Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Nov 2026

Design and assessment of a preventive behavioral training program for Sexual Transmited 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

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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 Transmited 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

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Tehran ,Jalal Ale Ahmad ,Nasr, Tarbiat Modares University

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Faculty of Medical Sciences, Tarbiat Modares University

Full name of responsible person
Yaghoub Fathollahi

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Tarbiat Modarres University,Jalal Al-Ahmad ,Bridge Nasr

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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

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PhD student in health education and health promotion

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Master

Other areas of specialty/work
Health Promotion

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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