

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Seyed Basir Hashemi

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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

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

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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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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