

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

22 Jun 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)

##### Phone

+98 31 3778 1644

##### Email address

kiani.shamim@ajums.ac.ir

##### 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**

Isfahan

**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**  
Ahvaz University of Medical Sciences  
**Full name of responsible person**  
Mitra Tadayon  
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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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Mitra Tadayon  
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the coach  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

#### Contact

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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