# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 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
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Imam Khomeini Hospital Complex, Tohid Square, Tehran, Iran
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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
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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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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Other areas of specialty/work**
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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**