Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of education based on theory of planned behavior on intention to vaccine against human papillomavirus in Female Students of Mashhad University of Medical Sciences

Protocol summary

Study aim

Determining the effect of education based on the theory of planned behavior on the intention to vaccinate against human papillomavirus (HPV) in female students if Mashhad University of Medical Sciences

Design

Controlled educational trial with control group. Available sampling randomly with a sealed envelope.

Settings and conduct

This control educational trial will be conducted in Mashhad University of Medical Sciences. 68 eligible female students will be selected based on random sampling available with a sealed envelope. They will be divided into intervention and control groups based on random allocation. The pre-test will be performed using a researcher-made questionnaire based on the theory of planned behavior and after determining the validity and reliability of the questionnaire. Then, the educational intervention will be performed by the researcher based on the structures of the theory of planned behavior during 4 sessions in the intervention group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: willingness to participate; no history of HPV vaccine; no previous or current genital warts and lack of sexual intercourse. Exclusion criteria: completing the questionnaire completely; being absent from more than one training session, and canceling further study.

Intervention groups

Intervention group: group training is performed in 4 sessions, 60 to 90 minutes at intervals of one session per week with the content of the structures of the theory of planned behavior for the purpose of vaccination against HPV by lecture, question and answer training and presentation of training package at the end of the first session. The control group does not receive training and receives the training package after completing the study.

Main outcome variables

Intention for receiving the human papilloma virus vaccination

General information

Reason for update

Acronym

HPV vaccine

IRCT registration information

IRCT registration number: **IRCT20200622047883N1**
Registration date: **2021-02-18, 1399/11/30**
Registration timing: **prospective**

Last update: **2021-02-18, 1399/11/30**
Update count: **0**

Registration date

2021-02-18, 1399/11/30

Registrant information

Name

Golchehre Zomorodi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4623 2455

Email address

zomorrodigl2@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-28, 1399/12/10

Expected recruitment end date

2021-07-06, 1400/04/15

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of education based on theory of planned behavior on intention to vaccine against human papillomavirus in Female Students of Mashhad University of Medical Sciences

Public title
The effect of education based on the theory of planned behavior on the intention to be vaccinated against human papillomavirus
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Willingness to participate in the study First year student in the field of study Be a resident of Mashhad Age 18-26 years old No current or previous genital warts No history of HPV vaccine No contraindications for HPV vaccine (pregnancy, history of allergic reaction to any vaccine) No history of unfortunate events (death of loved ones, etc.) during the last 6 months
Exclusion criteria:
Do not want to continue the study Incomplete and correct completion of questionnaires Getting genital warts during the study having sex Genital warts during the study Occurrence of an unfortunate event (death of loved ones, etc.) during the study
Age
From **18 years** old to **26 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **68**
Randomization (investigator's opinion)
Randomized
Randomization description
Sampling is available and random allocation in both groups is sealed through an envelope.
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 Mashhad University of Medical Sciences
Street address
School of Nursing and Midwifery, Crossroads Doctora, Ibne Sina Street
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913199
Approval date
2020-06-22, 1399/04/02
Ethics committee reference number
IR.MUMS.NURSE.REC.1399.023

Health conditions studied

1

Description of health condition studied
Human papillomavirus vaccination
ICD-10 code
Z25.8
ICD-10 code description
Need for immunization against other specified single viral diseases

Primary outcomes

1

Description
Intention
Timepoint
Pre-test (before the intervention), post-test (one month after the last session)
Method of measurement
The overall score obtained from the intention section of the questionnaire based on planned behavior theory

2

Description
Attitude
Timepoint
Pre-test (before the intervention), post-test (one month after the last session)
Method of measurement
The overall score obtained from the attitude section of the questionnaire based on planned behavior theory

3

Description
Perceived behavioral control

Timepoint
Pre-test (before the intervention), post-test (one month after the last session)
Method of measurement
The overall score obtained from the Comprehensive Behavioral Control Section of the Questionnaire based on planned behavior theory

4

Description
Perceived behavioral control
Timepoint
Pre-test (before the intervention), post-test (one month after the last session)
Method of measurement
The overall score obtained from the Comprehensive Behavioral Control Section of the Questionnaire based on planned behavior theory

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: group training in 4 sessions, each session lasting at least 60 to 90 minutes with one session per week with content based on behavioral planning structures programmed to vaccinate against human papillomavirus including the prevalence and importance of human papillomavirus infection, symptoms, complications To this disease, risk factors, causes and ways of HPV infection, the effects and complications of the disease on various aspects of health and the importance of prevention, benefits and social norms related to HPV and its vaccine will be obstacles and solutions to solve it. The teaching method includes lectures, and for the structure of the attitude of question and answer and presentation of the educational package (containing the mentioned content and in line with the structure of mental norm and the importance of parents' opinion, educational pamphlet for mothers) will be implemented at the end of the first session.
Category
Behavior

2

Description
Control group: the control group does not receive any training. they will receive the training package after completion of the study.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Mashhad University of Medical Sciences
Full name of responsible person
Dr. Seyed Mohammad Hossein Bahraini Tusi
Street address
Daneshgah Street
City
Mashhad
Province
Razavi Khorasan
Postal code
91357345
Phone
+98 51 3841 3007
Fax
+98 51 3841 3006
Email
Bahreynimh@mums.ac.ir
Web page address
https://www.mums.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi
Street address
Daneshgah Street
City
Mashhad
Province
Razavi Khorasan
Postal code
91357345
Phone
+98 51 3841 3007
Email
tafaghodim@mums.ac.ir
Web page address
http://www.mums.ac.ir/
Grant name
Grant code / Reference number
981670
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
Golchehre Zomorodi

Position
Master's degree student in reproductive health

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

Street address
School of Nursing and Midwifery, Crossroads Doctora, Ibne Sina Street

City
Mashhad

Province
Razavi Khorasan

Postal code
9137913199

Phone
0098 51 38591511-3

Email
zomorrodigl2@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Maryam Moradi

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Reproductive Health

Street address
School of Nursing and Midwifery, Crossroads Doctora, Ibne Sina Street

City
Mashhad

Province
Razavi Khorasan

Postal code
9137913199

Phone
0098 51 3-38591511-3

Email
moradim@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Golchehreh Zomorodi

Position
Master's degree student of reproductive health

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

Street address
School of Nursing and Midwifery, Crossroads Doctora, Ibne Sina Street

City
Mashhad

Province
Razavi Khorasan

Postal code
9137913199

Phone
0098 51 38591511-3

Email
zomorrodigl2@mums.ac.ir

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
Yes - There is 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
Not applicable

Title and more details about the data/document
Publication of research results in the form of scientific article printing

When the data will become available and for how long
data will become available after publication of the article.

To whom data/document is available
The general public and all researchers

Under which criteria data/document could be used
To inform the public about the vaccination of human papillomavirus and scientific use based on the article

From where data/document is obtainable
Dr. Maryam Moradi, Assistant Professor, Mashhad School of Midwifery Nursing, e-mail: moradim@mums.ac.ir

What processes are involved for a request to access data/document
Request to access data/documents would be assessed by

the research team.

Comments