

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 2026

**Investigating the effectiveness of combined methods according to the cortical hubs in the tinnitus networks on improvement of loudness-annoyance and cognitive-auditory processing in tinnitus sufferers with hearing loss.**

### Protocol summary

#### Study aim

Investigating the effectiveness of combined methods according to the cortical hubs in the tinnitus networks on improvement of loudness-annoyance and cognitive-auditory processing in tinnitus sufferer with hearing loss.

#### Design

one blind clinical trial with 2 groups which is assigned to rehabilitation groups by the method of 4 random blocks.

#### Settings and conduct

persons after meeting the entry criteria will be included in the study. before the start of the intervention Quick Speech In Noise (Q-sin), Pich Patern Test (PPT), Dichotic Digit Test (DDT), Test of Everyday Attention - Elevator (TEA), n-back tests, and EEG will be performed. Then they will be divided into 2 groups. Each group receives A or B intervention the post-test phase will be conducted for behavioral auditory and cognitive tests and EEG recording. Follow-up for behavioral tests will be performed 1 and 3 months after the last session of intervention. this study is done in one blind and participants don't ever of kind of invention.

#### Participants/Inclusion and exclusion criteria

inclusion criteria; adults with chronic and subjective tinnitus with acoustic coverage and hearing loss and mild to severe hearing loss in the frequency range of 2-8 KHz, aged 25-55 years old, not using hearing AIDS and parallel treatments with a total score of mild to severe in Tinnitus Handicap Inventory (THI) and maximum 10 in Hospital Anxiety and Depression Scale (HADS ). non-inclusion criteria; unwillingness to cooperate

#### Intervention groups

group A- customized sound therapy with transcranial direct current stimulation in the left temporoparietal area. group B- customized sound therapy with tDCS in the dorsolateral prefrontal cortex area.

#### Main outcome variables

Q-SIN test score; Dichotic Digit tes score; TEA test score; EEG parameter and n-back test score.

### General information

#### Reason for update

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20230513058159N1**

Registration date: **2023-05-30, 1402/03/09**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-05-30, 1402/03/09**

Update count: **0**

#### Registration date

2023-05-30, 1402/03/09

#### Registrant information

##### Name

Seyedeh Manoosh Sobhani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

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##### Email address

manooshsobhany@gamil.com

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2023-05-22, 1402/03/01

#### Expected recruitment end date

2023-11-22, 1402/09/01

#### Actual recruitment start date

empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
Investigating the effectiveness of combined methods according to the cortical hubs in the tinnitus networks on improvement of loudness-annoyance and cognitive-auditory processing in tinnitus sufferers with hearing loss.

**Public title**  
The combined effect of customized sound therapy and transcranial current stimulation in tinnitus sufferers

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
sufferers with chronic and subjective tinnitus aged between 25-55 years the average hearing threshold are between 20-60 in frequencies between 2-8 KHz in at least 1 hear acoustic coverability of tinnitus not using hearingAIDS and not perfuming paralleled drug and non drug treatment at the same time as this research non-intensification of tinnitus in a residual inhibition assessment absence of pulsatile or multitone tinnitus absence of Meniere's disease or any fluctuation in hearing level absence of conductive and severe to profound hearing lost and obvious complaint of hyperacusis earn maximum points sever in HADS questionnaire earn points mild to sever in THI questionnaire complete the consent form to participate in the rehabilitation in the program  
**Exclusion criteria:**  
unwillingness to cooperate in each stage of the research no infection of neurologic legion epilepsy convulsions and no evidence of cardiovascular disease no taking sedatives

**Age**  
From **25 years** old to **55 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **46**  
More than 1 sample in each individual  
Number of samples in each individual: **2**  
binaural

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
For random allocation, six blocks of 8, AABB, ABAB, ABBA, BBAA, BAAB, BABA will be prepared and placed in envelopes in order of entry of the persons, one of the envelopes was selected at random, and based on the obtained block 4 patients will be assigned into 2 groups.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**  
in each clinical trial design, 3 groups can influence the results of the study. experiments, researcher, evaluated, or analyst. in this study, by randomly selecting participants in 2 groups and applying 2 different independent variables to each group which is blinded to the type of intervention that received. also the analyst of EEG and statistic are not ewer of the kind of intervention in the groups and they become practically blind.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Social welfare and rehabilitation sciences

