

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 Jul 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)

##### Phone

+98 31 3338 9259

##### Email address

bahar.sadeghian@ajums.ac.ir

##### 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                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | <b>Secondary Ids</b>                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Scientific title</b><br>The effect of mindfulness counseling on sexual self-efficacy of HIV positive women                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | empty                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Public title</b><br>The effect of mindfulness counseling on sexual self-efficacy of HIV positive women                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <b>Ethics committees</b>                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Purpose</b><br>Education/Guidance                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | <u>1</u>                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Inclusion/Exclusion criteria</b><br><b>Inclusion criteria:</b><br>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<br><b>Exclusion criteria:</b><br>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 | <b>Ethics committee</b><br><b>Name of ethics committee</b><br>Ethics Committee of Jundishapur University of Medical Sciences<br><b>Street address</b><br>Golestan Ave, Jundishapur University of Medical Sciences<br><b>City</b><br>Ahvaz<br><b>Province</b><br>Khuzestan<br><b>Postal code</b><br>15794-61357<br><b>Approval date</b><br>2021-03-17, 1399/12/27<br><b>Ethics committee reference number</b><br>IR.AJUMS.REC.1399.967 |
| <b>Age</b><br>From <b>25 years</b> old to <b>45 years</b> old                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <b>Health conditions studied</b>                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Gender</b><br>Female                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | <u>1</u>                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Phase</b><br>N/A                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | <b>Description of health condition studied</b><br>Human Immunodeficiency virus<br><b>ICD-10 code</b><br>B20<br><b>ICD-10 code description</b><br>Human immunodeficiency virus [HIV] disease                                                                                                                                                                                                                                           |
| <b>Groups that have been masked</b><br><i>No information</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | <b>Primary outcomes</b>                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Sample size</b><br>Target sample size: <b>66</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | <u>1</u>                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Randomization (investigator's opinion)</b><br>Randomized                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | <b>Description</b><br>sexual self-efficacy<br><b>Timepoint</b><br>At the beginning of the study, week 8 and week 12 after the intervention<br><b>Method of measurement</b><br>Sexual Self-Efficacy Questionnaire by Bells et al                                                                                                                                                                                                       |
| <b>Randomization description</b><br>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.                                                                                                                                                                                                                                         | <b>Secondary outcomes</b>                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Blinding (investigator's opinion)</b><br>Not blinded                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | empty                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Blinding description</b><br><b>Placebo</b><br>Not used<br><b>Assignment</b><br>Parallel<br><b>Other design features</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | <b>Intervention groups</b>                                                                                                                                                                                                                                                                                                                                                                                                            |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | <u>1</u>                                                                                                                                                                                                                                                                                                                                                                                                                              |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | <b>Description</b><br>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

### City

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### Province

Khouzestan

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### Phone

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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

#### Street address

Golestan St., Ahvaz University of Medical Sciences

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#### Phone

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#### Email

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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**  
Ph.D.  
**Other areas of specialty/work**  
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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

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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