

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Comparing the effect of self-efficacy counselling and routine care on self-efficacy of breast-feeding in women with gestational diabetes

Protocol summary

Study aim

Evaluation of counselling on self-efficacy of breast-feeding in women with gestational diabetes

Design

This study is parallel, double blind clinical trial. A total of 100 mothers with gestational diabetes hospitalized at Emam Khomeini hospital, in Arak will be enrolled in this study. We will divide patients in 2 groups by simple randomization.

Settings and conduct

In this study, a total of 100 mothers with gestational diabetes hospitalized at Emam khomeini hospital in Arak will be enrolled in this study. This clinical trial is double blind in which outcome assessor and analyzer don't aware from grouping.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Pregnant mothers with gestational diabetes, being at the age of 18 to 40 years, single pregnancy, first and second births. Non-inclusion criteria: Lack of consent to participate in the study, infant hospitalized for more than 12 hours, infant with congenital malformations or metabolic disorders, illiterate mothers, severe postpartum complications, having prohibition of lactation.

Intervention groups

The intervention group will receive self-efficacy sessions as GATHER counseling in 6 sessions that will receive 2 sessions in the third trimester of pregnancy (first session between 32 to 33 weeks and the second session between 35 to 36 weeks and 4 postpartum sessions with intervals of 14 to 16 days, 28 to 30 days, two months and three months after delivery respectively). The control group will also receive routine care.

Main outcome variables

Self-efficacy, proper weight-bearing, fissure, mastitis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020258N139**

Registration date: **2020-04-02, 1399/01/14**

Registration timing: **registered_while_recruiting**

Last update: **2020-04-02, 1399/01/14**

Update count: **0**

Registration date

2020-04-02, 1399/01/14

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 3222 2003

Email address

f.farokhi@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2020-09-22, 1399/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of self-efficacy counselling and routine care on self-efficacy of breast-feeding in women

with gestational diabetes

Public title

The effect of counselling on self-efficacy of breast-feeding in gestational diabetes

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Pregnant mothers with gestational diabetes Ages 18 to 40 years Single pregnancy First and second births

Exclusion criteria:

Lack of consent to participate in the study Infant hospitalized for more than twelve hours Infant with congenital malformations or metabolic disorders Illiterate mother Severe postpartum complications Having prohibition of lactation

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple individual randomization; randomization with envelopes and allocating into two groups A and B. In this method, we select a number of cards or letters as an intervention group and the same number of cards for the control group, then the cards are mixed. One card is taken out and its allocation is registered and the card is returned to the box near other cards. Then the cards are mixed again and we take out another card. This process continues to reach a random sequence according to sample size.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is double blind. Researcher who complete questionnaire and analyzer are blind (double blind). Outcome assessor and analyzer don't aware from grouping. Groups are named as A and B and will be available to analyzer and outcome assessor using these codes

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

Ethics committee, Research center, Payambar Azam complex, Basij square ,Sardasht, Arak

City

Arak

Province

Markazi

Postal code

3848176941

Approval date

2019-09-22, 1398/06/31

Ethics committee reference number

IR.ARAKMU.REC.1398.181

Health conditions studied

1

Description of health condition studied

Gestational diabetes

ICD-10 code

O24.4

ICD-10 code description

Gestational diabetes mellitus

Primary outcomes

1

Description

Self-efficacy of breast-feeding

Timepoint

Before consultation and then every month until 4 months later

Method of measurement

Self-efficacy of breast-feeding questionnaire

2

Description

neonate weight gain

Timepoint

Before consultation and then every month until 4 months later

Method of measurement

Scale

3

Description

Catching fissure

Timepoint

Before consultation and then every month until 4 months later

Method of measurement

Physical examination

4

Description

Mastitis

Timepoint

Before consultation and then every month until 4 months later

Method of measurement

Physical examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group will receive self-efficacy sessions as GATHER counseling in 6 sessions that will receive 2 sessions in the third trimester of pregnancy (first session between 32 to 33 weeks and the second session between 35 to 36 weeks and 4 postpartum sessions with intervals of 14 to 16 days, 28 to 30 days, two months and three months after delivery).

Category

Treatment - Other

2

Description

Control group: The control group will also receive routine care.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini hospital

Full name of responsible person

Dr Katayon Vakilian

Street address

Imam Khomeini Hospital, South Belt Road in front of Razavi town

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3848176941

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+98 86 3278 2021

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catty.v@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Alireza Kamali

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Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak

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alikamaliir@yahoo.com

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

Dr Mahbobeh Khorsandi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

Street address

Midwifery and nursing department, Payambar azam complex, Basij square, Sardasht, Arak

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr Katayon Vakilian
Position
Assisstant professor
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Ph.D.
Other areas of specialty/work
Reproductive Health
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Person responsible for updating data

Contact

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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

Data results

When the data will become available and for how long

After the article is published

To whom data/document is available

Researcher in university

Under which criteria data/document could be used

If there are additional questions

From where data/document is obtainable

Dr Katayon Vakilian

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

They have to write letters to the professors and the university

Comments