Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the Effectiveness of Acceptance and Commitment Therapy and Compassion-Focused Therapy on Relapse Risk and Craving in Amphetamine/Methamphetamine Users

Protocol summary

Study aim

Relapse and craving are important problems in the treatment of amphetamine/methamphetamine use disorder. This study aimed to compare the effectiveness of acceptance and commitment therapy (ACT) and compassion-focused therapy (CFT) on the likelihood of relapse and craving for substance use.

Design

A randomized controlled trial (RCT) with a parallel-group design—comprising three treatment arms (Acceptance and Commitment Therapy, Compassion-Focused Therapy, and a control group)—was conducted on 45 patients with amphetamine use disorder. Random Allocation Software was used to randomly assign participants to the groups..

Settings and conduct

Psychiatry and Addiction Clinics affiliated with Isfahan University of Medical Sciences. Screening and Sample Selection: The primary sampling method was convenience sampling among clients who were referred by psychiatrists to receive psychological interventions.

Participants/Inclusion and exclusion criteria

Age range: Between 18 and 50 years old. Residence: Living in Isfahan Education level: Having at least a high school diploma. Type of substance use disorder: Abuse of amphetamine/methamphetamine only (no dependence or concurrent abuse of other substances such as alcohol, opioids, etc.)

Intervention groups

The study included two intervention groups of 15 participants, both of whom received Matrix Model sessions along with 8 weekly 45-minute sessions of psychological therapy: Group 1 - Acceptance and Commitment Therapy (ACT): The intervention content focused on accepting unpleasant thoughts and emotions related to the temptation to use, the concept of creative helplessness, mindfulness, and strengthening the "observer self" (using metaphors such as a chessboard and bus passengers). They were also taught to clarify personal values and take committed action to build a substance-free life.

Main outcome variables

Comparing the effect of ACT with CFT

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260915071060N1**
Registration date: **2026-10-03, 1405/07/11**
Registration timing: **retrospective**

Last update: **2026-10-03, 1405/07/11**
Update count: **0**

Registration date

2026-10-03, 1405/07/11

Registrant information

Name

ELHA. MOHEBATI

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3633 0642

Email address

dr.eli.mohebati.1983@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-22, 1400/04/01

Expected recruitment end date

2022-12-16, 1401/09/25

Actual recruitment start date

2025-04-30, 1404/02/10

Actual recruitment end date

2026-01-13, 1404/10/23

Trial completion date

2026-02-21, 1404/12/02

Scientific title

Comparison of the Effectiveness of Acceptance and Commitment Therapy and Compassion-Focused Therapy on Relapse Risk and Craving in Amphetamine/Methamphetamine Users

Public title

Comparison of the Effectiveness of Acceptance and Commitment Therapy and Compassion-Focused Therapy on Relapse Risk and Craving in Amphetamine/Methamphetamine Users

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age range: 18 to 50 years. Place of residence: Resident of Isfahan Education: Minimum of a high school diploma. Diagnosis: Confirmed diagnosis of amphetamine abuse or dependence (without abuse of other substances or alcohol). Treatment history: No pharmacological or psychological intervention for substance abuse in the past six months.

Exclusion criteria:

Absence from sessions: Missing three or more treatment sessions (intervention protocol). Relapse: Experiencing any relapse or return to amphetamine use during the intervention period. Non-cooperation: Expression of unwillingness to participate or discontinuation of cooperation by the participant during the course of treatment.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Care provider
- Outcome assessor

Sample size

Target sample size: **45**

Actual sample size reached: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

Based on the article text (sud.docx), the randomization process was conducted using the specialized "Random Allocation Software." The details are as follows: Implementation method: Following the initial selection of participants and the verification of inclusion criteria, the researchers used the aforementioned software to assign participants to different groups. Grouping: Participants were randomly divided into three main groups: Intervention Group 1: Acceptance and Commitment Therapy (ACT) Intervention Group 2: Compassion-Focused Therapy (CFT) Control Group The use of this software in clinical trials is a standard and valid method employed to minimize bias in participant selection and group allocation, thereby enhancing the study's internal validity.

Blinding (investigator's opinion)

Double blinded

Blinding description

Package coding: Medications are dispensed by an independent pharmacist or a random coding system with coded labels so that the doctor and patient can code A or B without knowing the nature of the medication.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

This study was designed in accordance with the principles of the Declaration of Helsin

Street address

Isfahan University of Medical Sciences

City

Isfahan

Province

Isfehan

Postal code

81746-73461

Approval date

2024-06-08, 1403/03/19

Ethics committee reference number

IR.ARI.MUI.REC.1403.040

Health conditions studied

1

Description of health condition studied

Amphetamine use disorder

ICD-10 code

F15.2

ICD-10 code description

Other stimulant dependence

Primary outcomes

1

Description

Comparing the effectiveness of CFT with ACT

Timepoint
Two months
Method of measurement
Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention group: Act psychotherapy treatment
Category
Treatment - Other

