Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

"Determining the Effect of a Sexual Self-Care Education Intervention on Sexual Health and Marital Satisfaction of Healthy Women with HIV-Positive Husbands: A Randomized Controlled Clinical Trial"

Protocol summary

Study aim
Determining the effect of sexual self-care education intervention on sexual health and marital satisfaction of healthy women with HIV-infected partners

Design
A randomized, controlled, single-blind clinical trial with a control group on 80 subjects. The method of assigning the intervention to subjects was random and using a permutation block method with a block size of 4.

Settings and conduct
Individuals who meet the inclusion criteria will be included in the study after obtaining written informed consent. The initial questionnaire will be completed before random assignment to two groups, and the designed intervention will be provided to the experimental group. The effectiveness of the intervention will be assessed by completing the questionnaire before and four weeks after the intervention. The assessment in the control group will be conducted in the same way as in the intervention group. Location: Sari County Behavioral Diseases Counseling Center and Imam Khomeini Hospital, Tehran

Participants/Inclusion and exclusion criteria
Inclusion criteria: Inclusion: Being a woman and having an HIV-positive partner, people of reproductive age 18 to 49 years, having lived with their current partner for at least 6 months, being sexually active, not suffering from psychiatric illnesses or cognitive disorders, not using psychotropic or narcotic drugs. Exclusion criteria: Women becoming infected with HIV during the study, not attending more than three sessions of the intervention program, changing marital status during the study.

Intervention groups
The intervention group will receive 6 health promotion counseling sessions on sexual health, twice a week for 90 minutes. The control group will not receive any intervention other than usual care until the end of the study.

Main outcome variables
Sexual health score and marital satisfaction score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170513033951N2**
Registration date: **2025-06-02, 1404/03/12**
Registration timing: **registered_while_recruiting**

Last update: **2025-06-02, 1404/03/12**
Update count: **0**

Registration date
2025-06-02, 1404/03/12

Registrant information

Name
mohadeseh motaharinezhad

Name of organization / entity
school of midwifery and nursing, Tehran university of medical science

Country
Iran (Islamic Republic of)

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Email address
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-05-31, 1404/03/10

Expected recruitment end date
2025-07-21, 1404/04/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
"Determining the Effect of a Sexual Self-Care Education Intervention on Sexual Health and Marital Satisfaction of Healthy Women with HIV-Positive Husbands: A Randomized Controlled Clinical Trial"

Public title
The effect of sexual self-care education on sexual health and marital satisfaction of women with HIV-infected partners.
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Being a woman and having an HIV-positive spouse (confirmed by medical documents or medical records) Negative HIV test result in the woman (woman is HIV negative = incompatible couple) Women of reproductive age 18 to 49 years Having lived together with your current spouse for at least 6 months Ability to read and write Having sexual activity Informed consent to participate in the study Absence of psychiatric illnesses or cognitive disorders (based on self-report) Not using psychotropic or narcotic drugs Not pregnant at the time of intervention No participation in similar interventions within the past 6 months
Exclusion criteria:
HIV infection in women during the study period Unwillingness to continue cooperation at any stage of the study Individuals not attending more than three sessions of the intervention program The occurrence of severe family or personal crises that disrupt the individual's participation process The woman became pregnant during the study Change in marital status during the study (divorce) Use of medications or treatments that have a serious impact on sexual or psychological functioning during the implementation of the intervention Development of a previously undiagnosed psychiatric or cognitive disorder during the study
Age
From **18 years** old to **49 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Data analyser

