

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Comparison of the effectiveness of counseling based on health promoting behaviors on fasting blood glucose and glucose tolerance test in pregnant and overweight and obese women

Protocol summary

Study aim

reduce the incidence of gestational diabetes

Design

Based on random numbers, the final sample size was 132 people (66 in the control group and 66 in the intervention group)

Settings and conduct

4 Counselling sessions: 1- Understanding the goals, rules of the group 2- Expressing the feelings of the patients about the change, teaching the appropriate physical activities in pregnancy 3. Dietary education in pregnancy 4. Stress management training and interpersonal communication, 5. Understanding temptation situations, training spiritual growth and accountability, summing up and summing up previous session exercises. The place of intervention is in the classroom at Rouhani Hospital.

Participants/Inclusion and exclusion criteria

inclusion criteria; normal fasting blood shouger, age more than 16 years, BMI => 25 reading and writing literacy, single pregnancy and gestational age between 12 weeks and 1 day to 16 weeks and 6 days. Exclusion criteria include disorders such as the diagnosis of pre-pregnancy blood pressure, diabetes, kidney disease, lupus, anti-phospholipid syndrome, tuberculosis, anemia, thalassemia, intestinal colic, thyroid disorders and neurological disorders.

Intervention groups

counseling based on health promoting behaviors
standard pregnancy care

Main outcome variables

mean scores of fasting glucose and glucose tolerance test, mean scores of health promotion behaviors, psychological well-being.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120125008822N3**

Registration date: **2018-07-05, 1397/04/14**

Registration timing: **prospective**

Last update: **2019-08-17, 1398/05/26**

Update count: **1**

Registration date

2018-07-05, 1397/04/14

Registrant information

Name

Narges Motahari

Name of organization / entity

Mazandaran University of medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 15 1226 7345

Email address

n.motahari@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-23, 1397/05/01

Expected recruitment end date

2019-03-01, 1397/12/10

Actual recruitment start date

2018-07-23, 1397/05/01

Actual recruitment end date

2019-02-09, 1397/11/20

Trial completion date

2019-04-09, 1398/01/20

Scientific title

Comparison of the effectiveness of counseling based on health promoting behaviors on fasting blood glucose and glucose tolerance test in pregnant and overweight and obese women

Public title

The effect of counseling based on health-promoting behaviors on fasting blood glucose control and glucose tolerance test

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

pregnant women with gestational age 12 -16 weeks and body mass index ≥ 25

Exclusion criteria:

Age

From **16 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **132**

Actual sample size reached: **148**

Randomization (investigator's opinion)

Randomized

Randomization description

Initially, eligible pregnancies are selected from pregnant women referred to the pregnancy clinic of the Educational and Therapeutic Babol Rohani Hospital and then divided into two intervention and control groups according to the random numbers table.

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

Health Research Center of Babol University of Medical Sciences

Street address

Babol, Ganj Afrouz Avenue, Babol University of Medical Sciences

City

Babol

Province

Mazandaran

Postal code

4717647745

Approval date

2018-06-10, 1397/03/20

Ethics committee reference number

IR.MUBABOL.HRI.REC.1397.068

Health conditions studied

1

Description of health condition studied

Diabetes mellitus in pregnancy

ICD-10 code

024

ICD-10 code description

Diabetes mellitus in pregnancy

Primary outcomes

1

Description

mean of fasting blood glucose-glucose tolerance test

Timepoint

First between 12 to 16 weeks of pregnancy and then between 26 to 28 weeks of gestational

Method of measurement

Laboratory measurement

Secondary outcomes

1

Description

Comparison of the mean of health promotion behaviors in overweight and obese pregnant women

Timepoint

The first between 12 to 16 and then between 26 to 28 gestational

Method of measurement

Questionnaire

2

Description

Mean scores of psychological well-being in over weight and obese pregnant women

Timepoint

At first between 12 to 16 weeks and then between 26 to 28 gestational

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention group: The Impact of counseling based on

health promoting behaviors
Category
Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
Roohani Hospital
Full name of responsible person
Narges Sadat Motahari Tabari
Street address
Babol Roohani Hospital Ave, Gangafroose
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
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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
Babol 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
Babol University of Medical Sciences
Full name of responsible person
Narges Sadat Motahari Tabari
Position
Midwifery Instructor
Latest degree
Master
Other areas of specialty/work
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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

No - There is not a plan to make this available