

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Study of the effectiveness of a combination of methadone treatment with group treatment based on Acceptance & Commitment therapy (ACT) versus methadone treatment in the prevention rate of relapse in people with abuse opioids.

Protocol summary

Summary

Objectives: Study of the effectiveness of a combination of Methadone treatment with group treatment based on Acceptance & Commitment therapy (ACT) versus Methadone treatment in the prevention rate of relapse in people with abuse opioids. Study design: Intervention, randomly allocated to intervention & control groups, not blind, non-placebo. The method of the study: The study population: Patients treated with Methadone in drug rehabilitation center is the Zanjan city. Inclusion criteria: Having informed consent to participate in research; Taking at least two weeks Methadone; Being male; Having a minimum of 18 & maximum of 45 years old. Exclusion criteria: Patient will be deleted after the two meeting absence; More severe problems, such as suicidal thoughts or have psychotic disorders. After screening and study of variables, the available sample size of 30 patients will be selected randomly assigned to experimental and control groups. Randomization was simple and to draw from the list of patients was performed. The study interventions in the study for combination therapy with Methadone treatment protocol based on Acceptance & Commitment Therapy Acceptance & Commitment Hayes (2002) is used. Time Intervention will take two months. 8 is a 90-minute session. The primary outcome or consequences of the study: The effectiveness of Methadone & Acceptance & Commitment group combination therapy & Methadone therapy in the prevention rate of relapse in people with opium abuse. Inclusion criteria: Having informed consent to participate in research; Taking at least two weeks Methadone; Being male; Having a minimum of 18 & maximum of 45 years old. Exclusion criteria: Patient will be deleted after the two meeting absence; More severe problems, such as suicidal thoughts or have psychotic disorders

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016062328603N1**

Registration date: **2017-03-02, 1395/12/12**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-03-02, 1395/12/12

Registrant information

Name

Abbas Hemmat

Name of organization / entity

Zanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 24 3342 4766

Email address

samhemmat@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Zanjan University of Medical Sciences

Expected recruitment start date

2016-07-22, 1395/05/01

Expected recruitment end date

2016-08-22, 1395/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the effectiveness of a combination of methadone treatment with group treatment based on Acceptance & Commitment therapy (ACT) versus methadone treatment in the prevention rate of relapse in people with abuse opioids.

Public title

Comparison between the effectiveness of methadone & Acceptance & Commitment group combination therapy & methadone therapy in the prevention rate of relapse in people with opium abuse.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Having informed consent to participate in research; Taking at least two weeks Methadone; Being male; Having a minimum of 18 & maximum of 45 years old. Exclusion criteria: Patient will be deleted after the two meeting absence; More severe problems, such as suicidal thoughts or have psychotic disorders

Age

From **18 years** old to **45 years** old

Gender

Male

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Zanjan University of Medical Sciences

Street address

Zanjan University of Medical Sciences; Azadi Bolvar;
Zanjan

City

Zanjan

Postal code**Approval date**

2016-05-04, 1395/02/15

Ethics committee reference number

ZUMS.REC.1395.34

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

Mental & behavioural disorders due to use of opioids

ICD-10 code

F11

ICD-10 code description

Mental and behavioural disorders due to use of opioids

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

Relapse prevention

Timepoint

Before the intervention, The intervention, Three months after the intervention.

Method of measurement

Cravings questionnaire (DDQ), urine test kits

Secondary outcomes**1****Description**

Anxiety

Timepoint

Before the intervention; The intervention time; Three months after the intervention.

Method of measurement

Beck Anxiety Inventory

2**Description**

Depression

Timepoint

Before the intervention; The intervention time; Three months after the intervention.

Method of measurement

Beck Depression Inventory

3**Description**

Craving

Timepoint

Before the intervention; The intervention time; Three months after the intervention.

Method of measurement

Craving Questionnaire (DDQ)

4

Description

Quality of life

Timepoint

Before the intervention; The intervention time; Three months after the intervention.

Method of measurement

Quality of Life Questionnaire (WHO)

Intervention groups

1

Description

Intervention groups: Combination therapy with Methadone therapy uses a protocol based on Acceptance & Commitment Therapy Acceptance & Commitment Hayes (2002). Sessions: 8 sessions of 90 minutes.

Category

Prevention

2

Description

Control group: Methadone; Drug name: Methadone; Dose: 20 cc; Duration: 5 Months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Mohsen Dadashi

Street address

Shahid Beheshti Hospital; Street Arg; Zanzan

City

Zanzan

2

Recruitment center

Name of recruitment center

Harm Reduction Center

Full name of responsible person

Ali Navidi

Street address

Harm reduction; crossroads Saadi; Zanzan

City

Zanzan

3

Recruitment center

Name of recruitment center

Specialized Addiction Raja Clinic

Full name of responsible person

Reza Mousavi

Street address

Beheshti Hospital; Gate the Arg; Sadi Crossroad; Zanzan

City

Zanzan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research Zanzan University of Medical Sciences

Full name of responsible person

Soghrat Faghihzade

Street address

Zanzan University of Medical Sciences; Azadi Bolvar; Zanzan

City

Zanzan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research Zanzan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Zanzan University of Medical Sciences

Full name of responsible person

Mohsen Dadashi

Position

PHD of Clinical Psychology

Other areas of specialty/work

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Abbas Hemmat

Position

M.Sc. candidate in clinical psychology

Other areas of specialty/work**Street address**

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Web page address**Position**

M.Sc. Candidate in clinical psychology

Other areas of specialty/work**Street address**

Shahid Beheshti Hospital; Street Arg; Zanjan

City

Zanjan

Postal code**Phone****Fax****Email**

Hemmat5a@yahoo.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty

Person responsible for updating data

Contact

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Abbas Hemmat