

# 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

+98 21 4365 1000

##### Email address

abdollahian.m@tak.iums.ac.ir

##### 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

##### City

tehran

##### Province

Tehran

##### Postal code

۱۹۹۶۷۱۳۸۸۳

#### 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

#### Street address

Shahrud. Avenue 22 Bahman Bahar Hospital

#### City

shahrud

#### Province

Semnan

#### Postal code

۳۶۱۴۷-۷۳۹۴۷

#### Phone

+98 23 3222 4091

#### Fax

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#### Email

info@shmu.ac.ir

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Iran University of Medical Sciences

#### Full name of responsible person

Maryam Abdollahian

#### Street address

Valiasr Ave (Aj), above Vanak Square, Rashid Yasemi Street

#### City

Tehran

#### Province

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#### Phone

+98 21 8888 2885

#### Fax

+98 21 8820 1978

#### Email

fnm@iums.ac.ir

#### 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

#### Street address

Valiasr Ave, above Vanak Square, Rashid Yasemi Street Faculty of Nursing and Midwifery of Iran

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#### Province

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#### Phone

+98 21 4365 1000

#### Email

maryamabdollahian@yahoo.com

## Person responsible for scientific 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**

Medical Education

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fnm@iums.ac.ir

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

maryam abdollahian

**Position**

student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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Street

**City**

tehran

**Province**

Tehran

**Postal code**

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**Phone**

+98 21 8888 2886

**Email**

fnm@iums.ac.ir

**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**