

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effectiveness of psychological immunization on the level of worry and anxiety in women with Gestational diabetes mellitus

Protocol summary

Study aim

Determining the effectiveness of psychological immunization on the level of worry and anxiety

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, on 84 participants. Random blocking of 4 will be used for randomization

Settings and conduct

The location of the study will be the Diabetes Clinic of Tohid Hospital affiliated to Kurdistan University of Medical Sciences. For the intervention group, 6 sessions of psychological immunization training classes will be held, and for the control group, routine care will be done. Outcome assessors will mask to treatment allocation during the study

Participants/Inclusion and exclusion criteria

Inclusion criteria: 18–44 years old women; diagnosed with gestational diabetes based on expert opinion; able to read and write in Persian language; singleton pregnancy absence of other diseases for high-risk pregnancies (pregnancy poisoning, abnormal bleeding, placenta Previa and etc. ..); absence of any history of using drugs, psychotropic substances, alcohol, cigarettes and tobacco; absence of any history of hospitalization in a psychiatric ward or taking related drugs Absence of unfortunate events during the previous month; obtaining a score above the cut-off in one of psychological disorders (worry, anxiety), except for severe cases that require referral Exclusion criteria : unwillingness to continue the study; occurrence of any complication during pregnancy; Occurrence of major stressful events during the study (such as the death of a family member and divorce...)

Intervention groups

The intervention group includes women with gestational diabetes who will receive 6 sessions of psychological immunization training class. The control group consists of women with gestational diabetes who will receive routine care intervention.

Main outcome variables

anxiety, worry

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160821029446N12**

Registration date: **2023-03-14, 1401/12/23**

Registration timing: **registered_while_recruiting**

Last update: **2023-03-14, 1401/12/23**

Update count: **0**

Registration date

2023-03-14, 1401/12/23

Registrant information

Name

Maryam Damghanian

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-05, 1401/12/14

Expected recruitment end date

2023-09-22, 1402/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of psychological immunization on the level of worry and anxiety in women with Gestational diabetes mellitus

Public title

The effectiveness of psychological immunization on the level of worry and anxiety

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

pregnant women aged 18–44 years old diagnosed with gestational diabetes based on expert opinion able to read and write in Persian language singleton pregnancy absence of other diseases for high-risk pregnancies (pregnancy poisoning, abnormal bleeding, placenta Previa, early delivery and etc. ...) absence of any history in using drugs, psychotropic substances, alcohol, cigarettes and tobacco absence of any history of hospitalization in a psychiatric ward or taking related drugs Absence of unfortunate events during the previous month obtaining a score above the cut-off in one of psychological disorders (worry, anxiety) , except for severe cases that require referral

Exclusion criteria:

unwillingness to participate in the study absence in any of the training sessions occurrence of any complication during pregnancy Occurrence of major stressful events during the study (such as the death of a family member and divorce...)

AgeFrom **18 years** old to **44 years** old**Gender**

Female

Phase

N/A

Groups that have been masked

- Data analyser

Sample sizeTarget sample size: **84****Randomization (investigator's opinion)**

Randomized

Randomization description

En Assignment of samples to intervention (A) and control (B) groups (42 people in each group) will be done using blocks with size of 4. In this way, 6 possible modes will be considered using a table of random numbers. These 6 modes are written on 6 separate cards and the cards will be placed in a black bag (for concealment) . A card will be issued for 21 times to finally get 84 letters written as the sample size. The intervention group will be the group that will receive psychological immunization training sessions in addition to childbirth preparation classes, and the control group will be the group that will receive only childbirth preparation classes.

Blinding (investigator's opinion)

Single blinded

Blinding description

This study is a Randomized Controlled single-blind Trial, in which the statistical analyst is not aware of the type of intervention used for the two groups.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Tehran University of Medical Sciences

Street address

School of Nursing & Midwifery, Tehran University of Medical Sciences, tohid sq, Tehran, Iran

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Tehran

Province

Tehran

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1419733172

Approval date

2022-11-28, 1401/09/07

Ethics committee reference number

IR.TUMS.FNM.REC.1400.116

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

level of worry

ICD-10 code

R45.82

ICD-10 code description

Worries

2**Description of health condition studied**

anxiety

ICD-10 code

F06.4

ICD-10 code description

Anxiety disorder due to known physiological condition

Primary outcomes

1

Description

worry

Timepoint

before intervention and after the intervention

Method of measurement

worry score in Prenatal Distress questionnaire

2

Description

anxiety

Timepoint

before intervention and after the intervention

Method of measurement

anxiety score in pregnancy related anxiety questionnaire

Secondary outcomes

1

Description

Maternal blood glucose levels(Serum fasting glucose values)

Timepoint

before intervention and after intervention

Method of measurement

self report by glucometer

Intervention groups

1

Description

Intervention group: For the people of the intervention group, the psychological immunization training class will be held in the form of 6 sessions of 90 minutes, two sessions per week. Psychological immunization sessions in the form of group interviews (in the form of talking in class), performing relaxation techniques, examining mothers' views and worries about diabetes, examining environmental and internal stressors and factors causing anxiety and worry in mothers, answering each These symptoms, teaching relaxation techniques, teaching coping techniques against stress, giving correct information to mothers, checking mothers' sense of sufficiency and teaching them the necessary points, expressing mothers' feelings and fears, etc. will be held.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

diabetes clinic of Sanandaj tohid hospital

Full name of responsible person

Leila Ghavami Garabad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Leila Ghavami Garabad

Position

دانشجوی ارشد مامایی

Latest degree

Bachelor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available