

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

Effects of Cognitive- Behavioral Therapy on Health Related Quality of Life of Females with Premenstrual Syndrome

Protocol summary

Summary

Objectives: The purpose of this study is to investigate the effects of Cognitive- Behavioral Therapy on health related quality of life in female students of Shahid Chamran University with premenstrual syndrome.

Design: The design of the study is pre and posttest with control group. Participants including major eligibility criteria: The sample of the study will consist of 40 students with PMS whom were randomly, and according to inclusion criteria, assigned to an intervention or a control group. Inclusion criteria consist of having regular menstrual cycles (24-35days); do not taking hormonal, psychotropic, vitamins, oral contraceptives at the time; not being pregnant or lactating; not experiencing stressors such as marriage, surgery, death of relatives, and etc. during the previous three months; not being under any kind of treatment to relieve the symptoms during the study and not having internal, gynecological, and psychiatric disorders. Exclusion criteria are absence of the above conditions. **Intervention:** Participants in the intervention group will receive 10 sessions of Cognitive-Behavioral Therapy. Women in control group will not receive any intervention. **Main outcome measures (variables):** Primary outcome measure is health related quality of life. The scale for assessing health related quality of life will be administered on both groups at pretest, posttest, and the follow-up stages (2 months after the treatment).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015062822960N1**

Registration date: **2015-10-21, 1394/07/29**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-10-21, 1394/07/29

Registrant information

Name

Maryam Izadi-Mazidi

Name of organization / entity

Shahed University

Country

Iran (Islamic Republic of)

Phone

+98 917 134 6040

Email address

m.izadi@shahed.ac.ir

Recruitment status

Recruitment complete

Funding source

Vicechancellor for research, Shahid Chamran University of Medical Sciences

Expected recruitment start date

2015-07-31, 1394/05/09

Expected recruitment end date

2016-07-30, 1395/05/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Cognitive- Behavioral Therapy on Health Related Quality of Life of Females with Premenstrual Syndrome

Public title

Effect of Cognitive Behavioral Therapy on premenstrual syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: having regular menstrual cycles (24-35days); do not taking hormonal, psychotropic, vitamins, oral contraceptives at the time; not being pregnant or lactating; not experiencing stressors such as marriage, surgery, death of relatives, and etc. during the previous three months; not being under any kind of treatment to relieve the symptoms during the study and not having internal, gynecological, and psychiatric disorders. Exclusion criteria: Absence of the above conditions.

Age

No age limit

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 40

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

.....

Secondary trial Id

.....

Registration date

2017-11-21, 1396/08/30

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Chamran University of Medical Sciences

Street address

Department of education and graduate, Shahid Chamran University, Golestan, Ahvaz city, Khozestan province

City

Ahvaz

Postal code

Approval date

2011-01-19, 1389/10/29

Ethics committee reference number

No:2030778

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

Health Related Quality of Life

Timepoint

Before intervention, 70 days after the start of intervention, 2month after the end of intervention

Method of measurement

Health Related Quality of Life Questionaire

Secondary outcomes

1

Description

Premenstrual Syndrome

Timepoint

before intervention, 70 days after the start of intervention, 2 month after the end of intervention

Method of measurement

Daily Record of Severity of Problems

Intervention groups

1

Description

Intervention group: Participants in the intervention group, will receive ten weekly 90-minute group cognitive-behavioral therapy sessions (each session, 90 minutes). The intervention will consist of relaxation, PMS attribution training, challenging beliefs, stress management, education on diet and problem solving.

Category

Treatment - Other

2

Description

control group: The subjects of control group received no interventions until the end of the study

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Chamran University

Full name of responsible person

Maryam Izadi-Mazidi

Street address

Shahid Chamran University of Medical Sciences,
Golestan, Ahvaz city, Khozestan province

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vicechancellor for research, Shahid Chamran
University of Medical Sciences

Full name of responsible person

Ebrahim Hajidavalloo

Street address

Vicechancellor for research, Shahid Chamran
University, Golestan, Ahvaz city, Khozestan province

City

Ahvaz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vicechancellor for research, Shahid Chamran 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

Shahed University

Full name of responsible person

Maryam Izadi-Mazidi

Position

PhD student of clinical psychology

Other areas of specialty/work**Street address**

Shahed University, In front of Behesht-e Zahra,

Persian Gulf Freeway, Tehran, Iran

City

Tehran

Postal code

3319118651

Phone

+98 215121362

Fax**Email**

Maryam.izadi.psy@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahed University

Full name of responsible person

Maryam Izadi-Mazidi

Position

PhD student of clinical psychology

Other areas of specialty/work**Street address**

Shahed University, In front of Behesht-e Zahra,
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Web page address

Person responsible for updating data

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Web page address

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