Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Investigating the effect of mindfulness based cognitive therapy on sexual satisfaction and distress of married women with cyclic mastalgia

Protocol summary

Study aim
Determining the effectiveness of cognitive therapy counseling based on mindfulness on sexual satisfaction and distress of married women with periodic mastalgia.

Design
Randomized controlled clinical trial, with parallel groups, randomized, on 72 married women with periodic breast pain in the comprehensive health centers of Qazvin city, and the four block method is used for random allocation. In order to determine the sequence of allocation by the block method of four, random allocation sequence generation software is used.

Settings and conduct
This study is conducted on 72 married women suffering from periodic breast pain in health community centers of Qazvin city, and cognitive therapy counseling based on mindfulness is provided to them individually and virtually during eight sessions of approximately two hours, and the first session In order to get to know and explain the objectives of the research, it is in person.

Participants/Inclusion and exclusion criteria
Inclusion criteria: having breast pain for more than 5 days per month according to the Cardiff breast pain table and pain intensity greater than 4 in every 5 days according to the objective pain ruler; Married women Exclusion criteria: having marital conflicts based on the person's statement; pregnancy; breastfeeding

Intervention groups
Cognitive therapy based on mindfulness will be planned in the form of eight approximately two-hour sessions and will be held virtually twice a week. The control group will also receive routine care and no intervention will be done for them. At the end of the study, the prepared files will be provided to them, and if necessary, a counseling session will be held for them.

Main outcome variables
Primary outcomes: sexual satisfaction; sexual distress; Mindfulness Secondary outcome: severity of breast pain

General information

Reason for update

Acronym
MBCT

IRCT registration information
IRCT registration number: **IRCT20240520061847N1**
Registration date: **2024-08-21, 1403/05/31**
Registration timing: **prospective**

Last update: **2024-08-21, 1403/05/31**
Update count: **0**

Registration date
2024-08-21, 1403/05/31

Registrant information

Name
elnaz abedi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 28 3366 1768

Email address
elnazabedi13780@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-09-22, 1403/07/01

Expected recruitment end date
2025-02-19, 1403/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of mindfulness based cognitive therapy on sexual satisfaction and distress of married women with cyclic mastalgia

Public title
Investigating the effect of mindfulness based cognitive therapy on sexual satisfaction and distress of married women with cyclic mastalgia

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Having breast pain for more than 5 days per month according to the Cardiff breast pain table and pain intensity greater than 4 in every 5 days according to the objective pain ruler . Married women Age range of 20 years to before menopause Having regular menstrual periods Willingness to participate in the study

Exclusion criteria:
Having marital conflicts based on the person's statement Pregnancy Breastfeeding Suffering from physical and mental illnesses (self-reported) Personal or family history of breast cancer receiving medical treatment to reduce breast pain in the last three months Using hormonal methods to prevent pregnancy History of surgery or breast sampling

Age
From **20 years** old to **55 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **72**

Randomization (investigator's opinion)
Randomized

Randomization description
For random allocation, four block method will be used. In order to determine the sequence of allocation by the four block method, random allocation sequence generation software will be used. The quadruple block method is used to avoid significant imbalances in the number of participants assigned to each group. Block randomization ensures that there is no significant imbalance between groups at any time during randomization and that at any given point the number of participants in each group is equal. By using the balanced block randomization method (block randomization balanced) with blocks of four, they will be placed in two test and control groups. By choosing 18 quadruple blocks, people will be randomly assigned to test and control groups. Hiding the allocation sequence: In order to hide the allocation sequence, the papers specifying the group of people will be placed in white envelopes and coded in the same order. Then, a questionnaire with the same code will be completed for the person who will be in the intervention group.

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
Ethics committee of Qazvin University of Medical Sciences

Street address
Qazvin University of Medical Sciences, Shahid Bahonar Boulevard

City
Qazvin

Province
Qazvin

Postal code
34197-59811

Approval date
2024-08-07, 1403/05/17

Ethics committee reference number
IR.QUMS.REC.1403.190

Health conditions studied

1

Description of health condition studied
Cyclic mastalgia

ICD-10 code
N64.4

ICD-10 code description
Mastodynia

2

Description of health condition studied
sexual satisfaction

ICD-10 code

ICD-10 code description

3

Description of health condition studied
sexual distress

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Sexual satisfaction score in the Sexual Satisfaction Scale for Women
Timepoint
Measurement of sexual satisfaction at the beginning of the study (before the intervention) and in the follow-ups one and three months after the intervention
Method of measurement
The Sexual Satisfaction Scale for Women

2

Description
Sexual distress score in the Sexual Satisfaction Scale for Women
Timepoint
Measurement of sexual distress at the beginning of the study (before the intervention) and in the follow-ups one and three months after the intervention
Method of measurement
The Sexual Satisfaction Scale for Women

3

Description
Mindfulness score in The Five Facet Mindfulness Questionnaire
Timepoint
Measurement of mindfulness at the beginning of the study (before the intervention) and in the follow-ups one and three months after the intervention
Method of measurement
The Five Facet Mindfulness Questionnaire

Secondary outcomes

1

Description
The intensity of breast pain according to the score of Visual analog scale
Timepoint
At the beginning of the study (before the start of the intervention) and in the follow-ups 1 and 3 months after the intervention
Method of measurement
Visual analog scale

Intervention groups

1

Description
Intervention group: Cognitive therapy based on mindfulness will be planned in the form of eight approximately two-hour sessions and will be held virtually twice a week.How to present the intervention: The first session of this consultation will be in person at the comprehensive health centers of Qazvin city to introduce and explain the objectives of the study as well as explanations about periodic breast pain. Other meetings will be held individually through virtual networks (ITA, Telegram, WhatsApp) that are available to the participants. For this purpose, the time of each of the online meetings will be determined in advance based on the convenience of the participant. On the designated date, the participant and the researcher will be online at the same time. The researcher will first present the desired content to the participant in each session, and the possibility of interaction between the participant and the researcher will be provided for question and answer and to ensure the correct understanding of the presented content. These meetings will be online, which leads to two-way communication between the consultant and the participant, and people can easily talk about their problems and get the answers they need from the consultant. Educational content will be provided to the participants in the form of audio and text files along with online counseling.
Category
Treatment - Other

2

Description
Control group: The control group will also receive routine care and no intervention will be done for them. At the end of the study, the prepared files will be provided to them, and if necessary, a counseling session will be held for them.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Comprehensive health centers of Qazvin city
Full name of responsible person
Elnaz Abedi
Street address
Qazvin, University Street, located in the center of Shahid Blandian
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Phone
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elnazabedi13780@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Qazvin University of Medical Sciences

Full name of responsible person
Seyed Mahdi Mirhashemi
Street address
Qazvin, Shahid Bahonar Boulevard, Qazvin University of Medical Sciences
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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
Qazvin University of Medical Sciences

Proportion provided by this source
1

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
Elnaz Abedi
Position
Masters student
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Position
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Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Elnaz Abedi
Position
Masters student
Latest degree
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Other areas of specialty/work
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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

Only part of the data is shared

When the data will become available and for how long

5 months

To whom data/document is available

researchers

Under which criteria data/document could be used

Research design

From where data/document is obtainable

Elnaz Abedi, elnazabedi13780@gmail.com, postal code: 3419759811

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

Email submission process: elnazabedi13780@gmail.com

Comments