

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Investigating the effectiveness of brief acceptance and commitment therapy (ACT) on reducing the symptoms of depression, anxiety, stress, rumination and worry, and increasing the quality of life and the number of CD4 lymphocytes in people with HIV.

Protocol summary

Study aim

Investigating the effectiveness of short-term acceptance and commitment therapy (ACT) on reducing the symptoms of depression, anxiety, stress, rumination and worry, and increasing the quality of life and the number of CD4 lymphocytes in people with HIV

Design

This study is a single-blind clinical trial, and the sample collection method is available. 60 people are selected in two groups of 30 including the intervention group (four-session form of acceptance and commitment therapy in the form of 60 to 90-minute sessions that are conducted individually once a week by a PhD student in clinical psychology The observed course will be implemented for them under the supervision of the supervisor) and the control group will be replaced. Allocation of people to two groups will be in the form of block randomization which will be done by RANDOM ALLOCATION SOFTWARE after the completion of the treatment sessions and also at the end of each period of follow-up (2-6-12 months), the questionnaires will be re-implemented.

Settings and conduct

Imam Khomeini Hospital, Iran AIDS Study Center

Participants/Inclusion and exclusion criteria

Inclusion criteria: having informed consent to participate in the research and sign a written consent form; age over 18 years old; not having an active addiction; not suffering from severe psychiatric disorders; score equal to or above 9 in the PHQ-9 questionnaire. Exit criteria: receiving other treatments at the same time; report suicidal thoughts or intent; absence of more than 3 consecutive sessions; taking psychotropic drugs; unwillingness to participate in treatment.

Intervention groups

People with HIV who are under the care of Iran AIDS Study Center are treated with four sessions of ACT. To

achieve the goal of a full, rich and meaningful life

Main outcome variables

Improving quality of life and reducing symptoms related to mental health

General information

Reason for update

Acronym

HIV-ACT

IRCT registration information

IRCT registration number: **IRCT20230809059103N1**

Registration date: **2023-09-28, 1402/07/06**

Registration timing: **prospective**

Last update: **2023-09-28, 1402/07/06**

Update count: **0**

Registration date

2023-09-28, 1402/07/06

Registrant information

Name

farshad aliyari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6562 3484

Email address

farshadaliyari98@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-22, 1402/07/30

Expected recruitment end date

2024-02-19, 1402/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effectiveness of brief acceptance and commitment therapy (ACT) on reducing the symptoms of depression, anxiety, stress, rumination and worry, and increasing the quality of life and the number of CD4 lymphocytes in people with HIV.

Public title

Investigating the effectiveness of brief acceptance and commitment therapy (ACT) on reducing the symptoms of depression, anxiety, stress, rumination and worry, and increasing the quality of life and the number of CD4 lymphocytes in people with HIV.

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Having informed consent to participate in the research and sign a written consent form Age over 18 years Not having an active addiction Not suffering from severe psychiatric disorders A score equal to or above 9 in the PHQ-9 questionnaire

Exclusion criteria:

Receiving other treatments at the same time Report suicidal thoughts or intent Absence of more than 3 consecutive sessions Taking psychotropic drugs Unwillingness to participate in treatment

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Allocation of people to two groups will be done by block randomization, which will be done by RANDOM ALLOCATION SOFTWARE, in this method, both groups will have the same number of subjects, which will minimize the effect of confounding variables.

Blinding (investigator's opinion)

Single blinded

Blinding description

The participants will not be aware of their allocation to the control and experimental groups, and the people who are in the control group will be told that your intervention (according to the time required to perform

interventions on the experimental group) will begin some time later.

Placebo

Not used

Assignment

Other

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

Faculty of Medicine - Shahid Beheshti University of Medical Sciences

City

tehran

Province

Tehran

Postal code

193954631

Approval date

2023-07-24, 1402/05/02

Ethics committee reference number

IR.SBMU.MSP.REC.1402.210

Health conditions studied**1****Description of health condition studied**

HIV

ICD-10 code

B20

ICD-10 code description

Human immunodeficiency virus [HIV] disease

Primary outcomes**1****Description**

Symptoms of depression, anxiety, stress,

Timepoint

The beginning and end of the study, TWO months later, six months later and twelve months later

Method of measurement

.Depression: the score that a person gets in the depression subscale of the DAAS questionnaire.Anxiety: the score that a person gets in the anxiety subscale of the DAAS questionnaire.Stress: the score that a person gets in the stress subscale of the DAAS questionnaire.

2

Description

Quality of life

Timepoint

The beginning and end of the study, TWO months later, six months later and twelve months later

Method of measurement

(WHO-QOL-BRIEF)

3

Description

Worry

Timepoint

The beginning and end of the study, TWO months later, six months later and twelve months later

Method of measurement

PSWQ

4

Description

Rumination

Timepoint

The beginning and end of the study, TWO months later, six months later and twelve months later

Method of measurement

(RRS)

5

Description

CD4 lymphocytes

Timepoint

The beginning and end of the study, TWO months later, six months later and twelve months later

Method of measurement

CD4 count by flow cytometry and complete blood count will be determined by a licensed clinical laboratory in Imam Khomeini Hospital.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: this group is subjected to the same four session ACT treatment intervention

Category

Treatment - Other

2

Description

Control group: After the intervention group, they are subjected to the same treatment measures.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital, Iran AIDS Study Center

Full name of responsible person

DR. SEYED AHMAD SEYED ALINAGHI

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Imam Khomeini Hospital

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1419733141

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Abbas Masjedi

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shahid beheshti medical science university

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Web page address

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Private

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Amirsam Kiani Moghadam

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Person responsible for updating data

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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

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

No - There is not a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

results will be published in the article that will be written after finishing the thesis.

When the data will become available and for how long

After finishing the thesis and writing the article

To whom data/document is available

researchers

Under which criteria data/document could be used

Researchers who research HIV treatment

From where data/document is obtainable

National Center for AIDS Studies

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

The request should be sent to the deputy of the research center, Dr. Ali Naghi, via email and will be reviewed by him.

Comments