

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Effectiveness of an educational intervention based on fear appeals on attitude, behavioral intention and breast cancer preventive behaviors

Protocol summary

Summary

objectives: The aim of this study is to evaluate the attitude, behavioral intention and preventive behavior of breast cancer in women. This study is a population based study, and Inclusion criteria: women 40 years and older who do not have breast cancer and history , their first-degree relatives do not have this disease, have ability to read and write and have not psychological disorders will be in study. If there will not be even one of these criteria,the participant will reject . Study design:about 600 people will be sampled (according to the number of 40 years old and older women in Tehran and the time and financial limits), this number will be selected. Of course, we will try to maintain the characteristics of this type of study. This study is a cluster randomized control .Tehran is divided to 22 districts.Every districts in this study will subdivided to some blocks which are related to population so large districts will have more blocks. To avoid information contamination in study, blocks will be used separately for intervention and control . Blocks will randomly allocate to intervention and control and number of them are the same in every district.This study is not blinded . Some skilled female questioners will be educated and they visit women in their home in selected places. people will consent and give phone number for follow-up then will complete the researcher-made questionnaire (prepared on the basis of studies and its validity and reliability is done, and is approved by specialist) .Implementation: the intervention group will receive (the 2 pamphlets which are designed and tested on the basis of fear appeals) at baseline and after 2 weeks. They are different in messages and photographs but in the same content. After 3 months follow up will be done, both the intervention and control group will complete the questionnaire again, control group will receive the two pamphlets used in the study to observe the ethics . The control group will receive nothing as educational material in this study. The main variables in this study are attitude,behavioral intention and

preventive behaviors of breast cancer.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017013032315N1**

Registration date: **2017-09-14, 1396/06/23**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-09-14, 1396/06/23

Registrant information

Name

Vahideh Termeh zonuzy

Name of organization / entity

Faculty of Medical Sciences, Tarbiat Modares University

Country

Iran (Islamic Republic of)

Phone

+98 21 8288 3421

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research,Tarbiat Modares University.

Expected recruitment start date

2017-10-01, 1396/07/09

Expected recruitment end date

2017-12-29, 1396/10/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Effectiveness of an educational intervention based on fear appeals on attitude, behavioral intention and breast cancer preventive behaviors

Public title
fear appeal effect on attitude,behavioral intention and breast cancer preventive behaviors in women

Purpose
Prevention

Inclusion/Exclusion criteria
]Inclusion Criteria:40 years old and above :Have ability to read and write :Not have breast cancer and it's history: Not have breast cancer in her relative(mother,sister,daughter) and not have psychiatric disorders. Exclusion Criteria: If there will not even one inclusion criteria(like younger than 40), the participant will remove from study.

Age
From **40 years** old to **99 years** old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **600**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Randomization in selecting blocks to intervention or control will be done with Excel software.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee in Faculty of Medical Sciences,
Tarbiat Modares University

Street address

pole nasr, Jalal al ahmad, Faculty of Medical Sciences,
Tarbiat Modares University

City

Tehran

Postal code

Approval date
2015-11-09, 1394/08/18

Ethics committee reference number
IR.TMU.REC.1394.150

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

Attitude

Timepoint

Before and3 months after manipulation

Method of measurement

Using questionnair is made by researcher for this study

2

Description

Behavioral intention

Timepoint

Before and3 months after manipulation

Method of measurement

Using questionnair is made by researcher for this study

3

Description

Behavior

Timepoint

Before and3 months after manipulation

Method of measurement

Using questionnair is made by researcher for this study

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: using 2 designed pamphlets based on fear appeals. people receive the first one after completing the questionnaire at baseline and, after 2 weeks.

Category

Prevention

2

Description

Control group: There is no implementation in control group in this study.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

samples will be collected in Tehran(in all 22 districts).

Full name of responsible person

Dr. Shamsedin Niknami

Street address

Pole Nasr, Jalal Al Ahmad, Faculty of Medical Sciences, Tarbiat Modares University, Tehran, Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tarbiat Modares University

Full name of responsible person

Dr. Shamsedin Niknami

Street address

Pole Nasr, Jalal Al Ahmad, 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, Tarbiat Modares University

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

Faculty of Medical Sciences, Tarbiat Modares

University

Full name of responsible person

Dr. Shamsedin Niknami

Position

Faculty Member

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Health Sciences Research Institute, Jahad Daneshgahi

Full name of responsible person

Dr. Ali Montazeri

Position

Head of institute - phd

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

Faculty of Medical Sciences, Tarbiat Modares University

Full name of responsible person

Vahideh Termeh Zonouzy

Position

phd student

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