Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Nov 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 Questionaire (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
City
Kashan
Province
Isfehan
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 Questionaire (CERQ-P)

2

Description
Emotion Regulation
Timepoint
Before the intervention, after the intervention, and three months after the intervention.
Method of measurement
Emotion Regulation Questionaire

3

Description
defficulity in Emotion Regulation
Timepoint
Before the intervention, after the intervention, and three months after the intervention.
Method of measurement
Defficulities 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
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

Full name of responsible person
Zeinab Rezaei

Position
MA student

Latest degree
Bachelor

Other areas of specialty/work
Psychology

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Assistant professor

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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