

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 30-24 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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Web page address

Person responsible for updating data

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
maryam hoseinzadeh
Position
Postgraduate Student Midwifery
Other areas of specialty/work
Street address
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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