

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 2026

### Comparison of the effect of role playing method with lecture on knowledge and attitude toward HIV/AIDS in general population (18-49 years old) of Khorramabad countryside

#### Protocol summary

##### Study aim

Assessing the effect of Role Playing and lecture methods on HIV-related knowledge and attitude among 18-49 years olds marginal population in Khorramabad

##### Design

270 people. Falkaldin region: role-playing method; stack region: the lecture method; Massor area: control group. The clinical trial is phase 3

##### Settings and conduct

270 people aged 18-49 years from the general population of the suburbs in Rasht and Falkaddin areas of Khorramabad and Masur residents are considered as the control population, using random sampling. Class and selection criteria will be selected and included in the study. Three suburban areas will be allocated to intervention and control groups by cluster randomization method. In the Falkadine area, the role-playing method is considered to be the lecture method in the Poshteh area. A questionnaire for all individuals will be completed prior to the intervention. Interventions are grouped and the training program will be held once a week, once a week. In order to better study the groups, the groups will be broken down into 20-person subgroups, with 4 one-hour training sessions in each group. After two weeks, the questionnaire will be completed again for all individuals in all three groups. Finally, the information collected before and after the intervention will be analyzed.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: • 18-49 years old • Iranian citizenship • A resident of Falkodin, Ridge, and Masur areas of Khorramabad • literate • Mental ability to understand training and answer questions • informed consent to participate  
Exclusion criteria: • unwillingness to participate in the study • Excluded from the study due to immigration or death

##### Intervention groups

Teaching by lecture; Role-Playing Training

#### Main outcome variables

Knowledge and attitude towards HIV

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190807044467N1**

Registration date: **2019-12-15, 1398/09/24**

Registration timing: **prospective**

Last update: **2019-12-15, 1398/09/24**

Update count: **0**

##### Registration date

2019-12-15, 1398/09/24

##### Registrant information

##### Name

maryam nasirian

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3792 3246

##### Email address

maryamnasirian17@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-12-22, 1398/10/01

##### Expected recruitment end date

2020-02-20, 1398/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Comparison of the effect of role playing method with lecture on knowledge and attitude toward HIV/AIDS in general population (18-49 years old) of Khorramabad countryside

**Public title**  
The impact of role playing and speaking on population knowledge and attitude

**Purpose**  
Education/Guidance

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Elementary Literacy Mental ability to understand education and answer question Resident in the study areas informed consent to participate in the study  
**Exclusion criteria:**  
Under 18 year Over 49 year Unwillingness to participate in the study Exclusion due to immigration or death Known mental disorders and severe visual and auditory disorders

**Age**  
From **18 years** old to **49 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**

- Participant

**Sample size**  
Target sample size: **270**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Cluster random allocation; The three regions of Poshteh, Masour, and Falkodin in Khorramabad will be considered as clusters and assigned randomly to intervention group 1 (lecture = Falkodine), intervention 2 (role-playing = Poshteh), control (Masseur) Were. Subjects were then randomly selected in each district.

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
In order to blind the participants, individuals in each of the intervention and control groups were selected from three separate marginal areas to avoid communication with each other and not to be informed about each other's education.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**  
empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Institutional research ethics committee, Isfahan University of medical Sciences

##### Street address

hezarjarib

##### City

Isfahan

##### Province

Isfahan

##### Postal code

۷۳۴۶۱-۸۱۷۴۶

#### Approval date

2019-10-23, 1398/08/01

#### Ethics committee reference number

IR.MUI.RESEARCH.REC.1398.482

## Health conditions studied

### 1

#### Description of health condition studied

HIV

#### ICD-10 code

Z71.7

#### ICD-10 code description

Human immunodeficiency virus [HIV] counseling

## Primary outcomes

### 1

#### Description

knowledge

#### Timepoint

two weeks

#### Method of measurement

A standardized questionnaire assessing the knowledge and attitude of the general population regarding HIV

### 2

#### Description

attitude

#### Timepoint

two weeks

#### Method of measurement

A standardized questionnaire assessing the knowledge and attitude of the general population regarding HIV

## Secondary outcomes

empty

## Intervention groups

## 1

### Description

"Intervention group 1: pamphlets and lecture"; Four one-hour training sessions per week; One month training period.; The educational content will be prepared from the brochure "A New Approach to HIV Education", published by the Ministry of Health and Medical Education.

### Category

Behavior

## 2

### Description

"Intervention group 2: pamphlets and role-playing"; Four one-hour training sessions per week; One month training period.; The educational content will be prepared from the brochure "A New Approach to HIV Education", published by the Ministry of Health and Medical Education.

### Category

Behavior

## 3

### Description

No training will be provided except for a pamphlet.

### Category

Behavior

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Lorestan university of medical sciences

#### Full name of responsible person

Mina Jomezadeh

#### Street address

Moalem st

#### City

Khorram Abad

#### Province

Lorestan

#### Postal code

6813833946

#### Phone

+98 66 3330 0661

#### Email

publicrelation@lums.ac.ir

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Esfahan University of Medical Sciences

#### Full name of responsible person

Shaghayegh Haghjooy Javanmard

#### Street address

hezarjarib

#### City

Isfahan

#### Province

Isfahan

#### Postal code

۷۳۴۶۱-۸۱۷۴۶

#### Phone

+98 31 3792 3161

#### Email

maryamnasirian17@gmail.com

### Grant name

### Grant code / Reference number

### Is the source of funding the same sponsor organization/entity?

No

### Title of funding source

Deputy of Research and Technology in Isfahan 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

Khoram-Abad University of Medical Sciences

#### Full name of responsible person

Mina Jomezadeh

#### Position

Manager of Health Workers Training Center

#### Latest degree

Master

#### Other areas of specialty/work

Health Promotion

#### Street address

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#### City

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#### Province

Lorestan

#### Postal code

6813833946

#### Phone

0986633232171

#### Email

pomin15@yahoo.com

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Esfahan University of Medical Sciences

**Full name of responsible person**

Maryam Nasirian

**Position**

Faculty Member

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Epidemiology

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Hezarjarib

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Maryam Nasirian

**Position**

Faculty Member

**Latest degree**

Ph.D.

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**Street address**

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

confidential consideration about HIV issue and marginalized population

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available