Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effect of face-to-face and social network-based education based on the health belief model on model structures and breast self-examination behavior of women

Protocol summary

Study aim
Comparison of the effect of face-to-face and social network-based education based on the health belief model on model structures and breast self-examination behavior

Design
Clinical trial with a control group; two intervention groups, parallel groups; double-blind; randomized by random allocation method and permutation blocks in 9 blocks of 18

Settings and conduct
Comprehensive health centers of Shiraz; intervention with face-to-face and virtual training; double blinding of the participants in the study and data analyst

Participants/Inclusion and exclusion criteria
participants; all women referring to the selected comprehensive health centers of Shiraz; Entry criteria; Women aged 18 to 50 years; Having literacy and the ability to work with a smart phone and informed consent to participate in the research; Absence of breast diseases in the past and present; Not having a history of participating in a training class on breast screening; Exit criteria; Moving people's residences; Absence of more than one meeting in the face-to-face group; Not seeing the messages uploaded by people in the social network-based group and not sending a confirmation message; Failure to answer more than 20% of the questions in each of the questionnaires before and after the intervention

Intervention groups
Education about breast cancer and prevention methods is based on the health belief model in the intervention group based on social networks in a virtual form and in the face-to-face education group. After teaching each part based on the structure of the model, the questions related to it are provided to the people. The control group will also receive common services from comprehensive health centers.

Main outcome variables
perceived sensitivity and severity of breast cancer; perceived benefits and barriers of breast self-examination; Efficacy; health motivation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160404027216N11**
Registration date: **2024-02-15, 1402/11/26**
Registration timing: **prospective**

Last update: **2024-02-15, 1402/11/26**
Update count: **0**

Registration date
2024-02-15, 1402/11/26

Registrant information

Name
Fatemeh Vizeshfar

Name of organization / entity
Shiraz University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 71 3647 4258

Email address
vizeshfarf@sums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-04-20, 1403/02/01

Expected recruitment end date

2024-05-04, 1403/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of face-to-face and social network-based education based on the health belief model on model structures and breast self-examination behavior of women

Public title

Comparison of the effect of face-to-face and social network-based education based on the health belief model on model structures and breast self-examination behavior of women

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Women with a minimum age of 18 and a maximum age of 50 years Having literacy and the ability to work with a smart phone Having informed consent to participate in the research Absence of breast diseases in the past and present Not having a history of participating in a training class on breast screening

Exclusion criteria:

Moving people's place of residence Absence of more than one session of people present in the face-to-face training intervention group Failure to see the messages uploaded by the people in the social network-based intervention group and failure to send confirmation messages by them Failure to answer more than 20% of the questions in each of the questionnaires before and after the intervention

Age

From **18 years** old to **50 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **159**

Randomization (investigator's opinion)

Randomized

Randomization description

3 comprehensive health centers were selected by a simple random method from among 32 comprehensive health centers in Shiraz city, and after referring and coordinating with the relevant officials of the centers, women with entry criteria will be determined based on active cases in the Sib system, and then the samples will be contacted by phone. . The conditions of the research have been explained to the subjects and if they have consent, they will be entered into each of the intervention and control groups by random allocation method and permutation block method in 9 blocks of 18; Otherwise, according to the table of random numbers, the sample will be added to complete the number of 53 people in each center.

Blinding (investigator's opinion)

Double blinded

Blinding description

The participants will be contacted separately and will enter the study, and the people of each group will be unaware of the existence of the other two groups. The data is provided to the data analyst in the form of three groups, and he is unaware of the intervention and control groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Namazi Square, Faculty of Nursing and Midwifery of Hazrat Fatemeh

City

Shiraz

Province

Fars

Postal code

13119–71936

Approval date

2024-02-04, 1402/11/15

Ethics committee reference number

IR.SUMS.NUMIMG.REC.1402.131

Health conditions studied

1

Description of health condition studied

Constructs of health belief model related to breast cancer (Champion's Health Belief Model)

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Perceived susceptibility score of breast cancer in

Champion Health Belief Model Questionnaire

Timepoint

Before the intervention, immediately after the intervention, 2 months after the intervention

Method of measurement

Champion Health Belief Model Questionnaire

2

Description

Perceived severity score of breast cancer in Champion Health Belief Model Questionnaire

Timepoint

Before the intervention, immediately after the intervention, 2 months after the intervention

Method of measurement

Champion Health Belief Model Questionnaire

3

Description

The score of the perceived benefits of breast self-examination in the Champion Health Belief Model Questionnaire

Timepoint

Before the intervention, immediately after the intervention, 2 months after the intervention

Method of measurement

Champion Health Belief Model Questionnaire

4

Description

The score of perceived barriers to breast self-examination in the Champion Health Belief Model Questionnaire

Timepoint

Before the intervention, immediately after the intervention, 2 months after the intervention

Method of measurement

Champion Health Belief Model Questionnaire

5

Description

Self-efficacy score of breast self-examination in Champion health belief model questionnaire

Timepoint

Before the intervention, immediately after the intervention, 2 months after the intervention

Method of measurement

Champion Health Belief Model Questionnaire

6

Description

Health motivation score in Champion Health Belief Model Questionnaire

Timepoint

Before the intervention, immediately after the intervention, 2 months after the intervention

