

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

Effect of Acceptance and Commitment Therapy (Acceptance and Commitment Therapy) on admission, perceived stress and obsessive-compulsive use of narcotic drugs in methadone-treated male patients referred to Shahid Beheshti Hospital in Kerman

Protocol summary

Study aim

The aim of this study was to evaluate the efficacy of Acceptance and Commitment Therapy (ACT) on admission, perceived stress and craving in methadone-treated male patients referred to Shahid Beheshti Hospital in Kerman.

Design

Clinical practice with a control group without randomized blindness This study will be performed on 66 addicted men methadone treated. These individuals will be randomly divided into two groups of 33

Settings and conduct

This study will be carried out at Shahid Beheshti Hospital in Kerman. The subjects of both experimental and control groups in the two stages of pre-test and post-test were questionnaires before the OCDUS, Acceptance Questionnaire-Second Edition (AAQ-II), the perceived stress questionnaire of 14 items (PSS-14), completed before and after the intervention. Participants were re-evaluated three months after the completion of ACT sessions.

Participants/Inclusion and exclusion criteria

The criteria for entering the study include aged 20 to 45 years, at least 6 months of methadone intake, primary education to a diploma, the absence of severe psychiatric disorders, including psychosis, and the absence of acute and chronic physical and psychological disorders affecting the person's mood and mood Was

Intervention groups

The control group performed routine care, but the intervention group received ten sessions of ninety-minute therapies based on admission and awareness

Main outcome variables

Changes in perceived stress, changes in acceptance and practice, changes in obsessive compulsive drug use

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190510043544N1**

Registration date: **2019-05-23, 1398/03/02**

Registration timing: **registered_while_recruiting**

Last update: **2019-05-23, 1398/03/02**

Update count: **0**

Registration date

2019-05-23, 1398/03/02

Registrant information

Name

sahar salajeghe

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3211 1396

Email address

saharsalajeghe1373@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-22, 1398/03/01

Expected recruitment end date

2019-06-22, 1398/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Acceptance and Commitment Therapy (Acceptance and Commitment Therapy) on admission, perceived stress and obsessive-compulsive use of narcotic drugs in methadone-treated male patients referred to Shahid Beheshti Hospital in Kerman

Public title

Effect of Acceptance and Commitment Therapy (Acceptance and Commitment Therapy) on admission, perceived stress and obsessive-compulsive use of narcotic drugs in methadone-treated male patients referred to Shahid Beheshti Hospital in Kerman

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Having a 20 to 45 year old Passed at least 6 months of taking methadone Elementary education up to diploma Being a man

Exclusion criteria:

Severe psychiatric disorders, including psychosis Acute and chronic physical illnesses had an effect on the person's mood and emotional state

Age

From **20 years** old to **45 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, 66 addicted men methadone treatment clients were selected from randomly selected random sampling from a random sampling period in Shahid Beheshti Hospital. After obtaining conscientious consent with simple randomization using Lottery method was divided into two groups of 33 participants (intervention and control)

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 Kerman University of Medical Sciences

Street address

Kerman University of Medical Sciences Vice-President of Research and Technology, Avicenna Street

City

Kerman

Province

Kerman

Postal code

7616913555

Approval date

2018-12-31, 1397/10/10

Ethics committee reference number

IR.KMU.REC.1397.291

Health conditions studied

1

Description of health condition studied

Drug addiction

ICD-10 code

F11

ICD-10 code description

Opioid related disorders

Primary outcomes

1

Description

Alert drug use

Timepoint

The first and ninety days after the end of treatment sessions

Method of measurement

Questionnaire

2

Description

Perceived Stress

Timepoint

The first and ninety days after the end of treatment sessions

Method of measurement

Questionnaire

3

Description

Acceptance and practice

Timepoint

The first and ninety days after the end of treatment sessions

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 33 methadone addicted men who were scheduled to receive ten classes of acceptance and awareness therapy in a nine-

Category

Behavior

2

Description

Control group: 33 addicted men were treated with methadone for which no additional action was taken during this period

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Sahar Salajeghe

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Boulevard Republic

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Sahar Salajeghe

Position

Resident Psychiatrist

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

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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