

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 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

##### Name

Morad Rasouli-Azad

##### Name of organization / entity

Kashan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 989355392455

##### Email address

rasouliazad-m@kaums.ac.ir

##### 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

**City**

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 Rajaei 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**

Gholamali Hamidi

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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  
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Zeinab Rezaei  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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