Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Creating of Acoustic Coordinated Reset Neuromodulation Application and Investigating Its Effects on Tinnitus Handicap and Loudness Discomfort Level in Tinnitus Patients With and Without Hyperacusis

Protocol summary

Study aim
Reduction in the Intensity and Annoyance of Tinnitus and Hyperacusis Symptoms and Improvement in Disability Caused by These Disorders

Design
This Quasi-Experimental Clinical Trial Study Consisted of a Group of People with Tinnitus and a Group of People with Tinnitus and Hyperacusis. The Tinnitus Group Consisted of 18 People and the Tinnitus and Hyperacusis Group Consisted of 10 People.

Settings and conduct
this quasi-experimental clinical trial, compared the effects of three months of coordinated sound modulation therapy on tinnitus characteristics in two groups: individuals with tinnitus only and those with both tinnitus and hyperacusis. Psychoacoustic assessments and questionnaires were administered both before and after the intervention to compare the outcomes.

Participants/Inclusion and exclusion criteria
Individuals With Chronic Tinnitus and Hyperacusis؛ Hearing Thresholds Better than 40 dB؛

Intervention groups
Treatment With Acoustic Coordinated Reset Both Treatment Groups (the Tinnitus Group and the Tinnitus and Hyperacusis Group) will Undergo Sound Therapy Using the Acoustic Coordinated Reset Method for Three Months. Individuals will be Required to Listen to a Personalized Audio Piece Based on the Tinnitus Frequency for Three Hours a Day for Three Months.

Main outcome variables
Tinnitus loudness (dB SL and VAS-L)؛ Tinnitus annoyance (VAS-A)؛ scores of the THI questionnaires؛ Scores of the HQ questionnaires؛ Tinnitus Frequency

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20231016059744N2**
Registration date: **2025-11-20, 1404/08/29**
Registration timing: **retrospective**

Last update: **2025-11-20, 1404/08/29**
Update count: **0**

Registration date
2025-11-20, 1404/08/29

Registrant information
Name
Maryam Sadeghijam
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-09-04, 1403/06/14

Expected recruitment end date
2024-12-20, 1403/09/30

Actual recruitment start date
2024-09-04, 1403/06/14

Actual recruitment end date
2024-12-20, 1403/09/30

Trial completion date
2024-12-20, 1403/09/30

Scientific title
Creating of Acoustic Coordinated Reset Neuromodulation

Application and Investigating Its Effects on Tinnitus Handicap and Loudness Discomfort Level in Tinnitus Patients With and Without Hyperacusis

Public title
Investigating Effect of Acoustic Coordinated Reset on Tinnitus Handicap and Loudness Discomfort level
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Individuals must have Chronic Tinnitus (have Experienced Tinnitus for Over 6 Months) Tinnitus should be Tonal Participants Pure Tone Audiometric Thresholds can Range from Normal Hearing to Mild to Moderate Hearing Loss (Thresholds Better than 40 dB HL)
Exclusion criteria:
Individuals must not have any Neurological Disorders (History of Head Trauma, Acoustic Neuroma, MS,...) and Otologic Diseases (Meniere, Otosclerosis, Otitis,...)
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **28**
Actual sample size reached: **28**
Randomization (investigator's opinion)
N/A
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
Shahid Hemmat Highway, Iran University of Medical Sciences
City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
Approval date
2024-09-03, 1403/06/13
Ethics committee reference number
IR.IUMS.REC.1403.487

Health conditions studied

1

Description of health condition studied
Tinnitus
ICD-10 code
H93.1
ICD-10 code description
Tinnitus

2

Description of health condition studied
Hyperacusis
ICD-10 code
H93.2
ICD-10 code description
Other abnormal auditory perceptions

Primary outcomes

1

Description
Tinnitus Loudness (dB SL)
Timepoint
Measurement of Tinnitus Loudness Before the Start of the Intervention and at the End of the Three Month Treatment Period
Method of measurement
Psychoacoustic Tinnitus Measurement

2

Description
Tinnitus Loudness
Timepoint
Measurement of Index Score Before the Start of the Intervention and at the End of the Three Month Treatment Period
Method of measurement
Visual-Analogue Index of Loudness

3

Description
Tinnitus Annoyance
Timepoint
Measurement of Index Score Before the Start of the Intervention and at the End of the Three Month Treatment Period
Method of measurement
Visual Analogue Index of Annoyance

4

Description
Tinnitus Handicap Index Questionnaire Score
Timepoint
Measurement of Questionnaire Score Before the Start of the Intervention and at the End of the Three Month Treatment Period
Method of measurement
Tinnitus Handicap Index Questionnaire

5

Description
Khalfa Hyperacusis Questionnaire Score
Timepoint
Measurement of Questionnaire Score Before the Start of the Intervention and at the End of the Three Month Treatment Period
Method of measurement
Khalfa Hyperacusis Questionnaire

6

Description
Tinnitus Frequency
Timepoint
Measurement of Tinnitus Frequency Before the Start of the Intervention and at the End of the Three Month Treatment Period
Method of measurement
Psychoacoustic Tinnitus Measurement

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Individuals with Tinnitus Receiving Sound Therapy Using the Acoustic Coordinated Reset Method for Three Months and 3 Hours a Day. Acoustic Coordinated Reset Consists of Four Pure Tones Around the Individual's Tinnitus Frequency, Which are Created According to a Specific Algorithm Based on The Tonotopic Arrangement of the Auditory Cortex. This Method Consists of Three Cycles, Each of Which has Tones in a Different Order, Followed by Two Cycles of Silence or Pause, and This Pattern is Repeated. The Person with Tinnitus must Listen to This Sounds for a Certain Amount of Time Daily, and the Ultimate Goal of this Method is to Counteract Abnormal Neural Synchronization.
Category
Rehabilitation

2

Description
Intervention group 2: Individuals with Tinnitus and Hyperacusis Receiving Sound Therapy Using the Acoustic Coordinated Reset Method for Three Months. Acoustic Coordinated Reset Consists of Four Pure Tones Around the Individual's Tinnitus Frequency, Which are Created According to a Specific Algorithm Based on The Tonotopic Arrangement of the Auditory Cortex. This Method Consists of Three Cycles, Each of Which has Tones in a Different Order, Followed by Two Cycles of Silence or Pause, and This Pattern is Repeated. The Person with Tinnitus must Listen to This Sounds for a Certain Amount of Time Daily, and the Ultimate Goal of this Method is to Counteract Abnormal Neural Synchronization.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Iran University of Medical Sciences Schools of Rehabilitation
Full name of responsible person
Farnoush Jarollahi
Street address
Faculty of Rehabilitation, Madadkaran Ave., Shahnazari Ave., Madar SQ., Mirdamad Blvd, Tehran
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Email
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr. Majid Safa
Street address
Iran University of Medical Sciences (IUMS), Shahid Hemmat Highway
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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
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
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Other areas of specialty/work
Audiology
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
No more information 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