Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Studying the effectiveness of emotion-focused therapy on anxiety sensitivity, perceived stress, action flexibility, and rumination in women undergoing medical treatment with type 2 diabetes in Ahvaz city.

Protocol summary

Study aim

The aim of this study is to examine the effectiveness of Emotion-Focused Therapy in reducing anxiety sensitivity, perceived stress, and rumination, and in increasing psychological flexibility in women with type 2 diabetes undergoing pharmacological treatment.

Design

A single-blind, randomized, parallel-group, phase 2 clinical trial on 40 patients. For randomization, a physical lottery method (equivalent to traditional randomization methods) was used.

Settings and conduct

Diabetes Clinics in Ahvaz (2025). 40 patients. Physical randomization. - Intervention: Group EFT (8 sessions) - Control: Usual drug therapy Blinded assessor. Informed consent obtained.

Participants/Inclusion and exclusion criteria

Participants must be diabetic women aged 20 to 40 with at least a high school diploma, no mental or neurological disorders, no substance use, and committed to treatment. Withdrawal from the study will occur in case of absence, violation of rules, or lack of cooperation.

Intervention groups

Experimental Group (Receiving EFT): - Intervention: Group-based Emotion-Focused Therapy (EFT) - Protocol: Watson et al.'s model (2005) - Structure: 8 weekly sessions, 90 minutes each - Content: Emotion regulation, reduction of rumination, enhancement of psychological flexibility Control Group (Receiving TAU): - Intervention: Treatment as usual for diabetes (pharmacotherapy without psychotherapy) - Conditions: Continuation of routine medications, no psychotherapy during the study, option to receive EFT after the study

Main outcome variables

1. Anxiety Sensitivity ۲. Perceived Stress ۳. Psychological Flexibility ۴. Rumination

General information

Reason for update

Acronym

EFSRD

IRCT registration information

IRCT registration number: **IRCT20250629066290N1**
Registration date: **2025-07-16, 1404/04/25**
Registration timing: **registered_while_recruiting**

Last update: **2025-07-16, 1404/04/25**
Update count: **0**

Registration date

2025-07-16, 1404/04/25

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-07-15, 1404/04/24

Expected recruitment end date

2026-01-14, 1404/10/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Studying the effectiveness of emotion-focused therapy on anxiety sensitivity, perceived stress, action flexibility, and rumination in women undergoing medical treatment with type 2 diabetes in Ahvaz city.

Public title
The effect of emotion-focused therapy on anxiety, stress, and repetitive thoughts in diabetic women in Ahvaz

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Women aged 20 to 40 years with type 2 diabetes No history of substance use and no current or previous major psychiatric symptoms; no history of brain diseases such as brain tumors Not participating in other psychotherapy sessions for at least one month before the study Signing a written informed consent form and commitment to participate in treatment sessions Minimum education level: diploma (high school degree) Definite diagnosis of type 2 diabetes by a specialist physician

Exclusion criteria:
Having brain diseases such as brain tumors Presence of current or past psychotic symptoms or severe psychiatric disorders Substance abuse Participation in other psychotherapy sessions at least one month before the study Not having at least a high school diploma No confirmed diagnosis of type 2 diabetes by a specialist physician Unwillingness to participate or refusal to sign the written informed consent form

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
1.Randomization Method & Description: - Method Used:Simple Random Allocation - Participants were randomly assigned (via lottery draw) to either the intervention or control group. - No manipulation or bias in group selection was applied. 2. Unit of Randomization: - Individual:Each participant was randomized independently. 3. Stratification (if applicable): - Not Used: - Due to the relatively small sample size (N=40) and homogeneity of the study population (all women with type 2 diabetes), stratification was not applied. 4. Randomization Tool: - Manual (Lottery Draw): - Names were written on separate papers, mixed in a container, and drawn randomly. - Digital tools (e.g., randomization software) were not used due to practical constraints. 5. Sequence Generation: - Unpredictable Sequence: - The order of drawing names from the container determined the random sequence. 6. Allocation Concealment: - Partial Concealment: - Researchers and participants were aware of group allocation post-randomization. - However, outcome assessments (pre-test/post-test) were conducted by blinded assessors to minimize measurement bias.

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 of Ahvaz

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Ahvaz Golestan-Farhangshahr Highway

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Approval date
2025-04-05, 1404/01/16

Ethics committee reference number
IR.IAU.AHVAZ.REC.1404.002

Health conditions studied

1

Description of health condition studied
Type 2 Diabetes

ICD-10 code
E08

ICD-10 code description
Diabetes mellitus due to underlying condition

Primary outcomes

1

Description
1. Anxiety Sensitivity - Measurement: Total score of the Anxiety Sensitivity Index-3 (ASI-3) - Change indicator:Reduction of ≥30% from baseline. Primary Outcomes:Change in Anxiety Sensitivity (ASI-3) score at the end of the intervention

Timepoint

1. Pre-test:Measurement of dependent variable (anxiety sensitivity) before the intervention began for both experimental and control groups. 2. Post-test:Re-measurement of variable immediately after completing the treatment sessions (after 8 sessions of Emotion-Focused Therapy). 3.Follow-up:Measurement of variable one month after the intervention ended to assess the durability of treatment effects.

