Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the effect of Tele-counselling using Leventhal's self-regulation model on anxiety and depression of pregnant mothers with diabetes in Qazvin province in 2024

Protocol summary

Study aim

Determining the effect of telephone counseling using Leventhal's self-regulation model on anxiety and depression of pregnant mothers with diabetes in Qazvin province.

Design

Clinical trial with control group, with parallel groups, without blinding, randomized, on 70 patients. Random allocation sequence generation software is used to determine the allocation sequence using the quadruple block method.

Settings and conduct

Obtaining approval from the ethics committee of Qazvin University of Medical Sciences, registering the design in RCT - randomly selecting samples from pregnant women with diabetes - obtaining informed consent, completing questionnaires in both groups - randomizing into two intervention groups (telephone consultation) by the self-regulation method by telephone and individually in three sessions. Follow-up immediately, one and two months after the intervention) and the control group (without intervention), again completing the mental health questionnaire, understanding of the disease and adherence to treatment in both groups

Participants/Inclusion and exclusion criteria

Entry requirements: Willingness to participate in research. Ability to speak and understand Farsi language. 6-10 weeks of pregnancy. Definitive diagnosis of diabetes/ Conditions of non-entry: Having a known mental illness. Concurrently suffering from other acute and chronic physical diseases. Attending simultaneous psychology counseling sessions.

Intervention groups

In the test group, the intervention of Levantal self-regulation method on depression and anxiety of pregnant mothers with diabetes is implemented as a telephone consultation in 3 sessions of 30 minutes. The educational booklet is presented to the patients at the end of the third session. In the control group, patients received only routine hospital care without intervention.

Main outcome variables

Anxiety and depression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231204060261N1**
Registration date: **2024-05-20, 1403/02/31**
Registration timing: **prospective**

Last update: **2024-05-20, 1403/02/31**
Update count: **0**

Registration date

2024-05-20, 1403/02/31

Registrant information

Name

fatemeh rostami

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-07-10, 1403/04/20

Expected recruitment end date

2024-09-10, 1403/06/20

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of Tele-counselling using Leventhal's self-regulation model on anxiety and depression of pregnant mothers with diabetes in Qazvin province in 2024

Public title
Investigating the effect of Tele-counselling using Leventhal's self-regulation model on anxiety and depression of pregnant mothers with diabetes in Qazvin province in 2024
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Willingness to participate in research Ability to speak and understand Farsi language Being in 6-10 weeks of pregnancy Diagnosing diabetes definitively by testing fasting blood sugar with a cut-off point of 93 and blood sugar 2 hours after a meal with a cut-off point of 120 and entering the mother's name as a pregnant mother with diabetes in the list of the health department of the province Suffering from depression and anxiety confirmed in the initial screening with a cut-off point of 12
Exclusion criteria:
Suffering from a known and diagnosed mental illness based on self-report and health records Suffering from other acute and chronic physical diseases at the same time such as blood pressure, kidney diseases, heart disease, multiple sclerosis, liver diseases based on the health record of the pregnant mother and the history of the disease as self-reported and entered in the medical record. Participation in psychological counseling sessions at the same time as the present study
Age
No age limit
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
For random allocation, considering that there is an intervention method (consultation with Levanthal's self-adjustment method) and two control and intervention groups, random allocation sequence generation software will be used to change the allocation sequence to quadruple block method. Quadruple block method is used to avoid significant imbalances in the number of participants assigned to each group. Block randomization ensures that there is no significant imbalance between groups at any time during randomization, and at certain points the number of participants in each group is equal. By using the balanced block randomization method, they will be placed in two test and control groups with quadruple blocks. By choosing 20 blocks out of 6 possible blocks from the quadruple combination of the two test and control groups, the selection process will be The default form is specified and the patients will be assigned to two groups respectively. 1-AABB/ 2-ABBA/ 3-BAAB/ 4-ABAB/ 5-BABA/ 6-BBAA
Blinding (investigator's opinion)
Not 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 Qazvin University of Medical Sciences
Street address
Shahid Serhang Lashgari St., Shahid Gurban Ali Rostami Alley, first door
City
ziaabad
Province
Qazvin
Postal code
3485153344
Approval date
2024-05-12, 1403/02/23
Ethics committee reference number
IR.QUMS.REC.1403.030

Health conditions studied

1

Description of health condition studied
Investigating the effect of Tele-counselling using Leventhal's self-regulation model on anxiety and depression of pregnant mothers with diabetes in Qazvin province in 2024
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
depression and anxiety
Timepoint
Before the start of the intervention, immediately after, one month and two months after the intervention
Method of measurement
Demographic questionnaire, mental health, understanding of the disease, adherence to treatment

Secondary outcomes

1

Description
Understanding the disease, compliance with the treatment
Timepoint
Before the intervention, immediately, one month and two months after the intervention
Method of measurement
Demographic questionnaire, mental health, understanding of the disease, adherence to treatment

Intervention groups

1

Description
Intervention group: Intervention group: in the test group, in addition to receiving the usual care and training, their counseling needs are first determined and a counseling program is designed based on that. The educational content is based on the stages of Leventhal's self-regulation theory, before the intervention, questionnaires of demographic characteristics, mental health, understanding of the disease and adherence to treatment will be completed. Then, the researcher will start the intervention during three 30-minute sessions in three consecutive weeks by phone and individually, after the intervention, the mentioned questionnaires will be completed again immediately and one month and two months after the intervention.
Category
Other

2

Description
Control group: The control group completes demographic, mental health, disease understanding and treatment compliance questionnaires and only receives training and routine care.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Qazvin Province Health Deputy
Full name of responsible person
fatemeh rostami
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Shahid Serhang Lashgari St., Shahid Gurban Ali Rostami Alley, first door
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Dr. Seyed Mehdi Mirhashmi
Street address
Shahid Beheshti Blvd., Maudet Sub-District, Research and Technology Vice-Chancellor of Qazvin University of Medical Sciences
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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
Qazvin 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
Qazvin University of Medical Sciences

Full name of responsible person
nasim bahrami

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Midwifery

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Qazvin - Shahid Bahonar Boulevard - University Campus Complex - Faculty of Nursing and Midwifery

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Person responsible for updating data

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Position
Master's student in counseling in midwifery

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
-

When the data will become available and for how long
-

To whom data/document is available
-

Under which criteria data/document could be used
-

From where data/document is obtainable
-

What processes are involved for a request to access data/document
-

Comments
-