Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Nov 2026

study of the Effect of Dialectical Behavior Therapy – Skills Training (DBT-ST) on Cognitive Function in Methadone Maintenance Treatment Patients.

Protocol summary

Study aim
investigate the effect of teaching of dialectical behavioral therapy skills (DBT-ST) on cognitive functions in patients undergoing methadone maintenance therapy.

Design
The present study is a semi experimental design with pretest-posttest with control group. First, the researcher will refer to the addiction treatment clinics by conducting clinical interviews with the people who will have the criteria for entering the study, and then the participants will be randomly assigned using a random number table. The two groups will be treated and controlled.

Settings and conduct
40 patients will be selected in the study with a diagnosis of dependence on eligible opioids and referred to Omid Clinic, Kashan, Teachers' Square, Iran. Double-blind clinical trial parallel.

Participants/Inclusion and exclusion criteria
Inclusion criteria Age range from 18 to 45 years Detection of opioid dependence (opium, sap and heroin) Treated at least one month of MMT consent to participate in study Level of at least third degree education (cycle) Exit criteria: Positive morphine test during initial assessment and post-test The presence of a phase of mania or current depression The presence of psychoactive or micropsychotic courses in patients There is a history of head injury that has led to anesthesia Four absentee sessions for each patient during treatment

Intervention groups
The first group will receive training for dialectical behavioral therapy (DBT-ST) for 12 weeks. The second group will be treated with methadone for 12 weeks

Main outcome variables
Risk Decision Making using Gambling Assignment (IGT), Attention with Continuous Performance Task (CPT), Cognitive Flexibility Using Wisconsin Card Classification (WCST), Planning using London Tower Execution (TOL), Problem Solving Using the Wisconsin Card Classification (WCST), psychological symptoms using the Dass-42 questionnaire

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20180721040541N1**
Registration date: **2018-09-26, 1397/07/04**
Registration timing: **prospective**

Last update: **2018-09-26, 1397/07/04**
Update count: **0**

Registration date
2018-09-26, 1397/07/04

Registrant information
Name
kiamars khezrian
Name of organization / entity
Country
Iran (Islamic Republic of)
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khezrian-k@kaums.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-10-02, 1397/07/10
Expected recruitment end date
2018-12-11, 1397/09/20
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date

empty

Scientific title
study of the Effect of Dialectical Behavior Therapy – Skills Training (DBT-ST) on Cognitive Function in Methadone Maintenance Treatment Patients.

Public title
The Effect of Dialectical Behavior Therapy – Skills Training (DBT-ST) on Cognitive Function

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age range from 18 to 45 years Detection of opioid dependence (opium, sap and heroin) Treatment for at least one month with methadone Participant consent Level of at least third degree education (cycle)

Exclusion criteria:
Positive morphine test during initial assessment and post-test The presence of a phase of mania or current depression The presence of psychoactive or micropsychotic courses in patients There is a history of head injury that has led to anesthesia Four absentee sessions for each patient during treatment

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

Gender
Male

Phase
N/A

Groups that have been masked

- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization with random numbers, simple randomization.

Blinding (investigator's opinion)
Double blinded

Blinding description
Individual and group data are not coded as code and analytical and evaluation results are not known from the titles of individuals and groups.

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
2018-06-20, 1397/03/30

Ethics committee reference number
IR.KAUMS.MEDNT.REC.1397.016

Health conditions studied

1

Description of health condition studied
Mental and behavioral disorders due to the use of opioids

ICD-10 code
F11

ICD-10 code description
Mental and behavioral disorders due to the use of opioids

Primary outcomes

1

Description
Risky Decision Making

Timepoint
Before the intervention , after intervention

Method of measurement
Iowa gambling task

Secondary outcomes

1

Description
Attention

Timepoint
Before the intervention , after intervention

Method of measurement
Continuous performance task

2

Description
Cognitive Flexibility

Timepoint
Before the intervention , after intervention

Method of measurement
Wisconsin card sorting test

3

Description
Planning
Timepoint
Before the intervention , after intervention
Method of measurement
London Tower Test

4

Description
Problem - Solving
Timepoint
Before the intervention , after intervention
Method of measurement
Wisconsin card sorting test

5

Description
Psychological Signs
Timepoint
Before the intervention , after intervention
Method of measurement
DASS-42

Intervention groups

1

Description
Intervention group: DBT-ST (Methadone maintenance treatment)
Category
Behavior

2

Description
Control group: MMT
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Omid addiction treatment clinic
Full name of responsible person
Majid farhad
Street address
Teachers' Square, Motahari Boulevard
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Kashan
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8715981151
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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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Kashan, Rowdani Bolt
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hamidi_gh@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
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kiamars khezrian
Position
Master student
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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