Method of measurement

1. Anxiety Sensitivity - Tool: Anxiety Sensitivity Index (ASI) - Original version:* Reiss et al. (1985) - Persian version:Used in domestic studies with confirmed validity and reliability - Description: - Consists of 16 items assessing fear of anxiety symptoms (e.g., "When my heart beats rapidly, I get scared"). -Three subscales: Physical, cognitive, and social concerns.- Scoring: 5-point Likert scale (0=Not at all to 4=Very much).

2

Description

2. Perceived Stress - Measurement: Total score of the Perceived Stress Scale-10 (PSS-10) -Change indicator: Reduction of ≥25% from baseline. Primary Outcomes:Change in Perceived Stress (PSS-10) score at the end of the intervention.

Timepoint

1. Pre-test:Measurement of dependent variable (perceived stress) before the intervention began for both experimental and control groups. 2. Post-test:Re-measurement of variable immediately after completing the treatment sessions (after 8 sessions of Emotion-Focused Therapy). 3.Follow-up:Measurement of variable one month after the intervention ended to assess the durability of treatment effects.

Method of measurement

2. Perceived Stress - Tool: Perceived Stress Scale (PSS) - Original version:* Cohen et al. (1983)- Persian version:Safaei & Shokri (2014) with satisfactory validity and reliability- Description: - 14 items evaluating an individual’s perception of stressful situations (e.g., "How often have you felt nervous or stressed in the past month?").- 5-point Likert scale (0=Never to 4=Very often).

3

Description

3. Psychological Flexibility - Measurement: Total score of the Connor-Davidson Resilience Scale-10 (CD-RISC-10) - Change indicator: Increase of ≥20% from baseline. Primary Outcomes: Change in Psychological Flexibility (CD-RISC-10) score at 1-month follow-up.

Timepoint

1. Pre-test:Measurement of dependent variable (cognitive flexibility) before the intervention began for both experimental and control groups. 2. Post-test:Re-measurement of variable immediately after completing the treatment sessions (after 8 sessions of Emotion-Focused Therapy). 3.Follow-up:Measurement of variable one month after the intervention ended to assess the durability of treatment effects.

Method of measurement

3. Cognitive Flexibility -Tool: Cognitive Flexibility Inventory (CFI) - Original version:Dennis & Vander Wal (2010)- Persian version:Ghorbani & Kaviani (2015)- Description:- 20 items measuring the ability to adapt thinking to new conditions (e.g., "I can think of multiple solutions to a problem"). 7-point Likert scale (1=Strongly disagree to 7=Strongly agree).

4

Description

4.Rumination -Measurement: Total score of the Ruminative Response Scale (RRS) - Change indicator: Reduction of ≥15% from baseline.Primary Outcomes: Change in Rumination (RRS) score at the end of the intervention

Timepoint

1. Pre-test:Measurement of dependent variable (Rumination) before the intervention began for both experimental and control groups. 2. Post-test:Re-measurement of variable immediately after completing the treatment sessions (after 8 sessions of Emotion-Focused Therapy). 3.Follow-up:Measurement of variable one month after the intervention ended to assess the durability of treatment effects.

Method of measurement

4. Rumination - Tool: Ruminative Responses Scale (RRS) - Original version: Nolen-Hoeksema & Morrow (1991) - Persian version:Bagherinejad et al.(2011)- Description:- 22 items assessing repetitive negative thoughts (e.g., "I think about how sad I feel").-4-point Likert scale (1=Almost never to 4=Almost always). --- Procedure1. Pre-test: All participants completed the questionnaires before the intervention. 2. Post-test: Both groups were reassessed after 8 sessions of Emotion-Focused Therapy (EFT).3. Follow-up: The experimental group was reevaluated one month later to assess the persistence of effects.Data Analysis - A Mixed ANOVA (Repeated Measures ANOVA) was used to compare changes across three time points (pre-test, post-test, follow-up) between the two groups.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: - Description:This group consisted of 20 women with type 2 diabetes who received Emotion-Focused Therapy (EFT).- Key Characteristics: - Intervention Method:- 8 weekly sessions (90 minutes each)- Protocol based on Greenberg's (2004) model and the manual by Rasouli & Pour Ebrahim (2010) - Focused on emotion regulation, emotional processing, and reduction of rumination- Concurrent Conditions:- Continued standard pharmacological treatment (no dosage changes during the study)- No concurrent participation in other psychotherapy

Category

Treatment - Other

2

Description
Control group: Description:This group consisted of 20 women with type 2 diabetes who received only standard pharmacological treatment and no psychotherapy intervention.- Key Features:- Follow-up method: - Received routine medical care (same as the intervention group)- Did not receive Emotion-Focused Therapy (EFT) or any structured psychotherapy during the study- Controlled conditions:- Assessed at the same time intervals (pre-test, post-test, follow-up)- Were unaware of the intervention group's session content (partial blinding)

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Diabetes Research Center of Ahvaz

Full name of responsible person
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Sponsors / Funding sources

1

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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
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
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Position
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Other areas of specialty/work
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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

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