Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of empowerment program for mothers of infants with congenital heart disease on their resilience and neonatal growth criteria

Protocol summary

Study aim
The effect of empowerment program for mothers with infants with heart disorders on their resilience and neonatal

Design
non-randomized clinical trial with control group on 60 mothers with infants with heart disease It is not possible to randomly assign the intervention and control group due to the nature of the intervention, which is educational and in one place.

Settings and conduct
This study is a clinical trial and is performed individually for each mother. Sampling is done by available method among mothers and their infants admitted to the NICU ward of Imam Reza Hospital who meet the research criteria and are willing to participate in the study. Therefore, first the samples of the control group are included in the study .After receiving a written letter of introduction from the officials of the University of Medical Sciences, research unit selection form will be completed to check the inclusion criteria. The informed consent form is obtained. We will have a total of 60 samples in two groups (intervention group and control group). Then the designed intervention will be done within 9 days.

Participants/Inclusion and exclusion criteria
A baby with congenital heart disease Has not had heart surgery. No other chronic disease not under mechanical ventilation. Term or near term (above 35 weeks) Direct care of the baby by the mother

Intervention groups
The intervention includes a mothers empowerment program in infant care as well as emotional empowerment in 4 one-hour sessions, performed every other day. In between sessions, the material taught is practically practiced by the mother under the supervision of the researcher. Their functional problems will be solved and their questions will be answered. In the control group, education is done to mothers orally and by giving educational pamphlets.

Main outcome variables
Mother resilience, Infant growth criteria (weight and head circumference)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200625047914N1**
Registration date: **2020-12-10, 1399/09/20**
Registration timing: **registered_while_recruiting**

Last update: **2020-12-10, 1399/09/20**
Update count: **0**

Registration date
2020-12-10, 1399/09/20

Registrant information

Name
rayehe joneidy

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 3840 3015

Email address
joneidir971@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-08-05, 1399/05/15

Expected recruitment end date
2021-08-06, 1400/05/15

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of empowerment program for mothers of infants with congenital heart disease on their resilience and neonatal growth criteria

Public title

The effect of empowerment program for mothers of infants with congenital heart disease on their resilience and neonatal growth criteria

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

infant with congenital heart disease Term or near term (above 35 weeks) Direct care of the baby by the mother

Exclusion criteria:

Has not heart surgery No other chronic disease No history of birth of a baby with heart disease in family Not bad state and not under mechanical ventilation. The mother does not have a known mental disorder or the mother is taking neuroleptics Not experiencing severe accidents (such as death of loved ones) in 6 months

Age

From **1 day** old to **10 days** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of mashhad univercity of Medical Sciences

Street address

Ebne sina Street

City

mashhad

Province

Razavi Khorasan

Postal code

93145856263

Approval date

2020-06-02, 1399/03/13

Ethics committee reference number

IR.MUMS.NURSE.REC.1399.024

Health conditions studied

1

Description of health condition studied

congential heart disease

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Resilience score in Conner-Davidson Resilience Questionnaire. In this questionnaire, the maximum score is 125 and the minimum score is zero, and the score of each subject is equal to the total score of each of the questions.

Timepoint

after the intervention and at one month of age

Method of measurement

For maternal resilience variable: Connor-Davidson resilience questionnaire

2

Description

infant growth criteria(weight and head circumference)

Timepoint

after the intervention and at one month of age

Method of measurement

Measure the infant's weight and head circumference

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the first meeting, an introduction will be made and explanations will be given about the study and the baby's illness . The next day, an emotional empowerment session will be held to teach coping techniques and stress management techniques. The third session will teach them about the impact of nutrition and nutrition on improving the condition of patients with congenital heart disease. .The fourth

session is about drugs and the importance of their correct and timely use, their side effects and how to control them.On the last day and the fifth session, will be explained to the mothers about the effect of the infection and its symptoms on the baby and how to control and prevent the infection and the necessary care in case of infection of the infant.The duration of the sessions will vary from 45 minutes to one hour and a day, depending on the mother's needs. The teaching method is in the form of lectures, practical demonstrations, questions and answers, showing educational videos through mobile phones and role-playing. During the sessions with the mothers, the given exercises will be reviewed and practiced more. And if needed, mothers' questions will be answered.

Category

Lifestyle

2

Description

Control group: In the control group, routine care is provided for nutrition and medication, and trainings are also given orally by the nurse or giving pamphlet to mothers.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital, Mashhad

Full name of responsible person

Dr. Naghmeh Razaghi

Street address

Ebne Sina Street

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joneidir971@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodim

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Grant name

Vice Chancellor for Research, Mashhad University of Medical Sciences

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

Dr Naghmeh Razaghi

Position

Assistant Professor - faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person
dr.razaghi
Position
proffessor
Latest degree
Ph.D.
Other areas of specialty/work
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Person responsible for updating data

Contact
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Other areas of specialty/work
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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
Part of the data, can be shared such as information about the main outcome, ie maternal resilience and infant growth criteria, .
When the data will become available and for how long
14 monthes
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
All requests are reviewed for access to data or documentation
From where data/document is obtainable
Refer to the researcher, Dr. Razaghi. Email: razaghin@mums.ac.ir
What processes are involved for a request to access data/document
Just send an email. Will be answered within 3 days.
Comments