

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

The effect of Peer Education on self-efficacy of Breast Self-Examination(BSE) in woman

Protocol summary

Study aim

Determining the Effect of Peer Education on Women's Self-efficacy in Breast Implantation

Design

A community-based control-controlled clinical trial with randomized, double-blind, randomized, factorial groups.

Settings and conduct

An interventional study was conducted in Dehloran city. Exit participants and evaluators were blinded. They did not know they were compared to the other group. Control and intervention groups were located in two different cities, and the groups were not related.

Participants/Inclusion and exclusion criteria

Entry requirements included the absence of a history of breast cancer in the participant and first-degree family members, having reading and writing skills, the absence of a disease or any disability that makes the study difficult, and the conditions for withdrawal The lack of participation in two sessions of the educational program and failure to complete the questionnaire.

Intervention groups

The intervention group was trained in breast self-examination. The control group did not receive any training.

Main outcome variables

Breast self-examination, peer education, self-efficacy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181001041194N1**

Registration date: **2018-12-23, 1397/10/02**

Registration timing: **retrospective**

Last update: **2018-12-23, 1397/10/02**

Update count: **0**

Registration date

2018-12-23, 1397/10/02

Registrant information

Name

Kazemieh Sadeghirad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 84 3372 9535

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-21, 1397/02/01

Expected recruitment end date

2018-06-22, 1397/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Peer Education on self-efficacy of Breast Self-Examination(BSE) in woman

Public title

The effect of Peer Education on self-efficacy of Breast Self-Examination(BSE) in woman

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

The absence of a history of breast cancer in a person

participating in research and first-degree family Members Having reading and writing Skills Lack of illness or any disability that makes the study difficult.

Exclusion criteria:

Not attending two sessions of the training program.
Failure to complete the questionnaire.

Age

From **25 years** old to **55 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Using a lottery, eight centers of the two centers were selected. From the two selected centers, using a lottery, a center was assigned for the intervention group and one center for the control group. A random number table method was used to select individuals in each center.

Blinding (investigator's opinion)

Double blinded

Blinding description

The participants did not know that their results would be compared to one another. The peer ladies who were responsible for assessing the outcome of the study were unaware that their results would be compared to one another. In the random selection of centers, two centers from two different cities were selected for study. The groups were not connected.

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, next to Milad Tower, Hemat Highway, Tehran

City

Tehran

Province

Tehran

Postal code

۱۴۹۶۱۴۵۳۵

Approval date

2018-02-25, 1396/12/06

Ethics committee reference number

IR.IUMS.FMD.REC.1396.9311690006

Health conditions studied

1

Description of health condition studied

Effect of training on self-efficacy in BSE

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

self-efficacy

Timepoint

Before the intervention and one month after the intervention is completed.

Method of measurement

Use of self-efficacy section in "Champion questionnaire".

Secondary outcomes

1

Description

Breast self-examination

Timepoint

Before the intervention and one month after the intervention.

Method of measurement

questionnaire

Intervention groups

1

Description

Intervention group: Four sessions per hour (including two sessions of theoretical education and two practical training sessions) were presented to the participants during the four consecutive weeks in the form of group discussions, lectures and demonstrations.

Category

Prevention

2

Description

The Control group did not receive any intervention.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Dehloran Health Care Network

Full name of responsible person

Dr. Asadollah Mohajer

Street address

Dehloran Health Care Network, Jomhoori Street,
Dehloran City

City

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Ilam

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6981615431

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

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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

Iran 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**

Iran University of Medical Sciences

Full name of responsible person

Miss, Marhamat Frahaninia

Position

Instructor

Latest degree

Master

Other areas of specialty/work

Nursery

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Valiasr St., Above the Vanak Square, Rashid Yasemi
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Person responsible for scientific inquiries

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Full name of responsible person

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Position

instructor

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Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Kazmieh Sadeghirad

Position

collegian

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available