

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Assessment of The effect of Spiritual Therapy for Improving the Quality of life in Women with Breast Cancer

Protocol summary

Summary

The purpose of the current trial is to study whether a support intervention based on widely used spiritual intervention could improve the quality of life of breast cancer patients in comparison to the control group or not. The target population is newly diagnosed breast cancer patients under radiation therapy who consents to participate in this study. The participants will be randomly assigned into control group receiving standard management and treatment and also routine education program or intervention group receiving both routine management/education and also an additional 6 sessions (6 weeks) educational program based on spiritual therapy intervention. The spiritual therapy sessions include: introduction, relaxation and meditation, control, identity, relationships with self, others and God, prayer therapy. The quality of life will be assessed by The specific European Organisation for Research and Treatment of Cancer quality of life group for breast cancer (EORTC BR-23 and QLQC30) and the spirituality will be assessed by FACIT-SP12.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138904024242N1**

Registration date: **2011-05-31, 1390/03/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-05-31, 1390/03/10

Registrant information

Name

Najmeh Jafari

Name of organization / entity

Isfahan University of Medical Sciences (IUMS)

Country

Iran (Islamic Republic of)

Phone

+98 31 1771 1112

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2010-09-20, 1389/06/29

Expected recruitment end date

2010-10-30, 1389/08/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of The effect of Spiritual Therapy for Improving the Quality of life in Women with Breast Cancer

Public title

Assessment of The effect of Spiritual Therapy for Improving the Quality of life in Women with Breast Cancer

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion Criteria: Newly diagnosed breast cancer patients, Active participation in educational programs

Exclusion criteria: Patients who do not consent to participate, Metastatic Breast cancer patients, Concomitant chronic disease, Major depression disorder

Age
From **18 years** old to **70 years** old

Gender
Female

Phase
0

Groups that have been masked
No information

Sample size
Target sample size:

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The ethics committee of Isfahan University of Medical Sciences research administration

Street address

Isfahan University of Medical Sciences, Hezarjarib St., Isfahan

City

Isfahan

Postal code

Approval date

2010-12-25, 1389/10/04

Ethics committee reference number

389319

Health conditions studied

1

Description of health condition studied

Breast cancer

ICD-10 code

C50

ICD-10 code description

Malignant neoplasm of breast

Primary outcomes

1

Description

Quality of life

Timepoint

before intervention and after that(six weeks after initiation on intervention)

Method of measurement

EORTCQLQC30 and BR23 questionnaires

Secondary outcomes

1

Description

spirituality

Timepoint

before intervention and after that(six weeks after initiation on intervention)

Method of measurement

FACIT-SP12 questionnaire

Intervention groups

1

Description

Intervention group: both routine management/education and also an additional 6 sessions (6 weeks) educational program based on spiritual therapy intervention. The spiritual therapy sessions include: introduction, relaxation and meditation, control, identity, relationships with self, others and God, prayer therapy

Category

Lifestyle

2

Description

Control group: patients in control group will receive standard management and treatment and also routine education program in 6 weeks period.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Breast Cancer Research Center/St. S. Al-shohada hospital

Full name of responsible person

Street address

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences
Full name of responsible person
Dr Adibi
Street address
Hezarjeryb Street
City
Isfahan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Isfahan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Isfahan University of Medical Sciences
Full name of responsible person
Najmeh Jafari
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty