

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

Effect of physical activity group counseling on blood glucose and pregnancy outcomes in women with gestational diabetes; based on the theory of planned behavior

Protocol summary

Summary

In a randomized clinical trial study, the effect of physical activity group counseling on blood glucose and pregnancy outcomes in women with gestational diabetes will be studied based on the theory of planned behavior in 2015. Research environment includes Endocrinology and Metabolic Research Center of Zanjan hospital ,research population consists of women with gestational diabetes are referred to the center. intervention include 6 sessions of group counseling with the frequency of three times a week and each session will be for 50 to 60 minutes. It will be done after approving the diagnosis of gestational diabetes in pregnant women who have inclusion criteria and before using insulin (according to the protocol country of Iran).If they have the restriction or prohibition of physical activity or sport side effects, and the loss of any of the criteria will be excluded. Content of consultation will be the relation to the activities of the four areas of activity in the house, traveling in the form of the walking , sport and business activities . based on theory of planned behavior (behavioral intention attitude to the subjective norms and perceived control) . Sample size estimate 80 persons . the follow-up will be done six weeks by diary, telephone . Primary outcomes included fasting plasma glucose,blood sugar two hours after eating, hemoglobin A1C- weight, the baby's height and head size. Apgar score at one and five minutes after birth, gestational age at birth, the baby's blood sugar one hour after birth, distress respiratory, neonatal injury at birth, hyperbilirubinemia 24 hours after delivery.-type delivery, induction of labor with oxytocin, during the first and second stages of labor,weight gain during the third trimester of pregnancy, systolic and diastolic blood pressure , number of hospitalizations, the satisfaction of physical activity, insulin is descriptive data collection will be a standard questionnaire of physical activity during

pregnancy - questionnaire of physical activity based on theory-based physical activity and reports of Tested

General information

Acronym

Zanjan Diabetes Survey

IRCT registration information

IRCT registration number: **IRCT2015073123423N1**

Registration date: **2015-08-13, 1394/05/22**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-08-13, 1394/05/22

Registrant information

Name

Azam Maleki

Name of organization / entity

Zanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Zanjan University of Medical Sciences; Endocrinology and Metabolic Diseases Research Center

Expected recruitment start date

2015-07-23, 1394/05/01

Expected recruitment end date

2015-12-20, 1394/09/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of physical activity group counseling on blood glucose and pregnancy outcomes in women with gestational diabetes; based on the theory of planned behavior

Public title

Effect of physical activity group counseling on blood glucose and pregnancy outcomes in women with gestational diabetes: based on the theory of planned behavior

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: healthy pregnant women with gestational diabetes at 26 to 30 weeks of pregnancy; consent to participate in the study; be resident in Zanjan city; no history or risk of premature labor, threatened abortion, incompetent cervix, multiple pregnancy, intrauterine growth retardation in recent pregnancy, chronic disease before and during pregnancy (known as pulmonary heart disease, seizures, and thrombophilia, pulmonary embolism, chronic hypertension, diabetes mellitus, hemoglobin less than 10 mg per deciliter ml).
Exclusion criteria: if participants have restrictions or prohibition of physical activity or exercise side effects, and the loss of any of the criteria will be excluded.

Age

From **18 years** old to **50 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

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

Zanjan University of Medical Sciences

Street address

Zanjan University of Medical Sciences, Azadi Square

City

Zanjan

Postal code

Approval date

2015-07-28, 1394/05/06

Ethics committee reference number

ZUMS.REC.1394.88

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

Fasting blood sugar

Timepoint

Before and 6 weeks after intervention

Method of measurement

Enzymatic glucose oxidase

2

Description

2 hours post prandial blood sugar

Timepoint

Before and 6 weeks after intervention/ daily

Method of measurement

Glucometer

3

Description

Hb A1c

Timepoint

Before and 6 weeks after intervention

Method of measurement

Kali Metric

Secondary outcomes

1

Description

Maternal outcome

Timepoint

24 hours after delivery

Method of measurement

Check list

2

Description

Neonatal Outcome

Timepoint

24 hours after delivery

Method of measurement

Check list

3

Description

Physical activity

Timepoint

Before and 2, 4 and 6 weeks after intervention

Method of measurement

Standard questionnaire of physical activity in pregnancy

Intervention groups

1

Description

The control group will receive only routine care including nutritional counseling and expert advice to regulate blood sugar.

Category

N/A

2

Description

According to the Protocol of our country, before insulin therapy in women with gestational diabetes advice regimen and physical activity is recommended for 2 weeks after diagnosing of diseases. In this study, the intervention will be done at this stage of the disease. Physical activity group counseling will be done at 6 meeting within two weeks. The content of counseling will be related to activities in four areas, activity in the house, the walk, exercised and business activities and based on theory of planned behavior (behavioral intention, attitude, subjective norm and perceived control) will be implemented. In counseling, participants better know their disease and self-care behaviors such as physical activity through conversations with advisers in an environment full of compromise. They learn how to make decisions, and finally find the solution to their problem. The combination of counseling with theories of health education can provide a clear framework for the guidance of the consultant's advice.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Endocrine and Metabolic Diseases Research Center

Full name of responsible person

Fatemeh Dousti

Street address

Endocrine and Metabolic Diseases Research Center,
Vali Asr Square

City

Zanjan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Dr. Soghrat Faghihzadeh

Street address

Zanjan University of Medical Sciences, Azadi Square

City

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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

Zanjan 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

Zanjan University of Medical Sciences

Full name of responsible person

Fatemeh Dousti

Position

MSc student in Consulting in Midwifery

Other areas of specialty/work

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

Zanjan University of Medical Sciences

Full name of responsible person

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PhD student in midwifery

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Department of Midwifery, School of Nursing and Midwifery, Zanjan University of Medical Sciences

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Person responsible for updating data**Contact****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*