

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Assessment of effectiveness of self-care package in pregnant diabetic women

Protocol summary

Summary

The aim of this study is to determine the efficacy of a self-care package on glycemic control and self-efficacy, which has been prepared for diabetic pregnant women. In this experimental study, a control group and an intervention group (70 persons in each group) will participate. The criteria to take part in the study include: being pregnant, having diabetes confirmed by reliable tests according to the Health Ministry guideline, being literate (able to read and write in Persian), being able to answer the related questionnaire independently and sign the consent letter, having no visual or hearing impairment or mental illnesses which needs medication or psychiatrist continuous care, and having no previous experience of participation in any diabetes self-management training programs. To randomize, block randomization method is used. The control group uses routine educational programs and the intervention group is trained according to the confirmed educational curriculum. Three training sessions will be held every week in the Diabetes Center by applying group training method. A comparison of glycemic control will be done between the two groups before and after the intervention. Long-term outcomes include delivering outcomes such as birth weight, Apgar, method of delivery and neonatal admission. Self-efficacy will also be determined by "Stanford Scale for Self-Efficacy in Diabetic Patients."

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015102824753N1**

Registration date: **2016-01-09, 1394/10/19**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-01-09, 1394/10/19

Registrant information

Name

Mitra Kolivand

Name of organization / entity

Shahrood University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Budget of PhD Thesis

Expected recruitment start date

2016-04-20, 1395/02/01

Expected recruitment end date

2017-01-20, 1395/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of effectiveness of self-care package in pregnant diabetic women

Public title

The Effectiveness of self-care package on glycemic control and self efficacy in pregnant diabetic Women

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: being pregnant; having diabetes (gestational or overt) confirmed by reliable tests according to the Health Ministry guideline; being able to read and write in Persian; being able to answer the questionnaire independently and sign the consent letter; having no visual or hearing impairment or mental illnesses which needs medication or psychiatrist continuous care; and having no previous experience of participation in any diabetes self care training programs; not being addicted to alcohol; cigarette or drugs; gestational diabetes has been diagnosed not more than a month; gestational age should not be more than 28 weeks; the patient should not experience any intensive stressful events during the study. Exclusion criteria: refusing from cooperation in the study; being absent for two or more educational sessions; occurrence of high-risk pregnancy complications such as vaginal bleeding; preeclampsia; preterm labor; admission in hospital due to any reason; multiple pregnancy; the patient should not be a member of medical and paramedical staff.

Age

From **14 years** old to **49 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **280**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

To randomize, block randomization method is used.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahroud University of Medical Sciences

Street address

Shahroud University of Medical Sciences, HafeTirSquare, Shahroud, IRAN

City

Shahroud

Postal code

Approval date

2015-05-13, 1394/02/23

Ethics committee reference number

IR.SHMU.REC.1394.23

Health conditions studied

1

Description of health condition studied

Pregnancy Diabetes

ICD-10 code

O24.0, O24

ICD-10 code description

Pre-existing diabetes mellitus, insulin-dependent, Pre-existing diabetes mellitus, non-insulin-dependent, Diabetes mellitus arising in pregnancy

Primary outcomes

1

Description

self-efficacy

Timepoint

baseline (pre-intervention) and one month after intervention

Method of measurement

by use of self-efficacy questionnaire of Stanford University

2

Description

blood sugar

Timepoint

baseline (pre-intervention) and one month after intervention

Method of measurement

level of fast blood sugar, and 2 hour post prandial

Secondary outcomes

1

Description

maternal and neonatal results

Timepoint

in and after delivery

Method of measurement

Determining Apgar score, neonatal birth weight, method of delivery and neonatal admission

Intervention groups

1

Description

Intervention group will be trained based on an approved schedule and curriculum which is the result of a qualitative study with nominal group. Intervention can be as follows: educational program is delivered within six training sessions which are held every five days in the

diabetes center. Training method will be group work. At most, eight pregnant women will participate in each session. Training include: face to face education by the use of slideshows, movie and an educational package in the form of a book. Insulin injection is taught by using a human body moulage. Relaxation training and appropriate pregnancy exercises will be taught to reduce stress in the participants in one session. Regarding the related topics, different methods of giving lecture, having a question-and-answer session and group discussion will be used. All the topics will be done by a trained researcher, and if necessary the patients is referred to a specialist (nutritionist, endocrinologist...). To becommitted to Supportive Self- Management Education (SSME), we consider a contact number for patients. Definitive component of intervention will be determined after the second stage of the researcher's Thesis.

Category

Behavior

2

Description

The Control group will be received routine care of Clinic.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinic and Research Center of Diabetes

Full name of responsible person

Dr.MehrAli Rahimi

Street address

Clinic and Research Center of Diabetes of Kermanshah University of Medical Sciences, Kermanshah, IRAN Islamic Republic Of

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Kermanshah University of Medical Sciences

Full name of responsible person

Dr Mehr Ali, Rahimi

Street address

Naft square, Kermanshah University of Medical Sciences, Kermanshah, IRAN

City

Kermanshah

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, 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

Shahroud University of Medical Sciences

Full name of responsible person

Mitra Kolivand

Position

Student of Reproductive Health-PHD Degree

Other areas of specialty/work

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Person responsible for scientific inquiries

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Dr. Afsaneh Keramat

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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