

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 2026

### Assessing the effect of education intervention program on improving self-management among women with gestational diabetes:Application of Health Belief Model

#### Protocol summary

##### Summary

(1)Objectives: To determine the effect of educational intervention program on improving self-management among women with gestational diabetes: Application of Health Belief Model (2) Design: Interventional trial based on random allocation using randomized four blocks method in order to select two intervention and control groups. (3)Setting and conduct: This study is an interventional one which study population is women with gestational diabetes. Sample size considers 110 participants which will randomly select in two groups. (4)Participants including major eligibility criteria: Inclusion criteria: confirm gestational diabetes; tendency to study participation; history of at least one year of gestational diabetes. Exclusion criteria: unwillingness to study participation; not attendance in educational sessions. (5) Intervention: After determining the sample size, questionnaires will be completed by both intervention and control groups. Then, according to collected data, four educational sessions which will be lasted about 30 to 40 minutes using group discussion and question and answer accompany with educational package during one month. Then, in order to determine the effect of educational intervention program, questionnaires will be filled up after 3 and 6 months later. (6) Main outcome measures (variables):Self-management improvement.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016072612460N10**  
Registration date: **2016-09-19, 1395/06/29**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-09-19, 1395/06/29

##### Registrant information

###### Name

Roya Sadedgi

###### Name of organization / entity

Tehran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 912 327 5692

###### Email address

sadeghir@tums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Education vice chancellor of Tehran

##### Expected recruitment start date

2015-10-05, 1394/07/13

##### Expected recruitment end date

2016-02-05, 1394/11/16

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Assessing the effect of education intervention program on improving self-management among women with gestational diabetes:Application of Health Belief Model

##### Public title

Assessing the effect of educational intervention program on improving self-management among women with

gestational diabetes:Application of Health Belief Model

### **Purpose**

Prevention

### **Inclusion/Exclusion criteria**

Inclusion criteria: confirm gestational diabetes;tendency to study participation; history of at least one year of gestational diabetes. exclusion criteria: unwillingness to study participation; not attendance in educational sessions.

### **Age**

From **18 years** old to **49 years** old

### **Gender**

Female

### **Phase**

N/A

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **110**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

### **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**

The Ethics committee of Tehran University of Medical Sciences

##### **Street address**

Poursina Ave.

##### **City**

Tehran

##### **Postal code**

#### **Approval date**

2015-08-04, 1394/05/13

#### **Ethics committee reference number**

IR.TUMS.REC.1394.982

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Type 2 diabete

#### **ICD-10 code**

024

### **ICD-10 code description**

Diabetes Mellitus Arising In Pregnancy

## **Primary outcomes**

### 1

#### **Description**

Self-management

#### **Timepoint**

Baseline and 3 and 6 month after intervention

#### **Method of measurement**

Standard Self-management Questionnaire

## **Secondary outcomes**

### 1

#### **Description**

Health Believe Model constructs

#### **Timepoint**

Baseline and 3 and 6 months after intervention

#### **Method of measurement**

Researcher made Questionnaire

## **Intervention groups**

### 1

#### **Description**

Intervention program will be conducted during one month including four educational sessions based on blended educational intervention program (Lecture,Group discussion,Question & Answer, Role playing,Educational film). Each session's time is about 30-40 minutes.The meetings will try to discuss on diabetes,its complications,how to Self-management and diabetic diet.

#### **Category**

Prevention

### 2

#### **Description**

In the control group education will be in accordance with care centers usual process.

#### **Category**

Prevention

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

South of Tehran health centers

##### **Full name of responsible person**

Dr.Javad Barzegr

##### **Street address**

No.4,Shafeei Alley,Quods Ave,Enghelab Square

##### **City**

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Vice chancellor for education, Tehran University of Medical Sciences

**Full name of responsible person**

Dr.Mohammad Jalili

**Street address**

Central Building of Tehran University of Medical sciences,Quods St.

**City**

Tehran

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice chancellor for education, Tehran University of Medical Sciences

**Proportion provided by this source****Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

*empty*

### 2

#### Sponsor

**Name of organization / entity**

Vice chancellor for research, Tehran university of Medical Sciences

**Full name of responsible person**

Dr.Masood Yonesiyan

**Street address**

Central Building of Tehran University of Medical sciences,Quods St.

**City**

Tehran

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice chancellor for research, Tehran university of Medical Sciences

**Proportion provided by this source****Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

#### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr.Roya Sadeghi

**Position**

PhD/Academic staff

**Other areas of specialty/work****Street address**

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**City**

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**Postal code**

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**Email**

sadeghir@tums.ac.ir

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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

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**Full name of responsible person**

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**Position**

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## Person responsible for updating data

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*