# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## Investigating the Impact of Palliative Care on the Coping of Mothers with Hospitalized Neonates in the NICU

### Protocol summary


**Study aim**

To evaluate the effect of palliative care on the adaptation of mothers with neonates admitted to the NICU.

**Design**

This randomized clinical trial includes two groups (intervention and control), with 48 participants per group using simple random sampling. The study is single-blind (participants). Data will be collected at three time points and analyzed statistically.

**Settings and conduct**

This randomized clinical trial will be conducted in the NICUs of Shahid Sadoughi and Afshar hospitals in Yazd. Mothers will be randomly assigned to intervention (spiritual care) and control (routine care) groups. Data will be collected before and after the intervention. Randomization will be done using sealed envelopes, and only participants will be blinded.

**Participants/Inclusion and exclusion criteria**

Inclusion criteria: 1.Having a hospitalized neonate with complex medical conditions 2.Willingness and informed consent to participate in the study 3.Possession of Iranian nationality 4.Minimum literacy in reading and writing Exclusion criteria: 1.History of limiting physical illness in the mother (such as physical disabilities, mobility impairments, malignancies, or chronic/terminal diseases) 2.Documented history of psychiatric disorders in the mother 3.Previous experience of preterm birth or having a newborn admitted to the neonatal intensive care unit (NICU)

**Intervention groups**

The intervention group consists of mothers receiving palliative care focused on spiritual care, including five 45-minute group sessions with meditation, relaxation, and coping skills training. The control group receives routine NICU care. Data are collected before and after the intervention in both groups.

**Main outcome variables**

Improved maternal psychological adaptation; reduced stress and anxiety due to neonatal hospitalization; enhanced maternal coping skills; strengthened mother-infant bonding.


### General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20250416065351N1**
Registration date: **2025-06-01, 1404/03/11**
Registration timing: **prospective**

Last update: **2025-06-01, 1404/03/11**
Update count: **0**

**Registration date**

2025-06-01, 1404/03/11

**Registrant information**


**Name**

Shima Daftari raeeni

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 35 3824 1751

**Email address**

shimadaftari@gmail.com


**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2025-06-22, 1404/04/01

**Expected recruitment end date**

2025-09-23, 1404/07/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**
empty

**Scientific title**
Investigating the Impact of Palliative Care on the Coping of Mothers with Hospitalized Neonates in the NICU

**Public title**
Investigating the Impact of Palliative Care on the Coping of Mothers with Hospitalized Neonates in the NICU

**Purpose**
Supportive

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Having a hospitalized neonate with complex medical conditions. Willingness and informed consent to participate in the study. Possession of Iranian nationality. Minimum literacy in reading and writing.

**Exclusion criteria:**
History of limiting physical illness in the mother (such as physical disabilities, mobility impairments, malignancies, or chronic/terminal diseases). Documented history of psychiatric disorders in the mother. Previous experience of preterm birth or having a newborn admitted to the neonatal intensive care unit (NICU).

**Age**
No age limit

**Gender**
Both

**Phase**
3

**Groups that have been masked**

- Participant

**Sample size**
Target sample size: **88**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
Eligible participants will be randomly assigned into two groups using a simple randomization method based on a list generated by PASS 2023 software. To ensure allocation concealment, participant numbers will be placed inside sealed envelopes. As eligible participants are enrolled, they will receive envelopes in order, which will then be provided to the researcher for intervention assignment.

**Blinding (investigator's opinion)**
Single blinded

**Blinding description**
This study is conducted as a single-blind trial in which the participants (mothers) are unaware of the type of intervention they receive (intervention or control group). Random allocation is performed using a list generated by PASS 2023 software and a simple randomization method. To ensure allocation concealment, group assignment codes are placed in opaque, sealed envelopes. Upon enrollment, each participant receives one envelope in sequential order and is assigned to a group accordingly. The researcher is aware of the group allocation, but the participants remain blinded throughout the study.

**Placebo**
Not used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Ethics Committee of Shahid Sadoughi University of Medical Sciences, Yazd

**Street address**
Central Administration, Shahid Dr. Bahonar Square, Shahid Sadoughi University of Medical Sciences, Yazd, Iran

**City**
Yazd

**Province**
Yazd

**Postal code**
۸۹۱۶۹۷۸۴۷۷

**Approval date**
2025-05-13, 1404/02/23

**Ethics committee reference number**
IR.SSU.REC.1404.023

## Health conditions studied

### 1

**Description of health condition studied**
Psychological Adaptation of Mothers with Infants Admitted to the Neonatal Intensive Care Unit (NICU)

**ICD-10 code**

**ICD-10 code description**

## Primary outcomes

### 1

**Description**
Psychological adjustment of mothers with neonates admitted to NICU, assessed using the Carver’s Coping Skills Questionnaire.

