Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Jun 2026

The effectiveness of mindfulness-based cognitive therapy on the happiness of women with HIV

Protocol summary

Study aim
Determining the effect of cognitive therapy based on mindfulness on the happiness of women with HIV

Design
Pre-post-test trial, follow-up with control group, with parallel groups, randomized

Settings and conduct
The sample of HIV-positive women referred to the center of high-risk diseases in Ahvaz, who were selected from among the research community and have low happiness, the total number of participants is 92, with 46 in each group. The intervention is carried out as a pre-test, post-test and follow-up stage, so that the intervention group completes the self-reported happiness questionnaire at the beginning of the study, immediately after completion and 8 weeks after the intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: HIV-positive women, willingness to participate in research, obtaining a score of less than 42 from the happiness questionnaire, age between 20-45 years. Inclusion criteria: suffering from moderate or severe depression according to the Beck depression questionnaire (score higher than 18), taking antidepressants, consuming alcohol and psychoactive substances by the patient, simultaneously benefiting from counseling and other educational services in order to increase happiness and well-being, major stressors in the last 3 months.

Intervention groups
The intervention and control group includes HIV positive women with low happiness, during 8 group counseling sessions (one session per week), with the cognitive therapy approach based on mindfulness with the aim of improving happiness. The control group received no intervention.

Main outcome variables
happiness; Life satisfaction ; Self-esteem ; positive mood; the health ; Efficiency

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20231004059614N1**
Registration date: **2023-10-12, 1402/07/20**
Registration timing: **prospective**

Last update: **2023-10-12, 1402/07/20**
Update count: **0**

Registration date
2023-10-12, 1402/07/20

Registrant information

Name
Nahid Asadi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 61 3445 5959

Email address
nahid.asadi.mid@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-10-23, 1402/08/01

Expected recruitment end date
2024-03-10, 1402/12/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effectiveness of mindfulness-based cognitive therapy on the happiness of women with HIV

Public title

The effectiveness of mindfulness-based cognitive therapy on the happiness of women with HIV

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Consent and informed desire to participate in the research Ability to participate in meetings and cooperate in doing assignments Physical and psychological stability (not having obvious physical or psychological symptoms that interfere with participation in meetings, such as fatigue, muscle pain, etc.) Having at least reading and writing literacy Obtaining a score less than 42 from the happiness questionnaire Age range between 20 and 45 years Having a test (rapid test or ELISA) that shows that the person is HIV positive One year has passed since the person was infected with HIV

Exclusion criteria:

The presence of acute and severe symptoms of the disease in a way that makes it difficult or almost impossible for the patient to participate in the present study Suffering from moderate or severe depression according to the Beck depression questionnaire (getting a score higher than 18 Taking antidepressants consumption of alcohol and psychoactive substances by the patient بهره مندی همزمان از مشاوره و خدمات آموزشي ديگر در جهت افزایش شادکامی و بهزیستی Major stressors in the last 3 months such as loss of loved ones and divorce

Age

From **20 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **92**

Randomization (investigator's opinion)

Randomized

Randomization description

The current research will be a clinical trial study that will be conducted with the aim of determining the effectiveness of cognitive therapy based on mindfulness on the happiness of women with HIV. After obtaining the code of ethics and registration in the clinical trial center, and obtaining the letter of recommendation, the researcher will visit the high-risk disease center in Ahvaz in person to collect the samples. Using targeted sampling, samples will be selected from women who are eligible and who meet the entry criteria and do not have the exit criteria. Due to the lack of presence of all women in the center at the same time, the researcher will conduct the sampling both in person and from the files registered in the center in such a way that he will extract the contact numbers of the people from the file and firstly about the objectives of the research and how The intervention will give the same explanation to each eligible person and ask for written consent from the eligible people. Completing the demographic, depression and happiness questionnaire will be done by the samples who meet the conditions for entering the study (the researcher will be present at the center and if the participants have any questions, he will answer their questions). One of the conditions for entering the study is to score less than 42 in the happiness questionnaire total number of participants in the study will be 92 people based on statistical calculations, and 46 people will enter the research in each group. After the initial selection of the samples, the method of assigning people to the control and test groups will be randomly and blocks of four (using the table of random permutations). After determining the size of the block, which is 4 in this study, a list of blocks (23 blocks of 4) will be prepared and numbers will be assigned to them, then random numbers between 1 and 6 will be selected (1) AABB, (2) ABAB, (3) ABBA, (4) BBAA, (5) BABA, (6) BAAB). Due to the nature of this study, it will not be possible to blind the researcher and the participant. Since the sample size of people in the mindfulness treatment group should not exceed 14 people, because the effectiveness of psychotherapy decreases with the increase in the number of groups, so the intervention group was divided into 4 groups (2 groups of 11 people and 2 groups of 12 people)) will be divided, then the intervention will be implemented in the form of 8 counseling sessions and a follow-up phase (8 weeks after the end of the counseling sessions) so that all women in both groups (intervention and control) at the beginning and immediately after the intervention and 8 weeks (39) After the end of the intervention, they will complete the happiness questionnaire in the form of self-reporting. Counseling will be done by a trained researcher (the researcher will participate in a three-day mindfulness workshop and receive a certificate) under the supervision of the respected scientific advisor at the center. The women of the intervention group will undergo 8 group counseling sessions (one session per week) with a cognitive therapy approach based on mindfulness with the aim of improving happiness. The content of the sessions will be compiled using the book "Mindfulness-Based Interventions in the Context: Past, Present and Future" written by Kabat Zain and under the supervision of the scientific advisor of the research. Group meetings, one 90-minute meeting per week will be held between the counselor and the clients according to the schedule. Considering that the control group will not receive any intervention despite the low happiness, in order to comply with the ethical standards, after completing the study, they will be given a training booklet and a summary of the contents of the sessions.