##### Street address

Kodakyar ave., Daneshjo Blvd., Evin

##### City

Tehran

##### Province

Tehran

##### Postal code

1985713871

#### Approval date

2023-01-22, 1401/11/02

#### Ethics committee reference number

IR.USWR.REC.1401.230

## Health conditions studied

### 1

#### Description of health condition studied

tinnitus

#### ICD-10 code

H93.1

#### ICD-10 code description

Tinnitus

### 2

#### Description of health condition studied

hearing loss

#### ICD-10 code

H90

#### ICD-10 code description

Conductive and sensorineural hearing loss

## Primary outcomes

### 1

**Description**

quick-speech in noise test score

**Timepoint**

before the intervention- after the intervention- 1 and 3 months after the end of the intervention

**Method of measurement**

the percentage of correctly expressed target words - the amount of SNR loss based on the calculation formula.

### 2

**Description**

Dichotic digit test

**Timepoint**

before the intervention- after the intervention- 1 and 3 months after the end of the intervention

**Method of measurement**

according to percentage of correct answers

### 3

**Description**

pitch patern test

**Timepoint**

before the intervention- after the intervention- 1 and 3 months after the end of the intervention

**Method of measurement**

according to percentage of correct answers

### 4

**Description**

sustained attention score in the test of everyday attention (TEA-elevator counting)

**Timepoint**

before the intervention- after the intervention- 1 and 3 months after the end of the intervention

**Method of measurement**

according to percentage of correct answers

### 5

**Description**

selective attention score in the test of everyday attention (TEA-elevator counting with distraction )

**Timepoint**

before the intervention- after the intervention- 1 and 3 months after the end of the intervention

**Method of measurement**

according to percentage of correct answers

### 6

**Description**

n-back test

**Timepoint**

before the intervention- after the intervention- 1 and 3 months after the end of the intervention

**Method of measurement**

according to percentage of correct answers

### 7

**Description**

componence of electroencephalography (EEG)

**Timepoint**

before the intervention- after the intervention

**Method of measurement**

with EEGLab software

### 8

**Description**

the score of Tinnitus Handicap Inventory (THI) questionnaire

**Timepoint**

before the intervention- after the intervention- 1 and 3 months after the end of the intervention

**Method of measurement**

Score obtained out of 100

### 9

**Description**

Visual Analog Score (VAS) of tinnitus

**Timepoint**

before the intervention- after the intervention- 1 and 3 months after the end of the intervention

**Method of measurement**

Score obtained out of 10

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**

Intervention group: Group A- customize sound therapy will be provided together with LTA transcranial direct current stimulation (tDCS) for 20 min , the current intensity of 2 mA will be applied 6 sessions (3 sessions per week )

**Category**

Rehabilitation

### 2

**Description**

Intervention group: Intervention group: Group A- customize sound therapy will be provided together with DLPFC transcranial direct current stimulation (tDCS) for 20 min , the current intensity of 2 mA will be applied 6 sessions (3 sessions per week )

**Category**

Rehabilitation

## Recruitment centers

## 1

### Recruitment center

**Name of recruitment center**

University of Social Welfare and Rehabilitation Sciences

**Full name of responsible person**

Seyed Ali Hosseini

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### Sponsors / Funding sources

## 1

### Sponsor

**Name of organization / entity**

University of social welfare and rehabilitation sciences

**Full name of responsible person**

Hamidreza Khankeh

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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**

University of social welfare and rehabilitation 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**

University of social welfare and rehabilitation sciences

**Full name of responsible person**

Manoosh Sobhani

**Position**

Student

**Latest degree**

Master

**Other areas of specialty/work**

Audiology

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### Person responsible for scientific inquiries

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**Position**

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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**

Not applicable

**Data Dictionary**

Not applicable