Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effectiveness comparison of auriculotherapy with the cognitive therapy based on mindfulness in treatment of premenstrual syndrome in female students

Protocol summary

Summary

The aim of this study was to determine and comparison of auriculotherapy with the cognitive therapy based on mindfulness in treatment of premenstrual syndrome in female students. Inclusion criteria: female students living in dormitories University of Medical Sciences; Having two healthy ears (for auriculotherapy); no history or treatment of disorders like depression or anxiety; eating disorders; anemia; thyroid disease; diabetes; lack of birth control pills for medical reasons; Not taking any herbal medicine and effective treatment of premenstrual syndrome; Not treated with drugs; mental disorders and other non-pharmacological methods; Having at least 30% increase in severity of symptoms within 5 days before menstruation; Non-participation in another related study until the completion of the current study period. Exclusion criteria: Premenstrual Dysphonic disorder. Research community: Girls with premenstrual syndrome. The sample size in this Clinical trial is 84 girls will be elected with sampling targeted among students who counting inclusion criteria and randomized allocated into three groups by computer randomly. Data will be collected for pre-test, post-test, So that Premenstrual syndrome screening tool will be completed by the research units in three groups, in the first session before the intervention, at the end of week eight and the twelfth week after the start of the study. Follow-up sessions will be done by the researcher with the consent of the subjects via SMS.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017051330897N2**
Registration date: **2017-06-27, 1396/04/06**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2017-06-27, 1396/04/06

Registrant information

Name

Batoul Ghaedamini

Name of organization / entity

Shahid Sadoughi University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 38 3338 3821

Email address

bghamini@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Shahid Sadoughi University of Medical Science

Expected recruitment start date

2016-04-17, 1395/01/29

Expected recruitment end date

2016-12-20, 1395/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness comparison of auriculotherapy with the cognitive therapy based on mindfulness in treatment of premenstrual syndrome in female students

Public title

The effectiveness comparison of auriculotherapy with the cognitive therapy based on mindfulness in treatment of premenstrual syndrome in female students

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: female students living in dormitories University of Medical Sciences; Having two healthy ears (for auriculotherapy); no history or treatment of disorders like depression or anxiety; eating disorders; anemia; thyroid disease; diabetes; lack of birth control pills for medical reasons; Not taking any herbal medicine and effective treatment of premenstrual syndrome; Not treated with drugs; mental disorders and other non-pharmacological methods; Having at least 30% increase in severity of symptoms within 5 days before menstruation; Non-participation in another related study until the completion of the current study period.
Exclusion criteria: Premenstrual dysphoric disorder.

Age
From **18 years** old to **35 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **84**

Randomization (investigator's opinion)
Randomized

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
Shahrekord University of Medical Sciences

Street address
Ayatollah Kashani Avenue, Shahrekord

City
Shahrekord

Postal code
8815713471

Approval date
2016-04-11, 1395/01/23

Ethics committee reference number
IR.SKUMS.REC.1394.321

Health conditions studied

1

Description of health condition studied
Premenstrual syndrome

ICD-10 code
F50

ICD-10 code description
Eating disorders

2

Description of health condition studied
Premenstural Syndrome

ICD-10 code
F51

ICD-10 code description
Nonorganic sleep disorders

3

Description of health condition studied
Premenstural Syndrome

ICD-10 code
F54

ICD-10 code description
Psychological and behavioural factors associated with disorders or diseases classified elsewhere

4

Description of health condition studied
Premenstural Syndrome

ICD-10 code
F59

ICD-10 code description
Unspecified behavioural syndromes associated with physiological disturbances and physical factors

Primary outcomes

1

Description
Premenstrual syndrome

Timepoint
Before the intervention, after intervention and one month after intervention

Method of measurement
Premenstrual syndrome screening tool

Secondary outcomes

empty

Intervention groups

1

Description
The first group (intervention): Perform 8 Sessiones of

Auriculotherapy once a week, stimulate pointes of both ears for 5 to 15 seconds by (Excel Pointer) at every meeting. After Auriculotherapy in each session, put seed on points for 2 to 3 days on the ears and recommend, press seed every 2 hours for 1-2 minutes.

Category

N/A

2

Description

The second group (intervention): Perform 8 sessions of Mindfulness based cognitive behavioral therapy once a week for 90-120 minutes.

Category

N/A

3

Description

Control group: Before intervention, Week Eight and The twelfth week after the intervention, Will be completed the screening tool premenstrual syndrome. this group will not receive any intervention. but the effectiveness of each interventions, after the end of the study, at The twelfth week If them want, will be given the necessary training.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Sisters Dorm of Shahrekord University of Medical Sciences

Full name of responsible person

Batoul Ghaedamini

Street address

Residences Shahrekord University of Medical Sciences, Rahmatieh, Shahrekord

City

Shahrekord

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research of Shahid Sadoughi University of Medical Science

Full name of responsible person

Mojgan Sharify

Street address

School of Nursing and Midwifery, Boualli Sina Alley, Teamsar Fallahi Street, Safaieh, Yazd

City

Yazd

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for Research of Shahid Sadoughi University of Medical Science

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

shaheid sadoughi University of Medical Sciences

Full name of responsible person

Btoul ghaeidamini

Position

MAS Student of Midwifery Counseling

Other areas of specialty/work

Street address

School Nursing of and Midwifery, Boualli Sina Alley, Teamsar Fallahi Street, Safaieh, Yazd

City

yazd

Postal code

Phone

+98 35 3824 1751

Fax

Email

bghamini@yahoo.com; bghamini@ssu.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Dr Tahmineh Farajkhoda

Position

PHD in reproductive health

Other areas of specialty/work

Street address

School of Nursing and Midwifery, Boualli Sina Alley, Teamsar Fallahi Street, Safaieh, Yazd

City

yazd

Postal code

Phone

+98 35 3824 1751

Fax

Email
farajkhoda_t@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Shahid Sadoughi University of Medical Sciences
Full name of responsible person
batoul ghaeidamini
Position
MAS Student of Midwifery Counseling
Other areas of specialty/work
Street address
School of Nursing and Midwifery, Boualli Sina Alley, Teamsar Fallahi Street, Safaieh, Yazd
City
Yazd
Postal code
Phone
+98 913 980 3861
Fax
Email
bghamini@yahoo.com; bghamini@ssu.ac.ir
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty