Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The Impact of Spiritual Care on anxiety and spiritual health of mothers of premature infant in Neonatal Intensive Care Unit

Protocol summary

Study aim

Comparing the Anxiety and Spiritual Health of mothers before and after the implementation of the spiritual care program for the mothers of newborn in neonatal intensive care unit

Design

In this research, 66 mothers of premature infants who were enrolled in the intensive care unit were selected and non-random divided into intervention and control groups, each assigned a code.

Settings and conduct

The researcher referred to the medical and therapeutic center of Ommlbanin Hospital during the 9 to 15 hours of sampling. After selecting mothers, the necessary 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, you will be informed in writing and the questionnaires will be completed. At the time of discharge, the questionnaires will be completed for both groups

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, 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.

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 and explaining the course of the disease of the infant), support for religious ceremonies Family (Providing the necessary facilities for worship such as Mehr and Sajjad, prayers and tents of prayer, Quran, Motifah, Quranic software and supplication), 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 and routine supportive system will be implemented.

Main outcome variables

Spiritual Health; Anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171014036764N1**
Registration date: **2017-12-28, 1396/10/07**
Registration timing: **retrospective**

Last update: **2017-12-28, 1396/10/07**
Update count: **0**

Registration date

2017-12-28, 1396/10/07

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
Deputy of Research of Isfahan Islamic Azad University (Khorasgan) branch

Expected recruitment start date
2017-03-21, 1396/01/01
Expected recruitment end date
2017-11-21, 1396/08/30
Actual recruitment start date
2017-03-21, 1396/01/01
Actual recruitment end date
2017-11-11, 1396/08/20
Trial completion date
empty

Scientific title
The Impact of Spiritual Care on anxiety and spiritual health of mothers of premature infant in Neonatal Intensive Care Unit

Public title
The Impact of Spiritual Care on anxiety and spiritual health of mothers of premature infants
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
Single
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
۸۵۱۴۱۴۳۱۳۱
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
Anxity
ICD-10 code
F41.1
ICD-10 code description
Anxiety that is generalized and persistent but not restricted to, or even strongly predominating in, any particular environmental circumstances

2

Description of health condition studied
Spiritual Health
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Anxiety Score in Beck's questionnaire
Timepoint
Admit/ Discharge time
Method of measurement
Beck Anxiety Questionnaire

2

Description
Spiritual health
Timepoint

Admit/ Discharge time

Method of measurement

Pulotzian and Ellison spiritual health 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

City

Mashhad

Province

Razavi Khorasan

Postal code

9144663595

Phone

+98 51 3223 1061

Fax

Email

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

City

Isfehan

Province

Isfehan

Postal code

8155139998

Phone

+98 31 3535 4001

Email

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
Bachelor
Other areas of specialty/work
Nursery
Street address
Islamic Azad University,Khorasgan Branch, University Blvd, Arqavanieh, Jey Street
City
Isfehan
Province
Isfehan
Postal code
9139898653
Phone
+98 512121001
Fax
Email
smmousavi@khuisf.ac.ir

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
Street address
Islamic Azad University, Khorasgan Branch, University Blvd, Arqavanieh, Jey Street
City
Isfehan
Province
Isfehan
Postal code
8155139998
Phone
+98 31 3535 4058
Fax
Email
n45sadeghi@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Seyed Maryam Mousavi
Position
Master of Pediatric Nursing
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
Islamic Azad University, Khorasgan Branch, University Blvd, Arqavanieh, Jey Street
City
Mashhad
Province
Razavi Khorasan
Postal code
9139898653
Phone
+98 51 3212 1001
Fax
Email
smmousavi@khuisf.ac.ir
Web page address

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