Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparing the effectiveness of acceptance and commitment therapy with mindfulness-based cognitive therapy on psychological flexibility, life satisfaction, life expectancy, and stress in elderly people with type 2 diabetes

Protocol summary

Study aim
The aim of the study was to compare the effectiveness of acceptance and commitment therapy with mindfulness-based cognitive therapy on psychological flexibility, life satisfaction, life expectancy, and stress in elderly people with type 2 diabetes

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

Settings and conduct
Elderly men residing in care centers in Neyshabur city who are eligible will be included in the study and will be randomly assigned to the intervention and control 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: Elderly people over 65 years of age, at least a high school diploma, type 2 diabetes, no neurological disorders, and no disease that prevents cooperation; Exclusion criteria: Presence of severe mental disorders, use of psychiatric medications affecting mood and anxiety, simultaneous participation in another clinical trial, severe sensory and motor problems

Intervention groups
Intervention group 1 (Acceptance and commitment therapy): An evidence-based therapy that aims to increase psychological flexibility. Structure: Group therapy in 8 weekly sessions, each session lasting 60 minutes. Session content: Introduction to the therapeutic model and the concept of experiential avoidance, training in accepting internal experiences rather than controlling them. Intervention group 2 (Mindfulness-based cognitive therapy): A third-wave approach that aims to become aware of thought patterns. Structure: Group therapy is provided in 8 weekly sessions, each session lasting 60 minutes. Session content: Body scan and breathing exercises.

Main outcome variables
Psychological flexibility, life satisfaction, life expectancy, and stress

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250923067331N2**
Registration date: **2026-08-04, 1405/05/13**
Registration timing: **registered_while_recruiting**

Last update: **2026-08-04, 1405/05/13**
Update count: **0**

Registration date
2026-08-04, 1405/05/13

Registrant information

Name
Mohsen Rafie

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
2026-06-22, 1405/04/01
Expected recruitment end date
2026-08-23, 1405/06/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the effectiveness of acceptance and commitment therapy with mindfulness-based cognitive therapy on psychological flexibility, life satisfaction, life expectancy, and stress in elderly people with type 2 diabetes

Public title
Comparing the effectiveness of two psychotherapy approaches in elderly people with type 2 diabetes
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Seniors over 65 years old Minimum educational qualification: Diploma Suffering from type 2 diabetes Not having neurological diseases or any disease that prevents cooperation.
Exclusion criteria:
Presence of other mental disorders, such as schizophrenia spectrum disorders, bipolar disorder, or depression with psychotic features Taking psychiatric medications that affect mood and anxiety 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 Alcohol, drug use, or active addiction, which may reduce adherence to treatment or confound outcomes Severe physical disability that prevents regular attendance at meetings
Age
From **65 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 and clinical trial code, two centers are randomly selected from among the medical centers in Neyshabur city, and one center is randomly selected as the first experimental group and one center is randomly selected 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 the eligible individuals and written consent will be obtained. Participants are randomly assigned to one of two groups using simple computer randomization using Excel software random numbers.
Blinding (investigator's opinion)
Single blinded
Blinding description
Data related to treatment groups are replaced with non-identifiable codes. Any information that associates participants with treatments, such as names or intervention details, is also removed from the data set presented to the analyst. The statistical analyst performs predetermined 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, SBMU
Street address
Fifth Floor, Building No.2, Shahid Arabi Street, Yemen Street, Shahid Chamran Highway
City
Tehran
Province
Tehran
Postal code
1985717444
Approval date
2025-12-14, 1404/09/23
Ethics committee reference number
IR.SBMU.RETECH.REC.1404.709

Health conditions studied

1

Description of health condition studied
Type 2 diabetes in the elderly
ICD-10 code
E11
ICD-10 code description
Type 2 diabetes mellitus

Primary outcomes

1

Description

Psychological flexibility score in the Acceptance and Action Questionnaire, Second Edition (AAQ-II)

Timepoint

Examining the level of psychological flexibility 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. Acceptance and Action Questionnaire, Second Edition (AAQ-II)

2

Description

Life expectancy score on the Schneider Life Expectancy Questionnaire (SHS)

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 (SHS)

3

Description

Life satisfaction score on the Diner Life Satisfaction Questionnaire

Timepoint

Assessing life satisfaction 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. Diener Life Satisfaction Scale

4

Description

Stress score on the Dass 21 questionnaire

Timepoint

Assessing stress levels 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. Depression, Anxiety, and Stress Scale DASS-21

