Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effect of education based on Health Belief Model on protective behaviors against Human Papillomavirus in vulnerable women

Protocol summary

Summary

The aim of this study is to assess the effect of Health Belief model based education on protective behaviors against Human Papillomavirus in vulnerable women. This study design is a cluster randomized clinical trial without blinding and randomization divides centers two groups, control and intervention and takes place in two phases. The first phase of it is study tool construction and the second is educational intervention. Since the study primary outcome variables which is health-belief model structures, is supposed to be applied for the first time, researchers need to implement the first phase of the study to build the assessment tools, then proceed to the study intervention. The study population is substance abuser women, referring to the drop-in centers, harm reduction centers and camps who are over 18 years old, sexually active, able to read and write. The study Intervention is Health Belief model based education including providing information about human papillomavirus for vulnerable women, based on the pattern structures. The primary outcomes of this study are perceived susceptibility, perceived severity, perceived benefits, perceived barriers, cues to action and self efficacy. The effect of intervention on samples will be measured immediately, four weeks and twelve weeks later by researcher made tools.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016121131346N1**
Registration date: **2017-03-01, 1395/12/11**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-03-01, 1395/12/11

Registrant information

Name
Maryam Shokoohi
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Recruitment status

Recruitment complete

Funding source

Research Deputy School of Nursing and Midwifery of Iran University of Medical Sciences

Expected recruitment start date

2017-02-19, 1395/12/01

Expected recruitment end date

2017-05-22, 1396/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of education based on Health Belief Model on protective behaviors against Human Papillomavirus in vulnerable women

Public title

The effect of education on protective behaviors of Human Papillomavirus

Purpose

Prevention

Inclusion/Exclusion criteria
Inclusion criteria: 1.Minimum age of 18 2.Substance abuse disorder 3.Sexually active 4. Absence of warts on the genitals and anus in women based on self-reported or register file 5.Be able to read and write Exclusion criteria: 1. Being absent more than one session in a training class
Age
No age limit
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
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
Iran University of Medical Sciences
Street address
Tehran, Shahid Hemmat Highway, next Milad tower, Iran University of Medical Sciences
City
Tehran
Postal code
1449614535
Approval date
2016-08-08, 1395/05/18
Ethics committee reference number
IR.IUMS.REC.1395.29385

Health conditions studied

1

Description of health condition studied
Humanpapillomavirus
ICD-10 code
B07
ICD-10 code description
Viral infections characterized by skin and mucous membrane lesions

Primary outcomes

1

Description
Perceived Susceptibility
Timepoint
Before the intervention, 4 weeks and 12 weeks after the intervention
Method of measurement
Researcher made tools with the 5 items Likert scale

2

Description
Perceived Severity
Timepoint
Before the intervention, 4 weeks and 12 weeks after the intervention
Method of measurement
Researcher made tools with the 5 items Likert scale

3

Description
Perceived Benefits
Timepoint
Before the intervention, 4 weeks and 12 weeks after the intervention
Method of measurement
Researcher made tools with the 5 items Likert scale

4

Description
Perceived Barriers
Timepoint
Before the intervention, 4 weeks and 12 weeks after the intervention
Method of measurement
Researcher made tools with the 5 items Likert scale

5

Description
Cues to Action
Timepoint
Before the intervention, 4 weeks and 12 weeks after the intervention
Method of measurement
Researcher made tools with the 5 items Likert scale

6

Description
Self Efficacy
Timepoint
Before the intervention, 4 weeks and 12 weeks after the intervention
Method of measurement

Researcher made tools with the 5 items Likert scale

7

Description
Protective Behavior of Human Papillomavirus
Timepoint
Before the intervention, 4 weeks and 12 weeks after the intervention
Method of measurement
Researcher made tools with the 5 item Likert scale

Secondary outcomes

1

Description
Number of Safe Sex
Timepoint
Before, 4 weeks ,12 weeks after intervention
Method of measurement
Questionary

2

Description
Number of partner
Timepoint
Before, 4 weeks ,12 weeks After intervention
Method of measurement
Questionary

3

Description
Number of sexual relationship types
Timepoint
Before, 4 weeks ,12 weeks After intervention
Method of measurement
Questionary

Intervention groups

1

Description
Intervention Group: In this group, intervention is protective behavior of papillomavirus education base on Health Belief model structures. The number of meetings and training content will be determined after needs assessment and includes condom use in sex with a partner who has high risk behaviors, Having sex within marriage, Not having oral and anal sex and not smoking and recognition virus signs in partner.
Category
Prevention

2

Description
Control group: The control group only receive Routine training of centers which they will be referred.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Mikhak center
Full name of responsible person
Shokoohi Maryam
Street address
Tehran, Valiasr st, Rashidyasemi, School of Nursing & Midwifery Iran University of Medical Sciences
City
Tehran

2

Recruitment center
Name of recruitment center
Kaj center
Full name of responsible person
Shokoohi Maryam
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3

Recruitment center
Name of recruitment center
mehr protetive center
Full name of responsible person
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Street address
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4

Recruitment center
Name of recruitment center
shahid emami center
Full name of responsible person
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5

Recruitment center
Name of recruitment center
mojeze aria pak center
Full name of responsible person

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Street address

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6

Recruitment center

Name of recruitment center

lavizan residency

Full name of responsible person

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Recruitment center

Name of recruitment center

payamavaran hamyari center

Full name of responsible person

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Recruitment center

Name of recruitment center

navid hamrazi Iranian center

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Recruitment center

Name of recruitment center

khane mian rah center

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Recruitment center

Name of recruitment center

simaye sabze rahaei center

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Deputy school of Nursing and Midwifery of Iran University of Medical Sciences

Full name of responsible person

DR Rafiei Forough, DR Mousavi Alijavad

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Tehran, Shahid Hemmat Highway, Iran University of Medical Sciences, 1449614535

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Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research Deputy school of Nursing and Midwifery of Iran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

School of Nursing & Midwifery Iran University ofMedical Sciences

Full name of responsible person

Shokoohi Maryam

Position

Master of Midwifery student

Other areas of specialty/work

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Person responsible for updating data

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty