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 toTinnitus 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