

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 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

Email address

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 Rajaei 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

City

Qom

Province

Ghoum

Postal code

1985717443

Phone

+98 25 3771 2825

Email

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

Rajaei Heart Hospital, Faculty of Nursing and Midwifery

City

Tehran

Province

Tehran

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 Rajaei Heart Hospital, Faculty of Nursing and Midwifery

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 8865 5366

Email

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

Street address

tehran

City

Tehran

Province

Tehran

Postal code

1985717443

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+98 919 453 6915

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farzanehnasiri@sbmu.ac.ir

Person responsible for updating data

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

Street address

tehran

City

Tehran

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Tehran

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1985717443

Phone

+98 919 453 6915

Fax

Email

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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