Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of motivational interview on breastfeeding self-efficacy of mothers with neonates hospitalized

Protocol summary

Study aim
Determining the effect of motivational interview on breastfeeding self-efficacy of mothers with hospitalized infants

Design
Clinical trial with control group, with parallel group, double-blind, randomized, on 100 patients, by accessible method and simple random

Settings and conduct
Study on mothers with hospitalized infants, Arash and Valiasr hospitals, mothers with selected method available, filling out Dennis and demographic questionnaire, people with breastfeeding self-efficacy below 100 are divided into two groups of intervention and control by simple random method.

Participants/Inclusion and exclusion criteria
.Be a primiparous mother. . The baby is single. . The infant should not be breastfed according to a pediatrician. . The mother has no history of mental disorders. . The intrauterine age of the baby is 37 weeks or more. . The weight of the baby at birth is 2500 grams or more. . The mother has no anatomical problems such as nipple sagging and fissures in the breast . Mothers who have a breastfeeding self-efficacy score below 100 .Absence of more than one session . Mother canceling while studying . Infant death for any reason during the study . Identify contraindications during breastfeeding during the study . The need to hospitalize the infant in the neonatal intensive care unit during the study period

Intervention groups
For the intervention group, 5 motivational interview sessions will be held in groups, twice a week and each session will be held for 45 minutes in groups of 8-12 people. They are breastfed

Main outcome variables
Increase breastfeeding self-efficacy, increase breastfeeding success rate

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210523051371N1**
Registration date: **2021-06-14, 1400/03/24**
Registration timing: **prospective**

Last update: **2021-06-14, 1400/03/24**
Update count: **0**

Registration date
2021-06-14, 1400/03/24

Registrant information

Name
Mahdieh Sayad Safapour

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 2244 7922

Email address
mahd.safapor.6777@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-06-24, 1400/04/03

Expected recruitment end date
2021-07-10, 1400/04/19

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effect of motivational interview on breastfeeding self-efficacy of mothers with neonates hospitalized

Public title
The effect of motivational interview on breastfeeding self-efficacy of mothers with neonates hospitalized

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Be a primiparous mother Be baby is single The baby should not be breastfed by a pediatrician The mother has no history of mental disorders Intrauterine age of the baby is 37 weeks or more The weight of the at birth is 2500 grams or more The mother has no anatomical problems such as nipple sagging and fissures in the breast Mothers who have a breastfeeding below 100

Exclusion criteria:
Absence for more than one session Maternal withdrawal during study Infant death for any reason during the study Diagnosis of contraindications during breastfeeding The need for hospitalization of the infant in the neonatal intensive care unit during the study period

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
Randomization method = simple randomization, in this method, each of the research units has an equal and independent chance to be selected and are randomly selected from a list of community members and the researcher has no involvement in the selection of samples. Crash tool = lottery،In this method, we list the people of the community and then select the required number of samples from them by drawing lots.

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
Faculty of Medicine, Islamic Azad University of Medical Sciences, Tehran

Street address
No. 16-Nasr St. 7- Jihad St. - Shahid Mahallati -Army HighwayTown

City
Tehran

Province
Tehran

Postal code
1955743557

Approval date
2021-05-22, 1400/03/01

Ethics committee reference number
IR.IAU.TMU.REC.1400.051

Health conditions studied

1

Description of health condition studied
Breastfeeding self-efficacy below 100 in the Dennis questionnaire

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Breastfeeding self-efficacy in Dennis questionnaire above 100

Timepoint
Measurement of breastfeeding self-efficacy before intervention and one month after intervention

Method of measurement
Dennis Breastfeeding Self-Efficacy Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The intervention group will hold 5 motivational interview sessions in groups, twice a week and each session for 45 minutes in groups of 8-12 people, one month after the last motivational interview session and when mothers go to the hospital clinic and According to the previous agreement with the researcher, the breastfeeding self-efficacy questionnaire will be filled in again by the intervention group

Category
Lifestyle

2

Description
Control group: The control group will receive only the routine training of the hospital regarding breastfeeding while they are in the hospital, and they will fill in the breastfeeding self-efficacy questionnaire again when they go to the clinic and according to the previous appointment with the researcher (second time).

Category
Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
Arash Women's Comprehensive Hospital-Valiasr Naja Hospital

Full name of responsible person
Dr. Laden Kashani, Dr. Ayatollah Ebadi

Street address
Valiasr Hospital, NAJA,above Mirdamad,Valiasr St.,Tehran -Arash Women's Comprehensive Hospital, corner of 162 Alley ,Shahid Baghdarnia St. (North Rashid),after Shahid Bagheri Highway,Resalat Highway

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1443119967-165391598

Phone
+98 21 8877 0022

Email
hosp_arash@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University

Full name of responsible person
Dr. Farshad Hashemian

Street address
Islamic Azad University of Medical Sciences Tehran,Khaghani St.,Shariati St.,Tehran

City
Tehran

Province
Tehran

Postal code
1916893813

Phone
+98 21 2200 6660

Email
Iaumst.pr@gmail.com

Grant name

Grant code / Reference number

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

Title of funding source
Islamic Azad University

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
Islamic Azad University

Full name of responsible person
Mahdieh Sayad Safapour

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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No 16,Nasr 7 Street,Jahad Street,Shahid Mahalati Town,Artesh Autobahn,Tehran city

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Student

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Person responsible for updating data

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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
Lack of knowledge about sample satisfaction

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
After the data is not identifiable

When the data will become available and for how long
No timeline has been set yet

To whom data/document is available
Researchers

Under which criteria data/document could be used
In order to remove the restrictions

From where data/document is obtainable
mahd.safapor.6777@gmaill.com

What processes are involved for a request to access data/document
Available by email to researchers after reviewing the application if it is acceptable

Comments