Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

Email address

n_jafari@med.mui.ac.ir

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

Position

MD/resident of community medicine

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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MD/community medicine specialist

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Contact

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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