

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Investigating The Effect of Dialectical Behavior Therapy on Emotion regulation, Executive function, Risky decision making and Craving in Opioid substance use disorder co morbid with ADHD Symptoms in adult Patients

Protocol summary

Study aim

Investigating The Effect of Dialectical Behavior Therapy on Emotion regulation, Executive function, Risky decision making and Craving in Opioid substance use disorder co morbid with attention deficit hyperactivity disorder (ADHD) Symptoms in adult Patients.

Design

The present study is a semi-experimental design with pretest-posttest with control group. First, the researcher will select the people who will be admitted to the study by referring to the addiction treatment clinics by conducting the clinical interview and then the participants will be randomly assigned to the treatment and control groups using the random number table.

Settings and conduct

Sixty patients with a diagnosis of opioid dependence with co morbid ADHD symptoms and referred to tavan clinic in Kashan , kargar street, Iran will be selected in the study

Participants/Inclusion and exclusion criteria

Inclusion criteria: patient's informed consent , Diagnosis of Opioid substance use disorder (syrup, opium, heroin, burnt) with ADHD symptoms Not having a minimal mild brain injury record Age from 18 to 45 years minimum level of education third grade of middle school, Exclusion criteria: Unwillingness to attend therapy sessions, having severe psychotic disorders, Positive morphine test, Having severe physical illness

Intervention groups

The first group will receive dialectical treatment therapy for 12 weeks. The second group will be treated with methadone for 12 weeks.

Main outcome variables

Emotion regulation, Executive function, Risky decision making and Craving

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190407043185N1**

Registration date: **2019-09-03, 1398/06/12**

Registration timing: **prospective**

Last update: **2019-09-03, 1398/06/12**

Update count: **0**

Registration date

2019-09-03, 1398/06/12

Registrant information

Name

Ebrahim Balandeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3322 9912

Email address

balandeh-e@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-22, 1398/06/31

Expected recruitment end date

2019-11-22, 1398/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating The Effect of Dialectical Behavior Therapy on Emotion regulation, Executive function, Risky decision making and Craving in Opioid substance use disorder co morbid with ADHD Symptoms in adult Patients

Public title

The Effect of Dialectical behavior therapy in Opioid substance use disorder co morbid with ADHD in adult patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

patient's informed consent Diagnosis of Opioid substance use disorder (syrup, opium, heroin, burnt) with ADHD symptoms Not having a minimal mild brain injury record Age from 18 to 45 years minimum level of education third grade of middle school

Exclusion criteria:

Unwillingness to attend therapy sessions having severe psychotic disorders Positive morphine test Having severe physical illness

Age

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

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization using random number table: Random number table is a set of numbers that are completely randomly generated without any particular order and become a table. The researcher must first read side the numbers Pre-set the table. The second researcher's default is to consider numbers for different groups. The researcher then touches on to one of the numbers and moves in one of the predetermined directions, recording the number and assigning it to different groups.

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

gotbe Ravandi blvd, kashan

City

Kashan

Province

Isfahan

Postal code

8715981151

Approval date

2019-02-18, 1397/11/29

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1397.108

Health conditions studied

1

Description of health condition studied

Opioid use disorder

ICD-10 code

F11

ICD-10 code description

Opioid related disorders

2

Description of health condition studied

attention deficit and hyperactivity disorder in adults

ICD-10 code

F90

ICD-10 code description

Attention-deficit hyperactivity disorders

Primary outcomes

1

Description

Craving

Timepoint

pre-treatment, post-treatment and follow up

Method of measurement

Craving beliefs Questionnaire

2

Description

Emotion Regulation

Timepoint

pre-treatment, post-treatment and follow up

Method of measurement

Difficulties in Emotion Regulation Scale

3

Description

risky decision making

Timepoint

pre-treatment, post-treatment and follow up

Method of measurement

Iowa Gambling Task

4

Description

executive function

Timepoint

pre-treatment, post-treatment and follow up

Method of measurement

Tower of London Test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: dialectical behavioral therapy which includes emotion regulation , distress tolerance , mindfulness and effective communication in twelve sixty to ninety minute sessions , twice a week , done in groups with Methadone maintenance treatment (MMT)

Category

Behavior

2

Description

Control group: methadone maintenance therapy

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Tavan clinic

Full name of responsible person

SyedAlireza moraveji

Street address

After the pedestrian bridge,kargar street

City

kashan

Province

Isfahan

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8715744461

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ebalandeh72@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Hamid Reza Banafsheh

Street address

5th of Qotb -e Ravandi Blvd, Kashan, IRAN

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Fax

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Email

research@kaums.ac.ir

Web page address

<http://kaums.ac.ir/>

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

ebrahim balandeh

Position

Master of Science (MSc)

Latest degree

Bachelor

Other areas of specialty/work

Psychology

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5th of Qotb -e Ravandi Blvd, Kashan, IRAN

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Ebrahim Balandeh
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Person responsible for updating data

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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

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Only part of the information, such as information about the main outcome or the like, and the demographic information, can be shared.

When the data will become available and for how long

The start of the access period will be available 2 years after the results are published.

To whom data/document is available

Only available to scholars working in academic and academic institutions.

Under which criteria data/document could be used

In the case of any use, the names of the researchers must be mentioned in acknowledgments, no one has the right to use the data for inhumane experiments, such as those that endanger human life. Submitting an application should be in accordance with the usual academic procedure and be reviewed for a month. One should not have any connection with anti-human and terrorist organizations.

From where data/document is obtainable

ebalandeh72@gmail.com ebrahim balandeh University of Medical Sciences Faculty of Medicine, Kashan, Iran

What processes are involved for a request to access data/document

It will be assessed and answered by the researcher.

Comments