Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparing the effect of education on the prevention of human papillomavirus infection and cervical cancer on the components of the planned behavior model in women of reproductive age using two methods based on an application and a lecture

Protocol summary

Study aim
This study aims to determine the impact of training based on the theory of planned behavior using two methods: lectures and a mobile application, on the knowledge and attitudes of women of reproductive age visiting comprehensive health service centers in the city of Dezful regarding the prevention of cervical cancer and human papillomavirus infection, in 2025.

Design
The clinical trial is a controlled study with parallel groups, unblinded, randomized, and phase 0, conducted on 120 patients.

Settings and conduct
After obtaining the necessary permissions from Dezful University of Medical Sciences, initial coordination with the research environment (comprehensive health service centers) will be conducted to implement the study. Samples will be selected based on the eligibility criteria, and informed consent will be obtained. A pre-test will be administered first, followed by the educational intervention. Subsequently, post-tests will be conducted in two stages.

Participants/Inclusion and exclusion criteria
Eligibility criteria include women aged 15 to 49 years, residents of Dezful, not being part of a treatment team, having literacy skills, owning a smartphone (for the mobile-based intervention group), not having a history of mental health disorders, not having a history of hysterectomy or sexually transmitted diseases, and not having a history of cervical cancer.

Intervention groups
There are three groups: the mobile application intervention, the lecture, and the control. In the mobile application intervention group, educational content will be sent to patients through the app every 48 hours for one month. The lecture group will have four educational sessions lasting 30 to 45 minutes each. The control group will not receive any educational intervention.

Main outcome variables
Awareness; attitude; subjective norms; perceived behavioral control; behavioral intention.

General information

Reason for update

Acronym
AEHPVS

IRCT registration information
IRCT registration number: **IRCT20250102064255N1**
Registration date: **2025-02-28, 1403/12/10**
Registration timing: **prospective**

Last update: **2025-02-28, 1403/12/10**
Update count: **0**

Registration date
2025-02-28, 1403/12/10

Registrant information

Name
Parisa Ebrahimi

Name of organization / entity

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Iran (Islamic Republic of)

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+98 81 3823 2933

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date

2025-04-04, 1404/01/15

Expected recruitment end date

2025-05-05, 1404/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of education on the prevention of human papillomavirus infection and cervical cancer on the components of the planned behavior model in women of reproductive age using two methods based on an application and a lecture

Public title

Investigating the effect of application-based education on women's knowledge and attitudes about human papillomavirus infection and cervical cancer

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Women aged 15-49 years, residing in Dezful city, not a member of the treatment team, literate, having a phone equipped with Android system (software-based intervention group), no history of neurological or psychiatric illness, no history of hysterectomy or sexually transmitted disease, no history of uterine cancer.

Exclusion criteria:

Participation in similar training classes, change of residence, unwillingness to participating in the study.

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: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

First, each of the comprehensive urban health service centers of Dezful is considered as a cluster and 3 centers are randomly selected from them (cluster sampling). In the next step, based on household information in the integrated health system, eligible women will be identified and randomly invited to participate in the study. Then, samples from each center will be randomly assigned to three groups of mobile software intervention, lecture intervention, and control group using a random number table (simple randomization).

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 Dezful University of Medical Sciences

Street address

Azadegan Blvd

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Dezful

Province

Khouzestan

Postal code

6461653476

Approval date

2024-03-05, 1402/12/15

Ethics committee reference number

IR.DUMS.REC.1402.071

Health conditions studied

1

Description of health condition studied

human papilloma virus

ICD-10 code

B97.7

ICD-10 code description

Papillomavirus as the cause of diseases classified elsewhere

Primary outcomes

1

Description

Mean score of awareness

Timepoint

Measurement of awareness before the intervention, immediately after the intervention, and 2 months after the completion of the educational intervention

Method of measurement

Researcher-made questionnaire

2

Description

Mean score of attitude

Timepoint

Measurement of attitude before the intervention, immediately after the intervention, and 2 months after the completion of the educational intervention

Method of measurement
Researcher-made questionnaire

3

Description
Mean score of subjective norms
Timepoint
Measurement of subjective norms before the intervention, immediately after the intervention, and 2 months after the completion of the educational intervention
Method of measurement
Researcher-made questionnaire

4

Description
Mean score of Perceived behavioral control
Timepoint
Measurement of Perceived behavioral control before the intervention, immediately after the intervention, and 2 months after the completion of the educational intervention
Method of measurement
Researcher-made questionnaire

5

Description
Mean score of behavioral intention
Timepoint
Measurement of behavioral intention before the intervention, immediately after the intervention, and 2 months after the completion of the educational intervention
Method of measurement
Researcher-made questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
First intervention group: In this group, a set of trainings will be provided to the user gradually through a designed mobile application. The trainings are in the areas of symptoms, risk factors, prevention methods, self-care, treatment, consequences of HPV infection, genital warts and cervical cancer. In this method, the trainings will be sent to the patients every 48 hours (every two days). To ensure that the educational content is received and studied by the patient, they will be contacted within 24 hours after the content is sent and the samples will be discussed about the content sent.
Category
Lifestyle

2

Description
Second intervention group: For the lecture intervention group, four 30- to 45-minute training sessions will be held. The training will be delivered face-to-face in small groups (maximum 10 people). The sessions will be provided weekly (one session per week) for one month at selected comprehensive health service centers in Dezful. The educational content of the first session includes an explanation of the objectives of the study, completing a pre-test, and explaining the introduction of the disease, symptoms, and risk factors for HPV infection, genital warts, and cervical cancer. The second session will answer participants' questions about the first session, transmission routes, the importance of prevention, and methods for preventing HPV infection, genital warts, and cervical cancer. The third session will answer participants' questions about the content presented in the second session, ways to treat cervical cancer, HPV infection, and genital warts, and preventing their transmission to others. The fourth session will also include answers to participants' questions about the content presented in previous sessions, the complications and consequences of these diseases, and a review of the entire course content.
Category
Lifestyle

3

Description
Control group: During the study, the control group will not receive any training (except for routine center training provided by center personnel). At the end of the study, in order to comply with ethical principles, educational content will be provided to the control group members.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Urban Comprehensive Health Services Center No. 5
Full name of responsible person
Parisa Ebrahimi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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info@dums.ac.ir
Web page address
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Dezfoul 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
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Person responsible for updating data

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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
There is no further information.

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
Not applicable

Data Dictionary
Not applicable