Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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Iran (Islamic Republic of)

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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

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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
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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?
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
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Student

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Person responsible for updating data

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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