

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)

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Email address

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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

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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

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Sponsors / Funding sources

1

Sponsor

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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

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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