

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

The effect of Mindfulness-Based Stress Reduction (MBSR) group consultation with or with out partner on psychological reaction and some inflammatory tests of women with breast cancer referred to physicians offices and medical settings of Kerman University of Medical Sciences, 2018

Protocol summary

Study aim

determining the effect of Mindfulness-Based Stress Reduction (MBSR) group consultation with or with out partner on psychological reaction and some inflammatory tests of women with breast cancer referred to physicians offices and medical settings of Kerman University of Medical Sciences, 2018

Design

Clinical clinical trial with a control group with parallel, randomized groups

Settings and conduct

Eight weekly sessions Group counseling of stress-based mindfulness in two intervention groups with and without spouse's, and comparison of stress, anxiety and depression before and after intervention using a questionnaire, as well as the level of cortisol and CRP before and after intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria 1. Women with married breast cancer who have been between 3 months and 5 years of age since diagnosis began. 2- Not using any psychological treatment before and during the period during which the subjects undergo intervention. 3. Non-addiction to any drug 4. Non-acute psychiatric disorders (psychosis, severe mood disorder, etc.) based on self-report 5. Not having mental disorders 6. Non-use of anti-anxiety and anti-depressant drugs 7. Have at least one course of chemotherapy or surgery 8- The age of 18-70 years 9. Breast cancer without metastasis 10-No use of corticosteroids, psychedelic and hormonal drugs Exit criteria: 1- Absence (the patient or his wife) in more than 3 sessions of the MBSR sessions 2. Unwillingness to attend the study 3. Physical inability due to illness and treatment 4- Start taking corticosteroids, fluorescent and

hormonal drugs 5- In the event of a major crisis during or about three months before intervention, such as the death of loved ones 6. Co-infection with autoimmune diseases 7. History of participation in mindfulness groups 8. Endocrine diseases like Cushing

Intervention groups

In the intervention group, eight weekly sessions of mindfulness are counseling for a Interventions group, with the difference that in a group women with breast cancer are involved in the presence of a spouse, and in another group, women with breast cancer are absent from their husbands.

Main outcome variables

Stress, anxiety, depression, cortisol and CRP

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180113038333N1**

Registration date: **2018-02-15, 1396/11/26**

Registration timing: **registered_while_recruiting**

Last update: **2018-02-15, 1396/11/26**

Update count: **0**

Registration date

2018-02-15, 1396/11/26

Registrant information

Name

Motahare Mirmahmoodi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3285 0744

Email address

m.mirmahmodi@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-21, 1396/11/01

Expected recruitment end date

2018-07-21, 1397/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Mindfulness-Based Stress Reduction (MBSR) group consultation with or without partner on psychological reaction and some inflammatory tests of women with breast cancer referred to physicians' offices and medical settings of Kerman University of Medical Sciences, 2018

Public title

The effect of Mindfulness-Based Stress Reduction (MBSR) group consultation with or without partner on psychological reaction and some inflammatory tests of women with breast cancer

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Women with breast cancer without metastases Age between 18 and 70 years Married

Exclusion criteria:

acute psychiatric disorders (psychosis, severe mood disorder, etc.) based on self-report take corticosteroid, psychedelic and hormonal drugs

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignments will be used by blocking. In this way, in each block, two of the intervention group in the presence of the spouse, two of the intervention group will enter the intervention group without the presence of the spouse and two participants of control 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

Deputy of Research and Technology of Kerman University of Medical Sciences

Street address

tahmasebabad

City

kerman

Province

Kerman

Postal code

7616913555

Approval date

2017-10-09, 1396/07/17

Ethics committee reference number

IR.KMU.REC.1396.440

Health conditions studied

1

Description of health condition studied

breast cancer

ICD-10 code

C50.11

ICD-10 code description

Malignant neoplasm of central portion of breast, female

Primary outcomes

1

Description

depression

Timepoint

Before and after intervention

Method of measurement

Beck Depression Inventory

2

Description

anxiety

Timepoint

Before and after intervention

Method of measurement

Beck anxiety inventory

3

Description

stress

Timepoint

Before and after intervention

Method of measurement

Perceived Stress Scale

4

Description

cortizol

Timepoint

Before and after intervention

Method of measurement

blood test

5

Description

C-reactive protein (CRP)

Timepoint

Before and after intervention

Method of measurement

blood test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Eight weekly sessions A group mindfulness- based stress redaction for women with cancer at the presence of spouse

Category

Lifestyle

2

Description

Intervention group: Eight weekly sessions A group mindfulness- based stress redaction for women with cancer without spouse presence

Category

Lifestyle

Recruitment centers

1

Recruitment center**Name of recruitment center**

Kerman University of Medical Sciences

Full name of responsible person

Sedighe Iranmanesh

Street address

Haftbagh

City

Kerman

Province

Kerman

Postal code

7616913555

Phone

+98 34 3132 5700

Email

m.mirmahmodi@kmu.ac.ir

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Kerman University of Medical Sciences

Full name of responsible person

Abas Pardakhti

Street address

Haftbagh

City

Kerman

Province

Kerman

Postal code

7616913555

Phone

+98 34 3132 5700

Email

mirmahmoodi95@gmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Kerman University of Medical Sciences

Proportion provided by this source

100

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**

Kerman University of Medical Sciences

Full name of responsible person

Sedighe Iranmanesh

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery
Street address
Haftbagh of Kerman University of Medical Sciences.
Razi Nursing and Midwifery Faculty
City
Kerman
Province
Kerman
Postal code
7616913555
Phone
+98 34 3132 5700
Email
mirmahmoodi95@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Sedighe Iranmanesh
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Haftbagh of Kerman University of Medical Sciences.
Razi Nursing and Midwifery Faculty
City
Kerman
Province
Kerman
Postal code
7616913555
Phone
+98 34 3132 5700
Email
mirmahmoodi95@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Motahare Mirmahmoodi

Position
Nurse
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
11, bostanmahdi ave.,havanirooz blv
City
Kerman
Province
Kerman
Postal code
7616913555
Phone
+98 34 3285 0744
Fax
Email
mirmahmoodi95@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

The main consequence of the data is publishable

When the data will become available and for how long

Six months after the publication of the article

To whom data/document is available

individuals in academic institutions

Under which criteria data/document could be used

The personal data of the participants is not available

From where data/document is obtainable

Motahare Mirmahmoodi . mirmahmoodi95@gmail.com

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

Six months after the publication of the article 2019

Comments