Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of problem solving skills on stress coping styles and emotional self-efficacy in mothers of premature infants

Protocol summary

Study aim
To determine the effect of problem solving skills on coping styles and emotional self-efficacy in preterm infants. Special purpose: 1- Determining the effect of problem solving skills on problem-focused coping styles in mothers of preterm infants; 2- Determining the effect of problem solving skills on emotion-focused stress coping styles in mothers of preterm infants; 3- Determine the effect of problem solving skills on emotional self-efficacy in mothers of preterm infants.

Design
A clinical trial, with control group and intervention, randomized based on time block, available method, 60 mothers hospitalized infants

Settings and conduct
The research units were randomly assigned to 4 teaching hospitals of Mashhad (Imam Reza-A-, Ghaem-Aj-, Umol-Banin-S- and Hashemi Nejad) in a randomized allocation method at least 48 hours after birth. Subjects were divided into 3 to 5 groups for 6 sessions of at least 60 minutes three times a week training in problem solving skills by the Dezurilla and Gold Fried method. 2 weeks later and one month after step 2 the tools will be filled.

Participants/Inclusion and exclusion criteria
Inclusion criteria: infant age less than 32 weeks; no maternal well-known chronic physical and mental illness; minimum level of maternal education at primary level; mother 18 years and over; no history of preterm birth in previous maternal deliveries; lack of any malformations congenital major in infant. Exclusion criteria: mother's withdrawal from continuing study, infant death, infant discharge before intervention, and absence of more than one session in intervention sessions.

Intervention groups
Control: receiving routine care. Intervention: in addition to routine care, they receive problem solving skills.

Main outcome variables
Coping styles of stress; emotional self-efficacy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191211045696N1**
Registration date: **2020-01-13, 1398/10/23**
Registration timing: **registered_while_recruiting**

Last update: **2020-01-13, 1398/10/23**
Update count: **0**

Registration date
2020-01-13, 1398/10/23

Registrant information

Name
Mahbobe Bagheri maraghe

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 58 3623 3706

Email address
bagherimm951@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-01-10, 1398/10/20

Expected recruitment end date
2020-06-09, 1399/03/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effect of problem solving skills on stress coping styles and emotional self-efficacy in mothers of premature infants

Public title
The effect of problem solving skills on stress coping styles and emotional self-efficacy
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Mothers with premature infants babies less than 32 weeks of gestation The mother has no known chronic physical or mental illness The minimum level of education for mothers is at the elementary level The mother is 18 years of age or older Lack of birth record of premature infan in previous maternity Lack of any congenital major malformations in the infants At least 48 hours have passed since the infant birth
Exclusion criteria:
Maternal withdrawal from continuing study Mother's absence is more than one session in intervention sessions The infant is discharged before the intervention is completed Death is the infants
Age
From **18 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Sample size will be divided into control and intervention groups by random allocation method (based on time blocks).
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 research of Mashhad School of Nursing and Midwifery
Street address
Four ways doctorate
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Approval date
2019-11-05, 1398/08/14
Ethics committee reference number
IR.MUMS.NURSE.REC.1398.068

Health conditions studied

1

Description of health condition studied
Stress Coping Styles
ICD-10 code
ICD-10 code description

2

Description of health condition studied
Emotional self-efficacy
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Stress Coping Styles
Timepoint
Before - two weeks later - a month later
Method of measurement
Lazarus Coping Questionnaire

2

Description
Emotional self-efficacy
Timepoint
Before - two weeks later - a month later
Method of measurement
Emotional Self-efficacy Questionnaire-ESES

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In addition to routine care, they receive problem solving skills for 6 sessions at least 60 minutes 3 times a week using the Dezurilla & Gold Fried method in groups of 3-5 .
Category

Behavior

2

Description
Control group: receive only routine care. After completing the task, the control group will be trained on how to apply problem solving skills.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Qaem Hospital
Full name of responsible person
Dr. Monir Ramezani
Street address
Taqi Abad Square
City
Mashhad
Province
Razavi Khorasan
Postal code
13944-91388
Phone
+98 51 3841 2081
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+98 51 3841 3006
Email
ramezanimn@mums.ac.ir
Web page address

2

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Dr. Monir Ramezani
Street address
Four ways doctor
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Fax
+98 51 3841 3006
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Web page address

3

Recruitment center
Name of recruitment center
Amolbanin Hospital
Full name of responsible person
Dr. Monir Ramezani
Street address
Zarineh Intersection - Corner of Ayatollah Behjat 16
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Email
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Web page address

4

Recruitment center
Name of recruitment center
Hashemi Nejad Hospital
Full name of responsible person
Dr. Monir Ramezani
Street address
Mashhad-Talab-Aboureihan Boulevard-Shahid Hasheminejad Hospital
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Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr. Rabab Latif Nejad Roodsari
Street address
The first three floors south, University 15, University street, Imam Khomeini street
City
Shirvan
Province
North Khorasan
Postal code
9461987634
Phone

+98 58 3623 3706

Email

bagherimm951@mums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Mahboubeh Bagheri Maragheh

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

The first three floors south, University 15, University street, Imam Khomeini street

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Shirvan

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Postal code

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mahboubeh Bagheri Maragheh

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

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Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mahboubeh Bagheri Maragheh

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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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

At the end of the work and after publishing the article, with permission from the Mashhad School of Nursing and Midwifery and related professors, information will be

available in the Central Library of Mashhad School of Nursing and Midwifery.

When the data will become available and for how long

At the end of the work and after publishing the article, with permission from the Mashhad School of Nursing and Midwifery and related professors, information will be available in the Central Library of Mashhad School of Nursing and Midwifery.

To whom data/document is available

Scholars working in academic and scientific institutions and students

Under which criteria data/document could be used

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From where data/document is obtainable

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

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Comments