

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The Effectiveness of an Intimate Relationship Skills Training (Pairs) on Marital Adjustment and Satisfaction In in Women with HIV positive

Protocol summary

Study aim

Determining the Effect of Counseling on Crisis Relationship Skills (Peirce Model) on Increasing Marital Satisfaction and Adoption of HIV-positive Women Referring to Imam Khomeini Hospital's Research Center for Behavioral Illnesses in Tehran

Design

In this research, 50 eligible patients referring to voluntary and counseling center for HIV. will chose purposefully and a code will allocate to each one of them. Then, patients randomly will divide into two control and intervention groups. block randomization and intervention is group counseling

Settings and conduct

En It is a randomized controlled clinical trial without blinding. setting and conduct: voluntary and counseling testing Center of Imam Khomeini Hospital in Tehran.

Participants/Inclusion and exclusion criteria

Inclusion criteria: • Having minimum cycle education • Having a regular sex partner • Has a positive HIV partner • The desire to attend training courses and the lack of individual counseling services outside of the sessions • Complete the consent form for research Exit criteria: • Having a history of hospitalization in psychiatric hospitals • Use of any psychoactive drugs • alcohol consumption • Cancellation and inability to complete sessions (no participation in two sessions) • Get other psychological and counseling services • Lack of sexual function based on the gender identity questionnaire score

Intervention groups

The intervention group received eight sessions of the class; the control group received a national protocol

Main outcome variables

satisfaction and material adjustment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160503027728N11**

Registration date: **2019-03-14, 1397/12/23**

Registration timing: **registered_while_recruiting**

Last update: **2019-03-14, 1397/12/23**

Update count: **0**

Registration date

2019-03-14, 1397/12/23

Registrant information

Name

Zohreh Mahmoodi

Name of organization / entity

Nursing&Midwifery faculty

Country

Iran (Islamic Republic of)

Phone

+98 26 3430 4433

Email address

zohrehmahmoodi@abzums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-09, 1397/10/19

Expected recruitment end date

2019-07-10, 1398/04/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effectiveness of an Intimate Relationship Skills Training (Pairs) on Marital Adjustment and Satisfaction In in Women with HIV positive

Public title

The Effectiveness of an Intimate Relationship Skills Training (Pairs) on Marital Adjustment and Satisfaction In in Women with HIV positivet

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

- Having a regular sex partner Has a positive HIV partner

The desire to attend training courses and the lack of individual counseling services outside of the sessions Complete the consent form for research Having minimum cycle education

Exclusion criteria:

Having a history of hospitalization in psychiatric hospitals Use of any psychoactive drugs alcohol consumption Cancellation and inability to complete sessions (no participation in two sessions) Get other psychological and counseling services Lack of sexual function based on the gender identity questionnaire score

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 50

Randomization (investigator's opinion)

Randomized

Randomization description

En First, the sampling will be available and according to the active records in the center. Then they will be divided into two groups based on random blocks. Also for statistical matching, the statistical tests are used to match the underlying variables The randomization method is done using block randomization so that the sample size of both groups is equal.

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

Ethics committee of Alborz University of Medical Sciences

Street address

Alborz University of Medical Sciences, Shahrake Edari, North Taleghai square, Karaj, Iran

City

karaj

Province

Alborz

Postal code

3149779453

Approval date

2019-03-02, 1397/12/11

Ethics committee reference number

IR.ABZUMS.REC.1397.196

Health conditions studied

1

Description of health condition studied

Human immunodeficiency virus

ICD-10 code

B20

ICD-10 code description

Human immunodeficiency virus [HIV] disease

Primary outcomes

1

Description

Marital Satisfaction - Marital Compatibility

Timepoint

En Before intervention _ Immediately after the intervention -4 weeks after intervention

Method of measurement

Marital satisfaction questionnaire score and Marital adjustment questionnaire score

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: In this group, women with HIV live in addition to routine counseling centers, eight group training sessions are provided based on pairs model.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran Imam khomani hospital voluntary and counseling center

Full name of responsible person

Dr Zohreh Mahmoodi

Street address

The Department of Infectious and tropical Disease,
Imam Khomeini Hospital, Keshavarz Blvd

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tehran

Province

Tehran

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14-19-733141

Phone

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Email

zohrehmahmoodi2011@gmail.com

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Karaj University of Medical Sciences

Full name of responsible person

Dr moohammad Noori sepehr

Street address

Noor street, Taleghani Square, Karaj

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

En Alborz 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**

Karaj University of Medical Sciences

Full name of responsible person

Zohreh Mahmoodi

Position

Ph.D

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

Street address

Karaj-Meidan-e-Prophet-end of the West Buali-higher
of the University of Arts-Campus University of Medical
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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Karaj University of Medical Sciences

Full name of responsible person

Zohreh Mahmoodi

Position

pHD

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

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Person responsible for updating data

Contact**Name of organization / entity**

Karaj University of Medical Sciences

Full name of responsible person

Zohreh Mahmoodi

Position

PHD

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

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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

Yes - There is 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

Yes - There is 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

The English version of the article entitled The Effect of
Crisis Relationship Skills Counseling (Pierce's Model) on
Marital Satisfaction and Adaptation in HIV-positive
Women Referring to the Behavioral Disease Research
Center of Tehran Imam Khomeini Hospital, Tehran,
1939-98, is published in the Journal of Prestige.

**When the data will become available and for how
long**

En 10 month later

To whom data/document is available

En Iranian research center for HIV/AIDS , Alborz
University of Medical Sciences

Under which criteria data/document could be used

En path analysis

From where data/document is obtainable

AIDS Research Center, Tehran University of Medical
Sciences and Alborz Medical School

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

En send an email to Dr. Zohreh Mahmoodi

Comments