

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jun 2026

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

Protocol summary

2017-03-01, 1395/12/11

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

Registrant information

Name

Maryam Shokoohi

Name of organization / entity

School nursing and midwifery Iran university of medical science

Country

Iran (Islamic Republic of)

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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, Rashidiasemi, School of Nursing & Midwifery Iran University of Medical Sciences

City

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2

Recruitment center

Name of recruitment center

Kaj center

Full name of responsible person

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3

Recruitment center

Name of recruitment center

mehr protetive center

Full name of responsible person

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4

Recruitment center

Name of recruitment center

shahid emami center

Full name of responsible person

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Street address

Tehran, Valiasr st, Rashidiasemi, School of Nursing & Midwifery Iran University of Medical Sciences

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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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7

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

Full name of responsible person

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Recruitment center

Name of recruitment center

khane mian rah center

Full name of responsible person

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Recruitment center

Name of recruitment center

simaye sabze rahaei center

Full name of responsible person

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Street address

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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

Street address

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 of Medical Sciences

Full name of responsible person

Shokoohi Maryam

Position

Master of Midwifery student

Other areas of specialty/work

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Full name of responsible person

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Other areas of specialty/work**Street address**

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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