

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of Mindfulness-based spirituality training on the hope and anxiety of women with breast cancer

Protocol summary

Study aim

Determining the Effect of Spirituality Based Mindfulness Education on the Hope and Anxiety of Women with Breast Cancer

Design

60 patients were selected based on entry and exclusion criteria. Then, they were randomly assigned to intervention and control groups. Each group included 30 patients with breast cancer.

Settings and conduct

After selecting patients and randomly assigning them to intervention and control groups, 8 training sessions of 60 minutes were performed in Faculty of Nursing and Midwifery Nasibe (Sari) for the intervention group. The control group did not receive any intervention.

Participants/Inclusion and exclusion criteria

1. Having a desire to participate in the study 2. Female Sex 3. age group 18-70 years 4. Have a mild to moderate anxiety 5. Being at zero, one or two cancer 6. use of psychological drugs 7. participation in similar training sessions 8. intermediate Education and higher education

Intervention groups

The intervention group included 30 patients with breast cancer. The intervention was conducted in 8 sessions of 60 minutes and grouped. The intervention included spirituality-mindedness training, attention to the effect of spirituality on stress and hope, relaxation techniques, familiarity with the technique of respiratory meditation, familiarity with body examination technique, abdominal respiration technique. The control group also included 30 patients with breast cancer who did not receive any intervention.

Main outcome variables

Stress and Hope

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171203037723N4**

Registration date: **2019-03-03, 1397/12/12**

Registration timing: **retrospective**

Last update: **2019-03-03, 1397/12/12**

Update count: **0**

Registration date

2019-03-03, 1397/12/12

Registrant information

Name

Hamideh Azimi Lolaty

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3336 7343

Email address

azimihamideh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-21, 1397/02/01

Expected recruitment end date

2018-04-23, 1397/02/03

Actual recruitment start date

2018-07-01, 1397/04/10

Actual recruitment end date

2018-09-22, 1397/06/31

Trial completion date

2018-09-22, 1397/06/31

Scientific title

The effect of Mindfulness-based spirituality training on the hope and anxiety of women with breast cancer

Public title

The Effect of Spirituality Based Mindfulness Training on the Hope and Anxiety of Women with Breast Cancer

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Having a willingness to participate in the study Female sex Age group is 18-70 years old Having a mild to moderate anxiety Being at zero, one or two cancer intermediate Education and higher education

Exclusion criteria:

use of psychological drugs Participate in similar training sessions

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The samples will be selected by the available sampling method from the research community and randomly divided into intervention (30) and control (30 persons) groups.

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 Mazandaran University of Medical Sciences

Street address

Sari Street Teacher, Student Research Deputy

City

sary

Province

Mazandaran

Postal code

48157-33971

Approval date

2018-06-24, 1397/04/03

Ethics committee reference number

162.IR.MAZUMS.REC.1397

Health conditions studied

1

Description of health condition studied

Patients with breast cancer

ICD-10 code

Malignant

ICD-10 code description

C50

Primary outcomes

1

Description

Anxiety score

Timepoint

Before the intervention - Immediately after intervention

Method of measurement

Beck Anxiety Inventory

2

Description

Hope

Timepoint

Before the intervention - Immediately after intervention

Method of measurement

Miller's Hope Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 30 patients with breast cancer participated in educational sessions. Eight sessions of one hour, group and weekly held. The content of the training sessions included spirituality-based mind-awareness training, the effect of spirituality on stress and hope, body examination, breathing meditation, abdominal respiration, and relaxation techniques. The lecture and questioning method was used.

Category

N/A

2

Description

Control group: Thirty women with breast cancer entered the control group. The control group did not attend the training sessions. This group only completed questionnaires.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Baghban Specialist Clinic

Full name of responsible person

Hamideh Azimi Lolaty

Street address

Sari - Khazar Boulevard

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Mazandaran

Postal code

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Fax**Email**

azimihamideh@gmail.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Hamideh Azimi Lolaty

Street address

Mazandaran University of Medical Sciences, Three
Way Joybar, Beginning of the Highway of Vali Asr,
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4816715793

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midnasibeh@yahoo.com

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

Yes

Title of funding source

Sari 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**

Mazandaran University of Medical Sciences

Full name of responsible person

Hamideh Azimi Lolaty

Position

Professor Assistant

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Amir Mazandaran Blvd., Vesal Shirazi Ave. Nasibe
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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

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Position

Professor Assistant

Latest degree

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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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

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When the data will become available and for how long

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To whom data/document is available

.....

Under which criteria data/document could be used

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From where data/document is obtainable

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

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Comments

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