

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 2026

### Examining the Effectiveness of solution-focused brief consultation with emphasis on self-efficacy on stress and depression and anxiety of mothers with gestational diabetes under insulin treatment

#### Protocol summary

##### Study aim

Examining the Effectiveness of solution-focused brief consultation with emphasis on self-efficacy on stress and depression and anxiety of mothers with gestational diabetes under insulin treatment 1.comparison mean score of stress in mothers with gestational diabetes under insulin treatment before and after intervention in intervention group and control group 3.comparison mean score of anxiety in mothers with gestational diabetes under insulin treatment before and after intervention in intervention group and control group 5.comparison mean score of depression in mothers with gestational diabetes under insulin treatment before and after intervention in intervention group and control group

##### Design

A randomized, blinded, controlled clinical trial with a parallel group design of 56 patients, enrolled between October 2020 and September 2020, and are followed at 16 week after intervention.

##### Settings and conduct

Mothers were chosen randomly in kamkar hospital.consultation were given in health center mothers were unaware of planing for others and analyzer dont know of intervention and control group

##### Participants/Inclusion and exclusion criteria

mothers with gestational age at 10-38 week,under insulin treatment,condition that cannot enter:when disaster happens or morbidity related to pregnancy happens or mother absent more than one session

##### Intervention groups

intervention consist of 6 session of problem solution consultation at 90 minute weekly is done,mothers with gestational diabetes under insulin treatment in control group mothers with gestational diabetes under insulin treatment that take routine prenatal care

##### Main outcome variables

Mean score of stress in intervention group is lesser than

control group

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200202046339N1**

Registration date: **2020-02-17, 1398/11/28**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-02-17, 1398/11/28**

Update count: **0**

##### Registration date

2020-02-17, 1398/11/28

##### Registrant information

##### Name

zahra rafiee

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 25 3289 6264

##### Email address

z.rafiei@arakmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-10-23, 1398/08/01

##### Expected recruitment end date

2020-03-19, 1398/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Examining the Effectiveness of solution-focused brief consultation with emphasis on self-efficacy on stress and depression and anxiety of mothers with gestational diabetes under insulin treatment

**Public title**

Examining the Effectiveness of solution-focused brief consultation on mothers with gestational diabetes under insulin treatment

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria****Inclusion criteria:**

Mothers at 10-38 week gestational age Mothers Have at least a fifth grade(primary) education non-smoking and no addiction to psychological drug or alcohol,... no history of medical illnesses, such as, cardiovascular diseases, hypertension, epilepsy, migraine, thyroid disease, connective tissue disease, asthma, respiratory disorders, kidney failure, anemia, and stroke, no history of hospitalization due to mental illnesses or abuse of psychological drugs under insulin treatment singleton pregnancy

**Exclusion criteria:**

individuals who were unwilling to continue the research absent more than one session, of 6 consultation sessions. who experienced pregnancy-related complications, including bleeding, hypertension, early delivery, and surgery or hospitalization for current pregnancy, as well as delivery or abortion during the study severe psychiatric disorders or disaster, happened in pregnancy occurrence of major stressful events during the study

**Age**

No age limit

**Gender**

Female

**Phase**

3

**Groups that have been masked**

- Outcome assessor
- Data analyser

**Sample size**

Target sample size: 56

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Urn RandomizationUrn method was used to allocate individuals in each study group A research assistant who was not involved in the recruitment of participants prepared the 56 papers, back of 56 paper was written control or intervention group,He mixed it up, provided one of the relevant papers for every one . Participants allocated to the control group (n = 28) received standard care. Participants assigned to the intervention group (n = 28) also received standard care plus solution-focused brief consultation , The intervention consisted of 6

solution-based counseling sessions that were held weekly before the intervention questionnaires were completed by two group .6 weeks and 16 weeks after the intervention, the post test was conducted for both experimental and control groups to evaluate the effect of the intervention after the intervention and 16 weeks after the intervention

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

due to nature of intervention participants and researcher was not blind but Outcome assessors and analyzer were blind

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Arak University of Medical Sciences

