Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of mobile application-based educational intervention on promoting the knowledge of vulnerable women to human papillomavirus (HPV)

Protocol summary

Study aim
Determining the effect of educational application based on the mobile application on improving the knowledge of vulnerable women about human papillomavirus (HPV)

Design
A randomized controlled clinical trial, One-way blind, phase 3, on 40 vulnerable women. (with a 20% drop). The random function of Excel software will be used for randomization

Settings and conduct
The research community is vulnerable women who refer to the Special Women's Health Counseling Center of Sari. First, a call will be installed at the Center for Vulnerable Women. The officials present at the center are then asked to use the list of people active in the center and if they are eligible and willing to participate in the study, they will enter the study. Due to the nature of the intervention, it will not be possible to keep participants blind during the intervention process. The responsible researcher will be blinded during the randomization process. Also, in order to control the bias at the evaluator level, the blinding process will be performed on the people who are responsible for collecting information and analyzing data.

Participants/Inclusion and exclusion criteria
Iranian nationality Fluency in Persian Be one of the groups of vulnerable women. Literacy for reading and writing Has smartphones and the ability to use it

Intervention groups
The intervention group will receive the application. Users will study the educational content for one month after installing the application. After a month, the application will be automatically deactivated and users' access will be cut off. Then the post-test process will be done immediately and 5 weeks later. The women in the control group will receive the center's routine care. After completing the last questionnaire, in order to enjoy the benefits of reading, an application link will be sent to them.

Main outcome variables
knowledge

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160619028528N6**
Registration date: **2022-01-29, 1400/11/09**
Registration timing: **prospective**

Last update: **2022-01-29, 1400/11/09**
Update count: **0**

Registration date
2022-01-29, 1400/11/09

Registrant information

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Name of organization / entity
Mazandaran University of Medical Science
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-02-04, 1400/11/15

Expected recruitment end date
2022-04-21, 1401/02/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of mobile application-based educational intervention on promoting the knowledge of vulnerable women to human papillomavirus (HPV)

Public title
The effect of mobile application-based educational intervention on promoting the knowledge of vulnerable women to human papillomavirus (HPV): a randomized controlled clinical trial
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Iranian nationality Fluency in Persian Be part of a vulnerable group of women Literacy for reading and writing Has a smartphone and the ability to use it
Exclusion criteria:
women with acute psychiatric disorders such as schizophrenia (Inserted in the health record)
Age
No age limit
Gender
Female

Phase
3
Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Blocked random allocation method will be used for random assignment of samples to two intervention groups and control group (routine care). For this purpose, quadruple blocks will be considered. The six blocks may be TCTTCC, CTTC, CTCT, CCTT, TCTC, TCCT, with T being for the intervention group and C for the control group. The randbetween function in Excel will be used to randomly select blocks. Production numbers will be between 1 and 6 and will be selected based on the production number of the desired block and all 4 samples will be assigned to the intervention and control group.
Blinding (investigator's opinion)
Single blinded
Blinding description
Due to the nature of the intervention, it will not be possible to keep participants blind during the intervention process. Blinding will take place at the level of the responsible researcher. In this way, the researcher will not be aware of how the individuals are randomized to the intervention and control groups. Also, in order to control the bias at the level of the evaluator (detection bias), the blinding process will be performed on the people who are responsible for collecting information and analyzing the data.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mazandaran University of Medical Sciences
Street address
Vice chancellor for research, Mazandaran University of Medical Sciences ,Moalem Square, Sari, Mazandaran, Iran
City
Sari
Province
Mazandaran
Postal code
48178-57344
Approval date
2022-01-12, 1400/10/22
Ethics committee reference number
IR.MAZUMS.REC.1400.641

Health conditions studied

1

Description of health condition studied
human papillomavirus (HPV)
ICD-10 code
B97.7
ICD-10 code description
Papillomavirus as the cause of diseases classified elsewhere

2

Description of health condition studied
Anogenital warts
ICD-10 code
A63.0
ICD-10 code description
Anogenital (venereal) warts

Primary outcomes

1

Description
Knowledge about human papillomavirus
Timepoint
At the time of enrollment - immediately after the intervention - five weeks after the intervention
Method of measurement
Questionnaire of knowledge, attitude, practice about human papillomavirus

Secondary outcomes

1

Description
Attitudes about human papillomavirus
Timepoint
At the time of enrollment - immediately after the intervention - five weeks after the intervention
Method of measurement
Questionnaire of knowledge, attitude, practice about human papillomavirus

2

Description
Practice about human papillomavirus
Timepoint
At the time of enrollment - immediately after the intervention - five weeks after the intervention
Method of measurement
Questionnaire of knowledge, attitude, practice about human papillomavirus

Intervention groups

1

Description
This intervention is based on improving the knowledge of human papillomavirus as a first outcome and promoting the attitude and practice of vulnerable women as a secondary outcome through the mobile application. The content of the application has been prepared by a master's student in midwifery counseling. The research team includes a reproductive health specialist, a reproductive epidemiologist, a sexual health specialist, a psychiatrist, and a midwifery counseling student. After randomly assigning, the intervention group receives the application installation link, and after installing the application on the smartphone, users self-learning for a month. After a month, the application is automatically deactivated and users' access to the app content is cut off. Educational objectives are classified into three areas: affective, psychomotor, and cognitive. In the field of cognition, users are expected to learn about the nature of the HPV virus, its abbreviation, how it is transmitted, its prevalence in vulnerable women, preventive behaviors, the HPV vaccine, and high-risk behaviors after one month. In the field of affective, participants are expected to become familiar with common but incorrect beliefs and attitudes and replace them with the right attitudes.In the field of psychomotor, we expect vulnerable women to express behavioral goals that they have learned cognitively about preventive behaviors as behavioral intentions or to seek prevention and treatment if they have a midwife or specialist. The training framework will be implemented through this software in the method of repeated learning. In this context, users will receive a single content using a variety of methods, in simple language, understandable to the target group, and attractive to gradually reinforce the behavioral intent in them. The educational content before loading on the application will be evaluated by the panel of experts, scientifically, literary, and the opinion of the same audience group. Post-loading evaluation: Educational content after loading on the application by two groups of hardware technicians and the matched audience group is evaluated. The effect of the application on improving the outcome (knowledge about human papillomavirus) will be calculated through indicators such as the Effect Size index.
Category
Prevention

2

Description
Control group: The women in the control group will receive routine care from the Vulnerable Women's Center. This care is provided in the context of health-focused visits, gynecological examinations, and counseling on high-risk behaviors related to AIDS. After completing the last questionnaire (5 weeks after the last follow-up), in order to enjoy the benefits of the study, an application link will be sent to them and we will answer their questions.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Special Women's Health Counseling Center
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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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
Mazandaran 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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Student (MSc)
Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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