Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 critrria: 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
Isfehan

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
Isfehan
Postal code
8715744461
Phone
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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
+98 31 5557 5057
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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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Ebrahim Balandeh

Position
Student of master

Latest degree
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Other areas of specialty/work
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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