

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The Impact of Spiritual Care on Depression of Mothers of Premature Infant in Neonatal Intensive Care Unit

#### Protocol summary

##### Study aim

Comparing the depression of mothers before and after the implementation of the spiritual care program for the mothers

##### Design

66 mothers of premature infants who were enrolled in the intensive care unit were selected and non-random divided into intervention and control groups.

##### Settings and conduct

The researcher referred to Ommlbanin Hospital during the 9 to 15 hours of sampling. After selecting mothers, explanations about the research and the research goals are given to each mother in the neonatal intensive care unit in accordance with the need and knowledge level of the mother in face-to-face form. If you would like to participate in the study, the questionnaires will be completed. At the time of discharge, the questionnaires will be completed

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: mothers of premature infants hospitalized; at the start of the study, at least one day and a maximum of one week from the time the infant is admitted; do not use drugs (or any psychoactive substances such as cigarettes, opium). Exclusion criteria: participate in spiritual care classes; have a history of mental illness according to family; more than one week after admission of the infant.

##### Intervention groups

In the intervention group, according to the needs assessment, the spiritual care included: protectionist presence (the presence of a researcher alongside mothers, verbal and non verbal communication, active listening and answering the questions of mothers), support for religious ceremonies Family (Providing the necessary facilities for worship such as Mehr and Sajjad), the use of supportive systems (spiritual presence and counseling, the presence of family along with the baby when Taking remedial measures and establishing the possibility of a farewell to the infant), will be presented.

In the control group, the usual treatment will be implemented.

##### Main outcome variables

Depression

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20171014036764N2**

Registration date: **2018-04-14, 1397/01/25**

Registration timing: **retrospective**

Last update: **2018-04-14, 1397/01/25**

Update count: **0**

##### Registration date

2018-04-14, 1397/01/25

##### Registrant information

##### Name

seyed maryam mousavi

##### Name of organization / entity

Isfahan Islamic Azad University

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3535 4001

##### Email address

smmousavi@khuisf.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-03-21, 1396/01/01

##### Expected recruitment end date

2017-11-22, 1396/09/01

##### Actual recruitment start date

2017-03-21, 1396/01/01  
**Actual recruitment end date**  
2017-11-21, 1396/08/30  
**Trial completion date**  
empty

**Scientific title**  
The Impact of Spiritual Care on Depression of Mothers of Premature Infant in Neonatal Intensive Care Unit

**Public title**  
The Impact of Spiritual Care on Depression of Mothers of Premature Infant

**Purpose**  
Supportive

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
To be satisfied with the study Mothers of premature infants hospitalized At the start of the study, at least one day and a maximum of one week from the time the infant is admitted Do not use drugs (or any psychoactive substances such as cigarettes, opium, glass, hashish, heroin, cocaine)  
**Exclusion criteria:**  
Participate in spiritual care classes Have a history of mental illness According to family More than one week after admission of the infant

**Age**  
No age limit

**Gender**  
Female

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **66**  
Actual sample size reached: **66**

**Randomization (investigator's opinion)**  
Not randomized

**Randomization description**

**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**  
Music Therapy and Beautification unit

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee Islamic Azad University, Najaf Abad

Branch  
**Street address**  
Blvd daneshgah, Najaf Abad, Islamic Azad University, Najaf Abad Branch  
**City**  
Isfahan  
**Province**  
Isfahan  
**Postal code**  
۸۵۱۴۱۳۱۳۱  
**Approval date**  
2017-05-04, 1396/02/14  
**Ethics committee reference number**  
IR.AU.NAJAFABAD.REC.1396.21

## Health conditions studied

### 1

#### Description of health condition studied

Depression

#### ICD-10 code

F32.8

#### ICD-10 code description

Other depressive episodes

## Primary outcomes

### 1

#### Description

Depression

#### Timepoint

Admit/ Discharge time

#### Method of measurement

Beck Depression Questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: According to the needs assessment and interview with the mothers, audiobooks, educational books, and worship objects will be placed in a dressing room designed for relaxation and, in accordance with the mother's request, the materials provided by the researcher through the telegram, CD, Flash and mobile transfer will be provided to the mother. The posters for space maternity and maternity rooms will be provided. The 9 spiritual actions proposed in this study included: Spiritual Action 1: Facilitate spiritual care including prayer ceremony and facilitate the organization of religious ceremonies appropriate to the culture and the family. Spiritual Action 2: Spiritual protection involves providing worship objects and encouraging participation in ceremonies. Spiritual Action 3: Presence includes physical presence and availability. Spiritual Action 4:

Active listening involves listening without judgments to mothers' speeches, providing memos to moms for writing and expressing their concerns and religious care. Spiritual Action 5: Goodness and goodwill, including familiarizing the staff with spiritual care and how to deal with mothers. Spiritual Action 6: Touch involves hugging mother and baby with the parent's permission and facilitating and encouraging the presence of the father alongside the mother and helping to establish Correct relationship with the baby. Spiritual Action 7: Increasing self-awareness involves increasing knowledge about how to care for the baby with CDs and educational books and raising awareness about the course of the baby's disease. Spiritual Action 8: Voice Therapy featuring indifferent music and religious sound therapy. Spiritual Action 9: Instilling hope, including the beauty of the section and placing the contents of the hope and tranquility of the room of the mothers based on the requirements of the needs assessment. The intervention group of your choice and as required in the need assessment stage, one or more cases They will receive the mentioned spiritual care in their approved forms.

**Category**

Other

**2**

**Description**

Control group: The mothers of the control group did not receive any intervention, and at the beginning they would complete the questionnaire of spiritual well being and demographic anxiety. At the time of discharge, they will complete the Beck Spiritual Intelligence and Beck Anxiety Inventory.

**Category**

N/A

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

OmmIbanin Hospital

**Full name of responsible person**

Seyed Maryam Mousavi

**Street address**

No. 16 Ayatollah Behjat, Ayatollah Behjat Ave.,  
OmmIbanin Hospital

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m.mosavi1375@yahoo.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Narges Sadeghi

**Street address**

Islamic Azad University, Khorasgan Branch, University Blvd, Arqavanieh, Jey Street

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n45sadeghi@yahoo.com

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Islamic Azad University

**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**

Islamic Azad University

**Full name of responsible person**

Seyed Maryam Mousavi

**Position**

Master of Pediatric Nursing

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Narges Sadeghi

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

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## Person responsible for updating data

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**Latest degree**

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## 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**

No - There is not 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**

Results of the data and method are published in the article

**When the data will become available and for how long**

Start the access period 3 months after printing the results

**To whom data/document is available**

All people who make a request

**Under which criteria data/document could be used**

Use in scientific research is allowed.

**From where data/document is obtainable**

Seyed Maryam Mousavi smmousavi@khuisf.ac.ir  
00989158529689

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

The person requesting the application should send e-mail. Reply will be provided within 2 weeks.

**Comments**