

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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Sponsors / Funding sources

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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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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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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