

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effectiveness of Dialectical Behavior Therapy on Emotion regulation strategies, Distress tolerance, Craving and Depression of patients receiving Methadone Maintain Therapy

Protocol summary

Study aim

The purpose of present study is effectiveness of dialectical behavior therapy in emotional regulation strategies, distress tolerance, craving and depression for individuals under treatment with methadone.

Design

In this research, 40 eligible patients with opiate dependence diagnosis according to DSM-IV criteria are enrolled and a code was allocated to each one of them. Then, patients were randomly divided into two control and intervention groups.

Settings and conduct

40 eligible patients with opiate dependence diagnosis referred to Gholabchi Clinic affiliated to Kashan University of Medical Sciences, Kashan, Iran will be selected in the study. Parallel double-blind (both patients and researchers) randomized controlled clinical trial.

Participants/Inclusion and exclusion criteria

Inclusion criteria are being masculine; recent opiates dependency (opium, heroin); negative morphine test and Exclusion Criteria are Unwillingness to participate in the study; having severe psychotic disorders; having antisocial personality disorder

Intervention groups

The first group will receive dialectical behavior therapy-skills training (DBT-ST) for 12 weeks. The second group will receive methadone maintenance treatment (MMT) for 12 weeks.

Main outcome variables

Distress tolerance is evaluated with Distress tolerance Scale (DTS); craving is evaluated with Obsessive Compulsive Drug Use Scale (OCDUS) and depression is evaluated with Beck Depression Inventory (BDI-II) Before the intervention, after the intervention, and three months after the intervention. Emotion Regulation Strategies also is evaluated with Cognitive Emotion Regulation Questionnaire (CERQ-P), after the intervention,

and three months after the intervention.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170314033079N3**

Registration date: **2017-12-17, 1396/09/26**

Registration timing: **retrospective**

Last update: **2017-12-17, 1396/09/26**

Update count: **0**

Registration date

2017-12-17, 1396/09/26

Registrant information

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Name of organization / entity

Kashan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Kashan University of Medical Sciences

Expected recruitment start date

2017-06-22, 1396/04/01

Expected recruitment end date

2017-07-23, 1396/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of Dialectical Behavior Therapy on Emotion regulation strategies, Distress tolerance, Craving and Depression of patients receiving Methadone Maintain Therapy

Public title

Effectiveness of Dialectical Behavior Therapy in methadone maintenance treatment patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Being masculine Recent opiates dependency (opium, heroin) Negative morphine test Education at least third grade middle school

Exclusion criteria:

Unwillingness to participate in the study Positive morphine test in at least three weeks (relapse) Absence more than 4 session Having severe psychotic disorders Having antisocial personality disorder

Age

No age limit

Gender

Male

Phase

N/A

Groups that have been masked*No information***Sample size**

Target sample size: 40

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment will be done by the use of computer-generated random numbers.

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 Kashan University of Medical Sciences

Street address

Ghotbe Ravandi Boulevard, Kashan

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Kashan

Province

Isfahan

Postal code

8715981151

Approval date

2017-05-31, 1396/03/10

Ethics committee reference number

IR.KAUMS.REC.1396.36

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

Mental and 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**

Distress tolerance

Timepoint

Before the intervention, after the intervention, and three months after the intervention.

Method of measurement

Distress tolerance Scale (DTS)

2**Description**

Craving

Timepoint

Before the intervention, after the intervention, and three months after the intervention.

Method of measurement

Obsessive Compulsive Drug Use Scale (OCDUS)

3**Description**

Depression

Timepoint

Before the intervention, after the intervention, and three months after the intervention.

Method of measurement

Beck Depression Inventory (BDI-II)

4**Description**

Positive Affect

Timepoint

Before the intervention, after the intervention, and three

months after the intervention.

Method of measurement

Positive Affect Negative Affect Scale (PANAS)

5

Description

Negative Affect

Timepoint

Before the intervention, after the intervention, and three months after the intervention.

Method of measurement

Positive Affect Negative Affect Scale (PANAS)

Secondary outcomes

1

Description

Emotion Regulation Strategies

Timepoint

Before the intervention, after the intervention, and three months after the intervention.

Method of measurement

Cognitive Emotion Regulation Questionnaire (CERQ-P)

2

Description

Emotion Regulation

Timepoint

Before the intervention, after the intervention, and three months after the intervention.

Method of measurement

Emotion Regulation Questionnaire

3

Description

defficulty in Emotion Regulation

Timepoint

Before the intervention, after the intervention, and three months after the intervention.

Method of measurement

Defficulties in Emotion Regulation Scale (DERS)

Intervention groups

1

Description

Intervention group: Dialectical Behavior Therapy- Skills Training (DBT-ST)

Category

Behavior

2

Description

Control group: Methadone maintenance treatment (MMT)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Gholabchi Clinic

Full name of responsible person

Morad Rasouli-Azad

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Shahid Rajaee Avenue, Kashan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

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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

Kashan 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

Kashan University of Medical Sciences

Full name of responsible person

Zeinab Rezaei

Position

MA student

Latest degree

Bachelor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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