

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Core and Psychological Indicators of Chronic Pain, Coping Strategies and Treatment Adherence in the Effectiveness of Acceptance and Commitment Therapy(ACT) and Dialectical Behavior Therapy(DBT) Interventions with and without exercise activities in Substance Dependent Patients with chronic pain

Protocol summary

Study aim

The effect of acceptance and commitment therapy (ACT) and dialectical behavior therapy (DBT) with and without exercise on the essential indicators of pain, catastrophic pain, depression, pain consequences, improvement of coping strategies, patience, pain acceptance, craving and desire to treat substance-dependent men with chronic pain.

Design

In a regular random method, we select three centers: Hayat Dobareh, Taban and Omid from the addiction treatment centers of Zahedan city and take the sample in a targeted manner and using a random table, place the people in 4 intervention groups and one control group.

Settings and conduct

Using tests and clinical interviews, patients are selected and then placed in the centers under the interventions of ACT, DBT and exercise for two months, then the test is performed and two months after the end of the interventions, we measure the effectiveness.

Participants/Inclusion and exclusion criteria

Entry criteria: Being a man, completing detoxification, having pain for 6 months, literacy, age 18 to 55 years, not taking psychotropic drugs and drugs that help control chronic pain, obtaining written consent. Exit criteria: Dissatisfaction, absence of more than two sessions and discontinuation of addiction treatment, creating physical problems during the period that require hospitalization.

Intervention groups

To control chronic pain in this study, we used two intervention groups with ACT(with and without exercise), two intervention groups with DBT(with and without exercise) and a control group that did not receive any

intervention.

Main outcome variables

After the study, we expect chronic pain control and a desire to treat patients to improve.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210111050000N1**

Registration date: **2021-04-02, 1400/01/13**

Registration timing: **prospective**

Last update: **2021-04-02, 1400/01/13**

Update count: **0**

Registration date

2021-04-02, 1400/01/13

Registrant information

Name

Abbasali Oveisi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3344 0323

Email address

abbasali.ovisi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-07, 1400/01/18

Expected recruitment end date

2021-04-15, 1400/01/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Core and Psychological Indicators of Chronic Pain, Coping Strategies and Treatment Adherence in the Effectiveness of Acceptance and Commitment Therapy (ACT) and Dialectical Behavior Therapy (DBT) Interventions with and without exercise activities in Substance Dependent Patients with chronic pain

Public title

The effect of ACT and DBT with and without exercise on the core and psychological indicators of chronic pain and improving adherence to substance abuse

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

They complete the detoxification treatment and stay at the beginning of the maintenance treatment period. Lack of chronic pain due to an obvious problem such as infection or bone fracture and ... No serious psychiatric illness (diagnosis by DSM-5 diagnostic interview) Obtaining a score in the Chronic Pain Diagnosis Questionnaire and confirming the chronic pain by the treating physician They complete the detoxification treatment and stay at the beginning of the maintenance treatment period Do not take psychotropic drugs during interventions Failure to attend other sessions of psychotherapy and the Association of Anonymous Addicts

Exclusion criteria:

Dissatisfaction with continuing to participate in treatment sessions Absence from more than two sessions and discontinuation of addiction treatment Creating physical problems during the period that require hospitalization

Age

From **18 years** old to **55 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

From the list of addiction treatment centers for men in Zahedan, select two centers in a cluster method and after a diagnostic interview and test and determine patients suffering from chronic pain, Using a random number table, they were placed in four groups of 15

interventions (ACT with exercise and ACT without exercise) and (DBT with exercise and DBT without exercise) and a group of 15 controls and after performing the pre-test, they were exposed to the effects of variables. We are independent.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Factorial

Other design features**Secondary Ids**

empty

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

Etics committee of Birjand University

Street address

between 6 and 8, Qalanbor Blvd, Zahedan

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816647446

Approval date

2021-02-08, 1399/11/20

Ethics committee reference number

IR.BIRJAND.REC.1399.004

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

chronic pain

ICD-10 code

G89.4

ICD-10 code description

Chronic pain syndrome

Primary outcomes**1****Description**

Reduce chronic pain

Timepoint

Before the intervention and immediately after the intervention and 2 months after the intervention

