auditory cortex region. The intensity of the electrical excitation current is equal to 2 mA in both cases. Each person receives multi-site electrical stimulation in 8 sessions and in a period of 4 weeks. The total duration of providing multi-site electrical stimulation in each session is 30 minutes, which is divided into two consecutive 15-minute stimulations presented to separate areas in the cortex (multi-site presentation).
Category
Treatment - Devices

3

Description
Third intervention group: In this group, the tRNS+DC offset method is used to provide multi-site electrical stimulation. In each session, first, high frequency tRNS stimulation with an intensity of 2 mA plus 1 mA of direct current (DC) is provided to the DLPFC area, and then low frequency tRNS stimulation with an intensity of 2 mA and without DC is presented to the auditory cortex area. Each person receives multi-site electrical stimulation in 8 sessions and in a period of 4 weeks. The total duration of providing multi-site electrical stimulation in each session is 30 minutes, which is divided into two consecutive 15-minute stimulations presented to separate areas in the cortex (multi-site presentation).
Category
Treatment - Devices

4

Description
Control group: In this group, the electrical stimulation protocol is similar to the tDCS-tRNS group, with the difference that the electrical stimulation in each of the tDCS and tRNS modes is provided only for 30 seconds and then the electrical current is stopped. The purpose of providing sham stimulation is that the participant feels the passage of electrical current through his skin and cannot distinguish between receiving real and sham stimulation, so as to prevent bias in the research results.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Faculty of Rehabilitation, Tehran University of Medical Sciences
Full name of responsible person
Farzaneh Fatahi
Street address
No 336, At the corner of safialishah St., Enghelab Ave.
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Phone
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Email
Jfatahi@tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Akbar Fotouhi
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No 226, At the corner of Ghods St., Keshavarz Blvd.
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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
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Sahand Nazeri
Position
PhD Student
Latest degree
Master
Other areas of specialty/work
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Person responsible for scientific inquiries

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Assistant professor
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Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Sahand Nazeri
Position
PhD Student
Latest degree
Master
Other areas of specialty/work
Audiology
Street address
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
All the data related to the investigated indicators can be shared.
When the data will become available and for how long
One year after the publication of study results in scientific journals
To whom data/document is available

Researchers working in academic centers or prestigious research institutes

Under which criteria data/document could be used

Further publication and analysis of the data must be done with the permission of the researcher.

From where data/document is obtainable

Sahand Nazeri S_nazeri@razi.tums.ac.ir

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

Providing the purpose of the data request along with the scientific resume via email

Comments