Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The Effect of Cognitive Behavioral Counseling On Lifestyle and Self-efficacy in WomenWith 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

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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 WomenWith 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; occure 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 Medica l Sciences

Street address
Building No, 2 of Kermanshah University of Medical Sc iences, 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 Diabets

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

Street address
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
Master Student of Counselling in Midwifery

Other areas of specialty/work

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Person responsible for scientific inquiries

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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