

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Design, implementation and evaluation of the intervention based on intervention mapping (IM) approach on breast cancer screening with mammography in Fasa city women

Protocol summary

Study aim

Determining the effectiveness of intervention mapping approach in breast cancer prevention using mammography

Design

A clinical trial with a control group, a blind strain, randomized, is conducted on 300 participants.

Settings and conduct

Intervention in the field of mammography screening in health centers is carried out in two intervention and control groups. The selection of participants is voluntary and the intervention and control groups are done in separate centers so that the people of the groups are not in contact with each other.

Participants/Inclusion and exclusion criteria

Informed written consent, literate, between 40 and 59 years old, able to participate in educational classes, having an active health record.

Intervention groups

In this study, the effect of the intervention in increasing breast cancer screening in the intervention and control groups is investigated.

Main outcome variables

mammography; breast self-examination; Increasing awareness ; removing barriers to screening; Reducing stress ; improving health care; Coherent training

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230617058501N1**

Registration date: **2023-12-02, 1402/09/11**

Registration timing: **prospective**

Last update: **2023-12-02, 1402/09/11**

Update count: **0**

Registration date

2023-12-02, 1402/09/11

Registrant information

Name

asiyeh yari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 76 3333 8583

Email address

a.yari@hums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-21, 1402/09/30

Expected recruitment end date

2024-02-19, 1402/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Design, implementation and evaluation of the intervention based on intervention mapping (IM) approach on breast cancer screening with mammography in Fasa city women

Public title

Mammography in breast cancer screening

Purpose

Screening

Inclusion/Exclusion criteria

Inclusion criteria:

Women aged 40 to 59 who have not had a mammogram

Exclusion criteria:

People with breast cancer

Age

From **40 years** old to **59 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **300**

Randomization (investigator's opinion)

Randomized

Randomization description

Among the 4 comprehensive health service centers in Fasa, two comprehensive health service centers were selected, which in terms of distance and geographical distance have the least probability of contact between the two intervention and control groups, and randomly the referents of a comprehensive health service center as the intervention group and the referents. The other center is divided as a control group. Then, with the introduction letter in hand, the vice president of research of the university will refer to those centers. Sampling in each comprehensive health service center will be done in a simple random manner and based on the electronic health record of the said centers' Sib system and based on the entry criteria.

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 Hormozgan University of Medical Sciences

Street address

Bandar Abbas, Shahid Chamran Blvd., Hormozgan University of Medical Sciences and Health Services
Postal code: 13885-79166

City

Bandar Abbas

Province

Hormozgan

Postal code

13885-79166

Approval date

2023-06-17, 1402/03/27

Ethics committee reference number

IR.HUMS.REC.1402.101

Health conditions studied

1

Description of health condition studied

Mammography in women aged 40 to 59 years

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Percentage of people who do mammography screening

Timepoint

Mammography screening measurement will be at the beginning of the study (before the start of the intervention) three and six months later

Method of measurement

Using a questionnaire and sheet containing mammography results

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group will conduct a training course on breast cancer prevention and mammography screening. Training methods will include face-to-face training and lectures. The training sessions will be according to the pre-test results. The control group will not receive any training but will receive a training package at the end of the study. Before the intervention and 3 months after the intervention, the questionnaire will be completed by the study subjects and the results will be reviewed and reported.

Category

Prevention

2

Description

The control group will not receive any training but will receive a training package at the end of the study. Before the intervention and 3 months after the intervention, the questionnaire will be completed by the study subjects and the results will be reviewed and reported

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive health service centers of Fasa city

Full name of responsible person

Laleh Hassani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bandare-abbas University of Medical Sciences

Full name of responsible person

Vali Alipour

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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

Bandare-abbas 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**

Bandare-abbas University of Medical Sciences

Full name of responsible person

Asiyeh Yari

Position

Student

Latest degree

Master

Other areas of specialty/work

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Email

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