

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jul 2026

### The effect of group counseling and telephone counseling on the life style of women with gestational diabetes

#### Protocol summary

##### Study aim

Determine and compare the effects of both group counseling and telephone counseling on the life style of women with gestational diabetes

##### Design

This study is a randomized clinical trial with three groups of patients, each group consisting of 22 pregnant women with gestational diabetes, available in each group

##### Settings and conduct

Diabetes Clinic and Beqaei Pour Clinic Available in Samples

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: age 20 to 40 years old; Iranian citizenship; confirmation of gestational diabetes with the approval of a specialist Diabetes Center in accordance with the guidelines; satisfaction to participate in the research; education level up; gestational age 24-28 weeks; native and resident of Yazd; phone access; not attending diabetes education classes before entering the study; having no diabetes before pregnancy by having a normal blood glucose test at the beginning of pregnancy. Exit criteria: existence of severe or debilitating physical or mental illnesses that can be present; disconnects the program from the person; dissatisfaction with the continuation of the study; use of psychotropic substances and substance abuse.

##### Intervention groups

The study population of this study is all young women aged 20-40 years old with gestational diabetes referred to the Yazd Diabetes Care Research Center. Pregnant mothers who are pregnant with gestational diabetes based on the criteria of the Ministry of Health (FBS over 100); if they are eligible for inclusion in the study, they are invited to participate in the study.

##### Main outcome variables

Lifestyle associated with diabetes

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20171106037289N2**

Registration date: **2018-04-24, 1397/02/04**

Registration timing: **retrospective**

Last update: **2018-04-24, 1397/02/04**

Update count: **0**

##### Registration date

2018-04-24, 1397/02/04

##### Registrant information

##### Name

Fatemeh Dehghan Manghabadi

##### Name of organization / entity

Shahid Sadoughi University of Medical Sciences Yazd

##### Country

Iran (Islamic Republic of)

##### Phone

+98 35 3838 0590

##### Email address

fdehghan3788@ssu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-05-22, 1396/03/01

##### Expected recruitment end date

2017-08-23, 1396/06/01

##### Actual recruitment start date

2017-09-23, 1396/07/01

##### Actual recruitment end date

2018-01-21, 1396/11/01

##### Trial completion date

empty

**Scientific title**

The effect of group counseling and telephone counseling on the life style of women with gestational diabetes

**Public title**

The effect of group counseling and telephone counseling on the life style of women with gestational diabetes

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age 20 to 40 years old Iranian citizenship Confirmation of gestational diabetes with the approval of a Diabetes Center specialist according to the instructions Satisfaction to participate in research Top Level Education Gestational age 24-28 weeks Native to Yazd Phone access Not attending diabetes education classes before entering the study Having no diabetes before pregnancy by having a normal blood glucose test at the beginning of pregnancy

**Exclusion criteria:**

Existence of severe or debilitating physical or mental illnesses that can be present Disconnects the program from the person Dissatisfaction with the continuation of the study Use of psychotropic substances and substance abuse

**Age**

From **20 years** old to **40 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

**Sample size**

Target sample size: **66**

Actual sample size reached: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Samples were randomly divided into three groups of 20 individuals using randomized sampling. In the selection of individuals, participants, referees and researchers did not interfere.

**Blinding (investigator's opinion)**

Triple blinded

**Blinding description**

The participants, the main researcher, especially in the trials that Rasa University scholars have started, include health care personnel (doctors, nurses, physiotherapists, etc.) who are responsible for patient care, data collection authorities and those who Evaluate the outcome and, to a lesser extent, the Data Safety and Monitoring Committee's safety and data monitoring committee, and those who prepare the draft article, did not interfere in the assignment of samples to the three groups.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Shahid Sadoughi University of Medical Sciences, Yazd

**Street address**

Yazd, Bahonar Square, Central building of Shahid Sadoughi University of Medical Sciences, Yazd

**City**

yazd

**Province**

Yazd

**Postal code**

8949333865

**Approval date**

2017-06-22, 1396/04/01

**Ethics committee reference number**

IR.SSU.MEDICINE.REC.1396.56

**Health conditions studied****1****Description of health condition studied**

Gestational diabetes and lifestyle

**ICD-10 code**

E10-E14

**ICD-10 code description**

Diabetes mellitus

**Primary outcomes****1****Description**

life style

**Timepoint**

Before intervention, after intervention and one month after intervention

**Method of measurement**

Diabetes Life Style Questionnaire

**Secondary outcomes****1****Description**

Quality Score

**Timepoint**

Before intervention, after intervention and one month after intervention

**Method of measurement**

Quality of Life questionnaire

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

Intervention group one (group counseling): An intervention program is organized in a total of 8 sessions of 90 minutes, a weekly one-session, in which each group counseling session will consist of 6 to 8 participants.

**Category**

Lifestyle

**2****Description**

Intervention group two (telephone counseling): The intervention program is held in a total of 8 sessions, a weekly meeting is held in the form of telephone counseling each week for thirty to forty-five minutes.

**Category**

Lifestyle

**3****Description**

Control group: This group does not receive any intervention. In order to observe ethical standards, at the end of the study, the educational content provided for the intervention group is given to the control group in print

**Category**

Lifestyle

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

diabetes Center and Baghaee Pour Clinic

**Full name of responsible person**

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

Yazd University of Medical Sciences

**Full name of responsible person**

Dr. Amir Houshang Mehparvar

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Yazd, Bahonar Square, Headquarters of Yazd University of Medical Sciences

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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**

Yazd 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**

Yazd University of Medical Sciences

**Full name of responsible person**

Fatemeh Dehghan Manghabadi

**Position**

Midwife

**Latest degree**

Bachelor

**Other areas of specialty/work**

Midwifery

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Yazd University of Medical Sciences  
**Full name of responsible person**  
Shahnaz Mujahid  
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Professor and faculty member of the university  
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**Other areas of specialty/work**  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
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**Full name of responsible person**

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

### Justification/reason for indecision/not sharing IPD

No more info

### Study Protocol

No - There is not a plan to make this available

### Statistical Analysis Plan

No - There is not a plan to make this available

### Informed Consent Form

No - There is not a plan to make this available

### Clinical Study Report

No - There is not a plan to make this available

### Analytic Code

No - There is not a plan to make this available

### Data Dictionary

No - There is not a plan to make this available