

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The impact of education based on Health Belief Model on promoting Self-care behaviors in first degree relatives of breast cancer patients

Protocol summary

Summary

Major eligibility objectives: The determination of impact of education based on Health Belief Model on promoting Self-care behaviors in first degree relatives of breast cancer patients Design:clinical trial phase 2-3. Setting and Conduct: After explaining The purpose of the study to the participants, as the pretest, questionnaires in the context of demographic characteristics, knowledge, beliefs about breast cancer with the use of health belief model and self-care behaviors affecting breast cancer and also perceived stress were filled up by both control and intervention groups. Educational content based on Health Belief Model was presented to intervention group. Eight weeks after education, the same questionnaires were filled up as the post test. At the end of the study, educational booklets were given to both groups. Participants: 76 females who had the history of breast cancer in first degree relatives and were literate that were willing to participate in the study, were included in the study; And who didn't desire to participate or had suspicious ultrasound or mammogram or were absent in more than one session, were excluded. Interventions: In the intervention group, four educational sessions, each one lasted 90 seconds, were held based on health belief model. The control group participants didn't receive any education. main outcome: self-care behaviors

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016082129446N1**

Registration date: **2017-04-26, 1396/02/06**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-04-26, 1396/02/06

Registrant information

Name

Maryam Damghanian

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2016-07-22, 1395/05/01

Expected recruitment end date

2016-10-22, 1395/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The impact of education based on Health Belief Model on promoting Self-care behaviors in first degree relatives of breast cancer patients

Public title

The impact of education on self-care behaviors affecting breast cancer

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Having the minimum literacy; Lack of any known cancer; No known mental illness; Having a family history of breast cancer in the first degree relatives (mother, sister, daughter); Willingness to cooperate. Exclusion criteria: suspicious mass on ultrasound or mammogram; Absence in more than one training session; Not willing to continue cooperation.

Age

No age limit

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 76

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**

Ethics committee of Tehran University of Medical Sciences

Street address

Ghods street, Enghelab squer, Tehran, Iran

City

Tehran

Postal code**Approval date**

2016-05-25, 1395/03/05

Ethics committee reference number

IR.TUMS.VCR.REC.1395.60

Health conditions studied**1****Description of health condition studied**

breast cancer

ICD-10 code

C50.9

ICD-10 code description

Breast, unspecified

Primary outcomes**1****Description**

self - care behaviors

Timepoint

Before and 2 months after intervention

Method of measurement

questionnaire

Secondary outcomes**1****Description**

Awareness

Timepoint

Before and 2 months after intervention

Method of measurement

questionnaire

Intervention groups**1****Description**

In the intervention group, four educational sessions, each one lasted 90 seconds, were held based on health belief model. The content of education were The anatomy of breast, defining the breast cancer and its types, symptoms and risk factors of breast cancer, complications and consequences of late diagnosis, effective self-care behaviors on prevention and early detection of breast cancer, the expression of incorrect beliefs about breast cancer and self-care. The methods including lecture, group discussion, question and answer, were used. Self-care assessments were done before and two months after intervention.

Category

Prevention

2**Description**

The control group participates didn't receive any education. Evaluation of self-care behaviors were done before and two months after intervention.

Category

Prevention

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

Cancer Institute of Imam Khomeini Hospital

Full name of responsible person

Dr Mahmoudi

Street address

Imam Khomeini Hospital, The end of Keshvarz
Blvd, Tehran, Iran

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tehran University of
Medical Sciences

Full name of responsible person

Esmat Karimi

Street address

No23, Dameshgh street, Valiasr street, Tehran, Iran

City

Tehran

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, Tehran 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

Nursing and Midwifery Faculty, Tehran University of
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Full name of responsible person

Behjat Khorsandi

Position

Master student of midwifery

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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