Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effectiveness of acceptance and commitment therapy (ACT) on emotional overeating, emotion regulation and psychological well-being in women with diabetes

Protocol summary

Study aim
The effectiveness of Acceptance and Commitment Therapy on emotional overeating, emotion regulation, and psychological well-being in women with type 2 diabetes.

Design
This study is a quasi-experimental pretest–posttest study with a control group on 40 women with type 2 diabetes. Participants will be selected by convenience sampling and then randomly assigned by simple randomization into two groups of 20. The intervention group will receive 8 ACT sessions, while the control group will receive no intervention. This is not a drug trial and has no trial phase.

Settings and conduct
This study will be conducted in Rasht among women with type 2 diabetes using a pretest–posttest design with a control group. The intervention group will receive 8 ACT sessions, and no blinding will be performed.

Participants/Inclusion and exclusion criteria
Inclusion criteria: a) A diagnosis of diabetes confirmed by a specialist physician. b) Ability to attend eight group sessions. c) Written informed consent to participate in the study. d) Age range between 20 and 50 years. Exclusion criteria: a) Severe active psychiatric disorders, including clinical depression or anxiety requiring immediate treatment. b) Absence from at least two ACT sessions. c) Unwillingness to continue attending the sessions.

Intervention groups
This study will be conducted as a quasi-experimental study with a control group. Participants will be randomly assigned to two groups. The intervention group will receive 8 ACT sessions, while the control group will receive no intervention. Emotional eating, emotion regulation, and psychological well-being will be assessed at pretest and posttest.

Main outcome variables
Emotional eating, emotion regulation, and psychological well-being.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260503069247N1**
Registration date: **2026-06-25, 1405/04/04**
Registration timing: **registered_while_recruiting**

Last update: **2026-06-25, 1405/04/04**
Update count: **0**

Registration date
2026-06-25, 1405/04/04

Registrant information
Name
Avishan Aghaeipour
Name of organization / entity
The university of tonekabon
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-06-23, 1405/04/02

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

The effectiveness of acceptance and commitment therapy (ACT) on emotional overeating, emotion regulation and psychological well-being in women with diabetes

Public title

The effectiveness of acceptance and commitment therapy (ACT) on emotional overeating, emotion regulation and psychological

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

a) Diagnosis of diabetes confirmed by a specialist physician.b) Ability to attend 8 group sessions.c) Written informed consent for participation in the study.d) Age range between 20 and 50 years.

Exclusion criteria:

a) Severe active mental disorders (clinical depression or anxiety requiring immediate treatment).b) Absence from at least two ACT sessions.c) Lack of willingness to continue attending the sessions.

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: **40**

Randomization (investigator's opinion)

Not randomized

Randomization description

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, Tonekabon Branch

Street address

Km 3, Chalous Road, Valiabad, Islamic Azad University Tonekabon Complex

City

Tonekabon

Province

Mazandaran

Postal code

۴۶۸۴۱۶۱۱۶۷

Approval date

2026-04-15, 1405/01/26

Ethics committee reference number

IR.IAU.TON.REC.1405.018

Health conditions studied

1

Description of health condition studied

Type 2 diabetes

ICD-10 code

E11.0

ICD-10 code description

Type 2 diabetes mellitus with hyperosmolarity

Primary outcomes

1

Description

Score of emotional eating based on the Eating Behavior Questionnaire.

Timepoint

Assessment of variables at baseline (pretest) and one week after the intervention sessions (posttest).

Method of measurement

The study variables will be measured using the following instruments: Van Strien’s Eating Behavior Questionnaire for emotional eating.

Secondary outcomes

1

Description

Emotion regulation score based on the 16-item short form of the Emotion Regulation Questionnaire (ERQ).

Timepoint

At the beginning of the study (pretest) and one week after the completion of the intervention sessions (posttest)

Method of measurement

Sixteen-item short form of the Emotion Regulation Questionnaire for measuring emotion regulation.

2

Description

Psychological well-being score based on Ryff’s Psychological Well-Being Questionnaire.

Timepoint

At the beginning of the study (pretest) and one week after the completion of the intervention sessions (posttest)

Method of measurement

Ryff Psychological Well-Being Questionnaire for measuring psychological well-being.

Intervention groups

1

Description

Intervention group: The intervention group will receive 8 sessions of group-based Acceptance and Commitment Therapy. Each session will last 60 minutes and will be conducted by a trained psychologist. The content of the sessions includes training and practice on concepts such as acceptance, cognitive defusion, mindfulness, value clarification, and committed action, with the aim of improving emotional eating and emotion regulation.

Category

Lifestyle

2

Description

Control group: Participants in this group will not receive any psychological intervention during the study period and will continue to receive routine medical care related to type 2 diabetes according to standard clinical practice. After the completion of data collection, and if they are willing, the educational content of Acceptance and Commitment Therapy (ACT) will be provided to this group in a condensed format.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Milad Hospital, Lahijan, Gilan, Iran

Full name of responsible person

Khadijeh Hatamipour

Street address

4th Dead-end, 3rd Alley, Sheikh Zahed St., Lahijan, Gilan, Iran

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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University, Tonekabon Branch

Full name of responsible person

Masood Ghane

Street address

Km 3, Chalous Road, Valiabad, Islamic Azad University Tonekabon Complex

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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, Tonekabon Branch

Proportion provided by this source

100

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, Tonekabon Branch

Full name of responsible person

Khadijeh Hatamipour

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

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Person responsible for scientific inquiries

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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
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
The results, tables, and the treatment protocol.
When the data will become available and for how long
The access period will begin 6 months after the publication of the results
To whom data/document is available
Access to the anonymized study data is restricted to researchers affiliated with academic universities, scientific institutions, and research centers holding valid ethical approval, subject to the review of their request and approval by the Ethics Committee.
Under which criteria data/document could be used
Access to the documentation of this clinical trial is restricted to academic and scientific researchers and is permitted only upon obtaining authorization from the principal investigator.
From where data/document is obtainable
Correspondence via email: Aveshen Aghaeipour. avishan_376@yahoo.com
What processes are involved for a request to access data/document
Any request for access to the data or documentation of this study must be submitted through a formal written request to the principal investigator or the academic supervisor. The request should include the applicant's identification information, the purpose of using the data, the type of data requested, and the method for ensuring confidentiality of the information. After receiving the request, the following aspects will be reviewed: the applicant's academic identity and institutional affiliation, evaluation of the research purpose and its alignment with the ethical principles of the study, and final approval by the principal investigator and, if necessary, the university ethics committee. If approved, the data will be provided in an anonymized form and limited to the requested items, in a format suitable for scientific use. Use of the data is permitted only with proper citation of the source and strict adherence to the confidentiality of participants' information
Comments