

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Assessing the effect of education intervention program on improving self-management among women with gestational diabetes:Application of Health Belief Model

Protocol summary

Summary

(1)Objectives: To determine the effect of educational intervention program on improving self-management among women with gestational diabetes: Application of Health Belief Model (2) Design: Interventional trial based on random allocation using randomized four blocks method in order to select two intervention and control groups. (3)Setting and conduct: This study is an interventional one which study population is women with gestational diabetes. Sample size considers 110 participants which will randomly select in two groups. (4)Participants including major eligibility criteria: Inclusion criteria: confirm gestational diabetes; tendency to study participation; history of at least one year of gestational diabetes. Exclusion criteria: unwillingness to study participation; not attendance in educational sessions. (5) Intervention: After determining the sample size, questionnaires will be completed by both intervention and control groups. Then, according to collected data, four educational sessions which will be lasted about 30 to 40 minutes using group discussion and question and answer accompany with educational package during one month. Then, in order to determine the effect of educational intervention program, questionnaires will be filled up after 3 and 6 months later. (6) Main outcome measures (variables):Self-management improvement.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016072612460N10**
Registration date: **2016-09-19, 1395/06/29**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-09-19, 1395/06/29

Registrant information

Name

Roya Sadedgi

Name of organization / entity

Tehran University of Medical Sciences

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Phone

+98 912 327 5692

Email address

sadeghir@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Education vice chancellor of Tehran

Expected recruitment start date

2015-10-05, 1394/07/13

Expected recruitment end date

2016-02-05, 1394/11/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessing the effect of education intervention program on improving self-management among women with gestational diabetes:Application of Health Belief Model

Public title

Assessing the effect of educational intervention program on improving self-management among women with

gestational diabetes:Application of Health Belief Model

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: confirm gestational diabetes;tendency to study participation; history of at least one year of gestational diabetes. exclusion criteria: unwillingness to study participation; not attendance in educational sessions.

Age

From **18 years** old to **49 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **110**

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 committee of Tehran University of Medical Sciences

Street address

Poursina Ave.

City

Tehran

Postal code

Approval date

2015-08-04, 1394/05/13

Ethics committee reference number

IR.TUMS.REC.1394.982

Health conditions studied

1

Description of health condition studied

Type 2 diabete

ICD-10 code

024

ICD-10 code description

Diabetes Mellitus Arising In Pregnancy

Primary outcomes

1

Description

Self-management

Timepoint

Baseline and 3 and 6 month after intervention

Method of measurement

Standard Self-management Questionnaire

Secondary outcomes

1

Description

Health Beliefe Model constructs

Timepoint

Baseline and 3 and 6 months after intervention

Method of measurement

Researcher made Questionnaire

Intervention groups

1

Description

Intervention program will be conducted during one month including four educational sessions based on blended educational intervention program (Lecture,Group discussion,Question & Answer, Role playing,Educational film). Each session's time is about 30-40 minutes.The meetings will try to discuss on diabetes,its complications,how to Self-management and diabetic diet.

Category

Prevention

2

Description

In the control group education will be in accordance with care centers usual process.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

South of Tehran health centers

Full name of responsible person

Dr.Javad Barzegr

Street address

No.4,Shafeei Alley,Quods Ave,Enghelab Square

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for education, Tehran University of Medical Sciences

Full name of responsible person

Dr.Mohammad Jalili

Street address

Central Building of Tehran University of Medical sciences,Quods St.

City

Tehran

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

Yes

Title of funding source

Vice chancellor for education, Tehran University of Medical Sciences

Proportion provided by this source**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

2

Sponsor

Name of organization / entity

Vice chancellor for research, Tehran university of Medical Sciences

Full name of responsible person

Dr.Masood Yonesiyan

Street address

Central Building of Tehran University of Medical sciences,Quods St.

City

Tehran

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

Yes

Title of funding source

Vice chancellor for research, Tehran university of Medical Sciences

Proportion provided by this source**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

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Full name of responsible person

Dr.Roya Sadeghi

Position

PhD/Academic staff

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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