

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

The Comparison between of the Effectiveness of Cognitive-Behavioral Group Therapy ; Cognitive Therapy based on Mindfulness and combined therapy of Cognitive_ Behavioral /The recognition of the Therapy based on Mindfulness on Improving Sleep Quality, life Quality Perceived Social Support and Increase CD4 in Admitted HIV/AIDS

Protocol summary

Study aim

Improve CD4; HIV / AIDS patients

Design

The present study was a semi-experimental applied study and a targeted sampling method was available. The sample size was 45 people in 3 groups of 15 and Sampling interstitial permutation block was used. To determine the subjects, the subjects were classified into 4 classes according to age category and sex in each category.

Settings and conduct

This research will be carried out on 45 HIV / AIDS patients at the Ahvaz Counseling Center for Behavioral Disease and will be treated for at least 16 weeks of psychological interventions. Each treatment group is 15 people. After coordination with the Center for Behavioral Disease Counseling, a telephone conversation will be held to convene psychological treatment sessions. Also, according to the treatment, the control group for each treatment group of 15 people is included in this study. It should be noted that, in certain medical conditions, consultation with the infectious clinic at the Counseling Center for Behavioral Diseases is required. For monitoring the subjects, 3 to 4 months of intervention and 2 months of Follow up are considered.

Participants/Inclusion and exclusion criteria

entry : Age 25 to 50 years old, A resident of Ahwaz .
Minimum education Ability to speak fluent persian.
Minimum 350 CD4 patients. Exclusion criteria included:
Taking psychosocial drugs . having addiction and suicidal thoughts.

Intervention groups

Subjects in the target group were closed for 8 sessions.
The 45-minute meeting time is 16 weeks. Before the

intervention and after that the questionnaire will be completed. Questionnaire is given to the control group before and after the intervention..

Main outcome variables

Quality of life, quality of life, perceived social support and changes in CD4 cells

General information

Reason for update

Acronym

HIV/AIDS

IRCT registration information

IRCT registration number: **IRCT20190223042813N1**

Registration date: **2019-09-02, 1398/06/11**

Registration timing: **retrospective**

Last update: **2019-09-02, 1398/06/11**

Update count: **0**

Registration date

2019-09-02, 1398/06/11

Registrant information

Name

Shahla Molavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3558 5677

Email address

shahla_molavi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-06, 1398/02/16

Expected recruitment end date

2019-06-06, 1398/03/16

Actual recruitment start date

2019-05-10, 1398/02/20

Actual recruitment end date

2019-06-10, 1398/03/20

Trial completion date

2019-09-11, 1398/06/20

Scientific title

The Comparison between of the Effectiveness of Cognitive-Behavioral Group Therapy ; Cognitive Therapy based on Mindfulness and combined therapy of Cognitive_ Behavioral /The recognition of the Therapy based on Mindfulness on Improving Sleep Quality, life Quality Perceived Social Support and Increase CD4 in Admitted HIV/AIDS

Public title

Effectiveness of Cognitive-Behavioral Group Therapy ; Cognitive Therapy based on Mindfulness and combined therapy of Cognitive_ Behavioral /The recognition of the Therapy based on Mindfulness on Improving Sleep Quality, life Quality Perceived Social Support and Increase CD4 in Admitted HIV/AIDS to Ahwaz City

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

. Age 25 to 50 years old A resident of Ahvaz Minimum cycle education . Ability to speak fluent persian. At least 350 CD4 patients

Exclusion criteria:

Having history of mental illness, depression mental disorder Taking psychosocial drugs Suicidal thoughts. Having addiction

AgeFrom **25 years** old to **50 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

No information

Sample sizeTarget sample size: **45**Actual sample size reached: **45****Randomization (investigator's opinion)**

Randomized

Randomization description

An in-class randomized permutation block is used. Subjects are divided into 4 classes. The first floor is women 30 to 50 years old Second step women from 25 to 29 years old Third of men is 30 to 50 years old Fourth, 25-29 years According to the sample size of 15 people in each treatment group, 45 people were enrolled in the study and each floor is 15 people. A group of segments was coded in each class Group 1: Code 10, 11, 12 and The second group is code 20, 21, 22 and

..... Group 3 code 30, 31, 32 and
..... The fourth group code 40, 41, 42 and
..... Then, randomization is done in the treatment of CBT, MBCT, combination of both treatment and control group. . We encode groups based on latin letters. A: CBT B: MBCT C: Combination of both treatments D: Control group We assign a number from 1 to 8 each. ABCD. ACBD BACD.BCAD. CABD.CBAD. DABC.DACB We use a random number table to construct. On each floor, one of the numbers 1, 2, 3, 4, 5, 6, 7, 8, it turned out that one of these blocks is selected, and if another number appears We take the absurd and go to the next selection and invite selected people in groups A, B, C and D to attend class meetings separately. For follow up, subjects will have 3-4 months of interventional therapy and a follow-up period of 2 months.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Other

Other design features**Secondary Ids**

empty

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

Ethics committee of AHVAZ branch Islamic Azad University

Street address

Angle Street Aboozar Children's Clinic. Ahvaz Behavioral Counseling Counseling Center

City

AHVAZ

Province

Khouzestan

Postal code

6187898434

Approval date

2019-05-04, 1398/02/14

Ethics committee reference number

IR.IAU.AHVAZ.REC.1398.003

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

HIV/AIDS

ICD-10 code

B20

ICD-10 code description

Human immunodeficiency virus [HIV] disease resulting in infectious and parasitic diseases

Primary outcomes

1

Description

Quality of life and

Timepoint

It will take 16 weeks to complete. For monitoring the subjects, 3 to 4 months of intervention and 2 months of follow-up are considered.

