

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effectiveness of mindfulness based cognitive group therapy on reducing depression and anxiety symptoms and improving quality of life in AIDS patients

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

Determining the Effectiveness of Mindfulness-Based Cognitive Group Therapy (MBCT) on Reducing Depression, Anxiety, and Improving Quality of Life

Design

This study is a pretest-posttest clinical trial with control group

Settings and conduct

Samples were randomly assigned to one of two experimental and control groups. The number of participants in both groups was 40 (20 female, 20 male). The participants in both the experimental and control groups (BDI Depression Inventory, Beck Anxiety Inventory BAI, and SF-36 Quality of Life Questionnaire) were simultaneously carried out At the Bu-Ali Center of the Shahid Beheshti University of Medical Sciences

Participants/Inclusion and exclusion criteria

Beck Depression Score (BDI) scores between 20 and over 40 (mild to severe) Beck Anxiety Score (BAI) Between 20 and Over 40 (Mild to Severely) Ability and willingness to participate in the study Not having a particular speech and hearing problem Having a minimum level of middle school education

Intervention groups

20 AIDS patients in the intervention group 20 AIDS patients in the control group

Main outcome variables

Depression, Anxiety, Quality of life

General information

Reason for update

Acronym

AIDS

IRCT registration information

IRCT registration number: **IRCT20180312039056N1**

Registration date: **2018-06-12, 1397/03/22**

Last update: **2018-06-12, 1397/03/22**

Update count: **0**

Registration date

2018-06-12, 1397/03/22

Registrant information

Name

Seyed Mojtaba Ahmadi

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-09, 1397/01/20

Expected recruitment end date

2018-07-22, 1397/04/31

Actual recruitment start date

2018-04-09, 1397/01/20

Actual recruitment end date

2018-07-22, 1397/04/31

Trial completion date

empty

Scientific title

The effectiveness of mindfulness based cognitive group therapy on reducing depression and anxiety symptoms and improving quality of life in AIDS patients

Public title

The effectiveness of mindfulness based cognitive group

therapy on reducing depression and anxiety symptoms and improving quality of life in AIDS patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Beck Depression Score (BDI) scores between 20 and over 40 (mild to severe) Beck Anxiety Score (BAI) Between 20 and Over 40 (Mild to Severely) Power and willingness to participate in the study Not having a particular speech and hearing problem Having a minimum level of cycle education

Exclusion criteria:

Abuse or dependency to drug during treatment The presence of symptoms of psychosis TB disease

Age

From **24 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **40**

Actual sample size reached: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples were randomly assigned to one of two experimental and control groups, The number of participants in both groups was 20 (10 female, 10 male), At one time, the participants in both the experimental and control groups (BDI Depression Inventory, Beck Anxiety Inventory BAI, and SF-36 Quality of Life Questionnaire) were administered.

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants in the intervention and control group were evaluated on different days and without knowledge of the program of the other group

Placebo

Not used

Assignment

Parallel

Other design features

Among all people with (AIDS) referred to the Behavioral Disease Counseling Center, which had conditions for group treatment (MBCT), 40 male (male / female) patients who had entered the study based on entry criteria (age range from 24 to 50 years of non-addictive status, lack of tuberculosis) were available in a sampling method. Simple randomization was placed in one of the two experimental and control groups. The number of subjects in each of the experimental groups was 20 (10 female, 10 male) and 20 subjects (10 female, 10 male), At one time, for both experimental and control groups, a BDI depression questionnaire, BAI anxiety inventory and SF-36 quality of life questionnaire were used. After pre-

test, MBCT treatment program was performed for 8 sessions for the experimental group and no program was performed for the control group during this period. One month after the end of the training sessions, in order to compare the effect of the intervention, both groups were tested and the results of the pre-test and post-test were compared for each group, Also, about the rules of participation in the research such as secrecy, observance of order and regular attendance at the training sessions, the participants were explained and the general trend of the program and training sessions was explained to them. After the end of the study, the control group performed 8 sessions of treatment.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Academic Ethics Committee on Biomedical Research
170

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7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo
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Approval date

2015-05-31, 1394/03/10

Ethics committee reference number

SBMU.REC.1394.34

Health conditions studied

1

Description of health condition studied

AIDS

ICD-10 code

B24

ICD-10 code description

AIDS

Primary outcomes

1

Description

Depression

Timepoint

Before and immediately after the intervention and one month after the end of the treatment

Method of measurement

Beck Depression Inventory

2

Description

anxiety

Timepoint

Before and immediately after the intervention and one month after the end of the treatment

Method of measurement

Beck Anxiety Inventory

3

Description

Quality of Life

Timepoint

Before and immediately after the intervention and one month after the end of the treatment

Method of measurement

Short-Form Health Survey Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: This group will receive mindfulness based cognitive group therapy. The treatment includes eight weeks (one session per week for 45 minutes)..A guide to mindfulness based on cognitive-behavioral therapy of Segal et al. Was used. The content of each session is: Session 1: An Explanation of the Importance of Present Attendance and the Concept of Mindfulness for Patients Session 2: Body checkout, 10 minutes of mind-set on the respiratory flow, training for recording the desired events, exercising thoughts and feelings, defining emotions and identifying the positive and negative emotions. Session 3: Relax the wandering mind with breathing exercises and body browsing Session 4: Awareness of breathing, body, sounds and thoughts. Session 5: Complete awareness of thoughts and feelings and acceptance without judgment and direct intervention Session 6: Awareness of breathing, body, sounds and thoughts, communicating with your thoughts and feelings and expanding them, and accepting unwanted thoughts and emotions without judgment, discussing that thoughts are not reality. Session 7: Awareness of breathing, body, sounds and thoughts, understanding the relationship between activity and creation, providing a list of pleasurable activities and activities that feel the mastery of a person, 3 minutes of regular breathing space. Session 8: Planning for the future and using the techniques of being present to continue their lives and generalizing them to the whole life cycle.

Category

Treatment - Other

2

Description

Control group: control group

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Boouli Behavioral Disease Counseling Center

Full name of responsible person

Dr. Sedgh Azar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

10

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

Fsa.psy@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Seyyed Mojtaba Ahmadi

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Latest degree

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Email**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

Yes - There is a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is 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

spss پروتکل درمان و داده وارد شده به نرم افزار

When the data will become available and for how long

After printing the first article

To whom data/document is available

Researchers working on similar topics

Under which criteria data/document could be used

Contact the scientific writer in the present article and obtain permission from them

From where data/document is obtainable

corresponding author

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

Allow the authorities of this trial to provide data

Comments