Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 inflamatory tests of women with breast cancer refered 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 mindfulnes 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

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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 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

Public title

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

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 participant 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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
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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
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