

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparison of the effect of foot reflexology and cognitive-behavioral therapy on symptoms of premenstrual syndrome in female students

Protocol summary

Study aim

Comparison of the effect of foot reflexology and cognitive behavioral therapy on symptoms of premenstrual syndrome in female students

Design

The sampling method is available and based on entry and exit criteria until the sample size is completed. Allocation of samples in the studied groups is done by random block method. The sample size was calculated based on the study of Başoğlu et al. 36 people in each group. Taking into account the possibility of a 10% sample drop, the final volume in each group was estimated to be 40 people. This research will be conducted as a randomized clinical trial with three groups in parallel.

Settings and conduct

This research will be conducted as a randomized clinical trial with three parallel groups. The research environment is the dormitories of Lorestan University of Medical Sciences in Khorramabad city. The studied population is female students of Lorestan University of Medical Sciences. After receiving the approval from the university's ethics committee, the researcher will provide the students with the PSST questionnaire form according to the entry criteria, in order to complete and diagnose the presence of PMS symptoms. This questionnaire is completed by students for two consecutive cycles before the start of the study, and based on the scores obtained in the questionnaire, people with moderate to severe PMS symptoms are placed in three study groups. No intervention is performed in the control group. The intervention groups undergo training and intervention for 8 weeks.

Participants/Inclusion and exclusion criteria

The samples of this study will be selected from the students who have moderate to severe symptoms according to the Premenstrual Symptoms Screening Questionnaire (PSST) and other inclusion criteria.

Intervention groups

foot reflexology cognitive behavioral therapy Control

Main outcome variables

Severity of premenstrual syndrome symptoms

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230509058131N1**

Registration date: **2023-05-18, 1402/02/28**

Registration timing: **registered_while_recruiting**

Last update: **2023-05-18, 1402/02/28**

Update count: **0**

Registration date

2023-05-18, 1402/02/28

Registrant information

Name

Hanieh Barimani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3360 0613

Email address

cchangavi.f@lums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-10, 1402/02/20

Expected recruitment end date

2023-11-11, 1402/08/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of the effect of foot reflexology and cognitive-behavioral therapy on symptoms of premenstrual syndrome in female students

Public title
foot reflexology and CBT on PMS

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
 Regular menstrual cycle (21-35 days) The presence of moderate to severe symptoms based on the PSST questionnaire from two cycles before entering the study
 Living in a dormitory Being single Absence of symptoms of depression and anxiety based on the Dass_21 questionnaire Not having special diets (vegetarianism, etc.) Not having a physical education unit in the current semester
Exclusion criteria:

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
Allocation of samples in study groups is done by random block method. In order to equalize the distribution of premenstrual syndrome severity, a class is created based on this variable as severe/moderate, and then by Block Randomization, and using the R software Blockrand package in 3 study groups in a balanced way. After the random sequence is determined by the epidemiologist, the researcher will identify and inform the epidemiologist of the female students who meet the criteria for entering the study, and the people will be divided into 3 control groups, reflexology groups based on the random sequence determined. Foot and cognitive behavioral therapy will be included.

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

Ethics committee of Lorestan University of Medical Sciences

Street address

lorestan university of medical science, khorramabad

City

khorramabad

Province

Lorestan

Postal code

6816979151

Approval date

2023-05-06, 1402/02/16

Ethics committee reference number

IR.LUMS.REC.1402.042

Health conditions studied

1

Description of health condition studied

premenstrual syndrome

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Severity of premenstrual syndrome symptoms

Timepoint

before the start of the intervention and immediately after it and months 1 and 2

Method of measurement

PSST screening questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: foot reflexology

Category

Other

2

Description

Intervention group: cognitive behavioral therapy

Category

Behavior

3

Description

Control group: no intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Goldis dormitory

Full name of responsible person

Hanieh Barimani

Street address

goldis apartment, naser khosro st

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Khorramabad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hanieh Barimani

Full name of responsible person

Hanieh Barimani

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hanieh Barimani

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

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Khoram-Abad University of Medical Sciences

Full name of responsible person

Hanieh Barimani

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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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

all data

When the data will become available and for how long

One year after the publication of the article

To whom data/document is available

Researchers and students

Under which criteria data/document could be used

Researchers and students

From where data/document is obtainable

Researcher

What processes are involved for a request to access data/document

Send the request to the researcher

Comments