Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

"Design, implementation and evaluation of cervical cancer screening education intervention among middle-aged women served by the comprehensive health centers of Shiraz city: Integration of the Extended Parallel Process Model into the PRECEDE-PROCEED planning model"

Protocol summary

Study aim

This study aims to enhance cervical cancer screening rates among middle-aged women, providing a model for other regions in Iran and similar countries.

Design

The educational program for women to increase awareness and encourage cervical cancer screening consists of six 60-minute sessions, held in person or virtually. With a sample size of 188 individuals and specific entry criteria (age 30-59, married, divorced, or widowed; resident in the area; and no history of cervical cancer) and specific exit criteria, educational interventions are designed using the EPPM model and will include lectures, group discussions, film screenings, and multimedia content. The ultimate goal of this program is to increase women's knowledge, attitudes, and behaviors toward cervical cancer screening.

Settings and conduct

In this study, middle-aged women (married, divorced, and widows) in Shiraz will be selected as the target population.

Participants/Inclusion and exclusion criteria

Iranians aged 30 to 59 years and eligible for Pap smear according to national guidelines Married, divorced, widowed and not pregnant • Not participating in similar studies Exclusion and exclusion criteria: • Withdrawal from further cooperation and loss to follow-up and transfer and pregnancy during the study Death

Intervention groups

The intervention group will receive educational intervention according to study planning. The control group, which will not receive intervention within the intended timeframe, will be held at the number of intervention group sessions after the educational intervention is completed. And the educational content is available.

Main outcome variables

Attitude towards screening Attitude toward cervical cancer Screening behavior Intention to do the screening Threats Perception of the effectiveness of actions Perception of the ability to take action Captaining factors Reinforcing factors

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20111017007816N25**
Registration date: **2025-06-14, 1404/03/24**
Registration timing: **prospective**

Last update: **2025-06-14, 1404/03/24**
Update count: **0**

Registration date

2025-06-14, 1404/03/24

Registrant information

Name
Mahin Nazari

Name of organization / entity
School of health

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2025-06-22, 1404/04/01
Expected recruitment end date
2026-03-20, 1404/12/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
"Design, implementation and evaluation of cervical cancer screening education intervention among middle-aged women served by the comprehensive health centers of Shiraz city: Integration of the Extended Parallel Process Model into the PRECEDE-PROCEED planning model"

Public title
Design, implementation and evaluation of cervical cancer screening education intervention among middle-aged women
Purpose
Screening
Inclusion/Exclusion criteria
Inclusion criteria:
• Iranian 30-59 years old• Eligible for Pap smear according to national guidelines• Married, divorced, widowed• Resident in the study area• Providing informed consent for participation• No history of cervical cancer diagnosis or treatment• Ability to participate in educational sessions• Ability to understand and communicate• Not pregnant• Not participating in similar studies
Exclusion criteria:
Age
From **30 years** old to **59 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **188**
Randomization (investigator's opinion)
Randomized
Randomization description
A multi-stage sampling procedure is used for this study. In the first stage, from the two health centers in Shiraz (Shohadaye Enghelab and Shohadaye Valfajr), Shohadaye Valfajr Health Center is selected as the primary sampling unit because it has easier access to the required research data. This health center oversees 20 comprehensive health centers across Shiraz, covering both urban and suburban areas (including Saadi, Sahlabad, Ghaleno, etc.). This study will focus specifically on the suburban areas. In the second phase, four comprehensive health centers will be randomly selected in the suburban areas. These four centers will then be assigned to either the intervention group (two centers) or the control group (two centers), using block randomization to ensure a balanced distribution. This allocation process will take into account the appropriate geographical distance between centers to prevent information contamination between the intervention and control groups. In the third phase, a list of individuals who meet the study's inclusion criteria is compiled by each comprehensive health center. A random number table will be used to select the required number of participants from each center. Participants will be assigned to either the intervention or control group based on the previously randomized assignment of their respective comprehensive health care center. To calculate the sample size, we will use the formula for randomized cluster studies, taking into account the cluster design of the study, and include the design effect in our calculations.
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
Faculties of Health, Nutrition and Food Sciences, Shiraz University of Medical Sciences.
Street address
Central Building of Shiraz University of Medical Sciences, Zand Street, Shiraz, Fars Province, Iran.
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shiraz
Province
Fars
Postal code
715367554
Approval date
2025-03-16, 1403/12/26
Ethics committee reference number
IR.SUMS.SCHEANUT.REC.1404.015

Health conditions studied

1

Description of health condition studied
Cervical cancer
ICD-10 code
C47.0
ICD-10 code description
Malignant neoplasm of peripheral nerves of head, face

and neck

Primary outcomes

1

Description
Attitude to screening - Attitude to Cervical Cancer - Screening BehaviorIntention to perform screening - threatening perception - perception of the effectiveness of actions-—perceived actions-—enabling of enabling-—reinforcing agents

Timepoint
Before the intervention - immediately after the intervention - 2 months after the intervention - 4 months after the intervention

Method of measurement
In this study, researcher-made questionnaires will be designed and formulated based on the theory of parallel development process and the model. These questionnaires are approved by the panel of specialists in order to evaluate the factors associated with cervical cancer screening behavior, according to the results of the early stages of the study.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group Type of intervention: Educational programme based on the EPPM model for cervical cancer screening Intervention details: Number of sessions: Minimum of 6 sessions (may be modified based on pre-test results) Duration of each session: 60 minutes Mode of delivery: In-person and virtual Design basis: PRECEDE-PROCEED model (phase 3) + EPPM model Implementation process: Pretest: Assessment of knowledge, attitude, perceived sensitivity, perceived severity, self-efficacy and response effectiveness Identification of training needs based on the results of the pre-test Training content includes: Accurate information about cervical cancer and screening methods Changing negative attitudes and false beliefs Increasing perceived sensitivity and severity Strengthening self-efficacy and response effectiveness Educational methods: Lecture, group discussion, film screening, visual aids, questions and answers, presentation of successful experiences, multimedia materials

Category
Behavior

2

Description
Control group: Type of intervention: Usual treatment (control)Intervention details: During the study: Routine education by comprehensive health centres (no specific intervention)After the study: All educational resources of the intervention group will be made available to this group. Educational sessions will be held according to the intervention group. A 6-session training programme based on the EPPM model will be conductedEthical considerations: This approach ensures that the control group also benefits from the educational intervention.

Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Shohadaye Valfajr Health Center, Shiraz, Fars Province, Iran

Full name of responsible person
Alireza Shariati

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Shohadaye Valfajr Health Center, Next to the Governor’s Office, Shohadaye Emdadgar Street, Shiraz, Fars Province, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

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
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Position
Associate professor of health education & promotion,shiraz university of medical sciences
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
All potential data can be shared after non -identification.
When the data will become available and for how

long

Starting an access period 6 months after printing results

To whom data/document is available

All members of the community to the journal in which the article is published.

Under which criteria data/document could be used

Supervisor's opinion

From where data/document is obtainable

Shiraz School of Health Promotion Department of Dr. Mahin Nazari

What processes are involved for a request to access data/document

It takes about a week to a month from the author responsible for the coordinator.

Comments