Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the Effect of Sexual Health Model-Based Education and the Serious Game 'Counselor Monopoly' on Knowledge, Reasoning Skills, and Attitudes of Nursing and Midwifery Students about the Human Papillomavirus

Protocol summary

Study aim
Determining and comparing the effect of an educational intervention based on the Sexual Health Model using the serious game 'Consultant Monopoly' on the knowledge, reasoning skills, and attitudes of nursing and midwifery students regarding the Human Papillomavirus.

Design
The sample size is 96 participants, accounting for attrition. To control for confounders, stratified randomization will assign participants to two groups. The allocation process involves two stages: Random sequence generation: Using Random Allocation software. Allocation concealment: A trained individual, independent from intervention implementation and data analysis, will implement the sequence to keep interventions concealed until formal group assignment. Blinding of participants and intervention providers is not feasible due to the nature of the interventions.

Settings and conduct
This study is a randomized controlled trial with a pretest-posttest-follow-up design. The setting of this study is the Nursing and Midwifery School at Shahid Sadoughi University of Medical Sciences in Yazd

Participants/Inclusion and exclusion criteria
Inclusion Criteria : Nursing and midwifery students from the third semester onwards at Shahid Sadoughi University of Medical Sciences in Yazd. Willingness to participate and provision of informed consent. Exclusion Criteria : Unwillingness to continue participation in the study.

Intervention groups
The Sexual Health Model-based group will receive three in-person, 2-hour group sessions. The serious game group will play "Consultant Monopoly" in person, in groups of six. For both groups, the educational content is designed based on the Sexual Health Model, focusing on HPV-related knowledge, attitudes, and reasoning skills.

Main outcome variables
knowledge، reasoning skills، attitudes

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260104068539N1**
Registration date: **2026-05-01, 1405/02/11**
Registration timing: **retrospective**

Last update: **2026-05-01, 1405/02/11**
Update count: **0**

Registration date
2026-05-01, 1405/02/11

Registrant information

Name
zahra Rastegarqhavi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-02-15, 1404/11/26

Expected recruitment end date
2026-03-17, 1404/12/26

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

Scientific title
Comparison of the Effect of Sexual Health Model-Based Education and the Serious Game 'Counselor Monopoly' on Knowledge, Reasoning Skills, and Attitudes of Nursing and Midwifery Students about the Human Papillomavirus

Public title
Comparison of the Effect of Sexual Health Model-Based Education and the Serious Game 'Counselor Monopoly' on Knowledge, Reasoning Skills, and Attitudes of Nursing and Midwifery Students about the Human Papillomavirus
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Nursing and midwifery students from the third semester at Shahid Sadoughi University of Medical Sciences in Yazd Willingness and having informed consent to participate in the study
Exclusion criteria:
Age
From **19 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **96**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants were allocated to the two intervention groups using a stratified randomization method based on field of study (nursing/midwifery) and academic semester. Accordingly, participants were first categorized into homogeneous strata according to the aforementioned variables, and then within each stratum, group allocation was performed randomly using Random Allocation software. To ensure allocation concealment, the allocation sequence was generated and maintained by a trained individual who was independent of both the intervention implementation and data analysis teams, and it remained concealed until participants were assigned to the groups.
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 Shahid Sadoughi University of Medical Sciences, Yazd
Street address
Bu Ali Alley, Timsar Fallahi Street
City
Yazd
Province
Yazd
Postal code
۸۹۱۵۸۱۸۴۱۱
Approval date
2025-11-05, 1404/08/14
Ethics committee reference number
IR.SSU.REC.1404.116

Health conditions studied

1

Description of health condition studied
Human Papillomavirus
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Knowledge was assessed using a questionnaire.
Timepoint
before the intervention , immediately after the intervention , and 4 and 12 weeks post-intervention
Method of measurement
The Knowledge and Attitude Questionnaire regarding Human Papillomavirus

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The educational intervention in this group will be delivered through a designed educational game titled "Consultant Monopoly." This game was developed by adapting and localizing the game Polmonopoly (or Monopoly) and is tailored to the curriculum of the Sexual Health Model-based

intervention. Initially, participants will attend an orientation session to become familiar with the game mechanics and its objectives. Subsequently, after screening, they will be randomly divided into eight groups of six using simple randomization while adhering to the principle of homogenization. The results of the group allocation will then be communicated to them.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Nursing and Midwifery School, Shahid Sadoughi University of Medical Sciences, Yazd

Full name of responsible person

Mahshid bokaie

Street address

Bu Ali Alley, Timsar Fallahi Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

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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

Yazd 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

Yazd University of Medical Sciences

Full name of responsible person

مهشید بکایی

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

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Position

Professor

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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Master's student

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Midwifery

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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