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group 1: Acceptance and Commitment Therapy (ACT): This therapy is an evidence-based approach from the third wave of cognitive-behavioral therapies whose main goal is to increase individuals' psychological flexibility. This therapy helps individuals to change their relationship with these experiences, accept them, and take action towards their personal values and goals, instead of trying to eliminate or control unpleasant thoughts, emotions, and experiences. General structure of the intervention: This intervention will be implemented in a group setting in the form of 8 weekly sessions. Each session will last 60 minutes. The sessions will include teaching the main concepts of ACT, experiential exercises, group discussion, mindfulness exercises, therapeutic metaphors, and homework to generalize the skills learned to everyday situations. Content of the intervention sessions: Session One: Introduction to ACT therapy and the concept of psychological flexibility In this session, group members are introduced to the general principles of ACT therapy, treatment goals, the role of thoughts and emotions in human behavior, and the concept of psychological flexibility. The concept of experiential avoidance and its impact on psychological problems are taught, and participants identify personal patterns of avoiding unpleasant experiences. Session Two: Accepting internal experiences and reducing efforts to control emotions In this session, the concept of acceptance in ACT is introduced and the difference between active acceptance and surrender is explained. Participants learn how to face unpleasant thoughts, feelings, and memories without making excessive efforts to eliminate them. Experiential exercises related to observing and tolerating emotions are conducted. Session Three: Cognitive Dissociation In this session, participants learn to observe their thoughts as mental events, not as definitive facts. Techniques such as naming thoughts, observing thoughts separately from themselves, and cognitive exercises to reduce engagement with negative thoughts are taught. Session Four: Contact with the Present Moment and Mindfulness Training This session teaches the concept of being present in the present moment. Mindfulness exercises include observing thoughts, feelings, and sensory experiences without judgment, focusing on breathing, and increasing awareness of the current experience. Session Five: Self as Context This session teaches the concept of distinguishing between the “observing self” and the “experienced content.” The goal of this session is to help individuals distance themselves from roles, fleeting thoughts, and emotions and increase their observational perspective on personal experiences. Session 6: Clarifying Personal Values In this session, individuals identify and prioritize the important values in their lives in areas such as family, relationships, health, personal growth, and personal goals. The difference between values and short-term goals is explained, and exercises are given to determine a value-based life path. Session 7: Committed Action in Alignment with Values In this session, participants learn how to set practical and actionable goals in line with their values. Possible barriers, inhibiting thoughts, and difficult emotions are examined, and a plan is made for engaging in committed behaviors. Session 8: Integrating Skills and Relapse Prevention In the final session, the core concepts of ACT

are reviewed, and participants integrate the skills of acceptance, cognitive dissonance, mindfulness, and committed action. A plan is also developed for using the skills in daily life and facing future problems. Homework: During the sessions, home exercises including recording thoughts and emotions, acceptance exercises, mindfulness exercises, performing values-based activities, and implementing committed actions will be provided to facilitate the transfer of therapeutic skills to the individual's living environment.

Category

Treatment - Other

2

Description

Intervention Group 2: Mindfulness-Based Cognitive Therapy: This therapy is an evidence-based group intervention that combines the principles of cognitive-behavioral therapy and mindfulness exercises. The main goal of this therapy is to increase the individual's awareness of thoughts, emotions, and bodily sensations, reduce rumination, create distance from negative thoughts, and prevent the return of maladaptive psychological patterns. In this approach, individuals learn to observe their thoughts and emotions as mental events, without automatically engaging with them or considering them as absolute reality. General structure of the intervention: This intervention will be implemented in a group setting and in the form of 8 weekly sessions. Each session will last 60 minutes. The sessions will include training in mindfulness concepts, formal mindfulness exercises (such as body scans, breathing exercises, sitting meditation, and conscious stretching), informal exercises in daily activities, training in cognitive concepts related to automatic thoughts, and daily homework. Content of the intervention sessions: Session 1: Introduction to mindfulness and the mind-body connection. In this session, the concept of mindfulness, treatment goals, and the role of attention in psychological experiences are introduced. Participants are introduced to the concept of living in an automatic state and its impact on thoughts, emotions, and behaviors. Introductory exercises include practicing mindful eating and paying attention to sensory experiences. Session 2: Body awareness and body scan exercise. In this session, participants are introduced to increasing awareness of physical sensations and their connection to emotions and thoughts. The body scan exercise is guided and participants learn to observe their physical experiences without judgment. Session Three: Focusing on Breathing and Sustained Attention Training This session teaches breathing focus exercises. The goal is to strengthen the ability to return attention to the present moment and observe thoughts and distractions without automatic reaction. The concept of accepting the current experience and repeatedly returning attention to the object of focus is taught. Session Four: Recognizing Automatic Thoughts and the Relationship Between Thoughts, Emotions, and Behaviors This session teaches the cognitive principles of cognitive-behavioral therapy. Participants learn to identify negative automatic thoughts, cognitive errors, and their impact on emotions and behavior. Thought recording and mental pattern observation are practiced. Session Five: Distancing from Thoughts and Reducing Cognitive Involvement This session teaches the concept of “thoughts are not reality.” Participants practice observing their thoughts as mental events and distance themselves from engaging and identifying with negative thoughts. Mindfulness exercises are performed for thoughts and emotions. Session 6: Accepting Unpleasant Emotions and Mindfully Facing Difficult Experiences This session teaches the concept of accepting internal experiences. Participants learn to face difficult emotions with an accepting and conscious approach instead of avoiding or suppressing them. Mindfulness exercises are performed for dealing with unpleasant emotions. Session 7: Using Mindfulness in Daily Life and Preventing Maladaptive Patterns This session examines the application of mindfulness skills in real-life situations. Participants learn how to recognize early signs of negative thoughts, rumination, and maladaptive behavioral patterns and choose more conscious responses. Session 8: Integrating Skills and a Relapse Prevention Program In the final session, all of the skills taught are reviewed and integrated. Participants develop a personal plan to continue mindfulness practices, manage difficult thoughts and emotions, and prevent relapse. Homework: Throughout the course, participants will be required to complete daily mindfulness practices including breathing exercises, body scans, sitting meditation, practicing being present in daily activities, recording thoughts and emotions, and practicing observing internal experiences without judgment. These practices are designed to increase the generalization of therapeutic skills to daily life.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

