Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The Effectiveness of Illness Perception Educational Intervention on Perceived Stress of Women with Gestational Diabetics Rasht (2017)

Protocol summary

Study aim

Determining the effect of perceived disease-based intervention on perceived stress in women with gestational diabetes

Design

In this study, 80 samples of women with gestational diabetes mellitus admitted to the prenatal department of Alzahra Hospital in Rasht are randomly assigned to two intervention and control groups and each participant is assigned a code.

Settings and conduct

This study will be carried out in the prenatal section of Al-Zahra Hospital in Rasht. 80 patients are randomly divided into two groups of control and intervention. If they have entry criteria after obtaining written informed consent, a demographic information, perceived stress questionnaire Will be completed in two groups. In the control group, no interventions will be performed by the researcher and patients will receive only routine care. In the intervention group, an intervention based on the understanding of the disease was performed individually in 3 sessions of 30 minutes Will be a booklet compiled by the researcher at the end of the second session Patients are offered. After the intervention, the perceived stress questionnaire will be completed in both groups.

Participants/Inclusion and exclusion criteria

Entry criteria: Having a willingness to participate in research, definite diagnosis of diabetes by routine screening tests during the 24th to 28th weeks of pregnancy, the ability to speak and understand Persian, lack of chronic disease other than gestational diabetes, no known and diagnosed mental illness According to self-declaration, there is no history of gestational diabetes in the previous pregnancy. Exit criteria: Any maternal and fetal complications; Transfer to a treatment center during the study.

Intervention groups

In the control group, no intervention will be performed by the researcher and patients will only receive routine care. In the intervention group, an intervention based on an understanding of the disease will be performed individually in 3 sessions of 30 minutes. A booklet compiled by the researcher will be provided at the end of the second session to the patients.

Main outcome variables

Perceived Stress

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171103037191N1**
Registration date: **2018-02-17, 1396/11/28**
Registration timing: **registered_while_recruiting**

Last update: **2018-02-17, 1396/11/28**
Update count: **0**

Registration date

2018-02-17, 1396/11/28

Registrant information

Name

Samaneh Khodaparast

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 13 3351 9344

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-25, 1396/11/05

Expected recruitment end date

2018-04-25, 1397/02/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effectiveness of Illness Perception Educational Intervention on Perceived Stress of Women with Gestational Diabetics Rasht (2017)

Public title

The Effect of Increasing the understanding Of Gestational Diabetes Patients on Perceived Stress

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 then Gestational Diabetes lack of Recognized and recognized Psychological illness based on self_declaration Not having of Gestational Diabetes during the pregnancy

Exclusion criteria:

Any complications of mother and fetus Transfer to a treatment center during the study

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Random Block, Individual, Quadruple Blocking

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

City

Qazvin

Province

Qazvin

Postal code

34197-59811

Approval date

2017-11-22, 1396/09/01

Ethics committee reference number

IR.QUMS.REC.1396.327

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

Perceived Stress

Timepoint

before and after intervention

Method of measurement

Cohen Perceived Stress scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention based on individual disease (face to face training) in 3 sessions of 30 minutes in 3 consecutive days in the morning shift. Session 1: At the first session, after initial communication with the patient and asking questions about his understanding of the current condition and its implications, the content will be presented. This session is based on five dimensions of understanding the illness and the impact of understanding the illness on psychological outcomes. These dimensions include the nature of the disease (on the adhesive and symptoms associated with the disease,

such as fatigue, weakness); the cause of the onset of the disease; the duration or perception of the person during the illness; the outcomes and expected findings of the person from the disease; the effectiveness of control, treatment and improvement of the disease will be. To interfere with the understanding of the disease, 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. Session 2: After reviewing the session's training, 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. At the end of the second session of the booklet, which includes identifying and defining the disease, what should be observed in your diet, physical activity and exercise, a brief explanation of the laboratory findings and psychological recommendations for reducing stress that the researcher will provide and Will be made available to the patient. Third Session (Evaluation and Closing): The session will be informed to the patient about this closing 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.

Category

Prevention

2

Description

Control group: In this group, there will be no intervention by the researcher and patients will only receive routine care.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra hospital

Full name of responsible person

Samane khodaparast

Street address

opposite Shahid Azodi Stadium,Namjoo Street, Rasht town

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Amir Peymani

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Deputy Minister for Research and Technology, Qazvin University of Medical Sciences,Alley Mavaddat, Shahid Beheshti Blvd

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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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Person responsible for scientific inquiries

Contact
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Position
Associate professor
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Person responsible for updating data

Contact
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Samaneh.Khodaparast
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Master's degree in midwifery counseling
Latest degree
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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
No - There is not a plan to make this available
Analytic Code
Not applicable
Data Dictionary
No - There is not a plan to make this available