Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of leventhal's self-regulatory theory on illness perception of women with gestational diabetes

Protocol summary

Study aim
Determining the effect of levantin's theory on illness perception of women with gestational diabetes

Design
A clinical trial was conducted in two parallel groups, which consisted of 80 women with gestational diabetes mellitus in the prenatal department of the hospital who were randomly assigned to control and intervention groups.

Settings and conduct
This study was conducted in the Pre-Nantal Department of Azzahra Hospital in Rasht. If the criteria for entering written consent were met, demographic questionnaire and perceived disease questionnaire were completed in both groups. In the control group, no intervention was performed by the researcher. In the experimental group, an intervention based on the illness perception was performed individually in 3 sessions of 60 to 90 minutes. A booklet was compiled by the researcher at the end of the third session to the patients in the experimental group and one month after the intervention in the control group. After intervention and one month after intervention, the illness perception questionnaire was completed again in both groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Having a desire to participate in research, Detection of diabetes by routine screening tests at weeks 24 to 28 of pregnancy, Ability to speak and understand Persian language, Not having chronic disease other than gestational diabetes, Not having a history of gestational diabetes Exclusion criteria: Any complications in mother and fetus

Intervention groups
In the experimental group, intervention based on illness perception was performed individually in 3 sessions of 60-90 minutes. The booklet was compiled by the researcher and presented to the patients at the end of the third session. In the control group, no intervention was performed by the researcher and patients received only routine hospital care.

Main outcome variables
Illness perception

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20171103037191N2**
Registration date: **2019-01-02, 1397/10/12**
Registration timing: **registered_while_recruiting**

Last update: **2019-01-02, 1397/10/12**
Update count: **0**

Registration date
2019-01-02, 1397/10/12

Registrant information

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Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-11-21, 1397/08/30

Expected recruitment end date
2019-02-19, 1397/11/30

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of leventhal's self-regulatory theory on illness perception of women with gestational diabetes

Public title

The effect of leventhal's self-regulatory theory on illness perception of women with gestational diabetes

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Having a willingness to participate in the research Definitive diagnosis of diabetes by routine screening tests during the weeks 24 to 28 of pregnancy The ability to speak and understand Persian Lack of chronic disease other than gestational diabetes Not having known and diagnosed mental illness based on self-declaration Not having a history of gestational diabetes during the previous pregnancy

Exclusion criteria:

Any complications in mother and fetus

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Actual sample size reached: **67**

Randomization (investigator's opinion)

Randomized

Randomization description

In the first step, 80 samples were selected according to the Inclusion criteria. In the next step, these patients were assigned into two groups (intervention and control) by adopting 4-way blocking method. Each group consisted of 40 samples. By assigning cards to 6 blocks possible with numbers 1-6 and placed in the container, then by selecting 20 cards from 6 cards (block), the appropriation could be done as follows.The sequence was continued until sample 80 was reached.

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

Qazvin University of Medical Sciences, Shahid Bahonar Blvd

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Qazvin

Province

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Postal code

34197-59811

Approval date

2018-11-17, 1397/08/26

Ethics committee reference number

IR.QUMS.REC.1397.187

Health conditions studied

1

Description of health condition studied

Gestational Diabetes

ICD-10 code

O24.41

ICD-10 code description

Gestational diabetes mellitus in pregnancy

Primary outcomes

1

Description

Illness perception

Timepoint

Before and After Intervention

Method of measurement

Illness perception Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention based on the illness perception individually (face to face training) will be performed in 3 sessions of 60-90 minutes in 3 consecutive days in the morning shift. In the first session, after the initial communication with the patient and asking questions about his illness perception and its consequences, the content will be presented. This session is based on five dimensions of illness perception and the impact of illness perception psychological

outcomes. These dimensions include the nature of the disease (illness symptoms, such as fatigue, weakness); the cause of the onset of the disease; the duration or perception of the person during the illness; the outcomes of the person expected from the disease; the effectiveness of control, treatment and improvement of the disease. To interfere with the illness perception, self-control techniques, verbal encouragement, goal design (such as reducing dietary sugar), feedback and behavioral assessment, and the use of experiences from successful disease patients will be used.In the second session, after reviewing the sessions, the patient will be asked to talk about the emotions and ambiguities of her illness. The unique interventions will be adjusted according to the patient's need. Training will be designed to change the misconception and negative perception of the disease.Patients will be told if they have left a question beforehand, they can ask the researcher. In the third session (evaluation and termination), the patient will be notified of the appointment before the end of the session. First, review the training of the previous sessions, and then ask the patient about the effects of new training and experiences. Problems and barriers will be investigated for each patient. At the end of the third session, an educational booklet containing of items such as: diagnosis and definition of the diseases, points that must be observed in the diet, exercising and playing sports and also a short explanation of the laboratory finding, prepared and planned by the researcher,is given to the patient.

Category

Prevention

2

Description

Control group: In the control group, no intervention was performed by the researcher and patients received only routine hospital care.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Al Zahra Hospital

Full name of responsible person

Samaneh Khodaparast

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Azzahra Training Center,opposite Shahid Azodi Stadium,Namjoo Street,Rasht

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

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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

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

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
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not 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
Not applicable

Data Dictionary
No - There is not a plan to make this available