

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 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)

Phone

+98 31 5554 0021

Email address

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

Isfahan

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

lowa 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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+98 31 5554 8627

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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

kiamars khezrian

Position

Master student

Latest degree

Bachelor

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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