

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

The effectiveness of the health education models intervention by peer group on breast cancer screening in women with positive family history

Protocol summary

Summary

This study is a single blind field trial with control group to evaluate effectiveness of the health education models intervention by peer group on breast cancer screening in women with positive family history. Target group are women and daughters with family history of breast cancer. Total sample size is 100. Sample size will be collected among women with a first or second degree relative of breast cancer that are referred to Saied Shohola Hospital in Isfahan. First questionnaire will be filled by questioner for women who filled the consent. If women are in pre contemplation, contemplation or relapse stages of Tran's theoretical model of breast cancer screening will be entered in the study. Then women will be allocated to intervention and control groups by computer randomized soft ware. We will choose some women with action or maintenance stages of breast cancer screening as educators in this step. At the beginning of the intervention educators will be educated by health expert on health belief model. In the second stage intervention group will be educated by educators. Immediate and 3 months after the intervention questionnaire will be filled by control and intervention groups to evaluate their knowledge, health beliefs and screening practice again.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015051921447N2**

Registration date: **2015-07-03, 1394/04/12**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-07-03, 1394/04/12

Registrant information

Name

Fariba Fathollahi Dehkordi

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2015-05-26, 1394/03/05

Expected recruitment end date

2015-09-11, 1394/06/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of the health education models intervention by peer group on breast cancer screening in women with positive family history

Public title

Effectiveness of education intervention on breast cancer screening

Purpose

Screening

Inclusion/Exclusion criteria

Inclusion criteria: history of breast cancer in first or second degree relative; stay on pre contemplation, contemplation or relapse stages for education receiver;

stay on action or maintenance stages for educators;
tendency to participate in the study Exclusion criteria:
not complete more than 20% of questionnaire; not
participate in more than on session; not tendency to
continue the study; breast cancer development during
the study

Age

From **20 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jerib
Street

City

Isfahan

Postal code

8174673461

Approval date

2015-05-24, 1394/03/03

Ethics committee reference number

mui.rec394130

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

Clinical breast examination

Timepoint

Before and 3 months after intervention

Method of measurement

questionarie

2

Description

Mammography screening

Timepoint

Before and 3 months after intervention

Method of measurement

questionarie

Secondary outcomes

1

Description

Knowledge about breast cancer and screening

Timepoint

Before, immediate after and 3 moth after the
intervention

Method of measurement

questionarie

2

Description

Health belief about breast cancer and screening

Timepoint

Before, immediate after and 3 moth after the
intervention

Method of measurement

questionarie

3

Description

Distribution of breast cancer screening stage of change
excluding maintenance stage

Timepoint

Before, immediate after and 3 moth after the
intervention

Method of measurement

questionarie

Intervention groups

1

Description

We have an educational intervention in three sessions for
intervention group. Intervention group will be educated
with individuals in action or maintenance stage of breast
cancer screening behavior. These sessions will be held

on health belief model to increase participant perceived sensitivity and intensity about breast cancer, their knowledge about breast cancer signs, symptoms and risk factors, early detection methods, perceived benefit and barriers. In all sessions educator will tell about her successful experiences. At the end of the intervention we will give an education program booklet and CD to participants.

Category

Early detection

2**Description**

To preserving ethical principles, we give an educational program booklet and CD at the end of study.

Category

Early detection

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

Saied Shohada hospital

Full name of responsible person

Simin Hematti

Street address

After Shiri Bridge, Mottahari Street

City

Isfahan

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

Vice Chancellor for research of Isfahan University of Medical Sciences

Full name of responsible person

Mahdi Nematbakhsh

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Vice Chancellor for research, building number 4, Isfahan University of Medical Science, Hezar Jerib street

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Isfahan

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 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**

Isfahan University of Medical Sciences

Full name of responsible person

Ziba Farajzadegan

Position

Professor

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

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Full name of responsible person

Fariba Fathollahi

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Resident of Community Medicine

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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