

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

The effect of a Mindfulness-Based Stress Reduction (MBSR) Program on Coping Behaviors, and Attachment of Mothers of Neonates with Congenital Diseases in the selected hospitals affiliated to Shahid Beheshti University of Medical Sciences. 2019.

Protocol summary

Study aim

General purpose Determining the effect of "Mindfulness-based stress reduction" program on "Coping Behaviors" and "Attachment" of mothers of infants with congenital disease in selected hospitals of Shahid Beheshti University of Medical Sciences.

Design

Clinical trial with control and intervention group, randomized, in parallel.

Settings and conduct

Referring to the Mofid and Mahdiah hospitals for four weeks once a week, then randomly selecting the control and intervention groups and then training the intervention period of 45-120 minutes.

Participants/Inclusion and exclusion criteria

Entry criteria: 1. The mother has the ability to read and write. 2. The mother has the ability to speak Persian. 3. Infant under one week of infantile congenital anemia that does not lead to a baby's death based on prediction and diagnosis. 4. The mother has no mental illness or anxiety disorders based on the documentation of the case. 5. The mother has no previous experience of having another child with congenital malformation, according to her mother's case and file documentation. Non-compliance criteria: 1. The probability of a baby's impending death is based on clinical evidence and medical documentation. 2. The mother does not want to participate in the research.

Intervention groups

Mothers with a newborn with congenital malformations in the intervention group receive interventions for reducing mental stress-related stress. The control group, which also includes the same mothers, does not receive the intervention.

Main outcome variables

Coping behaviors; attachment.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190123042471N1**

Registration date: **2019-08-29, 1398/06/07**

Registration timing: **retrospective**

Last update: **2019-08-29, 1398/06/07**

Update count: **0**

Registration date

2019-08-29, 1398/06/07

Registrant information

Name

Nahid Naseri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3552 7863

Email address

nahid.naseri93@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-13, 1397/12/22

Expected recruitment end date

2019-06-29, 1398/04/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	Secondary Ids empty
Scientific title The effect of a Mindfulness-Based Stress Reduction (MBSR) Program on Coping Behaviors, and Attachment of Mothers of Neonates with Congenital Diseases in the selected hospitals affiliated to Shahid Beheshti University of Medical Sciences. 2019.	Ethics committees 1 Ethics committee Name of ethics committee Ethics Committee, Faculty of Pharmacy, Nursing and Midwifery, Shahid Beheshti University of Medical Street address Faculty of Nursing and Midwifery, Shahid Beheshti University of Medical Sciences, Intersection of niyayesh ,Valiasr St. City Tehran Province Tehran Postal code 19857174443 Approval date 2018-12-31, 1397/10/10 Ethics committee reference number IR.SBMU.PHARMACY.REC.1397.198
Public title The effect of a Mindfulness-Based Stress Reduction (MBSR) Program on Coping Behaviors, and Attachment of Mothers of Neonates with Congenital Diseases in the selected hospitals affiliated to Shahid Beheshti University of Medical Sciences. 2018.	Health conditions studied 1 Description of health condition studied Congenital disorders of the nervous system ICD-10 code Q05.0 ICD-10 code description Cervical spina bifida with hydrocephalus
Purpose Education/Guidance	2 Description of health condition studied Stress ICD-10 code F40 ICD-10 code description Phobic anxiety disorders
Inclusion/Exclusion criteria Inclusion criteria: The mother has reading and writing skills. The mother has ability to speak in Persian. Having a Neonates under one week of congenital diseases that does not lead to a baby's death based on prediction and diagnosis. The mother has no mental illness or anxiety disorders based on the documentation of the baby case. The mother has no previous experience of having another child with congenital malformations, according to her mother's, and documentation of the case. Mother has no education in psychology and medical sciences. Be a biological mother. The mother is not afflicted with sensory disorders such as deafness, blindness and Mother has the desire and ability to attend a meeting. Access to mobile phones and familiarity with Telegram software. Exclusion criteria: Mother's reluctance to participate in research. Likely death of the baby according to clinical evidence and medical documentation.	3 Description of health condition studied Congenital malformations of the digestive system ICD-10 code Q39.0 ICD-10 code description Atresia of esophagus without fistula
Age No age limit	4 Description of health condition studied Cleft lip and palate cleft ICD-10 code Q35.5 ICD-10 code description
Gender Female	
Phase N/A	
Groups that have been masked No information	
Sample size Target sample size: 32	
Randomization (investigator's opinion) Randomized	
Randomization description Use Random Number Tables	
Blinding (investigator's opinion) Not blinded	
Blinding description	
Placebo Not used	
Assignment Parallel	
Other design features	

Cleft hard palate with cleft soft palate

5

Description of health condition studied

Congenital malformations of the liver, gall bladder and bile ducts

ICD-10 code

Q44.2

ICD-10 code description

Atresia of bile ducts

Primary outcomes

1

Description

Mother's coping behaviors

Timepoint

Measuring maternal coping behaviors before and after intervention (before the first session of mindfulness-based stress reduction program) and after intervention (four weeks after intervention, after four sessions of mindfulness-based stress reduction program face to face weekly).

Method of measurement

The McCobin Coping Health Inventory for Parents (CHIP) tool for measuring compatibility behaviors.

2

Description

maternal attachment to the infant

Timepoint

Measurement of maternal attachment to infant before and after intervention (before the first session of mindfulness-based stress reduction program) and after intervention (four weeks after intervention, after four sessions of mindfulness-based stress reduction program face to face weekly).

Method of measurement

The maternal attachment questionnaire for Candundas and Corkindal is used to measure attachment.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The purpose of the intervention in this study is to conduct four sessions with maternal mindfulness-focused mental retardation content. The content of the sessions, respectively, includes the first session, referring, expressing feelings and thoughts, body scanning meditation, the second session including body scan exercises, three-minute breathing, the third session involves repeating the previous sessions and performing yoga movements. Finally, the fourth session

will review the exercises and complete the questionnaires. Meetings will be held once a week and will last for 45-120 minutes.

Category

Behavior

2

Description

Control group: In the control group, mothers will not participate in mindfulness-related stress reduction sessions and will only complete the Health Alert Scale for parents and the attachment questionnaire for Candida and Corkindal's mother and infant.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Mahdieh hospital

Full name of responsible person

Nahid Naseri

Street address

Shahid Rajabnia Street, Shisheh gar khaneh alley, Fadaian Islam St, Shosh Square

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2

Recruitment center

Name of recruitment center

Mofid hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mahrokh Dolatian
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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Bachelor
Other areas of specialty/work
Nursery
Street address
Shahid Beheshti Nursing Midwifery Faculty,
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Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Nahid Naseri
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Master's student of Neonatal Intensive Care
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Bachelor
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Person responsible for updating data

Contact

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to

make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Information about the questionnaire and only part of the main outcome information.

When the data will become available and for how long

Six months

To whom data/document is available

Nurses and nursing students

Under which criteria data/document could be used

Use in research related to knowledge of research subject.

From where data/document is obtainable

nahid.naseri93@gmail.com Nahid Naseri

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

Ten days after receipt of the email, the data will be available.

Comments