

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

Phone

+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

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Province

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Postal code

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Phone

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Fax**Email**

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

Ghaemshahr, Razi Hospital

Full name of responsible person

Jila Gangi

Street address

Vesal shirazi street

City

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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

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Postal code

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Phone

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Email

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

Street address

Deputy of Research and Technology of Mazandaran University of Medical Science

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Province

Mazandaran

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Email
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

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 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