**Street address**

Naghshe jahan Apt.No. 15, EDALATAvenu, Ensegam street , Qom Town

**City**

Qom

**Province**

Ghous

**Postal code**

3713436969

**Approval date**

2019-12-15, 1398/09/24

**Ethics committee reference number**

ir.arakmu.rec.1398.253

**Health conditions studied****1****Description of health condition studied**

stress,anxiety,depression, in mothers with gdm

**ICD-10 code**

O24.41

**ICD-10 code description**

Gestational diabetes mellitus in pregnancy

**Primary outcomes****1****Description**

stress score in dass21 scale

## **Timepoint**

Before intervention, 6 week and 16 week after intervention

## **Method of measurement**

dass21 scale

## **2**

### **Description**

anxiety score in dass21 scale

### **Timepoint**

Before intervention, 6 week and 16 week after intervention

### **Method of measurement**

dass21 scale

## **3**

### **Description**

depression score in dass21 scale

### **Timepoint**

Before intervention, 6 week and 16 week after intervention

### **Method of measurement**

dass21 scale

## **4**

### **Description**

Behavioral strategies for coping with stress

### **Timepoint**

Before intervention, 6 week and 16 week after intervention

### **Method of measurement**

ciss scale

## **Secondary outcomes**

### **1**

#### **Description**

self efficacy

#### **Timepoint**

Before intervention, 6 week, 16 week after intervention

#### **Method of measurement**

Dmses scale

## **Intervention groups**

### **1**

#### **Description**

Intervention group: prenatal care + intervention, Intervention consist of 6 session: In the first session, introduction, After that, mothers were provided with the content of Principles of solution-focused brief consultation, the mothers were provided with information about diabetes and help them, identification of the problem, clearly, How does gestational diabetes affect mother and her child? 2- In the second session setting the goals of consultation in gdm In this session participants were Helped understand their abilities,

participants were educated to understand each other's perspectives, motivating each other, who is at risk for pregnancy complications, creation of alternative solutions, the participants were taught about the effect of the diabetes on pregnancy and self-care (nutrition, physical activity, prevention of infection, vaccination, drug, etc.). 3 In the third session,--Change viewpoint and highlight self-efficacy In this session, the participants were taught about the effect of the diabetes on pregnancy and self-care (nutrition, physical activity prevention of infection, vaccination, drug, etc assessment of consequences, selection of the solution, how to treat gestational diabetes, diet and exercise in gestational diabetes and self care, daydreaming.). Principles of self-care- 4In the fourth session- use of Practical Techniques in problem solving and the Nutritionist's Guide and exercise and treatment In Gestational Diabetes were taught, the interventionist emphasized understanding one's own thoughts and feelings and modifying self-dialogue towards more positive messaging. Therefore, the patients were taught to reflect on their thinking and respond to situations, solved the problems, and used their thoughts to help follow through with the decision they made previously, and evaluation of the outcomes Using a miracle question by a consultant And consulting with the person who understands the good and the bad moments is the result of his thoughts and behavior, Blood glucose monitoring, use of Glucometer, Assignment. 5In fifth session, Use Principles of problem solving consultation (miracle and scale questions) and monitor blood sugar Pregnancy with normal gestational diabetes, Relaxation, normal delivery or c/section in gdm, 6-In the last session (final) the interventionist summarizing the content and emphasize postpartum blood glucose monitor, the intervention were evaluated. Moreover, the interventionist answered the mothers' questions Use the word instead to experience new emotions Highlighting responses to postpartum maternal hyperglycemia, relaxation,

#### **Category**

Lifestyle

### **2**

#### **Description**

Control group: just take routine prenatal care

#### **Category**

Prevention

## **Recruitment centers**

### **1**

#### **Recruitment center**

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

kamkar Hospital

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

Rafiee Zahra

##### **Street address**

Apt Naqshe Gahan, No 15 Edalat, Ensejam, Qom

##### **City**

Qom

**Province**  
Ghoum  
**Postal code**  
3713436969  
**Phone**  
+98 25 3289 6264  
**Email**  
z.rafiel@arakmu.ac.ir

**Other areas of specialty/work**  
Midwifery  
**Street address**  
Apt Naqshe Gahan, No15 Edalat, Ensegam, QOM  
**City**  
Qom  
**Province**  
Ghoum  
**Postal code**  
3713436969  
**Phone**  
+98 25 3289 6264  
**Email**  
Zrfyy475@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Arak University of Medical Sciences  
**Full name of responsible person**  
Dr. Kamali Alireza ,Deputy OF Technology Research of Arak Medical university  
**Street address**  
Arak University Of Medical Scienes, Basij Sq, Arak  
**City**  
Arak  
**Province**  
Markazi  
**Postal code**  
38481-7-6941  
**Phone**  
+98 86 3417 3638  
**Fax**  
**Email**  
amoozesh@arakmu.ac.ir  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Arak 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**  
Arak University of Medical Sciences  
**Full name of responsible person**  
Rafiee Zahra  
**Position**  
student  
**Latest degree**  
Bachelor

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Arak University of Medical Sciences  
**Full name of responsible person**  
Vakilian Katayon  
**Position**  
Professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Reproductive Health  
**Street address**  
Medical University, Basij Squire, Arak  
**City**  
Arak  
**Province**  
Markazi  
**Postal code**  
38481-7-6941  
**Phone**  
+908634173638  
**Email**  
cattv2002@yahoo.com

## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Arak University of Medical Sciences  
**Full name of responsible person**  
Rafiee Zahra  
**Position**  
student  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Midwifery  
**Street address**  
Apt Naqshe Gahan, No15 Edalat, Ensegam, Qom  
**City**  
QOM  
**Province**  
Ghoum  
**Postal code**

3713436969

**Phone**

+98 25 3289 6264

**Email**

z.rafiel@arakmu.ac.ir

## 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**

Undecided - It is not yet known if there will be 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**

No - There is not a plan to make this available

**Data Dictionary**

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