Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 Yousel 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. $n = [2 \times (Z1-\alpha/2 + Z1-\beta)^2 \times \sigma^2] / \Delta^2$ Based on the study by Yousel and colleagues (2023), with 80% power and α=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 Youssel 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
Street address
Unit 16, No. 44, between Golestan 11 and 12, Eskandarzadeh Street, Payambar Sharghi Street, Ashrafi Esfahani Highway
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elahetavakoliyan@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr. Afshin Zarqi
Street address
Unit 16, No. 44, between Golestan 11 and 12, Eskandarzadeh Street, Payambar Sharghi Street, Ashrafi Esfahani Highway
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1985717443
Phone
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Email
info@sbmu.ac.ir
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
Street address
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Person responsible for scientific inquiries

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Shahid Beheshti University of Medical Sciences
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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