

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Sep 2026

Effect of spiritual care Program on pain self-management in breast cancer patients

Protocol summary

Summary

This study was two-group two-stage clinical trial in which 50 women with breast cancer were selected based on the inclusion criteria through simple continuous sampling and randomly allocated into two groups of study and control. The inclusion criteria were being aged from 30 to 55 years, being diagnosed for at least 1 month, being under medical treatments, and having passed at least one course of chemotherapy. The exclusion criteria were unwillingness to participate, missing more than 3 sessions and incidence of an acute physical or mental problem. Ten group educational sessions of spiritual care were organized for the study group while the control group participated in 2 sessions about their experiences of the disease. Data were gathered through Pain Self-Management Checklist, in before and six month after intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017083120912N6**

Registration date: **2017-11-20, 1396/08/29**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-11-20, 1396/08/29

Registrant information

Name

Mohsen Shahriari

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 2915

Email address

shahriari@nm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice-Chancellery for Research, Isfahan University of Medical Sciences

Expected recruitment start date

2015-11-23, 1394/09/02

Expected recruitment end date

2016-08-23, 1395/06/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of spiritual care Program on pain self-management in breast cancer patients

Public title

spiritual care on pain self-management

Purpose

Supportive

Inclusion/Exclusion criteria

The inclusion criteria were being aged from 30 to 55 years, being diagnosed for at least 1 month, being under medical treatments, having passed at least one course of chemotherapy and being able to understand and speak Farsi language. The exclusion criteria were unwillingness to participate, missing more than 3 sessions and incidence of an acute physical or mental problem.

Age

From **30 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 50

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

Isfahan University of Medical Sciences

Street address

isf ahan, hezarjrib Ave,Isfahan University of Medical Sciences,School of Nursing and Midwifery

City

isfahan

Postal code

Approval date

2013-10-27, 1392/08/05

Ethics committee reference number

292140

Health conditions studied

1

Description of health condition studied

Breast Cancer

ICD-10 code

C50.9

ICD-10 code description

C50-C50

Primary outcomes

1

Description

pain self-management

Timepoint

pre intervention, 6 weeks after intervention

Method of measurement

Pain Self-Management Checklist

Secondary outcomes

1

Description

none

Timepoint

none

Method of measurement

none

Intervention groups

1

Description

10 group educational sessions of spiritual care

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Omid Hospital

Full name of responsible person

Mohsen Shahriari

Street address

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Ahmad Movahedian Attar

Street address

Vice-Chancellery for Research, Isfahan University of Medical Sciences

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
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Person responsible for updating data

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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