

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

The Effect of self care education on quality of life of women with gestational diabetes

Protocol summary

Summary

This quasi-experimental study will be done to determine the effect of self-care education on quality of life in women with gestational diabetes. The main inclusion criteria will be women with a singleton pregnancy associated with gestational diabetes without having physical and mental illnesses will refer to an endocrinology clinic in Karaj city. They will be randomly divided into in 4 groups of 60 persons (240 persons). Before intervention, for each of the four groups, information of subjects will gather with individual-fertility questionnaire and quality of life for gestational diabetes questionnaire. Then for first (patients will be treated with diet plus self care education) and third (patients will be treated with insulin plus self care education) groups, patients are companied in four 45-minute sessions weekly for a month's in self care education program. Then the patients for two months will follow with telephone counseling every two weeks and visiting them at the end of each month in the center for sampling and holding a question and answer session. Second (patients will be treated with diet without self care education) and fourth (patients will be treated with insulin without self care education) groups will receive all routine care but not get any self care education. Quality of life for all patients will evaluate again 3 months after by the investigator and finally the quality of life before and after the intervention in the different groups will be compared with each other.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201406022892N3**

Registration date: **2014-06-26, 1393/04/05**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-06-26, 1393/04/05

Registrant information

Name

Mani Mirfeizi

Name of organization / entity

Islamic Azad University Karaj branch

Country

Iran (Islamic Republic of)

Phone

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mani@kiau.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Islamic Azad University, Karaj branch

Expected recruitment start date

2014-06-22, 1393/04/01

Expected recruitment end date

2015-04-21, 1394/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of self care education on quality of life of women with gestational diabetes

Public title

The effect of educational intervention on quality of life in pregnant women with diabetes

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Pregnant women with diagnosis of gestational diabetes and singleton pregnancies; disease is diagnosed by a specialist physician ; not suffering from any physical or mental diseases condition according to his medical records and statements ; No alcohol, smoking and drugs ; Wanted pregnancies ; Less than one month from the time of diagnosis of gestational diabetes is made ; Pregnant women with gestational diabetes are treated with human insulin (not analog); Maternal gestational age 20-24 weeks at the time of study entrance ; Pregnant women before and during the study has not followed a specific exercise program. Exclusion criteria: Mother is suffering from diagnosed diabetes before pregnancy; Multiple pregnancies; Patients are component medical or paramedical groups.

Age

From **15 years** old to **49 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **240**

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

Ethics Committee of Islamic Azad University Karaj
Branch

Street address

Crossroad of Moazen Blv and Esteghlal Blv,
Rajaeeshahr, Karaj

City

Karaj

Postal code

Approval date

2014-03-12, 1392/12/21

Ethics committee reference number

0065

Health conditions studied

1

Description of health condition studied

Diabetes mellitus in pregnancy

ICD-10 code

024.4

ICD-10 code description

Diabetes mellitus arising in pregnancy

Primary outcomes

1

Description

Quality of Life

Timepoint

Baseline (pre-intervention) and after three months

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

In interventional group: The first and third groups, patients with a family member who help the most in his life are companied in four 45-minute sessions weekly for a month's in self care education program. In each session in a maximum 6 patients and 6 person helping the patient will attend. At the end of each self care education session will be provided booklet or pamphlet (the total of two booklets and four pamphlets), to the patients depending on the treatment. Educational pamphlets and booklets containing all of the above training sessions, so patient it should be remembered and used. Self care education program is prepared by reading books and articles, according to the educational needs and literacy of patients. Teaching methods will be consisting of direct methods (combination of face-to-face, lectures, group discussions and the use of educational films) and indirect methods (pamphlets and educational booklets). Implementation of this education will be done by Internal Medicine (Dialectologist), dietitian and research assistant. Patients will be followed in the two months after the training sessions, by telephone counseling every two weeks by a researcher individually and refer them to the end of each month to sampling centers for verbal question and answer session.

Category

Lifestyle

2

Description

In control group: In second and fourth group (control)

patients received routine prenatal visits by Diabetologist and gynecologist or obstetrics for getting all necessary care routine but not get any self care education like as intervention group.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Endocrinology Clinic of Dr. Mani Mirfeizi

Full name of responsible person

Street address

Omid physicians clinic, Beheshti Avenue, Karaj

City

Karaj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Islamic Azad University of Karaj Branch

Full name of responsible person

Dr. Ahmad Jahan Latibary

Street address

Crossroad of Moazen Blv and Esteghlal Blv, Rajaeeshahr, Karaj

City

Karaj

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, Islamic Azad University of Karaj Branch

Proportion provided by this source

100

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

Alborz University of Medical Sciences

Full name of responsible person

Zahra Mehdizadeh Tourzani

Position

Faculty Member

Other areas of specialty/work

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Person responsible for scientific inquiries

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Position

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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