

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 2026

Evaluation of self-care education program's effect on breast self-examination behaviors in women attending to health care centers

Protocol summary

Summary

This quasi-experimental intervention study with pretest/post test was conducted to determine the effects of self-care education on performing breast self-exam (BSE) among women referred to health centers. 168 women were entered in the study. Inclusion criteria ; referring to health centers in Nurabad Mamasani; being at most 50 years old for married women and more than 25 years old for single ones; did not have breast cancer; continuous participation in the educational program. Exclusion criteria; being diagnosed with breast cancer based on self-reporting and medical records; being pregnant; breast-feeding. These women were non-randomly divided into intervention and control group. We had not blinding in the study. Main outcome in this study was self-care behavior that was measured by validated researcher-made questionnaire. Inclusion criteria ; referring to health centers in Nurabad Mamasani; being at most 50 years old for married women and more than 25 years old for single ones; did not have breast cancer; continuous participation in the educational program. Exclusion criteria; being diagnosed with breast cancer based on self-reporting and medical records; being pregnant; breast-feeding. The instruments were administered to both groups before intervention and after holding training classes for intervention group; one week and 10 weeks after the intervention the questionnaire were administered to both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017012115015N16**

Registration date: **2017-04-25, 1396/02/05**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-04-25, 1396/02/05

Registrant information

Name

Leila Ghahremani

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1725 1001

Email address

ghahramanl@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shiraz University of Medical Sciences

Expected recruitment start date

2014-04-21, 1393/02/01

Expected recruitment end date

2016-02-20, 1394/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of self-care education program's effect on breast self-examination behaviors in women attending to health care centers

Public title

Self-care education programs effect on breast self-examination behaviors

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria ; referring to health centers in Nurabad Mamasani; being at most 50 years old for married women and more than 25 years old for single ones; did not have breast cancer; continuous participation in the educational program. Exclusion criteria; being diagnosed with breast cancer based on self-reporting and medical records; being pregnant; breast-feeding.

Age

From **25 years** old to **100 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **168**

Randomization (investigator's opinion)

Not 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

Vice chancellor for research, Shiraz University of Medical Sciences

Street address

Shiraz University Of Medical Science, Namazi Square

City

Shiraz

Postal code

Approval date

2014-04-21, 1393/02/01

Ethics committee reference number

7259-93

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

Self-care behavior in prevention of breast cancer

Timepoint

Before intervaction , one week after intervention, ten weeks after intervention

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For the intervention group, the training program was self-care education on breast cancer. Training program was performed in four weekly 45-minute sessions. In each session lecture delivery and question-answer methods were used to educate participants. The education program included theoretical and practical training material which delivered through direct teaching methods, such as giving lecture, question and answer, breast self-exam (BSE) training videos, slideshows, and flip charts. At the end of the training sessions, educational pamphlets were also distributed among the participants of the intervention group. The questionnaire was administered to the women in both groups one week and 10 weeks after the intervention.

Category

Prevention

2

Description

Control group: without any intervention

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Health center city Nurabad Mamasani

Full name of responsible person

Miss.Zakiye Mosavi

Street address

Nourabad, Nurabad Mamasani Health Center

City

Nurabad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Shiraz University of Medical Science

Full name of responsible person

Dr. Leila Ghahramani

Street address

School of health, Koye Zahra, 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 Science

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

Dr. Leila Ghahramani

Position

Professor

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

School of health, Koye Zahra, Shiraz

City

Shiraz

Postal code**Phone**

+98 930 244 6689

Fax**Email**

mousavi_z@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

Dr. Leila Ghahramani

Position

Professor

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

School of health, Koye Zahra, Shiraz

City

Shiraz

Postal code**Phone**

+98 71 3725 1005

Fax**Email**

mousavi_z@sums.ac.ir

Web page address

Person responsible for updating data

Contact**Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Leila Ghahramani

Position

Professor

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

School of health, Koye Zahra, Shiraz

City

Shiraz

Postal code

00987137251005

Phone

+98 71 3725 1005

Fax**Email**

mousavi_z@sums.ac.ir

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