

# 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8898 9134

###### Email address

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 khazaei

**Street address**

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

**City**

Tehran

### 2

#### Recruitment center

**Name of recruitment center**

Health - care Center of Rey

**Full name of responsible person**

Maryam khazaei

**Street address**

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

**City**

Rey city

### 3

#### Recruitment center

**Name of recruitment center**

Health - care Center of Eslamshahr

**Full name of responsible person**

Maryam khazaei

**Street address**

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

**City**

Tehran

## 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

**City**

Tehran

**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 Khazaei Pool

**Position**

PhD student in health education

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

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

**City**

Tehran

**Postal code****Phone**

+98 21 8898 9134

**Fax****Email**

khazaie\_m@yahoo.com khazaie@razi.tums.ac.ir

**Web page address**

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Maryam Khazaei pool

**Position**

PhD student in health education

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

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

**City**

Tehran

**Postal code****Phone**

+98 21 8898 9134

**Fax****Email**

khazaie\_m@yahoo.com

**Web page address**

## **Person responsible for updating data**

### **Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Maryam Khazaee pool

**Position**

PhD student

**Other areas of specialty/work**

**Street address**

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

**City**

**Postal code**

**Phone**

+98 21 8898 9134

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khazaie\_m@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*