

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

The effect of mindfulness-based cognitive behavioral treatment on premenstrual syndrome

Protocol summary

Summary

The purpose of this study is to recognize the effectiveness of mindfulness-based cognitive-behavioral therapy on premenstrual syndrome (PMS). This study, as a clinical design, is carried on 40 women with PMS. Inclusion criteria are: Women 18- 35 years old; Availability during the next 6 months; Scale score between 33-64 of the premenstrual syndrome; being single .And exclusion criteria are: Cases diagnosed mental illness ;Addiction to alcohol, drugs and other psychotropic drugs ;The absence of more than three days; Studying counseling and psychology. Data are analyzed using questionnaire of premenstrual syndrome. As the necessary score is obtained through questionnaires, women are divided randomly into two experimental and control groups (20 in each group (. The intervention group receives 8 weeks 1-hour sessions for mindfulness-based cognitive-behavioral counseling conducted by researcher. After the end consultation and one month later, both groups reassess using questionnaire of Premenstrual Syndrome. The primary outcome of this study is to improve the symptoms of premenstrual syndrome in women in experimental group based on questionnaire score.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016110630750N1**
Registration date: **2016-12-09, 1395/09/19**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-12-09, 1395/09/19

Registrant information

Name

Saeedeh Askari

Name of organization / entity

Ahwaz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 84 3362 4173

Email address

askari.s@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor For Research Of Ahwaz Jundishapur University of Medical Sciences

Expected recruitment start date

2016-10-21, 1395/07/30

Expected recruitment end date

2016-12-20, 1395/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of mindfulness-based cognitive behavioral treatment on premenstrual syndrome

Public title

The effect of mindfulness-based cognitive behavioral treatment on premenstrual syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Women 18- 35 years old; Availability during the next 6 months; Scale score between 33-64 of the premenstrual syndrome; being single Exclusion

criteria: Cases diagnosed mental illness; Addiction to alcohol, drugs and other psychotropic drugs; The occurrence of adverse events (death of loved ones, accidents with disabilities.) During the consultation or earlier; Chronic diseases (diabetes, hypertension, epilepsy, etc.); The absence of more than three days; Studying counseling and psychology

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: **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

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Ground Floor, Department of Research and Information Technology of Ahvaz Jundishapur University of Medical Sciences, Ahvaz

City

Ahvaz

Postal code

Approval date

2016-10-22, 1395/08/01

Ethics committee reference number

IR.AJUMS.REC. 1395 .437

Health conditions studied

1

Description of health condition studied

premenstrual syndrom

ICD-10 code

N94.3

ICD-10 code description

Premenstrual tension syndrome

Primary outcomes

1

Description

Premenstrual Syndrome

Timepoint

Before intervention, immediately after intervention, a month after the intervention.

Method of measurement

Premenstrual Syndrome Scale

Secondary outcomes

1

Description

Physical Symptoms of Premenstrual Syndrome

Timepoint

Before intervention, immediately after intervention, one month after the intervention.

Method of measurement

Questionnaire physical symptoms of Premenstrual Syndrome

2

Description

Psychological symptoms - behavioral of Premenstrual Syndrome

Timepoint

Before intervention, immediately after intervention, one month after the intervention.

Method of measurement

Questionnaire psychological - behavioral symptoms of Premenstrual Syndrome

Intervention groups

1

Description

The intervention group received eight sessions of mindfulness-based cognitive-behavioral therapy helps. Each session is 60 minutes long and has a specific structure.

Category

Behavior

2

Description

The control group did not work and were on a waiting list.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Masumeh Dormitory of Chamran University
Ahvaz

Full name of responsible person

Saeedeh Askari

Street address

Golestan Blvd, Ahvaz, Khuzestan Province

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor For research Of Ahvaz Jundishapur
University of Medical Sciences

Full name of responsible person

Dr Behzad Sharief Makhmal

Street address

Ground Floor, Vice Chancellor For Research Of Ahvaz
Jundishapour University of Medical Sciences, Ahvaz

City

Ahvaz

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 Of Ahvaz Jundishapur
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

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Saeedeh Askari

Position

Master Student of Consultation in Midwifery

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

College of Nursing and Midwifery, Ahvaz Jundishapour

University of Medical Sciences, Ahvaz.

City

Ahvaz

Postal code**Phone**

+98 61 3373 8621

Fax**Email**

askari.s@ajums.ac.irsaedehaskare@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Zahra Abbaspoor

Position

PhD of Reproductive Health

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

College of Nursing and Midwifery, Ahvaz Jundishapour
University of Medical Sciences, Ahvaz

City

Ahvaz

Postal code**Phone**

+98 61 3336 7543

Fax**Email**

Abbaspoor_Z762@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Saeedeh Askari

Position

Master Student of Consultation in Midwifery

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

College of Nursing and Midwifery, Ahvaz Jundishapour
University of Medical Sciences, Ahvaz

City

Ahvaz

Postal code**Phone**

+98 84 3362 4173

Fax**Email**

Saedehaskare@yahoo.com

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