# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

19 Oct 2026

## Investigating the effect of non-pharmacological lifestyle modification intervention on self-efficacy, health-promoting lifestyle behaviors, and life satisfaction in women with gestational diabetes: A randomized clinical trial study

## Protocol summary

**Study aim**

Studying the effect of non-pharmacological lifestyle modification intervention on self-efficacy, health-promoting lifestyle behaviors, and life satisfaction in women with gestational diabetes

**Design**

This study is a randomized controlled clinical trial with a parallel design, single-blinded, conducted in phase II. After meeting the inclusion criteria, participants were randomly assigned to either the intervention or control group using block randomization with variable block sizes (4 and 6). The total sample size was 60 participants (30 in each group). The random sequence was generated using SPSS software, and allocation concealment was ensured through the use of sealed, opaque envelopes.

**Settings and conduct**

This study will be conducted in Kowsar hospitals in Qazvin. Before implementing the intervention, the level of self-efficacy, health-promoting lifestyle behaviors, and life satisfaction will be assessed. Then, the intervention will be carried out in the intervention group, and immediately after the end of the intervention, and again 3 months after the intervention, the questionnaires will be completed again in both groups.

**Participants/Inclusion and exclusion criteria**

Inclusion: confirmed gestational diabetes, 24–28 weeks gestation, age 18–40, literate, informed consent, access to communication, local residency. Exclusion: chronic debilitating diseases, severe psychiatric history, use of psychotropic or lifestyle-affecting drugs, participation in other interventions.

**Intervention groups**

The intervention consisted of a lifestyle modification program in the areas of nutrition, physical activity, stress management, sleep, and social support, which was implemented in person and virtually over a period of 6 weeks. The control group received only routine prenatal care.

**Main outcome variables**

Self-efficacy, health-promoting lifestyle behaviors, and life satisfaction

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20250408065253N1**
Registration date: **2025-04-14, 1404/01/25**
Registration timing: **prospective**

Last update: **2025-04-14, 1404/01/25**
Update count: **0**

**Registration date**

2025-04-14, 1404/01/25

**Registrant information**

**Name**

leila dehghankar

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 28 3333 8034

**Email address**

leiladehghankar66@gmail.com

**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2025-04-18, 1404/01/29

**Expected recruitment end date**
2025-12-02, 1404/09/11
**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Investigating the effect of non-pharmacological lifestyle modification intervention on self-efficacy, health-promoting lifestyle behaviors, and life satisfaction in women with gestational diabetes: A randomized clinical trial study

**Public title**
The effect of non-pharmacological lifestyle modification intervention on self-efficacy, lifestyle, and life satisfaction in women with gestational diabetes.
**Purpose**
Education/Guidance
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
18 and 40 years old Having a definitive diagnosis of gestational diabetes by a gynecologist or physician Gestational age between 24 and 28 weeks Willingness to participate in the study and written informed consent Ability to read and write No concurrent chronic debilitating diseases (as determined by a doctor)
**Exclusion criteria:**
Not filling the questionarrie before the beginning of the intervention No participation in two consecutive sessions
**Age**
From **18 years** old to **40 years** old
**Gender**
Female

**Phase**
N/A
**Groups that have been masked**

- Data analyser

**Sample size**
Target sample size: **60**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
In this study, a block randomization method with variable block sizes (4 and 6) was used to maintain a uniform distribution of participants in the two intervention and control groups. The randomization unit was the individual; each participant was independently assigned to one of the two groups. Stratified randomization was used to increase the balance between the groups in terms of age (under 30 years and 30 years and older) and education level (diploma and below, higher than diploma). The random sequence generation tool was SPSS statistical software version 26, which was implemented by an independent researcher (not involved in the data collection process or analysis of the results). The random sequence was first generated completely by the software and then the group allocation was concealed using serial numbering and opaque, unpredictable, and sealed envelopes. Allocation concealment was performed in such a way that the person responsible for registering and entering participants into the study was not aware of the allocation sequence, and the envelopes were opened sequentially only when the participant entered and confirmed the entry conditions.
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
This study is a single-blind clinical trial. Therefore, blinding will be implemented in the assessors who will analyze the study data. For this purpose, the questionnaires that will be completed by the researchers in all two groups will be identified by an agreement between the researchers with one of the English letters at the top, indicating which of the study groups the questionnaire was completed by the participants; however, the assessors analyzing the data will not be aware of the agreement between the researchers that has been assigned to each group.
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Research Ethics Committees of Qazvin University of Medical Sciences
**Street address**
1st Moaddat Alley, Moaddat Street, Shahid Beheshti Boulevard
**City**
Qazvin
**Province**
Qazvin
**Postal code**
3415613911
**Approval date**
2025-03-08, 1403/12/18
**Ethics committee reference number**
IR.QUMS.REC.1403.477

## Health conditions studied

### 1

**Description of health condition studied**
Gestational Diabetes
**ICD-10 code**
O24.4

**ICD-10 code description**
Gestational diabetes mellitus

## Primary outcomes

### 1

**Description**
Health-promoting lifestyle behaviors score was based on the HPLP-II questionnaire (Health-Promoting Lifestyle Profile II), which was measured in two stages before the intervention and 6 weeks after it.
**Timepoint**
Measurement of primary outcome variables will be conducted at two time points:At baseline (before the intervention)Six weeks after the end of the educational intervention
**Method of measurement**
To measure this variable, the Health Promoting Lifestyle Profile II questionnaire is used. This questionnaire consists of 52 items in six different dimensions and uses a 4-point Likert scale for scoring.

