

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### Design and assessment of a preventive behavioral training program for Sexual Transmitted Infections among women

#### Protocol summary

##### Study aim

The effect of an educational intervention on promoting preventive behaviors of sexual transmitted infections in women 18 to 48 years in Tehran.

##### Design

A clinical trial with control and interventions group.

##### Settings and conduct

According to the inclusion criteria, the target group is women aged 18 to 48 years in Tehran which will be announced through an internet call on several common social networks for participation in the study.

##### Participants/Inclusion and exclusion criteria

Living in Tehran, having the desire and ability to continue research, without any chronic debilitating diseases such as (cancer, MS, acute heart disease), age 18 to 48 years, no mental disorders, drug dependence and addiction, having a minimum Literacy and the ability to answer questions and discuss in classrooms exclusion criteria: Mental disorders, drug dependence and addiction

##### Intervention groups

.In the intervention group, the educational content will be presented based on the learning objectives pre-formulated in the second phase of the study in the form of mini lecture, group discussions, film screening, and infographic display. The number of training sessions will vary depending on the performance constraints, audience participation, number of dependent variables, and specific objectives in the third phase of the study, but at least about 4 2-hour training sessions over a period of one month are expected. In the beginning, no educational intervention will be done, but at the end of the study, a booklet containing information about sexually transmitted diseases will be given as a gift to the participants.

##### Main outcome variables

Promoting behaviors to prevent sexually transmitted infections, including the The intention for safe sex (using condom) The intention for doing a screening test (pap-

test, genital examination,ect)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200602047638N1**

Registration date: **2021-05-22, 1400/03/01**

Registration timing: **prospective**

Last update: **2021-05-22, 1400/03/01**

Update count: **0**

##### Registration date

2021-05-22, 1400/03/01

##### Registrant information

##### Name

Afsaneh Karami Joyani

##### Name of organization / entity

The University of Tarbiat Modares

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8822 0937

##### Email address

k.afsaneh@modares.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-08-23, 1400/06/01

##### Expected recruitment end date

2022-02-20, 1400/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

## Trial completion date

empty

## Scientific title

Design and assessment of a preventive behavioral training program for Sexual Transmitted Infections among women

## Public title

Educational program promoting preventive behaviors of sexually transmitted infections

## Purpose

Prevention

## Inclusion/Exclusion criteria

### Inclusion criteria:

Living in Tehran without any chronic debilitating diseases such as (cancer, MS, acute heart disease) age 18 to 48 years having a minimum literacy and ability to answer questions and discuss in training classes

### Exclusion criteria:

Mental disorders drug dependence and addiction

## Age

From **18 years** old to **48 years** old

## Gender

Female

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **150**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Random permutation block design of two treatments with quadruple blocks: Thus, the letter A is considered for the intervention group and the letter B is considered for the control group. Then we write all the permutation combinations of the letters A, A, B and B, which are 6 different combinations, on 6 cards as follows: BBAA, BABA, BAAB, ABAB, ABBA, AABB, We then randomly select a digit from digits 1 to 6 (by someone other than the researcher). For example, if the number 2 is selected, it means that the first person in the intervention group, the next two people in the control group and the fourth person in the intervention group, and we continue this operation until the sample size reaches the quorum

## 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 Tarbiat Modares University

##### Street address

Tehran ,Jalal Ale Ahmad , Nasr Bridge , Tarbiat Modares University

##### City

Tehran

##### Province

Tehran

##### Postal code

1411713116

#### Approval date

2020-06-22, 1399/04/02

#### Ethics committee reference number

IR.MODARES.REC.1399.039

## Health conditions studied

### 1

#### Description of health condition studied

sexually transmitted infections (STIs)

#### ICD-10 code

A50.0-A51.

#### ICD-10 code description

Early congenital syphilis, symptomatic-Early syphilis

## Primary outcomes

### 1

#### Description

Preventive behaviors of sexually transmitted diseases

#### Timepoint

it will be performed in three time periods immediately, 1 month and three months after the end of the educational intervention.

