Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Neurocognitive and Clinical Effects of a Culturally Adapted Subliminal Auditory Intervention Integrating Mindfulness and Existential Components on Suicidal Ideation in Adolescents

Protocol summary

Study aim

The aim of this study is to evaluate the clinical and neurocognitive effects of a culturally adapted subliminal auditory intervention, based on mindfulness and existential principles, on suicidal ideation and related psychological variables in Iranian adolescents.

Design

A cluster-randomized, parallel-group, double-blind, phase 2 clinical trial conducted on 600 adolescents with suicidal ideation in psychological clinics across Iran. Clinics are the unit of randomization, and the random allocation sequence is generated using computer-based random numbers in R.

Settings and conduct

This cluster-randomized study is conducted in psychological clinics across Iran. Clinics are allocated to intervention or control groups. The intervention group receives a culturally adapted subliminal audio file based on mindfulness and existential elements in 16 sessions; the control group receives a matched neutral file. Data are collected at pre-test, post-test, and 3-month follow-up. The trial is parallel and double-blind, and analyses use coded data.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Adolescents with suicidal ideation who have been screened in participating clinics. Exclusion criteria: Severe psychiatric disorders; cognitive limitations preventing participation; acute suicidal

Intervention groups

Intervention group: A culturally adapted subliminal audio file based on mindfulness and existential elements is delivered over 16 sessions, containing subliminal messages intended to reduce suicidal ideation and improve psychological variables. Control group: A neutral audio file matched in auditory features, without any subliminal or therapeutic content, used only to control expectancy and listening conditions.

Main outcome variables

suicidal ideation; rumination; anhedonia; mental health

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251116068014N1**
Registration date: **2025-11-19, 1404/08/28**
Registration timing: **prospective**

Last update: **2025-11-19, 1404/08/28**
Update count: **0**

Registration date

2025-11-19, 1404/08/28

Registrant information

Name
khatereh Arbabi
Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-11-22, 1404/09/01

Expected recruitment end date

2025-11-29, 1404/09/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Neurocognitive and Clinical Effects of a Culturally Adapted Subliminal Auditory Intervention Integrating Mindfulness and Existential Components on Suicidal Ideation in Adolescents

Public title

Examining the Effect of a Culturally Adapted Subliminal Stimulation Protocol on Suicidal Ideation in Adolescents

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Screening for eligibility through a clinical interview (conducted by a psychotherapist) and the Beck Scale (BSSI)for Suicide Ideation (with high scores indicating elevated suicidal thoughts) is administered.

Exclusion criteria:

Severe psychiatric disorders (psychosis, bipolar disorder, etc.) Acute suicide risk requiring immediate hospitalization Cognitive impairment that interferes with completing the intervention tasks

Age

From **13 years** old to **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **600**

Randomization (investigator's opinion)

Randomized

Randomization description

1. Randomization Method: This study employs cluster randomization, in which psychological clinics across Iran are considered clusters and are randomly assigned to either the Intervention group or the Control group. To maintain balance between the groups, block randomization at the cluster level will be applied. 2. Unit of Randomization: The unit of randomization is the psychological clinic. To prevent contamination between groups, all eligible adolescents within each clinic will be assigned to the same study arm. 3. Stratification Layers (if applied): This study will use stratified cluster randomization. The stratification layers include: Geographical region (north, south, east, west, central) Clinic size (low-caseload, medium-caseload, high-caseload) 4. Randomization Tools: The random allocation sequence will be generated using standard tools, including: R statistical software for computer-generated random numbers Variable block sizes to avoid predictability A researcher independent from participant recruitment will perform the randomization procedure. 5. Generation of the Random Allocation Sequence: Clinics will first be stratified based on predefined layers. A list of random numbers will then be generated using statistical software, and clinics will be assigned to blocks of 4 to 6 clusters. The allocation sequence will be generated by an independent researcher to prevent bias. 6.Allocation Concealment: To ensure proper allocation concealment: The randomization sequence will be placed in opaque, sealed, sequentially numbered envelopes. These envelopes will only be opened after the completion of baseline assessment at each clinic. The recruitment team will not have access to the allocation sequence. This method prevents prior knowledge of group assignment and reduces selection bias.

Blinding (investigator's opinion)

Double blinded

Blinding description

1. Participants: Participants are and will remain unaware of their group allocation (intervention or control). Both groups receive an audio file that is indistinguishable in terms of listening experience; therefore, participants remain blinded throughout the entire study. 2. Outcome Assessors: Outcome assessors do not and will not have access to group allocation. All data are provided to them in anonymized, coded format with no indicators of group assignment. 3. Data Collectors: Data collectors do not have access to the randomization sequence and receive all information only through participant codes. They remain blinded throughout the data collection process. 4. Principal Investigator: The principal investigator remains blinded during data collection and outcome assessment and will gain access to group allocation only after the completion of all analyses. Blinding of the principal investigator is maintained during the analysis phase. 5. Clinical Staff: Clinical staff who deliver the audio files to participants are unaware of the file type and the assigned group. Therefore, these staff members also remain blinded during the study procedures. 6. Data Safety and Monitoring Committee (DSMC): The DSMC has access only to coded, anonymized datasets. Unblinding occurs solely in the event of a serious safety concern. 7. Data Analysts and Manuscript Writers: Data analysts and manuscript authors work with fully de-identified datasets and remain blinded to group allocation until the completion of statistical analyses. Unblinding is performed only after the analysis is finalized.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Islamic Azad University, Qom Branch

