

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 2026

### The Comparison Effect of Narrative Writing and Art Therapy on Maternal Stress in Neonatal Intensive Care Settings

#### Protocol summary

##### Summary

This study is doing with purpose that to compare the efficacy of narrative writing and art therapy on maternal stress. Research is that kind of experimental design triple blind clinical trial. sampling is doing accidental (Random). The total volume of sample is , 54 mothers of premature infants hospitalized in neonatal intensive care units. This study is doing on mothers and the mothers accidental will Assigned to three groups of art therapy ,in the art therapy and narrative writing groups mothers of two groups in the second day of hospitalization(c) will complete the parental stress questionnaire. And they are doing at least three times drawing up in the sixth day of hospitalization (in the group art therapy) and narrative writing (in narrative writing group). and at last they will asked that complete the parenting stress questionnaire in the sixth day of hospitalization of their infants. But mothers of control group will complete the parenting stress questionnaire in the second day of hospitalization of their infants and then for these mothers are doing only routine interventions in the duration of hospitalization of their infants . and then they will be asked to complete the parenting stress questionnaire

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016020926478N1**

Registration date: **2016-04-03, 1395/01/15**

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

Last update:

Update count: **0**

##### Registration date

2016-04-03, 1395/01/15

##### Registrant information

##### Name

Negarín Akbari

##### Name of organization / entity

Shahroud University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 23 3239 5054

##### Email address

negarin@shmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research, Shahroud University of Medical Sciences

##### Expected recruitment start date

2016-04-03, 1395/01/15

##### Expected recruitment end date

2017-04-04, 1396/01/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The Comparison Effect of Narrative Writing and Art Therapy on Maternal Stress in Neonatal Intensive Care Settings

##### Public title

The Comparison Narrative Writing and Art Therapy on Maternal Stress

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

The inclusion criteria were: having an infant less than 38 gestational age with at least one day of hospitalization in NICU, Mothers who are literate, Mothers ' neonate with at

least six days hospitalization in the NICU, Mothers who do at least three times during the five-day narrative writing and art therapy , not having another child with the history of hospitalization in the NICU, not having sick children at home, not having a severe stressful problem in the last 2 months, not having a history of psychedelic and drug use ,being present in NICU at least three times a week. Mothers' exclusion criteria included: Narrative writing and art therapy less than three times a week, infant death, less than 6 days of infant's hospitalization and lack of interest in continue in the research .

**Age**

No age limit

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: 105

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Triple 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 Shahroud University of Medical Sciences

**Street address**

Hafte-Tir Sq, Shahroud, Iran

**City**

Shahroud

**Postal code****Approval date**

2010-09-23, 1389/07/01

**Ethics committee reference number**

SHMU.REC.1394.179

**Health conditions studied****1****Description of health condition studied**

Stress

**ICD-10 code**

F43.1

**ICD-10 code description**

F43.1

**Primary outcomes****1****Description**

Stress

**Timepoint**

2rd day, 6 th day

**Method of measurement**

Parental Stressor Scale

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group 1: In the art therapy group mothers will complete the parenting stress of mothers questionnaire in the second day of hospitalization of their infant. And they are drawing at least three times in the sixth day of hospitalization of their infants and at last they will asked that complete the parenting stress questionnaire in the sixth day of hospitalization of their infants

**Category**

Behavior

**2****Description**

Intervention group 2: In the narrative writing group mothers will complete the parenting stress of mothers questionnaire in the second day of hospitalization of their infant. And then they are writing at least three times in the sixth day of hospitalization of their infants and at last they will asked that complete the parenting stress questionnaire in the sixth day of hospitalization of their infants.

**Category**

Behavior

**3****Description**

Control group: Mothers of control group will complete the parenting stress questionnaire in the second day of hospitalization of infants and at last they will asked that complete the parenting stress questionnaire in the sixth day of hospitalization of their infants.

**Category**

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Emam hosein hospital

**Full name of responsible person**

Negarín Akbari

**Street address**

**City**

Shahroud

2

### Recruitment center

**Name of recruitment center**

Fatemie hospital

**Full name of responsible person**

Negarín Akbari

**Street address**

**City**

Shahroud

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Vice chancellor for research, Shahroud University of Medical Sciences

**Full name of responsible person**

Mohammad hasan Emamian

**Street address**

Shahroud University of Medical Sciences, Hafte-Tir Sq, Shahroud, Iran

**City**

Shahroud

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Vice chancellor for research, Shahroud University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Shahroud University of Medical Sciences

**Full name of responsible person**

Negarín Akbari

**Position**

Master of Nursing, Faculty member

**Other areas of specialty/work**

**Street address**

Hafte-Tir Sq, Shahroud, Iran

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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**Web page address**

*empty*

## **Sharing plan**

**Informed Consent Form**

*empty*

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

**Clinical Study Report**

*empty*

*empty*

**Study Protocol**

**Analytic Code**

*empty*

*empty*

**Statistical Analysis Plan**

**Data Dictionary**

*empty*