

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

The Effect of an Educational Intervention based on Pender's Theory on Quality of Life of Breast Cancer Patients after Mastectomy Surgery

Protocol summary

Summary

Background: Educational intervention can be effective in improvement of quality of life. The present study aimed to investigate the effect of educational intervention based on Pender's theory on quality of life of patients 6 months after mastectomy. Methods: This randomized pre/posttest clinical trial is conducted in Motehary polyclinic affiliated to Shiraz University of Medical Sciences, Shiraz, Iran. The patients are randomly divided in to an intervention (n=70) and a control group (n=70). Both groups are assessed regarding different aspects of quality of life using EORTC QLQ-C30 questionnaire, which consists of 30 questions, at different phases (pretest and posttest). The interventional group are participated in an educational program for 2 months, while the control group only received the polyclinic's routine care. The interventional group is invited to participate in educational intervention in five group of 10 to 15 persons. Educational intervention consisted of three 45 minutes sessions about patients present illness and nutrition , physical activity and methods of stress management. To enhance the effect of intervention the interventional group is asked with self monitoring by using Pender's questionnaire in three aspects such as physical activity , nutrition and stress management. They are asked to report their life aspects by using on the above mentioned questions one researcher is responsible to monitor their reports once every two weeks.

General information

Acronym

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IRCT registration information

IRCT registration number: **IRCT138806172432N1**

Registration date: **2016-06-27, 1395/04/07**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-06-27, 1395/04/07

Registrant information

Name

Azadeh Amiri

Name of organization / entity

Shiraz University Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1647 4254

Email address

amirlea@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Shiraz University of Medical Sciences

Expected recruitment start date

2008-07-20, 1387/04/30

Expected recruitment end date

2008-09-20, 1387/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of an Educational Intervention based on Pender's Theory on Quality of Life of Breast Cancer Patients after Mastectomy Surgery

Public title

The Effect of an Educational Intervention on Quality of Life after Mastectomy Surgery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria :aging 25-55 years, passage of 6 months from mastectomy surgery, and not suffering from lymphedema and other malignancies. Exclusion criteria:recurrence of the disease and metastasis to other organs.chemoterapy or radiotrappy

Age

From **25 years** old to **55 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

random number table

Secondary Ids

1

Registry name

.

Secondary trial Id

.

Registration date

2017-11-21, 1396/08/30

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences, Shiraz, Iran

Street address

School of Nursing and Midwifery

City

Shiraz

Postal code

7193613119

Approval date

2008-05-10, 1387/02/21

Ethics committee reference number

87-4018

Health conditions studied

1

Description of health condition studied

Breast cancer

ICD-10 code

c50.9

ICD-10 code description

Malignant Neoplasm OFBreast -Breast Unspecified Mass

Primary outcomes

1

Description

Quality of life

Timepoint

Before intervention and two mounths after intervention

Method of measurement

QLQ-C30 Quastionaire

Secondary outcomes

1

Description

-

Timepoint

-

Method of measurement

-

Intervention groups

1

Description

Interventional group: The interventional program is carried out through 3 training45 to 60 minutes sessions in three fields of nutrition, physical activity, and stress management. Thus, the intervention group participants take part in the training program in groups of10 to 15, so that group discussion forums become possible. The educational content included information about the disease, its treatment and complications, diet including healthy nutrition for the treatment process, and recovery including healthy food pyramid and foods that are essential for good health. High-risk foods and their low-risk alternatives in the course of treatment are expressed, as well. In addition, healthy cooking method of different food products is emphasized and necessary training is conducted in this area. Also, sports activities, including healthy physical activity pyramid, were emphasized in order to increase mobility at work and home in everyday life. Recommendations are, too, made about performing the activities that the patients can do. Besides, rehabilitation and recovery exercises, including stretching, isotonic, and isometric exercises, are taught to improve shoulder, scapula, and motor muscles movement in the process of treatment and recovery.

Moreover, the patients are trained about and are required to do stress reduction and relaxation techniques, such as diaphragmatic breathing, imagination, and positive thinking, every day. They are also provided with the necessary supports in different fields of the intervention. Furthermore, an educational booklet is prepared and given to the patients. During the study period, the researchers follows the patients by phone calls and ensured about their self-monitoring. In case the patients need assistance about other problems, they are trained individually or, if necessary, are referred to a specialist.

Category

Lifestyle

2**Description**

Control group: control group just will received the routine care of polyclinic.

Category

Lifestyle

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

Motahari polyclinic affiliated to Shiraz University of Medical Sciences, Shiraz, Iran

Full name of responsible person

Azade Amiri

Street address

Namazee Square ,Zand Street, Shiraz

City

Shiraz

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

Vice Chancellor for research of Shiraz University of Medical Sciences, Shiraz, Iran

Full name of responsible person

Dr Basir Hashemi

Street address

Zand Street, Shiraz University of Medical Sciences, Shiraz

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, Shiraz, Iran

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**

School Of Nursing and Midwifery Of Shiraz University of Medical Sciences,

Full name of responsible person

Azadeh Amiri

Position

Master of Science In Nursing -Faculty member of School of Nursing and Midwifery, Shiraz University o

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

Namazee Square, Zand Street, Hazrate Fateme School Of Nursing and Midwifery, Shiraz

City

Shiraz

Postal code

7193613119

Phone

+98 71 3647 4258

Fax

+98 71 3647 4252

Email

amirlea@sums.ac.ir

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

School of Nursing and Midwifery

Full name of responsible person

Marzieh Moattari

Position

Full Prfessor of Nursing Education

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

Namazee Square, Zand Street, Hazrate Fateme School Of Nursing and Midwifery, Shiraz

City

Shiraz

Postal code

: 7193613119

Phone

+98 71 3647 4252

Fax

+98 71 3647 4252

Email

moattar@yahoo.commoattari@yahoo.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

School of Nursing and Midwifery, Shiraz University of
Medical Sciences, Shiraz, Iran

Full name of responsible person

Azadeh Amiri

Position

Master of Science In Nursing -Faculty member
ofSchool of Nursing and Midwifery, Shiraz University
of

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

Namazee Square, Zand Street,Hazrate Fateme School
Of Nursing and Midwifery, Shiraz

City

Shiraz

Postal code

7193613119

Phone

+98 71 3647 4258

Fax

+98 71 3647 4252

Email

amirlea@sums.ac.irAzadehAmiri@yahoo.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