

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 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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9314733333

Phone

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Email

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

Street address

Daneshgah Street

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Razavi Khorasan

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Email

tafaghodim@mums.ac.ir

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

Street address

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Email

razaghin@mums.ac.ir

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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Razaghin@mums.ac.ir

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**Person responsible for updating data****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

Street address

Ebne Sina Street

City

mashhad

Province

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Postal code