Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Efficacy of Schema Therapy on Alexithymia, Cognitive Flexibility, Body Image and Food Craving Individuals with Type 2 Diabetes

Protocol summary

Study aim

This study aims to evaluate the effectiveness of group schema therapy in improving emotional awareness, cognitive flexibility, body image, and food craving in adults with type 2 diabetes mellitus (T2DM).

Design

Randomized controlled parallel-group trial with pre- and post-test assessments. Sample size: 50 participants across one center. Randomization was computer-generated and allocation was concealed.

Settings and conduct

This single-center trial will be conducted at Isfahan Endocrine and Metabolism Research Center (IEMRC). The procedure is as follows: Eligible participants will complete baseline assessments. They will then be randomly assigned to either the Schema Therapy group or the Standard Care control group using sequentially numbered, opaque, sealed envelopes (SNOSE). The intervention group will receive eight 90-minute weekly sessions of group Schema Therapy. The control group will receive eight 90-minute weekly sessions of structured diabetes education. Participants and outcome assessors are blinded to group allocation. All participants will be re-assessed on all outcomes immediately post-intervention.

Participants/Inclusion and exclusion criteria

Adults aged 30–60 years with T2DM and elevated food craving were included. Participants with current psychiatric disorders or using psychotropic medications were excluded.

Intervention groups

The intervention group will receive eight 90-minute sessions of schema-based group therapy. The control group will receive standard care.

Main outcome variables

Alexithymia, cognitive flexibility, body image, and food cravings will be measured with validated questionnaires.

General information

Reason for update

Updating the actual intervention start and end dates and recording the study completion date.

Acronym

IRCT registration information

IRCT registration number: **IRCT20251201068177N1**
Registration date: **2025-12-31, 1404/10/10**
Registration timing: **prospective**

Last update: **2026-09-12, 1405/06/21**
Update count: **1**

Registration date

2025-12-31, 1404/10/10

Registrant information

Name

Zahra Fathi

Name of organization / entity

Islamic Azad University, Najafabad Branch

Country

Iran (Islamic Republic of)

Phone

+98 31 3744 8620

Email address

zahra.fathi2280@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-10-12, 1404/07/20

Expected recruitment end date

2025-12-13, 1404/09/22

Actual recruitment start date

2026-01-17, 1404/10/27

Actual recruitment end date

2026-03-14, 1404/12/23

Trial completion date

2026-03-18, 1404/12/27

Scientific title
The Efficacy of Schema Therapy on Alexithymia, Cognitive Flexibility, Body Image and Food Craving Individuals with Type 2 Diabetes

Public title
The Efficacy of Schema Therapy in the treatment of diabetes

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Eligible individuals must be between 30 and 60 years old. Have at least a high school diploma Registration will only be done after participants provide written informed consent. Patients with current psychiatric disorders or taking psychotropic medications are not eligible to participate in the study.

Exclusion criteria:
Unforeseen or unexpected events occur Absence of more than 2 sessions

Age
From **30 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **50**
Actual sample size reached: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
This study will be conducted as a randomized controlled clinical trial (RCT). Participants will be randomly allocated to either the intervention group (schema therapy) or the control group (standard care) using a computer-generated simple random sequence. Allocation concealment will be ensured through the use of sequentially numbered, sealed, and opaque envelopes, which will be opened only after each participant has been enrolled. The randomization sequence will be generated by an independent statistician and will remain concealed from the study implementer until the time of allocation, thereby minimizing selection bias. Data analysis will be performed using SPSS software version 26. Descriptive and appropriate inferential statistical methods will be applied to analyze the data, and a significance level of $p < 0.05$ will be considered statistically significant.

Blinding (investigator's opinion)
Single blinded

Blinding description
The interventions in both groups will be designed to be sufficiently similar in terms of implementation schedule and delivery format to allow participant-level blinding. Accordingly, this study will be conducted as a single-blind trial. Participants will not be informed of their group allocation and will be unaware of whether they receive schema therapy or standard care. Due to the nature of the interventions, the therapist delivering the sessions will not be blinded.

