# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 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 t0 50 years can participate who meet the following criteria: Right-handedness, not using ant-depressant, 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**

Farnoush Jarollahi

**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**

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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**Postal code**

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**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 annoynce
**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**
Hossein Namvar Arefi
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## Sponsors / Funding sources

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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**
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

## Person responsible for general inquiries

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## Person responsible for scientific inquiries

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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**
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