Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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
iabetes Center and Baghaee Pour Clinic
Full name of responsible person
Fatemeh Dehghan Manghabadi
Street address
Shahid Dashti Blvd., 46th Alley, 13th Alley
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fdehghan3788@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Dr. Amir Houshang Mehparvar
Street address
Yazd, Bahonar Square, Headquarters of Yazd University of Medical Sciences
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Email
fdehghan446@gmail.com
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
Position
Professor and faculty member of the university
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Master
Other areas of specialty/work
Midwifery
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Person responsible for updating data

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Email
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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