

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Aug 2026

Survey on the effect of educational intervention using mobile application on breastfeeding self-Efficacy of mothers attending to the Health Center of Rasht

Protocol summary

Study aim

determination the effect of educational intervention using mobile application on breastfeeding self-Efficacy of mothers attending to the Health Center of Rasht

Design

The setting of this study will a comprehensive health center No.4, Rasht, Iran. Participants consist of mothers referring for thyroid screening of their neonates between the 3-5 days after birth. Participants will be selected by convenience sampling and based on the block Randomization will be allocated into two groups of the case and control

Settings and conduct

As mothers give birth in various hospitals (both public and private) in Rasht, but finally they are referred to Comprehensive Health Center No. 4 for screening test, so this center provides a suitable environment for Maternal sampling (5-2 days after delivery).

Participants/Inclusion and exclusion criteria

Satisfaction to participate in the study , Rasht city resident, no history of systemic disease, mental illness, alcohol addiction, cigarette smoking and drug abuse, uncomplicated pregnancy, breastfeeding within the last 24 hours, lack of medical contraindication for breastfeeding, ability to read and write, have an Android smartphone and its usage skills

Intervention groups

After completing the first phase questionnaire on the mobile phone of the mothers of the intervention group, the lactation knowledge software is installed and no intervention is conducted in the control group.

Main outcome variables

Initial Outcome: awareness of mothers in breastfeeding
Secondary Outcome: breastfeeding efficiency

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190615043895N1**

Registration date: **2019-11-09, 1398/08/18**

Registration timing: **retrospective**

Last update: **2019-11-09, 1398/08/18**

Update count: **0**

Registration date

2019-11-09, 1398/08/18

Registrant information

Name

A'azam Seddighi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3355 5056

Email address

faeghe.seddighi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-22, 1398/04/01

Expected recruitment end date

2019-08-23, 1398/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Survey on the effect of educational intervention using mobile application on breastfeeding self-Efficacy of mothers attending to the Health Center of Rasht

Public title

Survey on the effect of educational intervention using mobile application on breastfeeding self-Efficacy

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Satisfaction to participate in the study Mothers residing in Rasht city No history of systemic disease, mental disorder Lack of Addiction to alcohol, cigarettes and drugs (based on self-report) Breastfeeding in the last 24 hours Uncomplicated pregnancy Lack of medical prohibition for breastfeeding Have a reading and writing literacy Having an Android smartphone and the skill of using the software

Exclusion criteria:

history of systemic disease, mental disorder Feeding with milk powder multiple pregnancy

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **198**

Randomization (investigator's opinion)

Randomized

Randomization description

The investigation units: researchers who are studying the units, Will give them a number from 1 to 198. By random allocation software, a table with 50 rows of blocks Will be designed and each block Will be named A and B. Afterwards, the numbers Will Be placed in each house in order, after that , all numbers Will Be placed in blocks. 50 Quadruple blocks Will Be randomly selected. Random blocks Will be placed in sealed and locked envelopes and Will keep at the Community Health Center No. 4 and no one Will know their sequence. After starting the study, the blocks Are randomly selected daily. Those in house A Are placed in the test group and those in house B Are placed in the 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

National Ethics Committee for Biomedical Research

Street address

Tehran, Ghods Town (West), Between South Falamak and Zarafshan, Iran, Iran - Central Headquarters of the Ministry of Health and Medical Education, block A, thirteenth floor

City

Tehran

Province

Tehran

Postal code

4471683835

Approval date

2019-06-15, 1398/03/25

Ethics committee reference number

IR.GUMS.REC.1398.106

Health conditions studied

1

Description of health condition studied

Self-efficacy of mothers breastfeeding

ICD-10 code

P92.5

ICD-10 code description

Neonatal difficulty in feeding at breast

Primary outcomes

1

Description

The First Outcome: Mother's knowledge of breastfeeding

Timepoint

Day 2-5 after delivery. Before intervention

Method of measurement

A shortened and psychometric questionnaire for Denis's lactation self- efficacy. before the implementation of the breast feeding training program is completed by the researcher on the second to fifth day after delivery in both experimental and control groups. Mother's awareness is measured by a breastfeeding self-efficacy questionnaire.

