

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Aug 2026

The effect of acceptance and commitment-based counseling on self-care and obstetric outcomes in women with gestational diabetes.

Protocol summary

Study aim

The effect of ACT counseling on self-care in women with gestational diabetes The effect of ACT counseling on obstetric outcomes in women with gestational diabetes

Design

This intervention is a randomized controlled clinical trial with parallel groups. The sample (100 study participants) will be randomized using block randomization (50 in the control group and 50 in the intervention group).

Settings and conduct

Eligible women referring to the Shahroud city health center will enter the study after the intervention is explained to them.

Participants/Inclusion and exclusion criteria

1. Pregnant women aged 18 to 45 with gestational diabetes (individuals whose fasting blood sugar, one hour or two hours later, after a two-hour oral glucose tolerance test with 75 grams of glucose at 24-28 weeks of pregnancy, was greater than or equal to 92, 180, and 153 milligrams per deciliter, respectively) 2. Having informed consent 3. Iranian nationality 4. Having a reading and writing education 5. Able to communicate verbally 6. Being a resident of Shahroud 7. Gestational age 24 to 30 weeks 8. Single pregnancy

Intervention groups

For the intervention group, 4 weekly ACT counseling sessions will be held at the health center. During the clinical trial, the control group will benefit from routine pregnancy care, and no intervention will be performed by the research team. However, after the trial, the educational content will be provided to them.

Main outcome variables

Self-care, blood pressure, Apgar, weight, cesarean section

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170607034381N12**

Registration date: **2025-10-12, 1404/07/20**

Registration timing: **prospective**

Last update: **2025-10-12, 1404/07/20**

Update count: **0**

Registration date

2025-10-12, 1404/07/20

Registrant information

Name

Ferdos Pelarak

Name of organization / entity

Dezful Azad University

Country

Iran (Islamic Republic of)

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pelarak.f@dums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-11-01, 1404/08/10

Expected recruitment end date

2026-03-01, 1404/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of acceptance and commitment-based counseling on self-care and obstetric outcomes in women with gestational diabetes.

Public title

The impact of counseling on self-care of gestational diabetes

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Pregnant women aged 18 to 45 with gestational diabetes (individuals whose fasting blood sugar, one hour or two hours later, after a two-hour oral glucose tolerance test with 75 grams of glucose at 24-28 weeks of pregnancy, was greater than or equal to 92, 180, and 153 milligrams per deciliter, respectively) Having informed consent Iranian nationality Having a reading and writing education Able to communicate verbally Being a resident of Shahroud Gestational age 24 to 30 weeks Single pregnancy

Exclusion criteria:

Receive similar training or counseling Having other medical conditions

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

After determining the sequences, individuals will be selected using a simple random method and assigned to two groups using block randomization with a block size of 4. The procedure is as follows: the group assignments, based on the generated sequence, will be placed in sealed envelopes, and the envelopes will be numbered. For each individual, according to their order of entry into the study, the corresponding numbered envelope will be opened, and they will be assigned to one of the groups without the participant being aware

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

Research Ethics Committee of Shahroud University of Medical Sciences

Street address

Hafte Tir Square

City

Shahroud

Province

Semnan

Postal code

۳۶۱۴۷۷۳۹۴۳

Approval date

2025-09-23, 1404/07/01

Ethics committee reference number

IR.SHMU.REC.1404.092

Health conditions studied**1****Description of health condition studied**

Gestational diabetes

ICD-10 code

O24.41

ICD-10 code description

Gestational diabetes mellitus in pregnancy

Primary outcomes**1****Description**

Self care

Timepoint

Before and after the intervention

Method of measurement

Glasgow and Tobert Self-Care Questionnaire

2**Description**

Apgar

Timepoint

After delivery

Method of measurement

Hospital file

3**Description**

Infant weight

Timepoint

After delivery

Method of measurement

Hospital file

4**Description**

Cesarean section

Timepoint

Delivery

Method of measurement

Hospital file

5

Description

Blood pressure

Timepoint

After delivery

Method of measurement

Hospital file

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Acceptance and Commitment Therapy (ACT) – 4 Sessions Session 1: Introduction and getting to know group members* Introduction to the Acceptance and Commitment Therapy (ACT) approach* Information about gestational diabetes and the importance of balanced blood glucose levels Education on self-care and its impact on blood sugar control Teaching the concept of mindfulness Training in mindful breathing Identifying thoughts and obstacles related to practicing self-care Homework: Mindfulness exercises assigned for daily practice throughout the week Session 2: Review of previous homework Replacing control strategies with value-based behaviors Teaching that control is not the solution and can worsen the problem Encouraging behavior based on personal values instead of control Distinguishing personal judgments and evaluations from reality Training in observing thoughts and attitudes toward gestational diabetes rather than reacting to them Homework: List strategies to cope with negative emotions Session 3: Review of previous homework Training in diffusion techniques to deal with disturbing thoughts Strengthening connection with the present moment Addressing personal challenges such as communication with doctors, following dietary plans, and incorporating exercise into daily routines Exploring personal values and how to use them to pursue meaningful goals Homework: Design a personalized exercise and dietary plan and commit to following it Session 4: Providing strategies to overcome behavioral change obstacles and planning for continued commitment Reviewing personal values and achievements shared by participants Emphasizing mindful eating and the adoption of healthy dietary habits Enhancing the ability to be fully present in all aspects of life, especially during meals

Category

Behavior

2

Description

Control group: Performing routine care for patients in health centers

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Azima Health Services Center

Full name of responsible person

Razieh Arabameri

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahrour University of Medical Sciences

Full name of responsible person

Hosein Ebrahimi

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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

Shahrour University of Medical Sciences

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**

Shahroud University of Medical Sciences

Full name of responsible person

Razieh Arabameri

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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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

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All data is potentially shareable after unidentifiable individuals

When the data will become available and for how long

12 months after the results are published

To whom data/document is available

Researchers working in scientific and academic institutions

Under which criteria data/document could be used

According to the terms and conditions of Shahroud Medical Sciences University, the data can be used

From where data/document is obtainable

raziaharabamery@gmail.com

What processes are involved for a request to access data/document

Written request and consent of the Executor of the project and colleagues

Comments