

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

Effects of education based on planned behavior Theory on quality of life in HIV positive women

Protocol summary

Study aim

Educational / Counseling

Design

This study is a randomized controlled trial. The study population included 80 HIV positive women with access to the study, who are referred to the AIDS Research Center and the Behavioral Advice Center located in Imam Khomeini Hospital in order to receive health care. Without blinding, sampling in each center is done randomly. Intervention in intervention group within 1 month and 4 sessions, weekly one session for 120-190 minutes will be held as group training. Subsequently, a summary questionnaire on the quality of life of HIV positive patients will be completed eight and twelve weeks after the intervention for both intervention and comparison groups.

Settings and conduct

AIDS Research Center and Behavioral Disease Counseling Center located in Imam Khomeini Hospital where participants are randomly selected.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women who are infected with HIV infection, Iranian nationality, age 15 to 45 years old, knowing how to read and write
Exit criteria: Absence of participant more than two sessions in training classes, getting pregnant during the study.

Intervention groups

En Intervention group: 40 HIV positive women (15-45 years old) who are referred to the AIDS Research Center and Counseling Center for Behavioral Diseases at Imam Khomeini with Written consent, and tendency to participate in the study and receive educational interventions based on the theory of planned behavior.
Control group: 40 HIV positive women (15-45 years old) who are referred to the same center but do not receive any educational intervention.

Main outcome variables

Tutorial based on the TPB model, Quality of Life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120414009463N58**

Registration date: **2018-10-20, 1397/07/28**

Registration timing: **retrospective**

Last update: **2018-10-20, 1397/07/28**

Update count: **0**

Registration date

2018-10-20, 1397/07/28

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

2018-01-18, 1396/10/28

Expected recruitment end date

2018-05-18, 1397/02/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of education based on planned behavior Theory on quality of life in HIV positive women

Public title

Effects of education based on planned behavior Theory on quality of life in HIV positive women

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Women who are infected with HIV infection who had been diagnosed in at least 3 months person who doesn't have any experience of attending in tutorial courses for HIV or HIV counseling sessions Iranian nationality age 15 to 45 years old not being pregnant knowing how to read and write not being addicted on drugs not being addicted on alcohol not suffering from known chronic diseases, disorders and chronic psychiatric problems and malignant diseases (self-declaration).

Exclusion criteria:

Absence of participant more than two sessions in training classes getting pregnant during the study.

Age

From **15 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

samples will be selected by simple random sampling using random numbers table will be assigned to two groups of intervention and control, which will be considered after determining how to read the table numbers. odd numbers for the control group and the even numbers for the intervention 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**

The Ethics Committee of the Faculty of Nursing and

Midwifery, Tehran University of Medical Sciences

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PO Box 6459, Dr Mirkhani St. (Eastern Nusrat), Tohid Square

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1419733171

Approval date

2017-12-16, 1396/09/25

Ethics committee reference number

IR.TUMS.FNM.REC.1396.4262

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

HIV

ICD-10 code

B20.3

ICD-10 code description

HIV disease resulting in other viral infections

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

Quality of life

Timepoint

Before the intervention; eight weeks and twelve weeks after intervention

Method of measurement

Using standard WHOQOL-Brief questionnaire

Secondary outcomes

empty

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

Intervention group: Educational interventions based on the theory of planned behavior in order to improve the quality of life in 40 HIV positive women in the intervention group in 4 sessions, one week in a session for 120-190 minutes, and the quality of life in this group before The intervention will be measured eight to twelve weeks after the intervention.

Category

Other

2**Description**

Control group: In the control group, intervention is not performed, and only after completing the study for

observance of the ethics of all the teaching aids will be provided to this group.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Iranian Research Center for HIV/AIDS and Voluntary Counselling and Testing (VCT) centre of Imam Khom

Full name of responsible person

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

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Full name of responsible person

Dr. Mohammad Ali Sahraeian

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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

Dr. Zahra Behboodi Moghadam

Position

Ph.D in reproductive health

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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Person responsible for updating data

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Full name of responsible person

Fatemeh Najafi

Position

Master of Midwifery Student Reproductive Health

Latest degree

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Province

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