

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Effect of education, based on the Theory of Planned Behavior on preventive behaviors of Sexually transmitted disease in women

Protocol summary

Study aim

The purpose of the study is to determination effect of education, based on the Theory of Planned Behavior on preventive behaviors of Sexually transmitted disease in women

Design

The research sample is determined after the pilot study. The random allocation between the two intervention and control groups is done by using closed envelopes and selecting them.

Settings and conduct

This study is a clinical trial conducted on two groups of intervention and control. Study population are women referred to the Ziaeian hospital affiliated to Tehran University of Medical Sciences. First, the researcher-made questionnaire are completed by women who have the entry criteria. The training program is delivered in four sessions. For the control group, no educational intervention is conducted and they only receive the training booklet two months after the intervention. Immediately and two months after the intervention, the questionnaires is completed by the two groups of intervention and control.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: all women referred to the Ziaeian Hospital. Exclusion Criteria: Refusing (No consent) to participate in the study. Having a certain physical or mental illness, being Illiterate, or being single.

Intervention groups

Intervention group receive the training program. No educational intervention is provided for the control group.

Main outcome variables

Knowledge; Attitude; Abstract Norms; Perceived behavioral control; behavioral intention; prevention behaviors from sexually transmitted disease

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110425006284N12**

Registration date: **2018-12-01, 1397/09/10**

Registration timing: **retrospective**

Last update: **2018-12-01, 1397/09/10**

Update count: **0**

Registration date

2018-12-01, 1397/09/10

Registrant information

Name

Maryam Modarres

Name of organization / entity

Tehran university of Medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6656 8142

Email address

modarres@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-22, 1396/10/01

Expected recruitment end date

2018-06-22, 1397/04/01

Actual recruitment start date

2018-01-21, 1396/11/01

Actual recruitment end date

2018-06-22, 1397/04/01

Trial completion date

empty

Scientific title

Effect of education, based on the Theory of Planned Behavior on preventive behaviors of Sexually transmitted disease in women

Public title

Effect of education, based on the Theory of Planned Behavior on preventive behaviors of Sexually transmitted disease in women

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

women referred to the Ziaieian hospital

Exclusion criteria:

No consent to participate in the study have a certain physical or mental illness Illiterate Single

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 120

Randomization (investigator's opinion)

Randomized

Randomization description

The random allocation between two groups (Intervention and control) is done by using closed envelopes that are selected by the participants, which determine which group of intervention or control the participants are allocated to.

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

کمیته اخلاق دانشگاه علوم پزشکی تهران

Street address

Nosrat Ave, Tohid Sq, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1419733171

Approval date

2017-12-11, 1396/09/20

Ethics committee reference number

IR.TUMS.FNM.REC.1396.4228

Health conditions studied

1

Description of health condition studied

Sexually transmitted disease

ICD-10 code

A63.8

ICD-10 code description

Other specified predominantly sexually transmitted diseases

Primary outcomes

1

Description

preventive Behaviors from venereal Diseases

Timepoint

Before the intervention begins, Immediately and two months after intervention

Method of measurement

Use self - made questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group: First, the researcher-made questionnaire is completed by all subjects. Then, the training program for the intervention group is held in four sessions lasting 75 minutes. The planned behavior theory is used for training. Immediately and two months after the intervention the questionnaires are completed by the subjects again.

Category

Behavior

2

Description

Control group: No training intervention is made for the control group. They receive educational booklet two months after the intervention. Immediately and two months after the intervention, questionnaires are completed by the samples in control group.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Ziaieian hospital

Full name of responsible person

Maryam Modares

Street address

Falah Sq, Tehran,Iran

City

Tehran

Province

Tehran

Postal code

1419733171

Phone

+98 21 6692 2700

Email

ma_modars@yahoo.com

Web page address

<https://mg.mail.yahoo.com/neo/launch>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohamad Ali Sahraeean

Street address

Ghods Ave, Enghelab Sq, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1419733171

Phone

+98 21 8163 3686

Email

shamsef931@mums.ac.i

Web page address

<https://mail.mums.ac.ir/owa/#path=/mail>

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

Fatemeh Shamsolahi

Position

Senior obstetrics undergraduate

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

Nosrat Ave, Tohid Sq, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1419733171

Phone

+98 21 6692 2700

Email

shamsef931@mums.ac.ir

Web page address

<https://mail.mums.ac.ir/owa/#path=/mail>

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Maryam Modares

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Education

Street address

Ave Nosrat, Tohid Sq, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1419733171

Phone

+98 21 6692 2700

Email

ma_modars@yahoo.com

Web page address

<https://mg.mail.yahoo.com/neo/launch>

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Fatemeh Shamsolah

Position

Senior obstetrics undergraduate

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shamsef931@mums.ac.ir

Web page address

<https://mail.mums.ac.ir/owa/#path=/mail>

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not 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