Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effectiveness of self regulation training based on Leventhal's model on the severity of premenstrual syndrome symptoms in nursing students

Protocol summary

Study aim
Determining the effect of self-regulation training based on the Leventhal model on the severity of Premenstrual Syndrome (PMS) Symptoms

Design
A randomized controlled clinical trial will be conducted on 78 nursing students, who will be randomly allocated to intervention and control groups using computer-generated randomization with a 1:1 allocation ratio

Settings and conduct
This study is conducted at the School of Nursing and Midwifery, Tehran Islamic Azad University of Medical Sciences. Seventy-eight students are randomly allocated to intervention and control groups using computer-generated randomization (1:1). The intervention group receives Leventhal’s self-regulation training, while the control group receives no education. Data are collected at baseline, immediately post-intervention, and 8 weeks later.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Regular menstrual cycles during the past 6 months; being single; presence of moderate to severe PMS ; normal Body Mass Index Exclusion criteria: History of gynecological diseases; diagnosed psychiatric disorders; use of psychiatric medications; alcohol or tobacco use; presence of vaginal infection; and exposure to major stressful life events (e.g., death of a close relative) within the past three months.

Intervention groups
The intervention group will receive Leventhal’s self-regulation training in four weekly 60-minute sessions, while the control group will not receive any training. The content of the sessions includes introducing illness perceptions, identifying and modifying maladaptive beliefs, teaching emotion regulation, practicing coping skills, and designing an individualized symptom - management plan.

Main outcome variables
Severity of premenstrual syndrome

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20251214068337N1**
Registration date: **2026-03-28, 1405/01/08**
Registration timing: **registered_while_recruiting**

Last update: **2026-03-28, 1405/01/08**
Update count: **0**

Registration date
2026-03-28, 1405/01/08

Registrant information

Name
maryam Farmahini Farahani

Name of organization / entity

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-02-14, 1404/11/25

Expected recruitment end date
2027-06-19, 1406/03/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effectiveness of self regulation training based on Leventhal's model on the severity of premenstrual syndrome symptoms in nursing students

Public title
The effectiveness of Leventhal model self regulation on the severity of premenstrual syndrome symptoms
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Having a regular menstrual cycle in the last 6 months unmarried (single status) Presence of moderate to severe premenstrual syndrome (PMS) symptoms Normal Body Mass Index (BMI) Access to a smartphone and the internet (for following)
Exclusion criteria:
History or presence of gynecological diseases or previous gynecological surgery Diagnosis of psychiatric disorders Use of sedative or psychotropic medications Alcohol consumption or tobacco use Presence of vaginal infection Exposure to severe stressful life events (e.g., death of a close family member) within the past three months
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: **78**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants will be randomly assigned to the intervention and control groups using a simple randomization method with a 1:1 allocation ratio. To generate the random sequence, a numbered list of potential participants will first be created. Then, a random number will be generated for each participant using the RAND function in Microsoft Excel. After generating the random numbers, the list will be sorted in ascending order, and based on the new order, participants will be alternately assigned to the intervention and control groups to maintain a 1:1 allocation ratio. To ensure allocation concealment, codes will be prepared and placed in opaque, sealed, sequentially numbered envelopes. After confirming the eligibility of each participant, the researcher will open the next envelope in sequence and assign the participant to the group indicated by the code inside the envelope (intervention or control)
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
This study consists of two groups: an intervention group and a control group. Only participants in the intervention group will receive the educational intervention

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of the Faculty of Medicine, Tehran Islamic Azad University of Medical Sciences
Street address
Third Floor, Research and Technology Office, Headquarters Building, Islamic Azad University of Medical Sciences, Tehran, Corner of Gol Yakh Street, Ayeneh Boulevard, Amir Pabarja Street, Gholhak Junction, Dr. Shariati Street, Tehran, Iran
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Tehran
Province
Tehran
Postal code
1949635881
Approval date
2025-11-17, 1404/08/26
Ethics committee reference number
IR.IAU.TMU.REC.1404.399

Health conditions studied

1

Description of health condition studied
pre menstrual syndrome
ICD-10 code
N94.3
ICD-10 code description
Premenstrual tension syndrome

Primary outcomes

1

Description
Severity score of premenstrual syndrome symptoms in the Siah bazi questionnaire
Timepoint
The severity of premenstrual syndrome is measured at baseline before the training, immediately after the training, and 8 weeks after the completion of the training
Method of measurement
Premenstrual Symptoms Screening Tool (Siah bazi)

Secondary outcomes

empty

Intervention groups

1

Description
The intervention group will receive group-based training based on Leventhal's Self-Regulation Model in four weekly sessions, each lasting 60–90 minutes. The content of the training sessions will include introduction to illness perception, identification and modification of maladaptive beliefs related to Premenstrual Syndrome (PMS), cognitive restructuring, emotion regulation training, bodily awareness, practice of coping skills, and development of an individualized PMS symptom management plan. The sessions will be conducted by the researcher. In addition to receiving the training, participants will be assigned homework, including daily symptom monitoring, relaxation exercises, and implementation of a self-care plan. .

Category
Lifestyle

2

Description
Control group: The control group will not receive any educational intervention during the study period. After the completion of data collection, a single intensive educational session will be offered to them if they wish to participate

Category
Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
School of Nursing and Midwifery, Tehran Islamic Azad University of Medical Sciences

Full name of responsible person
Fatemeh Habashi

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Farhangegan Hospital, Hesarak direction, University Square, North end of Shahid Sattari Highway, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University

Full name of responsible person
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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
Islamic Azad University

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
Islamic Azad University

Full name of responsible person
Maryam Farmahini Farahani

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Reproductive Health

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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