Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Investigating the effect of face-to-face and remote rehabilitation on the treatment of tinnitus

Protocol summary

Study aim
Determining the effect of face-to-face and remote rehabilitation in the treatment of tinnitus

Design
This is a randomized clinical trial, in which 15 eligible patients will be randomly assigned to the intervention 1 and intervention 2 groups

Settings and conduct
The eligible patients with chronic tinnitus referring to the Audiology Clinic in Hamedan city during the study period will be enrolled in the trial and will be randomly assigned to the intervention 1 and intervention 2 groups through the drawing of lots.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age of 18 to 70 years, Non-pulsatile chronic tinnitus for more than 6 months, Being right-handed, Exclusion criteria: Hyperacusis, Use of hearing aids, Psychological disorders, Active diseases of the ear and nervous system

Intervention groups
Intervention group 1: visiting the audiology clinic for 24 sessions of 60 minutes during 12 weeks (twice a week). Listening bilaterally to wide band noise about 30 minutes with headphones and then a 30-minute counseling session in each session. Intervention group 2: 24 sessions of 60 minutes of counseling and sound therapy without attending the clinic. Listening bilaterally to wide band noise (white noise) for about 30 minutes with hands-free and then receiving counseling by making a video connection with Google Mate for 30 minutes.

Main outcome variables
Primary outcome: Tinnitus length, tinnitus annoyance, tinnitus handicap

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20241018063403N1**
Registration date: **2024-10-22, 1403/08/01**
Registration timing: **prospective**

Last update: **2024-10-22, 1403/08/01**
Update count: **0**

Registration date
2024-10-22, 1403/08/01

Registrant information

Name
Bahareh Khavarghazalani

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 81 3838 1571

Email address
b.khavarghazalani@umsha.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-11-05, 1403/08/15

Expected recruitment end date
2025-07-06, 1404/04/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of face-to-face and remote rehabilitation on the treatment of tinnitus

Public title
face-to-face and remote rehabilitation on the treatment

of tinnitus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 18 to 70 years, Non-pulsatile tinnitus for more than 6 months, Being right-handed,

Exclusion criteria:

Hyperoccosis, Use of hearing aids, Psychological disorders, Active diseases of the ear and nervous system

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: Random assignment of the patients to the intervention and control groups through the drawing of lots. To do this, we prepare two sheets and write "intervention 1" on one sheet and "intervention 2" on another. Then, by referring each patient, one of the sheets will be randomly taken and the patient will be assigned to the intervention 1 or intervention 2 groups; Concealment: with opaque sealed envelopes in a random sequence

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Hamadan University of Medical Sciences, Research square, Shahid Fahmideh St.

City

Hamadan

Province

Hamadan

Postal code

6517838736

Approval date

2024-10-05, 1403/07/14

Ethics committee reference number

IR.UMSHA.REC.1403.447IR.UMSHA.REC.1403.447

Health conditions studied

1

Description of health condition studied

Tinnitus

ICD-10 code

H93.1

ICD-10 code description

Tinnitus

Primary outcomes

1

Description

Tinnitus handicap

Timepoint

Before intervention and after 12 , 16 weeks after the start of the intervention

Method of measurement

Using the Tinnitus Handicap Inventory (THI) questionnaire

2

Description

Tinnitus annoyance

Timepoint

Before intervention and after 12 , 16 weeks after the start of the intervention

Method of measurement

Using visual analog scale (VAS)

3

Description

Tinnitus loudness

Timepoint

Before intervention and after 12 , 16 weeks after the start of the intervention

Method of measurement

Based on psycho-acoustic assessment

4

Description

tinnitus pitch

Timepoint

Before intervention and after 12 , 16 weeks after the start of the intervention

Method of measurement

Based on psycho-acoustic assessment

Secondary outcomes

empty

Intervention groups

1

Description
Control group: visiting the audiology clinic for 24 sessions of 60 minutes during 12 weeks (twice a week). Listening bilaterally to wide band noise about 30 minutes with headphones and then a 30-minute counseling session in each session.
Category
Rehabilitation

2

Description
Intervention group: 24 sessions of 60 minutes of counseling and sound therapy without attending the clinic. Listening bilaterally to wide band noise (white noise) for about 30 minutes with hands-free and then receiving counseling by making a video connection with Google Mate for 30 minutes.
Category
Rehabilitation

Recruitment centers

1

Recruitment center

2

Recruitment center
Name of recruitment center
Audiology Clinic in Hamadan city
Full name of responsible person
Maryam Emadi
Street address
Shahid Fahmideh St., Hamedan University of Medical Sciences, Faculty of Rehabilitation Sciences
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maryamemadi1396@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Dr. Reza Shokoohi
Street address
Hamadan, Shahid Fahmideh Blvd., University Headquarters, 4th Floor, Vice-Chancellor for Research and Technology
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6517838678
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Fanavari@umsha.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Hamedan 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
Hamedan University of Medical Sciences
Full name of responsible person
Maryam Emadi
Position
Assistant Professor of Audiology
Latest degree
Ph.D.
Other areas of specialty/work
Audiology
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Latest degree
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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
Reporting as a papers

When the data will become available and for how long
2026 and after

To whom data/document is available
All people

Under which criteria data/document could be used
Research plan: In accordance with Hamadan University of Medical Sciences copyright Paper: In accordance with the journal's policies to access the published paper

From where data/document is obtainable
Research plan: The library of the School of Rehabilitation, UMSHA Papers: Databases

What processes are involved for a request to access data/document
For the research plan, studying in the library For papers depends on the journal's policy.

Comments