

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

The Effect of Couples Counseling on Social Support and postpartum Glucose Tolerance Test doing in Mothers with Gestational Diabetes

Protocol summary

Study aim

The Effect of Couples Counseling on Social Support and Glucose Tolerance Test in Mothers with Gestational Diabetes

Design

The present randomized clinical trial will consist of a control and experimental group with 96 couples, which will be used for randomization by blocking method using random allocation software.

Settings and conduct

The research environment will be 4 health centers in south of Tehran. mothers in the last month of pregnancy will enter the study if they want to have the inclusion criteria if they wish after obtaining informed consent. Due to the nature of the study there is no possibility of blindness.

Participants/Inclusion and exclusion criteria

Inclusion criteria: - informed consent couples - Mothers aged 18 to 45 years - Diagnosis of gestational diabetes - The presence of the wife during the consultation - couple's primary education Exclusion criteria: - Overt Diabetes - Death of a spouse or divorce - Non-Iranian

Intervention groups

The control group will receive routine care by health care providers of the health center and couples counseling will be held in 2 sessions for the intervention group, the first session will be done in person and the second session will be virtual counseling.

Main outcome variables

The status of social support of the spouse after childbirth; The status of postpartum glucose tolerance test doing

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231103059938N1**

Registration date: **2023-12-23, 1402/10/02**

Registration timing: **prospective**

Last update: **2023-12-23, 1402/10/02**

Update count: **0**

Registration date

2023-12-23, 1402/10/02

Registrant information

Name

Zeinab Shakori

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-21, 1402/11/01

Expected recruitment end date

2024-09-20, 1403/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Couples Counseling on Social Support and postpartum Glucose Tolerance Test doing in Mothers with Gestational Diabetes

Public title

The Effect of Couples Counseling on Prevention of

Diabetes in Mothers

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Obtaining informed consent from couples to participate in the study Mothers aged 18 to 45 years Diagnosis of gestational diabetes during pregnancy according to a doctor's opinion Have at least a couple's primary education
Exclusion criteria:
Overt diabetes Death of a spouse or divorce Non-Iranian Nationality

Age
From **18 years** old to **45 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **96**

Randomization (investigator's opinion)
Randomized

Randomization description
The research environment will be the health centers of south of Tehran, which will be selected from among the centers with the highest number of pregnant mothers referring to the accident of 4 centers. The number of samples will be 96 couples with a 10% probability of loss, of which 48 will be divided into two groups of control and experiment. In each center, 24 couples were selected by available sampling method and through random allocation software by blocking method to 6 blocks 4 mothers will be divided in each health center with 12 mothers in the control group and 12 mothers in the experimental group.

Blinding (investigator's opinion)
Not blinded

Blinding description

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

13th Floor, Block A, Central Headquarters of Ministry of Health and Medical Education, Iran Simaye St.,

Ghods Town, Qods Town, Tehran, Iran

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1467664961

Approval date

2023-11-25, 1402/09/04

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1402.456

Health conditions studied

1

Description of health condition studied

Gestational Diabetes

ICD-10 code

E08

ICD-10 code description

Diabetes mellitus due to underlying condition

Primary outcomes

1

Description

Glucose tolerance test with 75 grams of glucose

Timepoint

6 weeks after delivery

Method of measurement

Checklist

2

Description

Husband's social support after childbirth

Timepoint

First and sixth week after delivery

Method of measurement

The Postpartum Partner Support Scale of Denise et al

Secondary outcomes

1

Description

Glucose tolerance test values with 75 grams of glucose

Timepoint

6 weeks after delivery

Method of measurement

Laboratory Test

Intervention groups

1

Description

Intervention group: For the intervention group, in addition to routine care, couples counseling will be held

in 2 sessions, the first session will be conducted in the form of one-hour in-person counseling (for couples) on 3-5 days after delivery (at the same time as newborn screening) and the second session will be virtual counseling for one hour at week 3 after birth. The content of the consultation in the first session includes: problems and possible questions of mothers and husbands in controlling postpartum complications of gestational diabetes mellitus and healthy lifestyle education during postpartum, the risk of type 2 diabetes in the coming years and short-term and long-term complications for mother and child in adulthood, importance of screening test in diagnosis of type 2 diabetes and the possibility of prevention or Treatment in the early stages if diagnosed early with lifestyle interventions (weight control, proper diet, physical activity and exercise), how spouses support mothers with gestational diabetes in postpartum, lactation, mental health improvement and postpartum depression prevention. In the second session, feedback will be taken from participants and necessary reviews will be made in consultation content based on their needs.

Category

Prevention

2**Description**

Control group: Routine care will be received by health care providers at the health center.

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Health centers south of Tehran

Full name of responsible person

Zeinab Shakori

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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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

Zeinab Shakori

Position

MSc Student of Midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Participants' demographic data will be shared after making people unidentifiable

When the data will become available and for how long

The start of access will be after the results are printed.

To whom data/document is available

Scientific researchers and health care workers

Under which criteria data/document could be used

Observing the rules based on the article

From where data/document is obtainable

Zeinab Shakori (MSc. Student of Midwifery Tehran University of Medical Sciences):
zeinabshakori2023@gmail.com Mehnaz Geranmayeh (Assistant Professor of Medical Education, Tehran University of Medical Sciences): geranmay@tums.ac.ir

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

Email to the main authors of the article

Comments