

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 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 sugar 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 referred 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 ($BMI \geq 30$); 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)

Phone

+98 51 3278 2261

Email address

rostamps951@mums.ac.ir

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 Randomize.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

Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

00000000

Phone

+98 51 3278 2261

Email

Rostamps951@mums.ac.ir

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

Street address

Mashhad

City

Mashad

Province

Razavi Khorasan

Postal code

000000

Phone

+98 51 3278 2261

Email

Rostamps@mums.ac.ir

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

Street address

Mashhad

City

Mashad

Province

Razavi Khorasan

Postal code

000

Phone

+98 51 3278 2261

Email

Rostamps951@mums.ac.ir

Person responsible for scientific 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

Street address

Mashad

City

Mashad

Province

Razavi Khorasan

Postal code

00000

Phone

+98 51 3278 2261

Email

Rostamps951@mums.ac.ir

Person responsible for updating data

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

Street address

Mashad

City

Mashad

Province

Razavi Khorasan

Postal code

0000

Phone

+98 51 3278 2261

Email

Rostamps951@mums.ac.ir

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