

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 Meet 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 Khavarghalani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3838 1571

Email address

b.khavarghalani@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 Meet 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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6517838687

Phone

+98 81 3838 1571

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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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Hamadan

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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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School of Rehabilitation, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

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Person responsible for scientific

inquiries

Contact

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Full name of responsible person

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Position

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Latest degree

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Person responsible for updating data

Contact

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Position

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Other areas of specialty/work

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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