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
premestrual 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

City

qazvin

Province

Qazvin

Postal code

متفاوت است

Phone

+98 28 3366 7140

Fax

+98 28 3366 7040

Email

elahe.cholbeigi77@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Dr. Mehdi Mir hashemi

Street address

Bahonar blvd

City

Qazvin

Province

Qazvin

Postal code

34197-59811

Phone

+98 28 3333 6001

Email

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

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

Azadegan blvd

City

Qazvin

Province

Qazvin

Postal code

341312343

Phone

+98 28 3368 0581

Email

elahe.cholbeigi77@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Zainab Alimoradi

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

Qazvin University Medical of Scienss, Bahonar blvd

City

Qazvin

Province

Qazvin

Postal code
341234567

Phone
+98 912 359 4581

Email
zainabalimoradi@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Qazvin University of Medical Sciences

Full name of responsible person
Elahe Cholbeigi

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

Street address
No.34,west Shahid Yousefi,Azadegan blvd

City
Qazvin

Province
Qazvin

Postal code
34123435

Phone
+98 28 3326 6268

Fax

Email
Elahe.cholbeigi77@gmail.com

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