

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Sep 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 routing 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)

###### Phone

+98 81 1838 0090

###### Email address

poorolajal@umsha.ac.ir

##### 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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behnoosh.jalili@yahoo.com

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

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Reza Shokoohi

**Street address**

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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**

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