# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 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 Geisha۹, 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**

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## Person responsible for scientific inquiries

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**Position**
Professor

**Other areas of specialty/work**

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## Person responsible for updating data

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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*