

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

The effect of family-centered care on self-care in mothers with gestational diabetes

Protocol summary

Study aim

Investigating the effect of family-centered care on glycemic index and self-care in mothers with gestational diabetes

Design

Randomized clinical trial with parallel groups on 46 patients in the intervention group (23 people) and the control group (23 people)

Settings and conduct

In mothers with gestational diabetes under the coverage of Southern comprehensive health centers affiliated to Tehran University of Medical Sciences

Participants/Inclusion and exclusion criteria

The inclusion criteria of pregnant mothers include: gestational diabetes, 24 to 28 weeks of pregnancy, minimum literacy to read and write, Willingness to participate in the study, The exclusion criteria include: vision and hearing impairment, suffering from chronic physical or mental diseases, alcohol or drug addiction, participation in other self-care training programs, unwillingness to continue participating in the research, acute illness during the study, divorce, accident, relocation, lack of access to samples, and premature birth. The inclusion criteria for an active family member include: minimum age of 18 years and maximum of 60 years, having minimum literacy to read and write, willingness to participate in empowerment sessions and accompany the patient, not participating in similar empowerment classes and courses, a key person in the patient's life and living with the patient and being a member of the patient's family, The exclusion criteria include: unwillingness to continue participating in the research and the occurrence of an acute event in which the person is unable to continue cooperation.

Intervention groups

In the intervention group, in order to empower the family in each of the axes of family-centered care measures will be taken.

Main outcome variables

self-care

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230203057312N1**

Registration date: **2023-02-26, 1401/12/07**

Registration timing: **prospective**

Last update: **2023-02-26, 1401/12/07**

Update count: **0**

Registration date

2023-02-26, 1401/12/07

Registrant information

Name

Sahar Mohseni

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4414 1699

Email address

mohsenis@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-21, 1402/02/01

Expected recruitment end date

2023-07-23, 1402/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of family-centered care on self-care in mothers with gestational diabetes

Public title
The effect of family-centered care on self-care in mothers with gestational diabetes

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
The inclusion criteria for the study of pregnant mothers include: gestational diabetes (based on fasting blood sugar and oral glucose tolerance test) 24 to 28 weeks of pregnancy Having minimum literacy to read and write Willingness to participate in the study The inclusion criteria for an active family member include: minimum age of 18 years and maximum of 60 years having minimum literacy to read and write willingness to participate in empowerment sessions and accompany the patient not participating in similar empowerment classes and courses a key person in the patient's life (according to the patient's statements) and living with the patient and being a member of the patient's family (spouse, parents, children, siblings)
Exclusion criteria:
The failure to enter criteria for a pregnant mother include: vision and hearing impairment suffering from chronic physical or mental diseases alcohol or drug addiction participation in other self-care training programs The exclusion criteria of a pregnant mother include: unwillingness to continue participating in the research acute illness during the study divorce accident relocation lack of access to samples premature birth The exclusion criteria of an active family member include: unwillingness to continue participating in the research and the occurrence of an acute event in which the person is unable to continue cooperation.

Age
From **18 years** old to **60 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **46**

Randomization (investigator's opinion)
Randomized

Randomization description
Using a simple random method, the samples will be randomly assigned to two intervention and control groups based on the Randomizer.org website. The random allocation will be hidden by using sealed opaque envelopes so that the name of the intervention or control group will be placed in the opaque envelopes, and an envelope will be randomly assigned to each person included in the study and the grouping status of people will be determined.

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 in Research Faculty of Nursing and Midwifery and Faculty of Rehabilitation - Tehran

Street address

No1. Corner of Mikhak Alley. Rahmani St. Moradi St. Shahreziba St.

City

Tehran

Province

Tehran

Postal code

1484999648

Approval date

2023-01-21, 1401/11/01

Ethics committee reference number

IR.TUMS.FNM.REC.1401.152

Health conditions studied

1

Description of health condition studied

gestational diabetes

ICD-10 code

O24

ICD-10 code description

Diabetes mellitus in pregnancy

Primary outcomes

1

Description

self-care

Timepoint

The beginning of the study and 3 months after that

Method of measurement

Standard self-report tool of self-care in patients with diabetes (SCODI)

Secondary outcomes

1

Description

glycemic index

Timepoint

The beginning of the study and 3 months after that

Method of measurement

Oral glucose tolerance test

Intervention groups

1

Description

Intervention group: In the intervention group, in order to empower the family in each of the axes of family-centered care (maintaining respect, sharing information, participation of patients and families in care, creating a basis for the cooperation of patients, families, health care providers in planning , implementation and evaluation of care) actions will be taken.

Category

Lifestyle

2

Description

Control group: In the control group, only the common care and education during pregnancy will take place. People belonging to the control group will receive the training that is usually provided during pregnancy through the Southern Comprehensive Health Centers affiliated to Tehran University of Medical Sciences in the form of face-to-face classes and educational pamphlets.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

South Comprehensive Health Centers affiliated with Tehran University of Medical Sciences

Full name of responsible person

Dr.Sarieh Poortaghi

Street address

Nosrat st. Tohid sq. Tehran I.IRAN

City

Tehran

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Postal code

141973317

Phone

+98 21 6691 4368

Email

S-Poortaghi@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr.Sarieh Poortaghi

Street address

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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

Dr.Sarieh Poortaghi

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr.Sarieh Poortaghi

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Sahar Mohseni

Position

Master student

Latest degree

Master

Other areas of specialty/work

Nursery

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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

-

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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is 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

-

When the data will become available and for how long

-

To whom data/document is available

-

Under which criteria data/document could be used

-

From where data/document is obtainable

-

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

-

Comments