Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Oct 2026

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

Protocol summary

Study aim
Determining the effect of mindfulness counseling on sexual self-esteem of HIV positive women

Design
The clinical trial has two groups of control and intervention block block allocation method, on 50 patients.

Settings and conduct
The sample of HIV-positive women referred to the High-Risk Diseases Center of Isfahan, who were selected from the research community and have low sexual self-esteem, the total number of participants is 50, with 25 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-esteem questionnaire as a self-report.

Participants/Inclusion and exclusion criteria
Inclusion criteria: HIV positive women, willingness to participate in research, married, age between 18-45 years, monogamy of women and people whose score in the Sexual Self-Esteem Questionnaire is a standard deviation below average. Inclusion criteria: simultaneous use of counseling and other educational services to increase self-esteem, severe psychiatric disorders, stressful and unfortunate events during the past 3 months, alcohol and psychotropic substances by the patient and spouse It is associated with other acute physical illnesses and endocrine disorders such as diabetes and thyroid disorders based on the patient's medical record.

Intervention groups
The intervention and control group includes HIV-positive women with low sexual self-esteem. During 8 sessions of group counseling (one session per week), with a mindfulness-based cognitive therapy approach to improve sexual self-esteem. The control group did not receive any intervention.

Main outcome variables
Sexual self-esteem؛ Sexual experience and skills؛Sexual attractiveness؛Sexual control؛ Sexual moral judgment؛ Sexual adaptation

General information

Reason for update

Acronym
HIV

IRCT registration information
IRCT registration number: **IRCT20210614051580N1**
Registration date: **2021-10-10, 1400/07/18**
Registration timing: **prospective**

Last update: **2021-10-10, 1400/07/18**
Update count: **0**

Registration date
2021-10-10, 1400/07/18

Registrant information

Name
Shamim Kiani

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-10-23, 1400/08/01

Expected recruitment end date
2022-01-30, 1400/11/10

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

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

Public title
The effect of mindfulness counseling on sexual self-esteem of HIV positive women
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Willingness to participate in research Married Age between 18-45 years People whose score in the Sexual Self-Esteem Questionnaire is a standard deviation less than the average Women monogamy HIV positive women
Exclusion criteria:
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 in order to increase self-esteem Having severe psychiatric disorders Occurrence of stressful and unfortunate events during the last 3 months Consumption of alcohol and psychotropic substances by the patient and his wife
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
How to make a block accident (9 blocks of 6). Create two groups A and B naming. After adding 6 of the two groups A and B, we write, for example, ABABAB -AAABBB-ABBAAB-BBBAAA Assign one combination to each block and assign people in each block to treatment groups. The randomization list is based on a table of random numbers.
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 Ahwaz University of Medical Sciences
Street address
No. 156c,Janbazan St., Ostad Mehryar Alley
City
Esfahan
Province
Isfehan
Postal code
15794-61357
Approval date
2021-06-13, 1400/03/23
Ethics committee reference number
IR.AJUMS.REC.1400.160

Health conditions studied

1

Description of health condition studied
human immunodeficiency viruses
ICD-10 code
B20
ICD-10 code description
Human immunodeficiency virus [HIV] disease

Primary outcomes

1

Description
Sexual self-esteem
Timepoint
At the beginning of the study, week 8 and week 12 after the intervention
Method of measurement
HIV Positive Women Sexual Self-Esteem Questionnaire(SSEI-W-SF)

2

Description
sexual experience and skills
Timepoint
At the beginning of the study, week 8 and week 12 after the intervention
Method of measurement
HIV Positive Women Sexual Self-Esteem Questionnaire(SSEI-W-SF)

3

Description
sexual attractiveness
Timepoint
At the beginning of the study, week 8 and week 12 after

the intervention

Method of measurement

HIV Positive Women Sexual Self-Esteem Questionnaire(SSEI-W-SF)

4

Description

sexual control

Timepoint

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

Method of measurement

HIV Positive Women Sexual Self-Esteem Questionnaire(SSEI-W-SF)

5

Description

sexual moral judgment

Timepoint

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

Method of measurement

HIV Positive Women Sexual Self-Esteem Questionnaire(SSEI-W-SF)

6

Description

sexual adaptation

Timepoint

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

Method of measurement

HIV Positive Women Sexual Self-Esteem Questionnaire(SSEI-W-SF)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 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-esteem. Group sessions, one 90-minute session per week as scheduled between the counselor and clients. Full awareness of thoughts and feelings Emphasizing the non-permanence of negative feelings, that thoughts are not true, and the ways in which thoughts can be viewed from different angles, and people's new beliefs are discussed. The content of the sessions is as follows: Session 1: (Automatic guidance) Raisin-conscious mind-eating exercise: A meditation in which participants spend a few minutes examining the sensory-visual, olfactory, and taste characteristics and touch of a raisin seed. And Exercise Exam: A meditation in which participants draw their attention to senses in different parts of the body. Session 2: (Facing Obstacles) Practice Examining the Body and Practicing Thoughts and Feelings: Participants visualize a scenario such as a friend not saying hello, then examine their reactions to such an event and the effect of mood. Session 3: (Presence of mind from breathing) Three-minute breathing space and conscious mind walking. Participants are invited to move according to the breathing pattern, the position of the legs and the bodily sensations caused by attention. Session 4: (Staying in the present) Meditation practice of seeing and hearing: Participants are asked to focus their attention on visual sights or sounds and to slowly return to these senses when their mind wanders. Session 5: (Reception) 40 minutes of sitting meditation, review exercise: Participants pay attention to breathing, body senses, sounds and thoughts. Also pay attention to the confusion of the mind. Session 6: (Thoughts are not facts) Imagine sitting for 40 minutes imagining as images on a movie screen or passing clouds or river leaves. Session 7: (Self-care) Pointing to the relationship between mood and activity: Preparing a list of activities and dividing them into increasing and decreasing the level of mood and energy Session8: (Using what has been learned) Review of past content, reflection

Category

Treatment - Other

2

Description

Control group: Due to the fact that the control group did not receive any intervention despite the low level of sexual self-efficacy. 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

Navab Safavid High Risk Disease Center of Isfahan

Full name of responsible person

Shamim kiyani

Street address

Ahmadabad Square, Bozorgmehr St., Navab Safavi Comprehensive Health Service Center

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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Position
the coach
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Other areas of specialty/work
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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
No - There is not 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 Ms. Mitra Tadayon mitratadayon2000@yahoo.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