Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of spiritual self-care education on stress level and spiritual health of mothers of premature newborns hospitalized in the neonatal intensive care unit at Bushehr Persian Gulf Martyrs Hospital

Protocol summary

Study aim
Determining the Effect of Spiritual Self-Care Education on the Level of Stress and Spiritual Well-Being of Mothers with Premature Infants Admitted to the Neonatal Intensive Care Unit at Shahid Khalij Fars Hospital in Bushehr

Design
The study is a quasi-experimental trial with sequential groups. Randomization and blinding will not be performed. The sample size will consist of 96 mothers of preterm infants.

Settings and conduct
Following the approval of the proposal and obtaining the ethics code from the Vice Chancellery for Research of Bushehr University of Medical Sciences, as well as securing the IRCT code and necessary permits to access the research setting, sampling will commence upon submitting an official letter of introduction to the head of Persian Gulf Martyrs Hospital in Bushehr. To prevent potential communication between the control and intervention groups, sampling will first be conducted for the control group at the beginning of the study. After all questionnaires from the control group have been completed, sampling for the intervention group will begin, and spiritual self-care training will be provided to them.

Participants/Inclusion and exclusion criteria
Inclusion criteria: the mother's willingness to participate in the study; minimum age of 18 years old; adherence to the Islamic faith; proficiency in the Persian language. Exclusion criteria: history of preterm delivery; previous neonatal death; congenital anomalies in the infant as indicated in the medical record; the mother experiencing severe mental health disorders based on self-report.

Intervention groups
Control Group: They received routine hospital training and interventions and will not receive any new training.
Intervention Group: Spiritual self-care training will be provided.

Main outcome variables
Spiritual Well-Being; Parental Stress

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250530065981N1**
Registration date: **2025-07-18, 1404/04/27**
Registration timing: **registered_while_recruiting**

Last update: **2025-07-18, 1404/04/27**
Update count: **0**

Registration date
2025-07-18, 1404/04/27

Registrant information

Name
Malihe Khezri

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-07-14, 1404/04/23

Expected recruitment end date
2025-10-22, 1404/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of spiritual self-care education on stress level and spiritual health of mothers of premature newborns hospitalized in the neonatal intensive care unit at Bushehr Persian Gulf Martyrs Hospital

Public title

Investigating the effect of spiritual self-care education on stress level and spiritual health of mothers of premature newborns

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

The mother's willingness to participate in the study Minimum age of 18 years Adherence to the Islamic faith Proficiency in the Persian language Ability to read and write Attendance of at least one visit with the infant in the neonatal intensive care unit (NICU) The infant's gestational age between 24 weeks and 36 weeks plus six days At least three days have passed since the infant's admission to the NICU

Exclusion criteria:

History of preterm delivery Previous neonatal death Congenital anomalies in the infant as indicated in the medical record The mother experiencing severe mental health disorders based on self-report The mother suffering from severe physical illnesses based on self-report A history of the mother's use of psychoactive substances or illicit drugs Presence of complications during delivery (e.g., instrumental delivery, severe postpartum hemorrhage, severe pre-eclampsia, and eclampsia) as noted in the medical record Lack of ability to read the Quran Employment of the mother within the healthcare system The mother experiencing stressful events (such as divorce, the death of close relatives, etc.) within the preceding three months Reluctance to continue participation in the study

Age

From **6 months** old to **8 months** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **96**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Bushehr province university of medical sciences

Street address

Bushehr University of Medical Sciences, Moallem St, Bushehr, Iran

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Province

Boushehr

Postal code

7514633341

Approval date

2023-08-09, 1402/05/18

Ethics committee reference number

IR.BPUMS.REC.1402.106

Health conditions studied

1

Description of health condition studied

Mothers with Preterm Newborns

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Spiritual health scores of mothers with premature babies

Timepoint

Before the Intervention Starts, Immediately After the Intervention

Method of measurement

Ellison and Paloutzian's Spiritual Well-Being Scale

2

Description

Parental stress scores of mothers with premature babies

Timepoint

Before the Intervention Starts, Immediately After the Intervention

Method of measurement

Miles's Parental Stressor Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group: The spiritual education intervention will be delivered over six hours (equivalent to six one hour sessions across six weeks) in designated classrooms at the School of Nursing and Midwifery located in Persian Gulf Martyrs Hospital in Bushehr. In the first session, the researcher and the spiritual educator will introduce themselves and explain the study objectives to the mothers. Participant responsibilities will then be clarified, and demographic forms, along with the Spiritual Wellbeing Questionnaire and the Parental Stress Questionnaire, will be completed in the presence of the participants. The spiritual educator will present educational content based on the six step model developed by Richards and Bergin, tailored to the individual needs of each mother. Religious assignments including the recitation of Surah Al-Fatiha seventy times, Salawat, the invocation "Ya Shafi" three hundred and ninety one times, and Istighfar one hundred times will be introduced as daily practices to enhance the religious dimension of spiritual wellbeing. Additionally, the researcher will provide individualized guidance and respond to mothers' concerns regarding the care of their premature infants, thereby promoting the existential dimension of spiritual wellbeing. During sessions two through five, the researcher will be responsible for reviewing the participants' assigned tasks from the previous session and will inform the spiritual educator accordingly. The educator will then provide feedback and address any difficulties faced by the mothers in completing the assignments. Each session will begin with a brief summary to connect previous discussions with new topics. The educator will then proceed with teaching the new content, leading relevant exercises, assigning tasks for the next session, and concluding with a summary of the session's material. In the sixth and final session, the spiritual educator will provide a comprehensive summary of the educational content. One week after the last session, the participants will complete the questionnaires again in person.

Category

Behavior

2

Description

Control Group: Participants will receive routine hospital interventions and training, and will not be provided with any additional education.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Persian Gulf Martyrs Hospital Bushehr

Full name of responsible person
Dr. Abdolresol Mallah Zadeh

Street address
Bushehr, Ayatollah Taleghani Boulevard, Persian Gulf Martyrs Hospital Bushehr

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Boushehr University of Medical Sciences

Full name of responsible person
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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
Boushehr 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
Boushehr University of Medical Sciences

Full name of responsible person
Malihe Khezri

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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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
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Not applicable

Title and more details about the data/document
The study data will be made publicly available after complete anonymization of participant identities.

When the data will become available and for how long
Data access will commence 6 months following publication of the study results.

To whom data/document is available
Researchers

Under which criteria data/document could be used
By citing a logical reason, citing the source, and conducting analyses.

From where data/document is obtainable
Data requests should be directed to the corresponding author, Dr. Roqayeh Gashmard, via email: roqayehgashmard@gmail.com

What processes are involved for a request to access data/document
Data will be available 6 months after the article is published, upon sending a logical reason to the corresponding author, Dr. Roqayeh Gashmard, and then, if accepted, within 10 working days.

Comments