Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of educational program based on the theory of reasoned action on sexual risk behaviors in patients with human papillomavirus

Protocol summary

Summary

The purpose of doing this study is to determine the effect of the education program based on the theory of logical action on the high-risk behaviors of people with human papillomavirus virus. This research is a randomized controlled trial (RCT) study, in which the impact of implementing a program based on rational action theory on the amount of high-risk behavior of patients with human papillomavirus virus has examined. The study is a double-blind intervention for the triables group and statistical analyzes. The community of research in this study was patients with human papilloma virus referred to the clinic of sexually transmitted diseases of Razi Hospital affiliated to Tehran University of Medical Sciences. In this study, The research sample consisted of 100 patients with hpv referred to the Clinic of Sexually Transmitted Diseases in Razi Hospital who had the conditions for entering the research during the study and who were randomly selected. The most important criterion for entering the study was the diagnosis of human viral papillomavirus by medicine and the age of 18 years. After selecting the intervention and control group and doing the pre-test from both groups, the control group went through their usual treatment, and the intervention group received the designed education based on the theory of logical action and based on the results of the analysis of the logical action questionnaire as a in person, Individual and face-to-face training sessions for 60 minutes (teaching female patients referred done by a female nurse supervised with a researcher and expert physician) with a built educational tool (booklet)and Using this tool was taught So that they can review the trained subjects during the two months After In-person training until Re-attending the clinic to continue the treatment process and re-examine two months later, Phone tracking was conducted every two weeks,focused on responding to possible patient questions and with emphasizing the main points of the training to be aware of their conditions and re-examine education based on theories. Two months after training, high risk sexual behavior in two intervention and control groups was investigated by using questionnaire again . At the end of the study, 100 samples were examined fully.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016121831453N1**
Registration date: **2017-10-08, 1396/07/16**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-10-08, 1396/07/16

Registrant information

Name

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Name of organization / entity

Tehran University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, University of Medical Sciences of Tehran University of Medical Science

Expected recruitment start date

2017-02-03, 1395/11/15

Expected recruitment end date

2018-02-04, 1396/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of educational program based on the theory of reasoned action on sexual risk behaviors in patients with human papillomavirus

Public title

Effect of educational program based on the theory of reasoned action on sexual risk behaviors in patients with human papillomavirus

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria: Patients with human papillomavirus is based psychiatrists. Minimum age of 18 years. Be literate. Patients have mental and physical disabilities. Willing to participate and cooperate in research. Exclusion criteria from the study: At the same time receive specific training with research from other sources in connection with the behavior Prkhtrjnsy Not wanting to continue to participate in the study for any reason. Acute physical and psychological complications during the treatment process Failure to attend training sessions Lack of complete follow up period

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Ethics Committee of Tehran University of Medical Sciences and Health Services

Street address

No. 21, Tehran University of Medical Sciences, Ghods St. Corner, Keshavarz Blvd,Tehran

City

Tehran

Postal code

Approval date

2017-04-18, 1396/01/29

Ethics committee reference number

IR.TUMS.FNM.REC.1396.2095

Health conditions studied

1

Description of health condition studied

Human Papilloma Virus

ICD-10 code

A63.0

ICD-10 code description

Anogenital (venereal) warts

Primary outcomes

1

Description

Sexual Risk Behaviors

Timepoint

Before And Two Months After The Intervention.

Method of measurement

Sexual Risk Scale(SRS) With Likert Scale (I Agree, I Think, Disagree)

Secondary outcomes

empty

Intervention groups

1

Description

"The intervention group": designed the training based on the theory of logical action and based on the results of the analysis of the logical action questionnaire as a face-to-face and face-to-face training session for 60 minutes (education of female patients referred by a female nurse supervised by the researcher and A specialist doctor) and a training tool (booklet), and they were trained to use this tool to review the trained subjects during these two months. Following on-the-job training and re-attending the clinic to continue the treatment process and re-examine it two months later, follow-up was conducted on a two-weekly basis focusing on responding to potential patient questions and emphasizing the main points of education, A review of education based on the theory of consciousness. Two months after training, again, high risk sexual behaviors were investigated in

two intervention groups using a questionnaire.

Category

Prevention

2

Description

"Control group": After selecting the intervention and control group and doing the pre-test from both groups, the control group underwent their normal medical treatment, two months after the initial referral, again the high risk sexual behavior in the control group was investigated using the questionnaire.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Skin Hospital

Full name of responsible person

Dr Tahere Soori

Street address

NO11, Islamic Unity Street, Area 12,Tehran, Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor For Research, University of Medical Sciences of Tehran University of Medical Science

Full name of responsible person

Dr. Ziba Taghizadeh

Street address

No. 21, Tehran University of Medical Sciences, Ghods St. Corner, Keshavarz Blvd,Tehran

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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

Vice Chancellor For Research, University of Medical Sciences of Tehran University of Medical Science

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

Tehran University of Medical Sciences and Health Services

Full name of responsible person

DR Hooman Shahsavari

Position

Faculty - Associate

Other areas of specialty/work

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Other areas of specialty/work

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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