Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Investigating the effectiveness of Sexual Health Model on Sexual Anxiety and Marital Conflicts of women with HIV

Protocol summary

Study aim
Determining the effectiveness of group counseling based on the sexual health model on sexual anxiety and marital conflicts of women with HIV

Design
A semi-experimental study (pre-test, post-test) will be done conducted on Sexual Anxiety and Marital Conflicts of women with HIV. Sampling will be done by census method. The number of samples will be 34 people. The intervention includes the sexual health model with the participation of eligible women with HIV.

Settings and conduct
Counseling based on the Sexual Health Model on Sexual Anxiety and Marital Conflicts of women with HIV will be held in Yazd Center of Behavioral Diseases. Sampling will be done by census. The samples will be placed in groups of 11-12 people. The intervention will be carried out in 3 sessions of 90 minutes weekly and during 3 consecutive weeks. Questionnaires will be completed at baseline, at the end of the intervention and 4 weeks after the end of the intervention.

Participants/Inclusion and exclusion criteria
Inclusion: Being Iranian, HIV infection based on the diagnosis of the Attending physician and the medical record at the Behavioral Disease Counseling Center of Yazd, Ability and interest to participate in counseling sessions, Having a common bed with a spouse.
Exclusion: Pregnancy, having any severe mental or physical illness, Unwillingness to participate in the study.

Intervention groups
For intervention group, 3 90-minute sessions based on the Sexual Health Model, once a week in the Yazd Center of Behavioral Diseases will be held in person.

Main outcome variables
Change in Mean scores of Marital Conflicts and Sexual Anxiety.

General information

Reason for update

Acronym
SHM

IRCT registration information
IRCT registration number: **IRCT20230110057094N1**
Registration date: **2023-02-02, 1401/11/13**
Registration timing: **prospective**

Last update: **2023-02-02, 1401/11/13**
Update count: **0**

Registration date
2023-02-02, 1401/11/13

Registrant information

Name
Zahra Ghasemi

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-02-08, 1401/11/19

Expected recruitment end date
2023-06-10, 1402/03/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effectiveness of Sexual Health Model on Sexual Anxiety and Marital Conflicts of women with HIV

Public title
Investigating the effect of Sexual Health Model on Sexual Anxiety and Marital Conflicts

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Being Iranian HIV infection based on the diagnosis of the attending physician and the medical record at the behavioral disease counseling center in Yazd Ability and interest to participate in counseling sessions Having a common bed with a spouse
Exclusion criteria:
Pregnancy Having any severe mental or physical illness (Schizophrenia, cancer...) Unwillingness to participate in the study

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **34**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shahid Sadoughi University of Medical Sciences, Yazd
Street address
Bahonar Square; Yazd
City
Yazd
Province
Yazd
Postal code
8916189165

Approval date
2023-01-24, 1401/11/04

Ethics committee reference number
IR.SSU.REC.1401.082

Health conditions studied

1

Description of health condition studied
Sexual anxiety counseling, Counseling of marital conflicts

ICD-10 code
B20

ICD-10 code description
Human immunodeficiency virus [HIV] disease

Primary outcomes

1

Description
Changes in mean scores of marital conflicts among women with HIV

Timepoint
In the baseline, completion of the intervention (End of the third week) and in the follow-up period (4 weeks after the completion of the intervention)

Method of measurement
MCQ_R Marital conflicts questionnaire

Secondary outcomes

1

Description
Changes in mean sexual anxiety scores of women with HIV

Timepoint
In the baseline, completion of the intervention (End of the third week) and in the follow-up period (4 weeks after the completion of the intervention)

Method of measurement
Sexual anxiety questionnaire (Davis)

Intervention groups

1

Description
Intervention group: The intervention of sexual health model is done face-to-face in a group at Yazd center of behavioral diseases for 3 sessions of 90 minutes, once a week by the researcher. The content of the sessions includes: introduction of psychological education of sexual health model, Education about culture, gender and gender identity, anatomy and sexual function, Sexual health care and safer sex, challenges, barriers of health and body image, imagination and sexual fantasy, sexual desires, intimacy in the relationship, spirituality. At the beginning of each session, a summary of the contents of the previous sessions will be reviewed and

the assigned tasks related to the previous session will be reviewed by the researcher. Women are asked to participate in discussions and raise their questions. At the end of each session, a summary of the important topics discussed is presented and people's questions are answered, and women are asked to do their homework in the next sessions.

Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Yazd center of behavioral diseases

Full name of responsible person
Mahshid Bokaie

Street address
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yazd University of Medical Sciences

Full name of responsible person
Alireza Moradi

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Central Organization of Shahid Sadoughi University of Medical Sciences, Yazd, Bahonar Square, Yazd

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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
Yazd 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
Yazd University of Medical Sciences

Full name of responsible person
Mahshid Bokaie

Position
Associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
Reproductive Health

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Not applicable
Title and more details about the data/document
All individual data of study participants can be shared after de-identification.
When the data will become available and for how long
After results publication.
To whom data/document is available
The data will be available to researchers working in academic and scientific institutions, and people working in industry can apply to receive them.
Under which criteria data/document could be used
Scientific usage.
From where data/document is obtainable
mah_bokaie@yahoo.com
What processes are involved for a request to access data/document
One week after receiving the applicant's email.
Comments