

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

The effect of postpartum home visit on mothers' knowledge and attitude about exclusive breastfeeding, incidence of some complications of lactation and physiological jaundice in neonates in hospital

Protocol summary

Study aim

The effect of postpartum home visits on mothers' knowledge and attitude about exclusive breastfeeding, the incidence of some neonatal complications and physiological jaundice in infants.

Design

The study consisted of two intervention and control groups. The sample size was 100. The sampling method was simple and purposeful. The method of randomization and division of samples is based on permutation block design with 4 sizes.

Settings and conduct

The study will be performed on vaginal delivery women at Imam Khomeini Hospital in Falavarjan. The intervention group received 5 home visits. During the visits the training will be carried out as scheduled, the problems of mothers and infants will be followed up and appropriate action taken.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Normal vaginal delivery mothers who were hospitalized for less than 48 hours. Exclusion criteria: Mothers with complications of pregnancy and childbirth or their neonates with pathological jaundice are excluded.

Intervention groups

Intervention group: after delivery receive 5 visits in home that education will be given to each patient according to the program and the patient will be followed for problems. Control group: receive postpartum care through health centers.

Main outcome variables

knowledge and attitude about exclusive breastfeeding.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200108046055N1**

Registration date: **2020-02-22, 1398/12/03**

Registration timing: **registered_while_recruiting**

Last update: **2020-02-22, 1398/12/03**

Update count: **0**

Registration date

2020-02-22, 1398/12/03

Registrant information

Name

raziieh fallahnejad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5263 0719

Email address

atosa2007r@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-04, 1398/11/15

Expected recruitment end date

2020-03-15, 1398/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of postpartum home visit on mothers' knowledge and attitude about exclusive breastfeeding,

incidence of some complications of lactation and physiological jaundice in neonates in hospital

Public title

The effect of postpartum home visit on mothers' knowledge and attitude about exclusive breastfeeding, incidence of some breastfeeding complications

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

1- Willingness to participate in the study 2- Uncomplicated normal delivery 3- Pregnancy age between 37 to 42 weeks 4- Infant weight between 2500 and 4000 g 5- Hospital stay less than 48 hours 6- Home distance to hospital less than 20 km 7- Iranian race Filling out the written form of consent to participate in the study.

Exclusion criteria:

1. Mothers with high-risk pregnancies such as: diabetes, hypertension, vaginal bleeding 2- neonatal premature 3- neonatal polycythemia 4- cephalohematoma 5- It can be excluded for any reason that the mother does not wish to continue the project.

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 100

Randomization (investigator's opinion)

Randomized

Randomization description

286/5000 4-block The sampling method is goal-based. Randomization: According to the four-dimensional random permutation blocks method (using the letter A for the intervention group and the letter B for the control group and using 4-blocks 1-AABB 2-BBAA 3 - ABAB 4-BABA And thus randomized sampling to complete sampling). The tool used to randomize software is Random Allocation.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of shiraz university of medical sciences

Street address

Central building of shiraz university of medical sciences.zand st. shiraz

City

shiraz

Province

Fars

Postal code

71345-1978

Approval date

2019-01-12, 1397/10/22

Ethics committee reference number

IR.SUMS.REC.1397.917

Health conditions studied

1

Description of health condition studied

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Mean score of knowledge and attitude about exclusive breastfeeding.

Timepoint

Before study and day 42 postpartum

Method of measurement

Knowledge and Attitude Questionnaire(Iowa infant feeding attitude scale)

Secondary outcomes

1

Description

breast engorgment rate.nipple sore.mastitis

Timepoint

-Days 3,7,14 and 42 postpartum

Method of measurement

Questionnaire

2

Description

The incidence of physiological jaundice

Timepoint

days 3 and 7 postpartum

Method of measurement

Questionnaire and researcher-made checklist
Questionnaire and researcher-made checklist

3

Description

Indicators of physical growth include height, weight and head circumference

Timepoint

Day 42 postpartum

Method of measurement

Tachometer, Tape Meter, Weight

4

Description

Exclusive breastfeeding rates

Timepoint

Day 42 postpartum

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention group: Five visits on day 1 (before hospital discharge) 3 - 7 - 14 - 42 Postpartum receive

Category

Lifestyle

2

Description

Control group: phone calls are made to them on days 3-7 - 14 - 42, their status is checked and questionnaires are completed by telephone. question is asked.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Razieh Fallahnejad

Street address

Basij Street, Islamic Republic Square

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Falavarjan

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Isfahan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mahnaz Zarshenas

Street address

Namazi Square

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Web page address

<https://nurs-midwif.sums.ac.ir/>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Razieh Fallahnejad

Position

Msc Student Of Midwifery

Latest degree

Master

Other areas of specialty/work

Midwifery

Street address

دانشگاه علوم پزشکی شیراز ، فلکه نمازی، دانشکده پرستاری
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Web page address<https://nurs-midwif.sums.ac.ir/>**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Mahnaz Zarshenas

Position

Phd

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Web page address<https://nurs-midwif.sums.ac.ir/>**Person responsible for updating data****Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Razieh Fallahnejad

Position

university student

Latest degree

Master

Other areas of specialty/work

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Email

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Web page address<https://nurs-midwif.sums.ac.ir/>**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

The total potential data can be shared after unidentifiable people

When the data will become available and for how long

After defending the thesis from May 2020 onwards

To whom data/document is available

Researchers working in academic and scientific centers

Under which criteria data/document could be used

To do more and to improve

From where data/document is obtainableCorresponding Author Dr. Mahnaz Zarshenas
mahnaz_zarshenas@yahoo.com**What processes are involved for a request to access data/document**

The responsible author is asked to be answered from week to month

Comments