

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jun 2026

### The Effect of Spiritual Care Training on self - efficacy of Mothers of Premature Infants Hospitalized in Neonatal Intensive Care Unit

#### Protocol summary

##### Study aim

Determining the effect of spiritual care training on the self-efficacy of mothers of premature babies admitted to the neonatal intensive care unit

##### Design

Clinical trial with intervention and control group, single blind, randomized

##### Settings and conduct

The training of the intervention group was done in groups of six people. Demographic information was collected using a self-made questionnaire and the self-efficacy of mothers was also collected by the self-efficacy questionnaire of Cpanel mothers of premature babies by the researcher in both groups. It should be mentioned that the self-efficacy questionnaire was completed again in the control group three weeks after entering the study and in the test group three weeks after the intervention. The intervention was developed by a spiritual care specialist and a psychologist and was implemented by the researcher. This study was conducted on 30 people in the test group and 30 people in the control group in the neonatal intensive care unit at Shahid Sadouqi Hospital in Yazd. The mothers of the two groups did not know which group they were in.

##### Participants/Inclusion and exclusion criteria

Mothers of premature infants  
People who want to participate in the study  
Do not have a history of premature birth  
Have the ability to read and write  
Have Iranian citizenship  
Non-entry criteria: Physical manifestation of congenital disease in a newborn

##### Intervention groups

Based on the intervention designed in this research, the intervention was done face-to-face and the intervention was carried out by students in four 45-minute sessions between 15:00 and 17:00 every day.

##### Main outcome variables

spiritual care; self-Efficacy

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230130057276N1**

Registration date: **2023-04-02, 1402/01/13**

Registration timing: **retrospective**

Last update: **2023-04-02, 1402/01/13**

Update count: **0**

##### Registration date

2023-04-02, 1402/01/13

##### Registrant information

##### Name

Iran Sedighi khavidak

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 35 3624 7838

##### Email address

z.sedighi@stu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-05-09, 1401/02/19

##### Expected recruitment end date

2023-01-20, 1401/10/30

##### Actual recruitment start date

2022-05-09, 1401/02/19

##### Actual recruitment end date

2022-12-30, 1401/10/09

##### Trial completion date

2022-12-30, 1401/10/09

##### Scientific title

The Effect of Spiritual Care Training on self – efficacy of Mothers of Premature Infants Hospitalized in Neonatal Intensive Care Unit

#### Public title

"the Effect of Spiritual Care on The Self\_efficacy of Mothers of Premature Infants"

#### Purpose

Education/Guidance

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

People who want to participate in the study Do not have a history of premature birth Be literate in reading and writing Do not have a confirmed physical or mental problem The baby does not have any other abnormality that can be recognized and causes the mother to worry and despair Have Iranian citizenship

##### Exclusion criteria:

Physical manifestation of congenital disease in a newborn

#### Age

No age limit

#### Gender

Female

#### Phase

N/A

#### Groups that have been masked

- Participant

#### Sample size

Target sample size: **60**

Actual sample size reached: **60**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

First, using the random allocation plugin in Excel software, a table of random numbers from 1 to 60 is prepared in a non-sequential and scattered manner, and intervention and control is done by the number allocation software into two groups of 30 people.

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

After selecting the samples, none of the sampled people will know about randomization and the process of allocation to groups.

#### Placebo

Not used

#### Assignment

Other

#### Other design features

### Secondary Ids

empty

### Ethics committees

#### 1

##### Ethics committee

Name of ethics committee

Research Ethics Committee of Shahid Sadoughi University of Medical Sciences, Yazd

#### Street address

No. 117, Khatami Square, Khorramshahr St

#### City

Yazd

#### Province

Yazd

#### Postal code

8914934418

#### Approval date

2022-04-17, 1401/01/28

#### Ethics committee reference number

IR.SSU.REC.1401.004

### Health conditions studied

#### 1

##### Description of health condition studied

The Effect of Spiritual Care Training on self – efficacy of Mothers of Premature Infants Hospitalized in Neonatal Intensive Care Unit

#### ICD-10 code

#### ICD-10 code description

### Primary outcomes

#### 1

##### Description

Self-efficacy of mothers of premature infants

##### Timepoint

Before entering the study and three weeks after entering the intervention

##### Method of measurement

Self-efficacy questionnaire of mothers of preterm infants  
C-pennel

### Secondary outcomes

empty

### Intervention groups

#### 1

##### Description

Intervention group: Spiritual care training in four 45-minute sessions

##### Category

N/A

### Recruitment centers

#### 1

##### Recruitment center

Name of recruitment center

Shahid Sadoughi Hospital

Full name of responsible person

Zahra Sedighi khavidak  
**Street address**  
Safaiyah, Shahid Qandi Blvd. - Ibn Sina Blvd  
**City**  
Yazd  
**Province**  
Yazd  
**Postal code**  
8915887857  
**Phone**  
+98 35 3822 4000  
**Email**  
sadoghi-hospital@ssu.ac.ir  
**Web page address**

## Sponsors / Funding sources

### 1

#### Sponsor

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

**Full name of responsible person**  
Zahra Pourmovahed

**Street address**  
Yazd, Jihad Boulevard, 16th St: BUAli St:

**City**  
Yazd

**Province**  
Yazd

**Postal code**  
8916978477

**Phone**  
+98 35 3724 0171

**Email**  
movahed446@yahoo.com

**Web page address**

**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**

zahra sedighi khavidak  
**Position**  
Master of nursing student  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Nursery  
**Street address**  
Yazd, Khatami Square, Khorramshahr St., No. 117,  
Elginal Alley  
**City**  
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**Province**  
Yazd  
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**Phone**  
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sedighinurse99@gmail.com  
**Web page address**

## Person responsible for scientific inquiries

#### Contact

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

**Full name of responsible person**  
zahra sedighi khavidak

**Position**  
Mastre of nursing student

**Latest degree**  
Bachelor

**Other areas of specialty/work**  
Nursery

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**Email**  
sedighinurse99@gmail.com

## Person responsible for updating data

#### Contact

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

**Full name of responsible person**  
zahra sedighi khavidak

**Position**  
Master of nursing student

**Latest degree**  
Bachelor

**Other areas of specialty/work**

Nursery

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**Postal code**

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**Email**

sedighinurse99@gmail.com

**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