Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparing the effectiveness of reality therapy with acceptance and commitment therapy on craving, self-control, hope, and distress tolerance in male substance abusers undergoing treatment in residential addiction treatment centers

Protocol summary

Study aim
The aim of the study was to compare the effectiveness of reality therapy with acceptance and commitment therapy on craving, self-control, hope, and distress tolerance in male substance abusers undergoing treatment.

Design
Clinical trial with parallel groups, single-blind, randomized, conducted on 68 patients, randomization is performed using Excel software

Settings and conduct
Male substance abusers residing in treatment centers in Neyshabur will be included in the study and will be randomly assigned to the intervention groups. This study will be conducted in a single-blind manner so that the statistical analyst will not be aware of the intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Individuals with substance use disorders, aged between 18 and 60 years, with a minimum of a high school diploma, no neurological disorders, and no illness that would prevent cooperation. Exclusion criteria: Severe mental disorders, use of psychiatric medications affecting mood and anxiety, concurrent participation in another clinical trial, severe sensory and motor problems

Intervention groups
Intervention group 1 (Reality therapy): An evidence-based approach that focuses on the individual's current choices and behaviors, and taking responsibility. Structure: Group therapy in 8 weekly sessions, each session lasting 90 minutes. Session content: Identifying basic desires and needs, examining current behaviors, identifying dysfunctional behaviors, and taking responsibility. Intervention group 2 (Acceptance and Commitment Therapy): A treatment that aims to increase psychological flexibility. Structure: Group therapy in 8 weekly sessions, each session lasting 90 minutes. Session content: Introduction to the therapeutic model and the concept of experiential avoidance, training in accepting internal experiences.

Main outcome variables
Craving, self-control, hope, and distress tolerance

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250923067331N3**
Registration date: **2026-08-28, 1405/06/06**
Registration timing: **prospective**

Last update: **2026-08-28, 1405/06/06**
Update count: **0**

Registration date
2026-08-28, 1405/06/06

Registrant information

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Mohsen Rafie

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
recruiting

Funding source

Expected recruitment start date

2026-09-22, 1405/06/31

Expected recruitment end date

2026-11-21, 1405/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effectiveness of reality therapy with acceptance and commitment therapy on craving, self-control, hope, and distress tolerance in male substance abusers undergoing treatment in residential addiction treatment centers

Public title

Comparing the effectiveness of two psychotherapy approaches in male substance abusers

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

People with substance use disorders Age between 18 and 60 years old Minimum educational qualification: Diploma No neurological disorders or any disease that prevents cooperation.

Exclusion criteria:

The presence of other mental disorders, such as schizophrenia, bipolar disorder, or depression with psychotic features Discharge or exit from a residential addiction treatment center in a way that makes it impossible to regularly participate in intervention sessions and research assessments. Concurrent participation in another clinical trial or receiving organized psychological treatment in the past six months Inability to read or write or severe vision or hearing problems

Age

From **18 years** old to **60 years** old

Gender

Male

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

After obtaining the ethics code and clinical trial code, two centers will be randomly selected from among the medical centers in Neyshabur city, and one center will be randomly selected as the first experimental group and one center as the second experimental group. The subjects will initially be examined in terms of entry criteria, and 34 people will be randomly selected from each center. The research objectives will be explained to eligible individuals and written consent will be obtained. Participants will be randomly assigned to one of the two groups using simple computer random numbers in Excel software.