#### Method of measurement

Quarterly Scale Questionnaire for Measuring Preventive Behaviors from Sexually Transmitted Infections

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

"Intervention group": After receiving the code of ethics of the Ethics Committee of the Research Department at the Faculty of Medical Sciences, Tarbiat Modarres University and approved the proposal initially achieved both by phone and by sending invitations through cyberspace, all interested women eligible to participate in the Educational program are invited will do. In the

intervention group, the educational content will be presented based on the learning objectives pre-formulated in the second phase of the study in the form of mini lecture, group discussions, film screening, and infographic display. The place of training sessions in the classes of the city will be under the supervision of the Women Empowerment Headquarters of Tehran Municipality. Evaluation of the effect of post-test training intervention will be done in three time periods immediately, 1 month and three months after the end of the training intervention. Assessment tools at all stages of the same before and after the intervention.

**Category**

Behavior

**2****Description**

Control group: In the control group, no educational intervention is performed, but at the end of the study, a booklet containing information about sexually transmitted diseases will be given as a gift to the participants.

**Category**

Behavior

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Faculty of Medical Sciences, Tarbiat Modares University

**Full name of responsible person**

Fatemeh Zarei

**Street address**

Tehran ,Jalal Ale Ahmad ,Nasr, Tarbiat Modares University

**City**

Tehran

**Province**

Tehran

**Postal code**

1411713116

**Phone**

+98 21 8288 4546

**Email**

f.zarei@modares.ac.ir

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Faculty of Medical Sciences, Tarbiat Modares University

**Full name of responsible person**

Yaghoob Fathollahi

**Street address**

Tarbiat Modarres University,Jalal Al-Ahmad ,Bridge

Nasr

**City**

Tehran

**Province**

Tehran

**Postal code**

141173116

**Phone**

+98 21 8288 2009

**Email**

fatolahi@modares.ac.ir

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

Yes

**Title of funding source**

Faculty of Medical Sciences, Tarbiat Modares University

**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**

Tarbiat Modares University

**Full name of responsible person**

Shamsuddin Niknami

**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Health Promotion

**Street address**

Tarbiat Modarres University,Jalal Al-Ahmad ,Bridge Nasr

**City**

Tehran

**Province**

Tehran

**Postal code**

141173116

**Phone**

+98 21 8288 3549

**Email**

niknamis@modares.ac.ir

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tarbiat Modares University  
**Full name of responsible person**  
Fatemeh Zarei

**Position**  
Assistant Professor

**Latest degree**  
Ph.D.

**Other areas of specialty/work**  
Health Promotion

**Street address**  
Tehran ,Jalal Ale Ahmad , Nasr Bridge , Tarbiat  
Modares University City Tehran

**City**  
Tehran

**Province**  
Tehran

**Postal code**  
1411713116

**Phone**  
+98 21 8288 4546

**Email**  
f.zarei@modares.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**  
The University of Tarbiat Modares University

**Full name of responsible person**  
Afsaneh Karami Joyani

**Position**  
PhD student in health education and health promotion

**Latest degree**  
Master

**Other areas of specialty/work**  
Health Promotion

**Street address**  
Tehran ,Jalal Ale Ahmad , Nasr Bridge , Tarbiat  
Modares University

**City**  
Tehran

**Province**  
Tehran

**Postal code**  
1411718541

**Phone**  
+98 21 8822 0937

**Email**  
K.Afsaneh@modares.ac.ir

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**  
Yes - There is a plan to make this available

**Study Protocol**  
Yes - There is a plan to make this available

**Statistical Analysis Plan**  
Yes - There is a plan to make this available

**Informed Consent Form**  
Undecided - It is not yet known if there will be a plan to  
make this available

**Clinical Study Report**  
Not applicable

**Analytic Code**  
Not applicable

**Data Dictionary**  
Not applicable

**Title and more details about the data/document**  
In this study, data can be shared after people are  
unrecognizable

**When the data will become available and for how  
long**  
Access to study documentation will begin 6 months after  
the results are published

**To whom data/document is available**  
Study documentation will be available to researchers in  
academic and scientific institutions

**Under which criteria data/document could be used**  
The use of data is allowed with the permission of the  
ethics committee of Tarbiat Modares University of Tehran

**From where data/document is obtainable**  
1- Dr. Fatemeh Zarei, Assistant Professor of Health  
Education and health promotion, Tarbiat Modares  
University, f.zarei@modares.ac.ir 2- Afsaneh Karami  
Joyani, PhD student in health education and health  
promotion K.Afsaneh@modares.ac.ir

**What processes are involved for a request to access  
data/document**  
A week after receiving the request via email the  
corresponding researcher. (f.zarei@modares.ac.ir)

**Comments**