

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### Investigating the effect of nutritional education on glycemic index based on Health Belief Model (HBM) on determining the risk of gestational diabetes mellitus among pregnant mother referring to health center, Omidiyeh.

#### Protocol summary

##### Study aim

The purpose of this study is to investigate the effect of nutritional education on glycemic index based on Health Belief Model (HBM) on determining the risk of gestational diabetes mellitus among pregnant women

##### Design

Samples with block randomization were randomly divided into intervention and control groups. Each group has 45 people.

##### Settings and conduct

This is an open label controlled -randomized interventional trial that will be carried out among pregnant women covered by Omidiyeh health care centers.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 12 to 16 weeks pregnancy, single-crowned pregnancy, having BMI > 25 or overweight, BMI > 30, age ≥ 25 years, having a family history of type 2 diabetes in first-degree relatives, having a history of GDM or glucose intolerance in her previous pregnancy, having a baby weighing >4000 gr, having a premature baby, or losing a baby during her previous pregnancy  
.exclusion criteria: having type 2 diabetes, thyroid disease, cardiovascular disease, respiratory disease, history of taking medications that affect the level of blood sugar like corticosteroids

##### Intervention groups

it is based on the glycemic index of food items and their glycemic load and their effect on the blood sugar of the pregnant mother. Pregnant women in the control group receive routine health care. The duration of the intervention is three months.

##### Main outcome variables

At the beginning and the end of the study will be measured fasting blood glucose, blood glucose 1h ppt and 2h ppt after giving 75 grams of oral glucose, Fasting

insulin, hs CRP, total cholesterol, LDL and HDL cholesterol, triglycerides, and the variables of the health belief model.

#### General information

##### Reason for update

- correction of maternal minimum age was 25 according to the inclusion criteria (by typo mistake had been written 18) - BMI replaced with pre-BMI (due to pregnancy period) -research place changed to Omidiyeh - sample size increased to 90 -in the "Other design features" open-label, Parallel - controlled randomized trial has been addressed -updating the actual date of enrolment and completion date -add secondary outcomes including HOMA-IR and HOMA-IS - complete the share plan section

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190227042858N1**  
Registration date: **2019-07-18, 1398/04/27**  
Registration timing: **prospective**

Last update: **2023-08-23, 1402/06/01**

Update count: **1**

##### Registration date

2019-07-18, 1398/04/27

##### Registrant information

##### Name

Shirin Alipour

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2237 6756

##### Email address

alipour.sh@ajums.ac.ir

**Recruitment status**

Recruitment complete

**Funding source**

**Expected recruitment start date**

2019-09-06, 1398/06/15

**Expected recruitment end date**

2019-11-06, 1398/08/15

**Actual recruitment start date**

2020-09-01, 1399/06/11

**Actual recruitment end date**

2021-03-02, 1399/12/12

**Trial completion date**

2022-04-30, 1401/02/10

**Scientific title**

Investigating the effect of nutritional education on glycemic index based on Health Belief Model (HBM) on determining the risk of gestational diabetes mellitus among pregnant mother referring to health center, Omidyeh.

**Public title**

The effect of nutritional education on glycemic index based on Health Belief Model (HBM) on determining the risk of gestational diabetes mellitus among pregnant mother

**Purpose**

Prevention

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Interested in participating in the study Gestational age 12-16 weeks Having reading and writing skills Single pregnancy over weight pre-BMI > 25 or obese pre-BMI > 30 Age ≥ 25 years Having a family history of type 2 diabetes in first-degree relatives Having a history of gestational diabetes or glucose intolerance in previous pregnancies Having a neonatal birth weight > 4000 grams Having a baby prematurely or losing a baby during the previous pregnancy

**Exclusion criteria:**

Having Type 2 Diabetes / Thyroid Disease / Cardiovascular Disease / Respiratory Disease Having a history of taking drugs that affect blood sugar level, such as corticosteroid medications Absence of active participation in class / training sessions

**Age**

From 25 years old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: 90

Actual sample size reached: 84

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

using block randomization , two groups of intervention and control (using random numbers table)

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

open label, Parallel - controlled randomized trial

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethics committee of Ahvaz University of Medical Sciences

