Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of auriculotherapy on the severity of premenstrual syndrome symptoms, anxiety and quality of life of women: Double-blind randomized clinical trial

Protocol summary

Study aim
Determining the effect of auriculotherapy on the severity of premenstrual syndrome symptoms, anxiety and quality of life in women: a double-blind clinical trial

Design
A clinical trial with a control group, with crossover groups, double-blind, randomized, on 70 patients. random.org software is used for randomization

Settings and conduct
A herbal seed is placed at each point by the researcher. The participants are instructed to press each point 3 times a day for 1 minute each time. Data collection will be conducted in 4 phases: at the start of the intervention (T1), week 5 (T2), week 9 (T3), week 13 after the start of the intervention (T4). Data collection will be performed by a research assistant who is blinded to the type of intervention.

Participants/Inclusion and exclusion criteria
Dormitory students of Torbat Heydarieh University of Medical Sciences

Intervention groups
The study design is a crossover, in which the research participants are divided into2 groups, A and B.in group A, the intervention involves auriculotherapy performed once a week for 4 weeks. In group B, the placebo group, a sham acupressure technique is applied to false auricular points once a week for 4 weeks during one menstrual cycle. after washout period, the groups are switched: group A receives the sham points pressure, and group B receives auricular acupressure on active points.

Main outcome variables
Premenstrual syndrome severity, quality of life, anxiety, stress, depression

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20241201063904N1**
Registration date: **2025-02-17, 1403/11/29**
Registration timing: **registered_while_recruiting**

Last update: **2025-02-17, 1403/11/29**
Update count: **0**

Registration date
2025-02-17, 1403/11/29

Registrant information
Name
Zahra Hosseini Haji
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 902 986 5974
Email address
zarhoseinihh@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2025-01-20, 1403/11/01
Expected recruitment end date
2025-04-09, 1404/01/20
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of auriculotherapy on the severity of premenstrual syndrome symptoms, anxiety and quality of life of women: Double-blind randomized clinical trial

Public title
Auriculotherapy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Presence of moderate to severe premenstrual syndrome according to the premenstrual syndrome instrument age 35-18 years Iranian nationality having regular menstrual cycles with equal intervals (22-35 days) no history of psychological diseases , chronic diseases and depression based on the DASS21 questionnaire no use of antidepressants, sedatives and hormonal drugs no mass, infection or scar on the external ear
Exclusion criteria:
pregnancy Diagnosis of secondary dysmenorrhea (due to causes such as cyst, fibroid or endometriosis) not attending all sessions Regular auriculotherapy (more than two absent sessions) failure to complete the premenstrual syndrome symptom registration table receiving another treatment method to improve premenstrual syndrome (medicine, herbal therapy, hormonal therapy)
Age
From **18 years** old to **35 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Care provider
- Data analyser

Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, the participants were randomly assigned to two intervention and control groups. Allocation of groups was done using random.org software. Randomization and allocation of groups was done by a person who was unaware of the groups. The interventionists and data analysts are unaware of the random assignment
Blinding (investigator's opinion)
Double blinded
Blinding description
In the present study, a double-blind methodology was employed. To ensure blinding, both the intervention implementers and the data analysts were blinded to the random allocation and group assignment of the study participants. Furthermore, the participants themselves were unaware of their group assignment and the type of intervention they received. To maintain blinding, a third party was utilized to perform group allocation and oversee the assignment process; the group codes were retained until the end of the study, following the completion of all stages.
Placebo
Not used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Torbat Heydarieh University of Medical Sciences
Street address
Mashhad- Torbat Heydarieh highway. Torbat Heydarieh University of Medical Sciences
City
Mashhad
Province
Razavi Khorasan
Postal code
9519633787
Approval date
2025-01-26, 1403/11/07
Ethics committee reference number
IR.THUMS.REC.1403.020

Health conditions studied

1

Description of health condition studied
premenstrual syndrome
ICD-10 code
F38.8
ICD-10 code description
Other specified mood [affective] disorders

