Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

A comparative study of sound therapy using a mobile application and therapeutic counseling with cognitive-behavioral methodology and combined therapy on reducing tinnitus annoyance in people with chronic tinnitus

Protocol summary

Study aim

A comparative study of sound therapy using a mobile application and therapeutic counseling with cognitive-behavioral methodology and combined therapy on reducing tinnitus annoyance in people with chronic tinnitus

Design

This study is designed as a randomized clinical trial with three parallel groups. Participants will be randomly assigned to three groups: the first group will receive sound therapy using a mobile application, the second group will receive CBT counseling, and the third group will receive a combination treatment, i.e., the two methods of using sound therapy using a mobile application and CBT counseling. The research design will be a pre-test-post-test with a 3-month follow-up. The target population of this study is adults aged 18 to 65 years with chronic tinnitus (more than 6 months) who refer to the ENT clinics of Loghman Hakim Hospital and then will be referred to the hospital's audiology department for research.

Settings and conduct

Loghman Hakim Hospital, Audiology Department

Participants/Inclusion and exclusion criteria

1- People with moderate to severe chronic tinnitus 36 ≤ THI 2- Tinnitus duration more than 6 months 3- People aged between 18 and 65 4- Access to a smartphone with software registration capability 5- Having a high school diploma or higher

Intervention groups

1- People receiving sound therapy 2- People receiving counseling therapy 3- People receiving combination therapy

Main outcome variables

Reducing the intensity and severity of tinnitus

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260519069452N1**
Registration date: **2026-06-03, 1405/03/13**
Registration timing: **prospective**

Last update: **2026-06-03, 1405/03/13**
Update count: **0**

Registration date

2026-06-03, 1405/03/13

Registrant information

Name

AYUB VALADBEIGI

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7756 1721

Email address

a_valadbeigi@sbmu.ac.ir

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-06-05, 1405/03/15

Expected recruitment end date

2027-01-05, 1405/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
A comparative study of sound therapy using a mobile application and therapeutic counseling with cognitive-behavioral methodology and combined therapy on reducing tinnitus annoyance in people with chronic tinnitus

Public title
Tinnitus treatments
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
People with tinnitus Chronic, annoying tinnitus
Exclusion criteria:
Conductive hearing loss Using hearing aids
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
0
Groups that have been masked
No information
Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Due to the nature of the experiment, a simple randomization method is used using sealed envelopes containing random numbers equal to the number of subjects studied.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Factorial
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shahid Beheshti University of Medical Sciences
Street address
Tehran, Imam Hossein (AS) Square, Damavand Street (New Tehran), opposite Bu Ali Hospital, Faculty of Rehabilitation Sciences, Shahid Beheshti University of Medical Sciences, First Floor, Audiology Department
City
Tehran
Province
Tehran
Postal code
1616913111
Approval date
2026-05-17, 1405/02/27
Ethics committee reference number
IR.SBMU.RETECH.REC.1405.074

Health conditions studied

1

Description of health condition studied
tinnitus
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Tinnitus severity
Timepoint
Initial evaluation, final evaluation after 3 months
Method of measurement
Tinnitus Disability Questionnaire, Visual Analogue Scale, ReSound Theapp Relief Tinnitus mobile app

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 1- Group receiving sound therapy 2- Group receiving counseling therapy 3- Group receiving combined therapy
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Loghman hospital
Full name of responsible person
Audiology part
Street address
Audiology department, first floor, Damavand Ave, Tehran, Iran
City
Tehran
Province

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a_valadbeigi@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Vice President for Research and Technology, Shahid Beheshti University of Medical Sciences
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Audiology department, first floor, Damavand Ave, Tehran, Iran
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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Ayub Valadbeigi
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Personal data is not suitable for publication.

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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable