

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### The effect of mindfulness counseling on self-esteem and psychological distress of HIV positive women

#### Protocol summary

##### Study aim

The effect of mindfulness counseling on self-esteem and psychological distress of HIV positive people

##### Design

The clinical trial has two groups of control and intervention block allocation method, on 46 patients.

##### Settings and conduct

The sample of HIV-positive women referred to the High-Risk Diseases Center in Ahvaz, who were selected from the research community. 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 Cooper-Smith self-esteem and depression BECK questionnaire as a self-report.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Willingness to participate in the study, Married, Age between 20-40 years old, Scoring less than 25 from Cooper Smith Questionnaire, Scoring less than 18 from BECK Depression Questionnaire, Continuous participation in group meetings, HIV positive women  
Exclusion criteria: Acute physical and other 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 self-esteem, severe psychiatric disorders, Occurrence of stressful and unfortunate events during the past 3 months, consumption of alcohol and psychotropic substances by the patient and his spouse during the past 3 months

##### Intervention groups

The control group includes HIV positive women with low self-esteem and psychological distress. During 8 sessions of group counseling mental cognitive therapy is performed with the aim of improving self-esteem and psychological distress. The control group does not intervene.

##### Main outcome variables

Self-esteem, General self-esteem, Social self-

esteem, Family self-esteem, Academic-occupational self-esteem, Anxiety level, Stress level, Depression level, Psychological distress

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210614051580N2**

Registration date: **2021-12-14, 1400/09/23**

Registration timing: **prospective**

Last update: **2021-12-14, 1400/09/23**

Update count: **0**

##### Registration date

2021-12-14, 1400/09/23

##### 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

2021-12-22, 1400/10/01

##### Expected recruitment end date

2022-03-21, 1401/01/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty  
**Trial completion date**  
empty

**Scientific title**  
The effect of mindfulness counseling on self-esteem and psychological distress of HIV positive women

**Public title**  
The effect of mindfulness counseling on self-esteem and psychological distress of HIV positive women

**Purpose**  
Education/Guidance

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Willingness to participate in research Married Age between 20-40 years Score less than 25 on the Cooper-Smith Questionnaire Score less than 18 on the BECK Depression Inventory Continuous participation in group meetings 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 **20 years** old to **40 years** old

**Gender**  
Female

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **46**

**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 Ahvaz University of Medical Sciences

**Street address**

Golestan St., Ahvaz University of Medical Sciences

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

15794-61357

**Approval date**

2021-01-23, 1399/11/04

**Ethics committee reference number**

lr.ajums.rec.1399.843

## 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**

Self-esteem

**Timepoint**

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

**Method of measurement**

Coopersmith Self-Esteem Questionnaire

### 2

**Description**

Public self-esteem

**Timepoint**

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

**Method of measurement**

Coopersmith Self-Esteem Questionnaire

### 3

**Description**

Social self-esteem

**Timepoint**

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

**Method of measurement**

#### 4

**Description**

Family self-esteem

**Timepoint**

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

**Method of measurement**

Coopersmith Self-Esteem Questionnaire

#### 5

**Description**

Academic-professional self-esteem

**Timepoint**

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

**Method of measurement**

Coopersmith Self-Esteem Questionnaire

#### 6

**Description**

Anxiety level

**Timepoint**

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

**Method of measurement**

Beck Depression Questionnaire

#### 7

**Description**

Stress levels

**Timepoint**

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

**Method of measurement**

Beck Depression Questionnaire

#### 8

**Description**

Level of depression

**Timepoint**

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

**Method of measurement**

Beck Depression Questionnaire

#### 9

**Description**

Psychological distress

**Timepoint**

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

**Method of measurement**

Beck Depression Questionnaire

## 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. 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 self-esteem and psychological disturbance of HIV-positive women. 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 of a raisin seed. And Body Exercise: A meditation in which participants focus their attention on the senses in different parts of the body through breathing. Session 2: (Facing Obstacles) Practice Examining the Body and Practicing Thoughts and Emotions: Participants visualize a scenario such as a friend not saying hello, then examine their reactions to such an event and the impact on 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 body 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) Sitting meditation 40 minutes Imagine thoughts 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 Session 7: (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 self-esteem and psychological turmoil. 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**

Khuzestan

**Province**

Khuzestan

**Postal code**

5587774144

**Phone**

+98 61 3445 4600

**Fax**

+98 61 3311 4329

**Email**

info@ajums.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Maryam Beheshti Nasab

**Street address**

Golestan St., Ahvaz University of Medical Sciences

**City**

Khuzestan

**Province**

Khuzestan

**Postal code**

15794-61357

**Phone**

+98 61 3311 4329

**Email**

info@ajums.ac.ir

**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**

Maryam Beheshti Nasab

**Position**

Instructor of Midwifery

**Latest degree**

Master

**Other areas of specialty/work**

Midwifery

**Street address**

Golestan St., Ahvaz University of Medical Sciences

**City**

AHWAZ

**Province**

Khuzestan

**Postal code**

15794-61357

**Phone**

+98 61 3311 4329

**Email**

MARY.MIDWIFE@GMAIL.COM

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Maryam Beheshtinasab

**Position**

Instructor of Midwifery

**Latest degree**

Master

**Other areas of specialty/work**

Midwifery

**Street address**

Golestan St., Ahvaz University of Medical Sciences

**City**

AHWAZ

**Province**

Khuzestan

**Postal code**

15794-61357

**Phone**

+98 61 3311 4329

**Email**

MARY.MIDWIFER@GMAIL.COM

## Person responsible for updating data

### Contact

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Maryam Beheshtinasab

**Position**

Instructor of Midwifery

**Latest degree**

Master

**Other areas of specialty/work**

Midwifery

**Street address**

Golestan St., Ahvaz University of Medical Sciences

**City**

Ahvaz

**Province**

Khouzestan

**Postal code**

15794-61357

**Phone**

+98 61 3311 4329

**Email**

Mary.midwifer@gmail.com

## 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. Maryam Beheshtinasab

**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**