

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Sep 2026

Investigating the impact of aerobic exercise on tinnitus severity among women patients with tinnitus referring to Loghman Hospital in 2025: a randomized clinical trial study

Protocol summary

Study aim

Investigating the effectiveness of regular aerobic exercise in reducing the severity and complications of tinnitus in affected women through the THI questionnaire, assessment of tinnitus intensity and frequency, and measurement of the amplitude and latency of the P300 electrophysiological response in a randomized clinical trial

Design

Sampling was performed using block randomization with a block size of 6. In this study, based on the study by Yousef and colleagues (9), with a 95% confidence level and 80% statistical power, or an effect size of 3.077, and considering a 20% increase in sample size, 60 patients were selected, including 20 receiving exercise and diet, 20 receiving only dietary intervention, and 20 in the control group. $n = [2 \times (Z_{1-\alpha/2} + Z_{1-\beta})^2 \times \sigma^2] / \Delta^2$ Based on the study by Yousef and colleagues (2023), with 80% power and $\alpha=0.05$, a standard deviation of 4.5, and $d=3.5$, the sample size for each group was 20 people (a total of 60).

Settings and conduct

A randomized clinical trial at Loghman Hakim Educational and Therapeutic Hospital in Tehran in 2025 among women with tinnitus visiting the ENT clinic

Participants/Inclusion and exclusion criteria

A female patient with bilateral subjective tinnitus visiting the ear, nose, and throat (ENT) clinic

Intervention groups

Based on the study by Yousef and colleagues (9), 60 people are considered as the sample size and are randomly divided into three groups, including 20 people in the exercise and diet group, 20 people in the diet-only group, and 20 people in the control group.

Main outcome variables

Age BMI Physical activity level Tinnitus Handicap Inventory P300 wave amplitude P300 wave latency

Tinnitus severity Tinnitus frequency

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251115068003N1**

Registration date: **2025-11-21, 1404/08/30**

Registration timing: **prospective**

Last update: **2025-11-21, 1404/08/30**

Update count: **0**

Registration date

2025-11-21, 1404/08/30

Registrant information

Name

Elahe Tavakolian Ardakani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4404 5919

Email address

elahetavakoliyan@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-11-22, 1404/09/01

Expected recruitment end date

2026-02-20, 1404/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the impact of aerobic exercise on tinnitus severity among women patients with tinnitus referring to Loghman Hospital in 2025: a randomized clinical trial study

Public title

Investigating the impact of aerobic exercise on tinnitus severity among women patients with tinnitus

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

All female patients aged 18 to 65 years with subjective bilateral tinnitus

Exclusion criteria:

Tinnitus patients with a history of surgery, hearing loss greater than 40 dB, abnormal eardrum examination and any middle ear pathology not following sports, living in a noisy environment, listening to music with hands-free for a long time patients taking medications such as chemotherapy, quinine, aminoglycosides, ACE inhibitors, chloroquine, furosemide, glucocorticoids, aspirin, depression and anxiety medications, beta blockers, amylotriptine Patients with a history of diabetes, hypertension, thyroid disorders, lupus, multiple sclerosis, and migraines were also excluded

Age

From **18 years** old to **65 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

A Three-Arm Randomized Clinical Trial

Blinding (investigator's opinion)

Double blinded

Blinding description

A Three-Arm Randomized Clinical Trial

Placebo

Not used

Assignment

Factorial

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

School of Medicine - Shahid Beheshti University of Medical Sciences (Research Ethics Committee)

Street address

Unit 16, No. 44, between Golestan 11 and 12, Eskandarzadeh Street, Payambar Sharghi Street, Ashrafi Esfahani Highway

City

Tehran

Province

Tehran

Postal code

1471764784

Approval date

2025-11-05, 1404/08/14

Ethics committee reference number

IR.SBMU.MSP.REC.1404.516

Health conditions studied**1****Description of health condition studied**

Patients with tinnitus

ICD-10 code

H93.1

ICD-10 code description

Tinnitus

Primary outcomes**1****Description**

The effect of exercise on baseline hearing assessment, including pure tone audiometry and tympanometry, as well as supplementary tinnitus evaluation tests, including the THI questionnaire, assessment of tinnitus intensity and frequency, and measurement of the amplitude and latency of the P300 electrophysiological response.

Timepoint

First assessment (before starting the intervention) and after 24 intervention sessions (after 2 months)

Method of measurement

Assessment using P300 and Tinnitus Handicap Inventory, as well as tinnitus intensity and frequency

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention Group 1: Therapeutic Exercise

Category

Treatment - Other

2**Description**

Intervention group: Exercise and diet

Category

Treatment - Other

3**Description**

Control group: Does not exercise

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**Loghman Hakim Educational and Therapeutic
Hospital, Tehran, Ear, Nose, and Throat Clinic**Full name of responsible person**

Elaheh Tavakolian Ardakani

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Afshin Zarqi

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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

Elahe Tavakolian Ardakani

Position

Sports Medicine Resident

Latest degree

Medical doctor

Other areas of specialty/work

Sport Medicine

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is 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

Title and more details about the data/document

Informed Consent Form

When the data will become available and for how long

Access period starts 3 months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

None

From where data/document is obtainable

None

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

Data access is available three months after the results are published

Comments