

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

The efficacy of mindfulness-based stress reduction on psychological symptoms and quality of life in students with premenstrual syndrome in 1401

Protocol summary

Study aim

Determining the effectiveness of mindfulness-based stress reduction therapy on psychological symptoms (anxiety, depression, irritability, aggression) and quality of life in students with premenstrual syndrome residing in dormitories of Kashan University of Medical Sciences in 1401

Design

A parallel quasi-experimental study with pre-test and post-test, non-randomized, with a control group, without blinding, on 60 people.

Settings and conduct

Mindfulness-based stress reduction training is organized by a clinical psychologist in the form of regular virtual courses for female students living in dormitories affiliated to Kashan University of Medical Sciences. The program consists of 8 sessions of 90 minutes, which will be done once a week as a group, this treatment is in accordance with the treatment protocol of Kabat Zain (2013).

Participants/Inclusion and exclusion criteria

Girls living in dormitories affiliated to Kashan University of Medical Sciences, single people with a diagnosis of PMS based on clinical signs in accordance with the PMS symptom scale checklist or a certificate from any obstetrician

Intervention groups

Intervention group: interventions based on mindfulness in a structured group. Control group: without mindfulness intervention.

Main outcome variables

Measuring quality of life improvement, depression and anxiety, aggression

General information

Reason for update

Acronym

pms: premenstrual syndrome

IRCT registration information

IRCT registration number: **IRCT20220625055268N1**

Registration date: **2023-02-24, 1401/12/05**

Registration timing: **retrospective**

Last update: **2023-02-24, 1401/12/05**

Update count: **0**

Registration date

2023-02-24, 1401/12/05

Registrant information

Name

Vajihe Rouhi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5533 5521

Email address

rouhivajihe@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-27, 1401/05/05

Expected recruitment end date

2023-01-25, 1401/11/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The efficacy of mindfulness-based stress reduction on psychological symptoms and quality of life in students with premenstrual syndrome in 1401

Public title

The efficacy of mindfulness-based stress reduction on psychological symptoms and quality of life in students with premenstrual syndrome in 1401

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Not receiving psychotherapy for at least the last 3 months
Diagnosis of pre-pregnancy symptoms by a questionnaire or certification by a specialist
Do not currently be under any mental illness treatment
Be single

Exclusion criteria:

History of substance abuse and stimulants
Unwillingness to participate in research

Age

From **18 years** old to **30 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Not 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

Medical Ethics Committee of Kashan University of Medical Sciences

Street address

Kashan, km 3, Ravand Road, Pezeshk Blvd., School of Medicine

City

Kashan

Province

Isfahan

Postal code

8715981151

Approval date

2020-09-08, 1399/06/18

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1399.099

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

Quality of Life

Timepoint

Mindfulness-based stress reduction training program is 8 sessions of 90 minutes that will be done once a week in groups.

Method of measurement

Premenstrual Symptoms Scale Questionnaire, DASS-21 Questionnaire (for measuring anxiety, stress and depression), IRQ Irritability Questionnaire, Bass and Perry Aggression Questionnaire and SF-36 Quality of Life Questionnaire)

Secondary outcomes

empty

Intervention groups

1

Description

Application of mindfulness training program to reduce mental and physical symptoms in dormitory girls diagnosed with premenstrual syndrome in 8 sessions of 90 minutes which are held once a week in groups. Each session begins with an exercise and is followed by a discussion. Continues with practice and ends with homework. This treatment is in accordance with the treatment protocol of Kabat Zain 2013. The relevant questionnaires are completed by the participants before and after the intervention (2 months later).

Category

Treatment - Other

2

Description

The control group will be trained in emotion regulation skills during the waiting sessions. In order to compare the results of the intervention, the relevant

questionnaires before and after the intervention (2 months) are also completed by the control group.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Dormitories affiliated to Kashan University of Medical Sciences

Full name of responsible person

Vajihe Rouhi

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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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

Kashan University of Medical Sciences

Proportion provided by this source

60

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**

Kashan University of Medical Sciences

Full name of responsible person

Vajihe Rouhi

Position

PhD student

Latest degree

Master

Other areas of specialty/work

Epidemiology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Kashan University of Medical Sciences

Full name of responsible person

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Position

Student

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

The work is interventional, personal and confidential.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available