

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Design, implementation, and evaluation of an intervention based on the social marketing model on the Pap-smear test uptake

Protocol summary

Study aim

Design, implementation, and evaluation of an intervention based on the social marketing model on the Pap-smear test uptake among women living in Qazvin

Design

A controlled, factorial, unblinded, randomized, phase 3 clinical trial for 90 women.

Settings and conduct

The population of this study consists of women aged 18 to 65 from Qazvin City. From this population, 90 people are randomly selected between two control and intervention groups. In this study, samples are visited at their doorsteps, and data is collected. Pamphlets and coupons are also delivered to the homes of the intervention group. Then a promotional message is sent to the intervention group. After three months, post-intervention data will be collected.

Participants/Inclusion and exclusion criteria

Female Age between 18 and 65 years Married Not participating in training courses in the field of Pap-smear test Not doing a Pap-smear test in the last three years

Intervention groups

A four-part intervention based on the 4Ps of social marketing: 1-1- Providing a coupon to cover part of the cost of the test (price: monetary costs) 2-1- Presentation of a pamphlet in the field of reducing anxiety about the test result (price: psychological costs) 3-1- Presentation of a pamphlet stating that the test has no effect on sexual relations to be presented to spouses (price: psychological costs) 2- Providing a schematic map and exact address of comprehensive health service centers in Qazvin city and access ways (place: explain the location of service provision) 3- Presenting an infographic introducing the Pap-smear test and how to perform the test (product: product introduction) 4- Sending SMS containing promotional message (promotion)

Main outcome variables

The percentage of Pap smear test

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221126056609N1**

Registration date: **2023-04-27, 1402/02/07**

Registration timing: **prospective**

Last update: **2023-04-27, 1402/02/07**

Update count: **0**

Registration date

2023-04-27, 1402/02/07

Registrant information

Name

Aisa Maleki

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3335 6749

Email address

a.maleki@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-05, 1402/02/15

Expected recruitment end date

2023-06-05, 1402/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Design, implementation, and evaluation of an intervention based on the social marketing model on the Pap-smear test uptake	
Public title	Name of ethics committee
Evaluation of the intervention based on the social marketing model on the Pap-smear test uptake	Ethical committee Qazvin University of Medical Sciences
Purpose	Street address
Screening	Research and Technology Vice-Chancellor, 1st Branch, Maudet Alley, Shahid Beheshti Blvd.
Inclusion/Exclusion criteria	City
Inclusion criteria:	Qazvin
Female Age between 18 and 65 years married Not participating in Pap-smear training courses Not doing a pap-smear test in the last three years	Province
Exclusion criteria:	Qazvin
Participation in codified training courses related to sexually transmitted diseases Having a history of screening for human papilloma or genital warts (Co-testing)	Postal code
	3415613911
Age	Approval date
From 18 years old to 65 years old	2023-04-18, 1402/01/29
Gender	Ethics committee reference number
Female	IR.QUMS.REC.1402.002
Phase	Health conditions studied
3	1
Groups that have been masked	Description of health condition studied
No information	Encounter for screening for malignant neoplasm of cervix
Sample size	ICD-10 code
Target sample size: 90	Z12. 4
Randomization (investigator's opinion)	ICD-10 code description
Randomized	
Randomization description	Primary outcomes
First, the female population of Qazvin is clustered based on urban health community centers. Then based on the share of each cluster in the total population, the number of samples required for both control and intervention groups is selected from each cluster. Randomization of intervention and control group samples is done at the individual level (not at the cluster level). First, the target community is divided into blocks (clusters) based on the comprehensive urban health center. Then, using a random number table, half of the intervention people and half of them are included as controls within each block.	1
Blinding (investigator's opinion)	Description
Not blinded	Pap-smear test
Blinding description	Timepoint
Placebo	Measuring the Pap-smear test uptake at the beginning of the study (before the start of the intervention) and three months after the start of the intervention
Not used	Method of measurement
Assignment	A questionnaire including demographic information, cervical cancer history and Pap smear test uptake
Factorial	
Other design features	Secondary outcomes
	empty
Secondary Ids	Intervention groups
empty	1
Ethics committees	Description
1	Intervention group: A four-part intervention based on the 4Ps of social marketing: 1-1- Providing a coupon to cover part of the cost of the test (price: monetary costs) 2-1- Presentation of a pamphlet in the field of reducing anxiety about the test result (price: psychological costs) 3-1- Presentation of a pamphlet stating that the test has no effect on sexual relations to be presented to spouses (price: psychological costs) 2- Providing a schematic map and exact address of comprehensive health service centers in Qazvin city and access ways (place: explain the location of service provision) 3- Presenting an infographic introducing the Pap-smear test and how to
Ethics committee	

perform the test (product: product introduction) 4- Sending SMS containing promotional message (promotion) In this study, samples are visited at their doorsteps, and data is collected. Pamphlets and coupons are also delivered to the homes of the intervention group. Then a promotional message is sent to the intervention group. After three months, post-intervention data will be collected.

Category

Prevention

2

Description

Control group: It does not receive any intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Vice-Chancellor of Health and Health Center of Qazvin province

Full name of responsible person

Aisa Maleki Nadnilooei

Street address

University health department and provincial health center, building number 2 of the university headquarters, Azadegan Blvd.

City

Qazvin

Province

Qazvin

Postal code

3414853135

Phone

+98 922 369 5917

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aisamalekii@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Mehdi Mirhashemi

Street address

Research and Technology Vice-Chancellor, 1st Branch, Maudet Alley, Shahid Beheshti Blvd.

City

Qazvin

Province

Qazvin

Postal code

3415613911

Phone

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Email

researchdpt@qums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Qazvin 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

Qazvin University of Medical Sciences

Full name of responsible person

Aisa Maleki Nadnilooei

Position

MSc Student in Health Services Management

Latest degree

Bachelor

Other areas of specialty/work

Health Service Management

Street address

Research and Technology Vice-Chancellor, 1st Branch, Maudet Alley, Shahid Beheshti Blvd.

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Omid Khosravizadeh

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

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Full name of responsible person

Aisa Maleki Nadnilooei

Position

MSc Student in Health Service Management

Latest degree

Bachelor

Other areas of specialty/work

Health Service Management

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Province

Qazvin

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3415613911

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Because the data is confidential and work for the master thesis will eventually become a training package

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available