

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 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)

Phone

+98 71 3262 3638

Email address

z.ghasemi@stu.ssu.ac.ir

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

Imam Jafar Sadiq Blvd

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: 8916715171

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mah_bokaie@yahoo.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Alireza Moradi

Street address

Central Organization of Shahid Sadoughi University of Medical Sciences, Yazd, Bamonar 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

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

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Person responsible for updating data**Contact****Name of organization / entity**

Yazd University of Medical Sciences

Full name of responsible person

Mahshid Bokaie

Position

Associate Professor

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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