

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

The effect of human papillomavirus prevention and treatment training based on the planned behavior model on the knowledge and attitude of women of reproductive age

Protocol summary

Study aim

The effect of education for prevention and treatment of human papillomavirus based on the model of planned behavior on the knowledge and attitude of women of reproductive age referred to comprehensive health centers in Shiraz in 1401-1400

Design

A randomized controlled clinical trial will be performed on 90 women of reproductive age referred to Shiraz Comprehensive Health Centers using Spss 22 software.

Settings and conduct

In selected comprehensive health centers of Shiraz, women aged 15 to 49 years are assigned to the intervention and control groups based on 6-block randomization by applying the entry conditions. The study is educational and has not been blinded

Participants/Inclusion and exclusion criteria

Admission requirements: resident of Shiraz, literate, no membership in the treatment team and no history of hysterectomy and sexually transmitted diseases and also not attending similar training classes; Conditions of non-entry: unwillingness to participate in the study, non-participation in more than one training session and change of residence

Intervention groups

The intervention is in the form of training and presentation of a related educational booklet that is given to the intervention group. The control group will not receive any training, but at the end of the study, an educational booklet will be presented to Atan

Main outcome variables

Knowledge and attitude of women of reproductive age before and after the intervention are assessed and compared with the control group

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220131053891N1**

Registration date: **2022-04-28, 1401/02/08**

Registration timing: **registered_while_recruiting**

Last update: **2022-04-28, 1401/02/08**

Update count: **0**

Registration date

2022-04-28, 1401/02/08

Registrant information

Name

Fatemeh Vizeshfar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3647 4258

Email address

vizeshfar@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-09, 1401/01/20

Expected recruitment end date

2022-06-21, 1401/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of human papillomavirus prevention and treatment training based on the planned behavior model on the knowledge and attitude of women of reproductive age

Public title

Evaluation of the effect of education in the prevention and treatment of human papillomavirus

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Women 15_49 years Resident of Shiraz No membership in the treatment team Literate Having a Smartphone No history of neurological disease No history of hysterectomy and sexual transmitted disease No cervical cancer

Exclusion criteria:

Participate in similar training classes History of HPV Reluctance to participate in further study Change of residence Dont attend more than one training session

Age

From **15 years** old to **49 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Among the comprehensive health centers of Shiraz, several centers are determined randomly and by lottery. Then, by determining the number of women of childbearing age referring to each center, the number of samples of each center will be allocated as a quota. After that, according to Apple's electronic file information, eligible women will be randomly invited to participate in the study. Finally, the samples are divided into two groups of intervention and control by block randomization method. For this purpose, randomization will be done for 90 people using the list randomization site and 6 blocks

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

Ethics Committee of Shiraz University of Medical Sciences

Street address

Shiraz University of Medical Sciences, Zand Boulevard, in front of Palestine Street

City

Shiraz

Province

Fars

Postal code

7134814336

Approval date

2022-03-14, 1400/12/23

Ethics committee reference number

IR.SUMS.NUMIMG.REC.1400.080

Health conditions studied

1

Description of health condition studied

Icd_10

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

People's knowledge and attitude score

Timepoint

Before the educational intervention, immediately and three months after the intervention

Method of measurement

Standard human papillomavirus and its vaccine questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After completing the informed consent form and pre-test questionnaire by group members, 3 training sessions of 30 to 45 minutes on the importance of prevention and vaccination of human papillomavirus and existing treatment methods weekly and in small groups (due to conditions Pandemic Quidd 19) will be held. An educational booklet is also given to these people. The duration of the course from the beginning of the intervention to the completion of the

last questionnaire will be 3 months. In fact, after the educational intervention, the test will be held immediately and 3 months later, in order to check the reliability of the training, individuals are again asked to complete the questionnaire.

Category

Prevention

2**Description**

Control group: will not receive any training during the study. After completing the last questionnaire, in order to maintain the principles of ethics in research, a booklet containing educational materials will be presented to them.

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shiraz Comprehensive Health Centers

Full name of responsible person

Fatemeh Vizeshfir

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Hazrat Fatemeh School of Nursing and Midwifery,
Namazi Square, Zand Boulevard

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Vizeshfir@yahoo.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Memarpour Mahtab

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Phone

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Fax**Email**

Memarpour@sums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

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

Vizeshfir Fatemeh

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Latest degree

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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

Not applicable

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

Outcome information can be shared under the supervision of the first author or facilitator after the subjects being unidentified

When the data will become available and for how long

3 months after printing the results

To whom data/document is available

Researchers with a license and code of ethics can apply

Under which criteria data/document could be used

Researchers who have an approved plan and intend to work in review, retrospective or meta-analysis

From where data/document is obtainable

Via emails; Leilarafiei64@yahoo.com and Vizeshfar@yahoo.com and researchers who do not have distance problems by referring to the School of Nursing, Department of Education

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

After receiving the message, the result will be sent up to one week

Comments