Street address
No. 33, Rasoulian Ave, Zabeti St, Heravi Area, Tehran Town
City
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Province
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Postal code
1667838614
Approval date
2025-11-16, 1404/08/25
Ethics committee reference number
IR.IAU.QOM.REC.1404.129

Health conditions studied

1

Description of health condition studied
Suicidal ideation, Rumination, Anhedonia, Mental health
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Primary outcome: Suicidal ideation score on the Beck Scale for Suicidal Ideation (BSSI)
Timepoint
Measured at pre-test, post-test, and 3-month follow-up.
Method of measurement
Beck Scale for Suicidal Ideation

Secondary outcomes

1

Description
Rumination score (RRS)
Timepoint
Measured at pre-test, post-test, and 3-month follow-up.
Method of measurement
Ruminative Responses Scale(RSS)

2

Description
Anhedonia score (SHAPS)
Timepoint
Measured at pre-test, post-test, and 3-month follow-up.
Method of measurement
Snaith–Hamilton Pleasure Scale(SHAPS)

3

Description
Mental health score (MHC-SF)
Timepoint
Measured at pre-test, post-test, and 3-month follow-up.
Method of measurement
Mental Health Continuum – Short Form(MHC-SF)

Intervention groups

1

Description
Intervention Group:Participants in the intervention group will attend 16 sessions, each lasting 45 minutes. The structure of each session is as follows:• First 15 minutes (Preparation Phase): Stabilizing the baseline state through brief relaxation, focused breathing, and attention adjustment. No direct therapeutic content is delivered in this phase.• Second 15 minutes (Core Intervention): Playback of a culturally adapted subliminal audio file based on mindfulness and existential components. Specifications of the audio file include:• Layer 1: Relaxation-based background music with a steady BPM (played at approximately 60–65 dB).• Layer 2: Therapeutic subliminal messages played below the threshold of conscious awareness (under 30 dB).• Content of subliminal messages: Brief statements targeting reductions in cognitive entrapment, rumination, emotional suppression, and enhancing acceptance, cognitive flexibility, and attentional grounding.• Playback conditions: Standard headphones, quiet setting, fixed sound level.• Final 15 minutes (Post-intervention Assessment): Participants respond to a structured set of questions capturing momentary emotional responses, perceived tension, attentional state, and subjective experience following the audio exposure. This phase is used for real-time monitoring of experiential and emotional changes.
Category
Treatment - Other

2

Description
Control group: Participants in the control group will attend 16 sessions, each lasting 45 minutes. The structure of each session is as follows:• First 15 minutes (Preparation): General settling-in period including brief orientation, relaxation, and adjustment of environmental conditions. No therapeutic content is provided.• Second 15 minutes (Placebo Audio): Participants listen to a neutral audio file without any subliminal messages. The file contains only soft instrumental music with fixed volume and no cognitive or emotional therapeutic content.• Final 15 minutes (Post-session Monitoring): Participants complete brief reports assessing their momentary feelings, emotional state, concentration, and subjective listening experience. No therapeutic techniques or interventions are included.This group serves as an auditory placebo, with identical duration, structure, and environmental conditions to the intervention group.
Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Rose White Chain Clinics

Full name of responsible person
Parvaneh Rahmati Sangkar

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No. 33, Rasoulian Lane, Zabeti Street, Heravi, Tehran Town

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Tehran

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Email
ka20121979@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Rose White Chain Clinics (affiliated with Imam Khomeini Relief Foundation)

Full name of responsible person
Parvaneh Rahmati Sangkar

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Imam Khomeini Relief Foundation

Proportion provided by this source
100

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Other

Person responsible for general inquiries

Contact

Name of organization / entity
Rose White Chain Clinics (affiliated with Imam Khomeini Relief Foundation)

Full name of responsible person
khatereh Arbabi

Position
Psychotherapist

Latest degree
Ph.D.

Other areas of specialty/work
Psychology

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Person responsible for scientific inquiries

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Position
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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
Title of documents: De-identified participant data, including questionnaire results (primary and secondary outcomes) Individual participant data will be shared after removal of all identifiable and personal information. Only data related to primary and secondary outcomes, including questionnaire scores at pre-test, post-test, and 3-month follow-up, will be accessible. Raw identifiable data, audio files, or any confidential information will not be shared.
When the data will become available and for how long
Data access will begin 6 months after publication of the study results and will remain available for 5 years following publication.
To whom data/document is available
Data will be available only to researchers affiliated with accredited academic or research institutions, upon formal request and review by the study's research committee.
Under which criteria data/document could be used
Conditions for data use: Data may be used only for scientific and research purposes. A defined and approved research proposal is required. Commercial use, redistribution, or sharing with third parties is prohibited. Any attempt to identify participants or restore personal information is strictly forbidden. Access will be granted only after signing a responsible data-use agreement.
From where data/document is obtainable
Investigator using the information below: Name and position: Dr. Khatereh Arbabi (Principal Investigator) Address: No. 33, Rasoulian Lane, Zabeti Street, Heravi, Tehran, Iran Email: arbabikhatere@gmail.com Phone: +98 912 224 3889 Requests will be accepted only via email or formal written communication and data access will be granted after review by the Principal Investigator and approval of the research committee.
What processes are involved for a request to access data/document
Process for Requesting and Receiving Data: Submit a formal request to the principal investigator's email, including a brief description of the proposed research. Initial review of the request by the principal investigator (within approximately 2 weeks). Submission of the full proposal, a data-use commitment form, and documentation of institutional affiliation. Final review and approval by the research committee (within approximately 2–4 weeks). Upon approval, de-identified data will be shared with the applicant through a secure transfer method.Estimated total time for the process: 4–6 weeks.
Comments