

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

The effect of counseling about the breast-feeding techniques versus no counselling on breast fissure in primiparous women: a randomized clinical trial

Protocol summary

Summary

Objectives: To assess the effect of counseling about the breast-feeding techniques versus no counselling on breast fissure in primiparous women. Design: A randomized clinical trial. Setting and conduct: The eligible primiparous women who will refer to health centers of Hamadan city during the study period will be enrolled into the trial. Inclusion criteria: Age of 18 to 35 years; monogamous delivery; exclusive breast-feeding; possibility of telecommunication or presence during study period. Exclusion criteria: Abnormality in neonate's mouth; feeding neonate with bottle; abnormality in nipple; using topical drugs for breast fissure, presence of infection in breast or mastitis. Intervention group: Routine cares plus face-to-face counseling about the breast-feeding techniques one hours a day for 3 days. Control group: Just routine cares. Primary outcome: Assessing breast fissure before counseling, 5, and 10 days after that through physical examination. Randomization: Random assignment of the patients to the intervention and control groups through drawing of lots. Blinding: Not possible.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201709059014N183**
Registration date: **2017-09-10, 1396/06/19**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-09-10, 1396/06/19

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan
University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

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

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-09-23, 1397/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of counseling about the breast-feeding techniques versus no counselling on breast fissure in primiparous women: a randomized clinical trial

Public title

The effect of counseling about the breast-feeding techniques versus no counselling on breast fissure in primiparous women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age of 18 to 35 years; monogamous delivery; exclusive breast-feeding; possibility of telecommunication or presence during study period.

Exclusion criteria: Abnormality in neonate's mouth; feeding neonate with bottle; abnormality in nipple; using topical drugs for breast fissure, presence of infection in breast or mastitis.

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **74**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization: Random assignment of the patients to the intervention and control groups through drawing of lots. Blinding: Not possible.

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 the Technology,
Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamadan

Postal code

Approval date

2017-07-08, 1396/04/17

Ethics committee reference number

IR.UMSHA.REC.1396.314

Health conditions studied

1

Description of health condition studied

Breast fissure

ICD-10 code

N64.0

ICD-10 code description

Fissure and fistula of nipple

Primary outcomes

1

Description

Assessing breast fissure

Timepoint

before counseling, 5, and 10 days after that

Method of measurement

through physical examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Routine cares plus face-to-face counseling about the breast-feeding techniques one hours a day for 3 days.

Category

Other

2

Description

Control group: Just routine cares.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Health centers

Full name of responsible person

Atefeh Vafadar

Street address

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

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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

Full name of responsible person

Dr Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid
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Hamadan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

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

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

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

School of Nursing and Midwifery

Full name of responsible person

Atefeh Vafadar

Position

Midwifery Student

Other areas of specialty/work**Street address**

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School of Nursing and Midwifery

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Position

Specialist in fertility hygiene

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Department of Epidemiology

Full name of responsible person

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Position

Associate Professor

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty