

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Aug 2026

### The Effect Spiritual Care on Hope and Self-Transcendence of Mothers of Premature infants hospitalized in NICU

#### Protocol summary

##### Study aim

Determination The Effect Spiritual Care on Hope and Self-Transcendence of Mothers of Premature infants

##### Design

The study group is consisted of mothers with preterm infants in intensive care units. Mothers are non randomly selected. This study will be done on 30 mothers. A quasi-experimental clinical trial performed on mothers. The study has only one group.

##### Settings and conduct

The research environment of this study is Shohadaye-Bonab Hospital and Shahid Beheshti Hospital, Maragheh, Iran. One group is selected non-randomly, and the mothers will be trained to give spiritual care, as an intervention. The assessments would be done before, right after the test, and three weeks after the test.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Mothers with premature neonates (28 to 34 weeks of gestational age); Being Iranian and Muslim; Residing in Tabriz city; being literate (having at least reading and writing skills). Non-inclusion criteria: Mothers with depression and other psychological disorders; History of using antidepressants or narcotics; A history of previous preterm infant hospitalization in the NICU; Having other illnesses other than prematurity

##### Intervention groups

Intervention and spiritual care training, four sessions, duration of each session, 45 minutes, the first session including referring, expressing goals and giving a pre-test questionnaire; the second session, identifying the spiritual needs; the third session, identifying the spiritual distress; the fourth session, in line with respect for The spiritual situation, the direction of the patient's beliefs and the encouragement and assistance of religious activities, including the expression of hopeful talk, morale and sympathy, the assessment of the effect of spiritual care and the closing of the sessions, and giving the mothers a post-test questionnaire .

##### Main outcome variables

Hope; Self-Transcendence

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20181117041679N1**

Registration date: **2019-01-13, 1397/10/23**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-01-13, 1397/10/23**

Update count: **0**

##### Registration date

2019-01-13, 1397/10/23

##### Registrant information

##### Name

Mahnaz Afaghi Roveshty

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3776 1238

##### Email address

mafagh1358@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-12-22, 1397/10/01

##### Expected recruitment end date

2019-03-21, 1398/01/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

**Scientific title**  
The Effect Spiritual Care on Hope and Self-Transcendence of Mothers of Premature infants hospitalized in NICU

**Public title**  
The Effect of Spiritual Care on Hope and Self-Transcendence

**Purpose**  
Supportive

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Mothers with premature neonates (28 to 34 weeks of gestational age). Being Iranian and Muslim Residing in Tabriz city being literate (having at least reading and writing skills)  
**Exclusion criteria:**  
Mothers with depression and other psychological disorders History of using antidepressants or narcotics A history of previous preterm infant hospitalization in the NICU Having other illnesses other than prematurity

**Age**  
From **18 years** old to **45 years** old

**Gender**  
Female

**Phase**  
N/A

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

**Sample size**  
Target sample size: **30**

**Randomization (investigator's opinion)**  
N/A

**Randomization description**

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

**Blinding description**

**Placebo**  
Not used

**Assignment**  
Single

**Other design features**  
Descriptive indexes are used to describe the data. For data analysis, statistical methods including descriptive statistics and t test and variance analysis of repeated measures are used.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

##### Street address

Valieaser Street, Niayesh Station, Nursing And Medical Faculty, Shahid Beheshti Medical University.  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1985717443  
**Approval date**  
2018-11-13, 1397/08/22  
**Ethics committee reference number**  
IR.SBMU.PHARMACY.REC.1397.153

## Health conditions studied

### 1

#### Description of health condition studied

Spiritual Care

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

The score of penjvini hope scale for mothers with preterm infants

#### Timepoint

The measurement of hope will be done at the beginning of the study (before the beginning of the study), and then after implementing the intervention during 6 sessions, and trainings will be done at the end of the intervention.

#### Method of measurement

Penjvini et al's hope scale for mothers with preterm infants

### 2

#### Description

Self-Transcendence score in the Reed questionnaire

#### Timepoint

At the beginning of the study (before the beginning of the study), and then after implementing the intervention

#### Method of measurement

"The Effect Spiritual Care on Self-Transcendence of Mothers of Premature" How to evaluate Reed's self-transcendence scale, which is translated and validated by Dr Farahani Shirin Abadi in 2016

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: In this study, only the effect of

variable on one group of intervention group is considered. It is a quasi-experimental clinical trial. First, before the intervention, the test will be performed, then in the intervention group, spiritual care will be performed. Face-to-face and individual intervention involves four sessions, three sessions a week in the intensive care unit. The duration of each session is 45 minutes and the sessions are as follows: first session, referrals and acquaintance with mothers, expressing goals and giving a questionnaire to mothers, second session, conducting spiritual examination and identifying the spiritual needs of mothers, meeting 3, identifying spiritual distress Mothers, fourth session, in order to respect the moral status of mothers, to guide the patient's beliefs and encourage and assist in religious activities, express hopeful speeches, morale and comfort to mothers. Examining the impact of spiritual care and closing sessions And giving the mothers a questionnaire. Questionnaires will be completed at the first session before the intervention, the sixth session at the end of the intervention and 3 weeks after the last intervention session.

**Category**  
N/A

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Hospital Shohada

**Full name of responsible person**

Mahnaz Afagh Roveshty

**Street address**

Bonab town

**City**

Bonab

**Province**

East Azarbaijan

**Postal code**

55518-87184

**Phone**

+98 41 3774 4530

**Fax**

+98 41 3773 0990

**Email**

mahnaz@domain.ac.ir

**Web page address**

[https://fa.irct.ir/user/trial/35298/update/recruitment\\_enter](https://fa.irct.ir/user/trial/35298/update/recruitment_enter)

### 2

#### Recruitment center

**Name of recruitment center**

Shahid Beheshti hospital

**Full name of responsible person**

Mahnaz Afagh Roveshty

**Street address**

Shahid Ayatollah Sadoughi Street, Street 15 Khordad

**City**

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**Province**

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**Email**

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**Web page address**

[https://fa.irct.ir/user/trial/35298/update/recruitment\\_enter](https://fa.irct.ir/user/trial/35298/update/recruitment_enter)

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Hasan Esmaeili

**Street address**

Valieaser Street, Niayesh Station, Nursing And Medical Faculty, Shahid Beheshti Medical Univercity.

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mafagh1979@gmail.com

**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

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Mahnaz Afagh Roveshty

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

Niayesh intersection; Valieaser Street

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**Province**

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**Email**

mafagh1358@gmail.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Mahna Afaghi Roveshty

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

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**Web page address**

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Mahnaz Afaghi Roveshty

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

Niayesh intersection; Valieaser Street

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## Sharing plan

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

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

No more information.

**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**

No - There is not a plan to make this available