Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effectiveness of acceptance and commitment therapy on cognitive emotion regulation and distress tolerance in individuals with generalized anxiety disorder.

Protocol summary

Study aim
Determining the effectiveness of acceptance and commitment therapy on cognitive emotion regulation and distress tolerance in individuals with generalized anxiety disorder

Design
Clinical trial of the effectiveness of the treatment group plus the control group, with a parallel group, does not have blinding. 30 people are selected through purposeful randomization and then they are placed into groups through simple randomization.

Settings and conduct
The study will be conducted among individuals aged 20 to 40 years with generalized anxiety disorder who are referred to counseling and psychological services centers in Ahvaz. After screening and meeting the entry requirements, 30 individuals will be selected through purposive sampling and randomly assigned to two experimental and control groups (15 individuals in each group). Interventions will be implemented over 8 90-minute sessions, once a week, for two months. The control group will not receive any intervention until the end of the study, and blinding will not be performed in this study.

Participants/Inclusion and exclusion criteria
Inclusion criteria included: diagnosis of generalized anxiety disorder based on DSM-5-TR criteria, age between 20 and 40 years, informed consent to participate in the study, and exclusion criteria included: severe psychiatric disorders, cognitive disability or mental retardation that prevents effective participation in sessions, and receiving other concurrent psychotherapy.

Intervention groups
The intervention group includes patients with generalized anxiety disorder who will undergo a therapeutic intervention protocol during 8 90-minute sessions, one session per week, while the control group will not receive any intervention.

Main outcome variables
Cognitive emotion regulation, distress tolerance

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260715070202N1**
Registration date: **2026-07-27, 1405/05/05**
Registration timing: **prospective**

Last update: **2026-07-27, 1405/05/05**
Update count: **0**

Registration date
2026-07-27, 1405/05/05

Registrant information

Name
Mohammad Mohammad soltani

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-08-01, 1405/05/10

Expected recruitment end date
2026-10-02, 1405/07/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of acceptance and commitment therapy on cognitive emotion regulation and distress tolerance in individuals with generalized anxiety disorder.

Public title

The effectiveness of acceptance and commitment therapy on cognitive emotion regulation and distress tolerance.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

.Diagnosis of generalized anxiety disorder based on DSM-5-TR criteria Aged between 20 and 40 years old Informed consent to participate in research

Exclusion criteria:

Having severe psychiatric disorders Cognitive disability or mental retardation that prevents effective participation in meetings. receiving other psychotherapy at the same time

Age

From **20 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment of eligible individuals to the intervention and control groups will be simple random, using a random sequence generated by a random number table on the Randomization.com website. (To prepare a randomization list on the Randomization.com website, first enter the number of samples, the number of groups, and the type of randomization (such as block); then the website automatically generates a random list for assigning individuals to the research groups, which can be used in the sampling or subject allocation process.) This sequence is written in lowercase letters and kept in a sealed envelope. When each individual is selected, the envelope is opened and the individual is assigned to the counseling or control group according to the code.

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 Islamic Azad University, Ahvaz Branch

Street address

Southern Kargar Boulevard, Culture City, Golestan Highway

City

Ahvaz

Province

Khouzestan

Postal code

6134937333

Approval date

2026-06-30, 1405/04/09

Ethics committee reference number

IR.IAU.AHVAZ.REC.1405.357

Health conditions studied

1

Description of health condition studied

Generalized anxiety disorder

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

Primary outcomes

1

Description

Cognitive excitement

Timepoint

At the start of the intervention, 2 weeks after the intervention, 8 weeks after the intervention, 2 months after the end of the intervention

Method of measurement

Cognitive Emotional Regulation Questionnaire

2

Description

Distress tolerance

Timepoint

At the start of the intervention, 2 weeks after the intervention, 8 weeks after the intervention, 2 months after the end of the intervention

