Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effectiveness of mindfulness-based cognitive therapy and Silva-based relaxation therapy on psychological capital, social anxiety and CD4 count in people with HIV

Protocol summary

Study aim

Comparison of the effectiveness of mindfulness-based cognitive therapy and Silva-based relaxation therapy on psychological capital, social anxiety and CD4 count in people with HIV

Design

90 people with HIV will be selected as a research sample. Then the statistical sample was randomly divided into 3 different groups; Group 1: Cognitive therapy based on mindfulness (30 people), Group 2: Silva method relaxation (30 people), and Group 3: Control (30 people) will be replaced.

Settings and conduct

This study is in the field of psychology education and will be conducted at the Behavioral Diseases Counseling Center of Imam Khomeini Hospital in Tehran.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Infected with HIV، Having full satisfaction for cooperation، Absence of acute disorders in the field of psychology and psychiatry، Not using drugs; Psychiatric drugs، Being literate in reading and writing Exclusion criteria: Refusal to cooperate with the researcher، Absence of more than two sessions in therapy training

Intervention groups

90 people will be randomly divided into 3 different groups: cognitive therapy based on mindfulness (30 people), Silva method relaxation (30 people) and control (30 people). In this research, cognitive therapy training based on mindfulness and relaxation will be conducted in the Silva way. Before implementing the aforementioned treatments, a pre-test will be performed for all three groups (completion of Lutans psychological capital and Lajarka social anxiety questionnaires, as well as 2 ml blood sampling (CD4)). Then, after two weeks of completing the training, the post-test will be conducted for all 3 groups, similar to the pre-test.

Main outcome variables

Evaluation of effective and applicable community-based interventions to promote mental health literacy in HIV-positive groups

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210216050373N5**
Registration date: **2023-03-11, 1401/12/20**
Registration timing: **prospective**

Last update: **2023-03-11, 1401/12/20**
Update count: **0**

Registration date

2023-03-11, 1401/12/20

Registrant information

Name

Seyed ahmad Seyed alinaghi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6658 1583

Email address

s_a_alinaghi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-03, 1402/01/14

Expected recruitment end date

2023-06-21, 1402/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of mindfulness-based cognitive therapy and Silva-based relaxation therapy on psychological capital, social anxiety and CD4 count in people with HIV

Public title

Comparison of the effectiveness of mindfulness-based cognitive therapy and Silva-based relaxation therapy on psychological capital, social anxiety and CD4 count in people with HIV

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

HIV infection Having full consent to cooperate Absence of acute disorders in the field of psychology and psychiatry Not using drugs; Psychiatric drugs Being literate in reading and writing

Exclusion criteria:

Refusing to cooperate with the researcher Absence of more than two sessions in therapy training

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

More than 1 sample in each individual

Number of samples in each individual: **2**

90 people with HIV will be selected as a research sample. Then the statistical sample was randomly divided into 3 different groups including Group 1: Mindfulness-based cognitive therapy (30 people), Group 2: Silva-based relaxation therapy (30 people) and Group 3: Control (30 people) will be replaced.

Randomization (investigator's opinion)

Randomized

Randomization description

The block randomization method will be used for randomization. According to the three study groups, blocks of fixed size will be used in this research, with six patients in each block. After generating the randomization sequence using the software (Random allocation software), the central randomization method will be used for allocation concealment. To implement allocation concealment using the central randomization method, the generated randomization sequence is provided to the research department of the Iranian Research Center for HIV/AIDS (IRCHA). After the patients' eligibility to enter the study and obtaining written informed consent from the patients, the researchers will call (phone) the relevant center (IRCHA) and ask about the allocation of the participants to the study groups.

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 Imam khomeini Hospital Complex- Tehran University of Medical Sciences

Street address

Imam Khomeini Hospital Complex, Tohid Square, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1419733141

Approval date

2023-02-14, 1401/11/25

Ethics committee reference number

IR.TUMS.IKHC.REC.1401.391

Health conditions studied

1

Description of health condition studied

HIV-1 infection

ICD-10 code

B20

ICD-10 code description

Human immunodeficiency virus [HIV] disease

Primary outcomes

1

Description

Conscious attention in the present with acceptance and non-judgment

Timepoint

1- At the beginning of the study (before the start of the intervention) 2- 14 days after the last educational intervention

Method of measurement

Questionnaire

2

Description
Awareness and alertness based on care and attention
Timepoint
1- At the beginning of the study (before the start of the intervention) 2- 14 days after the last educational intervention
Method of measurement
Questionnaire

3

Description
Increase mental strength and concentration
Timepoint
1- At the beginning of the study (before the start of the intervention) 2- 14 days after the last educational intervention
Method of measurement
Questionnaire

4

Description
CD4 count
Timepoint
1- At the beginning of the study (before the start of the intervention) 2- 14 days after the last educational intervention
Method of measurement
Blood test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Mindfulness-based cognitive therapy group training: Before the training, a pre-test will be conducted. In this way, the research questionnaires (Lutans psychological capital and Lajarka social anxiety) will be completed. Also, 2 ml blood sampling will be done for the CD4 count. After the pre-test, cognitive therapy sessions based on mindfulness will be held twice a week for one month (each training session is 40 minutes). After two weeks of training, the "post-test" will be conducted like the pre-test.
Category
Lifestyle

2

Description
Intervention group 2: Silva-based relaxation therapy: Group relaxation training in the Silva method: Before the implementation of the training, a pre-test will be performed. In this way, the research questionnaires (Lutans psychological capital and Lajerka social anxiety) will be completed. Also, 2 ml blood sampling will be done for the CD4 count. After the pre-test, the Silva relaxation sessions will be held twice a week for one month (each training session is 40 minutes). After two weeks of training, the "post-test" will be conducted like the pre-test.
Category
Lifestyle

3

Description
Control group: they don't see any training. The pre-test will be conducted in such a way that the research questionnaires (Lutans psychological capital and Lajarka social anxiety) will be completed. Also, 2 ml of blood sampling will be done for the CD4 count. After the pre-test and after cognitive therapy training sessions based on mindfulness and Silva-based relaxation therapy were implemented for the intervention groups, after two weeks From the implementation of the trainings, the "post-test" will be implemented like the pre-test for the control group.
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Iranian Research Center for HIV/AIDS
Full name of responsible person
Seyed Ahmad Seyed Alinaghi
Street address
Imam Khomeini Hospital Complex, Tohid Square, Tehran, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Vice-Chancellors of Research and Technology of Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Pegah Mirzapour

Position
Student

Latest degree
Ph.D.

Other areas of specialty/work
Psychology

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Imam Khomeini Hospital Complex, Tohid Square, Tehran, Iran

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Person responsible for scientific inquiries

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Epidemiology

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Person responsible for updating data

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Position
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Ph.D.

Other areas of specialty/work
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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
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

The research results will be presented and published only in the form of reports and articles.

When the data will become available and for how long

The access period starts 6 months after the results are published.

To whom data/document is available

It will be available to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

Researchers for use in articles and reports, especially systematic review articles.

From where data/document is obtainable

To receive the required documents or data, refer to the project manager, Dr. Seyed Ahmad Seyed Alinghi, at the Iranian Research Center for HIV/AIDS. Phone number: 00982166581583 Email: s.a.alinaghi@gmail.com Address: Iranian Research Center for HIV/AIDS, behind the Infectious Diseases Building, Imam Khomeini Hospital Complex, end of Keshavarz Boulevard, Tehran.

What processes are involved for a request to access data/document

After making the call(Phone, meet, Email) and providing the necessary documents(Written request), the documents or data files will reach the applicant.

Comments