

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

The Effect of Cognitive Behavioral Counseling On Lifestyle and Self-efficacy in Women With Gestational Diabetes

Protocol summary

Summary

The aim of this study was to determine the effects of cognitive behavioral counseling on lifestyle and self-efficacy in women with gestational diabetes. This study is a double blind randomized trial. Participants included 60 women with gestational diabetes who referred to diabetes clinic in Sanandaj city and elected by available the sampling method. Inclusion criteria were: age of pregnancy between 20 to 30 weeks; have negative attitude towards gestational diabetes; no mental illness and no taking psychiatric drugs. Using simple random sampling of participants in the intervention and control groups (each group 30 persons) will be allocated. After random distribution, the measures including lifestyle and self efficacy in both groups by Walkers promoting healthy lifestyle questionnaire and diabetes self-efficacy questionnaire carried out. For the intervention group Consultation in the form of groups of 10 people with cognitive behavioral approach during seven sessions of one and half hours every week in one of the health centers in Sanandaj, which is a suitable condition, will be executed. For the control group in addition to routine clinic care, after completing the assessments, a training plan will be held. After the intervention, and a month later measures will be repeated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017011631977N1**

Registration date: **2017-01-26, 1395/11/07**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-01-26, 1395/11/07

Registrant information

Name

Aazam Bakhteh

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

کرمانشاه

Email address

aa_bakhteh@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor

For Research, Kermanshah University of Medical Science
s

Expected recruitment start date

2017-01-14, 1395/10/25

Expected recruitment end date

2017-04-20, 1396/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Cognitive Behavioral Counseling On Lifestyle and Self-efficacy in Women With Gestational Diabetes

Public title

Effect of Cognitive Behavioral Counseling on Lifestyle and Self-efficacy in Women With Gestational Diabetes

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Pregnant women with gestational

diabetes at 20 -30 weeks of gestational age; has a negative attitude towards gestational diabetes; no history of infertility; least literate; fluent in Persian; no participate in class relaxation, yoga, exercise during pregnancy; no underlying physical illness or complication of pregnancy; no history of diabetes before pregnancy; no addiction; no mental illness; no history of mental, nerves and hypnotic drug use and No known diseases of the fetus. Exclusion criteria: lack of desire to continue to participate in the study; occur maternal or fetal complications during the study (abortion, fetal death, etc); occurrence any mental illness need medication during the intervention; Attending prenatal classes; no participate in more than two sessions of counseling sessions.

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double 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 Kermanshah University of Medical Sciences

Street address

Building No, 2 of Kermanshah University of Medical Sciences, Shaheid Beheshti Blvd, Kermanshah

City

Kermanshah

Postal code

6714673159

Approval date

2017-01-11, 1395/10/22

Ethics committee reference number

IR.KUMS.REC.1395.596

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

lifestyle

Timepoint

before intervention, after intervention and one month after intervention

Method of measurement

by using promoting healthy lifestyle questionnaire

Secondary outcomes

1

Description

Self-efficacy

Timepoint

Before intervention, After intervention and One month after intervention

Method of measurement

By using Diabetes Self-efficacy Questionnaire

Intervention groups

1

Description

For the intervention group Consultation in the form of groups of 10 people with cognitive behavioral approach during seven sessions of one and half hours in one of the health centers in Sanandaj, which is a suitable condition, will be executed

Category

Lifestyle

2

Description

For the control group in addition to routine clinic care, after completing the assessments, a training plan will be held.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabet Clinic In Sanandaj City

Full name of responsible person

Nahid Asadi

Street address

Kurdistan University of Medical Sciences, Azadi Square, sanandaj, Iran

City

Sanandaj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Department of Kermanshah University of Medical Sciences

Full name of responsible person

Kourosh Hamzehei

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Building No. 2 of Kermanshah University of Medical Sciences, Shaheid Beheshti Blvd, Kermanshah

City

Kermanshah

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Research Department of Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Nahid Asadi

Position

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Other areas of specialty/work

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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