

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 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

Premenstrual Syndrome

ICD-10 code

F51

ICD-10 code description

Nonorganic sleep disorders

3

Description of health condition studied

Premenstrual 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

Premenstrual 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 Sessions of

Auriculotherapy once a week, stimulate points 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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Dr Tahmineh Farajkhoda

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Full name of responsible person

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Position

MAS Student of Midwifery Counseling

Other areas of specialty/work**Street address**

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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