

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

The effectiveness of peer-based education on self-esteem , perceived vulnerability and performance towards prevention of HIV and hepatitis B in women with substance use disorder

Protocol summary

Summary

The aim of study is to assess the effectiveness of peer education on self-esteem, perceived vulnerability and performance towards prevention of HIV and hepatitis B in women with substance use disorder. This study design is cluster randomized controlled intervention trial without blinding and randomization are in the centers to five intervention and five control centers. The study population are 100 women with substance use disorder referring to Drop-in Centers, Harm reduction centers and camps who are over 18 years old, When filling out the questionnaire and participate in the class have the ability to answer and dialogue, Having at least degree of knowledge, substance use at least for 3 months, sexually active and lack of HIV infection. In this study intervention will be based on peer education by someone whit a history of substance use and provide information, including interpersonal skills, decision making skills and self-esteem, problem solving, the definition of hepatitis B and HIV and transmission of, techniques for the prevention of HIV, hepatitis b, dialogue and assertiveness techniques with the partner. Primary outcome are self-esteem, perceived vulnerability and performance toward HIV and hepatitis B that measuring with Rosenberg Self-Esteem questionnaire, Demographic, Sexual function questionnaire and Vulnerability to HIV and hepatitis B. Information will collecting before, immediately, one months and three months after the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201612113034N17**
Registration date: **2017-05-31, 1396/03/10**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-05-31, 1396/03/10

Registrant information

Name

Mansoureh Jamshidimanesh

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Research Deputy School of Nursing and Midwifery, Iran University of Medical Sciences

Expected recruitment start date

2017-05-10, 1396/02/20

Expected recruitment end date

2017-07-23, 1396/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of peer-based education on self-esteem , perceived vulnerability and performance towards prevention of HIV and hepatitis B in women with substance use disorder

Public title

The effectiveness of peer education on preventive behaviors of HIV and hepatitis B

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Age over 18 years; When filling out the questionnaire and participate in the class have the ability to answer and dialogue; Having at least degree of knowledge; substance use at least for 3 months; sexually active; lack of HIV infection. exclusion criteria: do not participate in training class for more than one session; Happening unexpected events

Age

From 18 years old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 100

Randomization (investigator's opinion)

Randomized

Randomization description

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

Iran University of Medical Science

Street address

Iran University of Medical Science, Next to the Milad Tower, Shahid Hemat Highway, Tehran, Iran

City

Teran

Postal code

19964

Approval date

2017-04-05, 1396/01/16

Ethics committee reference number

IR.IUMS.REC 1395.9311373001

Health conditions studied

1

Description of health condition studied

HIV

ICD-10 code

B20-B24

ICD-10 code description

Human immunodeficiency virus [HIV] disease

2

Description of health condition studied

Hepatitis B

ICD-10 code

B16

ICD-10 code description

Acute hepatitis B

Primary outcomes

1

Description

Self-esteem

Timepoint

Before intervention, immediately, 4 weeks and 12 weeks after intervention

Method of measurement

Rosenberg Self-esteem Questionnaire

2

Description

Perceived Vulnerability to HIV

Timepoint

Before intervention, immediately, 4 weeks and 12 weeks after intervention

Method of measurement

Vulnerability to HIV Questionnaire

3

Description

Perceived Vulnerability to Hepatitis B

Timepoint

Before intervention, immediately, 4 weeks and 12 weeks after intervention

Method of measurement

Vulnerability to Hepatitis B Questionnaire

4

Description

Performance

Timepoint

Before intervention, immediately, 4 weeks and 12 weeks after intervention

Method of measurement

Demographic, Sexual function questionnaire

Secondary outcomes

1

Description

Condom use

Timepoint

Before intervention, immediately, 4 weeks and 12 weeks after intervention

Method of measurement

Demographic, Sexual function questionnaire

2

Description

HIV test

Timepoint

Before intervention, immediately, 4 weeks and 12 weeks after intervention

Method of measurement

Demographic, Sexual function questionnaire

3

Description

HBV TEST

Timepoint

Before intervention, immediately, 4 weeks and 12 weeks after intervention

Method of measurement

Demographic, Sexual function questionnaire

4

Description

Type of sex

Timepoint

Before intervention, immediately, 4 weeks and 12 weeks after intervention

Method of measurement

Demographic, Sexual function questionnaire

5

Description

Number of partner

Timepoint

Before intervention, immediately, 4 weeks and 12 weeks after intervention

Method of measurement

Demographic, Sexual function questionnaire

6

Description

Number of save sex

Timepoint

Before intervention, immediately, 4 weeks and 12 weeks after intervention

Method of measurement

Demographic, Sexual function questionnaire

Intervention groups

1

Description

Control: To control group, a training session based on the protocol Ministry of Health to prevent HIV infection in the mother and child will be held after filling out the questionnaire.

Category

Prevention

2

Description

In this intervention peers education is the most important part of education. Researcher make a test, based on check list of intervention session and each peer who be able to get satisfaction score will select as a peer educator. Researcher will educate peers educators in 30 hours and education of intervention group will be in 6 session two days a week and each session is about 45 to 60 minutes. Educational content includes HIV and Hepatitis B disease definition and ways of prevention of them, save sexual behavior, use of condom, do HIV and Hepatitis B test, dialogue and assertiveness techniques with the partner and problem solving. For control group one session will hold according to the Ministry of Health protocol based on the prevention of HIV in mother and child after filling out questionnaire. It should be noted, researcher will monitor all stages of the intervention process.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Mikhak center

Full name of responsible person

Soheila Ahmadi

Street address

Tehran, Valiasr st, Rashidiasemi, School of Nursing & Midwifery Iran University of Medical Sciences

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2

Recruitment center

Name of recruitment center

Kaj center

Full name of responsible person

Soheila Ahmadi

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3

Recruitment center

Name of recruitment center

Mehr Protetive Center

Full name of responsible person

Soheila Ahmadi

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4

Recruitment center

Name of recruitment center

Mojeze Aria Pak center

Full name of responsible person

Soheila Ahmadi

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5

Recruitment center

Name of recruitment center

Llavizan Residency

Full name of responsible person

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6

Recruitment center

Name of recruitment center

Payamavaran Hamyari Center

Full name of responsible person

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7

Recruitment center

Name of recruitment center

Navid Hamrazi Iranian center

Full name of responsible person

Soheila Ahmadi

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Recruitment center

Name of recruitment center

khane Mian Rah center

Full name of responsible person

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9

Recruitment center

Name of recruitment center

Simaye Sabze Rahaei Center

Full name of responsible person

Soheila Ahmadi

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Recruitment center

Name of recruitment center

Shahid Emami Center

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Deputy school of Nursing and Midwifery of Iran University of Medical Sciences

Full name of responsible person

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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

Research Deputy school of Nursing and Midwifery of Iran

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

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Person responsible for general inquiries

Contact

Name of organization / entity

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Position

Master of Midwifery student

Other areas of specialty/work**Street address**

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty