Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jun 2026

Investigating the effect of virtual education intervention on breast self-examination in women referring to comprehensive health service centers

Protocol summary

Study aim
Determining the effect of virtual education intervention on breast self-examination

Design
A clinical trial with a control group, a randomized blind strain, will be conducted on 104 samples

Settings and conduct
The people participating in the study are selected from among the people who refer to the comprehensive service centers of Borujerd city. People participating in the study are assigned to two intervention and control groups. The people of the intervention and control groups will complete the questionnaire related to awareness, attitude and behavior in two stages before and three months after the intervention, and based on the results of the pre-test, an educational intervention will be designed. For the people of the intervention group, educational sessions about breast cancer and the importance of breast self-examination will be designed. In addition, after the end of the intervention in the test group and the collection of data and information, all educational items will be presented to the control group. In addition, at the beginning of the study, none of the participants know which group they belong to. will be placed.

Participants/Inclusion and exclusion criteria
Women who are between the ages of 10 and 54 Mobile phone access and connection to social networks Having enough knowledge and skills to use a smart mobile phone

Intervention groups
First, 5 centers are selected by cluster sampling from 10 comprehensive health service centers in Borujerd city. Then 104 people will be selected from these 5 centers in a consecutive and accessible manner based on the entry and exit criteria and until the completion of the sample size and in proportion to the number of visitors of each center. These 104 people are randomly assigned to intervention and control groups using a random number table.

Main outcome variables
Knowledge, attitude and behavior of breast self-examination

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190506043491N1**
Registration date: **2023-08-30, 1402/06/08**
Registration timing: **retrospective**

Last update: **2023-08-30, 1402/06/08**
Update count: **0**

Registration date
2023-08-30, 1402/06/08

Registrant information

Name
Morteza Mansourian

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 8877 5451

Email address
mansourian55@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-06-05, 1402/03/15

Expected recruitment end date
2023-08-06, 1402/05/15

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of virtual education intervention on breast self-examination in women referring to comprehensive health service centers

Public title
Investigating the effect of virtual education intervention on breast self-examination in women referring to comprehensive health service centers
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Women who are between the ages of 10 and 54 Mobile phone access and connection to social networks Having enough knowledge and skills to use a smart mobile phone
Exclusion criteria:
Having a history of breast cancer
Age
From **10 years** old to **54 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **104**
Randomization (investigator's opinion)
Randomized
Randomization description
Sampling method is sequential and available based on entry and exit criteria and until the sample volume is completed. Allocation of people in intervention and control group is done by simple random allocation method and using Blockrand package of R software. After the random sequence is specified by the study epidemiologist, the researcher will put the people into 2 control and intervention groups based on the specified random sequence.
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 Iran University of Medical Sciences
Street address
Iran University of Medical Sciences, Hemat Highway, next to Milad Tower, Tehran
City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
Approval date
2023-02-22, 1401/12/03
Ethics committee reference number
IR.IUMS.REC.1401.972

Health conditions studied

1

Description of health condition studied
Breast Cancer
ICD-10 code
C50
ICD-10 code description
Malignant neoplasm of breast

Primary outcomes

1

Description
Breast cancer self-examination
Timepoint
90 days
Method of measurement
questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In two stages before and three months after the intervention, they will complete the questionnaire related to knowledge, attitude and behavior, and based on the results of the pre-test, an educational intervention will be designed. The educational content consists of three parts: the first part includes the introduction of the disease, the second part: the benefits and importance of breast self-examination, and the third part is designed to teach how to perform breast self-examination. Health and through virtual space (through the formation of an educational channel

in the ITA program) will be done. Monthly reminders to perform breast self-examination will be done through SMS for three consecutive months to perform self-examination.

Category

Prevention

2

Description

Control group: The control group will complete the questionnaire related to awareness, attitude, and behavior in two stages before and three months after receiving routine care, and during three months only routine care will be done by referring to comprehensive health service centers that include the principles of self-care. Breast cancer will receive the symptoms of breast cancer and the ways of early detection and counseling. And after three months, they will complete the same questionnaire again.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive health service centers in Borujerd city

Full name of responsible person

Morteza Mansourian

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice President of Research and Technology of Iran University of Medical Sciences

Full name of responsible person

Dr. Reza Falak

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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

Vice President of Research and Technology of 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

Morteza Mansourian

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Sharing the data by email after publishing the result in valuable international journal
When the data will become available and for how long
six month after publishing the result
To whom data/document is available
other researchers
Under which criteria data/document could be used
for re- analyses the data
From where data/document is obtainable
to researchers by email
What processes are involved for a request to access data/document
maximum six month
Comments