

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluating the effect of educational program on Pap smear in women aged 18-70 referring to health centers

#### Protocol summary

##### Study aim

Examining the efficiency of Pap smear compliance questionnaire

##### Design

A clinical trial with a control group of 80 participants. The table of random numbers is used for randomization

##### Settings and conduct

The training workshop will be held in four 45-minute sessions at Mashhad Health College by using the contents prepared (video, PowerPoint,...) and lectures. Before, immediately and three months after the training, the participants will complete a Pap smear compliance questionnaire.

##### Participants/Inclusion and exclusion criteria

Conditions for entering the study - be Iranian - At least have completed elementary education - she has been married at least once (regardless of his current marital status) - At least three years have passed since he started having sex. - Willingness to participate in the study  
Conditions for withdrawing from the study: - Withdrawal from participating in the study - Cervical cancer or sexually transmitted diseases

##### Intervention groups

All women who meet the conditions for entering the study and did not perform pap smear or did it irregularly, will be divided into two intervention and control groups. No special action and training will be provided for the control group.

##### Main outcome variables

Improving performance on cervical cancer screening

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210604051490N1**

Registration date: **2022-09-04, 1401/06/13**

Registration timing: **prospective**

Last update: **2022-09-04, 1401/06/13**

Update count: **0**

##### Registration date

2022-09-04, 1401/06/13

##### Registrant information

###### Name

mansoore shariati sarcheshme

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 3882 4512

###### Email address

shariatism971@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-09-23, 1401/07/01

##### Expected recruitment end date

2023-03-20, 1401/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluating the effect of educational program on Pap smear in women aged 18-70 referring to health centers

##### Public title

Evaluating the effect of educational program on Pap smear

##### Purpose

Education/Guidance

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

be Iranian At least have completed elementary education. She has been married at least once (regardless of her current marital status) At least three years have passed since the beginning of sex Willingness to participate in the research

**Exclusion criteria:**

Refusal to participate in research Cervical cancer or other sexually transmitted diseases

**Age**

From **18 years** old to **70 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **80**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Among the 5 headquarters centers of Mashhad city, two centers will be selected by cluster method, and then two centers will be randomly selected from the health centers covered by each headquarters center. Then, based on the information available in the SINA system, a list of eligible samples will be prepared in each health center and if they wish to participate in the research, they will be divided into two control and intervention groups based on a random number table.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

The evaluation of the effectiveness of the educational intervention is based on the researcher's questionnaire, whose validity and reliability have been confirmed.

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Ethics Committee of Mashhad University of Medical Sciences

**Street address**

Health college, Daneshgah 18, Daneshgah street

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9137673119

**Approval date**

2021-06-15, 1400/03/25

**Ethics committee reference number**

IR.MUMS.FHMPPM.REC.1400.009

**Health conditions studied**

**1**

**Description of health condition studied**

Cervical cancer screening behavior

**ICD-10 code**

C53

**ICD-10 code description**

Malignant neoplasm of cervix uteri

**Primary outcomes**

**1**

**Description**

Cervical cancer screening (Pap smear)

**Timepoint**

Before the intervention, immediately and three months after the intervention

**Method of measurement**

questionnaire

**Secondary outcomes**

empty

**Intervention groups**

**1**

**Description**

Intervention group: The intervention group in this study includes 40 people. The intervention in this study will be educational. Before the start of the training, the questionnaire made by the researcher "compliance with pap smear" (which validity and reliability has been confirmed) will be completed by the participants and their points will be calculated. It should be noted that these people are randomly placed in the intervention group. Then, the educational content including a brief description of the reproductive system and the causes of cervical cancer, symptoms and complications of the disease, ways of prevention, introduction of pap smear and its importance, will be presented during 4 educational sessions in the form of lectures, film and slide shows, and group discussions. became. With the formation of the WhatsApp group, the process of communication with participants and questions and answers will continue. After the completion of 4 training sessions, the approximate duration of which is 45 minutes, immediately and three months later, the questionnaire will be completed and scored again, and the behavior of Pap smear will be checked.

**Category**

Behavior

## 2

### Description

Control group: The control group in this intervention consists of 40 people who are randomly placed in the control group after the pre-test and calculation of each person's score. There will be no intervention for the control group. Then the test will be taken using a questionnaire and the scores before and after will be compared. This post-test will be repeated immediately and 3 months after the end of the training for both groups under study.

### Category

Behavior

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Comprehensive health service centers covered by Mashhad University of Medical Sciences

##### Full name of responsible person

Mohammad Vahidian Shahroudi

##### Street address

Daneshgah 18, Daneshgah street

##### City

Mashhad

##### Province

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##### Postal code

9137673119

##### Phone

+98 51 3851 4548

##### Fax

+98 51 3852 2775

##### Email

VahedianM@mums.ac.ir

##### Web page address

<https://hehpdept.mums.ac.ir/>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Full name of responsible person

Dr. Majid Ghayor Mobarhan

##### Street address

University of Medical Sciences, University of Medical Sciences, University of Medical Sciences, Mashhad, Razavi Khorasan, 3rd Floor, University Research and Technology Vice-Chancellor

##### City

Mashhad

##### Province

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##### Postal code

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##### Phone

+98 51 3841 1538

##### Fax

+98 51 3843 0249

##### Email

GhayourM@mums.ac.ir

##### Web page address

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

##### Full name of responsible person

Mohammad Vahidian Shahroudi

##### Position

Associate Professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Health Promotion

##### Street address

Health colloque, Daneshgah 18, Daneshgah street

##### City

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##### Province

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##### Postal code

9137673119

##### Phone

+98 51 3189 2202

##### Email

Vahedianm@mums.ac.ir

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Full name of responsible person

Mohammad Vahidian Shahroudi

##### Position

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Health Promotion

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**Person responsible for updating data****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Vahedian Shahroodi Mohammad

**Position**

faculty member

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Health Promotion

**Street address**

Health University, Daneshgah Street, Mashhad

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9137673119

**Phone**

+98 51 3189 2202

**Email**

VahedianM@mums.ac.ir

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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**

Yes - There is 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

**Title and more details about the data/document**

In this study, data can be shared after de-identifying individuals.

**When the data will become available and for how long**

Access starts 6 months after results are published

**To whom data/document is available**

Study documentation will be available for researchers working in academic and scientific institutions.

**Under which criteria data/document could be used**

By mentioning the reason for using the documents, the issue will be raised and decided in a meeting with the project colleagues.

**From where data/document is obtainable**

Mohammad Vahedian Shahroodi vahedianm@mums.ac.ir  
Shariati Sarcheshme Mansoore  
shariatism971@mums.ac.ir

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

1-Official request for necessary documentation and reason for it via university email 2- Application plan in the group of colleagues 3- Sending documents in case of confirmation of the identity of the sender and confirmation of colleagues within a period of one month

**Comments**

The details of the data and information are not provided to people and only general results are sent.