# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

26 Jul 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)

**Phone**
+98 13 3351 9344

**Email address**
s.khodaparast@qums.ac.ir

**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

**City**
Rasht

**Province**
Guilan

**Postal code**
41667-54567

**Phone**
+98 13 3336 9323

**Fax**
+98 13 3336 9024

**Email**
azzahra@gums.ac.ir

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
Qazvin University of Medical Sciences

**Full name of responsible person**
Amir Peymani

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

**City**
Qazvin

**Province**
Qazvin

**Postal code**
34197-59811

**Phone**
+98 28 3333 7006

**Fax**

**Email**
apeymani@qums.ac.ir

**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

**Street address**
Qazvin University of Medical Sciences,Shahid Bahonar

Blvd

**City**
Qazvin

**Province**
Qazvin

**Postal code**
34197-59811

**Phone**
+98 28333360015

**Email**
nbahrami@qums.ac.ir

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**
Qazvin University of Medical Sciences

**Full name of responsible person**
Mohamad Ali soleimani

**Position**
Associate professor

**Latest degree**
Ph.D.

**Other areas of specialty/work**
Nursery

**Street address**
Qazvin University of Medical Sciences, Shahid Bahonar Blvd

**City**
Qazvin

**Province**
Qazvin

**Postal code**
34197-59811

**Phone**
+98 28333360015

**Email**
soleimany.msn@gmail.com

## Person responsible for updating data

**Contact**

**Name of organization / entity**
Qazvin University of Medical Sciences

**Full name of responsible person**
Samaneh.Khodaparast

**Position**
Master's degree in midwifery counseling

**Latest degree**
Bachelor

**Other areas of specialty/work**
Midwifery

**Street address**
Unit 4, Floor 2, Building of Parsa ,Alley 38,Shahid Rajaee Blvd

**City**
Rasht

**Province**
Guilan

**Postal code**
41667-54567

**Phone**
+98 13 3351 9344

**Email**
samane.khodaparast77@gmail.com

## 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