

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

elahetavakolijan@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

**City**  
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1471764784

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+98 21 4404 5919

**Email**  
elahetavakolijan@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**

+98 21 2243 9780

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

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences

**Full name of responsible person**  
Elahe Tavakolian Ardakani

**Position**  
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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**

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Elahe Tavakolian Ardakani

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