Primary outcomes

1

Description
Severity of premenstrual syndrome
Timepoint
Collecting information in four time stages: the beginning of the intervention (T1), after the first cycle of the intervention (fifth week) (T2), after the second cycle of the intervention (ninth week) (T3) and follow-up one month later in the 13th week after the start of the intervention (T4)
Method of measurement
premenstrual syndrome screening questionnaire (PSST)

Secondary outcomes

1

Description
Anxiety
Timepoint
The beginning of the intervention (T1), after the first cycle of the intervention (fifth week) (T2), after the second cycle of the intervention (ninth week) (T3) and follow-up one month later in the 13th week after the start of the intervention (T4)
Method of measurement
DASS21 questionnaire

2

Description
quality of life
Timepoint
The beginning of the intervention (T1), after the first cycle of the intervention (fifth week) (T2), after the second cycle of the intervention (ninth week) (T3) and follow-up one month later in the 13th week after
Method of measurement
WHO-QOL questionnaire

Intervention groups

1

Description
Intervention group: Auriculotherapy is performed once a week for four weeks during a monthly menstrual cycle (except for seven days of menstrual bleeding), starting seven days before the start of menstrual bleeding.
Category
Treatment - Other

2

Description
Control group: The pressure of false ear points (placebo group) is performed once a week for four weeks during a menstrual cycle.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Dormitory for medical students of Torbat Heydarieh University of Medical Sciences
Full name of responsible person
Seyedeh Zahra Hoseini Haji
Street address
Next to Islamic Azad University of Torbat Heydarieh
City
Torbat Heydarieh
Province
Razavi Khorasan
Postal code
9519633787
Phone
+98 51 5242 0128
Email
zarhoseinihh@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Torbate-Heidaria University of Medical Sciences
Full name of responsible person
Mohammad Eghbali
Street address
Torbat Heydarieh University of Medical Sciences
City
Mashhad
Province
Razavi Khorasan
Postal code
9519633787
Phone
+98 51 5242 0128
Email
eghbali.msn@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Torbate-Heidaria 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
Torbate-Heidaria University of Medical Sciences
Full name of responsible person
Seyedeh Zahra Hoseini Haji
Position
Instructor
Latest degree
Master
Other areas of specialty/work
Midwifery

Street address
Torbat Heydarieh University of Medical Sciences
City
Mashhad
Province
Razavi Khorasan
Postal code
9519633787
Phone
+98 51 5242 0128
Email
zarhoseinihh@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Torbate-Heidaria University of Medical Sciences
Full name of responsible person
Mohammad Eghbali
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Torbat Heydarieh University of Medical Sciences
City
Mashhad
Province
Razavi Khorasan
Postal code
9519633787
Phone
+98 51 5242 0128
Email
eghbali.msn@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Torbate-Heidaria University of Medical Sciences
Full name of responsible person
Seyedeh Zahra Hoseini Haji
Position
Instructor
Latest degree
Master
Other areas of specialty/work
Midwifery
Street address
Torbat Heydarieh University of Medical Sciences
City
Mashhad
Province
Razavi Khorasan
Postal code
9519633787
Phone
+98 51 5242 0128
Email
zarhoseinihh@gmail.com

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
Scientific documentation: includes research articles, technical reports, and conference presentations. Research data: raw data, processed data, and meta data.
When the data will become available and for how long
Immediately after accessing the data
To whom data/document is available
Principal investigators of the study Colleagues in other institutions Judges and review authorities Magazine reviewers Complementary medicine colleagues Help of researchers Students of the University of Medical Sciences Participants in conferences and seminars Future researchers: Access after verification: Access request system
Under which criteria data/document could be used
The following are considered for access: Open Licenses / Restricted Licenses / Data Content / General Information / Sensitive data/purposes of use/scientific and research use/commercial use Assurance of attribution/crediting/compliance with laws: Local and international laws/ agreements/ partnership agreements/ technical conditions Accessibility
From where data/document is obtainable
Researchers and authors of articles: Libraries and research centers: Online databases Governmental and non-governmental organizations: Research organizations: Conferences and seminars: Document preview: Research groups
What processes are involved for a request to access data/document
Need identification: Goal definition: Identify sources: Application preparation: Submit request Application review: Get the answer: Usage and reporting: Feedback and follow-up:
Comments