

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

A randomized clinical trial comparing the efficacy of psychosocial and behavioral interventions on reducing HIV/AIDS related high risk behaviors among secondary school students

Protocol summary

Summary

Objective: The purpose of this study is to determine the impact of a psycho-social and behavioral interventions on controlling and preventing risky sexual and addictive behaviors related to HIV transmission . The main inclusion and exclusion criteria: Secondary school students with age range 13-16 years with a history of using at least one substance drug or one friendly relationship with opposite sex during previous 6 month. Study participants and sample size: First all secondary school students studying in Shorghoon area will be screened using standard youth high risk behavior questionnaire to identify high risk students. Then, 200 students (100 girls & 100 boys) with high risk behaviors will be selected and categorized in two intervention groups randomly. Two hundred students with random allocation will put into control groups. Design: Proposed intervention will be randomized control trial with random allocation into control and intervention groups. Interventions: A brief psycho social and behavioral interventions (6 months) will be used. The study will be conducted at two stages including baseline and intervention. Primary outcome measure: Two groups in two genders will be compared regarding the effectiveness of intervention program on reducing HIV related high risk behaviors.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016051521684N3**

Registration date: **2016-05-30, 1395/03/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-05-30, 1395/03/10

Registrant information

Name

Mahmood AminiLari

Name of organization / entity

Shiraz HIV/AIDS Research Center, Shiraz University of Medical Science

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Shiraz University of Medical Sciences

Expected recruitment start date

2016-02-20, 1394/12/01

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A randomized clinical trial comparing the efficacy of psychosocial and behavioral interventions on reducing HIV/AIDS related high risk behaviors among secondary school students

Public title

Psychosociol and behavariol interventions among
Secondary school students

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Being secondary school student ; age range between 13-16 years; having a history of using at least 1 substance drug or one friendly relationship with opposite sex over the past sex month; completing inform consent. Exclusion criteria: Having severe mental and personality disorders.

Age

From **13 years** old to **17 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **400**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

The intervention and control groups were divided using table of random numbers.

Secondary Ids

1

Registry name

NA

Secondary trial Id

NA

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shiraz University of Medical Sciences

Street address

7th Floor, Central Building, Shiraz University of Medical Sciences, Zand Ave, Shiraz, Iran Shiraz

City

Shiraz

Postal code

Approval date

2015-03-01, 1393/12/10

Ethics committee reference number

IR.SUMS.REC.1394.S45

Health conditions studied

1

Description of health condition studied

High Risk Behaviors

ICD-10 code

Z20.6

ICD-10 code description

Mental and behavioural F19:disorders due to psychoactive substance use

Primary outcomes

1

Description

Addictive High Risk Behavior

Timepoint

Before intervention and immediately after intervention

Method of measurement

Youth High Risk Behaviors Questionnaire

2

Description

Sexual High Risk Behavior

Timepoint

Before intervention and immediately after intervention

Method of measurement

Youth High Risk Behaviors Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Educational interventions contain 3 sessions (1.5 H) including "Understanding of the new drugs and substance abuse", " The methods of preventing substance abuse" and " The method of preventing sexual and addictive high risk behaviors". Psychological interventions include individual counseling (5 sessions, 45 min) and Life skills training (24 hours). Social supports will be providing required facilities and introducing students to the art and sport centers.

Category

Behavior

2

Description

Control group will receive no intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Three secondary school in marginalized Shorghoon area

Full name of responsible person

Mr.Aghaei

Street address

Dabaghmanesh School, Vazir Abad

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Shiraz University of Medical Sciences

Full name of responsible person

Dr.Poostfroosh

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7th Floor, Central Building, Shiraz University of Medical Sciences, Zand Ave, Shiraz, Iran Shiraz

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Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for Research, Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz HIV/ AIDS Research Center, Shiraz University of Medical Sciences

Full name of responsible person

Mahmood AminiLari

Position

Executive Director

Other areas of specialty/work

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Person responsible for updating data

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Web page address	<i>empty</i>
Sharing plan	Informed Consent Form
	<i>empty</i>
Deidentified Individual Participant Data Set (IPD)	Clinical Study Report
<i>empty</i>	<i>empty</i>
Study Protocol	Analytic Code
<i>empty</i>	<i>empty</i>
Statistical Analysis Plan	Data Dictionary
	<i>empty</i>