

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### The effect of prenatal breastfeeding preparation counseling on breastfeeding self-efficacy and performance in early pregnant adolescents

#### Protocol summary

##### Study aim

Determining the effect of prenatal breastfeeding preparation counseling with RSB approach on breastfeeding self-efficacy and performance in first pregnant adolescents

##### Design

This is a parallel randomized clinical trial study in which 64 eligible individuals will be randomly assigned to the intervention and control groups.

##### Settings and conduct

Eligible women who refer to the comprehensive health centers of Hamadan city during the study will be randomly assigned to intervention and control groups.

##### Participants/Inclusion and exclusion criteria

Literacy in the sixth grade of elementary school, resident of Hamedan, having a single pregnancy with a healthy fetus and low risk pregnancy Ability to attend counseling sessions over 31 weeks of age and living independently of your family and a healthy mother and mother without physical illness And psychological according to the health record.Exclusioncriteria: The presence of a known abnormality in the baby or in the mother's breast that prevents breastfeeding.

##### Intervention groups

Intervention group: Three sessions of individual breastfeeding counseling (60-90 minutes) using GATHER model and RSB approach (first session in week 31 to 34-second session in week 35-37- third session in week 38 to 40) The control group will receive only routine care

##### Main outcome variables

breastfeeding self-efficacy breastfeeding performance

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200530047596N3**

Registration date: **2021-09-08, 1400/06/17**

Registration timing: **prospective**

Last update: **2021-09-08, 1400/06/17**

Update count: **0**

##### Registration date

2021-09-08, 1400/06/17

##### Registrant information

###### Name

Mansoureh Refaei

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 81 3838 0150

###### Email address

m.refaei@umsha.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-09-11, 1400/06/20

##### Expected recruitment end date

2022-04-09, 1401/01/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of prenatal breastfeeding preparation counseling on breastfeeding self-efficacy and performance in early pregnant adolescents

## Public title

The effect of breastfeeding counseling on self-efficacy and breastfeeding performance in adolescents

## Purpose

Education/Guidance

## Inclusion/Exclusion criteria

### Inclusion criteria:

be Literate (to the sixth grade) Resident of Hamedan Having a singleton pregnancy with a healthy fetus and low-risk pregnancy The possibility of attending counseling sessions Gestational age over 31 weeks Living independently of her family or her spouse family A healthy mother without physical and mental illnesses according to the health record

### Exclusion criteria:

The presence of a known abnormality in the baby or in the mother's breast that prevents breastfeeding.

## Age

To **19 years** old

## Gender

Female

## Phase

N/A

## Groups that have been masked

- Outcome assessor
- Data analyster

## Sample size

Target sample size: **64**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Initially, samples are selected by convenience sampling. Then, based on the pre-determined sequence numbered in the package envelope from number one to 64, they are assigned to one of the intervention or control groups. The sequence of random allocation will be determined by one of the researchers based on the permutation blocking method in two groups A and B, using RAS( Random allocation software) software. the determined sequence will be numbered from number one to 64 from beginning to end, respectively.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

After the intervention, the outcome variable will be evaluated by another person who is not aware of the study groups and also the statistical analyzer will not be aware of the assignment of the groups.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

## 1

### Ethics committee

#### Name of ethics committee

The Ethic Committee of Hamadan University of Medical Sciences

#### Street address

Shahid Fahmideh

#### City

Hamadan

#### Province

Hamadan

#### Postal code

6517838698

#### Approval date

2021-09-04, 1400/06/13

#### Ethics committee reference number

IR.UMSHA.REC.1400.447

## Health conditions studied

## 1

### Description of health condition studied

Breastfeeding self-efficacy and breast feeding performance

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

## 1

### Description

breastfeeding self efficacy

### Timepoint

Before the intervention, after the end of the third consultation session

### Method of measurement

Breastfeeding Self Efficacy Scale (BSES)

## Secondary outcomes

## 1

### Description

breastfeeding performance

### Timepoint

3-5 days after delivery

### Method of measurement

Bristol Breastfeeding Assessment Tool (BBAT)

## Intervention groups

## 1

### Description

Intervention group: In the intervention group, three sessions of individual breastfeeding counseling (60-90 minutes) using GATHER model and approach RSB (Ready, Set, Baby), (first session in week 31-34- second session in week 35-37- third session in week 38-40) will

be held by the researcher in one of the rooms of the health center.

**Category**

Behavior

**2**

**Description**

Control group: They only receive routine care

**Category**

N/A

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Comprehensive health centers of Hamedan

**Full name of responsible person**

Mansoureh Refaei

**Street address**

Shahid Fahmideh

**City**

Hamedan

**Province**

Hamadan

**Postal code**

6517838698

**Phone**

+98 81 3838 0535

**Email**

mansourehrefaei@yahoo.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Saeid Bashirian

**Street address**

Shahid fahmideh

**City**

Hamedn

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3838 0160

**Email**

info.research@umsha.ac.ir

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Hamedan 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**

Hamedan University of Medical Sciences

**Full name of responsible person**

Mansoureh Refaei

**Position**

Faculty member

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Midwifery

**Street address**

Shahid fahmideh

**City**

Hamedan

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3838 0535

**Email**

mansourehrefaei@yahoo.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Mansoureh Refaei

**Position**

Faculty member

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Midwifery

**Street address**

Shahid fahmideh

**City**

Hamedan

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3838 0353

**Email**

mansouhrefaei@yahoo.com

**Person responsible for updating data****Contact****Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Mansoureh Refaei

**Position**

Faculty member

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Midwifery

**Street address**

Shahid fahmideh

**City**

Hamedan

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3838 0353

**Email**

mansouhrefaei@yahoo.com

**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**

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