

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the effect of speech perception in noise training on quality of life in chronic tinnitus sufferers

Protocol summary

Study aim

Investigating the effect of speech perception in noise training on quality of life in chronic tinnitus sufferers

Design

Randomized clinical trial study with a control group in which eligible patients will be randomly assigned to two intervention and control groups, each group consisting of 14 patients.

Settings and conduct

This study will be conducted in the Faculty of Rehabilitation Sciences of Iran University of Medical Sciences and Health Services on 28 patients with chronic tinnitus. Patients will be randomly assigned to intervention and control groups by lottery. There is no possibility of blinding in this study.

Participants/Inclusion and exclusion criteria

Age range from 18 to 50 years; Normal hearing threshold; Suffering from chronic tinnitus for at least 6 months without History of ear surgery and neurological diseases such as migraine, multiple sclerosis, etc.

Intervention groups

Intervention group 1: Tinnitus Retraining Therapy (TRT) including counseling and sound therapy along with Word-in-Noise Training (WINT) for 8 sessions of 60 minutes, 30 minutes of which are devoted to TRT and 30 minutes to WINT. The WINT consists of two tracks. The first part has 600 words in 60 subgroups of 10 words, and the other part is the babbling noise of several speakers. In each session, 8 subgroups are presented in different signal-to-noise ratios. Control group: Tinnitus Retraining Therapy (TRT) including counseling and sound therapy for 8 sessions of 30 minutes.

Main outcome variables

Tinnitus Loudness; Tinnitus Annoyance; Tinnitus Functional Index; Quality of Life Questionnaire (SF-12); Speech Perception in Noise Score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231016059744N1**

Registration date: **2023-11-08, 1402/08/17**

Registration timing: **registered_while_recruiting**

Last update: **2023-11-08, 1402/08/17**

Update count: **0**

Registration date

2023-11-08, 1402/08/17

Registrant information

Name

Maryam Sadeghijam

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2222 2059

Email address

sadeghijam.m@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-23, 1402/08/01

Expected recruitment end date

2024-05-21, 1403/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of speech perception in noise training on quality of life in chronic tinnitus sufferers

Public title

Investigating the effect of speech perception training in tinnitus management

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

People with Subjective and Chronic Tinnitus (with more than 6 months of tinnitus experience) Normal Pure Tone Hearing Threshold at Frequencies from 250 to 8000 Hz (max. dBHL25) Normal Results in Tympanometry Test (Type An)

Exclusion criteria:

Obtaining more than 11 Score in the Hospital Anxiety and Depression Scale (HADS) questionnaire History of Exposure to Occupational Noise History of any Neurological Disease (including History of Head or Neck Injury, Migraine, Multiple Sclerosis, etc.) and Otological Disease (including Otosclerosis, Meniere's, Otitis, etc.)

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **28**

Randomization (investigator's opinion)

Not randomized

Randomization description

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 Iran University of Medical Sciences

Street address

Iran University of medical Science, Next to Milad Tower, Shahid Hemmat Highway

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2023-04-26, 1402/02/06

Ethics committee reference number

IR.IUMS.REC.1402.038

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 Loudness

Timepoint

Before the intervention and one week after the end of the intervention period

Method of measurement

Visual Analogue Scale (VAS)

2

Description

Tinnitus Annoyance

Timepoint

Before the intervention and one week after the end of the intervention period

Method of measurement

Visual Analogue Scale (VAS)

3

Description

Tinnitus Handicap

Timepoint

Before the intervention and one week after the intervention period

Method of measurement

Tinnitus Functional Index (TFI) Questionnaire

4

Description

Quality of Life

Timepoint

Before the intervention and one week after the intervention period

Method of measurement

Short Form 12 (SF-12) Questionnaire

5

Description

Ability to understand speech in noise

Timepoint

Before the intervention and one week after the intervention period

Method of measurement

Quick Speech in Noise Test (Quick SIN)

6

Description

Tinnitus Psychophysical Loudness

Timepoint

Before the intervention and one week after the intervention period

Method of measurement

Loudness Matching Using an Audiometer

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: People in the intervention group receive 8 sessions of Word-in-Noise Training (WINT) along with Tinnitus Retraining Therapy (TRT) including counseling and sound therapy. TRT counseling includes explanations about the anatomy and physiology of the normal and damaged auditory system/the role of the central auditory system and higher cortical processes/explanation of Jasterboff's neurophysiological model about tinnitus/the importance of activating the subcortical, limbic and autonomic nervous systems in tinnitus and etc. Sound therapy also includes explaining the importance of sound enrichment, setting up sound generators and explaining their use, evaluating sound generators, etc. The Word-in-Noise Training consists of two tracks. The first track has 600 words in 60 subgroups of 10 words, and the other track has babbling noise of several speakers. In each session, 8 subgroups are presented in different signal-to-noise ratios in such a way that the words in the first subgroup are at the intensity level of 62 dB HL without noise, and the second subgroup with a signal-to-noise ratio of about 12+ dB and in the following subgroups, Each time the noise increases by 2 dB until the signal-to-noise ratio is zero. The duration of each session is 60 minutes, of which 30 minutes are devoted to Tinnitus Retraining Therapy and 30 minutes to Word-in-Noise Training.

Category

Treatment - Other

2

Description

Control group: People in control group receive 8 sessions of Tinnitus Retraining Therapy (TRT) including counseling

and sound therapy. Counseling includes explanations about the anatomy and physiology of the normal and damaged auditory system/the role of the central auditory system and higher cortical processes/explanation of Jasterboff's neurophysiological model about tinnitus/the importance of activating the subcortical, limbic and autonomic nervous systems in tinnitus and etc. Sound therapy also includes explaining the importance of sound enrichment, setting up sound generators and explaining their use, evaluating sound generators, etc. The duration of each session is 30 minutes.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Iran University of Medical Science School of Rehabilitation Science

Full name of responsible person

Seyyed Jalal Sameni

Street address

Madadkaran St., Shahnazari Ave., Madar Squ., Mirdamad Blvd., Tehran

City

Tehran

Province

Tehran

Postal code

1545913487

Phone

+98 21 2222 2059

Email

jsameni1@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Reza Falak

Street address

Iran University of medical Science, Next to Milad Tower, Shahid Hemmat Highway

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 8670 2504

Email

research-m@iums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Iran 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**

Iran University of Medical Sciences

Full name of responsible person

Maryam Sadeghijam

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Audiology

Street address

Madadkaran St., Shahnazari Ave., Madar Squ.,
Mirdamad Blvd., Tehran

City

Tehran

Province

Tehran

Postal code

1545913487

Phone

+98 21 2222 2059

Fax**Email**

sadeghijam.m@iums.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Maryam Sadeghijam

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Audiology

Street address

Madadkaran St., Shahnazari Ave., Madar Squ.,
Mirdamad Blvd., Tehran

City

Tehran

Province

Tehran

Postal code

1545913487

Phone

+98 21 2222 2059

Fax**Email**

sadeghijam.m@iums.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Maryam Sadeghijam

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Audiology

Street address

Madadkaran St., Shahnazari Ave., Madar Squ.,
Mirdamad Blvd., Tehran

City

Tehran

Province

Tehran

Postal code

1545913487

Phone

+98 21 2222 2059

Fax**Email**

sadeghijam.m@iums.ac.ir

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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