

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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

Name

Rasoul Heshmati

Name of organization / entity

University of Tabriz

Country

Iran (Islamic Republic of)

Phone

+98 41 3475 7626

Email address

psy.heshmati@tabrizu.ac.ir

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 سينه

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

Street address

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

Ph.D.

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

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Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

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

Requesting from researcher and sending it by post or e-mail

Comments