Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Effect of Digital Storytelling-Based Education on Knowledge and Attitudes of Non-Medical Students Toward Human Papillomavirus (HPV) and Its Vaccination

Protocol summary

Study aim

The aim of this study is to determine the effect of digital storytelling-based education on the knowledge and attitudes of non-medical students toward human papillomavirus and its vaccination.

Design

This is a quasi-experimental pretest-posttest study with a control group and two parallel intervention groups. Participants are allocated by block randomization with variable block sizes and equal allocation ratio, stratified by gender and academic term. The sample size is 210 students (70 per group).

Settings and conduct

The study is conducted at two non-medical faculties of Islamic Azad University, Karaj Branch. Eligible participants are allocated into three groups: intervention one, intervention two, and control. The study is single-blinded and coded so that assessors and analysts are blinded to group allocation.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Non-medical students aged 18-25, enrolled at Islamic Azad University, Karaj Branch, written informed consent, access to a smartphone or computer with internet, and the ability to read and write Persian. Exclusion criteria: History of HPV vaccination, known HPV infection or related conditions, participation in HPV education in the last six months, severe psychiatric or neurological disorders, inability to use digital devices.

Intervention groups

Intervention Group 1: Digital storytelling education in four sessions over two weeks; each session includes a 5-minute video followed by a 20-minute online Q&A. Intervention Group 2 (Active Control): Traditional education in a single two-hour in-person session, including PowerPoint, images, and a printed pamphlet. Control Group: No training during the study; educational pamphlet provided after study completion.

Main outcome variables

Knowledge about human papillomavirus, Attitude towards human papillomavirus, Knowledge about HPV vaccine, Attitude towards HPV vaccine.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250522065849N1**
Registration date: **2025-08-24, 1404/06/02**
Registration timing: **prospective**

Last update: **2025-08-24, 1404/06/02**
Update count: **0**

Registration date

2025-08-24, 1404/06/02

Registrant information

Name

ELHAM ZANDI

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 993 266 2359

Email address

ellhamzandi.617@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-09-12, 1404/06/21

Expected recruitment end date

2025-11-12, 1404/08/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Digital Storytelling-Based Education on Knowledge and Attitudes of Non-Medical Students Toward Human Papillomavirus (HPV) and Its Vaccination

Public title

the effect of digital storytelling on students' knowledge and attitude toward hpv and its vaccination

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

being a student in a non-medical field at islamic azad university, karaj branch being enrolled in an undergraduate program at the time of study age between 18 and 25 years providing written informed consent to participate in the study Access to digital tools such as smartphones, laptops, or PCs to view the educational content (in the intervention group) ability to read, write, and understand persian

Exclusion criteria:

Prior HPV vaccination Known HPV infection or related conditions (e.g., genital warts/precancerous cervical lesions) Any formal/informal HPV or HPV-vaccine education within the past 6 months Severe psychiatric/neurological disorders impairing learning or questionnaire completion (self-report) Inability to use digital tools due to severe sensory/physical limitations.

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **210**

Randomization (investigator's opinion)

Randomized

Randomization description

This study uses computer-generated block randomization. Two non-medical faculties of Islamic Azad University, Karaj, are purposively selected; classroom recruitment follows eligibility screening and written informed consent. Participants are stratified into four strata by sex (female/male) and semester (lower [1–4]/upper ≥5) and, within each stratum, allocated 1:1:1 to intervention, active control, or passive control using variable block sizes of 6 and 9. Randomization lists are generated on randomizer.org by an independent person, with allocation concealed via sequentially numbered, opaque, sealed envelopes (SNOSE) opened at enrollment; to offset ≈10% attrition, each stratum's target is increased and rounded to the nearest multiple of 9. • Female, lower semester: N=54 (18/18/18), block sizes: 6 & 9; e.g., 6×9-person blocks (3/3/3). • Female, upper semester: N=51 (17/17/17), block sizes: 6 & 9; e.g., 3×9 + 4×6 blocks (3/3/3 and 2/2/2). • Male, lower semester: N=54 (18/18/18), block sizes: 6 & 9; e.g., 6×9. • Male, upper semester: N=51 (17/17/17), block sizes: 6 & 9; e.g., 3×9 + 4×6. (Total N=210; per 6-person block: 2 per arm; per 9-person block: 3 per arm.)

