

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

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Phone

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Email address

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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

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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**

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Full name of responsible person

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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