Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 andThe 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
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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؛
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8916978477
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+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
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Person responsible for updating data

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Position
Master of nursing student
Latest degree
Bachelor
Other areas of specialty/work

Nursery

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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