Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 Fatemieh 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

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Jalal Poorolajal
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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 (DMSES)

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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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Master of Midwifery
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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