Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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)

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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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Namazee Square ,Zand Street, Shiraz
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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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Shiraz University of Medical Sciences, Zand Street, Shiraz
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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

Contact

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Full name of responsible person
Azadeh Amiri

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

Latest degree
Master

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Nursery

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Person responsible for updating data

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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
-