Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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)

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+98 21 6562 3484

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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
Street address
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