

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

The effect of an educational intervention regarding the warning signs of cancer in knowledge and perceived beliefs of women who are coming to the health centers related to the Bushehr University of Medical Sciences by applying the Health Belief Model, 2014-2015

Protocol summary

Summary

Objectives: The effect of an educational intervention regarding the warning signs of cancer in knowledge and perceived beliefs of women in the Health Centers related to the Bushehr University of Medical Sciences by applying the Health Belief Model, 2015-2016 Specific objectives: (1) To determine the awareness of women referred to health centers affiliated to Bushehr University of Medical Sciences in the intervention and control groups before and after training warning signs of cancer with the approach of Health Belief Model, 2015- 2016. (2) Determine and compare the beliefs of women referred to health centers affiliated to Bushehr University of Medical Sciences According to the health belief model structures in the intervention and control groups before and after training warning signs of cancer with the approach of Health Belief Model, 2015- 2016. Design: This study is an experimental study with intervention (n=80) and control (n=80) groups. First of all urban health centers affiliated to Bushehr University of Medical Sciences classified in four clusters and then to select two examples of the intervention group and the control group were two samples to select Setting and conduct: After oral and written consent from research participants research data were collected by a questionnaire. The first part of the questionnaire was demographic – health information (16 questions). In the second part, questions about awareness the warning signs of cancer (10 questions), and in the third part of the questionnaire, there was a series of questions about Health Belief Model constructs, including perceived susceptibility, perceived severity, perceived benefits, perceived barriers, cues to action and self-efficacy (34 questions). Face validity and content quality of the questionnaire was approved by 10 faculty members in Shahid Beheshti University of Medical Sciences. Participants including major eligibility criteria:

Inclusion criteria: women referred to health centers of the city are covered by the centers and family health records. The subjects were literate and be able to respond to questions in the questionnaire. Of samples in the study were not diagnosed with cancer. Exclusion criteria: participation in training sessions and absences in more than one session Intervention: During the first session, a pre test questionnaires containing demographic information - health and perceived knowledge and beliefs (questions based model structures) by the women in the study in two groups of four health center completed. After pre-test according to information obtained from the analysis of questionnaires, review of educational intervention program was designed. Then, for the women in the intervention group training sessions with lectures, question and answer, group discussion and small group discussion in two of the samples performed in coordination with the authorities and centers (5 sessions, 45-30 minutes). Meetings once a week over a period of five weeks was held in centers. Entries in the form of booklets based on needs assessments conducted in the pre-test, teaching, and at the end of each session, participants in the intervention group were offered. At the beginning of each session, the last session was an overview of the content. Thus, in both the intervention and control groups completed questionnaires and data for comparisons within the group and between groups were analyzed. It is worth noting that in the end, after the final post test control group were given educational materials. main outcome measures (variables): Perceived barriers Awareness of the warning signs of cancer Structural health belief model (perceived susceptibility, perceived severity, perceived benefits, perceived barriers, cues to action, efficacy) Age Level of Education Previous data from cancer

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015090723937N1**

Registration date: **2016-10-15, 1395/07/24**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-10-15, 1395/07/24

Registrant information

Name

Iman Sharifi Kia

Name of organization / entity

Shiraz of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 71 3834 1255

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Recruitment status

Recruitment complete

Funding source

Governmental

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2015-12-22, 1394/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of an educational intervention regarding the warning signs of cancer in knowledge and perceived beliefs of women who are coming to the health centers related to the Bushehr University of Medical Sciences by applying the Health Belief Model, 2014-2015

Public title

The effect of an educational intervention regarding the warning signs of cancer in knowledge and perceived beliefs of women who are coming to the health centers related to the Bushehr University of Medical Sciences by applying the Health Belief Model, 2014-2015

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: women referred to health centers of the city are covered by the centers and family health records. The subjects were literate and be able to respond to questions in the questionnaire. Of samples in the study were not diagnosed with cancer; Exclusion criteria: participation in training sessions and absences in

more than one session

Age

From **18 years** old to **100 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **160**

Randomization (investigator's opinion)

