

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Design, Implementation and Evaluation of theory-based intervention program on promoting screening behavior of breast cancer in employed women University of Medical Sciences

Protocol summary

Study aim

The purpose of this study was to design, implement and evaluate a theoretical-focused interventional program to promote breast cancer screening behavior in employed women.

Design

The study will be conducted in two stages: descriptive-analytical and interventional. A descriptive step is to measure the extent of screening behavior and determine behavior predictors. In the intervention phase, women with low screening behaviors are included in the study.

Settings and conduct

This study was conducted in Hamedan, Iran, in all the departments of the University of Medical Sciences. Blinding in the study is only for Women participating.

Participants/Inclusion and exclusion criteria

Having ages 61 to 20 years, having no breast cancer and having satisfaction to participate in the study

Intervention groups

"Intervention group": Employed women with low screening behavior

Main outcome variables

Screening behaviors

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171224038026N1**

Registration date: **2018-04-27, 1397/02/07**

Registration timing: **prospective**

Last update: **2018-04-27, 1397/02/07**

Update count: **0**

Registration date

2018-04-27, 1397/02/07

Registrant information

Name

mitra dogonchi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3838 0360

Email address

m.dogoonchi@edu.umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-11, 1397/06/20

Expected recruitment end date

2019-02-09, 1397/11/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Design, Implementation and Evaluation of theory-based intervention program on promoting screening behavior of breast cancer in employed women University of Medical Sciences

Public title

Effect of theory-based intervention program on promoting screening behavior of breast cancer in employed women

Purpose

Screening

Inclusion/Exclusion criteria

Inclusion criteria:

Having ages 61-20 years Not having breast cancer
Having the consent to participate in the study
Exclusion criteria:
Age less than 20 years Having breast cancer discontent
to participate in the study

Age

From **20 years** old to **69 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **160**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants are unaware of being in the intervention and control group. The names of people will be selected in lottery and will be placed in one of the intervention and control groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

After preparing the plan names so that participants do not understand which of the control or intervention groups, respectively

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Assistance Research & Technology University of Medical Sciences

Street address

Hamedan, Shahid Fahmida St., Hamedan University of Medical Sciences

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2017-12-12, 1396/09/21

Ethics committee reference number

IR.UMSHA.REC.1396.609

Health conditions studied

1

Description of health condition studied

Increased screening

ICD-10 code

Z12.3

ICD-10 code description

Encounter for screening for malignant neoplasm of breast

Primary outcomes

1

Description

Doing behavior Screening

Timepoint

Before the intervention and one month and three months after the intervention

Method of measurement

Report behavior screening Through the questionnaire

Secondary outcomes

1

Description

Screening behavior

Timepoint

Before the intervention one month and three months after the intervention

Method of measurement

questionnaire

2

Description

Knowledge

Timepoint

Before and one and three months after the intervention

Method of measurement

questionnaire

3

Description

Perceived sensitivity

Timepoint

Before and one and three months after the intervention

Method of measurement

questionnaire

4

Description

Perceived severity

Timepoint

Before and one and three months after the intervention

Method of measurement

questionnaire

5

Description

Reward

Timepoint

Before and one and three months after the intervention

Method of measurement

questionnaire

6

Description

Response Costs

Timepoint

Before and one and three months after the intervention

Method of measurement

questionnaire

7

Description

fear

Timepoint

Before and one and three months after the intervention

Method of measurement

questionnaire

8

Description

Self Efficacy

Timepoint

Before and one and three months after the intervention

Method of measurement

questionnaire

9

Description

Response Efficacy

Timepoint

Before and one and three months after the intervention

Method of measurement

questionnaire

10

Description

Treat Appraisal

Timepoint

Before and one and three months after the intervention

Method of measurement

questionnaire

11

Description

Coping Appraisal

Timepoint

Before and one and three months after the intervention

Method of measurement

questionnaire

12

Description

Motivation

Timepoint

Before and one and three months after the intervention

Method of measurement

questionnaire

13

Description

Health Promotion

Timepoint

Before and one and three months after the intervention

Method of measurement

questionnaire

14

Description

Screening Behavior of Breast Cancer

Timepoint

Before and one and three months after the intervention

Method of measurement

questionnaire

15

Description

Social Support Theory

Timepoint

Before and one and three months after the intervention

Method of measurement

questionnaire

16

Description

Emotional Support

Timepoint

Before and one and three months after the intervention

Method of measurement

questionnaire

17

Description

Information Support

Timepoint

Before and one and three months after the intervention

Method of measurement

questionnaire

18

Description

Instrumental Support

Timepoint

Before and one and three months after the intervention

Method of measurement

questionnaire

19

Description

Appasial Support

Timepoint

Before and one and three months after the intervention

Method of measurement

questionnaire

Intervention groups

1

Description

"Intervention group": 3 training sessions for 90 minutes, 2 sessions, 60 minutes workshop, one instruction book, one instructional film, 3 pamphlets, 1 posters, 3 photo clips and e-learning

Category

Behavior

2

Description

"Control group": Distribution of booklets and pamphlets and educational CDs

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

All Department of University of Medical Sciences

Full name of responsible person

Mitra Dogonchi

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Hamedan, Shahid Fahmida St., Hamedan University of Medical Sciences

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6517838695

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dogonchi.mitra@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

saied bashirian

Street address

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Email

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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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

mitra dogonchi

Position

Ph.D. student health education and health promotion

Latest degree

Master

Other areas of specialty/work

Health Promotion

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Person responsible for scientific inquiries

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Full name of responsible person

mitra dogonchi

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Latest degree

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Other areas of specialty/work

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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

Undecided - It is not yet known if there will be 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

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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

Person responsible for updating data**Contact****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

mitra dogonchi

Position

Ph.D. student health education and health promotion

Latest degree

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Other areas of specialty/work

Health Promotion