

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 2026

### Effect of an Educational Intervention Based on Protection Motivation Theory on early detection behaviors of breast cancer in women who visit the Community Health Centers

#### Protocol summary

##### Study aim

Effect of an Educational Intervention Based on Protection Motivation Theory on early detection behaviors of breast cancer in women who visit the Community Health Centers.

##### Design

Semi-experimental study was performed on 20-50 year-old women referred to the health center who Non-randomized controls were divided into control and intervention groups.

##### Settings and conduct

Community health centers, khalkhal city

##### Participants/Inclusion and exclusion criteria

Women 20 to 50 years old Do not breast-feed or during pregnancy No previous training do not have breast cancer

##### Intervention groups

In the intervention group, early detection of cancer was conducted on the basis of the theory and evaluated with the control group that received only traditional education.

##### Main outcome variables

Early detection of cancer

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180304038952N1**

Registration date: **2019-02-27, 1397/12/08**

Registration timing: **retrospective**

Last update: **2019-02-27, 1397/12/08**

Update count: **0**

##### Registration date

2019-02-27, 1397/12/08

#### Registrant information

##### Name

LEILA HAKIMI

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 45 3242 4148

##### Email address

leila\_hakimi@sbmu.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

##### Expected recruitment start date

2018-11-22, 1397/09/01

##### Expected recruitment end date

2018-12-21, 1397/09/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

#### Scientific title

Effect of an Educational Intervention Based on Protection Motivation Theory on early detection behaviors of breast cancer in women who visit the Community Health Centers

#### Public title

The effect of educational intervention based on the theory of early detection of breast cancer

#### Purpose

Screening

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Reading and writing skills You have no medical education

During pregnancy or lactation is not.

**Exclusion criteria:**

The incomplete company attends training sessions  
Definitive diagnosis of breast cancer Incomplete questionnaires

**Age**

From **20 years** old to **50 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **90**

**Randomization (investigator's opinion)**

Not randomized

**Randomization description**

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Ethics Committee of Pharmacy and Nursing Schools,  
Midwifery

**Street address**

Madani Street

**City**

khakhal

**Province**

Ardabil

**Postal code**

5681756151

**Approval date**

2017-06-30, 1396/04/09

**Ethics committee reference number**

IR.SBMU.PHNM.1396.783

**Health conditions studied**

**1**

**Description of health condition studied**

Early detection of breast cancer symptoms

**ICD-10 code**

C50.9

**ICD-10 code description**

Malignant neoplasm of breast

**Primary outcomes**

**1**

**Description**

Change the behavior as a result of training

**Timepoint**

Immediately and then two months

**Method of measurement**

questionnaire

**Secondary outcomes**

empty

**Intervention groups**

**1**

**Description**

Intervention group: Prior to the intervention, a one-shot protection motivation questionnaire is taken from individuals in the early detection of breast cancer. Educational intervention is carried out in 6 sessions and then the questionnaire will be filled in immediately and in two months.

**Category**

Behavior

**2**

**Description**

Control group:the questionnaire is filled in three times and additional educational work is not done.

**Category**

Behavior

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Community Health Center

**Full name of responsible person**

Leila Hakimi

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Dastgeyb Ave

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HAKIMILEILA63@GMAIL.COM

## Sponsors / Funding sources

leila\_hakimi@sbmu.ac.ir

### 1

#### Sponsor

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Camelia Rohani

**Street address**

Velenjak St. , Shahid Chamran Highway

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**Province**

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**Postal code**

1985717443

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Intl\_office@sbmu.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Shahid Beheshti University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

Academic

## Person responsible for general inquiries

#### Contact

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Leila Hakimi

**Position**

Masters Degree in Nursing

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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Madani Ave

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## Person responsible for scientific inquiries

#### Contact

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**Other areas of specialty/work**

Nursery

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## Person responsible for updating data

#### Contact

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Camelia Rohani

**Position**

Assistant Professor, Department of Community Health Nursing

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available  
**Statistical Analysis Plan**  
Undecided - It is not yet known if there will be a plan to make this available  
**Informed Consent Form**  
Yes - There is a plan to make this available  
**Clinical Study Report**  
Yes - There is a plan to make this available  
**Analytic Code**  
Yes - There is a plan to make this available  
**Data Dictionary**  
Undecided - It is not yet known if there will be a plan to make this available  
**Title and more details about the data/document**

Further details will be provided after the completion of the study  
**When the data will become available and for how long**  
One month after the completion of the study  
**To whom data/document is available**  
Academic Institutions  
**Under which criteria data/document could be used**  
I have no condition  
**From where data/document is obtainable**  
Shahid Beheshti university of Medical Sciences  
**What processes are involved for a request to access data/document**  
The study objectives have a relative overlap  
**Comments**