# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

20 Nov 2026

## Effectiveness of acceptance and commitment therapy on reducing depression among people living with HIV/AIDS

## Protocol summary

**Summary**

The aim of the current study is determining the effectiveness of Acceptance and Commitment Therapy (ACT) on depression among HIV/AIDS patients. This quasi-experimental study is performed using pretest-posttest with the experimental and control groups. The study population consist of all HIV/AIDS patients referring to Imam Khomeini hospital in 2016. Twenty four patients will be selected by convenience sampling method and randomly assigned to the experimental and control groups based on inclusion criteria (containing: HIV positive patients; age between 20-65 years; getting at least 14 scores in the Beck Depression Inventory (BDI-II); having mild depression). Participants will be excluded from the study if they do not complete the therapy sessions. The experimental group (n=12) receive eight training sessions of ACT that each session lasts 60 minutes. The control group receives no intervention. Main outcome variable is depression.

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT201701304076N20**
Registration date: **2017-08-07, 1396/05/16**
Registration timing: **retrospective**

Last update:
Update count: **0**

**Registration date**

2017-08-07, 1396/05/16

**Registrant information**

**Name**

Minoo Mohraz

**Name of organization / entity**

Iranian Research Center for HIV/AIDS, Tehran University of Medical Sciences

**Country**

Iran (Islamic Republic of)

**Phone**

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**Recruitment status**

**Recruitment complete**

**Funding source**

Vice chancellor for research, Islamic Azad University, Central Tehran Branch

**Expected recruitment start date**

2016-04-19, 1395/01/31

**Expected recruitment end date**

2016-05-09, 1395/02/20

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Effectiveness of acceptance and commitment therapy on reducing depression among people living with HIV/AIDS

**Public title**

Effect of acceptance and commitment therapy on depression

**Purpose**

Supportive

**Inclusion/Exclusion criteria**

Inclusion criteria: HIV positive patients; age between 20-65 years; getting at least 14 scores in the Beck Depression Inventory (BDI-II); having mild depression.
Exclusion criteria: Not completing the therapy sessions.

**Age**

From **20 years** old to **65 years** old

**Gender**

Both

**Phase**
2
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **24**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
**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 Islamic Azad University Tehran Medical Branch
**Street address**
Tehran Medical Branch, Islamic Azad University, Khaghani St, Shariati Ave, Tehran, Iran
**City**
Tehran
**Postal code**
**Approval date**
2017-07-26, 1396/05/04
**Ethics committee reference number**
IR.IAU.TMU.REC.1396.74

## Health conditions studied

### 1

**Description of health condition studied**
HIV/AIDS
**ICD-10 code**
B24
**ICD-10 code description**
Unspecified human immunodeficiency virus [HIV] disease

### 2

**Description of health condition studied**
Depression
**ICD-10 code**
F32
**ICD-10 code description**
Depressive episode

## Primary outcomes

### 1

**Description**
Depression
**Timepoint**
Before intervention, after intervention
**Method of measurement**
Beck Depression Inventory (BDI-II)

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group: Intervention group participants receive eight training sessions of ACT that each session lasts 60 minutes. In summary, Goals of therapy sessions include: session 1) Making therapeutic relationship, Introducing the creative hopelessness. session 2) Helping clients recognize the dysfunctional control strategies and finding out the futility of them, Explaining differences between clean and dirty discomfort. session 3) Discussing about “Control is the problem, not the solution”, Introducing the acceptance (willingness) concept. session 4) Training mindfulness practices, Introducing the cognitive defusion. session 5) Continuing mindfulness practices, Introducing the conceptualized self and self as context. session 6) Continuing mindfulness practices, Introducing the value concept. session 7) Continuing mindfulness practices, Identifying goals and behavior models for reaching values. session 8) Continuing mindfulness practices, Emphasizing the committed action, Summarizing group therapy sessions.
**Category**
Behavior

### 2

**Description**
Control group: There is no intervention for control group.
**Category**
N/A

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Tehran Positive Club
**Full name of responsible person**
Matin Faezipour
**Street address**
Imam Khomeini Hospital, Keshavarz BLVd
**City**
Tehran

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Vice chancellor for research, Islamic Azad University, Central Tehran Branch
**Full name of responsible person**
Nader Beygzadeh
**Street address**
Building No.2, Valiasr complex, Next to Buali Hospital, Damavand St, Imam Hossein Sq.
**City**
Tehran
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Vice chancellor for research, Islamic Azad University, Central Tehran Branch
**Proportion provided by this source**
100
**Public or private sector**
*empty*
**Domestic or foreign origin**
*empty*
**Category of foreign source of funding**
*empty*
**Country of origin**
**Type of organization providing the funding**
*empty*

## Person responsible for general inquiries

**Contact**
**Name of organization / entity**
Islamic Azad University, Central Tehran Branch
**Full name of responsible person**
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Master of science
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## Person responsible for scientific inquiries

**Contact**
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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
*empty*
**Study Protocol**
*empty*
**Statistical Analysis Plan**
*empty*
**Informed Consent Form**
*empty*
**Clinical Study Report**
*empty*
**Analytic Code**
*empty*

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|---|---|
| **Data Dictionary** | *empty* |