Blinding (investigator's opinion)

Single blinded

Blinding description

This is a single-blind, assessor-blinded trial. Participants cannot be fully blinded due to the obvious nature of the interventions (digital storytelling, traditional lecture, or no intervention). However, outcome assessors who collect and code pre-test, post-test, and follow-up questionnaires will be blinded to group allocation. Implementation: Each participant will receive a unique numeric ID upon enrollment; only the allocation manager will know the corresponding group. The intervention delivery team is responsible for providing the educational content but has no role in data analysis. The data collection team will only see participant codes and will have no access to group allocation. The allocation list will be stored in a password-protected file and will only be opened after data collection is complete. Data analysis will be performed by a statistician blinded to group assignments, with group labels revealed only at the final analysis stage.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research ethics committees of Islamic Azad University-Karaj branch

Street address

Ethics Committee, Faculty of Medical Sciences, Islamic Azad University, Karaj Branch, Imam Ali Complex, Moazen Blvd, Rajaee Shahr, Karaj, Alborz

City

Karaj

Province

Alborz

Postal code

3149968111

Approval date

2025-06-24, 1404/04/03

Ethics committee reference number

IR.IAU.K.REC.1404.073

Health conditions studied

1

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

Primary outcomes

1

Description
knowledge level about Human Papillomavirus (HPV)
Timepoint
Before the intervention, immediately after the intervention, one month after the intervention
Method of measurement
Knowledge and Attitude toward HPV questionnaire – Knowledge section (Pourkazemi et al., 2017), 36 items in three domains: general knowledge (13 items), cervical cancer risk factors (9 items), transmission routes and predisposing factors (14 items).

2

Description
attitude toward HPV
Timepoint
Before the intervention, immediately after the intervention, one month after the intervention
Method of measurement
Knowledge and Attitude toward HPV questionnaire – Attitude section (Pourkazemi et al., 2017), 9 items, 3-point Likert scale (agree=3, neutral=2, disagree=1)

3

Description
knowledge about HPV vaccine
Timepoint
Before the intervention, immediately after the intervention, one month after the intervention
Method of measurement
HPV Vaccine Knowledge Questionnaire (Mojahed et al., 2023), 10 items assessing prevention effect, side effects, appropriate age, and administration conditions

4

Description
attitude toward HPV vaccination
Timepoint
Before the intervention, immediately after the intervention, one month after the intervention
Method of measurement
Attitude toward HPV Vaccination Questionnaire (McRee et al., 2010; Dempsey et al., 2014), 17 items, five domains: Access barriers (5), Harms (3), Effectiveness (3), Risk denial (3), Uncertainty (3)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention Group 1: Digital Storytelling-Based Education; This group will participate in a two-week educational program consisting of four sessions (two sessions per week). Each session includes the presentation of a 5-minute educational video based on real-life stories and scientifically validated information about Human Papillomavirus (HPV) and its vaccination. The videos will be delivered via secure online platforms or privacy-adjusted messaging applications.After watching each video, a 20-minute live online session will be held, led by the researcher, for Q&A, clarification, and discussion.Equipment and software used include InShot for video editing, Audacity for voice recording and editing, and standard audio-visual recording tools. All educational content will be reviewed and approved by two nursing and midwifery faculty members prior to implementation. The total duration of the intervention for each participant will be two weeks.
Category
Prevention

2

Description
Intervention Group 2 (Active Control): Traditional EducationThis group will attend a single, in-person, 2-hour educational session. The training will include PowerPoint presentations, educational images, and verbal explanations covering HPV, its transmission, complications, and the importance of vaccination. At the end of the session, a 20-minute Q&A segment will be conducted face-to-face. Additionally, a printed educational pamphlet containing scientifically validated information will be provided to participants.Educational tools include projector, laptop, PowerPoint presentation, and printed pamphlets. The entire intervention for this group will be delivered in one single session.
Category
Prevention

3

Description
Control Group (No Intervention): Participants in this group will receive no training or intervention during the study period. Only after completing the post-test will they be provided with an educational pamphlet similar to the active control group, in order to increase their awareness. This measure is intended to adhere to ethical principles and ensure all participants have access to scientifically accurate information.

Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Islamic Azad University Karaj Branch
Full name of responsible person
Ellham Zandi
Street address
Islamic Azad University, Karaj Branch, Imam Ali Complex, Moazen Blvd, Rajaee Shahr, Karaj, Alborz
City
Karaj
Province
Alborz
Postal code
3149968111
Phone
+98 901 183 7617
Fax
+98 26 3441 8156
Email
ellhamzandi.617@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Afshin Zargar
Street address
Islamic Azad University, Karaj Branch, Imam Ali Complex, Moazen Blvd, Rajaee Shahr, Karaj, Alborz
City
Karaj
Province
Alborz
Postal code
3149968111
Phone
+98 26 3418 2744
Fax
+98 26 3441 8156
Email
intl@kiau.ac.ir
Web page address
https://karaj.iau.ir/en
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Islamic Azad University Karaj branch
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
Islamic Azad University
Full name of responsible person
Sharareh Zeighami Mohammadi
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Islamic Azad University, Karaj Branch, Imam Ali Complex, Moazen Blvd, Rajaee Shahr, Karaj, Alborz
City
Karaj
Province
Alborz
Postal code
3149968111
Phone
+98 26 3418 2570
Fax
+98 26 3441 8156
Email
zeighamimohammadi@iau.ac.ir
Web page address
https://karaj.iau.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Sharareh Zeighami Mohammadi
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Islamic Azad University, Karaj Branch, Imam Ali Complex, Moazen Blvd, Rajaee Shahr, Karaj, Alborz
City
Karaj
Province

Alborz

Postal code

3149968111

Phone

+98 26 3410 2570

Fax

+98 26 3441 8156

Email

zeighamimohammadi@iau.ac.ir

Web page address

https://karaj.iau.ir/fa

Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Elham Zandi

Position

Master Science Nursing Student

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

No. 8 ،Nasr One،Jahazi Town،Mawzen Boulevard

City

Karaj

Province

Alborz

Postal code

3148618765

Phone

+98 66 4253 0680

Email

ellhamzandi.617@gmail.com

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

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

General Data Sharing Plan: In alignment with ICMJE's ethical principles and in recognition of participants' contributions, we plan to share study-related materials. These will be available after study completion and data analysis for up to five years. Data to be shared: Individual Participant Data (IPD): Yes De-identified participant data will be shared upon formal request and ethics approval. Study Protocol: Yes Available upon request for research or educational purposes. Statistical Analysis Plan: Yes Includes test types, software used, and variable definitions in PDF. Informed Consent Form: Yes A de-identified version will be made available. Clinical Study Report: Yes A comprehensive report will be shared post-analysis. Analysis Codes: Yes SPSS or other statistical software codes with documentation will be shared. Data Dictionary: Yes Includes definitions and coding of all study variables. Access Details: Time Frame: Up to five years after study completion Eligible Individuals: Access to the raw and analyzed data of this study will be strictly limited to the core research team, including the principal investigator, research collaborators, and the statistical analyst whose names are listed in the approved protocol and ethics committee approval. All team members will be required to sign a data confidentiality agreement prior to the initiation of the study. Data will be stored and analyzed in a coded format without any personally identifiable information. Access will be restricted to password-protected computers located in secure areas. Any transfer or sharing of data with individuals or organizations outside the research team will only be done with written approval from the Ethics Committee and in a de-identified form, in accordance with legal Request Process: Contact Elham Zandi Email: ellhamzandi.617@gmail.com | Phone: +98 901 183 7617 Conditions for Access: Signing a Data Use Agreement and ethics board approval

When the data will become available and for how long

Up to five years

To whom data/document is available

De-identified IPD, together with the data dictionary, study protocol, statistical analysis plan, and analysis code, will be available after study completion and primary analysis and for up to five years after publication of the primary results to qualified researchers. Access requires a formal request (including a secondary-analysis proposal), approval from an appropriate REC/IRB, and a Data Use Agreement (DUA); data will be provided in de-identified form via a secure institutional server and used for non-commercial scientific purposes (e.g., meta-analysis, validation, and related secondary analyses).

Under which criteria data/document could be used

Available upon request for research or educational purposes.

From where data/document is obtainable

Elham Zandi Masters Student of Islamic Azad University of Karaj Branch ellhamzandi.617@gmail.com 0901183761

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

Request Process: Contact Elham Zandi Email: ellhamzandi.617@gmail.com | Phone: +98 901 183 7617 Conditions for Access: Signing a Data Use Agreement and ethics board approval

Comments