

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Effect of virtual breastfeeding counseling versus control group on self-efficacy and continuity of breastfeeding in nulligravida women: a randomized clinical trial

Protocol summary

Study aim

To assess the effect of virtual breastfeeding counseling versus control group on self-efficacy and continuity of breastfeeding in nulligravida women

Design

This is a randomized clinical trial with control group without blinding, in which eligible patients will be randomly assigned through the block randomization to the intervention and control groups

Settings and conduct

This study will be performed in the Comprehensive Health Centers in Hamadan city on 70 eligible nulligravida pregnant women. The patients will be randomly assigned to the intervention and control groups through the block randomization. Blinding is not possible in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18 to 40 years Gestation age 36 to 48 weeks First pregnancy The possibility of using the Internet and WhatsApp Being literate Exclusion criteria: High risk pregnancy

Intervention groups

Intervention group: Routine care during breastfeeding in addition to intervention in the form of a face-to-face breastfeeding counseling session for 45 to 60 minutes once a week in the first month, then online breastfeeding counseling via WhatsApp for 20 to 30 minutes every 2 weeks in the second month and then once monthly until the end of 6 months Control group: Just routine care during breastfeeding

Main outcome variables

Primary outcome: Breastfeeding self-efficacy The type of infant feeding

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N456**

Registration date: **2023-01-09, 1401/10/19**

Registration timing: **prospective**

Last update: **2023-01-09, 1401/10/19**

Update count: **0**

Registration date

2023-01-09, 1401/10/19

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-21, 1401/11/01

Expected recruitment end date

2023-10-22, 1402/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of virtual breastfeeding counseling versus control group on self-efficacy and continuity of breastfeeding in nulligravida women: a randomized clinical trial

Public title

Effect of virtual breastfeeding counseling versus control group on self-efficacy and continuity of breastfeeding in nulligravida women

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 to 40 years Gestation age 36 to 48 weeks First pregnancy The possibility of using the Internet and WhatsApp Being literate

Exclusion criteria:

High risk pregnancy

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.

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

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2022-10-22, 1401/07/30

Ethics committee reference number

IR.UMSHA.REC.1401.623

Health conditions studied

1

Description of health condition studied

Breastfeeding difficulty

ICD-10 code

P92.5

ICD-10 code description

Neonatal difficulty in feeding at breast

Primary outcomes

1

Description

Breastfeeding self-efficacy

Timepoint

Before the intervention and 4 weeks after that

Method of measurement

Using Dennis questionnaire

2

Description

The type of infant feeding

Timepoint

before the intervention and 4 weeks after that

Method of measurement

Using a standardized questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Routine care during breastfeeding in addition to intervention in the form of a face-to-face breastfeeding counseling session for 45 to 60 minutes once a week in the first month, then online breastfeeding counseling via WhatsApp for 20 to 30 minutes every 2 weeks in the second month and then once monthly until the end of 6 months (including learning about the

benefits of exclusive feeding with breast milk, teaching the correct breastfeeding technique, choosing the best method of feeding an infant, signs of hunger and fullness of an infant, prevention and treatment of common breastfeeding problems, teaching how to milk and store milk, feeding in breastfeeding period, warning signs in infancy, factors that enhance breastfeeding, harms of feeding with powdered milk, use of pacifiers and bottles)

Category

Other

2**Description**

Control group: Just routing care during breastfeeding

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Comprehensive Health Centers in Hamadan city

Full name of responsible person

Behnoosh Jalili Khoei

Street address

School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Reza Shokoohi

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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

Behnoosh Jalili Khoei

Position

Midwifery Student

Latest degree

Master

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Soodabeh Aghababaii

Position

Reproductive Health Specialist

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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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