

# 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.

##### City

زاهدان

##### Province

Sistan-va-Balouchestan

##### Postal code

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

**City**

Zahedan

**Province**

Sistan-va-Balouchestan

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9813653174

**Phone**

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**Email**

abbasaliovisi@yahoo.com

**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**

Zahedan

**Province**

Sistan-va-Balouchestan

**Postal code**

9796644648

**Phone**

+98 54 3344 0323

**Email**

abbasali.ovisi@gmail.com

**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**

Between 6 and 8.; Qalanbar Blvd.

**City**

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**Province**

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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

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**Web page address**

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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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**Email**

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**Web page address**

<http://www.iaubir.ac.ir>

**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**