Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Impact of a Spiritual Health-Based Intervention on the Awareness, Attitude, and Intention to Receive the Human Papillomavirus (HPV) Vaccination in Female University Students

Protocol summary

Study aim
Determining the effect of a combined intervention based on spiritual health on knowledge, attitude, and intention of human papillomavirus vaccination in female students

Design
The field trial with intervention and control groups, with parallel groups, randomized using a random number table method, conducted spiritual health education intervention and papillomavirus education on 36 students and 36 students were considered as the control group

Settings and conduct
Female students will complete questionnaires before attending six 45-minute sessions (30 minutes on spiritual health, 15 minutes on HPV) held twice a week at the nursing faculty or dormitory. Content is based on Jafar Bolhari's "Teaching Spiritual Skills for Trainers" and includes group discussions, Q&A, slide presentations, session reviews, and motivational SMS messages. The control group will receive life skills training.

Participants/Inclusion and exclusion criteria
1. Female gender and and age between 18 and 25 years 2. Undergraduate medical students in Mashhad 3. Consent to participate in the study 4. No previous or current infection with the HPV virus 5. No vaccination against the HPV virus 6. No debilitating physical illness 7. No debilitating mental disorders 8. No previous participation in similar courses

Intervention groups
The intervention group, comprising female dormitory students, will attend six 45-minute sessions held twice a week. These sessions cover spiritual health topics (e.g., self-awareness, spiritual problem-solving, forgiveness, meditation) and HPV education (virus basics, transmission, health effects, prevention, vaccination). Motivational SMS messages will precede each session. The control group will receive life skills training and an HPV pamphlet instead.

Main outcome variables
Increasing awareness about HPV Improving attitudes about HPV Willingness to receive HPV vaccine

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250106064288N1**
Registration date: **2025-01-31, 1403/11/12**
Registration timing: **prospective**

Last update: **2025-01-31, 1403/11/12**
Update count: **0**

Registration date
2025-01-31, 1403/11/12

Registrant information

Name
Faezeh Ehsanfar

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 3823 0090

Email address
ehsanfarfz4022@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-02-19, 1403/12/01

Expected recruitment end date
2025-03-19, 1403/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Impact of a Spiritual Health-Based Intervention on the Awareness, Attitude, and Intention to Receive the Human Papillomavirus (HPV) Vaccination in Female University Students

Public title

"The Impact of Spiritual Health Education on Awareness and Intention to Vaccinate Against Human Papillomavirus"

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Female gender and over 18 years old. Undergraduate medical students in Mashhad. Consent to participate in the study. No previous or current infection with the HPV virus. No vaccination against the HPV virus. No debilitating physical illness. No debilitating mental disorders. No previous participation in similar courses.

Exclusion criteria:

Reluctance to continue participation at any time during the study. The occurrence of any illness that may prevent the individual from continuing participation in the study. Relocation outside the study area. Simultaneous participation in a similar training course.

Age

From **18 years** old to **25 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization method is simple randomization. The randomization unit is the individual. The randomization tool is a random number table. First, the control group is selected and the questionnaires are completed by them. Then the intervention group will be selected.

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

Faculty of Nursing and Midwifery, Mashhad University of Medical Sciences, Shahid Dr. Kharazmi Educational Complex, East Gate of Ferdowsi University of Mashhad, University Campus, Azadi Square

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Approval date

2024-11-19, 1403/08/29

Ethics committee reference number

IR.MUMS.NURSE.REC.1403.079

Health conditions studied

1

Description of health condition studied

Human Papilloma Virus (HPV)

ICD-10 code

B97.7

ICD-10 code description

Papillomavirus as the cause of diseases classified elsewhere

Primary outcomes

1

Description

The main outcome of the study is the effect of intellectual health intervention training program based on spiritual health and HPV education on students.

Timepoint

Initially, before the intervention, the questionnaires will be completed by the female students and then the intervention will take place. One month after the intervention, the female students will complete the questionnaires again.

Method of measurement

Kazrani and Abadi Awareness and Attitude Questionnaire (1398)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group consists of a selection of students from the female dormitory residents who will participate in the spiritual health training intervention, which includes training in areas such as spiritual self-awareness, problem-solving with a spiritual approach, forgiveness skills for repairing interpersonal relationships, and meditation as a spiritual skill. Additionally, HPV education will cover topics such as the introduction of the HPV virus and its prevalence, methods of transmission, its impact on health, at-risk individuals, clinical symptoms, various prevention methods, the importance of vaccination, and addressing concerns and misconceptions about vaccine safety. This will be conducted over six sessions of 45 minutes each, twice a week, at the Nursing and Midwifery School. Before each session, participants will receive a motivational text message to facilitate learning.

Category

Behavior

2

Description

Control group: The control group will serve as a comparative group for the intervention group. In this case, the control group will function similarly to the intervention group, with the difference that instead of the spiritual health and HPV education program, they will receive life skills training and a pamphlet about HPV.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Mashhad University of Medical Sciences Nursing and Midwifery Faculty

Full name of responsible person

Dr. Hamidreza Zendehtalab

Street address

Azadi Square, East Door of Ferdowsi University of Mashhad, University Campus, Shahid Dr. Kharazmi Martyr Educational Complex

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Phone

+98 51 3884 6730

Fax

Email

nms.pr@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mohsen Tafaqodi

Street address

Mashhad, Daneshgah Street, next to Hoveyzeh Cinema, University of Medical Sciences, Third Floor, Vice Chancellor for Research and Technology of the University

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Phone

+98 51 3841 1538

Email

TafaghodiM@mums.ac.ir

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

hamidreza zendehtalab

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Azadi Square, East Door of Ferdowsi University of Mashhad, University Campus, Dr. Kharazmi Martyr Educational Complex

City

Mashhad

Province
Razavi Khorasan
Postal code
9137913199
Phone
+98 51 3884 6730
Email
zendehtalabhr@mums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Hamidreza Zendehtalab
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Azadi Square, East Door of Ferdowsi University of Mashhad, University Campus, Dr. Kharazmi Martyr Educational Complex
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913199
Phone
+98 51 3884 6730
Email
nms.pr@mums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Faezeh Ehsanfar
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
Shahid Dr. Kharazmi Educational Complex, East Door of Ferdowsi University of Mashhad, University Campus, Azadi Square
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913199
Phone
+98 51 3884 6730
Email
ehsanfarFZ4022@mums.ac.ir

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
Due to the confidentiality of participant information
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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Some of the participant data, such as information related to the main outcome or the like, may be shared.
When the data will become available and for how long
Data is permanently accessible.
To whom data/document is available
The ethics committee and referees and editor of the journal that will publish the resulting article.
Under which criteria data/document could be used
Review and monitor the proper implementation of the plan and publication of findings
From where data/document is obtainable
Supervisor
What processes are involved for a request to access data/document
By formal request via email and by decision of the research team
Comments