Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effectiveness of acceptance and commitment therapy on craving, shame, self-control, and interpersonal sensitivity among men with Substance Use Disorders under methadone maintenance treatment.

Protocol summary

Study aim

To determine the effect of Acceptance and Commitment Therapy (ACT) on craving, shame, self-control, and interpersonal sensitivity among men with substance use disorder undergoing methadone maintenance treatment at Dr. Nourian Addiction Treatment Clinic in Kashan, Iran, in 2026.

Design

This is a controlled clinical trial with a parallel-group design, no blind, and non-random allocation conducted on 60 patients.

Settings and conduct

This study is a randomized clinical trial with a pretest–posttest design, a control group, and a three-month follow-up, conducted at Addiction Treatment Clinic in Kashan. A total of 60 individuals with substance use disorder will be selected through purposive sampling after obtaining informed consent. Participants will be assigned to intervention and control groups using block randomization (blocks of four) . The intervention group will receive Acceptance and Commitment Therapy (ACT) based on Harris's protocol in eight 90-minute sessions, while the control group will receive only routine methadone maintenance treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: • Informed consent and willingness to participate in the study • Age between 25 and 55 years • No severe psychiatric disorders (e.g., psychotic disorders or bipolar disorder) • No severe physical illnesses or conditions affecting physical appearance • No Acceptance and Commitment Therapy (ACT) within the previous two years Exclusion criteria: • Positive urine drug screening test

Intervention groups

Participants will be assigned to two groups: intervention and control. The control group will receive routine methadone maintenance treatment, while the intervention group will receive a 9-session Acceptance and Commitment Therapy (ACT) protocol in addition to routine treatment.

Main outcome variables

Primary outcome measures: craving, shame, self-control, and interpersonal sensitivity.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260616069837N1**
Registration date: **2026-07-19, 1405/04/28**
Registration timing: **registered_while_recruiting**

Last update: **2026-07-19, 1405/04/28**
Update count: **0**

Registration date

2026-07-19, 1405/04/28

Registrant information

Name

Razieh Shokri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5656 0643

Email address

shokri-r@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-07-11, 1405/04/20

Expected recruitment end date

2026-08-11, 1405/05/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of acceptance and commitment therapy on craving, shame, self-control, and interpersonal sensitivity among men with Substance Use Disorders under methadone maintenance treatment.

Public title

The effectiveness of Acceptance and Commitment Therapy on individuals with substance use disorder.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Provided informed consent and expressed willingness to participate in the study. Had a diagnosis of substance use disorder confirmed by a psychologist or psychiatrist. Had abstained from methadone use for at least one month prior to participation. Had no severe psychiatric disorders (e.g., psychotic disorders or bipolar disorder) based on the diagnosis of the center’s psychiatrist. Had no severe physical illnesses or conditions affecting physical appearance, such as cancer, multiple sclerosis, limb amputation, or physical disabilities. Had at least a middle school level of education. Were between 25 and 55 years of age. Had not received Acceptance and Commitment Therapy (ACT) within the two years preceding the study. Were not receiving any concurrent psychotherapy during the study period.

Exclusion criteria:

Use of any medication or substance other than methadone. Emergence of suicidal ideation. Emergence of acute psychiatric symptoms. Failure to complete the study questionnaires. A positive urine drug screening test.

Age

From **25 years** old to **55 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Not randomized

Randomization description

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

Kashan – Qotb-e Ravandi Boulevard – Pezeshk Boulevard

City

Kashan

Province

Isfehan

Postal code

8715973474

Approval date

2026-06-08, 1405/03/18

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1405.036

Health conditions studied

1

Description of health condition studied

Substance Use Disorder (SUD)

ICD-10 code

F11

ICD-10 code description

Opioid related disorders

Primary outcomes

1

Description

Total score of substance craving

Timepoint

Baseline (before intervention) , Immediately after completion of the intervention , Three months after completion of the intervention.

Method of measurement

Desires for Drug Questionnaire (DDQ)

Secondary outcomes

1

Description

Total Shame Score

Timepoint

Baseline (before intervention) , Immediately after completion of the intervention , Three months after

completion of the intervention.

