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

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Iran (Islamic Republic of)

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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
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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 volantary and counseling center

Full name of responsible person
Dr Zohreh Mahmoodi
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The Department of Infectious and tropical Disease, Imam Khomeini Hospital, Keshavarz Blvd
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Sponsors / Funding sources

1

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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
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Other areas of specialty/work
Reproductive Health
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Person responsible for updating data

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Other areas of specialty/work
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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