**Timepoint**
The primary outcome is measured at three time points: before the intervention, immediately after the completion of the intervention sessions, and three weeks post-intervention.

**Method of measurement**
Psychological adaptation is measured using the 40-item Carver Coping Strategies Questionnaire.

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group: Mothers in this group will receive a structured palliative care program with a spiritual care focus. The intervention includes five 45-minute group sessions providing meditation, progressive muscle relaxation, spiritual support, coping skills training, and enhancement of mother-infant bonding. The sessions are delivered by the researcher in the hospital setting.
**Category**
Behavior

### 2

**Description**
Control group: Mothers in this group will receive only the routine neonatal intensive care unit services provided by the hospital, with no additional intervention from the researcher.
**Category**
Behavior

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Shahid Sadoughi Hospital
**Full name of responsible person**
Khadijeh Dehghani
**Street address**
Shahid Sadoughi Hospital, Ebne Sina Street, Shahid Ghandi Boulevard, Safaieh, Yazd, Iran
**City**
Yazd
**Province**
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**Postal code**
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**Phone**
+98 35 3822 4000
**Email**
sadoghi-hospital@ssu.ac.ir

### 2

**Recruitment center**
**Name of recruitment center**
Mohammad Sadegh Afshar Hospital
**Full name of responsible person**
Khadijeh Dehghani
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Mohammad Sadegh Afshar Hospital, Jomhouri Eslami Boulevard, Yazd, Iran
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**Postal code**
۸۹۱۷۹۴۵۶۸۷
**Phone**
+98 35 3525 5011
**Email**
afsharhospital@ssu.ac.ir

## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Yazd University of Medical Sciences
**Full name of responsible person**
Mr. Houshang Mehrparvar
**Street address**
Imam Hossein Square, Beginning of Daneshjoo Boulevard, Emam Reza Complex, Deputy of Research and Technology, Yazd University of Medical Sciences, Yazd, Iran
**City**
Yazd
**Province**
Yazd
**Postal code**
۸۹۱۶۱۸۸۶۳۷
**Phone**
+98 35 3628 8114
**Email**
dvc.research@ssu.ac.ir
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Yazd 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**
Yazd University of Medical Sciences
**Full name of responsible person**
Khadijeh Dehghani
**Position**
Instructor
**Latest degree**
Master
**Other areas of specialty/work**

Pediatrics

**Street address**
School of Nursing and Midwifery, Bouali Street, Timsar Fallahi Street, Yazd, Iran

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**Province**
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## Person responsible for scientific inquiries

**Contact**

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**Position**
Instructor

**Latest degree**
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**Other areas of specialty/work**
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## Person responsible for updating data

**Contact**

**Name of organization / entity**
Yazd University of Medical Sciences

**Full name of responsible person**
Khadijeh Dehghani

**Position**
Instructor

**Latest degree**
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**Other areas of specialty/work**
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shadehghani@gmail.com

## 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**
Not applicable

**Data Dictionary**
Not applicable

**Title and more details about the data/document**
Individual participant data will be shared in SPSS format after removing all identifiable personal information. The dataset will include all variables used in the study, enabling researchers to reanalyze and utilize the data. Data sharing will occur after the study has been fully completed.

**When the data will become available and for how long**
Access to the de-identified dataset will be available starting six months after the publication of the final study results and will remain accessible for three years thereafter.

**To whom data/document is available**
The data and study documents will only be available to researchers and academic staff affiliated with medical universities and research centers. Requests from other individuals or organizations will be subject to review and approval by the ethics committee and research team.

**Under which criteria data/document could be used**
In addition to the aforementioned conditions, applicants must submit a written statement of their research objectives and commit to using the data solely for research purposes. Any commercial use, publication, or sharing without written permission is prohibited. Applicants are also required to maintain data confidentiality and adhere to research ethics. Data usage is limited to analyses related to the study topic, and any use beyond this requires further approval from the research team.

**From where data/document is obtainable**
Primary Contact: Ms. Khadijeh Dehghani Faculty member, School of Nursing and Midwifery, Shahid Sadoughi University of Medical Sciences, Yazd Email: shadehghani@gmail.com Mobile: +98 913 153 5531 Secondary Contact: Ms. Shima Daftari Raeini Faculty member, School of Nursing and Midwifery, Shahid Sadoughi University of Medical Sciences, Yazd Email:

shimadaftari@gmail.com Mobile: +98 938 612 1416 Postal Address: Yazd, Timsar Fallahi Street, Bu-Ali Street, School of Nursing and Midwifery, Shahid Sadoughi University of Medical Sciences, Yazd

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

After submitting a written request to one of the designated contacts, the request will be reviewed and approved. Upon approval, the process of preparing and delivering the data or documents will begin. Typically, this process takes between 2 to 4 weeks, depending on the volume of the request and the preparation needed. If additional information or final confirmation is required, the contact person will communicate with the applicant.

**Comments**