

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 2026

### Evaluation of Educational Program based on Integrated model health action process approach (HAPA) with Protection Motivation Theory (PMT) on breast cancer screening Behavior in women older than 40 years old

#### Protocol summary

##### Summary

Objectives: Evaluation of Educational Program based on Integrated model health action process approach (HAPA) with Protection Motivation Theory (PMT) on breast cancer screening is: Women over 40 years of age in health centers in Shahid Beheshti University of Tehran. Intervention group: (PARDIS Health Network). control group: (PARDIS Health Network) Sample size: The intervention group consisted of 40 individuals in the control group including 40 educational programs based on predictive structures Integrated model health action process approach (HAPA) with Protection Motivation Theory (PMT) in women 40 years old for 10 weeks .evaluation, and average score of structures before, after and 6 months after intervention. An intervention program with a group discussion class that will consider electronic learning facilities as part of the phase. Breast self-examination check list and initial questionnaire are used at intervals. There is no intervention in the control group.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017061134472N1**

Registration date: **2017-08-19, 1396/05/28**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-08-19, 1396/05/28

##### Registrant information

###### Name

Fatemeh Pourhaji

##### Name of organization / entity

Tarbiat Modares University

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 7742 8982

##### Email address

fatemeh.pourhaji@modares.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Tarbiat Modares University

##### Expected recruitment start date

2017-07-23, 1396/05/01

##### Expected recruitment end date

2018-12-02, 1397/09/11

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of Educational Program based on Integrated model health action process approach (HAPA) with Protection Motivation Theory (PMT) on breast cancer screening Behavior in women older than 40 years old

##### Public title

Integrated model health action process approach (HAPA) with Protection Motivation Theory (PMT)

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion criteria: lack of breast cancer disease in themselves and first-degree family members; a written consent to participate in the study; the age of the person

participating in the research must be over 40 years of age; individuals must have Iranian nationality. Exclusion criteria: if they have more than one-time attending classes, they will be excluded from the study; exposure to severe psychological stress during the past 6 months, including relatives' deaths or surgical procedures during the conduct of research.

#### Age

From **40 years** old to **80 years** old

#### Gender

Female

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **400**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Not blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

The intervention program is based on the predictive variables of the Integrated Health action Process Approach (HAPA) model with Protection Motivation Theory (PMT). The educational content includes breast cancer screening behavior. To determine the samples of the intervention and control groups for implementation of the educational program based on the integrated model of the Health Process Approach (HAPA) with the Protection Motivation Theory (PMT) from the 4 selected health centers, 2 health centers were randomly assigned to one of the two groups as an intervention and control group Taking place in one of the selected centers, interventions are carried out, and people in the center will be considered as witnesses. Participants are randomly selected in the study.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Medical school in Tarbiat Modares University of Medical Sciences

##### Street address

1 room, on the first floor of Medical Ethics, Tarbiat modares University, Paul Geisha, Tehran Tehran Tehran Iran, Islamic Republic Of

##### City

Tehran

#### Postal code

14115-111

#### Approval date

2016-05-03, 1395/02/14

#### Ethics committee reference number

IR.TMU.REC.1395.328

## Health conditions studied

### 1

#### Description of health condition studied

Breast cancer screening

#### ICD-10 code

C50

#### ICD-10 code description

Malignant neoplasm of breast

## Primary outcomes

### 1

#### Description

Determination and comparison of mean score of predictive structures of breast cancer screening behavior in intervention and control groups; Determination and comparison of mean scores of breast cancer screening behavior in intervention and control groups

#### Timepoint

Before, after and 6 months after intervention

#### Method of measurement

Questioner

## Secondary outcomes

### 1

#### Description

Determine and compare the rate of breast cancer screening behavior in the intervention and control group

#### Timepoint

Before, after and 6 months after intervention

#### Method of measurement

Questionar

## Intervention groups

### 1

#### Description

Intervention group: Conducting an educational program to enhance the structure of the integrated model of the health action process approach with the protection motivation theory in 4 sessions of 2 hours Follow up of the intervention group by 10 weekly reminders by texting and assigning assignments. Also, the film and poster of breast cancer screening behavior Will be sent through the compact disc.

#### Category

N/A

## 2

### Description

Control group: did not receive any training on breast cancer screening behavior. Follow up of this group only to complete questionnaires at specified intervals

### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahid Beheshti University of Medical Sciences of Iran

##### Full name of responsible person

Fatemeh Pourhaji

##### Street address

Units7, 4, 126, Molavi street, Etellaat Square, Tehranno, Tehran.

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for research, Tarbiat Modares University

##### Full name of responsible person

Dr. Ya'qub Fath Allahi Nane Karan

##### Street address

Third floor, Central Building 1, Tarbiat Modares University

##### 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

Tarbiat modares University

#### Full name of responsible person

Fatemeh Pourhaji

#### Position

PhD candidate of Health education and health promotion

#### Other areas of specialty/work

#### Street address

Room 111, 2nd, Faculty of Medicine 1, Paul Gisha, Tehran

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#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Tarbiat Modares University

#### Full name of responsible person

Dr. Fazlollah Ghofranipour

#### Position

Professor

#### Other areas of specialty/work

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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*