Method of measurement

Champion Health Belief Model Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The participants in the study will first complete the informed consent form and the demographic information questionnaire and the Champion Health Belief Model through a virtual link sent to their mobile phone or in person.The people present in the face-to-face training group (based on the available facilities and the conditions of the face-to-face training group are divided into several smaller groups) also undergo face-to-face training about breast cancer and prevention methods based on the health belief model along with questions and answers, during six sessions - 60 30 minutes will be arranged; In this way, in the first session, after explaining the objectives and completing the questionnaire in person, the trainings related to the perceived sensitivity part and the second session of the perceived intensity will be presented and the questionnaire related to these two parts will be provided to the people. In the third session, the trainings related to the perceived benefits of self-examination, the fourth session, presentation of content and brainstorming among members about the perceived obstacles of self-examination, and finally, the fifth and sixth sessions will be presented on how and when to perform self-examination to increase self-efficacy in women. At the end of each session, people's questions are answered and the questionnaire related to the presented part is given to the women to complete. Then, two months after the intervention, the link of the aforementioned questionnaire will be sent again to the participants in the social network-based training group and the control group, and if they do not complete the questionnaire, they will be followed up through text messages and phone calls; The people present in the face-to-face group will also complete the questionnaire in person. In order to comply with the ethical codes, after completing the study, the educational content in the form of a pamphlet is provided to the control group.

Category

Other

2

Description

Intervention group: The participants in the study will first complete the informed consent form and the demographic information questionnaire and the Champion Health Belief Model through a virtual link sent to their mobile phone or in person.First, in coordination with the women of the virtual training group, one of the software agreed upon by all the groups is installed on their mobile phones and a group is formed on the social network, then the people in the training group based on social networks, after completing the questionnaires, are trained virtually for 6 stage and will be placed once every

two days. For this purpose, health and educational messages are based on the health belief model, which includes statistics related to the incidence of disease, risk factors in the development of disease, prevention and screening methods, and how to perform breast self-examination in six stages, in the form of text, video and photos compiled by the researcher. And based on the materials and sources approved by the Ministry of Health, it will be sent to them, and after studying each section, they will be requested to send a message confirming the study to the researcher. A time will be set aside after each stage, with the agreement of the people in this group, to respond online to possible questions and ambiguities after each stage, and the researcher will answer them. Then the link to the questions related to that part of the model structure will be sent to them for completion. Then, two months after the intervention, the link of the aforementioned questionnaire will be sent again to the participants in the social network-based training group and the control group, and if they do not complete the questionnaire, they will be followed up through text messages and phone calls; The people present in the face-to-face group will also complete the questionnaire in person. In order to comply with the ethical codes, after completing the study, the educational content in the form of a pamphlet is provided to the control group.

Category

Other

3

Description

Control group: The participants in the study will first complete the informed consent form and the demographic information questionnaire and the Champion Health Belief Model through a virtual link sent to their mobile phone or in person.The control group will also receive common services and training from comprehensive health centers, and at the same time as they complete the questionnaire immediately after the intervention, they will also be provided with the link to complete the questionnaire.Then, two months after the intervention, the link of the aforementioned questionnaire will be sent again to the participants in the social network-based training group and the control group, and if they do not complete the questionnaire, they will be followed up through text messages and phone calls; The people present in the face-to-face group will also complete the questionnaire in person. In order to comply with the ethical codes, after completing the study, the educational content in the form of a pamphlet is provided to the control group. Then, two months after the intervention, the link of the aforementioned questionnaire will be sent again to the participants in the social network-based training group and the control group, and if they do not complete the questionnaire, they will be followed up through text messages and phone calls; The people present in the face-to-face group will also complete the questionnaire in person. In order to comply with the ethical codes, after completing the study, the educational content in the form of a pamphlet is provided to the control group.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive health centers in the city of Shiraz

Full name of responsible person

Fatemeh vizeshfar

Street address

Hazrat Fatemeh Midwifery Nursing School, , Namazi Square, Shiraz

City

Shiraz

Province

Fars

Postal code

7193613119

Phone

+98 71 3647 4258

Email

vizeshfarf@sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr Mohammadhashem Hashempour

Street address

Shiraz University of Medical Sciences, Zand St, Shiraz

City

Fars

Province

Fars

Postal code

7134814336

Phone

+98 71 3230 5410

Email

hashempurm@sums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Fatemeh Vizeshfar

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Hazrat Fatemeh Midwifery Nursing School, Namazi Square, Shiraz

City

Shiraz

Province

Fars

Postal code

7193613119

Phone

+98 71 3647 4258

Fax

Email

vizeshfarf@sums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Fatemeh Vizeshfar

Position

Faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Hazrat Fatemeh Midwifery Nursing School, Namazi Square, Shiraz

City

Shiraz

Province

Fars

Postal code

7193613119

Phone

+98 71 3647 4258

Fax

Email

vizeshfarf@sum.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Fatemeh Vizeshfar

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Hazrat Fatemeh Midwifery Nursing School, Namazi Square, Shiraz

City

Shiraz

Province

Fars

Postal code

7193613119

Phone

+98 71 3647 4258

Fax

Email

vizeshfarf@sums.ac.ir

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