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 Jundishapur University of Medical Sciences

Street address

Golestan Street, Jundishapur University of Medical Sciences

City

Ahvaz

Province

Khouzestan

Postal code

15794-61357

Approval date

2023-10-08, 1402/07/16

Ethics committee reference number

IR.AJUMS.REC.1402.344

Health conditions studied

1

Description of health condition studied

Human immunodeficiency virus [HIV] disease

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

happiness

Timepoint

At the beginning and immediately after the end of the intervention and 8 weeks after the end of the intervention

Method of measurement

Oxford Happiness Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: Using targeted sampling, samples will be selected from women who are eligible and who meet the entry criteria and do not have the exit criteria. Due to the lack of presence of all women in the center at the same time, the researcher will conduct the sampling both in person and from the files registered in the center in such a way that he will extract the contact numbers of the people from the file and firstly about the objectives of the research and how The intervention will give the same explanation to each eligible person and ask for written consent from the eligible people. Completing the demographic, depression and happiness questionnaire will be done by the samples who meet the conditions for entering the study (the researcher will be present at the center and if the participants have any questions, he will answer their questions). One of the conditions for entering the study is to score less than 42 in the happiness questionnaire. The total number of participants in the study will be 92 people based on statistical calculations, and 46 people will enter the research in each group. After the initial selection of the samples, the method of assigning people to the control and test groups will be randomly and blocks of four (using the table of random permutations). After determining the size of the block, which is 4 in this study, a list of blocks (23 blocks of 4) will be prepared and numbers will be assigned to them, then random numbers between 1 and 6 will be selected (1) AABB, (2) ABAB, (3) ABBA, (4) BBAA, (5) BABA, (6) BAAB). Due to the nature of this study, it will not be possible to blind the researcher and the participants. Since the sample size of people in the group therapy with mindfulness approach should not exceed 14 people, because the effectiveness of psychotherapy decreases with the increase in the number of groups, so the group The intervention will be divided into 4 groups (2 groups of 11 people and 2 groups of 12 people), then the intervention will be implemented in the form of 8 counseling sessions and a follow-up phase (8 weeks after the end of the counseling sessions) so that all the women of both groups (intervention and control) at the beginning and immediately after the end of the intervention and 8 weeks (39) after the end of the intervention, they will complete the happiness questionnaire in the form of self-reporting. Counseling will be done by a trained researcher (the researcher will participate in a three-day mindfulness workshop and receive a certificate) under the supervision of the respected scientific advisor at the center. The women of the intervention group will undergo 8 group counseling sessions (one session per week) with a cognitive therapy approach based on mindfulness with the aim of improving happiness. The content of the sessions will be compiled using the book "Mindfulness-Based Interventions in the Context: Past, Present and Future" written by Kabat Zain and under the supervision of the scientific advisor of the research (46). Group meetings, one 90-minute meeting per week will be held between the counselor and the clients according to the schedule.

Category

Other

2

Description

Control group: Considering that the control group will not receive any intervention despite the low happiness, in order to comply with the ethical standards, after

completing the study, they will be given a training booklet and a summary of the contents of the sessions.

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 Karmani - Zawiya Street - next to Abu Dhar Hospital - in front of Hedayat Alley - upper floor of children's clinic

City
Ahvaz

Province
Khouzestan

Postal code
5587774144

Phone
+98 61 3445 4600

Fax

Email
fgnrfrd@ygug.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Parvaneh Mousavi

Street address
Golestan Blvd., Esfand St., Jundishapur University of Medical Sciences, Faculty of Nursing and Midwifery.

City
Ahvaz

Province
Khouzestan

Postal code
61357-15794

Phone
+98 61 3373 8385

Email
mousavi-p@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
Nahid asadi

Position
student

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

Street address
Faculty of Nursing and Midwifery, Jundishapur university of medical sciences, Esfand Ave.,Golestan Blv.

City
Ahvaz

Province
Khouzestan

Postal code
15794 - 61357

Phone
+98 61 3373 8538

Email
nahid.asadi.mid@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Parvaneh Mousavi

Position
Midwifery instructor

Latest degree
Master

Other areas of specialty/work
Midwifery

Street address
Faculty of Nursing and Midwifery, Jundishapur university of medical sciences, Esfand Ave.,Golestan Blv.

City
Ahvaz

Province
Khouzestan

Postal code
15794 - 61357

Phone

+98 61 3373 8385

Email

mousavi-p@ajums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Nahid ASADI

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

Faculty of Nursing and Midwifery., Jundishapur university of medical sciences, Esfand Ave.,Golestan Blv.

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Phone

+98 61 3373 8538

Email

nahid.asadi.mid@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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