

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)

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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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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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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

Position

Master of Community Health

Latest degree

Master

Other areas of specialty/work

Nursery

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

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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