# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 2026

## Effectiveness of solution focused brief therapy on students’ perceived self-efficacy regarding Human Papillomavirus vaccination: A Randomized Controlled Trial

## Protocol summary


**Study aim**

Determining the effectiveness of Solution-Focused Brief Therapy on students' perceived self-efficacy regarding Human Papillomavirus vaccination.

**Design**

This study is an open-label, parallel-group randomized controlled trial. Eligible participants will be allocated to the intervention or control group using block randomization with a 1:1 allocation ratio. The random sequence will be generated using Microsoft Excel. The total sample size is 160 participants (80 per group)

**Settings and conduct**

The study will be conducted at Mazandaran University of Medical Sciences, Sari, Iran. Participants will be recruited from the Schools of Nursing and Midwifery, Medicine, Dentistry, Paramedical Sciences, Pharmacy, Health, and Advanced Technologies. The intervention sessions will be held in the amphitheater of the School of Pharmacy and Health.

**Participants/Inclusion and exclusion criteria**

Participants are female students of Mazandaran University of Medical Sciences (Sari Campus) who meet the eligibility criteria and provide written informed consent. Key inclusion criteria include no previous HPV vaccination, low to moderate perceived self-efficacy regarding HPV vaccination, and the ability to attend counseling sessions. Participants will be excluded if they withdraw from the study, receive the HPV vaccine during the study, or fail to complete more than 20% of the study questionnaires.

**Intervention groups**

Participants will be randomly assigned in a 1:1 ratio to either the intervention or the control group. The intervention group will receive Solution-Focused Brief Therapy (SFBT) delivered in group counseling sessions aimed at enhancing perceived self-efficacy, reducing hesitancy toward HPV vaccination, and strengthening motivation for informed decision-making. The control group will receive routine care.

**Main outcome variables**

Perceived self-efficacy regarding HPV vaccination.


## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20260704070060N1**
Registration date: **2026-08-10, 1405/05/19**
Registration timing: **registered_while_recruiting**

Last update: **2026-08-10, 1405/05/19**
Update count: **0**

**Registration date**

2026-08-10, 1405/05/19

**Registrant information**


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**Name of organization / entity**

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Iran (Islamic Republic of)

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**Recruitment status**

**recruiting**

**Funding source**

**Expected recruitment start date**

2026-08-08, 1405/05/17

**Expected recruitment end date**

2026-11-21, 1405/08/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Effectiveness of solution focused brief therapy on students' perceived self-efficacy regarding Human Papillomavirus vaccination: A Randomized Controlled Trial

**Public title**

Effectiveness of solution focused brief therapy on students' perceived self-efficacy regarding Human Papillomavirus vaccination

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Willingness to participate in the study and provision of written informed consent Female students Ability and willingness to participate in face-to-face group counseling sessions Current enrollment in one of the faculties of Mazandaran University of Medical Sciences (Sari Campus) during the 2025–2026 academic year Adequate proficiency in the Persian language to understand the study questionnaires content and participate in the counseling sessions No previous receipt of any dose of the Human Papillomavirus (HPV) vaccine, based on self-report Low to moderate perceived score self-efficacy regarding HPV vaccination, indicating eligibility for the intervention No self-reported history of infection with any HPV genotype or HPV-related malignancies (e.g., cervical cancer) No current use of psychotropic medications, based on self-report No current substance use disorder, based on self-report

**Exclusion criteria:**

Failure to complete more than 20% of the items in any of the study questionnaires Receipt of any dose of the HPV vaccine at any time during the study period (from screening to the end of follow-up) Participation in any specialized educational or counseling program related to HPV vaccination within the previous six months Presence of severe psychiatric disorders or other mental illnesses diagnosed by a psychiatrist, based on self-report, that may interfere with effective participation in the counseling sessions Pregnancy or intention to become pregnant during the study period Presence of any acute illness or medical condition constituting a contraindication to HPV vaccination (e.g., a history of severe allergic reactions), as confirmed in consultation with an infectious disease specialist unwillingness to continue participation at any stage of the study

**Age**

No age limit

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **160**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Participants who meet the eligibility criteria will be randomly allocated to the intervention or control group using block randomization with a 1:1 allocation ratio. The unit of randomization is the individual participant and no stratified randomization will be applied. The random allocation sequence will be generated before participant recruitment by a statistician who is not involved in participant recruitment or outcome assessment, using Microsoft Excel and the RANDBETWEEN function. Participants will be allocated in 40 blocks of four (total sample size = 160). Six possible block arrangements (TTCC, TCTC, TCCT, CCTT, CTCT, and CTTC) will be used, where T represents the intervention group and C represents the control group. Using the RANDBETWEEN function in Excel, a random number between 1 and 6 will be generated 40 times, and each generated number will correspond to one of the six block arrangements. Accordingly, participants will be assigned to the intervention or control group in a balanced manner within each block. To minimize selection bias, allocation concealment will be implemented. After generation of the random allocation sequence, the assignment for each participant will be placed in sequentially numbered, opaque, light-proof, sealed envelopes prepared by an individual who is not involved in participant recruitment. After confirming eligibility and obtaining written informed consent, the envelope corresponding to each participant will be opened sequentially to reveal the assigned group. Therefore, the researcher responsible for participant recruitment will remain unaware of the allocation until the moment of assignment.

**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 Mazandaran University of Medical Sciences

**Street address**

Moallem Square, Deputy of research and technology, Mazandaran University of Medical Sciences

**City**

Sari

**Province**
Mazandaran
**Postal code**
4817844718
**Approval date**
2026-08-05, 1405/05/14
**Ethics committee reference number**
IR.MAZUMS.REC.1405.184

## Health conditions studied

### 1

**Description of health condition studied**
This study aims to evaluate the effectiveness of Solution-Focused Brief Therapy (SFBT) on students' perceived self-efficacy regarding human papillomavirus (HPV) vaccination to promote HPV vaccination and prevent HPV infection.
**ICD-10 code**
Z11.51
**ICD-10 code description**
Encounter for screening for human papillomavirus (HPV)

## Primary outcomes

### 1

**Description**
Perceived self-efficacy regarding Human Papillomavirus (HPV) vaccination.
**Timepoint**
At baseline, immediately after completion of the counseling intervention, and one month after the intervention.
**Method of measurement**
The primary outcome is perceived self-efficacy regarding Human Papillomavirus (HPV) vaccination, which will be measured using the Health Belief Model Constructs Related to HPV Vaccination Questionnaire at three time points: baseline (before the intervention), immediately after completion of the counseling sessions, and one month after the intervention.

## Secondary outcomes

### 1

**Description**
Perceived susceptibility to Human Papillomavirus
**Timepoint**
will be measured at three time points: before the intervention (baseline), immediately after completion of the counseling sessions, and one month after the intervention
**Method of measurement**
using the Health Belief Model Constructs Related to HPV Vaccination Questionnaire.

### 2

**Description**
Perceived severity of the consequences of Human Papillomavirus
**Timepoint**
will be measured at three time points: before the intervention (baseline), immediately after completion of the counseling sessions, and one month after the intervention
**Method of measurement**
using the Health Belief Model Constructs Related to HPV Vaccination Questionnaire.

### 3

**Description**
Perceived benefits of Human Papillomavirus vaccination
**Timepoint**
will be measured at three time points: before the intervention (baseline), immediately after completion of the counseling sessions, and one month after the intervention
**Method of measurement**
using the Health Belief Model Constructs Related to HPV Vaccination Questionnaire.

### 4

**Description**
Perceived barriers to Human Papillomavirus vaccination
**Timepoint**
will be measured at three time points: before the intervention (baseline), immediately after completion of the counseling sessions, and one month after the intervention
**Method of measurement**
using the Health Belief Model Constructs Related to HPV Vaccination Questionnaire.

### 5

**Description**
Satisfaction with the intervention
**Timepoint**
will be assessed immediately after the final intervention session and at the one-month follow-up
**Method of measurement**
using the Visual Analog Scale (VAS) for intervention satisfaction

## Intervention groups

### 1

**Description**
Intervention group: Participants in the intervention group will receive four weekly group counseling sessions based on Solution-Focused Brief Therapy (SFBT), each lasting 45–60 minutes, delivered by the principal investigator certified in SFBT at the amphitheater of the School of Health and Pharmacy. Participants will be divided into four groups of 20. The sessions will incorporate standard

SFBT techniques, including the miracle question, exception finding, scaling questions, and coping questions, with the aim of enhancing perceived self-efficacy regarding HPV vaccination, reducing vaccination hesitancy, and strengthening motivation for informed decision-making.

**Category**

Behavior

**2**

**Description**

Control group: At the end of the intervention, the control group will receive one session of routine education on the importance of Human Papillomavirus (HPV) vaccination, delivered virtually via Google Meet.

**Category**

Behavior

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Diana Azizi

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## Sponsors / Funding sources

**1**

**Sponsor**

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**Grant name**

Mazandaran University of Medical Sciences

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Mazandaran 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**

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**Full name of responsible person**

Diana Azizi

**Position**

Assistant professor, Department of Reproductive Health and Midwifery, Sexual and Reproductive Health

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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