

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effectiveness of combination therapy of cognitive rehabilitation and emotion regulation based on dialectical behavior therapy on cognitive functions, emotional problems and quality of life of HIV patients with associated neurocognitive disorders.

Protocol summary

Study aim

The effectiveness of combination therapy of cognitive rehabilitation and emotion regulation based on dialectical behavior therapy on cognitive functions, emotional problems and quality of life of HIV patients with associated neurocognitive disorders.

Design

Interventional - Randomized Control Clinical Trial (Census Method) Using G power software, the number of subjects is estimated and randomization is done by software.

Settings and conduct

Patients will be randomly assigned into three groups (the first experimental group, the second experimental group and the control group). Classification will be done by the secretary of the center who is unaware of the type of intervention for each group.(Census method).Patients will be randomly assigned into three groups (experimental group 1, experimental group 2 and control group).Classification will be done by the secretary of the center who is unaware of the type of intervention for each group

Participants/Inclusion and exclusion criteria

-Receiving antiretroviral therapy for at least 6 months - Plasma HIV- RNA lesser or equal to 50 cells in one milliliter for at least 6 months -Number of lymphocytes +T CD4 less than 350 cells in 1 microliter for at least six months - No severe associated diseases such as neurodegenerative disease or Psychiatric disease, metabolic encephalopathy, use of psychotropic drugs or head trauma

Intervention groups

In experimental group 1, cognitive rehabilitation therapy is performed 12 sessions of one hour twice a week In experimental group 2, integrated cognitive rehabilitation therapy such as the first group and emotion regulation therapy based on dialectical behavior therapy will be

performed in 8 two-hour sessions (twice a week) In the control group, there is no treatment and only the usual treatments are received

Main outcome variables

Cognitive Functions Emotional problems Quality of Life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211118053093N2**

Registration date: **2022-01-09, 1400/10/19**

Registration timing: **registered_while_recruiting**

Last update: **2022-01-09, 1400/10/19**

Update count: **0**

Registration date

2022-01-09, 1400/10/19

Registrant information

Name

Kimia Sahraian

Name of organization / entity

Eghlid Higher Education Center

Country

Iran (Islamic Republic of)

Phone

+98 71 3630 3886

Email address

leilarazeghian1366@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-20, 1400/09/29
Expected recruitment end date
2022-04-18, 1401/01/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

The effectiveness of combination therapy of cognitive rehabilitation and emotion regulation based on dialectical behavior therapy on cognitive functions, emotional problems and quality of life of HIV patients with associated neurocognitive disorders.

Public title

combination therapy of cognitive rehabilitation and emotion regulation based on dialectical behavior therapy in HIV patients with associated neurocognitive disorders.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Receiving antiretroviral therapy for at least 6 months
Plasma HIV- RNA lesser or equal to 50 cells in one milliliter for at least 6 months
Number of lymphocytes +T CD4 less than 350 cells in 1 microliter for at least six months
Proficiency in Persian
Informed consent

Exclusion criteria:

neurodegenerative diseases
severe psychiatric disorder
metabolic encephalopathy
use of psychotropic drugs
head trauma

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: 70

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients in all three groups do not know what intervention will be made for them. Researcher and analyst also has no knowledge of which person is in which group

Placebo

Used

Assignment

Parallel

Other design features

In this study, it is assumed that if cognitive rehabilitation interventions and psychological interventions such as emotion regulation based on dialectical behavior therapy are used as a combination, applied and supportive therapeutic approach along with pharmacotherapy, due to the chronicity of this disease, the therapeutic effects will be long and profound and will lead to improvement of cognitive function and emotional problems and increasing the quality of life in these people.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Shiraz University of Medical Sciences

Street address

Ostad Mohrri Hospital, 13th Km Shiraz-Isfahan Highway

City

Shiraz

Province

Fars

Postal code

71444113331

Approval date

2021-12-12, 1400/09/21

Ethics committee reference number

IR.SUMS.MED.REC.1400.488

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

Quality of life of HIV patients with associated neurocognitive disorders.

Timepoint

Before treatment
End of treatment
Four months after treatment

Method of measurement

Quality of Life Questionnaire

2

Description

Cognitive Function

Timepoint

Before treatment End of treatment Four months after treatment

Method of measurement

Cognitive Function Questionnaire

3

Description

Emotional problems

Timepoint

Before treatment End of treatment Four months after treatment

Method of measurement

Emotional Problems Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

"Intervention group 1:" Cognitive rehabilitation 12 sessions one hour, twice a week Session1:Familiarity of members with each other Session2and 3: Members will learn to describe their emotional experiences without judgment and validate their emotions. Session4 and 5: Self assessment or observation of emotions Session6 and7: The role of awareness and being in the present in mental health Session 8and9: Members discuss how to do mindfulness exercises Session10: Training emotional relief skills Session11: Members will discuss how to apply relief skills Session12:Reassessment and planning for the application of education

Category

Treatment - Other

2

Description

"Intervention group 2:" 1.emotion regulation based on dialectic behavioral therapy and 2.emotion regulation based on dialectic behavioral therapy eight two-hour sessions twice a week. Session1:Familiarity of members with each other Session2and 3: Members will learn to describe their emotional experiences without judgment and validate their emotions. Session4 and 5: Self assessment or observation of emotions Session6 and7: The role of awareness and being in the present in mental health Session 8and9: Members discuss how to do mindfulness exercises Session10: Training emotional relief skills Session11: Members will discuss how to apply relief skills Session12:Reassessment and planning for the application of education Session13 and14:They will learn to view and describe their emotional experiences without judgment and to validate their emotions. Session15:Self-

assessment or observation of emotions Session16:

Performing different mindfulness exercises

Session17:Training discomfort tolerance skills Session18:

Training emotional relief skills Session19:Training

positive excitement skills Session20: Reassessment and

planning for the application of education

Category

Treatment - Other

3

Description

"Control group:" routine daily therapy without psychotherapy

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Behavioral Diseases Center of Shiraz University of Medical Sciences and Health Services

Full name of responsible person

Leila razeghian Jahromi

Street address

Ostad Mohrrari Hospital, 13th Km Shiraz-Isfahan Highway

City

Shiraz

Province

Fars

Postal code

71441-13331

Phone

+98 71 3260 5701

Email

leilazarazeghian1366@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Leila Razeghian Jahromi

Street address

Ostad Mohrrari Hospital, 13th Km Shiraz-Isfahan Highway

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Shiraz

Province

Fars

Postal code

71441-13331

Phone

+98 71 3260 5701

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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

Shiraz University of Medical Sciences

Proportion provided by this source

100

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

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Leila Razeghian Jahromi

Position

assistant professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

Street address

Ostad Mohrri Hospital, 13th Km Shiraz-Isfahan Highway

City

Shiraz

Province

Fars

Postal code

71441-13331

Phone

+98 71 3260 5701

Email

leilarazeghian1366@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Leila Razeghian Jahromi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

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Email

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Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Leila Razeghian Jahromi

Position

asistant professor

Latest degree

Specialist

Other areas of specialty/work

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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

No more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available