Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effectiveness of cognitive-behavioral group therapy on diabetes-related stress beliefs, diabetes self-care, and dysfunctional beliefs about diabetes in patients with type 2 diabetes.

Protocol summary

Study aim
Effectiveness of cognitive-behavioral group therapy on diabetes-related stress beliefs, diabetes self-care, and dysfunctional beliefs about diabetes in patients with type 2 diabetes.

Design
A phase II, non-randomized, purposive, double-blind, parallel-group controlled clinical trial conducted on 300 patients

Settings and conduct
The intervention protocol consisted of 12 weekly group therapy sessions, each lasting 90 minutes. The group therapy was conducted with the participation of 15 patients with type 2 diabetes and was led by a therapist trained in the cognitive-behavioral approach. The 15 participants in the control group did not receive any therapeutic intervention. It should be noted that the experimental group was reassessed 45 days later.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Diagnosis of type 2 diabetes. Exclusion criteria: Presence of severe psychiatric disorders (such as psychosis or severe cognitive impairment) that would prevent participation in the therapy sessions

Intervention groups
The intervention group consisted of patients with type 2 diabetes who received the cognitive-behavioral therapy (CBT) intervention. The control group consisted of patients with type 2 diabetes who did not receive the cognitive-behavioral therapy (CBT) intervention

Main outcome variables
Dysfunctional attitudes toward diabetes; diabetes-related distress; diabetes self-care behaviors among patients with diabetes; emotion regulation skills; patients' motivation for adherence to dietary and medication regimens; patients' self-efficacy in diabetes control.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20260224068938N1**
Registration date: **2026-04-30, 1405/02/10**
Registration timing: **prospective**

Last update: **2026-04-30, 1405/02/10**
Update count: **0**

Registration date
2026-04-30, 1405/02/10

Registrant information
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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
2026-05-22, 1405/03/01
Expected recruitment end date
2026-08-21, 1405/05/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effectiveness of cognitive-behavioral group therapy on diabetes-related stress beliefs, diabetes self-care, and dysfunctional beliefs about diabetes in patients with type 2 diabetes.

Public title
The Role of Psychological Therapies in Improving Psychological Adjustment and Self-Care in Diabetic Patients

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
All patients (men and women) with type 2 diabetes who referred to endocrine clinics in the city of Sari during the summer of 1405 (2026)

Exclusion criteria:
Presence of severe psychiatric disorders (such as psychosis or severe cognitive impairment) that would prevent participation in the therapy sessions. Concurrent participation in psychotherapy or similar psychological interventions during the study period. Absence from more than two therapy sessions Unwillingness to continue participation at any stage of the study.

Age
From **20 years** old to **50 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
In this clinical trial, participants were first selected through non-random purposive sampling based on the inclusion and exclusion criteria from among patients diagnosed with type 2 diabetes. After completing the sampling stage, simple randomization was used to allocate participants to the intervention and control groups. No quasi-random methods (such as allocation based on day of visit, medical record number, alphabetical order, etc.) were used. The unit of randomization was the individual, meaning that each eligible patient was independently entered into the randomization process and assigned to either the intervention or control group. Cluster randomization (based on treatment center, family, city, or other clusters) was not used in this study. The total sample size was 30 participants (15 in the intervention group and 15 in the control group). To generate the random sequence, a statistical software program (such as SPSS, Excel, or a similar tool) was used. After selecting the 30 eligible patients, each participant was assigned a unique code. Using statistical software (or a table of random numbers), a random allocation sequence was created for these codes. The random sequence was generated using labels “A” and “B” (intervention/control), ensuring that each group contained 15 participants. Based on this sequence, each patient was allocated to one of the two groups according to their assigned code. This study did not use block randomization or stratified randomization. To minimize allocation bias, allocation concealment was implemented as much as possible. The random sequence was generated by an individual not involved in participant screening or recruitment. Group codes (A/B) were placed inside opaque, sealed, sequentially numbered envelopes. After confirming eligibility and obtaining informed consent, the recruiter opened the next envelope in sequence and assigned the patient to the intervention or control group according to the label inside. Thus, the recruiter remained unaware of upcoming group assignments until the moment of allocation, reducing the risk of manipulation. No quasi-random allocation methods (such as allocation based on even/odd days, order of admission, alphabetical order, medical record number, or bed number) were used in this study, and group assignment was performed strictly according to the software-generated random sequence.

