

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of group counseling with problem solving approach on self-efficacy and self-care of women with gestational diabetes

Protocol summary

Study aim

Determining the effect of group counseling with problem solving approach on self-efficacy and self-care of women with gestational diabetes

Design

The study is a randomized controlled clinical trial. Initially, sampling will be carried out by convenience method. Qualified individuals will be divided into two intervention and control groups using randomized blocking. The number of samples in each group is 35 people.

Settings and conduct

The population of this study will be the women with gestational diabetes mellitus with gestational age of 24-30 weeks treated with insulin or diet that will be referred to diabetes clinic of Vali-e-Asr Hospital and Mousavi Hospital.

Participants/Inclusion and 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

Intervention groups

For the intervention group, the problem-solving counseling session will be organized in 6 sessions for 60-45 minutes, once a week and for the control group, routine pregnancy care will be provided. In group counseling, the number of members will be 12 in consultation sessions. After the interventions and reviewing the results for the control group, counseling sessions will also take place. Prior to conducting counseling sessions, after final consultation session and 1 month after the consultation, questionnaires will be filled by both groups.

Main outcome variables

Self- Efficacy And Self-care

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160521027994N5**

Registration date: **2018-07-27, 1397/05/05**

Registration timing: **registered_while_recruiting**

Last update: **2018-07-27, 1397/05/05**

Update count: **0**

Registration date

2018-07-27, 1397/05/05

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

Expected recruitment start date

2018-04-04, 1397/01/15

Expected recruitment end date

2018-10-07, 1397/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of group counseling with problem solving approach on self- efficacy and self-care of 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
N/A

Groups that have been masked
No information

Sample size
 Target sample size: **70**
 More than 1 sample in each individual
 Number of samples in each individual: **70**
 70 person

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization will be done by table of random numbers

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 Medical Uneversity

Street address

Zanjan Azadi Square

City

Zanjan

Province

Zanjan

Postal code

4513956113

Approval date

2018-06-20, 1397/03/30

Ethics committee reference number

IR.ZUMS.REC.1397.049

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

Self-Efficacy And Self-care

Timepoint

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

Method of measurement

Diabetes Self-Efficacy Inventory (DMSES), Glasgow's

Diabetes Self-care and Tuber questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The problem-solving counseling session in the intervention group will be held in group sessions in six sessions of 45-60 minutes, once a 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

Other

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

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabetes Clinic, Valiaser Hospital

Full name of responsible person

Shahla Osali

Street address

Valiaser Hospital, Valiaser Square, Zanjan

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Zanjan

Province

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Phone

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osali.sh@yahoo.com

2

Recruitment center

Name of recruitment center

Elective ward, Ayatollah Mousavi Hospital

Full name of responsible person

Shahla Osali

Street address

Ayatollah Mousavi Hospital, Gavazang Road

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Doctor Alireza Shoghli

Street address

Zanjan University of Medical Sciences, Azadi Square,
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Web page address

Grant name

tesis

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Zanjan 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

Zanjan University of Medical Sciences

Full name of responsible person

Shahla Osali

Position

Senior Counselling Student In Midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

School Of Nursing and Midwifery, Carmandan
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Person responsible for scientific inquiries

Contact

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Taraneh Emamgoli Khooshehchin

Position

Faculty

Latest degree

Ph.D.

Other areas of specialty/work

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

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

The release program is not yet known

When the data will become available and for how long

The release program is not yet known

To whom data/document is available

The release program is not yet known

Under which criteria data/document could be used

The release program is not yet known

From where data/document is obtainable

The release program is not yet known

What processes are involved for a request to access data/document

The release program is not yet known

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

Zanjan University of Medical Sciences

Full name of responsible person

Shahla Osali

Position

Senior Counselling Student In Midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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