

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 2026

### Effect of education of participation care versus no education on the control of blood glucose and lifestyle in women with gestational diabetes: a randomized clinical trial

#### Protocol summary

##### Study aim

To assess the effect of education of participation care versus no education on the control of blood glucose and lifestyle in women with gestational diabetes

##### Design

This is a randomized clinical trial, phase II, in which 80 eligible patients will be randomly assigned to the intervention and control groups using a block randomization.

##### Settings and conduct

The eligible women with gestational diabetes who will refer to Healthcare Centers of Hamadan City during the study period will be enrolled into the trial

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 40 years Gestational diabetes Gestational age of 6 to 10 weeks Literate  
Exclusion criteria: Cognitive disorder Mental disorder Inability or contraindication of physical activity

##### Intervention groups

Intervention group: Routine cares plus 5 educational sessions of participation care once a week in 45 to 60 minutes sessions Control group: Just routine cares

##### Main outcome variables

Primary outcome: (a) Assessing fasting blood sugar before intervention and 5 weeks after that through laboratory testing; (b) Assessing lifestyle before intervention and 5 weeks after that using Walker standard questionnaire

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120215009014N203**

Registration date: **2018-01-19, 1396/10/29**

Registration timing: **prospective**

Last update: **2018-02-14, 1396/11/25**

Update count: **1**

##### Registration date

2018-01-19, 1396/10/29

##### Registrant information

###### Name

Jalal Poorolajal

###### Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 81 1838 0090

###### Email address

poorolajal@umsha.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

##### Expected recruitment start date

2018-01-30, 1396/11/10

##### Expected recruitment end date

2019-01-30, 1397/11/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of education of participation care versus no education on the control of blood glucose and lifestyle in women with gestational diabetes: a randomized clinical trial

##### Public title

Effect of education of participation care versus no education on the control of blood glucose and lifestyle in women with gestational diabetes

#### **Purpose**

Treatment

#### **Inclusion/Exclusion criteria**

##### **Inclusion criteria:**

Age of 18 to 40 years Gestational diabetes Gestational age of 6 to 10 weeks Literate

##### **Exclusion criteria:**

Cognitive disorder Mental disorder Inability or contraindication of physical activity

#### **Age**

From **18 years** old to **40 years** old

#### **Gender**

Female

#### **Phase**

2

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

*No information*

#### **Sample size**

Target sample size: **80**

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

Randomized

#### **Randomization description**

The patients will be randomly assigned to intervention and control groups using block randomization.

#### **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**

Ethics Committee of Hamadan University of Medical Sciences

###### **Street address**

Vice-chancellor for Research and Technology,  
Hamadan University of Medical Sciences, Shahid Fahmideh Ave

###### **City**

Hamadan

###### **Province**

Hamadan

###### **Postal code**

6517838695

##### **Approval date**

2018-01-13, 1396/10/23

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

Ethic code: IR.UMSHA.REC.1396.720

### **Health conditions studied**

#### **1**

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

Gestational diabetes

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

O24.4

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

Gestational diabetes mellitus

### **Primary outcomes**

#### **1**

##### **Description**

Assessing fasting blood sugar

##### **Timepoint**

Before intervention and 5 weeks after that

##### **Method of measurement**

Through laboratory testing

#### **2**

##### **Description**

Assessing lifestyle

##### **Timepoint**

Before intervention and 5 weeks after that

##### **Method of measurement**

Using Walker standard questionnaire

### **Secondary outcomes**

empty

### **Intervention groups**

#### **1**

##### **Description**

Intervention group: Routine cares plus 5 educational sessions of participation care once a week in 45 to 60 minutes sessions

##### **Category**

Other

#### **2**

##### **Description**

Control group: Just routine cares

##### **Category**

Other

### **Recruitment centers**

#### **1**

##### **Recruitment center**

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

Healthcare Centers of Hamadan City

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

Sahar Derayesh

**Street address**

School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

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**Province**

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**Postal code**

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**Phone**

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**Email**

saharap89@gmail.com

**Position**

Master of Community Health

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr Saeid Bashirian

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info.research@umsha.ac.ir

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

Yes

**Title of funding source**

Hamedan 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**

Hamedan University of Medical Sciences

**Full name of responsible person**

Sahar Derayesh

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Naghid Mohammadi

**Position**

Master of Nursing of Community Health

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

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**Person responsible for updating data****Contact****Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr Jalal Poorolajal

**Position**

Professor of Epidemiology

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Epidemiology

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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**

Not applicable

**Informed Consent Form**

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

**Clinical Study Report**

Undecided - It is not yet known if there will be 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