2

Description
Intervention group: Intervention name (title): Acceptance and Commitment Therapy (ACT) with the Matrix Basic Model. Intervention description: In addition to receiving 8 weekly sessions of the Matrix Model (relapse prevention education, healthy lifestyle, and self-help programs), patients in this group underwent 8 weekly sessions of individual Acceptance and Commitment Therapy (ACT) for 45 minutes per session. The sessions were conducted by a psychiatrist who was proficient in the intervention, and the patients were followed up twice, two weeks apart. Intervention group: First session: Clinical interview, case conceptualization, and training on how the mind works. Second session: Examining ineffective strategies of mental restraint and control using the "tug-of-war" exercise and metaphor. Third session: Creating creative hopelessness through the "farm of life" metaphor. Fourth session: Psychoeducation of the inner and outer world, distinguishing between pure and impure suffering, using the "sensitive device" metaphor, and the "1-2-3" experimental exercise. Fifth session: Promoting psychological acceptance and willingness with the "uninvited guest" metaphor and identifying cognitive errors with the "bus" metaphor. Sixth session: Self-as-Context exercise and mindfulness of the conceptualized self using the "chessboard" and "billboard" metaphors.
Category
Treatment - Other

3

Description
Intervention group: Intervention group 2 (Compassion-Focused Therapy - CFT) (Create a new box by clicking the Add button and entering the following text) Intervention name (title): Compassion-Focused Therapy (CFT) with the basic matrix model Intervention description: In addition to 8 weekly sessions of the matrix model, patients in this group underwent 8 weekly sessions of individual compassion-focused psychotherapy (CFT) for 45 minutes per session by the same psychiatrist, and follow-up was conducted twice with two-week intervals. Title and content of CFT sessions: Intervention group: First session: Conclusion of a therapeutic contract, diagnostic compassion interview, providing feedback, and the first step of formulation and conceptualization. Second session: Second step of conceptualization based on the cultural context and history of the client, creating empathy and feedback based on compassion. Third session: Third step of conceptualization, functional analysis of different areas of life and identification of the pathological vicious cycle and unkindness to oneself. Fourth session: Training in the ancient/modern/conscious brain model and the triple model of motivation And the emotion of compassion to enhance the client's motivation to move towards compassion. Session Five: Explaining the effect of kindness and compassion in stopping the cycle of blaming and unkindness to oneself and the mind. Session Six: Conceptualizing and activating the "Compassionate Self", teaching its characteristics and comparing it with other vulnerable parts of the self. Session Seven: Assessing the alignment of the compassionate self with life values, reviewing caring for individual well-being with the "One Great Day" exercise, identifying internal/external barriers, and teaching compassion-based behaviors. Session Eight: Revisiting the conceptualization matrix, reviewing the disease cycle and ways to prevent the return of symptoms, teaching life practice, and assessing readiness and periodic follow-up.
Category
Treatment - Other

4

Description
Control group: Control group: Participants in this group received only the standard and basic substance withdrawal program (including 8 weekly sessions of the Matrix model aimed at teaching temptation and relapse prevention, healthy lifestyle, and participation in self-help programs) and no specific additional individual psychotherapy intervention (either ACT or CFT) was implemented for them. The initial assessment and follow-up of this group were conducted simultaneously with the two intervention groups (immediately after the course and follow-ups at two-week intervals) using the Relapse Prediction Questionnaire (RPS).
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Amin Hospital Addiction Treatment Clinic
Full name of responsible person
Dr.Elham mohebati
Street address
Shahid Keshvari Town-Golestan Boulevard, a doctors' complex

City
Isfahan
Province
Isfehan
Postal code
8169317544
Phone
+98 31 3633 0642
Email
dr.eli.mohebati.1983@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Dr. Gholam Reza Asgari
Street address
Isfahan University of Medical SciencesIsfahan University of Medical Sciences, Building No. 4, Research Associate of
City
Isfahan
Province
Isfehan
Postal code
81746-73461
Phone
+98 31 3668 7898
Email
research@mui.ac.ir
Grant name
Vice President for Research, Isfahan University of Medical Sciences
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Dr.Elham mohebati
Position
Assistant Professor of Psychiatry, Isfahan Medical School
Latest degree
Specialist
Other areas of specialty/work
Psychiatrics
Street address
Isfahan University of Medical Sciences
City
Isfahan
Province
Isfehan
Postal code
81746-73461
Phone
+98 31 3633 0642
Email
dr.eli.mohebati.1983@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Dr.Elham mohebati
Position
Assistant Professor of Psychiatry
Latest degree
Specialist
Other areas of specialty/work
Psychiatrics
Street address
Isfahan University of Medical Sciences
City
Isfahan
Province
Isfehan
Postal code
81746-73461
Phone
+98 31 3633 0642
Email
dr.eli.mohebati.1983@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Dr.Elham mohebati
Position
Associate Professor of Psychiatry
Latest degree
Specialist
Other areas of specialty/work
Psychiatrics
Street address
Isfahan University of Medical Sciences

City
Isfahan
Province
Isfehan
Postal code
81746-73461
Phone
+98 31 3633 0642
Email
dr.eli.mohebati.1983@gmail.com

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
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
There is a plan for the publication of approved items.
When the data will become available and for how long
One year
To whom data/document is available
Medical students and professors
Under which criteria data/document could be used
The best way to increase knowledge and awareness is through registration in a reputable scientific journal.
From where data/document is obtainable
Registration in a reputable journal
What processes are involved for a request to access data/document
By searching other similar articles
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