

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Sep 2026

### Depression in breast cancer patients referred to Shahid Motahhary clinic in Shiraz, 1396

#### Protocol summary

##### Study aim

The aim of this clinical trial is to assess the effect of spiritual course on stress, anxiety and depression in breast cancer patients.

##### Design

Single-blind randomized clinical trial.

##### Settings and conduct

96 subjects are divided into two groups, 48 subjects in each group of case and control. Subjects who meet the inclusion criteria are selected from patients with breast cancer through purposive sampling and simple random sampling. Then using block randomization with the block size of 4, they are divided into two groups of control and intervention. Subjects in the intervention group will participate in a training workshop on spiritual and religious points to help them elevate their ability to solve the problem and relieve their emotions more easily; the workshop consists of 4 training sessions and lasts for 2 weeks. Data will be collected from the control and intervention groups in three stages using Depression, Anxiety and Stress Scales (DASS-42) questionnaire: in the beginning of the study and then once again immediately after completion of the intervention. During the intervention, the two methods of problem-based learning and group discussion will be used; the training will include topics such as self-knowledge and self-awareness, recognition of weaknesses and strengths, acceptance of mistakes, important role of quality of life in psychological and physical aspects, etc.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: patients with breast cancer, being Muslim and Shiite and having an ordinary spiritual level; Exclusion criteria: lack of willingness to continue participation in the study, failure to attend.

##### Intervention groups

Subjects in the intervention group will attend a 2-week workshop and will participate in 4 sessions of spiritual trainings to elevate their ability to solve the problem and relieve their emotions more easily.

#### Main outcome variables

Anxiety

#### General information

##### Reason for update

##### Acronym

-

##### IRCT registration information

IRCT registration number: **IRCT20090908002432N6**

Registration date: **2018-08-07, 1397/05/16**

Registration timing: **retrospective**

Last update: **2018-08-07, 1397/05/16**

Update count: **0**

##### Registration date

2018-08-07, 1397/05/16

##### Registrant information

##### Name

Azadeh Amiri

##### Name of organization / entity

Shiraz University Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 1647 4254

##### Email address

amirlea@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-05-21, 1397/02/31

##### Expected recruitment end date

2018-07-22, 1397/04/31

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Depression in breast cancer patients referred to Shahid Motahhary clinic in Shiraz, 1396

**Public title**

Depression in breast cancer patients

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients with breast cancer Being Muslim and Shiite  
Having an ordinary spiritual level

**Exclusion criteria:**

Lack of willingness to continue participation in the study  
Failure to attend and miss more than one training session of the workshop Any other problem preventing the subject to continue the participation in the study

**Age**

No age limit

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: 96

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Subjects who meet the inclusion criteria are selected from patients with breast cancer through convenience sampling. Then participants will randomly assign to intervention and control groups. In order to evenly distribute the participants, a block randomization list (with block-sizes of 4 at 6 variation) will prepare by a statistician, and will give to two persons in reception unit in the form of sequentially numbered, sealed opaque envelopes, to provide concealment allocation to the group.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

Participants have no information about random allocation.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Shiraz University of Medical Sciences

**Street address**

Shiraz University of Medical Sciences,Zand Street

**City**

shiraz

**Province**

Fars

**Postal code**

7193613119

**Approval date**

2018-05-15, 1397/02/25

**Ethics committee reference number**

IR.SUMS.REC.1397.109

**Health conditions studied****1****Description of health condition studied**

Anxiety

**ICD-10 code**

F41.1

**ICD-10 code description**

Generalized anxiety disorder

**Primary outcomes****1****Description**

Anxiety

**Timepoint**

Before the intervention, after the intervention and 2-months later

**Method of measurement**

Depression, Anxiety and Stress Scales (DASS-42) questionnaire

**Secondary outcomes****1****Description**

Stress

**Timepoint**

Before the intervention, after the intervention and 2-months later

**Method of measurement**

Depression, Anxiety and Stress Scales (DASS-42) questionnaire

**Intervention groups**

## 1

### Description

Intervention group: Subjects in the intervention group will participate in a training workshop on spiritual and religious points to help them elevate their ability to solve the problem and relieve their emotions more easily; the workshop consists of 4 training sessions and lasts for 2 weeks.

### Category

Lifestyle

## 2

### Description

control group: The control group receives routine care.

### Category

Lifestyle

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Motahari polyclinic affiliated to Shiraz University of Medical Sciences, Shiraz, Iran

#### Full name of responsible person

Azadeh Amiri

#### Street address

Namazee Square ,Zand Street, Shiraz

#### City

Shiraz

#### Province

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#### Postal code

7193613119

#### Phone

+98 71 3647 4258

#### Fax

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#### Email

amiriea@sums.ac.ir

#### Web page address

http://sums.ac.ir/

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Shiraz University of Medical Sciences

#### Full name of responsible person

Dr. Seyed Basir Hashemi

#### Street address

Shiraz University of Medical Sciences, Zand Street, Shiraz

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#### Phone

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#### Fax

+98 71 3212 2430

#### Email

Hashemib@sums.ac.ir

#### Web page address

http://sums.ac.ir/

#### Grant name

-

#### Grant code / Reference number

-

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

#### Full name of responsible person

Azadeh Amiri

#### Position

Master of Science In Nursing -Faculty member of School of Nursing and Midwifery, Shiraz University o

#### Latest degree

Master

#### Other areas of specialty/work

Nursery

#### Street address

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Azadeh Amiri

**Position**

Master of Science In Nursing, Faculty member of School of Nursing and Midwifery

**Latest degree**

Master

**Other areas of specialty/work**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be 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**

Yes - There is 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**

University of Medical Sciences

**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**

-

## Person responsible for updating data

### Contact

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Azadeh Amiri

**Position**

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**Latest degree**

Master

**Other areas of specialty/work****Street address**

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**City**

Shiraz