

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

The effect of comprehensive sex education on promoting safe sexual behavior of HIV-positive youth

Protocol summary

Study aim

The effect of comprehensive sex education on safe sexual behavior of HIV positive young people aged 15 to 24 years

Design

Quantitative sampling of the study is done as available and continuous samples. In this way, all eligible individuals enter the study consciously after providing a full explanation of the purpose of the study and obtaining written consent. Then people are divided into two groups of experimental and intervention by simple random method. According to previous studies, with a significance level of 0.05 and a strength of 80% of the study, 27 people were selected in each group.

Settings and conduct

The research environment of Behavioral Diseases Counseling Centers is Tehran University of Medical Sciences. Individuals enter the two groups of intervention and control randomly.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. HIV-positive young people aged 15-24 2- Literate reading and writing Criteria for not entering: Lack of awareness of the status of your disease

Intervention groups

In the intervention and control group, before the training, first the questionnaire of demographic information and safe sexual behavior is completed by the samples and then in the intervention group, comprehensive sexual education is done in groups of 4-6 people in 5 sessions. In the control group, routine HIV care is performed. A questionnaire of safe sexual behavior in both groups is completed two months after re-intervention.

Main outcome variables

Safe sexual behavior

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120414009463N65**

Registration date: **2021-12-15, 1400/09/24**

Registration timing: **registered_while_recruiting**

Last update: **2021-12-15, 1400/09/24**

Update count: **0**

Registration date

2021-12-15, 1400/09/24

Registrant information

Name

Zahra Behboodi Moghadam

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6692 7171

Email address

behboodi@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-06, 1400/09/15

Expected recruitment end date

2022-03-06, 1400/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of comprehensive sex education on promoting safe sexual behavior of HIV-positive youth

Public title

effect of comprehensive sex education on promoting safe sexual behavior

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

HIV-positive young people aged 15-24 who were aware of their disease. Literate reading and writing

Exclusion criteria:

Lack of awareness of the status of the disease

Age

From **15 years** old to **24 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **27**

Randomization (investigator's opinion)

Randomized

Randomization description

By throwing the dice, people are divided into control and intervention groups. In this case, in case of even numbers (2, 4 or 6), people would enter the intervention group and in case of odd numbers (1, 3 or 5), people would enter the control group.

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 Tehran University of Medical Sciences

Street address

The 6th floor of The central organization of Tehran University of Medical Sciences, at the corner of Qods Street , Keshavarz street.

City

Tehran

Province

Tehran

Postal code

1419733171

Approval date

2020-02-12, 1398/11/23

Ethics committee reference number

IR.TUMS.FNM.REC.1398.176

Health conditions studied**1****Description of health condition studied**

HIV/AIDS

ICD-10 code

B20.3

ICD-10 code description

HIV disease resulting in other viral infections

Primary outcomes**1****Description**

safe sexual behavior

Timepoint

Before the intervention and two months after intervention

Method of measurement

Use of safe sexual behavior questionnaire (SSBQ)

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: All HIV-positive 15- to 24-year-olds eligible to enter the study entered the study consciously after receiving a full explanation of the purpose of the study and obtaining written consent. Training sessions will be held for two groups of 15-19 years old and 20-24 years old. This classification was taken from the protocol of "Adolescent and Youth Health and Counseling Club" of the Ministry of Health of the Islamic Republic of Iran. Meetings are in groups of 4-6 people. The first introductory session was held between the instructor and the participants, stating the goals, reproductive and sexual health issues and the Charter of Citizenship Rights with emphasis on reproductive and sexual rights. In the second session, the anatomy and hormonal and physical changes of puberty were taught, and at the end, people explain their experiences during puberty. In the third session, sexually transmitted diseases and methods of preventing unwanted pregnancies were taught. The fourth and fifth sessions will discuss safe sex, high-risk sexual behaviors, and accountability. Sessions are about 120 minutes. Before and two months after the last intervention session, the Safe Sexual Behavior Questionnaire is examined in both groups.

Category

Behavior

2

Description

Control group: The routine procedures of the Behavioral Diseases Counseling Center will be performed

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Voluntary Counselling and Testing (VCT) center of Imam Khomeini hospital

Full name of responsible person

Dr. Minoo Mohraz

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Iranian Research Center for HIV/AIDS, Imam Hospital.keshavarz Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Akbar Fotouhi

Street address

No23, Valiasr Avenue, Dameshgh Street, Vice chancellor for research, Tehran University of Medical Sciences

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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

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

Leila Asadi

Position

student

Latest degree

Master

Other areas of specialty/work

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Phone**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

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

Study Protocol

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

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

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

Analytic Code

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

Data Dictionary

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