

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jul 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

**City**

Sari

**Province**

Mazandaran

**Postal code**

4815733971

**Phone**

+98 11 3336 7342

**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,  
Imam Square

**City**

Sari

**Province**

Mazandaran

**Postal code**

4816715793

**Phone**

+98 11 7333 0547

**Email**

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  
Nursing and Midwifery Faculty

**City**

Sari

**Province**

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## Person responsible for scientific 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**

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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**

.....

**When the data will become available and for how long**

.....

**To whom data/document is available**

.....

**Under which criteria data/document could be used**

.....

**From where data/document is obtainable**

.....

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

.....

**Comments**

.....