

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

The Effectiveness of Telephone Supportive Counseling in Improving The Breastfeeding Self-efficacy of Mothers with Preterm Infant 34-36 Weeks

Protocol summary

Study aim

To Determine The Effect of Telephone Supportive Counseling In Improving of The Breastfeeding Self-efficacy of Mothers With Preterm Infant 34-36 Weeks

Design

Phase 3 of A Randomized Clinical Trial With A Control Group, With Parallel Groups, Will be Conducted On 65 Patients. Samples Will be Selected Using The Convenience Sampling Method and Then Will be Assigned To Two Intervention And Control Groups Using The Four Block Random Method. In This Study, We Do not Have Blinding. The Outcome of The Study is Breastfeeding Self-efficacy, Which Will be Measured Using The Dennis Breastfeeding Self-efficacy Questionnaire Before Counseling And Then Monthly Up To Four Months After Counseling.

Settings and conduct

In The Present Study, The Research Setting is Sina Hospital of Ahvaz And The Research Community is Mothers With Premature Infants Admitted To The Hospital. Consultation Sessions Will be Held At The Hospital. Telephone Support Counseling Will be Receive Individually, Daily For 14 Days From The Time of Discharged. Control Group will be received Routine Training During The Discharge.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Informed Consent to Participate in The Research; Gestational Age 34-37 Weeks; Infant Feeding With Mother's Breast. Exclusion Criteria: Intrauterine Growth Retardation; Congenital Disease.

Intervention groups

The Intervention Group, Telephone Support Counseling will be Receive Individually, Daily For 14 Days From The Time of Discharged. In The Control Group, Routine Training will be Given During The Discharge.

Main outcome variables

Breastfeeding Self-efficacy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150731023423N13**

Registration date: **2020-05-17, 1399/02/28**

Registration timing: **prospective**

Last update: **2020-05-17, 1399/02/28**

Update count: **0**

Registration date

2020-05-17, 1399/02/28

Registrant information

Name

Azam Maleki

Name of organization / entity

Zanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 24 3345 4264

Email address

malekia@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-19, 1399/02/30

Expected recruitment end date

2020-09-20, 1399/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effectiveness of Telephone Supportive Counseling in Improving The Breastfeeding Self-efficacy of Mothers with Preterm Infant 34-36 Weeks

Public title

The Effect of Telephone Supportive Counseling in The Breastfeeding Self-efficacy of Mothers with Preterm Infant 34-36 Weeks

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Gestational Age 34-37 Weeks Informed Consent to Participate in Research At Least 48 Hours Hospitalization in The Neonatal Intensive Care Unit Infant Feeding From The Mother's Breast

Exclusion criteria:

Intrauterine Growth Retardation Congenital Disease

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 65

Randomization (investigator's opinion)

Randomized

Randomization description

Convenience Sampling Method Was Employed to Select The Eligible Mothers and They Were Allocated Into Two Groups (Intervention and Control) According to The Four Block Design. In This Way, Six Possible Blocks Were Assigned to Groups A (Intervention) and B (Control) . Then, The Number of Blocks Was Selected From The Random Number Table Until The Study Sample Size Was Reached. To Ensure The Concealment of The Sequence of Enrollment, We Used The Sequentially Numbered, Opaque Sealed Envelopes.

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 Zanjan University of Medical

Sciences

Street address

Zanjan, Azadi Blvd., Zanjan University of Medical Sciences

City

Zanjan

Province

Zanjan

Postal code

4515613191

Approval date

2019-08-27, 1398/06/05

Ethics committee reference number

IR.ZUMS.REC.1398.240

Health conditions studied**1****Description of health condition studied**

Breastfeeding Self-efficacy

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Breastfeeding Self-efficacy

Timepoint

After Discharge And Monthly Up To Four Month

Method of measurement

Dennis Breastfeeding Self-Efficacy Questionnaire

Secondary outcomes**1****Description**

Breastfeeding Self-efficacy

Timepoint

After Discharge And Monthly Up To Four Month

Method of measurement

Dennis Breastfeeding Self-Efficacy Questionnaire

2**Description**

Breastfeeding Level

Timepoint

After Discharge And Monthly Up To Four Month

Method of measurement

A Question With Three Levels, Exclusive Breastfeeding, Combined Nutrition (Exclusive Nutrition And Bottle), Bottle

Intervention groups

1

Description

The Intervention Group Includes Eligible Women With Premature Infants Hospitalized In The Neonatal Intensive Care Unit Who Will be Received Individuality Telephone Supportive Counseling Daily For 14 Days After Discharge . How To Care of Her Baby And Breastfeeding Problems Will be educated To Mothers.

Category

Prevention

2

Description

Control group: The Control Group Also Has Eligible Women With Premature Infants And Will be Only Received Discharge Training .

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

NICU Hospital Sina, Abuzar, Imam Khomeini Ahvaz

Full name of responsible person

Marziyeh Mohammadiyan

Street address

Imam Khomeini Street, Sina Hospital, Ahwaz, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Dr Alireza Shoghli

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Grant name

Grant code / Reference number

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

No

Title of funding source

Lack of funding

Proportion provided by this source

1

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

Zanjan University of Medical Sciences

Full name of responsible person

Marziyeh Mohammadiyan

Position

Master of Degree Student in Midwifery Counseling

Latest degree

Master

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Dr.Azam.Maleki

Position

PhD in Maternal & Child Health

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Person responsible for updating data

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Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Maintaining Confidentiality And The Possibility of
Customer Dissatisfaction

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not 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