Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Effect of training package on self-care behavior and quality of life in pregnant women with gestational diabetic

Protocol summary

Summary

Objectives: This study aims to determine the effect of training package on self-care behavior and quality of life. Design: Two parallel arm Randomized Controlled Trial. Setting and conduct: This study will be conducted on 92 pregnant women with gestational diabetes referring to Tohid Hospital in Sanandaj. Eligible women will be selected convenience and will be randomly assigned into two groups with block sizes of 4 and 6 and allocation ratio of 1:1. A person from research team not involved in the recruitment and assigning participants will generate allocation sequence using a computerized program. Opaque sealed sequentially numbered envelops will be used for allocation concealment. Participants: Pregnant women with gestational age of 24-28 weeks that suffering from gestational diabetes. Interventions: Individuals in the intervention group will receive education about self-care behaviors regarding diabetes. Education plan includes four educational sessions as group discussion about 60 minutes; held for groups of 7 to 14 persons for four consecutive weeks. At the end of the first session, a booklet will be given to intervention group. The individuals in the control group will receive routine educations of prenatal care. Main outcome measures include self-care behavior and quality of life that will be assessed by self-care behavior and quality of life (QOL-GRAV) questionnaires before and four weeks after the end of intervention. Secondary outcomes include pregnancy outcomes (gestational age at delivery, delivery type and anthropometric indices of newborn) that will be assessed by checklist after childbirth.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015080510324N25**
Registration date: **2015-08-26, 1394/06/04**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2015-08-26, 1394/06/04

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2015-08-11, 1394/05/20

Expected recruitment end date

2015-11-11, 1394/08/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of training package on self-care behavior and quality of life in pregnant women with gestational diabetic

Public title

Effect of training package on self-care behavior and quality of life in pregnant women with gestational

diabetic.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Pregnant women with gestational diabetes under supervision in the diabetic clinic of Tohid Hospital in Sanandaj; Diagnosis of gestational diabetes by OGTT between 24-28 weeks of pregnancy; Singleton pregnancy ; Having at least secondary education; Self-care ability alone; Willingness to participate in the study; Possibility of going to hospital within 4 sequential weeks. Exclusion criteria: Having other physical diseases (asthma and heart disease) and known psychiatric disease according to patient’s expression.

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: **92**

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 Tabriz University of Medical Sciences

Street address

Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue, Tabriz, and East Azerbaijan Tabriz

City

Tabriz

Postal code

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

TBZMED.REC.1394.286

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

Self-care behavior

Timepoint

Before and four weeks after the end of intervention

Method of measurement

Questionnaire

2

Description

Quality of life

Timepoint

Before and four weeks after the end of intervention

Method of measurement

Quality of life (QOL-GRAV) questionnaire

Secondary outcomes

1

Description

Gestational age at the delivery

Timepoint

After childbirth

Method of measurement

Checklist

2

Description

Delivery type

Timepoint

After childbirth

Method of measurement

Checklist

3

Description

Anthropometric indices of newborn

Timepoint

After childbirth

Method of measurement

Checklist

Intervention groups

1

Description
Interventional group: Individuals in the intervention group will receive education about self-care behaviors regarding diabetes. Education plan includes four educational sessions as group discussion about 60 minutes; held for groups of 7 to 14 persons for four consecutive weeks. At the end of the first session, a booklet will be given to intervention group. The content of the training manual contains definition of diabetes, causes, complications, treatment and prevention of disease complications with an emphasis on physical activity and appropriate nutrition.
Category
Lifestyle

2

Description
Control group: The individuals in the control group will receive routine educations of prenatal care.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Tohid Hospital
Full name of responsible person
Havin Zandi Nava
Street address
Tohid hospital, Geriashan street, Sanandaj city, Kurdistan province
City
Sanandaj

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Tabriz University of Medical Sciences
Full name of responsible person
Mohammad Reza Rashidi
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Research department, third floor, central construction number 2, Tabriz medical science university, Golgasht Street, Azadi Avenue, Tabriz
City
Tabriz
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, Tabriz University of Medical Sciences
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
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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