Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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Iran (Islamic Republic of)

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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 hospitalizedAt 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

Isfehan

Province

Isfehan

Postal code

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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
Ommlbanin Hospital

Full name of responsible person
Seyed Maryam Mousavi

Street address
No. 16 Ayatollah Behjat, Ayatollah Behjat Ave., Ommlbanin Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University

Full name of responsible person
Narges Sadeghi

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

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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

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Person responsible for updating data

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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