### 2

**Description**
Participants' self-efficacy score was based on the standard Scherrer Self-Efficacy Scale, which was measured before the intervention and 6 weeks after the end of the intervention.
**Timepoint**
Measurement of primary outcome variables will be conducted at two time points:At baseline (before the intervention)Six weeks after the end of the educational intervention
**Method of measurement**
The standard Scherrer Self-Efficacy Scale (SGS) is used to measure self-efficacy. This instrument has 17 items that are scored using a 5-point Likert scale.

### 3

**Description**
Participants' life satisfaction score is measured using the Deaner Satisfaction With Life Scale (SWLS) at two time points before and after the intervention.
**Timepoint**
Measurement of primary outcome variables will be conducted at two time points:At baseline (before the intervention)Six weeks after the end of the educational intervention
**Method of measurement**
The Diner Satisfaction With Life Scale is used to measure life satisfaction. This scale consists of 5 items that are rated on a 7-point Likert scale.

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group: Intervention group: Participants in this group received a non-pharmacological educational program based on lifestyle modification. The program content included training in the following areas: healthy and balanced nutrition during pregnancy, appropriate physical activity for pregnant women, stress management and mind-relaxation strategies, improving sleep quality, strengthening social support and interpersonal communication. The program was held in person at the medical center in the form of 6 weekly sessions (each session about 90 minutes). Also, supplementary materials including multimedia files, nutritional guides and relaxation exercises were sent to the participants via messenger so that the education could continue continuously. The educational content was developed by members of the research team in collaboration with health education specialists and was based on reliable and up-to-date pregnancy health guides.
**Category**
Lifestyle

### 2

**Description**
Control group: This group will have routine and ongoing interventions, including receiving medication and conventional counseling.
**Category**
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Kowsar and hospital
**Full name of responsible person**
Leila Dehghankar
**Street address**
Kosar Hospital, Kowsar Alley (Electric Company), Shahid Taleghani Street
**City**
Qazvin
**Province**
Qazvin
**Postal code**
1317634156
**Phone**
+98 28 3323 6374
**Email**
leiladehghankar66@gmail.com

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**
Qazvin University of Medical Sciences
**Full name of responsible person**
Seyed Mehdi Hashemi
**Street address**
1st Moaddat Alley, Moaddat Street, Shahid Beheshti Boulevard
**City**
Qazvin
**Province**
Qazvin
**Postal code**
3415613911
**Phone**
+98 28 3333 7006
**Email**
researchdpt@qums.ac.ir

**Grant name**

**Grant code / Reference number**

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

**Title of funding source**
Qazvin 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**
Qazvin University of Medical Sciences
**Full name of responsible person**
Leila Dehghankar
**Position**
Faculty member
**Latest degree**
Master
**Other areas of specialty/work**
Nursery
**Street address**
Nor
**City**
Qazvin
**Province**
Qazvin
**Postal code**
3415613911
**Phone**
+98 28 3333 8034
**Fax**
**Email**
leiladehghankar66@gmail.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**
Qazvin University of Medical Sciences
**Full name of responsible person**
Leila Dehghankar
**Position**
Faculty member
**Latest degree**
Master
**Other areas of specialty/work**
Nursery
**Street address**
Nor
**City**
Qazvin
**Province**
Qazvin
**Postal code**
3415613911
**Phone**
+98 28 3333 8034
**Fax**
**Email**
leiladehghankar66@gmail.com

## Person responsible for updating data

**Contact**

**Name of organization / entity**
Qazvin University of Medical Sciences
**Full name of responsible person**
Leila Dehghankar
**Position**
Faculty member
**Latest degree**
Master
**Other areas of specialty/work**
Nursery
**Street address**
Nor
**City**
Qazvin
**Province**
Qazvin
**Postal code**
3415613911
**Phone**
+98 28 3333 8034
**Fax**
**Email**
leiladehghankar66@gmail.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Yes - There is 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**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

Only a portion of the data, such as information related to the main outcome and general demographic information, can be shared.

**When the data will become available and for how long**

Access period starts 3 months after results are published.

**To whom data/document is available**

Doctors, nurses, midwives, researchers working in universities, medical centers and hospitals, clinical psychologists

**Under which criteria data/document could be used**

For use for scientific purposes, with reference to the source used and request for the journal in which the article will be published.

**From where data/document is obtainable**

Communication via email (if sharing information is legally and ethically possible, such as sharing the primary outcome of the study) To receive information, contact the following email address: Corresponding author's email: leiladehghankar66@gmail.com

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

Find the email of the responsible author, state the reason, and comply with ethical and legal matters; in this case, a quick response will be given to the requesting person.

**Comments**