

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jun 2026

### The effect of group counselling with problem solving approach on perceived stress and quality of life in women with gestational diabetes

#### Protocol summary

##### Summary

According to high prevalence of gestational diabetes and negative effect of stress on gestational diabetes and quality of life in women with gestational diabetes, this study aims to determine the impact of group counseling with problem solving approach on perceived stress and quality of life in women with gestational diabetes. People under study will be women with gestational diabetes who referred to Valiaser and Ayatollah Mousavi Hospital. At first they will be chosen through easy sampling and will be screened through oral glucose tolerance test to identify gestational diabetes. Finally 76 women with gestational diabetes will be selected for study and will be randomly divided into 2 intervention and control groups. Randomization will be done through block randomization method. Intervention group: Problem- Solving counselling in the intervention group is planned through six 45-60 minute sessions (two sessions every week). The number of members in each group for group counselling will be 12 people and at the end of each session, some exercises will be given to the participants. Control group: In the control group, routine pregnancy care will be provided. If the participants of the control group want, problem- solving counselling sessions will also be held for them after the final stage. After a month, perceived stress and quality of life questionnaires will be filled by participants. Main outcomes: stress, quality of life.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016101227994N2**  
Registration date: **2017-11-19, 1396/08/28**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-11-19, 1396/08/28

##### Registrant information

###### Name

Taraneh Emamgholi khooshehchin

###### Name of organization / entity

Zanjan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 24 3314 8318

###### Email address

khoosheh@zums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research, Zanjan University of Medical Sciences

##### Expected recruitment start date

2017-09-16, 1396/06/25

##### Expected recruitment end date

2018-11-03, 1397/08/12

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of group counselling with problem solving approach on perceived stress and quality of life in women with gestational diabetes

##### Public title

The impact of group counselling on gestational diabetes mellitus

##### Purpose

Supportive

## **Inclusion/Exclusion criteria**

Inclusion criteria: Women with gestational diabetes with gestational age of 24-30 weeks; No other diseases; Without any history of the diseases; Absence of mental illness; Having reading and writing skills; The absence of major stressful events during the recent pregnancy.  
Exclusion criteria: Unwillingness to continue to study; Absence of complications and problems associated with pregnancy; Presence of diabetes mellitus before pregnancy

## **Age**

No age limit

## **Gender**

Female

## **Phase**

3

## **Groups that have been masked**

No information

## **Sample size**

Target sample size: 76

## **Randomization (investigator's opinion)**

Randomized

## **Randomization description**

## **Blinding (investigator's opinion)**

Not blinded

## **Blinding description**

## **Placebo**

Not used

## **Assignment**

Parallel

## **Other design features**

A randomized blocked design

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Zanjan University of Medical Sciences

##### **Street address**

Azadi Square- Zanjan

##### **City**

Zanjan

##### **Postal code**

#### **Approval date**

2017-08-22, 1396/05/31

#### **Ethics committee reference number**

ZUMS.REC.1396.141

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Gestational diabetes

#### **ICD-10 code**

024

#### **ICD-10 code description**

Diabetes mellitus in pregnancy

## **Primary outcomes**

### 1

#### **Description**

Stress

#### **Timepoint**

Before intervention, at the last consultation session and one month after intervention

#### **Method of measurement**

Cohen perceived stress questionnaire

## **Secondary outcomes**

### 1

#### **Description**

Quality of life

#### **Timepoint**

Before intervention, at the last consultation session and one month after intervention

#### **Method of measurement**

World Health Organization Quality of Life questionnaire

## **Intervention groups**

### 1

#### **Description**

Intervention group: Problem- Solving counselling in the intervention group is planned through six 45-60 minute sessions (two sessions every week). The number of members in each group for group counselling will be 12 people and at the end of each session, some exercises will be given to the participants.

#### **Category**

Behavior

### 2

#### **Description**

Control group: In the control group, routine pregnancy care will be provided. If the participants of the control group want, problem- solving counselling sessions will also be held for them after the final stage.

#### **Category**

N/A

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Diabetes Clinic, Valiaser Hospital

##### **Full name of responsible person**

Sara Maki

**Street address**

Valiaser Hospital, Valiaser Square, Zanjan

**City**

Zanjan

**2****Recruitment center****Name of recruitment center**

Elective ward, Ayatollah Mousavi Hospital

**Full name of responsible person**

Sara Maki

**Street address**

Ayatollah Mousavi Hospital, Gavazang Road

**City**

Zanjan

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice chancellor for research, University of Medical Sciences

**Full name of responsible person**

Doctor Alireza Shoghli

**Street address**

Zanjan University of Medical Sciences, Azadi Square, Zanjan

**City**

Zanjan

**Grant name**

پایان نامه

**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice chancellor for research, University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

empty

**Domestic or foreign origin**

empty

**Category of foreign source of funding**

empty

**Country of origin****Type of organization providing the funding**

empty

**Person responsible for general inquiries****Contact****Name of organization / entity**

Zanjan University of Medical Sciences

**Full name of responsible person**

Sara Maki

**Position**

Senior Counselling Student in Midwifery

**Other areas of specialty/work****Street address**

School of Nursing and Midwifery, Carmandan Boulevard, Zanjan

**City**

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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**Full name of responsible person**

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**Position**

PhD

**Other areas of specialty/work****Street address**

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**Person responsible for updating data****Contact****Name of organization / entity**

Zanjan University of Medical Sciences

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## **Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*