Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Study of the effectiveness of cognitive behavioral group therapy on perceived stress, emotional resilience, and meaning of life in women with type 2 diabetes

Protocol summary

Study aim
Determining the effectiveness of cognitive behavioral group therapy on perceived stress, emotional resilience, and meaning in life in women with type 2 diabetes

Design
A controlled clinical trial with parallel groups, without blinding, randomized, on 40 patients. The rand function of Excel software will be used for randomization.

Settings and conduct
The statistical population of this study will comprise all women diagnosed with Type 2 diabetes who visit Shafa Hospital in Ahvaz during the specified study period and receive a definitive diagnosis from a specialist. A convenience sampling method will be employed during the sampling stage. Once a sample size of 40 participants is reached, they will be randomly assigned to either the 'Cognitive-Behavioral Therapy' group (intervention group) or the 'Waitlist' group (control group), based on the predefined inclusion and exclusion criteria.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Women aged 20 to 40 years, women with type 2 diabetes with a definitive diagnosis from a specialist physician. Inclusion criteria: Participation in other psychotherapy sessions 6 months prior to the study, unwillingness to participate in the research.

Intervention groups
Intervention group: They will receive cognitive-behavioral therapy intervention. Cognitive behavioral therapy by Douglas and Robbie Chaud (2007), Tarjomehforooshan and Abedian (2014) will be administered to the experimental group in 8 90-minute sessions, two sessions per week. The therapeutic tools used will include cognitive model training, cognitive restructuring, relaxation techniques, and stress management. Control group: They will not receive any intervention.

Main outcome variables
Perceived stress, Emotional resilience, Meaning of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260608069712N1**
Registration date: **2026-08-01, 1405/05/10**
Registration timing: **prospective**

Last update: **2026-08-01, 1405/05/10**
Update count: **0**

Registration date
2026-08-01, 1405/05/10

Registrant information

Name
Mehrsa Balalzadeh

Name of organization / entity
Islamic Azad University, Ahvaz Branch

Country
Iran (Islamic Republic of)

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+98 61 3391 8542

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-08-06, 1405/05/15

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

Study of the effectiveness of cognitive behavioral group therapy on perceived stress, emotional resilience, and meaning of life in women with type 2 diabetes

Public title

The role of cognitive-behavioral therapies in promoting resilience and meaning in life in women with type 2 diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Women aged 20 to 40 years Definitive diagnosis of type 2 diabetes by a specialist doctor

Exclusion criteria:

Participation in other psychotherapy sessions in the 6 months prior to the study Unwillingness to participate in research

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

The statistical population of this study will include all women with type 2 diabetes who visit the hospital within the specified time period for the study and are given a definitive diagnosis of the disease by a specialist physician. In the sample selection stage, the available sampling method will be used. After selecting a sample size of 40 people, based on the study's entry and exit criteria, the participants will be randomly assigned to two groups: "cognitive-behavioral therapy" (intervention group) and "waiting list" (control group). Randomization will be performed using the random block method with variable sizes (4 and 6 people) by an independent statistician who is not involved in the implementation process. The random allocation list will be generated using the RAND function in Excel software and then placed in opaque, sealed, and numbered envelopes so that the researcher and participants are not aware of the allocation sequence (allocation concealment). The envelope will be opened and the allocation group will be informed only when each participant enters the study. To ensure the equality of baseline variables (such as anxiety level, age, and length of marriage), their distribution in the two groups will be examined during the statistical analysis stage.

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

Opposite Keshavarz Street, Farhang Shahr, Golestan Highway

City

Ahvaz

Province

Khouzestan

Postal code

6134937333

Approval date

2026-04-28, 1405/02/08

Ethics committee reference number

IR.IAU.AHVAZ.REC.1405.082

Health conditions studied

1

Description of health condition studied

Typw 2 Diabeted mellitus

ICD-10 code

E11.9

ICD-10 code description

Type 2 diabetes mellitus without complications

Primary outcomes

1

Description

Perceived stress

Timepoint

1. Pre-test: Before the intervention sessions begin.2. Post-test: Two weeks after the last intervention session.3. Follow-up: Four weeks (one month) after the last intervention session.

Method of measurement

The method of measurement will be the Cohen et al. (1983) Perceived Stress Questionnaire.

2

Description

Emotional resilience

Timepoint

1. Pre-test: Before the intervention sessions begin.2. Post-test: Two weeks after the last intervention session.3. Follow-up: Four weeks (one month) after the last intervention session.

Method of measurement

The measurement method will be using the Connor and Davidson (2003) Emotional Resilience Scale.

3

Description

The meaning of life

Timepoint

1. Pre-test: Before the intervention sessions begin.2. Post-test: Two weeks after the last intervention session.3. Follow-up: Four weeks (one month) after the last intervention session.

Method of measurement

The measurement method will be using the Meaning of Life Questionnaire by Steger et al. (2006).

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Cognitive-behavioral therapy intervention; Duration of each session: 90 minutes; Total number of sessions: 8 sessions; Sequence of sessions: twice a week; Therapeutic tools used: Cognitive model training (connection of thoughts, feelings, and behaviors); Cognitive restructuring (identifying and challenging automatic thoughts); Relaxation and stress management techniques; Problem-solving exercises; and value-based activities to promote meaning in life. Summary of session content: Session 1: Pre-test, familiarization with the cognitive-behavioral model, and training on the relationship between diabetes, negative thoughts, and stress; Session 2: Identification of automatic thoughts and cognitive biases related to the disease and stress management; Session 3: Training in relaxation techniques (such as deep breathing) to reduce perceived stress; Session 4: Cognitive restructuring and challenging dysfunctional thoughts about the limitations caused by diabetes; Session 5: Training in problem-solving skills and coping with everyday challenges of diabetes management; Session 6: Behavioral exercises to increase emotional resilience in the face of physical changes; Seventh session: Focusing on finding meaning in life and identifying personal values amid the challenges of the disease; Eighth session: Conclusion, teaching planning to prevent the return of stress, conducting a post-test, and determining the time for the follow-up test.

Category

Treatment - Other

2

Description

Control group: The control group will not receive any intervention during the research. However, to avoid factors that threaten the internal validity of the research, such as compensatory competition of the control group or demoralization, they are assured that they will receive the intervention at the next time (after data collection).

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shafa Hospital

Full name of responsible person

Mehrsa Balalzadeh

Street address

Shafa Hospital, Golestan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Aslan Egdarnezhad

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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
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
Mehrsa Balalzadeh

Position
Master's student

Latest degree
Bachelor

Other areas of specialty/work
Psychology

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

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

Statistical Analysis Plan
Not applicable

Informed Consent Form
Undecided - It is not yet known if there will be 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
Not applicable

Data Dictionary
Not applicable