

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jun 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 Lajarka 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

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 912 644 8153

Email

s.a.alinaghi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

SeyedAhmad SeyedAlinaghi

Street address

Imam Khomeini Hospital Complex, Tohid Square, Tehran, Iran

City

Tehran
Province
Tehran
Postal code
1419733141
Phone
+98 912 644 8153
Email
s.a.alinaghi@gmail.com
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
Street address
Imam Khomeini Hospital Complex, Tohid Square,
Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1419733141
Phone
+98 919 436 5685
Email
pegah.mirzapour@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
SeyedAhmad SeyedAlinaghi
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Epidemiology
Street address
Imam Khomeini Hospital Complex, Tohid Square,
Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1419733141
Phone
+98 912 644 8153
Email
s.a.alinaghi@gmail.com

Person responsible for updating data

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
Street address
Imam Khomeini Hospital Complex, Tohid Square,
Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1419733141
Phone
+98 919 436 5685
Email
pegah.mirzapour@yahoo.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
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