

# 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  $\geq 25$

##### 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  
**City**  
Babol  
**Province**  
Mazandaran  
**Postal code**  
4717647745  
**Phone**  
+98 11 3219 9592  
**Email**  
narges\_mth@yahoo.com

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**  
Babol University of Medical Sciences  
**Full name of responsible person**  
Narges Sadat Motahari Tabari  
**Street address**  
Babol Roohani Hospital Ave, Gangafroose  
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**Phone**  
+98 11 3219 9592  
**Email**  
narges\_mth@yahoo.com  
**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**  
Midwifery  
**Street address**  
Babol Roohani Hospital Ave, Gangafroose  
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narges\_mth@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
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Narges Sadat Motahari Tabari  
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naeges\_mth@yahoo.com

## Person responsible for updating data

### Contact

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Babol University of Medical Sciences

**Full name of responsible person**

Narges Sadat Motahari Tabari

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**Latest degree**

Master

**Other areas of specialty/work**

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**Email**

narges\_mth@yahoo.com

**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