Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Aug 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