

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The study of the effect of Emotion-Focused Therapy on premenstrual syndrome in First year undergraduate students residing in Shaghayegh dormitory's Shahrood University of Medical Sciences.

Protocol summary

Summary

(1) Objectives: o Determine the effect of Emotion-Focused Therapy on premenstrual syndrome. • Determination of mean score of PMS and mean score of general health in control group and intervention group before intervention, immediately after the intervention, 3 months after the intervention. (2) design: parallel, two groups, randomized, uncorrected, uncontrolled with medication, single-center, two-stage trials. (3) Population studied: First year undergraduate students residing in Shaghayegh dormitory's Shahrood University of Medical Sciences. (4) Method: Starting from 1/8/96 to 9/1/96. Evaluation before intervention, immediately after the end of the intervention and 3 months after the end of the intervention. (5) Instruments: Demographic Questionnaire, Premenstrual Symptoms Screening Tool (PSST), General Health Questionnaire (GHQ). (6) major Inclusion criteria: Confirmation of premenstrual syndrome by acquiring the PSST questionnaire. (7) major exclusion criteria: (7) major exclusion criteria : pharmaceutical and non-pharmaceutical treatments; history or affection chronic diseases;Incidents of unpleasant during the 3 months prior to the start of the study;Being absent more than one meeting. (8) Sample size: 50 persons in the intervention group .50 persons in the control group. (9) Interventions: 4 weekly sessions - 90 minutes. Provide information on the purpose of the study. Anatomy of the female reproductive system. Different stages of preterm delivery. Stress Management Training. Replacing Desirable Behavior Reviewing the Objectives of Answering Questions and Uncertainties. (10) Outcome: Primary outcome: Determine the mean score PMS in both groups immediately after the intervention and 3 months after the intervention. Secondary Outcome: Determining the mean of general health in both groups immediately after the intervention and 3 months after the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017082935980N1**

Registration date: **2017-09-27, 1396/07/05**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-09-27, 1396/07/05

Registrant information

Name

Zohreh Asghari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3239 2774

Email address

asghari.z@shmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Governmental

Expected recruitment start date

2017-10-07, 1396/07/15

Expected recruitment end date

2017-11-06, 1396/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The study of the effect of Emotion-Focused Therapy on premenstrual syndrome in First year undergraduate students residing in Shaghayegh dormitory's Shahrood University of Medical Sciences.

Public title

the effect of Emotion-Focused Therapy on premenstrual syndrome.

Purpose

Supportive

Inclusion/Exclusion criteria

major Inclusion criteria: First year undergraduate students residing in dormitory; Confirmation of premenstrual syndrome by acquiring a PSST questionnaire; Satisfaction to participate in the study; Being Iranian; Being Single; Resident living in dormitory; Normal menstruation at least 4 to 8 cycles in the last 6 months. major exclusion criteria: Regular exercise during the 3 months prior to the start of the study and at the time of study (membership in the sports teams of the province and Participate in regular exercise programs at least three times a week or more for at least 30 minutes); Have a specific diet (vegetarianism, raw food, Hydrotherapy). Drug; Herbal medicine and non-pharmacological treatments (relaxation exercises, yoga, acupuncture, medication) to improve premenstrual problems during the 3 months prior to the start of the study; history or affection chronic diseases, asthma, diabetes, hypertension, epilepsy, Migraine, Thyroid disorders, anemia, cardiovascular disease, Respiratory and Renal Diseases, Neuropsychiatry); Incidents of unpleasant (such as the death of one of the first-degree relatives, severe family disputes, and severe family financial problems) during the 3 months prior to the start of the study; Being absent more than one meeting; acquaintance with Life Skills.

Age

No age limit

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 100

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

So far, in Iran, the study on the effect of Emotion-Focused Therapy on premenstrual syndrome has not been done and this approach has been used only in couple relationships.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Shahrood University of Medical Sciences

Street address

Central building of Shahrood University of Medical Sciences, 7'th Tir square, Shahrood.

City

Shahrood

Postal code**Approval date**

2017-07-19, 1396/04/28

Ethics committee reference number

IR.SHMU.REC.1396.65

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**

Determine the mean score PMS in both groups

Timepoint

Before the intervention, immediately after the intervention and 3 months after the intervention

Method of measurement

Screening Scale for Premenstrual Symptoms (PSST)

Secondary outcomes**1****Description**

Determine the mean score of general health in both groups

Timepoint

Before the intervention, immediately after the intervention and 3 months after the intervention

Method of measurement

General Health Questionnaire (GHQ)

Intervention groups

1

Description

Intervention in the interventional group: Four sessions of group training in four consecutive weeks will be set up for 90 minutes with lecture, question and answer and group discussions. 1. The content of the first session will include providing the necessary information on the study and its objectives, providing the necessary training in the description of the female reproductive system, definition of premenstrual syndrome and its causes. 2. At the second session, emotions, emotions and psychological symptoms will be discussed about premenstrual syndrome. 3. The content of the third session will be stress management, coping with stress, avoiding unnecessary stress and replacing situations and accepting things that can not be changed. 4. At the fourth session, the assignments will be reviewed and the answers to questions and uncertainties will be discussed in a lecture, group discussion and question and answer.

Category

Behavior

2

Description

Interventions in the control group: Four sessions of group training on the topic of genitourinary tract infections in women, will be set up for a period of 90 minutes with lecture, question and answer methods and group discussion.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shaghayegh dormitory's Shahrood University of Medical Sciences

Full name of responsible person

Taheri Atefeh

Street address

Shaghayegh dormitory, next to the first door of the army garrison, Shahid Motahari Boulevard.

City

Shahrood

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shahrood University of Medical Sciences

Full name of responsible person

Mohammad Hasan Emamian

Street address

Central building of Shahrood University of Medical Sciences, 7th Tir square, Shahrood.

City

SHahrood

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, Shahrood University of Medical Sciences

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

Shahrood University of Medical Sciences

Full name of responsible person

Payam Azadeh

Position

IT expert

Other areas of specialty/work

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Zohreh Asghari

Position

master's student in midwifery counseling

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity Shahroud University of Medical Sciences
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Position Bachelor of Midwifery
Other areas of specialty/work
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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