Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Investigating the effectiveness of mindfulness counseling on mother - newborn attachment and The stress of at risk newborn parent under the care ACORN program

Protocol summary

Study aim
Evaluation of the effectiveness of mindfulness counseling on maternal and infant attachment and High-risk infants parental stress in care under the ACORN program

Design
The clinical trial has a control group, with parallel groups, randomized with online software by a statistical consultant, the sample size is 50 parents (100 people).

Settings and conduct
A parallel randomized controlled trial study was performed in 2021 on 50 parents (both parents) with infants admitted to the neonatal intensive care unit of Mobini Hospital in Sabzevar. . Due to the nature of the interventions, it is not possible to blind parents.

Participants/Inclusion and exclusion criteria
Admission requirements: 1.Having an unhealthy or at-risk baby under ACORN care. 2.Be literate. 3.No history of illness or mental disorders or taking psychiatric medication. 4.Predicting more than 2 weeks of hospitalization in the neonatal intensive care unit. 5.Meet the baby at least once a day. 6.Getting a score higher than 34 from the Parent Stress Scale Questionnaire in the Neonatal Intensive Care Unit. 7.Possibility and ability of the participants to use the Online meetings(if the corona conditions are continuous and it is not possible to hold the meetings in person). Conditions for not entering the study: 1.Parents who have experienced stressful life events over the past year. 2.Parents who received out-of-study counseling services. 3.It is not possible for the parents to see the baby

Intervention groups
The intervention group receives mindfulness-based counseling in 3 sessions of 60 minutes a week every other day, and the control group receives only one session of infant massage training.

Main outcome variables
Maternal and infant attachment, parental stress

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201208049647N1**
Registration date: **2020-12-14, 1399/09/24**
Registration timing: **prospective**

Last update: **2020-12-14, 1399/09/24**
Update count: **0**

Registration date
2020-12-14, 1399/09/24

Registrant information

Name
Masomeh Nodeh

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 4537 5025

Email address
nodeh@shmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-12-21, 1399/10/01

Expected recruitment end date
2021-05-22, 1400/03/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effectiveness of mindfulness counseling on mother - newborn attachment and The stress of at risk newborn parent under the care ACORN program

Public title
Investigating the effectiveness of mindfulness counseling on mother - newborn attachment and The Parental stress
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Having an unhealthy or at-risk baby under ACORN care Be literate No history of illness or mental disorders or taking psychiatric medication Predicting more than 2 weeks of hospitalization in the neonatal intensive care unit Meet the baby at least once a day Getting a score higher than 34 from the Parent Stress Assessment Questionnaire in the Neonatal Intensive Care Unit Possibility and ability of the participants to use the Online meetings(if the corona conditions are continuous and it is not possible to hold the meetings in person)
Exclusion criteria:
Parents who have experienced stressful life events over the past year Parents who received out-of-study counseling services It is not possible for the parents to see the baby
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Creating a random sequence is done by online software using 4 blocks and according to the number of samples 50 and the number of blocks (13) by the esteemed consultant of statistics. A table of 52 of sequences A and B is prepared and the closed envelope method is used to hide the allocation. In this method, based on the specified sequence, 13 blocks (each block contains 4 envelopes containing the letter (A (case) or B (control)) are prepared according to the random sequence table and in the order that the researcher is not aware of, Will be provided to the researcher. After selecting the eligible individuals and obtaining informed consent, the researcher will open the door of the envelope corresponding to the participating parents and assign the parents to the intervention or control group based on the type of group registered in it. Therefore, researchers do not know the order of random allocation.
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 Shahrood University of Medical Sciences
Street address
Corner of Shahid Bahonar Street, No. 738
City
Neghab
Province
Razavi Khorasan
Postal code
9647135448
Approval date
2020-12-01, 1399/09/11
Ethics committee reference number
IR.SHMU.REC.1399.124

Health conditions studied

1

Description of health condition studied
Mother and baby attachment
ICD-10 code
ICD-10 code description

2

Description of health condition studied
Parental stress
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Mother and baby attachment
Timepoint
Measuring the average score of mother and infant attachment in 3 times: Before the intervention, in the last session (7 days after the intervention) and 14 days after the intervention
Method of measurement
Checklist of Avant attachment behaviors

2

Description

Parental stress

Timepoint

Measuring the average score of Parental stress in 3 times: before the intervention, in the last session (7 days after the intervention) and 14 days after the intervention

Method of measurement

Parental stress scale In the neonatal intensive care unit questionnaire

Secondary outcomes

1

Description

Duration of the baby's hospitalization

Timepoint

One month after the start of the intervention

Method of measurement

Number of days of hospitalization of the infant recorded in the hospital file

Intervention groups

1

Description

Intervention group: The intervention group receives mindfulness-based counseling in 3 sessions of 60 minutes a week every other day. These sessions include: Session 1: Familiarity with the basics and foundations of mindfulness, Session 2: Attitudes that nurture mindfulness, Session 3: Mindfulness versus lack of mindfulness and conscious listening.

Category

Other

2

Description

Control group: The control group receives only one session of infant massage training on the first day of the intervention.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Sabzevar Mobini Hospital

Full name of responsible person

Masomeh Nodeh

Street address

No.12, North Kashfi Street, Mobini Hospital

City

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9648177444

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Email

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Masomeh Nodeh

Street address

Shahroud, 7th of Tir Square, Shahroud University of Medical Sciences and Health Services

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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

Shahroud 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

Shahroud University of Medical Sciences

Full name of responsible person

Masomeh Nodeh

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available