Blinding (investigator's opinion)

Single blinded

Blinding description

Data relating to treatment groups are replaced with non-identifiable codes. Any information relating participants to treatments, such as names or details of the intervention, is also removed from the data set presented to the analyst. The statistical analyst performs the pre-specified analyses without knowing which code refers to which treatment.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of the Vice Chancellor for Research and Technology, Shahid Beheshti University of M

Street address

5th Floor, Building No. 2, Shahid Arabi Street, Yemen Street, Shahid Chamran Highway

City

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Province

Tehran

Postal code

1985717444

Approval date

2025-12-13, 1404/09/22

Ethics committee reference number

IR.SBMU.RETECH.REC.1404.710

Health conditions studied

1

Description of health condition studied

Substance abuse

ICD-10 code

F19.2

ICD-10 code description

Other psychoactive substance dependence

Primary outcomes

1

Description

Craving score on the Samosa Craving Questionnaire

(BSCS)

Timepoint

Examining the level of craving before the start of the intervention, 60 days and 180 days after the start of the intervention

Method of measurement

The score that the subject reports on the questionnaire. Samosa Craving Questionnaire(BSCS)

2

Description

Self-control score on the Tangji Self-Control Questionnaire

Timepoint

Examining the level of self-control before the start of the intervention, 60 days and 180 days after the start of the intervention

Method of measurement

The score that the subject reports on the questionnaire. Tangji Self-Control Questionnaire

3

Description

Life expectancy score on the Schneider Life Expectancy Questionnaire

Timepoint

Examining life expectancy before the start of the intervention, 60 days and 180 days after the start of the intervention

Method of measurement

The score that the subject reports on the questionnaire. Schneider Life Expectancy Questionnaire

4

Description

Distress Tolerance Score on the Simmons and Gahr Questionnaire (DTS)

Timepoint

Examining distress tolerance before the start of the intervention, 60 days and 180 days after the start of the intervention

Method of measurement

The score that the subject reports on the questionnaire. Simmons and Gahr Distress Tolerance Questionnaire (DTS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group 1: Reality Therapy: An approach proposed by William Glasser and based on “Choice Theory.” Its basic assumption is that humans choose behaviors to satisfy their basic needs, and that psychological and interpersonal problems are largely created when a person uses ineffective strategies to satisfy these needs. Therefore, instead of focusing on the past and unconscious causes for a long time, reality therapy focuses mainly on the present, current behavior, choice, responsibility, relationships, and creating more effective behaviors. The goal of therapy is not for the therapist to tell the client what the “right” choice is; rather, it helps the client see for himself what the consequences of his current choices are and whether they bring him closer to his desired life. In Choice Theory, Glasser proposes five basic needs: survival, love and belonging, power, freedom, and recreation. Humans are constantly trying to satisfy these needs. Each person also has a “quality world”—a set of mental images of the people they love, the relationships they want, the conditions they value, and the lifestyle they want. When there is a gap between what they want and what they experience in reality, frustration occurs. The person then chooses behaviors to close this gap, but these behaviors may be ineffective. For example, a person with a strong need for love and belonging may choose to be aggressive, threatening, or controlling rather than effective communication when they feel rejected. This behavior may create a sense of control in the short term, but in the long term, it will damage the relationship and further distance them from their desired world. The therapist here tries to help the person understand this cycle. One of the central concepts of reality therapy is responsibility. Responsibility does not mean that the person is to blame for everything that happens in their life; rather, it means that the person examines what is within their sphere of choice and control in the current situation. For example, if a person’s spouse is behaving inappropriately, the client cannot directly control the spouse’s behavior, but they can decide how to respond, set boundaries, communicate, distance themselves, or seek help. So the therapist constantly shifts the focus from “others need to change” to “what choices do I have?” The practical core of reality therapy is the WDEP model. W stands for Wants, D stands for Doing or Direction, E stands for Evaluation, and P stands for Planning. These four stages are not strictly linear and rigid, and the therapist moves between them constantly throughout the course of therapy. The most important stage is E, or Self-Evaluation; That is, the client examines how much the current behavior contributes to his goal. In a short-term eight-session protocol, the first session is usually dedicated to establishing the therapeutic relationship, assessing the current problem, specifying the goal of treatment, and introducing the logic of choice theory. The therapist begins with questions such as “What made you come to therapy?”, “What would you like to change if the treatment was successful?”, “What is the most important thing you want right now?”, and “What do you do when you encounter this problem?” In this same session, the therapist introduces the concepts of basic needs, choice, and responsibility in simple language, and an initial goal for treatment is specified. The main techniques of this session include establishing a relationship, active listening, questioning, clarifying desires, and introducing choice theory. At the end, a simple task is usually assigned to observe current

