

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effectiveness of peer education on high-risk behavior, risk taking and participation in HIV screening test in transgenders

Protocol summary

Study aim

Determination of the effect of peer education on HIV related high risk behaviors, risk taking and HIV screening test in male to female transgenders

Design

In this study 80 male to female transgenders who have inclusion criteria such as having a smartphone

Settings and conduct

The app will install on smartphones in school of behavioral sciences, Iran University of Medical Sciences.
The data will collect by a smart phone app.

Participants/Inclusion and exclusion criteria

Male to Female transgenders who have smartphone and internet and HIV negative

Intervention groups

The intervention group will receive information about high risk behaviors, prevention skills and screening from their peers. The control group would not receive such information.

Main outcome variables

HIV related high risk behaviors Risk taking behaviors
Screening test taking

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100911004728N2**
Registration date: **2018-01-16, 1396/10/26**
Registration timing: **prospective**

Last update: **2018-01-16, 1396/10/26**

Update count: **0**

Registration date

2018-01-16, 1396/10/26

Registrant information

Name

Hadi Ranjbar

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6650 6862

Email address

ranjbar.h@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-20, 1396/12/01

Expected recruitment end date

2018-09-22, 1397/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of peer education on high-risk behavior, risk taking and participation in HIV screening test in transgenders

Public title

Effect of peer education on HIV related Behaviors

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Being a transgender Having Smart phone Age above 18
Male

Exclusion criteria:

HIV positive

Age

From **18 years** old to **65 years** old

Gender
Male

Phase
N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Peer educators are randomly allocate into one of two groups by throwing coins. Elected transgender subjects will be grouped into two groups by random numbers table.

Blinding (investigator's opinion)
Single blinded

Blinding description
The data will be collected by a mobile app and the data analyzer do not have information about allocation process

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Iran University of Medical Sciences

Street address
Tehran Province, Tehran, Hemmat Highway

City
Tehran

Province
Tehran

Postal code
۱۳۴۹۶۱۴۵۳۵

Approval date
2017-09-18, 1396/06/27

Ethics committee reference number
IR.IUMS.REC 1396.96-01-121-29335

Health conditions studied

1

Description of health condition studied
HIV related high risk behaviors and test screening

ICD-10 code

Z11.4

ICD-10 code description

Encounter for screening for human immunodeficiency virus [HIV]

Primary outcomes

1

Description
HIV related risk behaviors

Timepoint
3 month after intervention

Method of measurement
Mobile App Questionnaire

2

Description
HIV Screening Test

Timepoint
3 month after intervention

Method of measurement
Mobile App Questionnaire

3

Description
HIV related behavioral risk taking

Timepoint
3 month after intervention

Method of measurement
Mobile App Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Peer education of information about HIV related high risk behaviors and screening test

Category
Behavior

2

Description
Control group: Only Follow up by mobile App

Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center

School of Behavioral Sciences & mental health - Iran
Institute of Psychiatry

Full name of responsible person

Hadi Ranjbar

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No 1, Shahid Mansouri Street, Niyayesh Street,
Satarkhan Avenue,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Seyed Kazem Malakouti

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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Hadi Ranjbar

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data

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Fax**Email**

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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

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

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

All of the individual participant data collected during the trial, after deidentification

When the data will become available and for how long

Immediately following publication. No end date.

To whom data/document is available

Anyone who wishes to access the data.

Under which criteria data/document could be used

To gain access, data requestors will need to sign a data access agreement. The data is available for any purpose.

From where data/document is obtainable

All applications should be sent to
hadiranjbar@yahoo.com

What processes are involved for a request to access data/document

All requests will be answered within a maximum of one month by email.

Comments