Method of measurement

Distress Tolerance Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 1. First session: First, the therapist introduces himself and the group members to each other and explains the logic and purpose of forming the group. Then, the rules of treatment and why it is necessary to observe them are explained, such as confidentiality, respect for each person, timely and continuous attendance at sessions and refraining from leaving sessions early, commitment to participate in each therapy session, and active participation (each person in the group is allowed to actively choose the position he wants). 2. Second session: A summary of the previous session is presented. The first few minutes of the session are spent on general information and explaining the treatment process. Then, the initial problem of the clients is discussed and the reason for their entry into the treatment session is asked. The therapist asks the clients in which areas of their lives fear and anxiety have caused the most distress and disability, and what issue has disturbed them most over the past month? (Excessive description of symptoms or history of the disorder is not required) Feedback and assignment presentation. 3. Third session: Reviewing the assignment and providing summaries of the previous session. The session begins with a focus exercise. After that, the therapist examines the avoidance patterns, costs, and effectiveness of the previous session. By creating constructive frustration and using the analogy of a child in a hole, the therapist shows the client that his struggle against anxiety is useless and that he needs a completely different strategy to solve this problem. 4. Fourth session: Reviewing the assignment and providing a summary of the previous session. The session begins with the exercise of "accepting thoughts and feelings." After reviewing the daily exercises, the therapist shows the ineffectiveness of the previous strategies by practicing tug-of-war with the anxiety monster. Then, selecting important goals begins with the analogy of "feeding the anxiety tiger." It is explained that the goal of the remaining sessions is to get them back on track with the important goals of a fulfilling and healthy life, and with questions such as what is most important in his life? What would his life be like if he didn't have anxiety? And what more important activities would he do? Clients are guided to find their values. Feedback and assignment. 5. Session 5: Review assignment and provide a summary of the previous session. In this session, after reviewing the exercises, the therapist explains the nature of acceptance and awareness, followed by the anxiety acceptance exercise. Clients are then asked to discuss their experience and share their questions, opinions, and concerns. Factors that influence the "desire for control" are then discussed. Feedback is received and the assignment is presented. 6. Session 6: Review assignment and provide summaries of the previous session. The session begins with a focus exercise. After reviewing the exercises, the therapist explains the self as context versus the self as content in simple language to the clients using an analogy and a chessboard exercise. Then, by reviewing the client's entire life experience of the past week, the values are reviewed again, and the therapist examines those behaviors of the client in order to control anxiety that have prevented him from moving towards valuable goals. Finally, the clients were given a "Life Compass" sheet. After the therapist explained the valuable paths, they were asked to fill out the sheet (Life Compass) using the information they had entered in the sheet. Receive feedback and present the assignment. 7. Seventh session: The session began with a focus exercise. After reviewing the previous exercises, the client was asked to identify the cases in which he tried to control anxiety and fear with his behavior and to find the long-term and short-term costs of accepting "emotional desire" in his life. Then the therapist discussed the experience of anxiety and after that, the purpose of facing intense feelings and emotions as the therapist's "bus driver" was explained. Before starting this exercise, the therapist introduced a metaphor for guidance on how to do or not do something in times when intense and aggressive thoughts and feelings threaten the client and motivate him to avoid it. Then, the "Sense of Life" exercises were performed with the goal of a full, rich, and meaningful life. Receive feedback and present the assignment. 8. Session 8: The session begins with a focus exercise. The therapist reviews the clients' daily anxiety acceptance exercises and briefly talks to the clients about their experiences while doing these exercises and discusses examples of clients' behaviors to manage their thoughts, senses, and feelings. At this stage, clients will show a significant increase in coping with their anxiety. Then, through natural value-based behavioral activation, activities are selected by the clients based on the "Life Orientation" sheet and referring to the Life Compass and Valuable Paths sheets, and valuable paths, preparation of a hierarchy of activities, and commitment to action are discussed and examined using the Activities Sheet related to Valuable Life Goals. At the end of the treatment, clients are given explanations on how to prevent the problem from recurring. Session summary, post-test.

Category

Behavior

2

Description

Control group: They do not receive any intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Ideh Clinic
Full name of responsible person
Mohammad Izadi
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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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Email
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Web page address
https://ahvaz.iau.ir/fa

Grant name

Grant code / Reference number

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

Title of funding source
Islamic Azad University

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
Islamic Azad University
Full name of responsible person
Mohammad Mohammad soltani
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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
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
Study data, treatment protocol
When the data will become available and for how long
After publishing the articles
To whom data/document is available
All those interested in research in this field
Under which criteria data/document could be used
Any type of analysis on the submitted data is permitted and acceptable with attribution of the source
From where data/document is obtainable
Via Mohammad Mohammadsoltani email at: mm.soltani90@gmail.com
What processes are involved for a request to access data/document
Send an email to Mohammad Mohammadsoltani and after approval by the research team members, the data will be sent.
Comments