

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Investigating the Effect of Mindfulness Based On Cognitive Therapy on the Quality Of Life of Working Women with Premenstrual Syndrome

#### Protocol summary

##### Study aim

- Determining the impact of cognitive therapy training based on mindfulness on the quality of life of working women with premenstrual syndrome in Qazvin city.

##### Design

It has two intervention and control groups, which will be used for random allocation using cluster random allocation method and simple random method. Using the lottery method, departments will be randomly assigned to the control and intervention groups. In this way, 70 people will be allocated in each group.

##### Settings and conduct

Active departments of Qazvin city

##### Participants/Inclusion and exclusion criteria

Working women with premenstrual syndrome

##### Intervention groups

The participants who meet the study entry criteria (premenstrual syndrome based on DSM V criteria and using the daily symptom record sheet for two consecutive months), are randomly assigned to two control and intervention groups. There is no intervention in the control group and cognitive therapy based on mindfulness is used in the intervention group

##### Main outcome variables

Health-related quality of life  
Quality of working life  
Specific quality of life associated with premenstrual syndrome

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20221213056810N1**  
Registration date: **2023-05-05, 1402/02/15**  
Registration timing: **prospective**

Last update: **2023-05-05, 1402/02/15**

Update count: **0**

##### Registration date

2023-05-05, 1402/02/15

##### Registrant information

###### Name

Elahe Cholbeigi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 28 3326 6268

###### Email address

elahe.cholbeigi77@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-05-20, 1402/02/30

##### Expected recruitment end date

2023-06-20, 1402/03/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Investigating the Effect of Mindfulness Based On Cognitive Therapy on the Quality Of Life of Working Women with Premenstrual Syndrome

##### Public title

Investigating the Effect of Mindfulness Based On Cognitive Therapy on the Quality Of Life of Working Women with Premenstrual Syndrome

##### Purpose

Education/Guidance

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

regular mens have a job have a premenstrual syndrome  
Having at least reading and writing literacy  
Reporuductive age 18-49

**Exclusion criteria:**

Suffering from any physical and mental illness affecting the quality of life (diabetes, cardiovascular disease, various cancers, physical disabilities, thalassemia, etc.) based on the person's own statement Lack of employment for any reason during the study Suffering from physical and mental diseases aggravating premenstrual syndrome, including endometriosis, based on the person's own statement Taking drugs that reduce the symptoms of this syndrome, including: SSRIs, OCPs, etc.

**Age**

To **50 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **140**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In the first stage, the list of all active departments in Qazvin city will be prepared from the health policy secretariat office, the name of each department will be written on a sheet and the names of 20 departments (cluster) will be selected by a simple random method in the form of a lottery. . In the second step, random allocation of clusters to study groups (intervention or control) will be done using the lottery method (simple random). To do this, the names of the 20 departments selected in the previous step will be written on paper and drawn. They will be assigned to intervention or control groups. In the third step, the researcher will go to the offices and provide the daily symptom sheet to the ladies of the office. Then, based on the score obtained in the daily symptom registration sheet, it determines the qualified people. Considering that 7 people from each office must be included in the intervention, if there are more than 7 affected people in the screening stage, 7 people will be randomly selected using a simple random method (lottery). Then these people will enter the intervention or control group based on cluster grouping.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Qazvin University of Medical Sciences

**Street address**

Azadegan Boulevard, Koche 28 Yousefi, No 34

**City**

qazvin

**Province**

Qazvin

**Postal code**

341312567

**Approval date**

2023-04-19, 1402/01/30

**Ethics committee reference number**

IR.QUMS.REC.1402.010

**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**

Before the intervention - one and three months after the intervention

**Method of measurement**

Standard short form of quality of life

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: Cognitive therapy method based on MBCT mindfulness in the form of an 8-session program during 8 weeks, which will be presented in person by the researcher, including the first familiarization session, the second session: dealing with obstacles, the third session: mindfulness on breathing. The fourth session: staying in the present, the fifth session: dealing with difficult emotions, the sixth session: communication, the seventh session: self-care, the eighth session: applying the

teachings  
**Category**  
Behavior

2

#### Description

Control group: The control group will not receive any intervention, although after the end of the study and if the members wish, training will be applied to them as well

**Category**  
N/A

### Recruitment centers

1

#### Recruitment center

**Name of recruitment center**  
Active departments of Qazvin city  
**Full name of responsible person**  
Elahe Beigi  
**Street address**  
It is different in every office  
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qazvin  
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### Sponsors / Funding sources

1

#### Sponsor

**Name of organization / entity**  
Qazvin University of Medical Sciences  
**Full name of responsible person**  
Dr. Mehdi Mir hashemi  
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qums@qazvin.com  
**Web page address**  
**Grant name**  
**Grant code / Reference number**

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Qazvin University of Medical Sciences

#### Proportion provided by this source

50

#### 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**  
Qazvin University of Medical Sciences  
**Full name of responsible person**  
Elahe Cholbeigi  
**Position**  
Master of Midwifery student  
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Bachelor  
**Other areas of specialty/work**  
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### Person responsible for scientific inquiries

#### Contact

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**Person responsible for updating data**

**Contact**

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Qazvin University of Medical Sciences

**Full name of responsible person**

Elahe Cholbeigi

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**Latest degree**

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

All data and results will be published

**When the data will become available and for how long**

From the end of 1402 onwards

**To whom data/document is available**

every body

**Under which criteria data/document could be used**

Academic researchers

**From where data/document is obtainable**

Qazvin University of Medical Sciences website and library

**What processes are involved for a request to access data/document**

The shortest process

**Comments**