Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Examining the Effectiveness of the Information-Motivation-Behavioral Skills Counseling Model on Sexual Relationship Anxiety, Awareness Regarding the Human Papillomavirus Vaccine, and the Intention to Receive and Actual Receipt of the Vaccine Among Women with Cervical Dysplasia

Protocol summary

Study aim

Examining the Effectiveness of the Information-Motivation-Behavioral Skills Counseling Model on Sexual Anxiety, Awareness Regarding the Human Papillomavirus Vaccine, and the Intention to Receive and Actual Receipt of the Vaccine Among Women with Cervical Dysplasia

Design

A parallel-group randomized clinical trial. Randomization was performed using the permuted-block method with allocation concealment; 86 women were included (43 per group), with no blinding.

Settings and conduct

Participants at the Baghaeipour Clinic in Yazd will be assigned to either an intervention group or a control group using a permuted-block randomization method. The intervention group will receive counseling based on the IMB model, delivered through eight weekly 90-minute sessions via the Skyroom platform. Data will be collected using self-report questionnaires administered at the beginning of the study, at the end of week 8, and at the end of week 12. The control group will receive routine care such as education on strengthening the immune system, stress reduction, and personal hygiene practices related to sexual activity at the Baghaeipour Clinic.

Participants/Inclusion and exclusion criteria

•Inclusion criteria: •Reproductive age •Moderate to severe anxiety regarding sexual intercourse •Physician confirmed cervical dysplasia •Informed consent •Ability to read, write, and speak Persian •Women living with their spouses •Ownership of a smartphone Exclusion criteria: •Need for psychiatric referral •History of HPV vaccination •Concurrent participation in similar studies •Occurrence of stressful events within the past 6 months •Tobacco use •Conditions affecting sexual function •Gynecologic cancers •Pregnancy

Intervention groups

Group 1: Online group counseling based on the Information-Motivation-Behavioral Skills model, consisting of 8 sessions Group 2: Receiving routine care

Main outcome variables

Sexual anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260908070965N1**
Registration date: **2026-11-08, 1405/08/17**
Registration timing: **prospective**

Last update: **2026-11-08, 1405/08/17**
Update count: **0**

Registration date

2026-11-08, 1405/08/17

Registrant information

Name
narges seifi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 35 3722 5634
Email address
nargessyfi77@gmail.come

Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date
2026-11-22, 1405/09/01
Expected recruitment end date
2027-02-20, 1405/12/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Examining the Effectiveness of the Information-Motivation-Behavioral Skills Counseling Model on Sexual Relationship Anxiety, Awareness Regarding the Human Papillomavirus Vaccine, and the Intention to Receive and Actual Receipt of the Vaccine Among Women with Cervical Dysplasia

Public title
The Effect of Information-Motivation-Behavioral Skills Counseling on Sexual Relationship Anxiety, Awareness, and Willingness to Receive the Human Papillomavirus Vaccine
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Reproductive age Moderate to severe anxiety scores related to sexual activity, based on the Davis questionnaire Diagnosis of cervical dysplasia based on confirmation by the attending physician and the clinic's records. Having the desire and informed consent to participate in the research Ability to read, write, and speak Persian Women who live with their husbands and are their husbands' only wives Owning an Android or iOS smartphone
Exclusion criteria:
Need for referral to a psychiatrist and pharmacological treatment due to psychiatric disorders History of HPV vaccination Concurrent participation in similar studies Has not experienced stressful events such as migration, the death of a loved one, divorce, or financial difficulties within the past six months. Use of tobacco, illicit drugs, and alcohol, according to the patient and their medical record Presence of other conditions affecting sexual function, such as vaginismus, vestibulodynia, vulvar skin disorders, painful bladder syndrome or interstitial cystitis, and pregnancy Developing gynecological cancers, such as cancers of the cervix, uterus, ovary, etc Pregnancy
Age
From **15 years** old to **45 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **86**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants were assigned to study groups using a permuted block randomization method with a fixed block size of 4. The random allocation sequence was generated using the Random Allocation Software. This method was employed to maintain a balanced number of participants across the study groups. To ensure allocation concealment, the allocation sequences were placed in opaque, sealed, and numbered envelopes. These envelopes were opened sequentially following the enrollment and registration of each participant to prevent the researcher from having prior knowledge of the participants' group assignments.
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
No. 48,Azadshahr, between the 2nd and 3rd Roundabouts, Yas Alley
City
yazd
Province
Yazd
Postal code
8917876173
Approval date
2026-07-13, 1405/04/22
Ethics committee reference number
IR.SSU.REC.1405.070

Health conditions studied

1

Description of health condition studied
Human papillomavirus
ICD-10 code
N87
ICD-10 code description
Dysplasia of cervix uteri

Primary outcomes

1

Description
Sexual anxiety
Timepoint
The primary outcome variable, sexual anxiety, is measured at baseline (prior to the start of the intervention), at the conclusion of the intervention (week 8), and at the follow-up assessment (week 12).
Method of measurement
Davis Sexual Relationship Anxiety Assessment Questionnaire

Secondary outcomes

1

Description
The first secondary outcome variable is awareness regarding the human papillomavirus vaccine among women with cervical dysplasia
Timepoint
The secondary outcome variable awareness regarding the human papillomavirus vaccine among women with cervical dysplasia is measured at baseline (prior to the start of the intervention), at the conclusion of the intervention (week 8), and at the end of the study (week 12).
Method of measurement
Human Papillomavirus Vaccine Awareness Questionnaire

2

Description
Second secondary outcome variable intention to receive the human papillomavirus vaccine among women with cervical dysplasia
Timepoint
The secondary outcome variable intention to receive the human papillomavirus vaccine is measured in women with cervical dysplasia at baseline (prior to the intervention), at the conclusion of the intervention (week 8), and at the end of the study (week 12).
Method of measurement
It is examined using two questions in the questionnaire.

3

Description
Third secondary outcome variable administration of the human papillomavirus vaccine in women with cervical dysplasia.
Timepoint
The secondary outcome variable administration of the human papillomavirus vaccine is measured in women with cervical dysplasia at baseline (prior to the intervention), upon completion of the intervention at week 8, and at the end-of-study follow-up at week 12.
Method of measurement
It is examined using two questions in the questionnaire.

Intervention groups

1

Description
Intervention Group: Participants in the intervention group receive counseling based on the Information-Motivation-Behavioral Skills (IMB) model, delivered via the Skyroom platform across eight weekly, 90-minute sessions. The counseling is conducted by a researcher pursuing a master's degree in Midwifery Counseling—who is certified to administer IMB-based counseling—under the supervision of faculty advisors. The intervention consists of eight virtual group counseling sessions, each lasting 90 minutes, with content structured around the IMB counseling approach.The program consists of eight sessions covering the following topics: raising awareness about HPV; correcting misconceptions and boosting learning motivation; identifying signs of sexual anxiety; shifting attitudes toward healthy sexual relations; training couples in communication and anxiety-management behavioral skills; encouraging HPV vaccination; and reviewing and consolidating acquired skills. These sessions are conducted virtually once a week via the Skyroom platform, utilizing PowerPoint presentations and Q&A segments. Notably, a summary of key points from each session is recorded and made available to the participants for repeated viewing. To facilitate this, the researcher will collect participants' mobile numbers after obtaining informed consent and establish a messaging group managed by the researcher.The researcher will handle all necessary communications with study participants regarding coordination—such as participation in the group channel, delivery of session content at scheduled times, reminders about homework assignments, and handling private inquiries following group counseling sessions. It should be noted that summaries of key points from each session will be recorded and made available to the women for repeated viewing. To facilitate this, the researcher will collect participants' mobile numbers after obtaining informed consent and will set up and manage a messaging group.
Category
Behavior

2

Description
Control group: In the control group, routine care such as education on strengthening the immune system, stress reduction, and maintaining personal hygiene will also be provided at the Baghaeipour Clinic.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center

Baghaei-Pour Clinic, Shahid Sadoughi Hospital

Full name of responsible person
Mohammad Pourmira Fazlil

Street address
Ibn Sina Street

City
YAZD

Province
Yazd

Postal code
8916877443

Phone
+98 35 3183 3094

Email
baghaei@ssu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yazd University of Medical Sciences

Full name of responsible person
Mehran Karimi

Street address
Imam Hossein Square – Daneshjoo Boulevard

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Province
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8916188637

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Email
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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
Tahmineh Farajkhoda

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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Person responsible for updating data

Contact

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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
Not applicable
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Not applicable
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
All individual data of study participants can be shared after the individuals have been de-identified.
When the data will become available and for how long
After the results are published
To whom data/document is available
The data will be available to researchers affiliated with academic and scientific institutions, and individuals working in the industry may also apply to obtain them
Under which criteria data/document could be used
Should other researchers request access to the data for the purpose of conducting secondary analysis, such access will be granted only upon submission of a written request outlining the objectives and the proposed analytical methodology and subject to the approval of the principal investigator. The data will be provided to applicants solely in a de-identified format, with all participant-identifying information removed. Applicants are required to adhere to principles of confidentiality, ensure data security, and utilize the information exclusively for the approved objectives. Where applicable, obtaining approval from an ethics committee and securing any other necessary authorizations is mandatory prior to accessing the data
From where data/document is obtainable
farajkhoda.tahmineh31255@gmail.com Dr. Tahmineh Farajkhoda
What processes are involved for a request to access data/document
One week after receiving the applicant's email
Comments