Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of Mindfulness Based Stress Reduction (MBSR) hope and spirituality well-being of women with breast cancer

Protocol summary

Study aim

The effect of Mindfulness Based Stress Reduction (MBSR) on hope and spirituality well-being of women with breast cancer

Design

The sample of this study included 68 breast cancer patients selected from patients at Tabriz Hospitals and randomly allocated into two groups: MBSR group (n=34) and usual care, waitlist group (n=34).

Settings and conduct

After the randomization, participants will respond to the informed consent form. Patients in the intervention condition will receive a modified MBSR program for 8 sessions. Prior to performing the intervention, both experimental and control groups will complete the research questionnaires, and after completing 8 sessions of mindfulness training, they will respond to the questionnaires again. The project will be conducted in the oncology department of Tabriz Shahid Madani Hospital.

Participants/Inclusion and exclusion criteria

Inclusion criteria: (a) oncologist approved clinical diagnosis of stage I to IV breast cancer; (b) receiving the usual cancer interventions, (c) between 20 to 60 years of age, (d) having at least a high school diploma or equivalent. Exclusion criteria: (a) other chronic diseases; (b) experience practicing yoga and/or meditations; and (c) a history of alcohol, drug and substance abuse, personality disorders, dementia, and/or developmental disorders

Intervention groups

Experimental group will have mindfulness based stress reduction and control group were requested to refrain from taking part in any type of Mindfulness-Based Interventions or from participating in any meditations during the trial period. Patients in the waitlist group (control) were invited to take part in the 8-week MBSR program administered by the research team after the study period.

Main outcome variables

-Spiritual well-being - Hope

General information

Reason for update

During the recruitment process, the hospital authorities allowed us to have a larger number of patients, and we increased the sample size to increase the generalizability of the findings. We also changed some of the eligibility criteria and outcomes.

Acronym

MBSR

IRCT registration information

IRCT registration number: **IRCT20171203037729N1**
Registration date: **2018-01-02, 1396/10/12**
Registration timing: **prospective**

Last update: **2022-05-28, 1401/03/07**
Update count: **1**

Registration date

2018-01-02, 1396/10/12

Registrant information

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Rasoul Heshmati
Name of organization / entity
University of Tabriz
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-03, 1398/06/12

Expected recruitment end date

2019-12-29, 1398/10/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Mindfulness Based Stress Reduction (MBSR) hope and spirituality well-being of women with breast cancer

Public title

mindfulness based stress reduction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Oncologist approved clinical diagnosis of stage I to IV breast cancer Receiving the usual cancer interventions Between 20 to 60 years of age having at least a high school diploma or equivalent

Exclusion criteria:

Other chronic diseases Experience practicing yoga and/or meditations History of alcohol, drug and substance abuse, personality disorders, dementia, and/or developmental disorders

Age

From **20 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

- Block randomization - A list of random numbers generated by SPSS (version 24, SPSS Inc, Chicago, IL)

Blinding (investigator's opinion)

Single blinded

Blinding description

The assessors of the outcome

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

Street address

Central Building No. 2, Third Floor, Research & Technology Dept. Golghast St, Tabriz University of Medical Sciences.Tabriz.

City

Tabriz

Province

East Azarbaijan

Postal code

5166616471

Approval date

2017-11-18, 1396/08/27

Ethics committee reference number

IR.TBZMED.REC.1396.719

Health conditions studied

1

Description of health condition studied

Breast cancer

ICD-10 code

C00-D48

ICD-10 code description

سرطان سینه

Primary outcomes

1

Description

Hope

Timepoint

Measurement of hope at the beginning of the study (before the intervention) and 2 months after intervention

Method of measurement

The Snyder Hope Scale (SHS)

2

Description

Spiritual well-being

Timepoint

Measurement of spiritual well-being at the beginning of the study (before the intervention) and 2 months after intervention

Method of measurement

Spiritual Well Being Scale (SWBS)

Secondary outcomes

empty

Intervention groups

1

Description
Experimental group: This group underwent MBSR for two months.A qualified therapist, who has basic professional training in mindfulness-based intervention with ten years of experience in conducting mindfulness-based programs, implemented the MBSR program. Control group: The control group were requested to refrain from taking part in any type of Mindfulness-Based Interventions. These patients were invited to take part in the 8-week MBSR program after the study period.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Madani Hospital
Full name of responsible person
Rasoul Heshmati
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Golgasht street. Shahid Madani Hospital
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr. Abolghasem Jouyban
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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
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Rasoul Heshmati
Position
Associate Professor
Latest degree
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Psychology
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Person responsible for updating data

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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 is publishable after being unidentifiable
When the data will become available and for how long
6 month after publication
To whom data/document is available
for all researchers
Under which criteria data/document could be used
For use in other research work
From where data/document is obtainable
University of Tabriz-Department of Psychology- Prof. Rasoul Heshmati-09198260681 Email: psy.heshmai@gmail.com
What processes are involved for a request to access data/document
Requesting from researcher and sending it by post or e-mail
Comments