

# 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**

Kashan University of Medical Sciences

**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**

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Shafiqhe Yousefi

**Position**

Student

**Latest degree**

Master

**Other areas of specialty/work**

Psychology

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
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Shafighe Yousefi  
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Student  
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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