Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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.FHMPM.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

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Razavi Khorasan

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9137673119

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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

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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 collogue, Daneshgah 18, Daneshgah street

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Person responsible for scientific inquiries

Contact

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Full name of responsible person
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Position
Associate professor

Latest degree
Ph.D.
Other areas of specialty/work
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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
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Other areas of specialty/work
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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.