Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 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 45people.

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, Omidiyeh.

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
City
Omidiyeh
Province
Khouzestan
Postal code
6135715794
Phone
+98 61 3333 3477
Email
alipour.sh@ajums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Dr. Mohammad Badvi
Street address
Golestan Highway, Ahwaz University of Medical Sciences
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Phone
+98 61 3333 3477
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
Street address
Golestan Highway, Faculty of Paramedicine, Jundishapur University of Medical Sciences
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Phone
+98 613738319
Email
alipour.sh@ajums.ac.ir

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

Street address
Golestan Highway, Faculty of Paramedicine ، Ahwaz University of Medical Sciences

City
Ahvaz

Province
Khouzestan

Postal code
6135715794

Phone
+98 613738319

Email
borazjani-f@ajums.ac.ir

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
Master

Other areas of specialty/work
Nutrition

Street address
Golestan Highway, Faculty of Paramedicine, Ahwaz University of Medical Sciences

City
Ahvaz

Province
Khouzestan

Postal code
6135715794

Phone
+98 613738319

Email
alipour.sh@ajums.ac.ir

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, Omidiyeh.

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