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, Sari Branch

Street address
Sari

City
Sari

Province
Mazandaran

Postal code
4661611691

Approval date
2025-08-26, 1404/06/04

Ethics committee reference number
IR.IAU.SARI.REC.1404.252

Health conditions studied

1

Description of health condition studied
Type 2 Diabetes

ICD-10 code
E11.9
ICD-10 code description
Type 2 diabetes mellitus without complications

Primary outcomes

1

Description
Diabetes Beliefs Scale - DBS
Timepoint
Measurement of dysfunctional beliefs about diabetes at three time points: 1. At the beginning of the study (Baseline), 2. Immediately after the completion of the last Cognitive Behavioral Therapy (CBT) group session, and 3. 3 months after the completion of the intervention
Method of measurement
Dysfunctional Attitudes Towards Diabetes Scale (DATDS) (Polonsky & Fisher, 2015)

Secondary outcomes

1

Description
Diabetes Distress
Timepoint
Baseline (T0): Prior to randomization/intervention start.Post-treatment (T1): Immediately following the completion of the final CBT session.Follow-up (T2): Three months after the completion of the intervention."
Method of measurement
Diabetes Distress Scale (DDS) (Polonsky et al., 2005)

2

Description
Diabetes Self-Care
Timepoint
Baseline (T0): Prior to randomization/intervention start.Post-treatment (T1): Immediately following the completion of the final CBT session.Follow-up (T2): Three months after the completion of the intervention."
Method of measurement
Summary of Diabetes Self-Care Activities (SDSCA) (Toobert & Glasgow, 2002)

Intervention groups

1

Description
Intervention group:Session 1: Introduction, Group Formation, and Initial EducationIn the first session, group members and the therapist introduced themselves, and each participant briefly described their reasons for attending the group therapy sessions. The overall framework of cognitive–behavioral therapy, the goals of the group, the number of sessions, and mutual expectations were then explained.An introductory explanation about diabetes, diabetes-related distress, depression, and quality of life and their interrelationships was also provided. Group rules such as confidentiality, mutual respect, active participation, and completing homework assignments were discussed.Homework: Writing down personal expectations from treatment and identifying the most important psychological challenges related to diabetes.Session 2: The Relationship Between Thoughts, Feelings, and BehaviorsIn this session, the cognitive model was introduced and the triadic relationship between thoughts, emotions, and behaviors was explained through educational material and examples related to diabetes. The differences between thoughts, emotions, and behaviors were clearly clarified.Common dysfunctional thinking styles and cognitive distortions (such as catastrophizing, all-or-nothing thinking, and overgeneralization) were introduced.Homework: Identifying daily situations related to diabetes and recording the associated thoughts, feelings, and behaviors in the ABC worksheet.Session 3: Cognitive RestructuringHomework from the previous session was first reviewed. Then symptoms of depression and diabetes-related stress and the accompanying thoughts were examined.The four main steps of cognitive restructuring were taught: identifying dysfunctional thoughts, evaluating supporting and opposing evidence, replacing them with more rational thoughts, and examining the consequences of the revised thoughts.Homework: Completing a cognitive restructuring worksheet for at least two real-life situations.Session 4: Behavioral Chain (Antecedent–Behavior–Consequence)In this session, the concept of the behavioral chain (A-B-C) was examined in greater depth. Participants learned how behavioral consequences can themselves become antecedents for subsequent behaviors.Strategies for breaking maladaptive chains (such as changing antecedents, stopping behaviors, and modifying consequences) were presented.Homework: Identifying and recording a maladaptive behavioral chain related to diabetes self-care.Session 5: Nutrition, Physical Activity, and Dysfunctional Beliefs About DiabetesBasic information about carbohydrate metabolism, the differences between type 1 and type 2 diabetes, and principles of healthy nutrition were presented. Common misconceptions about diabetes (e.g., “I can no longer enjoy life”) were examined and corrected.The role of physical activity in blood glucose control and mood improvement was explained, and suitable exercises were introduced.Homework: Recording weekly dietary patterns and physical activity and identifying inhibiting thoughts.Session 6: AssertivenessThe concept of assertive behavior and its differences from passive and aggressive behavior were explained. Situations in which individuals experience difficulty expressing their needs (for example in family or healthcare settings) were discussed.Positive self-statements and behavioral exercises to increase assertiveness were introduced.Homework: Practicing one assertive behavior and recording the experience.Session 7: Impulsivity, Self-Control, and Mood ImprovementIn this session, the concept of impulsivity and its role in maladaptive behaviors (such as overeating or discontinuing

