Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effect of auriculotherapy on sleep quality, anxiety, and depression in female students living in dormitories

Protocol summary

Study aim
This study aim to determine the effect of auriculotherapy on sleep quality, anxiety, and depression in female students living in dormitories

Design
This study will be a two-group clinical trial (an experimental group and a control group with a 55 participants in each group), single-blind, in parallel, on female students living in the dormitory.

Settings and conduct
Randomization will be done using stratified block randomization. Base on field of study, participants will be placed into each strata. participants in each strata will be assigned to the control and the intervention groups using blocks of four whose sequence generate by the randomizer statistical software.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Iranian nationality, Age 18-25, First semester student, Single. Exclusion criteria: Presence of life stressors during the past three months -Having a history of severe psychiatric disorders -History of physical illnesses (migraines, ear infections) -Consumption of anti-anxiety and depressive medications, sleeping pills and sedatives, or drugs and alcoholic beverages -History of auriculotherapy treatment in the past 6 months -Those who engage in intense sports activities. Those who have online businesses or blogging pages on Telegram and Instagram

Intervention groups
The intervention group herbal seeds are placed in the intervention group, the shenmen point (right or left ear based on the assessment of the reaction site). The samples are instructed to press the seeds in a circular manner for 2-3 minutes every 8 hours (7 am, 3 pm, 11 pm). The control group the seeds are placed in an inert spot. The subjects are instructed to press the seeds in a circular motion for 2-3 minutes every 8 hours (7 am, 3 pm, 11 pm).

Main outcome variables
Mean score and severity of sleep quality, Mean score and severity of anxiety, mean score and severity of depression

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20090810002324N24**
Registration date: **2025-10-01, 1404/07/09**
Registration timing: **prospective**

Last update: **2025-10-01, 1404/07/09**
Update count: **0**

Registration date
2025-10-01, 1404/07/09

Registrant information

Name
Maryam Keshavarz
Name of organization / entity
Iran University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 21 4365 1813
Email address
keshavarz@iums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-10-18, 1404/07/26

Expected recruitment end date
2026-01-20, 1404/10/30

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of auriculotherapy on sleep quality, anxiety, and depression in female students living in dormitories

Public title
Auriculotherapy, sleep quality, anxiety, and depression in students living in dormitories
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Iranian nationality Age 18-25 First semester Single
Exclusion criteria:
Presence of life stressors during the past three months Having a history of severe psychiatric disorders Consumption of anti-anxiety and depressive medications, sleeping pills and sedatives Consumption of drugs and alcoholic beverages History of auriculotherapy treatment in the past 6 months engage in intense sports activities online businesses or blogging pages on Telegram and Instagram
Age
From **18 years** old to **25 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **110**
Randomization (investigator's opinion)
Randomized
Randomization description
Eligible students will be invited from seven girl's dormitories. Randomization will be done using stratified block randomization. Base on field of study, participants will be placed into each strata. participants in each strata will be assigned to the control and the intervention groups using blocks of four whose sequence generate by the randomizer statistical software. To prevent bias and comply with the principle of concealment, the order of allocation will be placed in sealed envelopes, and the researcher will not know the group each participant assign to until they enter the study.
Blinding (investigator's opinion)
Single blinded
Blinding description
Participants and the researcher will be aware of how individuals assign to each of the intervention and the control groups. Before and after the intervention, in order to blinding, all questionnaires will be presented and collected by a research assistant who is unaware of the allocation method and project objectives. Therefore, this study is single-blind.
Placebo
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 Sciences, next to Milad Tower, Hemmat Highway, Tehran, Iran.
City
Tehran
Province
Tehran
Postal code
1449614535
Approval date
2025-09-27, 1404/07/05
Ethics committee reference number
IR.IUMS.NURSE.REC.1404.004

Health conditions studied

1

Description of health condition studied
Sleep quality, anxiety, depression
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Mean score and severity of sleep quality
Timepoint
Before intervention and immediately after intervention
Method of measurement
Pittsburgh Sleep Quality Questionnaire (PSQI)

2

Description
Mean score and severity of anxiety
Timepoint
Before intervention and immediately after intervention
Method of measurement
Beck Anxiety Inventory (BAI)