behaviors and situations in which the problem arises. In the second session, the focus is more on the client's basic needs and desired world. The therapist examines which need the current problem is most closely related to; for example, belonging, power, freedom, or security. Then the client is asked to provide a picture of their desired life: "What would your relationship be like if life went the way you want it to?", "How would you like others to treat you?", "What would your desired life be like?". This session uses the techniques of need exploration, Quality World identification, questioning, and goal clarification. The goal is to determine exactly what the client is looking for and how far the current problem has come from their desired life. In the third session, the focus is on W and D, current wants and behaviors. The therapist helps to transform general wants into more specific goals. For example, if the client says, "I want my partner to pay more attention to me," the therapist asks, "What exactly would change in the relationship if you received more attention?" Then, it is examined what the client is currently doing to achieve this goal. Questions such as "What do you do when you feel ignored?", "What happens next?", and "What is the usual outcome of this behavior?" help identify the behavioral cycle. Techniques in this session include focusing on the current behavior, analyzing the behavior, questioning, and identifying the direction of the person's movement. In the fourth session, the E or Evaluation section becomes more important. At this stage, the therapist invites the client to evaluate his or her own behavior. For example, if the person is angry to get his or her partner's attention, the therapist does not say "Being angry is bad," but asks: "How much has being angry brought you closer to the relationship you want?", "Has this behavior met your need for belonging?", "If you continue this behavior, your relationship is likely to fail."

Category

Treatment - Other

2

Description

Intervention Group 2: Acceptance and Commitment Therapy (ACT): This therapy usually begins by establishing a therapeutic relationship based on acceptance, empathy, collaboration, and experience-centeredness. In ACT, the therapist does not necessarily have the role of an expert who is supposed to tell the client which thoughts are right and which are wrong; rather, he or she examines with the client what results his or her current strategies in life have produced. One of the basic questions the therapist asks is: "Is what you are doing to control this experience going to create the life you want for you in the long run?" If the answer is no, the therapy moves toward building flexibility and value-based behaviors. In a short-term protocol of 8 sessions, the first session is usually dedicated to establishing a therapeutic relationship, introducing the ACT model, and assessing the problem pattern. The therapist first identifies what the client has a problem with, what unpleasant experiences he or she is experiencing, and what he or she is doing to cope with them. Then, the concept of "control" is examined. For example, if the client says, "No matter what I do, my anxiety doesn't go away," the therapist asks, "What have you done so far to control your anxiety, and what have these actions done in the short and long term?" This introduces the concept of ineffective emotional control; that is, sometimes trying to control one's own internal experience has become part of the problem. One important exercise in this session can be examining the "cost of control"; the client writes on paper what they have done to get rid of anxiety, depression, unpleasant thoughts or memories, and what the short-term benefits of each were and what the long-term costs were. The goal of the first session is for the client to realize that the problem is not necessarily the presence of an unpleasant thought or feeling, but rather their inflexible relationship with that experience. In the second session, the focus is more on ineffective control and experiential avoidance. Using examples and experiential exercises, the therapist shows the client that trying to eliminate a mental experience may itself make it stronger. For example, the therapist can ask the client to try not to think about a particular thought for a few moments and then examine what happened. In this way, the concept that "the mind is not always controllable" is examined experientially. The concept of acceptance is then introduced; acceptance does not mean liking, approving, or giving in to circumstances, but rather creating a mental space to experience thoughts and emotions without unnecessarily fighting them. Exercises such as observing the emotion, paying attention to bodily sensations, and allowing the unpleasant experience to be without immediately trying to eliminate it can be used in this session. Homework can be to record situations in which the person has tried to control or suppress their unpleasant experience and what the results of this effort were. In the third session, the focus on acceptance and contact with the present moment deepens. The therapist explains that acceptance does not mean becoming passive; The person can accept the unpleasant experience and at the same time take action to change the external circumstances. Then mindfulness exercises enter the treatment. For example, the therapist can invite the client to a short breathing and thought observation exercise: "Close your eyes and just notice the in and out of your breath. If a thought comes, you don't have to eliminate it; just notice that a thought has come and bring your attention back to the present experience." In this session, the client learns to connect with the present experience instead of getting lost in the past or future. The main techniques include mindfulness, nonjudgmental observation, paying attention to bodily sensations, practicing acceptance, and connecting with the present moment. The main focus of the fourth session is cognitive defusion. In ACT, the goal is not to prove the content of the thought to be right or wrong; rather, the person learns to create a distance between "thought" and "reality." For example, a person who thinks, "I am worthless" often identifies with this thought and accepts it as the absolute truth. The therapist can ask the person to change the sentence from "I am worthless" to "I am experiencing the thought that I am worthless." This small change changes the person's

