Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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
Evaluation of the intervention based on the social marketing model on the Pap-smear test uptake
Purpose
Screening
Inclusion/Exclusion criteria
Inclusion criteria:
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
Exclusion criteria:
Participation in codified training courses related to sexually transmitted diseases Having a history of screening for human papilloma or genital warts (Co-testing)
Age
From **18 years** old to **65 years** old
Gender
Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
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.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Factorial
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethical committee Qazvin University of Medical Sciences
Street address
Research and Technology Vice-Chancellor, 1st Branch, Maudet Alley, Shahid Beheshti Blvd.
City
Qazvin
Province
Qazvin
Postal code
3415613911
Approval date
2023-04-18, 1402/01/29
Ethics committee reference number
IR.QUMS.REC.1402.002

Health conditions studied

1

Description of health condition studied
Encounter for screening for malignant neoplasm of cervix
ICD-10 code
Z12. 4
ICD-10 code description

Primary outcomes

1

Description
Pap-smear test
Timepoint
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
Method of measurement
A questionnaire including demographic information, cervical cancer history and Pap smear test uptake

Secondary outcomes

empty

Intervention groups

1

Description
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

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

Email

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

+98 28 3336 8124

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.

City

Qazvin

Province

Qazvin

Postal code

3415613911

Phone

+98 28 3336 8124

Email

aisamalekii@gmail.com

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

Health Service Management

Street address

Faculty of Health, Qazvin University of Medical Sciences, Shahid Bahonar Boulevard.

City

Qazvin

Province

Qazvin

Postal code

3419759811

Phone

+98 28 3333 6001

Email

omid.khosravizadeh@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Qazvin University of Medical Sciences

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

Street address

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City

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Province

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Postal code

3415613911

Phone

+98 28 3336 8124

Email

aisamalekii@gmail.com

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