treatment) was discussed. Strategies to improve self-control were taught.Increasing engagement in pleasant activities and its role in improving mood was also emphasized.Homework: Completing the pleasant activities worksheet and performing at least two enjoyable activities.Session 8: Stress Management and Problem SolvingThe concept of stress, diabetes-related stressors, and their psychological and physical effects were discussed. Stress management skills including stepwise problem solving and progressive muscle relaxation were taught.Homework: Practicing relaxation techniques and applying the problem-solving method to a real-life problem.Session 9: Self-Esteem and Self-ConceptIn this session, the concept of self-esteem and its relationship with negative thoughts about oneself and one's illness was discussed. Participants learned how negative self-evaluations can reduce self-esteem.Strategies to strengthen self-acceptance and a positive self-concept were presented.Homework: Completing the self-concept worksheet and identifying personal strengths.Session 10: Diabetes Self-CareDifferent dimensions of diabetes self-care (blood glucose monitoring, nutrition, physical activity, medication adherence, foot care, and stress management) were discussed. Cognitive and emotional barriers to self-care were identified and addressed.Homework: Designing a personal diabetes self-care plan.Session 11: Integration of SkillsIn this session, the skills learned throughout the program were reviewed and integrated. Participants learned how to apply these skills simultaneously in everyday life situations.Homework: Implementing the integrated skills plan in a real-life situation.Session 12: Relapse Prevention and ConclusionIn the final session, participants' progress was evaluated and a relapse prevention plan was developed. The importance of continued practice of the learned skills was emphasized and final feedback was provided.Finally, the effectiveness of cognitive-behavioral group therapy on dysfunctional beliefs about diabetes, diabetes-related distress, and self-care behaviors in patients with type 2 diabetes was summarized.

Category

Behavior

2

Description

Control group: Participants in the control group will not receive any structured psychological intervention throughout the study duration and will only continue to receive the usual medical care related to diabetes as provided by their physician or healthcare center. No Cognitive Behavioral Therapy (CBT) group sessions will be held for this group during this period.However, participants in this group will be assessed at the same time points as the intervention group (Baseline, Post-treatment, and 3-month Follow-up) using the research instruments, including the Diabetes Distress Scale (DDS), the Summary of Diabetes Self-Care Activities (SDSCA), and the Dysfunctional Attitudes Towards Diabetes Scale.To comply with ethical considerations, upon completion of data collection, a summary of the CBT educational content will be provided to the control group participants if they so desire.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Endocrinology Clinics in Sari

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Bahram Mirzaeian

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Islamic Azad University

Proportion provided by this source
1

Public or private sector
Private

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

Bahram Mirzaeian

Position

Master

Latest degree

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Other areas of specialty/work

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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

Participants' Lack of Willingness

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not 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