Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of Ocimum Basilicum leaf extract on the symptoms of Premenstrual Syndrome in the female university students

Protocol summary

Study aim
Determining the effect of basil leaf extract on premenstrual syndrome symptoms in female students

Design
the randomized clinical controled trial, triple-blind, on 128 patients, and SPSS 22 statistical software will be used for data analysis.

Settings and conduct
Location: Dormitories in Khorramabad-Lorestan In the experimental group, basil capsules and in the control group, placebo will be consumed once a night, at 9-10 p.m., one to two hours before bedtime and with a glass of water, from 7 days before the start of menstrual bleeding until the third day of menstruation for 2 consecutive cycles. Neither the patient nor the person evaluating the patient will know what medication has been received. Also, the data analyst will be blind to the grouping.

Participants/Inclusion and exclusion criteria
Entry criteria: 18-35 years of age single having PMS symptoms based on PSST Iranian residing in the dormitory having regular menstrual cycles Exclusion criteria: having a record of regular physical exercise consuming alcohol, narcotics, or smoking occurrence of menstrual disorders having a history of underlying conditions leading to PMS taking any type of drug regularly using therapeutic measures to prevent premenstrual problems having undergone an adverse experience or a disaster being stressed, anxious or depressed as indicated by DASS21 having a history of ovarian cyst or gynecological surgeries sensitivity to basil extract not taking basil capsules for two consecutive days being on a special diet

Intervention groups
The intervention group will receive a 250 mg basil capsule daily for two cycles, 7 days before the onset of menstruation until 3 days after menstrual bleeding. The control group will receive the placebo capsule during this time and under the same conditions.

Main outcome variables
Symptoms of premenstrual syndrome

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20250308064992N1**
Registration date: **2025-04-08, 1404/01/19**
Registration timing: **prospective**

Last update: **2025-04-08, 1404/01/19**
Update count: **0**

Registration date
2025-04-08, 1404/01/19

Registrant information
Name
Negin Rashti
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 61 4252 8986
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2025-04-21, 1404/02/01
Expected recruitment end date
2025-09-23, 1404/07/01
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of Ocimum Basilicum leaf extract on the symptoms of Premenstrual Syndrome in the female university students

Public title
The effect of Ocimum Basilicum on Premenstrual Syndrome

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
18-35 years of age single having PMS symptoms based on PSST questionnaire Iranian residing in the dormitory having regular menstrual cycles

Exclusion criteria:
having a record of regular physical exercise consuming alcohol, narcotics, or smoking Occurrence of menstrual disorders having a history of underlying conditions leading to PMS taking any type of drug regularly using therapeutic measures to prevent premenstrual problems having undergone an adverse experience or a disaster being stressed, anxious or depressed as indicated by DASS21 test having a history of ovarian cyst or gynecological surgeries sensitivity to basil extract during the study not taking basil extract capsules for two consecutive days being on a special diet

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

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **128**

Randomization (investigator's opinion)
Randomized

Randomization description
The sampling method is accessible and based on the study entry criteria. In this way, after obtaining written consent from the samples, people are assigned to intervention and control groups using block random allocation method and blocks of 4. By using this method, it can be ensured that an equal number of participants enter the intervention and control groups in consecutive time intervals. Entry of people into each of the groups is done according to the number of selected blocks and the arrangement inside the block. For blocks of 4, six modes are considered as follows, and the said blocks will be used approximately 6 times so that the final sample size is allocated to two treatment and intervention groups: 1. TTCC 2. TCTC 3. TCCT 4. CCTT 5. CTCT 6. CTTC All assessments and interventions will be conducted by the primary investigator, who is unaware of the group randomization.

Blinding (investigator's opinion)
Triple blinded

Blinding description
The drug (basil) and the placebo are placed in the same packaging and envelopes coded by a trained midwife with 2 codes (code A for basil capsule and code B for placebo), which are similar in shape and size. Neither the patient nor the person evaluating the patient will know what medication has been received. Also, the data analyst will be blind to the grouping.

Placebo
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
Headquarters of Lorestan University of Medical Sciences, Anoushirvan Rezaei Square, Moalem St.

City
Khorramabad

Province
Lorestan

Postal code
8197978133

Approval date
2025-03-08, 1403/12/18

Ethics committee reference number
IR.LUMS.REC.1403.498

Health conditions studied

1

Description of health condition studied
Premenstrual syndrome

ICD-10 code
N94.3

ICD-10 code description
Premenstrual tension syndrome

Primary outcomes

1

Description
severity of premenstrual syndrome

Timepoint
Symptom severity will be measured before the study,

one and two cycles after the study.

Method of measurement

The Premenstrual Symptoms Screening Tool

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group will receive a 250 mg basil capsule daily for two cycles, 7 days before the onset of menstruation until 3 days after menstrual bleeding.

Category

Treatment - Drugs

2

Description

The Control group will receive a 250 mg placebo capsule daily for two cycles, 7 days before the onset of menstruation until 3 days after menstrual bleeding.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Lorestan University of Medical Sciences dormitories

Full name of responsible person

Negin Rashti

Street address

Department of midwifery, faculty of nursing and midwifery, Pardis Medical Campus, Kamalvand, Khorramabad, Lorestan, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Khoram-Abad University of Medical Sciences

Full name of responsible person

Bahram Kamarei

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Department of midwifery, faculty of nursing and midwifery, Pardis Medical Campus, Kamalvand, Khorramabad, Lorestan, Iran

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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

Khoram-Abad 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

Khoram-Abad University of Medical Sciences

Full name of responsible person

Soheila Pirdadeh Beiranvand

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Latest degree
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Other areas of specialty/work
Midwifery

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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available