

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The impact of education on application of coping strategies and quality of life in women with breast cancer

Protocol summary

Summary

Objective: Determining the effect of education on applying coping strategies and quality of life among women with breast cancer. Inclusion criteria: Age less than 60 years old, Literate, Is living in Shiraz, Patients' agreement to participate in the study, Having been in the stages 1, 2 and 3 of the illness, Surgery and adjuvant therapy is completed, Has not participated in an educational program applying coping strategies previously. Exclusion criteria: Unwillingness of the patient to continue cooperating in the study, Metastasis to other organs or recurrence, Lymph edema is caused by the inability of the patient, Stressful events in a period close to the time of completing the questionnaire, Incidence to during the study of mental disease - psychological, Chronic disease or other malignancies during the study. Method: Randomized clinical trial with intervention and control. Groups population: Patients with breast cancer referred to Mottahari clinic shiraz university of medical sciences. Sample: 105 Patients (50 of Patients in intervention group and 55 Patients in control group). Intervention: Educational programs of quality of life and coping strategies were held as four sessions as group discussion and lecture for experiment group and questionnaire coping strategies and quality of life (before, one month and two months after intervention) were used at three different periods. Study outcome: Primary outcome was quality of life and coping strategies of the Patients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012091610844N1**

Registration date: **2014-05-28, 1393/03/07**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-05-28, 1393/03/07

Registrant information

Name

Somayeh Ramezanli

Name of organization / entity

Fatemeh (PBUH) College of Nursing and Midwifery, Shiraz

Country

Iran (Islamic Republic of)

Phone

+98 71 1647 4258

Email address

ramezanli@jums.ac.ir

Recruitment status

Recruitment complete

Funding source

Research Deputy Shiraz University of Medical Sciences

Expected recruitment start date

2012-08-25, 1391/06/04

Expected recruitment end date

2013-03-10, 1391/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The impact of education on application of coping strategies and quality of life in women with breast cancer

Public title

The impact of education on application of coping strategies and quality of life

Purpose

Supportive

Inclusion/Exclusion criteria
Inclusion criteria: Age less than 60 years old; Literate; Is living in Shiraz; Patients' agreement to participate in the study; Having been in the stages 1, 2 and 3 of the illness; Surgery and adjuvant therapy is completed; Has not participated in an educational program applying coping strategies previously. Exclusion criteria: Unwillingness of the patient to continue cooperating in the study; Metastasis to other organs or recurrence; Lymph edema is caused by the inability of the patient; Stressful events in a period close to the time of completing the questionnaire; Incidence to during the study of mental disease - psychological; Chronic disease or other malignancies during the study (according to specialist physician).

Age
To 60 years old

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: 105

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

1

Registry name
00

Secondary trial Id
00

Registration date
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Medical Research Ethics Committee of Shiraz
University of Medical Sciences

Street address
Seventh floor, Shiraz University of Medical Sciences and Health Services, Next to Red Crescent Organization, Zand blvd

City
Shiraz

Postal code
71345-1978

Approval date
2012-08-12, 1391/05/22

Ethics committee reference number
CT-91-6270

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, one month and two months after intervention

Method of measurement
Questionnaire EORTC QLQ-C30

Secondary outcomes

1

Description
Coping Strategies

Timepoint
Before, one month and two months after intervention

Method of measurement
Questionnaire

Intervention groups

1

Description
Intervention group: Education program on quality of life and coping strategies was conducted in 5 groups weekly for one month as group discussion and lecture for patients with breast cancer then one month or 2 after educational sessions in order to determine the effectiveness of this intervention, questionnaires were completed.

Category
Lifestyle

2

Description
Routine Care

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Motahhari Clinic Shiraz

Full name of responsible person

Fatemeh Hashemi

Street address

Namazi sq.

City

Shiraz

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice Chancellor for Research of Shiraz University of Medical Sciences

Full name of responsible person

Dr Gholam Reza Hattam

Street address

Seventh floor, Shiraz University of Medical Sciences and Health Services, Zand blvd

City

Shiraz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice Chancellor for Research of Shiraz 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**

Shiraz University of Medical Sciences

Full name of responsible person

Fatemeh Hashemi

Position

MS in nursing

Other areas of specialty/work**Street address**

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hashemif@sums.ac.ir

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

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ramezanli1362@gmail.com

Web page address**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