

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)

Phone

+98 21 7768 4889

Email address

s_nazeri@razi.tums.ac.ir

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 \geq 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.

City

Tehran

Province

Tehran

Postal code

1417653761

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.

City

Tehran

Province

Tehran

Postal code

1148965111

Phone

+98 21 7753 0636

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

Street address

No 226, At the corner of Ghods St., Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 81631

Email

tumspr@tums.ac.ir

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

Audiology

Street address

No. 336, At the corner of Safialishah St., Enghelab Ave.

City

Tehran

Province

Tehran

Postal code

1436913545

Phone

+98 21 7768 4889

Fax**Email**

S_nazeri@razi.tums.ac.ir

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

Tehran University of Medical Sciences

Full name of responsible person

Farzaneh Fatahi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Audiology

Street address

No 336, At the corner of Safialishah St., Enghelab Ave.

City

Tehran

Province

Tehran

Postal code

1148965111

Phone

+98 21 7768 4889

Email

Jfatahi@tums.ac.ir

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

No. 336, At the corner of Safialishah St., Enghelab Ave.

City

Tehran

Province

Tehran

Postal code

1436913545

Phone

+98 21 7768 4889

Fax**Email**

S_nazeri@razi.tums.ac.ir

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