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
The method of assigning the intervention to individuals will be random and using the random permutation block method with a block size of 4. The randomization list will be prepared in consultation with a statistician. In order to conceal the allocation, sealed and waxed opaque envelopes will be used. After randomization, a number of envelopes will be prepared based on the size of the research sample, and each of the random sequences created will be recorded on a card and the cards will be placed in the envelopes in order. In order to preserve the random sequence, numbering will be done in the same order on the outer surface of the envelopes. Finally, the envelopes will be sealed and placed in a box in order. At the start of participant registration, based on the order in which eligible participants entered the study, one of the envelopes will be opened in order and the assigned group of that participant will be determined. In this way, eligible individuals who wish to participate in the study will be randomly assigned to either the intervention or control groups.
Blinding (investigator's opinion)
Single blinded
Blinding description
This study will be a randomized, controlled, single-blinded interventional study. Due to the educational nature of the intervention, blinding of participants is not possible, but the data analyst will be blinded to group allocation.
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of shahroud University of Medical Sciences
Street address
Hafte-Tir Square, Imam Hossein Boulevard, Shahroud, Semnan Province, Iran
City
Shahroud
Province
Semnan
Postal code
7395536147
Approval date
2021-08-15, 1400/05/24
Ethics committee reference number
IR.SHMU.REC.1400.085

Health conditions studied

1

Description of health condition studied
Sexual health and marital satisfaction of healthy women with HIV-positive partners

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Sexual health score

Timepoint
At the beginning of the study (before the intervention), at the end of the intervention, and 4 weeks after the intervention.

Method of measurement
Sexual Self-Care Questionnaire for Women of Reproductive Age (FSHS): Female Sexual Health Self-care

2

Description
Marital satisfaction score

Timepoint
At the beginning of the study (before the intervention), at the end of the intervention, and 4 weeks after the intervention.

Method of measurement
ENRICH Marital Satisfaction Questionnaire: Evaluation and Nurturing Relationship Issues, Communication and Happiness

Secondary outcomes

1

Description
Sexual health score

Timepoint
At the beginning of the study (before the intervention), at the end of the intervention, and 4 weeks after the intervention.

Method of measurement
Sexual Self-Care Questionnaire for Women of Reproductive Age (FSHS): Female Sexual Health Self-care

2

Description
Marital satisfaction score

Timepoint
At the beginning of the study (before the intervention), at the end of the intervention, and 4 weeks after the intervention.

Method of measurement
ENRICH Marital Satisfaction Questionnaire: Evaluation and Nurturing Relationship Issues, Communication and Happiness

Intervention groups

1

Description
Intervention group: This study will be conducted as a randomized clinical trial with two experimental and control groups, after the necessary preparations, including approval by the Ethics Committee of Shahrood University of Medical Sciences and registration in the clinical trials registry, and with the participation and informed consent of individuals referring to behavioral disease counseling centers. Primary sampling will be conducted in a convenient manner, and in order to access the desired samples, the researcher will visit the selected center after obtaining the necessary permits, with a written letter of introduction, and after explaining the research objectives and methods to the center officials and obtaining their consent, will begin sampling in this center. The researcher will visit this center on weekdays according to a pre-determined schedule and, after explaining the research objectives and methods to individuals who refer to receive health and medical services, will take a history from the individuals. Individuals who meet the entry criteria for the study and are willing to participate in the study will enter the study after obtaining written informed consent. At the beginning of the study, participants will be explained whether they will be randomly assigned to one of the intervention or control groups. They will also be assured that if they do not wish to continue participating in the study during the study, they will be withdrawn from the study. The initial questionnaire will be completed before random assignment of individuals to the two groups, and the designed intervention will be provided to the test group. The number of sessions and hours required, based on a review of related studies and interventions, is 6 sessions of 60-90 minutes, twice a week, for three consecutive weeks. The control group will not receive any intervention other than usual care until the end of the study. The effectiveness of the intervention will be assessed by completing a questionnaire before and four weeks after the intervention. The assessment in the control group will be conducted in the same way as in the intervention group. Research population: Healthy women with HIV-positive partners in the reproductive age group of 18 to 49 years, referring to behavioral disease counseling centers affiliated with Mazandaran University of Medical Sciences and the Behavioral Disease Counseling Center at Imam Khomeini Hospital in Tehran. Research sample: Healthy women with HIV-positive partners in the reproductive age group of 18 to 49 years, referring to behavioral disease counseling centers affiliated with Mazandaran University of Medical Sciences and the Behavioral Disease Counseling Center at Imam Khomeini Hospital in Tehran, who are eligible for inclusion in the study.

Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Behavioral diseases counseling center at Imam Khomeini Hospital in Tehran

Full name of responsible person
Dr. Mohammad Farhad Ashtiani

Street address
Imam Khomeini Hospital Complex Infectious Diseases Department (next to the Infectious Ward) Keshavarz Boulevard, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1419733141

Phone
+98 21 6691 1296

Email
Imamhospital@tums.ac.ir

2

Recruitment center

Name of recruitment center
Sari City Behavioral Diseases Counseling Center

Full name of responsible person
Fatemeh Bozorgnia

Street address
Shahband, Amir Mazandarani St

City
Sari

Province
Mazandaran

Postal code
4816656116

Phone
+98 11 3339 3501

Email
bozorgnia1206@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahroud University of Medical Sciences

Full name of responsible person
Dr. Mohammad Hassan Emamian

Street address
Hafte-Tir Square, Imam Hossein Boulevard, Shahroud, Semnan Province, Iran

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Shahroud

Province
Semnan

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7395536147

Phone
+98 23 3239 5054

Email
thesis.shmu@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Shahroud University of Medical Sciences

Proportion provided by this source
1

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
Shahroud University of Medical Sciences

Full name of responsible person
Mohadese Motaharinezhad

Position
Student

Latest degree
Master

Other areas of specialty/work
Reproductive Health

Street address
Hafte-Tir Square, Imam Hossein Boulevard, Shahroud, Semnan Province, Iran

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahroud University of Medical Sciences

Full name of responsible person
Mohadese Motaharinezhad

Position
Student

Latest degree

Master

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Mohadese Motaharinezhad

Position

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Latest degree

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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

Yes - There is a plan to make this available

Title and more details about the data/document

Yes, the Individualized Data File (IPD) will be made available to interested researchers in an anonymized form after the analyses are completed and the results are published. Data will be provided through direct request and after evaluation of the applicant's research proposal. Contact information for requests: Motahari.m11@gmail.com

When the data will become available and for how long

The data access period will begin 6 months after the publication of the final study results in scientific journals and will continue for 3 years. Data will only be provided to qualified researchers with a valid research purpose, after submitting a written request and approval by the research team.

To whom data/document is available

Access to data will be available to researchers working in academic institutions, research centers, and industry professionals who have a clear, justified, and ethically approved research project. Applications will be reviewed by the research team, and data will be provided on an anonymized basis and in strict confidentiality.

Under which criteria data/document could be used

Non-identifiable personal data and documentation related to this study can only be used for research purposes. Researchers who wish to receive the data must submit their formal request to the research team, along with the research plan and the type of analysis desired. Only scientific and statistical analyses related to the topic of sexual health and marital satisfaction will be permitted. Use of the data for commercial, promotional, or non-research purposes is not permitted. Any access to the data will only be possible after approval by the Ethics Committee of Shahroud University of Medical Sciences and signing a confidentiality agreement.

From where data/document is obtainable

Applicants for data or documentation from this study can submit their request via email to the researcher responsible for the study. The request should include a complete introduction of the applicant, organizational affiliation, purpose of data use, a summary of the research design, and the type of analyses intended. Name: Mohadese Motaharinezhad Email address: Motahari.m11@gmail.com

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

After receiving the formal request from the applicant, the review process will be carried out as follows: Receipt of a written request including complete information about the applicant, proposed research plan, objectives, type of analysis desired, and organizational affiliation Initial review by the responsible researcher to assess the completeness of the documents and documentation (maximum 7 working days) Expert review by the research team to ensure that the purpose of the request is consistent with the nature of the data and compliance with research ethics principles (maximum 2 to 3 working weeks) If approved, the signing of a Data Use Agreement between the parties is necessary. After the agreement is finalized, the anonymized data will be provided to the applicant via encrypted email or secure link. The entire process from receipt of the request to delivery of the data usually takes between 3 to 4 working weeks.

Comments