Randomized

Randomization description

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

Bushehr University of Medical Sciences Ethics Committee

Street address

Salman Farsi street, Bahmani

City

Bushehr

Postal code

7518759577

Approval date

2015-07-20, 1394/04/29

Ethics committee reference number

bpums.rec.1394.9

2

Ethics committee

Name of ethics committee

Shahid Beheshti University of Medical Sciences Faculty Of Nursing And Midwifery Ethics Committee

Street address

Shahid Beheshti University of Medical Sciences Faculty Of Nursing And Midwifery, Intersection Niayesh, Tehran

City

Tehran

Postal code

Approval date

2015-12-14, 1394/09/23

Ethics committee reference number

Health conditions studied

1

Description of health condition studied

Health Belief Model

ICD-10 code

ICD-10 code description

2

Description of health condition studied

knowledge

ICD-10 code

ICD-10 code description

3

Description of health condition studied

cancer

ICD-10 code

c80.9

ICD-10 code description

Malignant neoplasm, primary site unspecified Cancer
NOS Carcinoma NOS Malignancy NOS Malignant cachexia
NOS Multiple cancer NOS

4

Description of health condition studied

warning signs of cancer

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Perceived barriers

Timepoint

Before and one month after intervention

Method of measurement

Structure of Health Belief Questionnaire

2

Description

Awareness of the warning signs of cancer

Timepoint

Before and one month after intervention

Method of measurement

Questionnaire awareness

3

Description

Perceived susceptibility

Timepoint

Before and one month after intervention

Method of measurement

4

Description

Perceived severity

Timepoint

Before and one month after intervention

Method of measurement

Structure of Health Belief Questionnaire

5

Description

Perceived benefits

Timepoint

Before and one month after intervention

Method of measurement

Structure of Health Belief Questionnaire

6

Description

Guide to action

Timepoint

Before and one month after intervention

Method of measurement

Structure of Health Belief Questionnaire

7

Description

Efficacy

Timepoint

Before and one month after intervention

Method of measurement

Structure of Health Belief Questionnaire

8

Description

Age

Timepoint

Baseline

Method of measurement

Demographic questionnaire.

9

Description

Level of Education

Timepoint

Baseline

Method of measurement

Demographic questionnaire.

10

Description

Previous data from cancer

Timepoint

Before and one month after intervention

Method of measurement

questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Cases: In this study, after obtaining permission first 11 urban health center affiliated city health center were classified in four clusters (Each cluster consists of three centers of the North, East, West and also the center of a cluster depend on the outskirts of the city of Bushehr found). Then randomly selected from each of the clusters was a center (Two to be selected for the intervention group and two samples of the control). Samples were selected in the centers, according to inclusion criteria were randomly. During the first session, a pre-test questionnaires containing demographic information - health and perceived knowledge and beliefs (questions based model structures) by the women in the study in two groups of four health center completed. After running pre test according to information obtained from the analysis of questionnaires, review of educational intervention program was designed. Then, for the women in the intervention group training sessions with lectures, Q & A, group discussion and small group discussion in two of the samples performed in coordination with the authorities and centers (5 training sessions of 30-45 minutes). Sessions once a week over a period of five weeks are held in centers. After the post-test at the end of training sessions, the questionnaire was completed by a group intervention.

Category

Behavior

2

Description

Control group: firstly to all participants in the control group and the intervention group was completed questionnaires were distributed and only by them (without any training). Finally, after the final post-test training materials available in the intervention group was the control group.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Bushehr University of Medical Sciences

Full name of responsible person

Sharifikia Iman

Street address

Bushehr University of Medical Sciences and Health Services, Moallem st, Standing in front of Friday Prayers

City

Bushehr

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shahid Beheshti University of Medical Sciences Faculty Of Nursing And

Full name of responsible person

Dolatian Mahrokh (Research Assistant)

Street address

Shahid Beheshti University of Medical Sciences Faculty Of Nursing And Midwifery, Intersection Niayesh, Tehran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Shahid Beheshti University of Medical Sciences Faculty Of Nursing And

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences Faculty Of Nursing And Midwifery

Full name of responsible person

Sharifikia Iman

Position

M.A Student

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty