Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effect of telenursing on self-efficacy, social support, and exclusive breastfeeding experience of primiparous mothers: A clinical trial study

Protocol summary

Study aim

Evaluating the Impact of Tele-Nursing on Self-Efficacy, Social Support, and Exclusive Breastfeeding Experience in First-Time Mothers

Design

A controlled, parallel-group, randomized phase 2 clinical trial conducted on 280 patients. Eligible participants were individually allocated to the intervention or control group using block randomization with a block size of four and a 1:1 allocation ratio.

Settings and conduct

Study location: The labor and delivery unit of Shahid Doctor Beheshti Hospital in Maragheh. Study population: Postpartum mothers following hospital discharge. Methodological note: No blinding will be performed in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Primiparous mothers; Informed parental consent to participate in the study; Breastfeeding the infant at the time of discharge; Having family support for the mother (mother, spouse, etc.); Gestational age of 37-42 weeks at delivery. Exclusion criteria: Medical contraindication for breastfeeding in mother or infant; Parents employed in hospital-related professions; Any congenital anomalies or abnormalities in the infant

Intervention groups

Control Group:The control group will receive only standard care. Intervention Group:An educational channel and training group will be established on approved national platforms. The intervention will consist of four stages of breastfeeding counseling, conducted according to the GATHER counseling principles.

Main outcome variables

Breastfeeding self-efficacy, maternal breastfeeding social support, mothers' exclusive breastfeeding experience

General information

Reason for update

The trial record is being updated to correct, complete, and clarify the information regarding the allocation of participants. In the previous version of the record, the participant allocation method was described as pseudorandom allocation based on the parity (even or odd) of the hospital record number. This description did not accurately and completely reflect the allocation method used in the conduct of the study. Therefore, the randomization-related information is being revised to accurately and transparently document the participant allocation procedure used in the trial. Specifically, the “Randomization (investigator's opinion)” field is being changed from “Not randomized” to “Randomized,” and the “Randomization description” field is being revised to describe individual-level block randomization with a block size of four and a 1:1 allocation ratio. The formation of six possible allocation sequences and the random selection with replacement of 70 blocks to generate the allocation sequence for 280 participants are also documented. This update is intended to improve the accuracy and transparency of the trial record and to accurately reflect the allocation method used in the study.

Acronym

IRCT registration information

IRCT registration number: **IRCT20241225064172N1**
Registration date: **2025-05-28, 1404/03/07**
Registration timing: **prospective**

Last update: **2026-09-30, 1405/07/08**
Update count: **1**

Registration date

2025-05-28, 1404/03/07

Registrant information

Name

Leila Hajitaghi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 914 907 6020

Email address

hajitaghi@mrgums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-06-05, 1404/03/15

Expected recruitment end date

2025-12-06, 1404/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of telenursing on self-efficacy, social support, and exclusive breastfeeding experience of primiparous mothers: A clinical trial study

Public title

The effect of telenursing on self-efficacy, social support, and exclusive breastfeeding experience of primiparous mothers

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Primiparous mothers Informed parental consent to participate in the study Exclusive breastfeeding at the time of discharge Ability to read and write in Persian (Parents) Family support for the mother from her mother, spouse, etc Owning a mobile phone compatible with the Ita app Gestational age of 37–42 weeks at the birth of term infants

Exclusion criteria:

Medical contraindication for breastfeeding for either mother or infant Employed in a hospital-related profession Congenital anomalies or abnormalities in the infant

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **280**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants were individually allocated to the intervention or control group using block randomization with a block size of four and a 1:1 allocation ratio. Six possible allocation sequences were formed, with each block containing two intervention and two control allocations in different sequences. Seventy blocks were randomly selected with replacement to generate the allocation sequence for the 280 participants. Participants were subsequently allocated sequentially to the intervention or control group according to the resulting randomization sequence. No stratified randomization was used. The randomization sequence was generated before participant allocation.

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

The Research Ethics Committee of Maragheh University of Medical Sciences

Street address

No. 113, North Saba Alley, Azadegan Street, Maragheh

City

Maragheh

Province

East Azarbaijan

Postal code

5517858600

Approval date

2025-04-16, 1404/01/27

Ethics committee reference number

IR.MARAGHEHPHC.REC.1404.001

Health conditions studied

1

Description of health condition studied

Breastfeeding Education for Mothers via Tele-Nursing

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Self-efficacy score of primiparous mothers

Timepoint

Before the intervention, and at one week, one month, and six months after the intervention

Method of measurement

Dennis Breastfeeding Self-Efficacy Scale-Short Form (BSES-SF)

2

Description

Maternal Breastfeeding Social Support

Timepoint

Before the intervention, and at one week, one month, and six months after the intervention

Method of measurement

Exclusive Breastfeeding Social Support Scale

3

Description

Mothers' Experience of Exclusive Breastfeeding

Timepoint

Before the intervention, and at one week, one month, and six months after the intervention

Method of measurement

Breastfeeding Experience Scale (BES)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: An educational channel and educational group will be established in nationally authorized settings, and the intervention will be carried out in four stages, according to the GATHER counseling principles and the Ministry of Health breastfeeding protocol. (Each of the stages will be carried out for one week, two days a week, on Saturdays and Mondays at 7 p.m.) We will explain to the mothers that they should view the educational content with a sponsor (mother or spouse or...). The questionnaires of the present study will be completed by the participants before the start of the intervention, one week, one month, and six months after the end of the intervention.

Category

Other

2

Description

Control group: Mothers in the control group will receive only standard care, including routine breastfeeding education and pamphlets about breastfeeding.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Beheshti hospital

Full name of responsible person

leila Hajitaghi

Street address

Shahid Dr. Beheshti Hospital Sadoughi Street (or: Shahid Sadoughi St.), Maragheh

City

Maragheh

Province

East Azarbaijan

Postal code

5513965895

Phone

+98 914 907 6020

Email

laila30968@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Maragheh University of Medical Sciences

Full name of responsible person

Dr Ebrahim Aliafsare

Street address

Central Headquarters Building, North Moallem Street, Adjacent to Road Traffic Police Department, Maragheh

City

Maragheh

Province

East Azarbaijan

Postal code

5517858600

Phone

+98 914 907 6020

Email

laila30968@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Maragheh 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
Maragheh University of Medical Sciences
Full name of responsible person
Leila Hajitaghi
Position
Instructor, Faculty Member of the Nursing Department
Latest degree
Master
Other areas of specialty/work
Pediatrics
Street address
No. 113, North Saba Alley, Azadegan Street, Maragheh
City
Maragheh
Province
East Azarbaijan
Postal code
5517858600
Phone
+98 914 907 6020
Email
laila30968@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Maragheh University of Medical Sciences
Full name of responsible person
leila Hajitaghi
Position
Instructor, Faculty Member of the Nursing Department
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
No. 113, North Saba Alley, Azadegan Street, Maragheh
City
Maragheh
Province
East Azarbaijan
Postal code
5517858600
Phone
+98 914 907 6020
Email
laila30968@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Maragheh University of Medical Sciences
Full name of responsible person
leila Hajitaghi
Position
Instructor, Faculty Member of the Nursing Department
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
No. 113, North Saba Alley, Azadegan Street, Maragheh
City
Maragheh
Province
East Azarbaijan
Postal code
5517858600
Phone
+98 914 907 6020
Email
laila30968@gmail.com

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
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
The study results will be published in the groups and channels created for participants, without mentioning any personal names
When the data will become available and for how long
Access period begins 6 months after results publication
To whom data/document is available
Mothers of infants
Under which criteria data/document could be used
For training purposes at the hospital
From where data/document is obtainable
laila30968@gmail.com
What processes are involved for a request to access data/document
Sending an email
Comments

Please ensure the registered data becomes visible after article publication.