Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

study of the effect Spiritual Care on Spiritual Health, Quality of Life and Self-efficacy in Women with Breast Cancer

Protocol summary

Study aim
Increasing the quality of life, self-efficacy and spiritual well-being of women with breast cancer

Design
Individuals are randomly assigned into two groups of control and experiment with a sample size of 70 people.

Settings and conduct
Spiritual care is performed in 6 sessions in selected centers of Qom with control and intervention group. After completing the intervention and follow-up two months, a similar intervention is performed in the control group

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1- Women with Iranian nationality aged 18-65 2. A definitive diagnosis of breast cancer (at each of stages 1 to 4) with pathological tests 3-Minimum 2 months of receiving diagnosis 4. Not having severe mental illness. 5. There is no other stressful event, such as divorce and death, of a close relative during the past year. 6. Aware of the time and place 7. Reading and writing literacy 8. Ability to speak Persian language. 9. Lack of disability and disability 10. Being Muslim. Exclusion criteria: 1-Patient dissatisfaction to continue the study 2-foot patient. 3-Lack of more than two sessions of spiritual care sessions

Intervention groups
The intervention group is group of women with breast cancer who have inclusion criteria and are randomly assigned to a intervention group that holds spiritual care for 6 sessions per week for them. This intervention is in relation to God, others, himself and the world of nature.The focus of those topics is prayer, repentance and passing, tendencies, patience, trust and happiness if there is no spiritual care for the control group at this time.

Main outcome variables
Increasing the quality of life Increased self-efficacy Increase spiritual health

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20171106037279N2**
Registration date: **2018-05-17, 1397/02/27**
Registration timing: **registered_while_recruiting**

Last update: **2018-05-17, 1397/02/27**
Update count: **0**

Registration date
2018-05-17, 1397/02/27

Registrant information

Name
farzaneh nasiri

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 919 453 6915

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farzanehnasiri@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-04-13, 1397/01/24

Expected recruitment end date
2018-06-14, 1397/03/24

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
study of the effect Spiritual Care on Spiritual Health, Quality of Life and Self-efficacy in Women with Breast Cancer

Public title
The effect of spiritual care on spiritual health, quality of life and self-efficacy in women with breast cancer

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Women with Iranian nationality A definitive diagnosis of breast cancer (at each stage 1 to 4) with pathological tests Passed 2 months after receiving diagnosis Not having severe mental illness, including psychotic or bipolar disorder Failure to deal with another tense event, such as the divorce and death of a close relative during the past year Aware of the time and place Literacy reading and writing Ability to speak Persian Lack of disability and disability Being Muslim

Exclusion criteria:
Dissatisfaction patients to continue the study Patient death Missing more than two sessions of spiritual care sessions

Age
From **18 years** old to **64 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization is done individually and random numbers are used

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Other

Other design features
Has an intervention and control group that runs after intervention and two months follow up for the control group to observe ethical issues of intervention.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address
Valiasr St., Intersection of Prayer, in front of Shahid Rajaee Heart Hospital, Faculty of Nursing and Midwifery

City
Tehran

Province
Tehran

Postal code
1985717443

Approval date
2017-03-06, 1395/12/16

Ethics committee reference number
644.1395.PHNM.SBMU.I

Health conditions studied

1

Description of health condition studied
breast cancer

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Quality of life score in the short form of quality of life of the World Health Organization

Timepoint
Before intervention, immediately after the intervention and two months after the end of the intervention

Method of measurement
World Health Organization Quality of Life Questionnaire Short Form

2

Description
Self-efficacy score of Sherer's general self-efficacy questionnaire

Timepoint
Before intervention, immediately after the intervention and two months after the end of the intervention

Method of measurement
Sherer General Self-efficacy Inventory

3

Description
Spiritual Health Score in Palutzin & Ellison Spiritual Health Questionnaire

Timepoint
Sherer General Self-efficacy Inventory

Method of measurement
Palutzin & Ellison Spiritual Health Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The intervention for the experimental group is 6 sessions per week. Intervention sessions are designed based on the review of existing texts and resources. Interventions are related to communication with God, others, themselves and the world of nature, whose focus is on prayer, repentance and passage, altruism, patience, trust.
Category
Other

2

Description
Control group: During the spiritual care intervention for the control group, there is no specific action, but after two months follow up to observe moral issues of spiritual care for them.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Sadra center
Full name of responsible person
Zohreh Keshavarz
Street address
no.19 .Alley10، Street 19 D
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1985717443
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farzanehnasiri100@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mahrokh Dolatyan
Street address
Valiasr St., intersection of prayer, in front of Shahid Rajaee Heart Hospital, Faculty of Nursing and Midwifery
City
Tehran
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Postal code
1985717443
Phone
+98 21 8865 5366
Email
farzanehnasiri100@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Zohreh Keshavarz
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Midwifery
Street address
Valiasr St., intersection of prayer, opposite Shahid Rajaee Heart Hospital, Faculty of Nursing and Midwifery
City
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keshavarzzohre@yahoo.com

Person responsible for scientific

inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
farzaneh nasiri

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

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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
All data is shareable because people are not identifiable

When the data will become available and for how long
Start the access period 2 months after printing the results

To whom data/document is available
The votes of researchers working in academia and academia will be available

Under which criteria data/document could be used
With the permission of the researcher

From where data/document is obtainable
farzanehnasiri100@gmail.com

What processes are involved for a request to access data/document
After correspondence via email within a week

Comments