3

Description
Mean score and severity of depression
Timepoint
Before intervention and immediately after intervention
Method of measurement
Beck's Depression Inventory (BDI-II)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: After 70% 70% alcohol, herbal seeds are placed in the intervention group, the shenmen point (right or left ear based on the assessment of the reaction site). The samples are instructed to press the seeds in a circular manner for 2-3 minutes every 8 hours (7 am, 3 pm, 11 pm) and record the frequency of the massage in a daily checklist. To ensure the correct massage method, the research samples are asked to perform the massage once in the presence of the researcher).
Category
Prevention

2

Description
Control group: Similar to the intervention group, after the ear disinfect with 70% 70% alcohol, the seeds will be placed in an inert spot. The subjects will be instructed to press the seeds in a circular motion for 2-3 minutes every 8 hours (7 am, 3 pm, 11 pm) and record the frequency of the exercise on a daily checklist
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Zahra Dormitory
Full name of responsible person
Leyla khademi
Street address
No. 63, Above Ehteshamiyeh Square, Shahid Rastavan Street, Nistan 3 , Pasdaran, Tehran, Iran.
City
Tehran
Province
Tehran
Postal code
1946614864
Phone
+98 21 2259 4440
Email
leylii.khademi@gmail.com

2

Recruitment center
Name of recruitment center
Motahari Dormitory
Full name of responsible person
Leyla khademi
Street address
No.39, Opposite the South Door of the Dutch Embassy, Hosseini Rad Alley, Larestan Street, Ostad Motahari Street, Tehran, Iran.
City
Tehran
Province
Tehran
Postal code
1595953511
Phone
+98 21 8891 2927
Email
leylii.khademi@gmail.com

3

Recruitment center
Name of recruitment center
Amol Dormitory
Full name of responsible person
Leyla khademi
Street address
No. 138, Amol Street, Opposite Pasargad Hospital, Before Taleghani Street, Shariati Street, Tehran, Iran.
City
Tehran
Province
Tehran
Postal code
1611813711
Phone
+98 21 7764 3930
Email
leylii.khademi@gmail.com

4

Recruitment center
Name of recruitment center
Ibn Sina Dormitory
Full name of responsible person
Leyla khademi
Street address
No. 2, South Shayeg, Amir Kabir Street, End of Jalal Highway.
City
Tehran
Province
Tehran
Postal code
1461614745
Phone
+98 21 4426 4111

Email
leylii.khademi@gmail.com

5

Recruitment center
Name of recruitment center
Shaghayegh Dormitory
Full name of responsible person
Leyla khademi
Street address
Opposite Turkmenistan, Before Shariati Street, End of Shahid Motahari Street.
City
Tehran
Province
Tehran
Postal code
1567618813
Phone
+98 21 8841 3378
Email
leylii.khademi@gmail.com

6

Recruitment center
Name of recruitment center
Alamdar Dormitory
Full name of responsible person
Leyla khademi
Street address
Alamdar Alley, Andarzgoo Street, Alamdar Seventh, Shahid Jahani Nasab Street, Water Organization Street, Sheikh Fadlallah Nouri Highway
City
Tehran
Province
Tehran
Postal code
1996713883
Phone
+98 21 4365 1139
Email
leylii.khademi@gmail.com

7

Recruitment center
Name of recruitment center
Golestan Dormitory
Full name of responsible person
Leyla khademi
Street address
Rehabilitation Faculty, Nezam Street, Shahid Shah Nazari Street, Madar Square, Mirdamad.
City
Tehran
Province
Tehran
Postal code
1545913487
Phone
+98 21 2225 6434
Email
leylii.khademi@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Majid safa
Street address
Iran University of Medical Sciences, next to Milad Tower, Hemmat Highway, Tehran, Iran.
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 912 573 2924
Email
MKmarkesh@gmail.com
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 Keshavarz
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Health
Street address
School of Nursing & Midwifery, Rashid Yasemi St., Valiasr St., Tehran, Iran
City

Tehran

Province
Tehran

Postal code
1996713883

Phone
+98 21 4365 1139

Email
MKmarkesh@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Maryam Keshavarz

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Reproductive Health

Street address
School of Nursing & Midwifery, Rashid Yasemi St., Valiasr St., Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1996713883

Phone
+98 21 4365 1139

Email
MKmarkesh@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Maryam Keshavarz

Position
Associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
Reproductive Health

Street address
School of Nursing & Midwifery, Rashid Yasemi St., Valiasr St., Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1996713883

Phone
+98 21 4356 1139

Email
MKmarkesh@gmail.com

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
Not applicable

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable