Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of educational intervention based on protection motivation theory on mothers' health literacy about human papilloma virus and mothers' intention to vaccinate teenage daughters against human papilloma virus

Protocol summary

Study aim
Determining the effect of educational intervention based on protection motivation theory on mothers' health literacy about human papilloma virus and intention to vaccinate teenage girls

Design
Randomized controlled clinical trial

Settings and conduct
The study will be conducted on women covered by community health service centers affiliated with Neyshabur University of Medical Sciences. First, two centers are randomly selected, then the samples are randomly assigned to the experimental and control groups based on a block of 4. First, a demographic information questionnaire, a researcher-made HPV health literacy questionnaire, a protection motivation and vaccination intention questionnaire are completed for both groups. Then, a 4-session educational intervention is held for mothers in the intervention group. The duration of each educational session is set to 45 minutes and the interval between sessions is set to one week. The questionnaire is completed for both groups immediately and 4 weeks after the intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Being Iranian, living in the city of Neyshabur, Literacy, age range of mothers 25-50 years and daughters 9-15 years, not participating in similar studies, no history of receiving HPV vaccine in girls, single girl, no severe stressful event in the past 6 months؛ Exclusion criteria: Mother's employment in healthcare systems,contraindications to receiving the human papillomavirus vaccine in girls

Intervention groups
Eligible persons are divided into two groups. An educational intervention group based on the protection motivation model received 4 weekly training sessions, and the control group without educational intervention only filled pre-test and post-test questionnaires.

Main outcome variables
mothers' HPV health literacy, vaccination intention

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20241013063345N1**
Registration date: **2024-12-15, 1403/09/25**
Registration timing: **prospective**

Last update: **2024-12-15, 1403/09/25**
Update count: **0**

Registration date
2024-12-15, 1403/09/25

Registrant information

Name
Zohre Mianbandi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 51 4222 8344

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zm8092@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-12-21, 1403/10/01

Expected recruitment end date

2025-03-21, 1404/01/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of educational intervention based on protection motivation theory on mothers' health literacy about human papilloma virus and mothers' intention to vaccinate teenage daughters against human papilloma virus

Public title
The effect of educational intervention based on protection motivation theory on mothers' health literacy about human papilloma virus and mothers' intention to vaccinate teenage daughters against human papilloma virus

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Being Iranian living in the city of Neyshabur Literacy age range of mothers 25-50 years and daughters 9-15 years not participating in similar studies no history of receiving HPV vaccine In girls single girl no severe stressful event in the past 6 months

Exclusion criteria:
Mother's employment in healthcare systems Contraindications to receiving the human papillomavirus vaccine in girls (including: history of allergic reaction to any type of vaccine, allergy to yeast, people with a weakened immune system)

Age
From **25 years** old to **50 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **78**

Randomization (investigator's opinion)
Randomized

Randomization description
The samples will be assigned to the test and control groups based on a block of 4. The sequence of random allocation of people will be done using the site www.sealedenvelope.com. It is worth mentioning that on the mentioned site, 19 blocks are selected from the six possible modes of blocks: AABB (1), ABAB (2), ABBA (3), BBAA (4), BABA (5) and BAAB (6). Next, people are assigned to groups B and A based on the block corresponding to the selected number. This work continues until the sample volume is completed.

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
Research Ethics committee of school of nursing & midwifery Mashhad University of Medical Sciences

Street address
Khorasan Razavi, Mashhad, Azadi Square, East Gate of Ferdowsi University of Mashhad, University Campus, Shahid Dr. Kharazmi Educational Complex

City
mashhad

Province
Razavi Khorasan

Postal code
9137913199

Approval date
2024-10-15, 1403/07/24

Ethics committee reference number
IR.MUMS.NURSE.REC.1403.071

Health conditions studied

1

Description of health condition studied
Human papillomavirus vaccination

ICD-10 code
Z25.8

ICD-10 code description
Need for immunization against other specified single viral diseases

Primary outcomes

1

Description
HPV health literacy

Timepoint
before starting training, immediately and 4 weeks after training

Method of measurement
Using HPV health literacy questionnaires

2

Description
vaccination intention

Timepoint

before starting training, immediately and 4 weeks after training

Method of measurement

vaccination intention questionnaire

Secondary outcomes

1

Description

protection motivation

Timepoint

Before the start of training, immediately and 4 weeks after training

Method of measurement

Using the protection motivation questionnaire

Intervention groups

1

Description

The educational intervention consisted of 4 sessions, with one session per week and each session lasting 45 minutes. Group discussion, brainstorming, question and answer methods, as well as PowerPoint teaching aids, slide shows, and educational videos will be used in the educational sessions. The educational content will be based on the constructs of the Protection Motivation Theory on the intention to vaccinate against the human papillomavirus and will include the prevalence and importance of human papillomavirus infection, symptoms, complications of this disease, risk factors, causes, and ways of contracting HPV, the effects and complications of the disease on various aspects of health, and the importance of prevention, the importance of vaccination, obstacles, and solutions to overcome them. At the end, an educational pamphlet will also be provided to the spouses.

Category

Prevention

2

Description

Control group: No intervention will be performed

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Neyshabur Urban Health Center

Full name of responsible person

Zohre Mianbandi

Street address

North Ferdowsi St., Behesht St., between 7 and 9 Behesht ،No،77.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

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Grant name

Mashhad University of Medical Sciences

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

Zohre Mianbandi

Position

graduate student

Latest degree

Bachelor

Other areas of specialty/work
Midwifery
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Person responsible for scientific inquiries

Contact
Name of organization / entity
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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
Yes - There is 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
Not applicable
Title and more details about the data/document
Publishing research results in the form of a scientific article
When the data will become available and for how long
The access period begins after the article is published.
To whom data/document is available
The general public and all researchers
Under which criteria data/document could be used
To inform and educate the public about human papillomavirus vaccination and scientific use, citing the article
From where data/document is obtainable
By email to Dr. Fatemeh Hadizadeh Talaasaz, Email:shahnazhadizadeh@yahoo.com
What processes are involved for a request to access data/document
Requests for access to data/documents will be reviewed by the research team.
Comments