relationship with the thought. Techniques such as labeling thoughts, repeating a word until it becomes a meaningless sound, observing the thought as a mental event, the metaphor of a leaf on water, and distancing oneself from the mental story can be used. The goal is not to make the thought disappear; the goal is to make the thought no longer automatically determine the person's behavior. In the fifth session, the focus is on the self-as-context. At this stage, the client learns to distinguish between the "I" and the content of his or her experiences. For example, instead of saying, "I am an anxious person," one can move to "I am a person who is currently experiencing anxiety." Through observational exercises, mindfulness, and reviewing various life experiences, the therapist shows that the person's thoughts, emotions, roles, and even self-perception have changed over time, but there is an observing capacity for these experiences. The goal of this section is to reduce attachment to fixed identities and limiting stories about oneself. In this session, the Self-as-Observer exercise, observing thoughts and feelings from the observer's position, and experiential exercises can be used. In the sixth session, therapy enters the Values axis. Values are different from goals. A goal is something that can be achieved; values are more indicative of the direction of life. For example, "passing an exam" is a goal, but "growth, learning, and competence" can be values. The therapist examines different areas of life such as relationships, family, career, personal growth, health, friendships, and social participation and asks: "If fear and anxiety were not your obstacle, how would you like to be in this area?", "I would like to

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
22 Bahman Hospital, Neyshabur
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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?
Yes
Title of funding source
Shahid Beheshti 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

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Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mohsen Rafee
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
It is not ethical

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
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
Treatment data: Information on the main outcome of treatment will be shared

When the data will become available and for how long
Access period starts 6 months after results are published.

To whom data/document is available
Academic researchers, faculty members, and graduate students

Under which criteria data/document could be used
De-identified personal data and study-related documentation will be made available to eligible researchers for research and scientific purposes only and within the scope of the purposes stated in the access request. Requesters must be researchers, faculty members, graduate students, or affiliated with an accredited research institution and submit their request in writing. The request must specify the purpose of the research, the research question or hypothesis, the type of data needed, the proposed statistical analysis method, the method of data protection, and the method of publication of the results. The data provided will be made available to the applicant only after the request has been reviewed and approved by the principal investigator or a committee/authority designated by the principal investigator. Use of the data is permitted only within the scope of the approved purpose and analytical design, and any new use or analysis outside the initial request will require a re-application and re-approval. Secondary statistical analyses on de-identified data, including descriptive, inferential, correlation, regression, analysis of variance, and multivariate analyses, are permitted if they are consistent with the approved research objective, data structure, and scientific and ethical principles. Analyses that may lead to direct or indirect identification of participants will not be permitted. The data will be provided solely in de-identified form, without information that directly identifies the participants. The data recipient is required to refrain from attempting to re-identify participants and not to transfer the data to third parties. The data must also be stored in a secure environment and system and deleted or destroyed after the agreed period, in accordance with the specified conditions. Study-related documentation, including the study protocol, statistical analysis plan, data dictionary, and other related documentation, if available and to the

