Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The Effect Of PLISSIT Model Counselling On Sexual Function Of Married Women With HIV

Protocol summary

Summary

The purpose of this randomized clinical trial is to examine the effect of counseling based on PLISSIT model on sexual function of women with HIV. The statistical population of this research includes all the Married women who go to Imam Khomeini Hospital of Tehran to receive routine care for HIV. This study will be on 60 Married women who are positive HIV, and who are qualified to participate for this research. The main inclusion criteria involves: HIV-positive married women and having an intact marriage; HIV-negative husband; Passing at least 3 months of HIV diagnosis in person; Do not use alcohol and drugs; No addiction; lack of mental and chronic physical illness; and the main exclusion criteria involves: If a woman does not want to continue take parting in this study or becomes pregnant. After taking a written testimonial, the researcher asked the qualified women to fill the questionnaires of demographic information, FSFI and Beck Depression questionnaires. Randomly the participants are assigned to two groups of intervention and control. In the intervention group, participants will be counseling based on PLISSIT model on sexual function of women. The control group will receive routine care for HIV . Training session will be held once a week. Data will be collected from participants at three points: before consultation, 1 months and 3 months after consultation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201211179463N10**
Registration date: **2016-06-13, 1395/03/24**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-06-13, 1395/03/24

Registrant information

Name

Zahra Behboodi Moghadam

Name of organization / entity

Tehran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2016-02-20, 1394/12/01

Expected recruitment end date

2016-09-20, 1395/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect Of PLISSIT Model Counselling On Sexual Function Of Married Women With HIV

Public title

The Effect Of PLISSIT Model Counselling On Sexual Function Of Married Women With HIV

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: Married women HIV And is stable life

with wife; HIV-negative wife; Passing at least 3 months of HIV diagnosis in person; With at least read and write; No history of participating in training classes or consulting with a focus on sexual function; Do not use alcohol and drugs; The lack of chronic disease (self-reported); The lack of; known mental illness (self-reported); Do not use medications that affect sexual function; Not pregnant. Exclusion criteria: Wife's death during the study; Not wanting to continue cooperation; Pregnancy during the study; Mental disease during the study.

Age
No age limit

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

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 Tehran University of Medical Sciences

Street address
The 6th floor of The central organization of Tehran University of Medical Sciences, at the corner of Qods Street , Keshavarz street.

City
Tehran

Postal code

Approval date
2016-01-20, 1394/10/30

Ethics committee reference number
IR.TUMS.REC.1394.1705

Health conditions studied

1

Description of health condition studied
HIV

ICD-10 code
B20.3

ICD-10 code description
HIV disease resulting in other viral infections

Primary outcomes

1

Description
Sexual Function

Timepoint
Before the intervention; one monthes and three monthes after intervention

Method of measurement
Female Sexual Function Index questionnare

Secondary outcomes

empty

Intervention groups

1

Description
intervention group, at first the FSFI questionnaire and Beck Depression in order to assess the sexual function completed with intervention group. Then participate with Sexual dysfunction without depression in counseling sessions. For individual counseling are using PLISSIT model. Finally, 1 months and 3 months after the last counseling session sexual function of subjects are assessed and compared.

Category
Other

2

Description
just Routine care is done in control group.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Voluntary Counselling and Testing (VCT) centre of Imam Khomeini hospital

Full name of responsible person
Minoo Mohraz

Street address
Iranian Research Center for HIV/AIDS, Imam Hospital.keshavarz Blvd

City
Tehran

2

Recruitment center

Name of recruitment center
Zamzam behavioral health center

Full name of responsible person
Dr.Seyed aham Seyed Alinaghi

Street address
Iranian Research Center for HIV/AIDS, Triangular clinic for sexual and behavioral disease.

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Tehran University of Medical Sciences

Full name of responsible person
Esmat Karimi

Street address
No23, Valiasr Avenue, Dameshgh Street

City
Tehran

Grant name

Grant code / Reference number

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

Title of funding source
Vice chancellor for research, Tehran University of Medical Sciences

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Nursing and Midwifery Faculty, Tehran University of Medical Sciences

Full name of responsible person
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Other areas of specialty/work

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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)
empty

Study Protocol
empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty