

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Investigating the effectiveness of music therapy with and without binaural beats stimulation on the handicap of tinnitus in hearing-impaired adults aged 20-55.

Protocol summary

Registration timing: **prospective**

Study aim

Comparison of the effectiveness of music therapy with and without binaural pulsatile stimulation on tinnitus-related disability in hearing-impaired adults aged 20-55.

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, on 30 patients. The rand function of Excel software was used for randomization.

Settings and conduct

Tehran oil refinery identification of patients based on criteria Entering the intervention based on the group in each patient to evaluate the tinnitus and the disability resulting from it Before and after interventions

Participants/Inclusion and exclusion criteria

Acute tinnitus patients with severe to profound unilateral hearing loss

Intervention groups

Intervention group 1: receiving a relaxing music file with pulsating stimulus of two 8 Hz headphones and frequencies of 436 and 428 Hz, 15 minutes, twice a day, 4 weeks Intervention group 2: receiving an empty relaxing music file, 15 minutes, twice a day, 4 weeks

Main outcome variables

THI Hearing Impairment Index Questionnaire Scores, TFI Tinnitus Functional Index Questionnaire Scores, HADS Anxiety and Depression Questionnaire Scores, Tinnitus Psychophysical Loudness Evaluation, Tinnitus Coverage Minimum Level Evaluation, Tinnitus Residual Interruption Phenomenon Evaluation, Quantitative VAS Score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231013059701N1**
Registration date: **2023-10-21, 1402/07/29**

Last update: **2023-10-21, 1402/07/29**

Update count: **0**

Registration date

2023-10-21, 1402/07/29

Registrant information

Name

Somayeh Bakhtarikia

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4455 4374

Email address

sbakhtarikia@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-22, 1402/07/30

Expected recruitment end date

2024-02-19, 1402/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effectiveness of music therapy with and without binaural beats stimulation on the handicap of tinnitus in hearing-impaired adults aged 20-55.

Public title

Investigating the effectiveness of music therapy with and

without binaural beats stimulation on tinnitus

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 1. Mild to moderate hearing loss (21-60 dB, Jargar) and symmetrical
 2. No hearing aid
 3. History of tinnitus for more than 6 months
 4. Mr.
 5. No neurological and psychological diseases
 6. Otoscopy and standard immittance audiometry (tympanogram: Type A and without transitional component)
 7. Have minimum reading and writing literacy so that they can read the questions of the questionnaire
Exclusion criteria:
 1. Severe to profound and asymmetric hearing loss
 2. Having a hearing aid
 3. History of tinnitus less than 6 months
 4. Suffering from severe neurological and psychological diseases
 6. Abnormal otoscopy and immittance audiometry (with transmission component)
 7. Not having minimum literacy and Writing so that they cannot read the questionnaire questions.

Age
From **20 years** old to **55 years** old

Gender
Male

Phase
N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
 Randomization method: individual with two blocks into two groups equal; Randomization and random sequence construction with Random software allocation;
 Concealment: with sealed opaque envelopes done with random sequence

Blinding (investigator's opinion)
Double blinded

Blinding description
 The participants were blinded to the type of music file received, the principal investigator as well as the person responsible for collecting the data and the outcome assessor, and to a lesser degree the Data Safety and Monitoring Committee and those who They prepare the draft of the article, they are blinded to the patients and the type of file they received.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Midwifery and Rehabilitation Faculty - Tehran
University of Medical Sciences

Street address

Enghelab street

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Tehran

Province

Tehran

Postal code

1148956111

Approval date

2023-10-11, 1402/07/19

Ethics committee reference number

IR.TUMS.FNM.REC.1402.141

Health conditions studied

1

Description of health condition studied

Tinnitus disorder

ICD-10 code

H93.1

ICD-10 code description

Tinnitus

Primary outcomes

1

Description

Handicap and assessment of tinnitus

Timepoint

Before and after the intervention

Method of measurement

Tinnitus assessment test and self-assessment questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: receiving relaxing music file with 8 Hz binaural beat stimulations with frequencies of 436 and 428 Hz, 15 minutes, twice a day(morning and night), 4 weeks

Category

Rehabilitation

2

Description

Control group: receiving an empty relaxing music file, without binaural beat stimulations 8 Hz, 15 minutes, twice a day (morning and night), 4 weeks

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran oil refinery

Full name of responsible person

Somayeh Bakhtarikia

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Hanie Rajabi

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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

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

Somayeh Bakhtarikia

Position

Audiologist

Latest degree

Bachelor

Other areas of specialty/work

Audiology

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

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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

Master thesis and article publication

When the data will become available and for how long

2025 onwards

To whom data/document is available

All

Under which criteria data/document could be used

Under the copyright laws of Tehran University of Medical Sciences to access Master's thesis and journal rules for access to published articles

From where data/document is obtainable

For articles to the databases of articles for the thesis to the faculty library Rehabilitation of Tehran University of Medical Sciences

What processes are involved for a request to access data/document

For the thesis, study in the library for the paper depending on the policy of the journal.

Comments