Method of measurement

Chronic Pain Case Test.; Asghari Moghadam (1995)

Secondary outcomes

1

Description

Catastrophic reduction of chronic pain

Timepoint

Before the intervention and immediately after the intervention and 2 months after the intervention

Method of measurement

Pain Catastrophe Questionnaire (Sullivan, Bishop and Pewick, 1995)

2

Description

Depression

Timepoint

Before the intervention and immediately after the intervention and 2 months after the intervention

Method of measurement

Center for Epidemiological Studies Short Depression Scale(CES-D)

3

Description

Pain coping strategies

Timepoint

Before the intervention and immediately after the intervention and 2 months after the intervention

Method of measurement

Coping Strategies Questionnaire

4

Description

Chronic Pain Acceptance

Timepoint

Before the intervention and immediately after the intervention and 2 months after the intervention

Method of measurement

Chronic Pain Acceptance Questionnaire

5

Description

Reduce cravings

Timepoint

Before the intervention and immediately after the intervention and 2 months after the intervention

Method of measurement

Craving test (Franken, Hendrix and Vandenbrink, 2002)

6

Description

Readiness to change and adhere to treatment

Timepoint

Before the intervention and immediately after the intervention and 2 months after the intervention

Method of measurement

Scale Stage of Readiness for Change and the Desire to

Treat Addiction

Intervention groups

1

Description

Intervention group 1: People who receive acceptance and commitment therapy (ACT) with exercise

Category

Treatment - Other

2

Description

Intervention group 2: People who receive acceptance and commitment therapy (ACT) without exercise

Category

Treatment - Other

3

Description

Intervention group 3: People who receive dialectical behavior therapy (DBT) with exercise.

Category

Treatment - Other

4

Description

Intervention group 4: People who receive dialectical behavior therapy (DBT) without exercise.

Category

Treatment - Other

5

Description

Control group: People who do not receive any intervention

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Residential treatment center Hayate Pack

Full name of responsible person

Arbab Omed

Street address

No. 25., Khorramshahr St.

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زاهدان

Province

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9817717866

Phone

+98 54 3344 0323

Email

Iranhamoon92@yahoo.com

2

Recruitment center

Name of recruitment center

Residential treatment center Taban

Full name of responsible person

Vosoughi-Mehr Younes

Street address

No. 5., Azadi St

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Zahedan

Province

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Postal code

9813653174

Phone

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Email

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3

Recruitment center

Name of recruitment center

Residential treatment center Omid

Full name of responsible person

shohli-bor Amanolahe

Street address

No, 3., Tabatabai St.

City

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Province

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Phone

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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Majid Aliabadi

Street address

Ayatollah Ghaffari Blvd

City

Birjand

Province

South Khorasan

Postal code

9717411111

Phone

+98 56 3244 9152

Fax

+98 56 3234 5591

Email

info@iaubir.ac.ir

Web page address

http://www.iaubir.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Islamic Azad University

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

Islamic Azad University

Full name of responsible person

Abbasali Oveisi

Position

PhD student

Latest degree

Master

Other areas of specialty/work

Psychology

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Abbasali Oveisi

Position

PhD student

Latest degree

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

Islamic Azad University

Full name of responsible person

Abbasali oveisi

Position

PhD student

Latest degree

Master

Other areas of specialty/work

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Web page address

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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

No - There is not 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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

After studying, it will be possible to access information related to the main outcome of the research.

When the data will become available and for how long

One year after the results are published

To whom data/document is available

Students, professors, researchers and clinicians

Under which criteria data/document could be used

Data should be requested with the aim of improving the level of research or clinical interventions.

From where data/document is obtainable

postal code 9816647446, No., 6, Qalanbar Blv, Zahedan city abbasali.ovisi@gmail.com

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

The request will be sent by e-mail and will be answered within one month after receiving the request.

Comments