

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 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

City

Tehran

Province

Tehran

Postal code

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

laumst.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

Street address

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

City

Tehran

Province

Tehran

Postal code

1955743557

Phone

+98 21 2244 7922

Fax

Email

mahd.safapor.6777@gmail.com

Person responsible for scientific 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

Street address

No 16,Nasr 7 Street,Jahad Street,Shahid Mahalati

Town,Artesh Autobahn,Tehran city
City
Tehran
Province
Tehran
Postal code
1955743557
Phone
+98 21 2244 7922
Fax
Email
mahd.safapor.6777@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Islamic Azad University
Full name of responsible person
Mahdieh Sayad Safapour
Position
Student
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Nursery
Street address
No 16,Nasr 7 Street,Jahad Street,Shahid Mahalati
Town,Artesh Autobahn,Tehran city
City
Tehran
Province
Tehran
Postal code
1955743557
Phone
+98 21 2244 7922

Fax
Email
mahd.safapor.6777@gmail.com

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@gmail.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