Secondary outcomes

1

Description

Secondary Outcome: the Breastfeeding Self-efficacy

Timepoint

8 weeks after the end of the Intervention

Method of measurement

Short-lived and psychometric inventory of Denis's

lactation self-efficacy

Intervention groups

1

Description

Intervention group: After filling the questionnaire, the promotion of the breastfeeding booklet published by the Ministry of Health, based on the benefits of breastfeeding for infants, breastfeeding benefits for mother, breastfeeding ingredients, the usage of pacifier, lactation numbers, how to breastfeed, symptoms of satiety and hunger, The correct stat of hugging the baby during lactation, the types of Breastfeeding, Breastfeeding Diagnosis, breast feeding Methods, how to save breast milk, melting the Frozen Breast milk, Common Causes of refusing the breast milk, Nipple fissure, breast hyperemia, lightweight and premature babies, capsules and powder to increase milk, mother's cold, taking the medicine and lactation at the same time, baby with diarrhea, how to increase mother's milk and the constancy of breastfeeding and Disadvantage of milk powder and an executable program will be installed on mother's smart phone via Bluetooth and one week after the installation of the software, they will be contacted and they will be answered any questions or problems that mothers have with the software. Then to remind them of this program, they will be sent a message every week. Also, they will give researcher's phone number to mothers that if they have any questions about the software, they will ask. Then, in the eighth week after delivery, the questionnaire of breastfeeding self-efficacy will be completed by the interviewer over the telephone.

Category

Other

2

Description

Control group: the control group does not receive any educational intervention. they receive only routine breastfeeding training, which includes training in hospital and comprehensive health centers by health care providers. Then, Two times, 3-5 days after delivery and eighth week after delivery, the questionnaire of breastfeeding self-efficacy will be completed by the interviewer over the telephone.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Center for Comprehensive Health No. 4 in Rasht

Full name of responsible person

DR Farkhonde Nourani

Street address

Rasht - Three Pasteurized Pathways - Comprehensive

Health Center

City

Rasht

Province

Guilan

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4471683835

Phone

+98 13 3382 0051

Email

faeghe.sedighe@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Vice-Chancellor's Office for Research

Street address

Rasht-yakhsazi Creator - Student Park- Shahid Beheshti Faculty of Nursing and Midwifery

City

Rasht

Province

Guilan

Postal code

4471683835

Phone

+98 13 3355 5056

Email

z_bostani@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Rasht 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

Rasht University of Medical Sciences

Full name of responsible person

Dr. Zahra Bostani khalesi

Position

Academic Board - Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

Rasht-yakhsazi Creator - Student Park- Shahid Beheshti Faculty of Nursing and Midwifery

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Other areas of specialty/work

Midwifery

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

Rasht University of Medical Sciences

Full name of responsible person

Zahra Bostani Khalesi

Position

Academic Board - Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Rasht University of Medical Sciences

Full name of responsible person

Zahra Bostani KHalesi

Position

Academic Board - Assistant Professor

Latest degree

Ph.D.

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Comparing the self-efficacy of mothers breastfeeding with and without using mobile software in the first and eighth week after completing a shortened and psychometric self-efficacy questionnaire for Denis

When the data will become available and for how long

1 years

To whom data/document is available

Faculty Members of Shahid Beheshti Faculty of Midwifery and Nursing, Rasht

Under which criteria data/document could be used

In order to verify the accuracy of the information and with a written and approved request from the research deputy of Shahid Beheshti Faculty of Nursing and Midwifery, Rasht

From where data/document is obtainable

Library of Shahid Beheshti Faculty of Midwifery and Nursing of Rasht as well as a written request from the project implementer

What processes are involved for a request to access data/document

Permission from the librarian of Shahid Beheshti Faculty of Midwifery and Nursing in Rasht in writing

Comments