Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

"Comparing the effectiveness of cognitive-behavioral and acceptance and commitment therapies in conventional and virtual reality-based methods on reducing sound annoyance in adults with misophonia."

Protocol summary

Study aim

Development and evaluation of a multi-sensory VR-based intervention for improving sound tolerance in misophonia, assessing its effects on emotional regulation to auditory triggers, and reducing auditory avoidance while improving social functioning.

Design

Randomized, controlled, parallel-group, open-label superiority clinical trial with 32 participants. Allocation will be performed in a 1:1 ratio using block randomization (block size = 3). The randomization sequence will be generated using the Sealed Envelope online randomization service.

Settings and conduct

This is a randomized clinical trial in two phases. Phase one involves the development of a multidimensional VR-based protocol including graded sound therapy and psychophysiological regulation. In phase two, participants (18–60 years) are randomized into CBT (control) and VR-based intervention groups. Outcomes (PHQ-9, GAD-7, MQ, VAS) are assessed at multiple time points, and VR safety is monitored.

Participants/Inclusion and exclusion criteria

Inclusion: Age 18–60, normal hearing and ear exams, confirmed reduced sound tolerance (SSSQ/MQ), no major neuropsychiatric disorders, and poor response to prior treatments. Exclusion: New hearing loss, LDL <40 dB, VR intolerance (e.g., epilepsy/Meniere's), new medications, non-compliance, symptom worsening, or pregnancy.

Intervention groups

Control Group: Participants received conventional Cognitive Behavioral Therapy (CBT).Intervention Group: Participants receiving Multisensory Virtual Reality (MSVR) therapy.

Main outcome variables

MQ (Misophonia Questionnaire) ,Visual Analog Scale (VAS), GAD, PHQ-9

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231013059701N2**
Registration date: **2026-07-01, 1405/04/10**
Registration timing: **prospective**

Last update: **2026-07-01, 1405/04/10**
Update count: **0**

Registration date

2026-07-01, 1405/04/10

Registrant information

Name

Somayeh Bakhtarikia

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-07-23, 1405/05/01

Expected recruitment end date

2028-07-22, 1407/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
"Comparing the effectiveness of cognitive-behavioral and acceptance and commitment therapies in conventional and virtual reality-based methods on reducing sound annoyance in adults with misophonia."

Public title
"Comparing the effectiveness of cognitive-behavioral and acceptance and commitment therapies in conventional and virtual reality-based methods on reducing sound annoyance in adults with misophonia."

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
1. Adults aged 18–60 years. 2. Normal hearing thresholds and normal middle ear function. 3. Confirmation of decreased sound tolerance based on (SSSQ, clinical interview, and MQ). 4. Sufficient literacy to complete the study questionnaires. 5. No history of neurological disorders. 6. Inadequate response to conventional treatments during the previous six months.

Exclusion criteria:
1. Presence of specific hearing abnormalities . 2. Critically low Loudness Discomfort Levels (LDLs) . 3. History of cybersickness or intolerance. 4. Initiation of ototoxic medications or psychotropic medications. 5. Inability to comply with the study protocol. 6.Pregnancy.

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: **32**

Randomization (investigator's opinion)
Randomized

Randomization description
3.2. Randomization Method All eligible participants will be allocated equally to the intervention and control groups using a block randomization method with a fixed block size of four, ensuring a 1:1 allocation ratio throughout the study. ### 3.3. Method Used to Generate the Random Allocation Sequence The randomization sequence will be generated using the online randomization service provided by Sealed Envelope Ltd. This system will be used to create a computer-generated allocation list according to the predefined block randomization scheme.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Type of TrialThis study is designed as a **superiority randomized controlled trial (RCT)**. A superiority trial aims to determine whether a new intervention is significantly more effective than a standard treatment or control condition. In this design, the null hypothesis assumes that no difference exists between the two interventions, whereas the objective of the study is to reject the null hypothesis and demonstrate the superiority of the new intervention.Superiority trials are employed when the investigational treatment is expected to produce greater improvements in clinical outcomes compared with conventional approaches. This design is one of the most commonly used methodologies in interventional research and clinical trials.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committee of the Faculty of Nursing and Midwifery, Tehran University of Medical Scie

Street address
Tehran, Valiasr Street, before Towhid (Tavanir) intersection, corner of Bakhshandegan Alley, Arian Building, 1st floor, Unit 6

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1516745136

Approval date
2026-06-17, 1405/03/27

Ethics committee reference number
IR.TUMS.FNM.REC.1405.053

Health conditions studied

1

Description of health condition studied
Decreased sound tolerance (misophonia)

ICD-10 code
H93.2

ICD-10 code description
Other abnormal auditory perceptions (including sound intolerance disorders without a specific ICD-10 code, such as misophonia).

Primary outcomes

1

Description
Misophonia Questionnaire Score

Timepoint
The misophonia questionnaire will be administered at

baseline (pre-intervention), post-intervention (8 weeks), and at 1- and 3-month follow-ups after cognitive-behavioral therapy (CBT).

Method of measurement

Completing the Misophonia Questionnaire

Secondary outcomes

1

Description

Visual Analog Scale score

Timepoint

Sound sensitivity scores (auditory exposure) will be assessed using a Visual Analogue Scale (VAS) at baseline (pre-intervention), post-intervention (8 weeks), and at 1- and 3-month follow-ups after cognitive-behavioral therapy (CBT).

Method of measurement

Visual Analog Scale

Intervention groups

1

Description

Intervention group: Individuals with misophonia receiving Cognitive Behavioral Therapy (CBT) combined with multi-sensory virtual reality (VR) intervention in 8 weekly 60-minute sessions.

Category

Rehabilitation

2

Description

Control group: Individuals with misophonia receiving Cognitive Behavioral Therapy (CBT) intervention in 8 weekly 60-minute sessions.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Kia Audiology Clinic

Full name of responsible person

Somayeh Bakhtarikia

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Ramin Kordi

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Somayeh Bakhtarikia

Position

Doctoral (PhD) student in Audiology

Latest degree

Master

Other areas of specialty/work

Audiology

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Person responsible for scientific inquiries

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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
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All data, after being de-identified, are potentially shareable.

When the data will become available and for how long
The data access period will begin 6 months after publication of the study results.

To whom data/document is available
It will be available to researchers affiliated with academic and scientific institutions.

Under which criteria data/document could be used
Access to de-identified data is restricted to researchers affiliated with academic institutions and is subject to approval by the Research Ethics Committee. Data use is permitted solely within the scope of the approved research objectives for scientific and statistical analyses. Any commercial use or sharing with third parties is strictly prohibited. All data are provided in coded form, and confidentiality as well as adherence to research ethics principles is mandatory.

From where data/document is obtainable
Eligible applicants may submit a formal request for access to data or study documents to the principal investigator. All requests will first be reviewed by the study investigator and, if approved, will be submitted for approval by the Research Ethics Committee. Official email of the principal investigator: skia171055@gmail.com, In-person correspondence: Faculty of Rehabilitation, Tehran University of Medical Sciences, Postal address: Faculty of Rehabilitation, Tehran University of Medical Sciences, Picheh Shemiran (Enghelab Street), Tehran, Iran, Telephone: +98 21 7753 0636. For further information, direct communication with the principal investigator is also available

What processes are involved for a request to access data/document
The applicant first submits a formal request along with a

research proposal. After an initial review by the principal investigator and approval by the Research Ethics Committee, a data use agreement is signed, and the de-identified, coded data are provided. Estimated timeline:2–4 weeks, depending on the approval process.

Comments