Method of measurement

Cohen et al. Shame Questionnaire

2

Description

Total Self-Control Score

Timepoint

Baseline (before intervention) , Immediately after completion of the intervention , Three months after completion of the intervention.

Method of measurement

Tangney Self-Control Scale (SCS)

3

Description

Total Interpersonal Sensitivity Score

Timepoint

Baseline (before intervention) , Immediately after completion of the intervention , Three months after completion of the intervention.

Method of measurement

Boyce and Parker Interpersonal Sensitivity Measure (IPSM)

Intervention groups

1

Description

Intervention group: Participants in the intervention group will receive Methadone Maintenance Treatment (MMT) according to the treatment center's protocol, in addition to participating in eight weekly 90-minute group sessions of Acceptance and Commitment Therapy (ACT). The sessions will focus on acceptance of internal experiences, cognitive diffusion, mindfulness, self-as-context, values clarification, and committed action in accordance with personal values. All sessions will be conducted by a trained therapist, while methadone maintenance treatment will continue throughout the intervention period.

Category

Rehabilitation

2

Description

Control group: Participants in the control group will receive Methadone Maintenance Treatment (MMT) according to the treatment center's standard protocol and will not receive any psychological intervention during the study period. Upon completion of data collection, they will be offered Acceptance and Commitment Therapy (ACT) if they wish to participate.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Addiction treatment centers affiliatd with Kashan University of Medical Sciences

Full name of responsible person

Razieh Shokri

Street address

Kashan – Qotb-e Ravandi Boulevard – Pezeshk Boulevard

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Maryam Hashemi Moghaddam

Street address

Kashan – Qotb-e Ravandi Boulevard – Pezeshk Boulevard

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shokri-r@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
Razieh Shokri

Position
Master's student in Clinical Psychology

Latest degree
Bachelor

Other areas of specialty/work
Psychology

Street address
Kashan – Qotb-e Ravandi Boulevard – Pezeshk Boulevard

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Person responsible for scientific inquiries

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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
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is 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

Title and more details about the data/document
De-identified individual participant data will be available after completion of the trial. Upon reasonable request from qualified researchers, access may be granted to raw data related to the primary outcome variables, including substance craving scores, shame scores, self-control scores, and interpersonal sensitivity scores. Personal identifying information will not be shared at any stage of data access.

When the data will become available and for how long
Access to de-identified individual participant data will begin 6 months after publication of the study results and will remain available for a period of 2 years thereafter. During this period, data will be shared with qualified researchers upon reasonable request and approval by the research team.

To whom data/document is available

De-identified individual participant data will be made available to qualified researchers. Requests will be accepted only from investigators affiliated with recognized academic institutions, research centers, or scientific organizations with a clear and relevant research purpose. Requests will be reviewed and approved by the study investigators. Access will not be granted to non-research individuals, commercial entities, or applicants outside the academic and scientific field.

Under which criteria data/document could be used

De-identified individual participant data will be used solely for scientific and non-commercial research purposes. Data use is limited to statistical analyses consistent with or complementary to the objectives of the original study. Commercial use, marketing purposes, or any non-scientific applications are strictly prohibited. Data recipients must maintain confidentiality, avoid any attempt to re-identify participants, and are not permitted to share the data with third parties without written permission from the study investigators. Access will be granted only after approval by the principal investigators and in accordance with ethical research principles.

From where data/document is obtainable

Requests for access to de-identified study data should be directed to the principal investigator or the study supervisor. Requests will be primarily handled via email. Additional correspondence may be conducted through the affiliated university if necessary. Principal Investigator: Razieh Shokri Supervisor: Dr.Zahra Zanjani Email:shokri-r@kaums.ac.ir Postal address: Faculty of Psychology and Educational Sciences, Kashan University, Iran

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

Upon receipt of a request for access to de-identified individual participant data, the request will be reviewed by the principal investigator and the research team. The first step involves assessing the scientific merit and eligibility of the applicant. If preliminarily approved, the requester will be required to sign a data use agreement, including confidentiality and non-reidentification commitments. After completion of the required documentation, the requested data will be prepared and shared electronically with the applicant. Additional clarifications, if needed, will be handled via email correspondence. The entire process typically takes between 2 to 4 weeks.

Comments