**Street address**

Golestan Highway, Jundishapur University of Medical Sciences

**City**

Ahvaz

**Province**

Khouzestan

**Postal code**

6135715794

**Approval date**

2018-11-10, 1397/08/19

**Ethics committee reference number**

IR.AJUMS.REC.1397.600

**Health conditions studied**

1

**Description of health condition studied**

Gestational Diabetes

**ICD-10 code**

O24.4

**ICD-10 code description**

Diabetes mellitus arising in pregnancy

**Primary outcomes**

1

**Description**

Fasting blood glucose

**Timepoint**

Before the intervention and three months after the intervention

**Method of measurement**

Serum sample

## 2

### **Description**

Blood Glucose Level One hour, two hours after giving 75 grams of glucose

### **Timepoint**

Before the intervention and three months after the intervention

### **Method of measurement**

Serum sample

## 3

### **Description**

Fasting Insulin serum

### **Timepoint**

Before the intervention and three months after the intervention

### **Method of measurement**

Serum sample

## 4

### **Description**

hs CRP measurement

### **Timepoint**

Before the intervention and three months after the intervention

### **Method of measurement**

Serum sample

## 5

### **Description**

Health belief model variables (awareness, sensitivity, severity, perceived benefits and barriers and self-efficacy)

### **Timepoint**

Before the intervention and three months after the intervention

### **Method of measurement**

Health Belief Model Questionnaire

## **Secondary outcomes**

## 1

### **Description**

Body Mass Index (BMI) measurements

### **Timepoint**

Before intervention and three months after the intervention

### **Method of measurement**

weight in kilograms (kg) by their height in meters (m) squared

## 2

### **Description**

Measuring maternal weight gain

### **Timepoint**

Before intervention and three months after the intervention

### **Method of measurement**

digital scale

## 3

### **Description**

Measure physical activity

### **Timepoint**

Before the intervention and three months after the intervention

### **Method of measurement**

Physical activity questionnaire

## 4

### **Description**

Measurement of triglyceride levels

### **Timepoint**

Before the intervention and three months after the intervention

### **Method of measurement**

Serum sample

## 5

### **Description**

Total cholesterol level measurements

### **Timepoint**

Before the intervention and three months after the intervention

### **Method of measurement**

Serum sample

## 6

### **Description**

Measuring LDL and HDL cholesterol

### **Timepoint**

Before the intervention and three months after the intervention

### **Method of measurement**

Serum sample

## 7

### **Description**

Insulin Sensitivity

### **Timepoint**

Before the intervention and three months after the intervention

### **Method of measurement**

Formula based

## 8

### **Description**

Insulin resistance

### **Timepoint**

Before the intervention and three months after the intervention

### **Method of measurement**

Formula based

## Intervention groups

### 1

#### Description

Intervention group: A general questionnaire and a physical activity questionnaire, a three-days food record and a researcher-made questionnaire based on the HBM model with subscales of; awareness, perceived susceptibility, perceived severity, perceived benefits, perceived barriers, self-efficacy and guidance for action before and after three-months will be collected. The education sessions is based on the dietary glycemic index of food items and their glycemic load and its effect on the maternal blood glucose, prevalence of gestational diabetes mellitus and its complications for mother and fetus, and prevention of gestational diabetes. At the end of the three-months intervention period, a face-to-face session, the HBM questionnaire, three-day food record and physical activity questionnaire will be collected.

#### Category

Prevention

### 2

#### Description

Control group: Pregnant women in the control group receive routine pregnancy training and care

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

public Health care Centers

##### Full name of responsible person

Shirin Alipour

##### Street address

public Health care Centers

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Omidiyeh

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##### Phone

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##### Email

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## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Ahvaz University of Medical Sciences

##### Full name of responsible person

Dr. Mohammad Badvi

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Golestan Highway, Ahvaz University of Medical Sciences

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#### Province

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#### Phone

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#### Email

alipour.sh@ajums.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Ahvaz 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

Ahvaz University of Medical Sciences

##### Full name of responsible person

Shirin Alipour

##### Position

Master Student

##### Latest degree

Master

##### Other areas of specialty/work

Nutrition

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Golestan Highway, Faculty of Paramedicine, Jundishapur University of Medical Sciences

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## Person responsible for scientific

## **inquiries**

### **Contact**

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Dr. Fatemeh Borazjani

**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

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## **Sharing plan**

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

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available

**Title and more details about the data/document**

Investigating the effect of nutritional education on glycemic index based on Health Belief Model (HBM) on determining the risk of gestational diabetes mellitus among pregnant mother referring to health center, Omidyeh.

**When the data will become available and for how long**

After the publication of the article

**To whom data/document is available**

All

**Under which criteria data/document could be used**

study

**From where data/document is obtainable**

Fatemeh Borazjani

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

E mail

**Comments**

## **Person responsible for updating data**

### **Contact**

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Shirin Alipour

**Position**

Masters Student

**Latest degree**

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**Other areas of specialty/work**

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