Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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)
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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 analyser

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Saeid Bashirian

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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
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

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Person responsible for updating data

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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