Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

Isfehan

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

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

City
Kashan

Province
Isfehan

Postal code
8715981151

Phone
+98 31 5554 0021

Fax

Email
rouhivajihe@gmail.com

Web page address
http://kaums.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kashan University of Medical Sciences

Full name of responsible person
Vajihe Rouhi

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

City
Kashan

Province
Isfehan

Postal code
8715981151

Phone
+98 31 5554 0021

Email
rouhivajihe@gmail.com

Web page address
http://kaums.ac.ir/

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

Street address
Kashan, Amir Al-Momenin St., 42 Zolfaqar Alley, Aseman Complex

City
Kashan

Province
Isfehan

Postal code
8715973446

Phone
+98 31 5554 0021

Fax

Email
rouhivajihe@gmail.com

Web page address
http://kaums.ac.ir/

Person responsible for scientific inquiries

Contact

Name of organization / entity
Kashan University of Medical Sciences

Full name of responsible person
Shafighe Yousefi

Position
Student

Latest degree
Master

Other areas of specialty/work
Psychology

Street address
Kashan, Natanz St., Sajjadieh Alley

City
Kashan

Province

Isfehan

Postal code

8715973446

Phone

+98 31 5520 3112

Email

sh.yusefi2012@yahoo.com

Web page address

http://kaums.ac.ir/

Isfehan

Postal code

8715973446

Phone

+98 31 5520 3112

Email

sh.yusefi2012@yahoo.com

Web page address

http://kaums.ac.ir/

Person responsible for updating data

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Shafighe Yousefi

Position

Student

Latest degree

Master

Other areas of specialty/work

Psychology

Street address

Kashan, Natanz St., Sajjadieh Alley

City

Kashan

Province

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