Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Jun 2026

The effect of mindfulness counseling on sexual self-efficacy of HIV positive women

Protocol summary

Study aim
Determining the effect of mindfulness counseling on sexual self-efficacy of HIV positive women in Ahvaz

Design
The clinical trial has two groups of control and intervention, randomized by permutation block method on 66 patients.

Settings and conduct
The sample of HIV-positive women referred to the High-Risk Diseases Center of Ahvaz, who were selected from the research community and have low sexual self-efficacy, the total number of participants is 60, which is 30 people in each group. The intervention is performed as a pre-test, post-test and follow-up stage so that the intervention group at the beginning of the study, week 8 and week 12 after the intervention complete the sexual self-efficacy questionnaire as a self-report. The control group despite low sexual self-efficacy They do not receive any intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Married age 25-45, possibility of continuous participation in training sessions, women whose sexual self-efficacy score is between 0 and 10;Exclusion criteria: use of drugs that affect sexual function, the patient's spouse has a sexual dysfunction, physical and other acute illnesses, simultaneous use of counseling and other educational services to increase sexual self-efficacy.

Intervention groups
The intervention group includes HIV-positive women with low sexual self-efficacy who are divided into three treatment groups of 7, during 8 sessions of group counseling (one session per week), with a mindfulness-based cognitive therapy approach to improve sexual self-efficacy. The control group consisted of 30 HIV-positive women with low sexual self-efficacy who did not receive any intervention.

Main outcome variables
Sexual self-efficacy; Readiness for sex; Self-stimulation; Communication without intimacy; Orgasm

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210317050736N1**
Registration date: **2021-04-27, 1400/02/07**
Registration timing: **prospective**

Last update: **2021-04-27, 1400/02/07**
Update count: **0**

Registration date
2021-04-27, 1400/02/07

Registrant information

Name
Bahareh sadeghian Dastjerdi

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-05-05, 1400/02/15

Expected recruitment end date
2021-07-27, 1400/05/05

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The effect of mindfulness counseling on sexual self-efficacy of HIV positive women

Public title
The effect of mindfulness counseling on sexual self-efficacy of HIV positive women

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Age 25-45 years Married Have a minimum literacy Have a test (rapid test or ELISA) that shows the person is HIV + Possibility of continuous participation in training sessions Women whose sexual self-efficacy score is between 0 and 10

Exclusion criteria:
Taking drugs that affect sexual function such as antidepressants, blood pressure and .... Infection of the patient's spouse with sexual dysfunction Consumption of alcohol and psychotropic substances by the patient and his spouse Having other physical and acute diseases and endocrine disorders such as diabetes and thyroid disorders based on the patient's medical record Simultaneous use of counseling and other educational services to increase sexual self-efficacy

Age
From **25 years** old to **45 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **66**

Randomization (investigator's opinion)
Randomized

Randomization description
The method of appointment will be random and with the method of random permutation blocks with block size 4 (using the table related to random permutations) and the ratio assigned to the intervention and control group will be 1: 1. The randomization list is prepared by a statistician. The code assigned to the intervention or control group will be placed in closed envelopes. These envelopes will be given to the secretary of the center. In this way, data analysts will not know what group everyone is in until they start studying.

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 Jundishapur University of Medical Sciences

Street address
Golestan Ave, Jundishapur University of Medical Sciences

City
Ahvaz

Province
Khouzestan

Postal code
15794-61357

Approval date
2021-03-17, 1399/12/27

Ethics committee reference number
IR.AJUMS.REC.1399.967

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
sexual self-efficacy

Timepoint
At the beginning of the study, week 8 and week 12 after the intervention

Method of measurement
Sexual Self-Efficacy Questionnaire by Bells et al

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Using purposive sampling, samples are selected from among women who are eligible and have inclusion criteria and no exclusion criteria. First, the same explanations are given to each eligible individual

about the objectives of the research and how to intervene. And written consent is obtained from eligible individuals. Completion of demographic and sexual self-efficacy questionnaire is done by samples that meet the inclusion criteria. The total number of participants in the study is based on statistical calculations of 60 people in each group 30 People will enter the research and then are divided into two groups of intervention and control by random block allocation method (4 blocks and 1: 1 allocation ratio). The sample size of people in group therapy with mindfulness approach should not exceed 14 people, because the effectiveness of psychotherapy decreases with increasing the number of groups, so the intervention group will be divided into three groups of 7 people, then the intervention as a pre-test, then The test and follow-up stage are performed so that all women in the three groups complete the sexual self-efficacy questionnaire at the beginning of the study, week 8 and week 12 after the intervention as a self-report. Counseling is done by a trained researcher and supervised by a consultant professor at the center. The women in the intervention group undergo 8 sessions of group counseling (one session per week) with a mindfulness-based cognitive therapy approach aimed at improving sexual self-efficacy. Meetings are held in groups, one 2-hour session per week as planned between the counselor and the client. During the sessions about realizing the wandering mind, full awareness of thoughts and feelings, emphasizing that negative feelings are not permanent, that thoughts They are not the truth, and the ways in which thoughts can be viewed from different angles are discussed, and people's new beliefs are discussed. Reminders to do homework and participate in group therapy are reminded daily by the researcher via SMS. After the end of 8 treatment sessions and 12 weeks after the intervention, the sexual self-efficacy questionnaire is completed by the intervention and control group.

Category

Treatment - Other

2

Description

Control group: Due to the low level of sexual self-efficacy, the control group did not receive any intervention. In order to make the research ethical, after completing the study, an educational booklet and a summary of the contents of the sessions are given to them.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz High Risk Diseases Center

Full name of responsible person

Shahla Molavi

Street address

Zaytoun Karmandi - Zavieh St. - Next to Abuzar Hospital - Opposite Hedayat Alley - Upper floor of Children's Clinic

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Parvin Abedi

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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

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Parvin Abedi

Position
Professor
Latest degree
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Other areas of specialty/work
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Person responsible for scientific inquiries

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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
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be 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
All data is potentially shareable after unidentified individuals
When the data will become available and for how long
Access period starts 6 months after the results are published
To whom data/document is available
The data will be available only to researchers working in academic and scientific institutions
Under which criteria data/document could be used
The data can be used for future studies.
From where data/document is obtainable
Send email to the responsible author Dr. Parvin Abedi parvinabedi@gmail.com
What processes are involved for a request to access data/document
After sending the email and reviewing the request and verifying the study, the request will be answered.
Comments