

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

The effect of intervention based on the theory of planned behavior on the breastfeeding pattern of mothers with preterm infants hospitalized in selected hospitals in Isfahan in 2021

Protocol summary

Study aim

Determining the effect of intervention based on the theory of planned behavior on the breastfeeding pattern of mothers with preterm infants hospitalized in selected hospitals in Isfahan in 2021

Design

Field trial study (with control and intervention group) with parallel groups, 72 participants and randomized

Settings and conduct

The research will be conducted in two groups of intervention and control. Pre-test in both groups is done by a researcher-made questionnaire. Training for the intervention group is provided in 4 sessions (each session for 60 to 90 minutes) through lectures, brainstorming, role-playing, training videos and pamphlets. The intervention and control groups will be followed for 4 months. Post-test will be performed immediately, 2 and 4 months after the intervention by completing a researcher-made questionnaire.

Participants/Inclusion and exclusion criteria

The baby is the result of a single pregnancy, mother's literacy, neonatal hospitalization due to preterm, Having Iranian nationality, living in Isfahan, no maternal and neonatal contraindications for breastfeeding

Intervention groups

During the research, the control and intervention group will receive the usual care and training by the researcher, and in addition, the intervention group will participate in 4 training sessions based on the theory of planned behavior.

Main outcome variables

Attitude score, Subjective norms, perceived behavioral control, behavioral intention; Breastfeeding pattern type

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210524051392N1**

Registration date: **2021-06-13, 1400/03/23**

Registration timing: **prospective**

Last update: **2021-06-13, 1400/03/23**

Update count: **0**

Registration date

2021-06-13, 1400/03/23

Registrant information

Name

Shirin Okhovat

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 38 3338 2219

Email address

shirinokhovat98@nm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-22, 1400/04/01

Expected recruitment end date

2021-09-22, 1400/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of intervention based on the theory of planned

behavior on the breastfeeding pattern of mothers with preterm infants hospitalized in selected hospitals in Isfahan in 2021

Public title

Breastfeeding pattern

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Having a desire to participate in the study Having literacy Having Iranian nationality Having a stable condition for the baby to start breastfeeding according to the doctor's instructions (no cyanosis, tachypnea, tachycardia) The baby is the result of a single pregnancy The gestational age according to the case documents is 34 to 36 weeks and 6 days Permanent marriage of the infant's parents Living in Isfahan

Exclusion criteria:

Using a surrogacy Employing mother in the medical and paramedical professions Having contraindications to breastfeeding according to medical records Presenting disorder affecting breastfeeding in the baby's mouth and tongue Having psychiatric problems and taking antidepressants based on the case document and the mother's statement Mother addiction based on dossier medical

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 72

Randomization (investigator's opinion)

Randomized

Randomization description

Participants are divided into two groups of control or intervention based on simple random allocation method. In order to randomize, the researcher will put two samples of cards, which in one page two word "control" and in other page the word "intervention" is written, in a large envelope, and asked participants to choose one of them without observing the cards in the envelope, which is determined according to the selected order of the participants participating in the test or control group.

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 Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jerib St.,

City

Esfahan

Province

Isfahan

Postal code

8174673461

Approval date

2021-05-24, 1400/03/03

Ethics committee reference number

IR.MUI.NUREMA.REC.1400.012

Health conditions studied

1

Description of health condition studied

Breastfeeding pattern

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Attitude score in a researcher-made questionnaire in two groups of intervention and control

Timepoint

Complete the questionnaire before, immediately, 2 and 4 months after the intervention

Method of measurement

Researcher-made questionnaire

2

Description

The score of mental norms in a researcher-made questionnaire in two groups of intervention and control

Timepoint

Complete the questionnaire before, immediately, 2 and 4 months after the intervention

Method of measurement

Researcher-made questionnaire

3

Description

Perceived behavioral control score in a researcher-made questionnaire in two groups of intervention and control

Timepoint

Complete the questionnaire before, immediately, 2 and 4 months after the intervention

Method of measurement

Researcher-made questionnaire

4

Description

Behavior intention score in a researcher-made questionnaire in two groups of intervention and control

Timepoint

Complete the questionnaire before, immediately, 2 and 4 months after the intervention

Method of measurement

Researcher-made questionnaire

5

Description

Frequency of lactation pattern in two groups of intervention and control

Timepoint

Ask questions before, immediately, 2 and 4 months after the intervention

Method of measurement

ask question

Secondary outcomes

1

Description

Neonatal growth indices (height, weight, head circumference) between the intervention and control groups

Timepoint

Measurement of indicators before, immediately, 2 and 4 months after the intervention

Method of measurement

Meters / scales

Intervention groups

1

Description

Intervention group: Holding 4 session that it takes about 60-90 minutes and they include: expressing the positive consequences of breastfeeding and playing an educational video on proper breastfeeding, training on breastfeeding ability and holding sessions based on gaining the support of others in breastfeeding, training on barriers to breastfeeding and solving problems in this regard.

Category

Behavior

2

Description

Control group: Receive routine care and training by the researcher.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti hospital

Full name of responsible person

Shirin Okhovat

Street address

Ostad Motahari St., metal bridge

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Email

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Web page address

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2

Recruitment center

Name of recruitment center

Amin hospital

Full name of responsible person

Shirin Okhovat

Street address

Ibn Sina Street, Shohada Square

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Province

Isfahan

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8148653141

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amin@mui.ac.ir

Web page address

3

Recruitment center

Name of recruitment center

Al-Zahra hospital

Full name of responsible person

Shirin Okhovat

Street address

Sefeh Boulevard, Shahid Keshvari Highway

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Isfahan

Postal code

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Fax

Email

alzahra@mui.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoy Javanmard

Street address

Isfahan University of Medical Sciences, Hezar Jerib St.

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sh_haghjoo@med.mui.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Shirin Okhovat

Position

Graduate student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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No. 18, Alley 10, Shams Tabrizi Street

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mojgan Jani Ghorban

Position

Assistant Professor of Reproductive Health

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shirin Okhovat

Position

Graduate student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

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Phone

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Email

shirinokhovat95@gmail.com

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