Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The Effect of Education Based on Health Belief Model on the Intention of Injection of HPV Vaccine in vulnerable women in Isfahan in 2018

Protocol summary

Study aim

The Effect of Education Based on Health Belief Model on the Intention of Injection of HPV Vaccine in vulnerable women in Isfahan in 2018

Design

The clinical trial has 1 intervention group (in two centers) and 1 control group, each group based on the lottery and randomly selected from 3 vulnerable women's counseling centers under welfare coverage. The sample size for each group was 36,but Considering the Chance of sample Loos, Sample Size was Increased to 72.

Settings and conduct

The research environment in this study is three vulnerable women's counseling centers under Supervision of Welfare Organization of Isfahan city, two of which will be randomly selected as an intervention group and one center will be selected as the control group. Firstly, by visiting these centers, a list of vulnerable women aged 15-45 and their telephone numbers will be extracted and invited by telephone to participate in the research. Group training sessions are organized in four sessions of an hour and a half with a one-hour interval in a room in these centers.

Participants/Inclusion and exclusion criteria

Vulnerable women, aged 15-45 years old, non-pregnant, women whose spouses have one of the following characteristics: drug users, current imprisonment or current imprisonment. Pregnancy During the study, prisoners should be imprisoned during the study, not completing the questionnaire, misdiagnosis (completeness without accuracy), abstaining from attending educational sessions more than once

Intervention groups

Intervention group: Group discussions and lectures and presentation of pamphlets will be held in four sessions, one and a half hours, which will take place approximately one week. Control group: no additional work

Main outcome variables

The Intention of Injection of HPV Vaccine

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110529006624N2**
Registration date: **2019-02-27, 1397/12/08**
Registration timing: **registered_while_recruiting**

Last update: **2019-02-27, 1397/12/08**
Update count: **0**

Registration date

2019-02-27, 1397/12/08

Registrant information

Name

zahra boroomandfar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3625 1726

Email address

boroumandfar@nm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-21, 1397/11/01

Expected recruitment end date

2019-03-18, 1397/12/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Education Based on Health Belief Model on the Intention of Injection of HPV Vaccine in vulnerable women in Isfahan in 2018

Public title
The Effect of Education Based on Health Belief Model on the Intention of Injection of HPV Vaccine in vulnerable women in Isfahan in 2018

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Vulnerable women Aged 15-45 years old Non-pregnant Women whose spouses have one of the following characteristics: drug users, current imprisonment or current imprisonment.

Exclusion criteria:
Pregnancy During the study Prisoners should be imprisoned during the study Not completing the questionnaire Misdiagnosis (completeness without accuracy) Abstaining from attending educational sessions more than once

Age
From **15 years** old to **26 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **72**

Randomization (investigator's opinion)
Randomized

Randomization description
3 The Special Women's Advice Center for vulnerable women under the Welfare Organization will be allocated to intervention teams based on the Health Belief Model (grouped by lecture, pamphlet, etc.) and the control group (2 centers of intervention and 1 control center) .Samples will be selected based on convenience sampling in centers.

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 Isfahan University of Medical Sciences

Street address
School of Nursing and Midwifery, Isfahan University of Medical Sciences,Hezar Jarib Street,Azadi Square

City
Isfahan, Iran

Province
Isfehan

Postal code
8174673461

Approval date
2018-10-03, 1397/07/11

Ethics committee reference number
IR.MUI.RESEARCH.REC.1397.224

Health conditions studied

1

Description of health condition studied
The Intention of Injection of HPV Vaccine in vulnerable women

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
The Intention of Injection of HPV Vaccine

Timepoint
Before the intervention, immediately and 6 weeks after the intervention

Method of measurement
Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Group discussions and lectures and presentation of pamphlets will be held in four sessions, one and a half hours, which will take place approximately one week.

Category
Other

2

Description
Control group: no additional work(No intervention)

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Social Services Base HASEH

Full name of responsible person
Zahra Arjmandi

Street address
Hasseh. First Street of Imam Khomeini

City
Isfahan, Iran

Province
Isfehan

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816637316

Phone
+98 31 3558 3593

Email
Z.arjmandi53@gmail.com

2

Recruitment center

Name of recruitment center
Arsenan Social Services Base

Full name of responsible person
Safiyan

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Email
ll_abab@yahoo.com

3

Recruitment center

Name of recruitment center
Women's Damage Center

Full name of responsible person
Leila Heidary

Street address
Robat St

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Isfahan, Iran

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816637316

Phone
+98 31 3337 8923

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leilaheidary.2012@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Dr. Shaghayegh Haghjouy Javanmard

Street address
Research &Technology Dept, Isfahan University of Medical Sciences. hezar Jareib St, Azadi Square

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Isfahan, Iran

Province
Isfehan

Postal code
319-81745

Phone
+98 31 3668 8138

Email
Research@mui.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Esfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Zahra Boroumandfar

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Reproductive Health

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School of Nursing and midwifery , Isfahan University of Medical Sciences.Hezar Jareyb St. Azadi Square,

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Person responsible for scientific inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Zahra Boroumanfar
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Health
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Person responsible for updating data

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Leila Abab
Position
student
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
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Isfahan, Iran
Province
Isfehan
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8174673461
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ll_abab@yahoo.com

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
No - There is not a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
The results of the clinical study will be published as article
When the data will become available and for how long
Immediately after publishing the results
To whom data/document is available
All researchers
Under which criteria data/document could be used
Scientific using with citation to article
From where data/document is obtainable
Email:boroumandfar@nm.mui.ac.ir
What processes are involved for a request to access data/document
Maximum one week after the communication by email
Comments