Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of electronic breastfeeding counseling on indicators related to breastfeeding in nulliparous women

Protocol summary

Study aim

The effect of electronic counseling on indicators related to breastfeeding in nulliparous women referring to health centers of Tehran University of Medical Sciences in 1401

Design

Samples 124 people are randomly divided into 2 groups:intervention and control. Primiparous women referred to the health center under the supervision of Tehran University of Medical Sciences, who are included in the study after examining the inclusion criteria. The groups are parallel and without blinding. After collecting the data, their statistical analysis will be performed by SPSS software using descriptive and analytical statistical methods.

Settings and conduct

This is a randomized clinical trial in the field of maternal and child health and breastfeeding, 5 counseling visits by the site of "Virtual Breastfeeding Clinic", of at least 15 minutes with the mother will be done in the intervention group and in each breastfeeding visit in both groups will be observed. Breastfeeding problems will be solved through face-to-face visits. Samples will be selected from the centers of the 10th, 11th, 16th, 17th and 19th regions.There is no blinding in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria:Mother access to the Internet and knowing how to use it, mother literacy, no fetal malformations, term gestational age, birth weight 2500 to 4000 grams, Single twin, primiparous mother, absence of chronic maternal and childhood diseases Exclusion criteria:hospitalization of the child for any reason, breastfeeding jaundice, absence more than one session in online counseling sessions, radiotherapy

Intervention groups

Intervention group: Electronic counseling in addition to routine breastfeeding procedures Control group: routine breastfeeding measures

Main outcome variables

breastfeeding technique - Mother's perception of milk insufficiency - Breastfeeding self-efficacy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210907052403N2**
Registration date: **2022-08-29, 1401/06/07**
Registration timing: **registered_while_recruiting**

Last update: **2022-08-29, 1401/06/07**
Update count: **0**

Registration date

2022-08-29, 1401/06/07

Registrant information

Name

Samira Romina

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3289 7461

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-30, 1401/02/10

Expected recruitment end date

2022-10-02, 1401/07/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of electronic breastfeeding counseling on indicators related to breastfeeding in nulliparous women

Public title
The effect of electronic breastfeeding counseling on indicators related to breastfeeding in nulliparous women

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Mother's access to the Internet and knowing how to use it mother's literacy mother's decision to continue breastfeeding, no fetal abnormalities birth weight 2500 to 4000 grams Singleton Nulliparous the absence of chronic maternal and childhood diseases, the absence of simultaneous or combined breastfeeding or formula the absence of drugs that affect milk that have contraindications to breastfeeding term gestational age

Exclusion criteria:
Hospitalization of the child for any reason breastfeeding jaundice absence of more than one session in online counseling sessions radiotherapy and maternal cancer any contraindications to breastfeeding Diagnosis of phenylketonuria

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **124**

Randomization (investigator's opinion)
Randomized

Randomization description
The research samples will be selected by the available method and then divided into two groups of intervention and control by random allocation method. The samples will be divided into 2 intervention and control groups by random allocation method. Based on the calculated sample size, 62 people will be in the intervention group and 62 people in the control group. A quadruple block will be used to allocate individuals in the control and intervention groups. Thus, all possible states are considered for placing the letters A and B in the four blocks, which include a total of 6 states. These 6 modes were numbered from 1 to 6 and the number of required 4 blocks was determined based on the number of samples studied. Then, according to the computer table, random numbers are randomly assigned to the required number of blocks. Then, based on the order of the numbers extracted from the table, the blocks related to each number are listed in order. Finally, when the samples are included in the study, each person will take a specific letter in the order obtained. And 4 random blocks are made with a 1: 1 allocation ratio. In the first stage, women in the first abdomen referred to Tehran Health Sciences Health Centers, who have successfully started breastfeeding in the first week after delivery, are included in the study after examining the inclusion criteria.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
In this study, a researcher-made questionnaire of demographic and lactation characteristics - Breastfeeding Self-Efficacy Questionnaire (BSES) - BBAT breastfeeding technique assessment checklist and mothers' perceived milk insufficiency questionnaire will be used.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of tehran University of Medical Sciences

Street address
Tehran University of Medical Sciences - Central Building - Fifth Floor - Organization Development Management and Human CapitalKeshavarz Blvd, Tehran.

City
tehran

Province
Tehran

Postal code
3441653363

Approval date
2021-08-04, 1400/05/13

Ethics committee reference number
IR.TUMS.IKHC.REC.1400.200

Health conditions studied

1

Description of health condition studied
Breastfeeding problems

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Maternal perception of milk insufficiency

Timepoint
Before the intervention and one week after the study
Method of measurement
Questionnaire of perceived milk insufficiency by mothers

2

Description
Breastfeeding self efficacy
Timepoint
Before the intervention and one week after the study
Method of measurement
Breastfeeding Self efficacy Scale

Secondary outcomes

1

Description
The correct breastfeeding technique
Timepoint
Before the intervention and one week after the study
Method of measurement
Bristol Breastfeeding Technique Assessment Checklist

Intervention groups

1

Description
Intervention group: The intervention in this study is in the form of providing educational materials based on the working method of similar texts and available scientific resources in relation to breastfeeding interventions under the title of professional intervention. Sessions are generally from 15 to 45 minutes and usually take more than 1 time. In this study, 5 consultation visits of at least 15 minutes with the mother were performed in the intervention group and in each breastfeeding visit, both groups will be observed. Each visit includes an educational and counseling component and psychological support. The content of the training includes the following headings: correct method of breastfeeding, frequency and duration of breastfeeding, correct way of hugging the infant, correct method of breastfeeding, effective sucking sign, diagnosis of breastfeeding adequacy in infants up to 6 months only with They are breastfed.
Category
Behavior

2

Description
Control group: Half of the samples that met the inclusion criteria were randomly assigned to the control group and during the study of routine care such as fixed activities (counseling in case of breastfeeding problems, counseling about breast problems in breastfeeding and ..) which is currently implemented in health centers, will benefit.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Health centers under the supervision of Tehran University of Medical Sciences in District 19
Full name of responsible person
Shirin Shahbaziseghalde
Street address
Tehran University of Medical Sciences - Central Building - Fifth Floor - Organization Development Management and Human Capital Keshavarz Blvd, Tehran.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
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Tehran University of Medical Sciences - Central Building - Fifth Floor - Organization Development Management and Human Capital Keshavarz Blvd, Tehran.
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tumspr@tums.ac.ir
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

Shirin Shahbaziseghalde

Position

Master and executor of the project

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Tohid St. School of Nursing and Midwifery, Tehran University of Medical Sciences

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Shirin Shahbaziseghalde

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

samira romina

Position

Senior Midwifery Student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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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

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable