

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

Comparison of the effectiveness of education based on the participation of spouses on social support and treatment compliance in women with gestational diabetes mellitus in two groups of control and intervention

Protocol summary

Study aim

Determining the Impact of Education Based on Spouse's Participation in Social Protection and Adherence to Treatment in Women with Gestational Diabetes

Design

Clinical trial with randomized control group. Sample size 80

Settings and conduct

The place of research is the Bahar Hospital affiliated to Shahrud University of Medical Sciences. The intervention program will be held in two individual sessions. Also, participants in the test group will receive a training message through the social telegram or WhatsApp on a daily basis, and once a week, feedback from the couples will be provided by telephone follow-up.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosis of gestational diabetes Being treated and controlled by diet, oral medication, or insulin. Couples aged 18 and over Couples have the ability to read and write Couples aged 18 and over Couples have the ability to read and write. Single pregnancy pregnancy without abnormalities primary par Pregnancy is between 20-30 weeks. Pregnancy is requested by couples. Couples have a mobile phone with Android OS or ios. Exclusion criteria: Have a preterm delivery. Spouse's separation or death during the study. Unwillingness to continue the presence of couples in intervention sessions The absence of couples even at a training session Failure to study messages by couples

Intervention groups

Women with gestational diabetes Mellitus in the control group who have no intervention. And women with gestational diabetes in the intervention group, who, together with their husbands, undergo two sessions of in-service training and continue through public media along with their husbands.

Main outcome variables

Adherence to social support treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180613040086N1**

Registration date: **2018-09-26, 1397/07/04**

Registration timing: **registered_while_recruiting**

Last update: **2018-09-26, 1397/07/04**

Update count: **0**

Registration date

2018-09-26, 1397/07/04

Registrant information

Name

Maryam Abdollahian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-21, 1397/05/30

Expected recruitment end date

2018-11-21, 1397/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of education based on the participation of spouses on social support and treatment compliance in women with gestational diabetes mellitus in two groups of control and intervention

Public title

Impact of education based on spouses on Social support and Treatment adherence

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of gestational diabetes in a patient's case is documented by a physician Being treated and controlled by diet, oral medication, or insulin Couples aged 18 and over Couples have the ability to read and write. Couples do not have chronic psychiatric and neurological diseases that disrupt consciousness and disturbance in the movement of the person, such as severe stroke, dementia and spinal cord injury. Also, they do not have visual hearing impairment Single pregnancy without abnormalities primary parous women Pregnancy is between 20-30 weeks Pregnancy is requested by couples. Couples have a mobile phone with Android OS or ios

Exclusion criteria:

Preterm labor divorce or death of a spouse during the study Unwillingness to continue the presence of couples in intervention sessions (2 in-person meetings and continued meetings with public outlets and follow-up) The absence of couples even at one training session Failure to read the messages in the Telegram Whats App by couples and the lack of telephone answering by couples in telephone follow-ups.

Age

From **18 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization not done

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

Ethics Committee of Iran University of Medical Sciences

Street address

خیابان ولی عصر (عج)، بالاتر از میدان ونک، خیابان رشید یاسمی

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Approval date

2018-05-14, 1397/02/24

Ethics committee reference number

IR.IUMS.REC.1396.9511686004 IR.IUMS. FMD.REC :

Health conditions studied

1

Description of health condition studied

Gestational diabetes

ICD-10 code

O24.41

ICD-10 code description

Gestational diabetes mellitus in pregnancy

Primary outcomes

1

Description

social support

Timepoint

4 weeks After the first intervention session

Method of measurement

Social support questionnaire in diabetic patients

Secondary outcomes

1

Description

Adherence to treatment

Timepoint

4 weeks After the first training session

Method of measurement

Compliance questionnaire from treatment

Intervention groups

1

Description

Intervention group: Pregnant women and their wives will be placed under a two-part training session and the remainder will be available for four weeks through the public media.

Category

Prevention

2

Description

Control group: No intervention program will be performed

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahroud University of Medical Sciences, Bahar Hospital

Full name of responsible person

maryam abdollahian

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Sponsors / Funding sources

1

Sponsor

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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Mansoureh Ashgholi Farahani

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

I'll publish it as needed

When the data will become available and for how long

20 day

To whom data/document is available

I'll publish it as needed

Under which criteria data/document could be used

I'll publish it as needed

From where data/document is obtainable

Responsible person

What processes are involved for a request to access data/document

I'll publish it as needed

Comments