Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The Effect of couples supportive counseling on self-care and blood sugar level in pregnant women with gestational diabetes

Protocol summary

Study aim
The effect of Couple Supportive counseling on Self-Care and blood suger Level in Women with Gestational Diabetes

Design
Clinical trial with community-based and pragmatic control group, with parallel groups, blind, randomized, with a sample size of 72

Settings and conduct
72 pregnant women refered to the diabetes mellitus clinic of Umm al-Banin Hospital in Mashhad, with a gestational age of 26-30 weeks with type A2 gestational diabetes, and having access to the study with their spouses, in three separate sessions of supportive counseling for each Couples are done. Sampling is easy and accessible, and the distribution of the two groups is randomized, the person allocating individuals to the groups is blinded. After obtaining informed consent, coordination is required for conducting the tests, and holding the meetings

Participants/Inclusion and exclusion criteria
Iranian nationality; type A2 gestational diabetes; written informed consent; Husband's willingness to study; stay in Mashhad; access to telephone; minimum fifth grade elementary education; not verbal communication; couples not employed in hospital; tobacco use And alcohol; lack of mental disorders; gestational age of 26-30 weeks based on first trimester ultrasound or accurate LMP; lack of obesity before pregnancy (BMI≥30); lack of medical illness; high risk pregnancy and corticoid use; Lack of stressful incidents in the last 6 months

Intervention groups
In the intervention group, three counseling sessions are held with the husbands of the research units for three consecutive weeks each week for 60 minutes using an emotion evacuation approach, supporting coping strategies, problem solving, and practical guidance. The control group will also receive the usual training for gestational diabetes

Main outcome variables
Self-care scores, fasting blood glucose and two hours after food and insulin consumption

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181002041202N1**
Registration date: **2018-11-10, 1397/08/19**
Registration timing: **registered_while_recruiting**

Last update: **2018-11-10, 1397/08/19**
Update count: **0**

Registration date
2018-11-10, 1397/08/19

Registrant information

Name
Sahar Rostampour

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-11-06, 1397/08/15

Expected recruitment end date
2019-03-20, 1397/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effect of couples supportive counseling on self-care and blood sugar level in pregnant women with gestational diabetes

Public title
The Effect of couples supportive counseling on gestational diabetes
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Type A2 gestational diabetes Husband's willingness to accompany the research Minimum fifth degree elementary education The gestational age is 26-30 weeks based on the first trimester ultrasound or precise LMP Iranian nationality Written informed consent Residence in Mashhad Phone Access Able to communicate verbally
Exclusion criteria:
Tobacco and alcohol use Mental disorders before Pregnancy Obesity Cure for medical conditions highRisk pregnancy and taking corticoids Stressful events over the past 6 months Couples are among the staff working in the hospital
Age
No age limit
Gender
Female

Phase
N/A
Groups that have been masked

- Data analyser

Sample size
Target sample size: **72**
Randomization (investigator's opinion)
Randomized
Randomization description
- Randomized Method: Blocked Block. - Random unit: Individual. - Randomization Tool: Random Number Tables using www.randomization.com, Packet Envelopes, Statistical Software. - How to create a random sequence: For this method, firstly, the size of each specified block (for example, the quadruple block). Then write the blocks list and assign them numbers (AABB (1) - ABAB (2) -ABBA (3) -BBAA (4) - BABA (5) - BAAB (6)) Then select random numbers between one to six (E.g., 1 4 5, etc.) and finally determine the allocation allocation based on random numbers (... AABB-BBAA-BABA-).. - Explanation about the concealment concealment method: The envelope method is that envelopes are prepared and printed by a member of the research team and random numbers with the help of the Randomaize.com site and inside the envelope. The door packs will be closed and its contents are not visible from the outside. Then, the purpose of the study is explained to the person who follows the conditions, and the person, if desired, signs the informed consent form and removes an envelope, then opens it and, based on the contents of the envelope, enters into the intervention or control group.
Blinding (investigator's opinion)
Single blinded
Blinding description
The sample allocator to groups and data analyzers are blinded in this study
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashad University of Medical Sciences
Street address
Mashad
City
Mashad
Province
Razavi Khorasan
Postal code
111111111111
Approval date
2018-09-18, 1397/06/27
Ethics committee reference number
IR.MUMS.NURSE.REC.1397.035

Health conditions studied

1

Description of health condition studied
Gestational Diabetes Mellitus
ICD-10 code
O24.4
ICD-10 code description
Diabetes mellitus arising in pregnancy

Primary outcomes

1

Description
Self-Care and Blood suger
Timepoint
Measure self-care scores and blood suger level at the beginning of the intervention and one month after the intervention
Method of measurement

Self-care diabetes questionnaire and fasting blood glucose and 2 hour plasma glucose test

Secondary outcomes

1

Description
Social support
Timepoint
At the beginning of the study and one month after the end of the intervention
Method of measurement
Social Support Questionnaire

Intervention groups

1

Description
Intervention group: In addition to the usual gestational diabetes education provided in Hospital, three sessions of supportive counseling with the husbands of research units in three consecutive weeks, each week for 60 minutes using the approach Based on the evacuation of emotions, support for coping strategies, problem solving and practical guidance.
Category
Behavior

2

Description
Control group: Typical gestational diabetes education in diet, physical activity, blood glucose monitoring, Drug use by a gynecologist at the hospital's diabetes clinic or in individual and group sessions in the training sessions Will be received by the midwife. The number of sessions will vary depending on the needs of the people
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Hospital of Obstetrics & Gynecology Oml-Benin Mashhad
Full name of responsible person
Rostampour, Sahar
Street address
Mashad
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Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr. Tafaghodi, Mohsen
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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
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Rostampour, Sahar
Position
Master Student Degree
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