

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 2026

### The effect of health coach program based on midwifery counselor on self-care behavior in women with gestational diabetes

#### Protocol summary

##### Study aim

The effect of health coach program based on midwifery counselor on self-care behavior in women with gestational diabetes

##### Design

Intervention Group: 4 sessions per week, 1 session 60-minute, group and face-to-face, and 4 sessions per person per person. At the end of the 4 interventions sessions, 4 weeks follow up, the questionnaires and blood glucose level in the intervention group will be completed to follow up. Control group: In the control group, after 4 weeks after completion the primary questionnaires, the questionnaires and blood sugar level will be completed again.

##### Settings and conduct

4 sessions per week, 1 session 60-minute, group and face-to-face, and 4 sessions per person per person. At the end of the 4 interventions sessions, 4 weeks follow up, the questionnaires and blood glucose level in the intervention group will be completed to follow up. In the control group, after 4 weeks after completion the primary questionnaires, the questionnaires and blood sugar level will be completed again. The study will be performed in the waiting room at the prenatal ward of the Razi Hospital in Qaemshahr.

##### Participants/Inclusion and exclusion criteria

58 women with gestational diabetes. inclusion criteria: Maternal gestational age 24-28 weeks. Exclusion Criteria: unwillingness to Continuation of research.

##### Intervention groups

Intervention Group: 4 sessions per week, 1 session 60-minute, group and face-to-face, and 4 sessions per person per person. At the end of the 4 interventions sessions, 4 weeks follow up, the questionnaires and blood glucose level in the intervention group will be completed to follow up. Control group: In the control group, after 4 weeks after completion the primary questionnaires, the questionnaires and blood sugar level will be completed again.

#### Main outcome variables

Perceived stress: self-care behavior: blood glucose

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20110827007422N2**

Registration date: **2019-04-11, 1398/01/22**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-04-11, 1398/01/22**

Update count: **0**

##### Registration date

2019-04-11, 1398/01/22

##### Registrant information

##### Name

Zhila Ganji

##### Name of organization / entity

Mazandaran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3336 7342

##### Email address

zhila.ganji@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-04-03, 1398/01/14

##### Expected recruitment end date

2019-05-04, 1398/02/14

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty  
**Trial completion date**  
empty

**Scientific title**  
The effect of health coach program based on midwifery counselor on self-care behavior in women with gestational diabetes

**Public title**  
The effect of health coach program based on midwifery counselor on self-care behavior in women with gestational diabetes

**Purpose**  
Education/Guidance

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Maternal gestational age 24-28 weeks reading and writing skills lack of addiction to drugs such as psychotropic substances and stimulants, alcoholic beverages, cigarettes and hookahs no history of medical illness (diabetes, heart disease, respiratory, kidney, thyroid disorders, Epilepsy, blood pressure, anemia and orthodox constraints) no history of high risk pregnancy (pregnancy poisoning, abnormal bleeding, placenta and twin pregnancy) no history of admission to psychiatry and psychiatric use  
**Exclusion criteria:**  
Unwillingness to continue to study absenteeism at each educational session occurrence of pregnancy-related complications major stressful events during the study (serious illness of the spouse and child, death of one of the loved ones, accident)

**Age**  
No age limit

**Gender**  
Female

**Phase**  
N/A

**Groups that have been masked**  
No information

**Sample size**  
Target sample size: 58

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
In order not to allow all individuals to intervene or control in succession in a group, we will insert the 5 envelopes of the intervention card and 5 cards into the envelope so that the individuals are randomly assigned to the two groups and after the first 10 were identified, the next 10 The same will be selected to complete the samples.

**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

Diabetes Research Center, Mazandaran University of Medical Sciences

##### Street address

Vesal shirazi street

##### City

Sari

##### Province

Mazandaran

##### Postal code

4816715793

#### Approval date

2018-12-14, 1397/09/23

#### Ethics committee reference number

IR.MAZUMS.IMAMHOSPITAL.REC.1397.056

## Health conditions studied

### 1

#### Description of health condition studied

Gestational Diabetes Melitus

#### ICD-10 code

O24.9

#### ICD-10 code description

Diabetes mellitus in pregnancy, unspecified

## Primary outcomes

### 1

#### Description

self-care behavior Score

#### Timepoint

1 month

#### Method of measurement

Questionnaire

### 2

#### Description

Perceived stress Score

#### Timepoint

1 month

#### Method of measurement

Questionnaire

## Secondary outcomes

### 1

#### Description

Self-care behavior Score

**Timepoint**

1 Month

**Method of measurement**

Self-Care Gestational Diabetes Questionnaire

4816715793

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+98 11 3336 7342

**Fax****Email**

zhila.ganji@yahoo.com

**Intervention groups****1****Description**

Intervention group: The training program will be performed in 4 sessions, each week 1 session in 60 minutes in group sessions and 4 telephone sessions for each person.

**Category**

Prevention

**2****Description**

Control group: The control group will not receive any education.

**Category**

Prevention

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Ghaemshahr, Razi Hospital

**Full name of responsible person**

Jila Gangi

**Street address**

Vesal shirazi street

**City**

Sari

**Province**

Mazandaran

**Postal code**

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**2****Recruitment center****Name of recruitment center**

Ghaemshahr, Razi Hospital

**Full name of responsible person**

Jila Gangi

**Street address**

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Sari

**Province**

Mazandaran

**Postal code****Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Akbar Hedayatizadeh Omran

**Street address**

Deputy of Research and Technology of Mazandaran University of Medical Science

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+98 11 3336 7342

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Akbar-hedayati@yahoo.com

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Sari 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

**2****Sponsor****Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Akbar Hedayatizadeh Omran

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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**  
Sari 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**  
Mazandaran University of Medical Sciences  
**Full name of responsible person**  
Sedigheh Hasanimoghadam  
**Position**  
Student  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Midwifery  
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## Person responsible for scientific inquiries

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**Position**  
Associate Professor  
**Latest degree**

Ph.D.  
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## Person responsible for updating data

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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