Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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)

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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
Street address
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
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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
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Person responsible for updating data

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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