

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Sep 2026

### The Effects of an educational intervention based on the theory of planned behavior on self-care behavior and blood glucose levels in pregnant women with gestational diabetes treated with insulin

#### Protocol summary

##### Summary

This randomized clinical trial study was done with the aim of determining the effect of an educational intervention based on the theory of planned behavior on self-care behavior and blood glucose levels in pregnant women with gestational diabetes treated with insulin. The main inclusion criteria was women with gestational diabetes treated with insulin with gestational age of 30-34 week, without having physical and mental illnesses Which were referred to Hospital Diabetes Clinic Ommolbanin Mashhad in 1393. They were randomly divided into two groups of 30 individuals (60 individuals). In intervention group, education based on the theory of planned behavior was performed with 4 sessions of 60 minutes and in the control group received no intervention. Data collection instruments was demographic questionnaire, knowledge and questionnaire theory of planned behavior questions and self-care behavior, perceived stress questionnaire. The blood sugar tests was including fasting blood sugar and Blood sugar two hours after a meal. Completed questionnaires before and four weeks after the completion of the intervention and Blood glucose tests were performed. In the end, based on the results was evaluated Impact theory-based intervention.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014080418682N1**  
Registration date: **2015-03-13, 1393/12/22**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-03-13, 1393/12/22

##### Registrant information

###### Name

maryam hoseinzadeh

###### Name of organization / entity

Mashhad University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 13 4254 0384

###### Email address

hoseinzadehm911@mums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Mashhad University of Medical Sciences

##### Expected recruitment start date

2014-10-31, 1393/08/09

##### Expected recruitment end date

2015-02-19, 1393/11/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The Effects of an educational intervention based on the theory of planned behavior on self-care behavior and blood glucose levels in pregnant women with gestational diabetes treated with insulin

##### Public title

The Effects of an educational intervention based on the theory of planned behavior on self-care and blood glucose levels in pregnant women with gestational

diabetes treated with insulin

**Purpose**  
Supportive

**Inclusion/Exclusion criteria**  
Inclusion criteria: (1) Written informed consent have for participation in the study (2) Maternal gestational age 20-24 weeks at the time of study entrance based on The first day of the last menstrual or the first half of pregnancy ultrasound (3) Iranian and resident of Mashhad (4) At least fifth grade literacy (5) Pregnant women with diagnosis of gestational diabetes are treated with human insulin (not analog) (6) Being able to communicate verbally. (7). No alcohol, smoking and drugs (8) dose not medical history of the medical disease (9). dose not referral to the psychiatrist or psychologist During the year prior and medication and hospitalization due to mental illness (10) dose not a high risk pregnancy (11) dose not to the cause underlying disease taking Continuously Glucocorticoid therapy (12) have The phone number for contact. Exclusion criteria during the study: (1) lack of willingness to continue participation in study (2) major stressful events during the study (3) the absence in any training sessions (4) The occurrence of pregnancy-related complications.

**Age**  
No age limit

**Gender**  
Female

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: 60

**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 committeeat the University ofMedical SciencesMashhad

**Street address**  
University Avenue-University of Medical Sciences headquarters

**City**

mashhad

**Postal code**

**Approval date**  
2014-10-29, 1393/08/07

**Ethics committee reference number**  
research/930418/1/199

2

**Ethics committee**  
**Name of ethics committee**  
Ethics Committee of Mashhad University of Medical Sciences

**Street address**  
Crossroads Doctora- Mashhad -school of Nursing and Midwifery

**City**  
mashhad

**Postal code**

**Approval date**  
2014-10-29, 1393/08/07

**Ethics committee reference number**  
research/930418/1/199

## Health conditions studied

1

**Description of health condition studied**  
gestational diabetes

**ICD-10 code**  
024.4

**ICD-10 code description**  
Diabetes mellitus arising in pregnancy

## Primary outcomes

1

**Description**  
self Care Behavior

**Timepoint**  
Baseline (pre-intervention) and one month after intervention

**Method of measurement**  
questionnaire

2

**Description**  
self care Behavior

**Timepoint**  
Baseline (pre-intervention) and one month after intervention

**Method of measurement**  
questionnaire

## Secondary outcomes

1

**Description**

blood glucose tests was including fasting blood glucose and Blood glucose two hours after a meal

**Timepoint**

before and four weeks after the completion of the intervention

**Method of measurement**

Blood tests

**2**

**Description**

Level Blood glucose

**Timepoint**

Baseline (pre-intervention) and one month after intervention

**Method of measurement**

Blood tests

**Intervention groups**

**1**

**Description**

patients in the control group received routine prenatal visits by Diabetologist and obstetrician or midwife and only education based on the theory of planned behavior did not receive So that was mentioned in the intervention group.

**Category**

Behavior

**2**

**Description**

In intervention group, education based on the theory of planned behavior was performed with 4 sessions of 60 minutes

**Category**

Behavior

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Ommolbanin hospital diabetes clinic

**Full name of responsible person**

maryam hoseinzadeh

**Street address**

**City**

mashhad

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Mohsen tafaghodi

**Street address**

mashhad- University avenue-University of Medical Sciencesheadquarters

**City**

mashhad

**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**

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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Maryam Hoseinzadeh

**Position**

post graduate student midwifery

**Other areas of specialty/work**

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**Web page address**

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

talat Khadivzadeh

**Position**

PhD in Reproductive Health - Member of Scientific Advisory Board

**Other areas of specialty/work**

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9137913199  
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## Person responsible for updating data

**Contact**  
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Mashhad University of Medical Sciences  
**Full name of responsible person**  
maryam hoseinzadeh  
**Position**  
Postgraduate Student Midwifery  
**Other areas of specialty/work**  
**Street address**  
Mashhad, University Avenue, Crossroads doctora, Ibn  
Sina Avenue, School of Nursing and Midwifery

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**Web page address**

## 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*