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, Najafabad Branch

Street address
No.46, Dead End 6, Alireza Akbari Alley, Yazdababd, Shahr-e Abrisham

City
Isfahan

Province
Isfehan

Postal code
8178916892

Approval date
2025-07-15, 1404/04/24

Ethics committee reference number
IR.IAU.KHSH.REC.1404.095

Health conditions studied

1

Description of health condition studied
Type 2 diabetes mellitus

ICD-10 code
E11

ICD-10 code description
Type 2 diabetes mellitus

Primary outcomes

1

Description
The average score obtained from the alexithymia questionnaire in the study subjects is considered as the primary outcome of the study, the sample size is also calculated in the initial proposal based on this variable, and other variables are examined as secondary outcomes.

Timepoint
Baseline (pre-intervention) and immediately post-intervention (after 8 weeks of schema therapy).

Method of measurement
Valid Persian version of the Toronto Alexithymia Scale-20

Secondary outcomes

1

Description
Average score obtained from the Cognitive Flexibility Questionnaire in adults with type 2 diabetes after an 8-week schema therapy intervention.
Timepoint
Baseline (pre-intervention) and immediately post-intervention (after 8 weeks of schema therapy).
Method of measurement
Valid Persian version of Dennis and Vanderwaal's Cognitive Flexibility Questionnaire

2

Description
Average score obtained from the Body Image Concern Questionnaire in adults with type 2 diabetes after an 8-week schema therapy intervention.
Timepoint
Pre-test (before intervention) and immediate post-test after intervention (after 8 weeks of schema therapy).
Method of measurement
Valid Persian version of Littleton's body image concerns

3

Description
Average score obtained from the Food Craving Questionnaire in adults with type 2 diabetes after an 8-week schema therapy intervention.
Timepoint
Baseline (pre-intervention) and immediately post-intervention (after 8 weeks of schema therapy).
Method of measurement
Valid Persian version of the Sidabnitto Food Craving Trait Questionnaire (PFQ_T)

Intervention groups

1

Description
Intervention groups: Participants allocated to the intervention group will receive group-based schema therapy in addition to standard medical care. The intervention will consist of eight 90-minute sessions conducted according to Young’s schema therapy model. The sessions will focus on identification and modification of early maladaptive schemas, enhancement of emotional awareness, cognitive restructuring, experiential techniques (including imagery rescripting), and development of adaptive coping strategies. All sessions will be delivered by a trained therapist under professional supervision, and treatment fidelity will be maintained throughout the study period.
Category
Behavior

2

Description
Control group: Participants assigned to the control group will receive standard care only. Standard care will include routine diabetes education, general health counseling, and non-specific supportive group sessions routinely provided by the clinic. No structured psychological intervention or schema therapy–based techniques will be administered to this group during the study period. This control condition is designed to reflect usual clinical practice.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Isfahan Endocrine and Metabolism Research Center (IEMRC), Iran
Full name of responsible person
Zahra Fathi
Street address
No. 46, Dead End 6, Alireza Akbari Alley, Yazdabad, isfahan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University, Najafabad Branch
Full name of responsible person
dr hamidreza nikyar
Street address
No.46, Dead End 6, Alireza Akbari Alley, Yazdabad, Isfahan
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Grant name

Grant code / Reference number

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

No

Title of funding source

This study was will be conducted without any external financial support or sponsorship.

Proportion provided by this source

10

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

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad University, Najafabad Branch

Full name of responsible person

Zahra Fathi

Position

student

Latest degree

Master

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

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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

Sensitive personal data includes clinical information and psychological questionnaires, and there are currently no plans to share them publicly.

Study Protocol

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

Statistical Analysis Plan

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

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

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

Data Dictionary

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