22 Bahman Hospital, Neyshabour

Full name of responsible person

Mohsen Rafie

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Corner of Attar Street, Imam Street, Neyshabour

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Dr Afshin Zarghi

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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

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Mohsen Rafie

Position
Phd Student

Latest degree
Master

Other areas of specialty/work
Psychology

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Person responsible for updating data

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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

Individuals authorized to request data: University researchers, faculty members, and graduate students; Submit a formal request with a specific research proposal. Requirements for submitting a request: Provide a specific research objective and analysis plan; Ethics Committee approval (if required); Sign a confidentiality and non-identification agreement. Types of authorized analyses: Secondary analyses for scientific and research purposes; Meta-analyses, systematic reviews, or supplementary statistical analyses; Any analysis outside the initial stated objectives will be subject to review and approval by the main research team. Permitted uses of documents: Use only for research and scientific purposes; Publication of results in scientific journals with acknowledgement of the data source; No commercial use of data without written permission. Limitations and monitoring mechanisms: Data will be provided anonymously and will not include any identifying information; Any transfer of data to third parties is prohibited; Use of data outside the scope of the agreement is not permitted; In case of violation of the conditions, access will be terminated and the matter will be followed up. Request review and approval process: Requests are reviewed by the main research team; if approved, data will be provided to the applicant on a limited basis and under an agreement; the duration of access and the scope of the data will be determined based on the type of project.

From where data/document is obtainable

Applicants for non-personally identifiable data or other documentation from 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 a research collaborator: If no response is received, applicants can apply through the research center or project partner; Name and surname: Dr. Amir Sam Kiani Moghadam; Organizational affiliation: Shahid Beheshti University of Medical Sciences; Email: as.kianimoghadam@gmail.com; Contact number: 09124857320. Request registration via website: If available, the data request form will be available via the website. -Register 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

Requests to receive non-personally identifiable data or documentation related to this study will be reviewed and managed according to the following process: Request registration; The applicant sends their request via email or other announced channels, along with the necessary documents (including the research objective, proposal, and analysis plan). Initial review; At this stage, the completeness of the documents and the initial compliance of the request with the announced conditions are checked. In case of deficiencies, the applicant will be asked to complete the information. Scientific and ethical evaluation; The request is reviewed by the main research team and the following items are evaluated: alignment of the research objective with the authorized use of the data; adequacy of the analysis plan; compliance with ethical considerations and the presence of approval by the ethics committee (if needed). Decision-making; Based on the evaluation results, the request is placed in one of the following three states: approval; need to correct or provide additional information; rejection of the request (with reasons). Conclusion of an agreement; If approved, the applicant will be required to sign a data use agreement including a commitment to confidentiality, non-identification of individuals, and restrictions on use. Data provision; After completing the above steps, the data will be provided to the applicant in an anonymized form and through a secure method (such as sending an encrypted file or restricted access). Monitoring and follow-up; Data use will be monitored within the framework of the agreement and the applicant is required to inform the research team of the results if published. Timing; The entire application review process, if the documents are complete, will usually be completed within 2 to 4 weeks.

Comments