Method of measurement

questionnaire

2

Description

quality of life

Timepoint

It will take 16 weeks to complete. For monitoring the subjects, 3 to 4 months of intervention and 2 months of follow-up are considered.

Method of measurement

questionnaire

3

Description

perceived social support

Timepoint

It will take 16 weeks to complete. For monitoring the subjects, 3 to 4 months of intervention and 2 months of follow-up are considered.

Method of measurement

questionnaire

4

Description

changes in CD4 cells

Timepoint

It will take 16 weeks to complete. For monitoring the subjects, 3 to 4 months of intervention and 2 months of follow-up are considered.

Method of measurement

Measuring the amount of cells CD4

Secondary outcomes

1

Description

Quality of life, quality of life, perceived social support and changes in CD4 cells

Timepoint

It will take 16 weeks to complete. For monitoring the subjects, 3 to 4 months of intervention and 2 months of follow-up are considered.

Method of measurement

questionnaire

Intervention groups

1

Description

Intervention group one: The effectiveness of the Cognitive-Behavioral Therapy Group's Agenda Therapy (Tashabala, 2018) on stigma HIV/AIDS that was modified by this guideline. This treatment was presented in 8 sessions, once a week, in 45-minute sessions based on the treatment protocol.

Category

Treatment - Other

2

Description

Intervention Group II: The Effect of Mindfulness-Based Cognitive Therapy on Aging Using Garcia, Boras, Lopez & McNeill 2016 for HIV, in which treatment is administered 8 sessions once a week for 45 minutes on a face-to-face basis. Treatment sessions were provided.

Category

Treatment - Other

3

Description

Intervention Group Three: Combined Cognitive-Behavioral Therapy / Mindfulness-Based Cognitive Therapy The combination of the Cognitive Behavioral Therapy Meeting Agenda (Tashabala, 2018) and the Mindfulness-Based Cognitive Therapy Agenda (Garcia et al., 2016) are both therapeutic approaches. Meetings are held once a week in 45-minute sessions.

Category

Treatment - Other

4

Description

control group: . Also, according to the treatments performed in the control group for each treatment group or 15-person treatment intervention in this study.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

. Behavioral Disease Counseling Center

Full name of responsible person

Shahla Molavi

Street address

Angle Street Children's Clinic. Behavioral Disease Counseling Center ش

City

ahvaz

Province

Khouzestan
Postal code
6187898434
Phone
+98 61 3445 4600
Fax
+98 61 3445 4600
Email
shahla_molavi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University
Full name of responsible person
Hosain Matori
Street address
Angle Street Children's Clinic. Behavioral Disease
Counseling Center
City
ahvaz
Province
Khouzestan
Postal code
6187898434
Phone
+98 61 3445 4600
Fax
+98 61 3445 4600
Email
shahla_molavi@yahoo.com

Grant name

zero

Grant code / Reference number

0

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

Yes

Title of funding source

Islamic Azad University

Proportion provided by this source

1

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

Other

Person responsible for general inquiries

Contact

Name of organization / entity
Islamic Azad University
Full name of responsible person
shahla molavi

Position
Masters of Consultation
Latest degree
Master
Other areas of specialty/work
Midwifery
Street address
Angle Street Children's Clinic. Behavioral Disease
Counseling Center
City
Ahvaz
Province
Khouzestan
Postal code
6187898434
Phone
+98 61 3445 4600
Fax
+98 61 3445 4600
Email
shahla_molavi@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Islamic Azad University
Full name of responsible person
shahla molavi
Position
Masters of Consultation
Latest degree
Master
Other areas of specialty/work
Midwifery
Street address
Zawei Street, Children's Health Center. Behavioral
Diseases Center
City
ahvaz
Province
Khouzestan
Postal code
6187898434
Phone
+98 61 3445 4600
Fax
+98 61 3445 4600
Email
shahla_molavi@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Islamic Azad University
Full name of responsible person
shahla molavi
Position
Masters of Consultation
Latest degree

Master

Other areas of specialty/work

Midwifery

Street address

Zawei Street, Children's Health Center. Behavioral
Diseases Center

City

Ahvaz

Province

Khouzestan

Postal code

6187898434

Phone

+98 61 3445 4600

Fax

+98 61 3445 4600

Email

shahla_molavi@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

It is not decided

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to
make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to
make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to
make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to
make this available