

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Effect of education and nurse-led telephone follow ups (Tele-nursing) versus control group on self-efficacy and quality of life in diabetic pregnant women: a single-blind randomized clinical trial

Protocol summary

Study aim

To assess the effect of education and nurse-led telephone follow ups (Tele-nursing) versus control group on self-efficacy and quality of life in diabetic pregnant women

Design

This is a single-blind randomized clinical trial, in which 80 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible diabetic pregnant women referring to the Fatemeh Hospital in Hamadan city during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the block randomization.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 45 years: Gestational diabetes; Literate; Possibility of making direct telephone calls with the patient or her active family member;
Exclusion criteria: Failure to answer the phone call three times;

Intervention groups

Intervention group: Routine education and care for diabetic pregnant women plus education and nurse-led telephone follow via Tele-nursing (including the amount of physical activity, type of diet, nutrients required at each meal, the importance of observing and performing blood sugar tests, identifying the signs and symptoms of hypoglycemia, self-care and improving quality of life) each time for 15 minutes twice a week in the first month and once a week in the second month (totally 12 times)
Control group: Routine education and care for diabetic pregnant women

Main outcome variables

Primary outcome: Self-efficacy, quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N409**

Registration date: **2021-11-27, 1400/09/06**

Registration timing: **prospective**

Last update: **2021-11-27, 1400/09/06**

Update count: **0**

Registration date

2021-11-27, 1400/09/06

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 81 1838 0090

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-16, 1400/09/25

Expected recruitment end date

2022-12-16, 1401/09/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of education and nurse-led telephone follow ups (Tele-nursing) versus control group on self-efficacy and quality of life in diabetic pregnant women: a single-blind randomized clinical trial

Public title

Effect of education and nurse-led telephone follow ups (Tele-nursing) versus control group on self-efficacy and quality of life in diabetic pregnant women

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age of 18 to 45 years: Gestational diabetes; Literate; Possibility of making direct telephone calls with the patient or her active family member;

Exclusion criteria:

Failure to answer the phone call three times;

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.

Blinding (investigator's opinion)

Single blinded

Blinding description

The examiner will not be aware of the education of pregnant women. Thus, the trial will be run as single-blind.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2021-10-22, 1400/07/30

Ethics committee reference number

IR.UMSHA.REC.1400.537

Health conditions studied**1****Description of health condition studied**

Gestational diabetes mellitus

ICD-10 code

O24.4

ICD-10 code description

Gestational diabetes mellitus

Primary outcomes**1****Description**

Self-efficacy

Timepoint

Before the intervention and 8 weeks after that

Method of measurement

Using the Diabetes Management Self-Efficacy Scale (DMSSES)

2**Description**

Quality of life

Timepoint

Before the intervention and 8 weeks after that

Method of measurement

Using Quality of Life Questionnaire for Diabetes Mellitus (QOLDP)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Routine education and care for diabetic pregnant women plus education and nurse-led telephone follow via Tele-nursing (including the amount of physical activity, type of diet, nutrients required at each meal, the importance of observing and performing blood sugar tests, identifying the signs and symptoms of hypoglycemia, self-care and improving quality of life) each time for 15 minutes twice a week in the first month and once a week in the second month (totally 12 times)

Category

Other

2

Description

Control group: Routine education and care for diabetic pregnant women

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemieh Hospital in Hamadan city

Full name of responsible person

Fariba Daneshvar

Street address

Fatemieh Hospital, Pasdaran Ave.

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faribadanesh96171@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Reza Shokoohi

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Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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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

Hamedan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Maryam Garoosian

Position

Master of Midwifery

Latest degree

Master

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Shahla Nasrolahi

Position

Dr. Shahla Nasrolahi

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for updating data**Contact****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available