

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Evaluation of the effectiveness of the educational intervention on promotion of preventive behavior of breast cancer on at risk women in Tehran

Protocol summary

Summary

The purpose of this study is implementation and evaluation of educational interventions to improve preventive behavior of breast cancer on women at risk in Tehran. The main criteria for inclusion is all women over 30 years without breast cancer, and the main exclusion criteria is all women over 30 years who has breast cancer. The population of current study is 260 women at risk of breast cancer in Tehran. Quasi random allocation technique will be used to divide the sample into experimental (n = 130) and control (n = 130) groups. At first, a meeting will conduct in order to explain the purpose of the study for both groups. Then, the questionnaire will be completed by all respondents and the data will be analyzed by SPSS software and based on the results of this analysis, the problems and weak points of participants regarding performing preventive behavior of breast cancer will be distinguished and based on these results a education program will be designed and implemented on the experimental group in 6 sessions. After implementing the educational program to improve preventive behavior of breast cancer through group discussion, lectures and pamphlet, the experimental group participants persuaded to comply with the preventive behavior of breast cancer and also reinforced to follow the instructions noted in the pamphlet regarding these behaviors. After 3 months the questionnaire, again were completed by both the experimental and control groups. Due to ethical issues, training will be conducted to control group after completion of the post test.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201305068742N2**

Registration date: **2013-06-12, 1392/03/22**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-06-12, 1392/03/22

Registrant information

Name

Fereshteh Majlessi

Name of organization / entity

Tehran University of Medical Sciences

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Phone

+98 21 8898 9134

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majlesif@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2013-06-20, 1392/03/30

Expected recruitment end date

2013-12-21, 1392/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of the educational intervention on promotion of preventive behavior of

breast cancer on at risk women in Tehran

Public title

The Impact of education on preventive behavior of breast cancer

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: all women over age 30 who are not diagnosed with breast cancer; Not have a history of breast biopsy; To have the literacy to understand the questions in the questionnaire; No history of chronic disease; They are living in Tehran; Informed consent to participate in research. Exclusion criteria: - All women over 30 year that: Do not have literate to understand and fill questions in the questionnaire; Have a history of chronic diseases (diabetes, hypertension, etc.); Have a history of breast cancer; Have a history of mammography and ultrasound for breast cancer; No resident in Tehran

Age

From 30 years old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 260

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

Tehran University of Medical
Science, Poursina, Enghelab

City

Tehran

Postal code

-

Approval date

2012-07-17, 1391/04/27

Ethics committee reference number

81549

Health conditions studied

1

Description of health condition studied

preventive behavior of breast cancer

ICD-10 code

C50

ICD-10 code description

Malignant neoplasm of breast

Primary outcomes

1

Description

Promotion of preventive behavior of breast Cancer

Timepoint

Before intervention and 3 months after intervention

Method of measurement

Researcher made questionnaire

Secondary outcomes

1

Description

Awareness of breast cancer prevention

Timepoint

Before and three months after education

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention Groups: face to face interviews and training with emphasis on doing preventive behavior of breast cancer. Regarding to implementation of intervention group participate to the face to face education in 6 session Content of interventional program will be based on preventive behavior of breast cancer. We will use different instructional media in order to facilitate learning about it. 3 month after delivery we will fill out post tests.

Category

Behavior

2

Description

Control: face to face training for the moral issues will perform in 6 sessions content of interventional program will be based on doing preventive behavior of breast cancer, to the control group after intervention

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Health - care Center of South

Full name of responsible person
Maryam khazaee

Street address
Department of Health Education and Promotion, School of Public Health, Tehran University of Medical Science, Poursina, Enghelab

City
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2

Recruitment center

Name of recruitment center
Health - care Center of Rey

Full name of responsible person
Maryam khazaee

Street address
Department of Health Education and Promotion, School of Public Health, Tehran University of Medical Science, Poursina, Enghelab

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Rey city

3

Recruitment center

Name of recruitment center
Health - care Center of Eslamshahr

Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Professor Akbar Fotouhi

Street address
Tehran University of Medical Science, Poursina, Enghelab

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

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
Tehran University of Medical Sciences

Full name of responsible person
Maryam Khazaee Pool

Position
PhD student in health education

Other areas of specialty/work

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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