Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jul 2026

Comparison of the effect of foot reflexology and cognitive-behavieral 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 Başoğul 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 symptomes 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)

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+98 11 3360 0613

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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-behavieral 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 dormity
Full name of responsible person
Hanieh Barimani
Street address
goldis apartment, naser khosro st
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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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