Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 past3 months , consumption of alcohol and psychotropic substances by the patient and his spouse during the past 3months
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)
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+98 31 3778 1644
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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

Khouzestan

Postal code

15794-61357

Approval date

2021-01-23, 1399/11/04

Ethics committee reference number

Ir.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

Coopersmith Self-Esteem Questionnaire

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Maryam Beheshti Nasab

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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
Maryam Beheshti Nasab

Position
Instructor of Midwifery

Latest degree
Master

Other areas of specialty/work
Midwifery

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Person responsible for scientific inquiries

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Position
Instructor of Midwifery

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Master

Other areas of specialty/work
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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
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