extent permitted, will be used solely for research purposes related to the approved request. Use of this documentation for commercial, promotional, or purposes inconsistent with the informed consent of participants and the ethical approvals of the study is not permitted. If data from this study are used in an article, dissertation, scientific report, presentation, or any research product, the recipient is required to appropriately cite the source of the data and the original study and include the trial registration ID in the report or article. Also, if a secondary analysis is performed, the researcher must clearly indicate that the analysis performed was a secondary analysis based on data from this trial and explain how it differs from previous analyses of the study. This is consistent with the ICMJE recommendations on the use of shared data. The requirements for submitting an access request include the following: 1) Complete details of the applicant and their institutional affiliation; 2) Statement of the research objective and question; 3) Identification of the data or documentation required; 4) Presentation of the proposed analysis plan or method; 5) Explanation of how the data will be stored and protected; 6) Commitment to not attempt to re-identify participants; 7) Commitment to not transfer data to third parties; 8) Commitment to use the data only within the scope of the approved request; 9) Compliance with research ethics requirements and confidentiality of participant information; and 10) Commitment to mention the data source and trial registration ID in all scientific outputs derived from the received data. Access to data or documentation will be subject to approval of the request and acceptance of the terms of use and confidentiality. If any use outside the approved purpose, attempts to re-identify participants, unauthorized transfer of data, or violation of ethical and confidentiality requirements are observed, the recipient individual or group's access to the data will be revoked.

From where data/document is obtainable

Applicants for non-personally identifiable data or other documentation of this study can apply through the following channels in order of priority: Contact the lead researcher; Name and surname: Mohsen Rafiei; Organizational affiliation: Shahid Beheshti University of Medical Sciences; Email: mohsenrafie7272@gmail.com; Contact number: 09362808337. Contact the research partner: If no response is received, applicants can apply through the research center or project partner; Name and surname: Amir Sam Kiani Moghadam; Organizational affiliation: Shahid Beheshti University of Medical Sciences; Email: as.kianimoghadam@gmail.com; Contact number: 09124857320. Submit a request via the website: If available, the data request form will be made available via the website.

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

Applicants for de-identified personal data or study-related documentation must submit their request in writing to the principal investigator/designated data sharing officer. The request must include the applicant’s organizational affiliation and affiliation, research objective and question, type and scope of data or documentation required, proposed analysis method, data use and retention, and publication of results. Upon receipt of the request, the completeness of the information and the application’s compliance with the terms of access and use of study data will be reviewed. If the request is incomplete, the applicant will be notified of the items required to be completed, and the application will be reviewed after receiving the additional information. The complete application will be reviewed by the principal investigator or designated authority from a scientific, ethical, and feasibility perspective. At this stage, the feasibility of providing the requested data or documentation, the absence of identifiable information, the compatibility of the request with informed consent of participants and ethical requirements, and the appropriateness of the proposed method of use and analysis will be reviewed. Complete applications will usually be reviewed and the applicant will be notified of the outcome within 15 business days of receipt of the complete application. In cases where the application requires further review or coordination with relevant authorities, the review time may be extended and the applicant will be notified of this. After the application is approved, the terms of use of data and confidentiality of information are communicated to the applicant and the applicant is required to accept the obligations regarding confidentiality, non-reidentification of participants, non-transfer of data to third parties and use of data only within the framework of the approved application before receiving the data. After the approval process is completed and acceptance of the terms of use, de-identified personal data or approved documentation will be prepared and provided to the applicant through a secure method. The data will be reviewed before delivery for deletion or masking of information that could lead to direct or indirect identification of participants. Data and documentation will typically be delivered within 10 business days of final approval of the application and completion of the data use commitments. Therefore, assuming the application is complete and no additional reviews are required, the entire process from receipt of the complete application to data delivery is expected to take approximately 25 business days. If the application is rejected, the reasons for the rejection will be communicated to the applicant. If the research objective, type of data requested, or method of data use needs to be revised, the applicant may resubmit their revised application and the review will begin from the beginning.

Comments