

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 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

Sabzevar

##### Province

Razavi Khorasan

##### Postal code

9648177444

#### Phone

+98 51 4401 1000

#### Email

info@medsab.ac.ir

#### Web page address

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahrood University of Medical Sciences

##### Full name of responsible person

Masomeh Nodeh

##### Street address

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

##### City

Shahrood

##### Province

Semnan

##### Postal code

۳۶۱۴۷۷۳۹۴۷

##### Phone

+98 23 3239 5054

##### Fax

+98 23 3239 5009

##### Email

info@shmu.ac.ir

##### Web page address

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Shahrood 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

Shahrood University of Medical Sciences

##### Full name of responsible person

Masomeh Nodeh

##### Position

Masters student

##### Latest degree

Bachelor

##### Other areas of specialty/work

Midwifery

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nodes1368@gmail.com

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## Person responsible for scientific 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**

Midwifery

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## Person responsible for updating data

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**Latest degree**

Bachelor

**Other areas of specialty/work**

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**Web page address**

## 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