Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor For Research Of Ahvaz 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
premenstural 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

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Golestan Blvd, Ahvaz, Khuzestan Province

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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

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

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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
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
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Master Student of Consultation in Midwifery

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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