

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

Investigating the efficacy of rehabilitation using auditory-visual attentional training in adults with chronic tinnitus: A quantitative electroencephalography (qEEG) study

Protocol summary

Study aim

Design and evaluation of rehabilitation using a novel auditory-visual attention training program (mobile application) in adults with chronic tinnitus using quantitative electroencephalogram (qEEG) and behavioral tests.

Design

Interventional, randomized, controlled clinical trial

Settings and conduct

Volunteers who are visited in audiology clinic and meet the study entrance criteria participate in this study. Subjects are randomly selected for one of the study groups and are blinded.

Participants/Inclusion and exclusion criteria

Adults between the age of 20 to 50 years can participate who meet the following criteria: Right-handedness, not using antidepressant, anti-seizure, and anesthetic drugs, no history of neurologic disorders such as brain tumors, Meniere's disease, chronic headache, otosclerosis, or psychological disorders that need professional intervention.

Intervention groups

This study has an intervention group and two control groups: The attention training with the simultaneous auditory-visual stimulus is done in the intervention group while the control groups receive only auditory or visual training. The training is based on Posner's attention theory and is designed as a mobile application. After logging in, the subjects perform a daily tinnitus evaluation. Then, the cues are presented and after that, the subject should choose the correct answer. The numbers and colors are used as the auditory and visual stimulus respectively. The training levels are designed from easy to hard. The reaction time, error rate, and level progress are saved into the software database.

Main outcome variables

Electrophysiological parameters (quantitative

electroencephalogram- qEEG and P300 response) and behavioral tests of the attention and questionnaires for tinnitus and depression and anxiety are evaluated before and after rehabilitation for comparison

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220206053952N2**

Registration date: **2022-08-10, 1401/05/19**

Registration timing: **prospective**

Last update: **2022-08-10, 1401/05/19**

Update count: **0**

Registration date

2022-08-10, 1401/05/19

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-23, 1401/07/01

Expected recruitment end date

2023-04-20, 1402/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the efficacy of rehabilitation using auditory-visual attentional training in adults with chronic tinnitus: A quantitative electroencephalography (qEEG) study

Public title

Investigating the efficacy of auditory-visual attention training in tinnitus

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Right-handedness Chronic tinnitus (more than 6 months) Normal hearing (hearing thresholds less than 25 dB HL) in conventional audiometry (250-8000 Hz) Not using anti-depressant, anti-seizure, and anesthetic drugs No history of neurologic disease such as brain tumors, Meniere disease, chronic headache, and otosclerosis No major psychological problem seeking to professional

Exclusion criteria:

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple Random Sampling

Blinding (investigator's opinion)

Single blinded

Blinding description

Only participants are withhold until the end of the study

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Iran University of

Medical Sciences

Street address

Hemmat Highway, Near Milad Tower, Iran University of Medical Sciences

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۱۴۳۹۶۱۴۵۳۵

Approval date

2022-07-27, 1401/05/05

Ethics committee reference number

IR.IUMS.REC.1401.399

Health conditions studied

1

Description of health condition studied

Tinnitus

ICD-10 code

H93.1

ICD-10 code description

Tinnitus

Primary outcomes

1

Description

Reaction time in Attention Network Test (ANT)

Timepoint

At the beginning of the study and 21 days after rehabilitation (attention training)

Method of measurement

Attention Network Test (ANT) software

2

Description

Error rate in Attention Network Test (ANT)

Timepoint

At the beginning of the study and 21 days after rehabilitation (attention training)

Method of measurement

Attention Network Test (ANT) software

3

Description

The amplitude of P300 electrophysiology response

Timepoint

At the beginning of the study and 21 days after rehabilitation (attention training)

Method of measurement

21 channel electroencephalography device

4

Description

The latency of P300 electrophysiology response

Timepoint

At the beginning of the study and 21 days after rehabilitation (attention training)

Method of measurement

21 channel electroencephalography device

5**Description**

The mean frequency of electroencephalogram (EEG) waves

Timepoint

At the beginning of the study and 21 days after rehabilitation (attention training)

Method of measurement

21 channel electroencephalography device

6**Description**

The absolute power of electroencephalogram (EEG) waves

Timepoint

At the beginning of the study and 21 days after rehabilitation (attention training)

Method of measurement

21 channel electroencephalography device

7**Description**

The relative power of electroencephalogram (EEG) waves

Timepoint

At the beginning of the study and 21 days after rehabilitation (attention training)

Method of measurement

21 channel electroencephalography device

8**Description**

Electroencephalogram (EEG) activity at the region of interests (ROIs)

Timepoint

At the beginning of the study and 21 days after rehabilitation (attention training)

Method of measurement

21 channel electroencephalography device

9**Description**

Reaction time in the Stroop task

Timepoint

At the beginning of the study and 21 days after rehabilitation (attention training)

Method of measurement

Stroop task software

10**Description**

Error rate in the Stroop task

Timepoint

At the beginning of the study and 21 days after rehabilitation (attention training)

Method of measurement

Stroop task software

11**Description**

Reaction time in the the Test of Attention in Listening (TAiL)

Timepoint

At the beginning of the study and 21 days after rehabilitation (attention training)

Method of measurement

Test of Attention in Listening (TAiL) software

12**Description**

Error rate in the the Test of Attention in Listening (TAiL)

Timepoint

At the beginning of the study and 21 days after rehabilitation (attention training)

Method of measurement

Test of Attention in Listening (TAiL) software

13**Description**

Hospital Anxiety and Depression Scale (HADS) questionnaire score

Timepoint

At the beginning of the study and 21 days after rehabilitation (attention training)

Method of measurement

Hospital Anxiety and Depression Scale (HADS) questionnaire

14**Description**

Tinnitus Handicap Questionnaire (THQ) score

Timepoint

At the beginning of the study and 21 days after rehabilitation (attention training)

Method of measurement

Tinnitus Handicap Questionnaire (THQ)

15**Description**

Tinnitus annoyance

Timepoint

At the beginning of the study and daily measurement during 21 days of rehabilitation (attention training)

Method of measurement

Visual Analogue Scale

16**Description**

Tinnitus loudness

Timepoint

At the beginning of the study and daily measurement during 21 days of rehabilitation (attention training)

Method of measurement

Visual Analogue Scale

17**Description**

Tinnitus loudness

Timepoint

At the beginning of the study and 21 days after rehabilitation (attention training)

Method of measurement

Psychoacoustic evaluation of tinnitus with audiometer device

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: The attention training with the simultaneous auditory-visual stimulus is done. The training is based on Posner's attention theory and is designed as a mobile application. After logging into the program, the subjects perform a daily evaluation of their tinnitus and then the training has begun. First, simultaneous auditory-visual cues are presented and then the subject should choose the correct answer in the next part of the training. The numbers and colors are used as the auditory and visual stimulus respectively. The subject directs to the next level after choosing the correct answer. The training levels are designed from easy to hard by decreasing the time of the cues and increasing the number of cues and items (the numbers and colors) in the training. The reaction time, error rate, and level progress are saved into the software database.

Category

Rehabilitation

2**Description**

First control group: The attention training is done the same as in the intervention group, but using the auditory-only stimulus.

Category

Rehabilitation

3**Description**

First control group: The attention training is done the same as in the intervention group, but using the visual-only stimulus.

Category

Rehabilitation

Recruitment centers**1****Recruitment center****Name of recruitment center**

Audiology clinic

Full name of responsible person

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Web page address**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Iran 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

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

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Phone**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

Undecided - It is not yet known if there will be a plan to
make this available

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

Undecided - It is not yet known if there will be a plan to
make this available