Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of spiritual care based on "Ghalb Salim" model on maternal anxiety and physiological parameters of preterm infants hospitalized in neonatal intensive care units of hospitals affiliated to Shiraz University of Medical Sciences

Protocol summary

Summary

1) Objective: Determining the effect of spiritual care based on "Ghalb Salim" model on maternal anxiety and physiological parameters of preterm infants hospitalized in neonatal intensive care units 2) Design: randomized clinical trial 3) Setting and action: total of 60 mothers with preterm infant enrolled in the study through convenience sampling method from hospitals that will be randomly divided into two experimental and control groups. The mothers in the experimental group will receive spiritual care during 4 sessions and each session 30 minutes, and after each session will perform kangaroo care for their infants. The mothers in the control group will perform kangaroo care for their infants during 4 sessions without any spiritual care. Mother's anxiety level will be measured by the Speilberger anxiety inventory before and after intervention, and infants heart rate, respiratory rate and blood oxygen saturation 10 minutes before, during and 10 minutes after kangaroo care will be measured. Finally, the changes in the anxiety score and the physiological parameters of the two groups will be compared. 4) Major inclusion criteria: No history of preterm infant hospitalization in previous pregnancies; having a neonate at the gestational age of 28-36 weeks; neonate with postnatal age of 3-5 days; and absence of any congenital abnormality in neonate. Major exclusion criteria: Mother's unwillingness to continue cooperation; neonatal death; and physical manifestation of any illness in neonate during the study. 5) Interventions: Spiritual care in the experimental group, anxiety assessment of the mothers using the Speilberger anxiety inventory before and after the intervention, recording the physiological parameters of the neonate before, during and after the kangaroo care. 6) Main outcome measures (variables): Heart rate, respiratory rate, and blood oxygen saturation of the neonate and mother's anxiety.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017041333410N1**
Registration date: **2017-08-13, 1396/05/22**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-08-13, 1396/05/22

Registrant information

Name
Zaynab Noeizad
Name of organization / entity
Shiraz University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 71 3647 4254
Email address
noeizad@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shiraz University of Medical Sciences

Expected recruitment start date

2017-07-23, 1396/05/01

Expected recruitment end date

2018-01-21, 1396/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of spiritual care based on "Ghalb Salim" model on maternal anxiety and physiological parameters of preterm infants hospitalized in neonatal intensive care units of hospitals affiliated to Shiraz University of Medical Sciences

Public title

The effect of spiritual care on maternal anxiety and physiological parameters of preterm infants

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion Criteria: Being Muslim; having primary school education (minimum); Persian speaking; not having known mental illness based on mother's statements; non-use of antidepressant drug or narcotics based on mother's statements; no history of preterm infant hospitalization in previous pregnancies; not being exposed to any other stressful event in the last 6 months; confirmation of the mother's ability to perform kangaroo care by their physician; having a neonate with a gestational age of at least 28th week to the end of the 36th week; neonate with postnatal age of 3-5 days; absence of any congenital abnormality in neonate; single preterm infant. Exclusion Criteria: Mother's unwillingness to continue cooperation; neonatal death; physical manifestation of any illness in neonate during the study; neonatal need for ventilator during the study.

Age

From **3 days** old to **5 days** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Study in two hospitals will be done in two steps. To do the first turn, by lottery method, hospitals were divided into two control and experimental groups. In the second turn, the control and experimental group will change.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shiraz University of Medical Sciences

Street address

Shiraz University of Medical Sciences, Zand Street, Shiraz

City

Shiraz

Postal code

Approval date

2017-07-19, 1396/04/28

Ethics committee reference number

IR.SUMS.REC.1396.72

Health conditions studied

1

Description of health condition studied

anxiety

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

2

Description of health condition studied

preterm infant

ICD-10 code

P07.3

ICD-10 code description

Other preterm infants

Primary outcomes

1

Description

Heart rate

Timepoint

10 minutes before, during and 10 minutes after kangaroo care

Method of measurement

Pulse oximetry

2

Description

mothers anxiety

Timepoint

Before the intervention, after the end of the intervention

Method of measurement

speilberger anxiety questionnaire

3

Description
Respiration rate
Timepoint
10 minutes before, during and 10 minutes after kangaroo care
Method of measurement
Observation

4

Description
Blood oxygen saturation
Timepoint
10 minutes before, during and 10 minutes after kangaroo care
Method of measurement
Pulse oximetry

Secondary outcomes

empty

Intervention groups

1

Description
In the intervention group, mothers receive the spiritual care education based on "Ghalb Salim" model in 4 sessions individually. The duration of each session will be 30 minutes.
Category
Other

2

Description
In the control group, no intervention will be performed.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Hafez hospital
Full name of responsible person
Ladan Homayoun sirat
Street address
Hafez hospital, Abiverdi Street, Shiraz
City
Shiraz

2

Recruitment center
Name of recruitment center
Hazrat-e-zeinab hospital
Full name of responsible person
Zahra Nazari
Street address
Hazrat-e-zeinab hospital, Holy Defense Square, Shiraz
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Shiraz University of Medical Sciences
Full name of responsible person
Dr. Seyed Basir Hashemi
Street address
Vice-Chancellor for Research, Shiraz University of Medical Sciences, Zand Street, Shiraz
City
Shiraz
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, Shiraz 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
Shiraz University of Medical Sciences - Hazrat-e-Fatemeh Nursing and Midwifery Faculty
Full name of responsible person
Zaynab Noeizad
Position
Neonatal Intensive Care Nursing Master of Science Student
Other areas of specialty/work
Street address
Hazrat-e-Fatemeh Nursing and Midwifery Faculty, Namazi Square, Shiraz
City
Shiraz
Postal code
Phone
+98 71 3647 4254
Fax

Email
noeizad@sums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences - Hazrat-e-Fatemeh Nursing and Midwifery Faculty
Full name of responsible person
Mitra Edraki
Position
Pediatric Nursing MS,Faculty member
Other areas of specialty/work
Street address
Hazrat-e-Fatemeh Nursing and Midwifery Faculty, Namazi Square, Shiraz
City
Shiraz
Postal code
Phone
+98 71 3647 4254
Fax
Email
Mitraedraki@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Zaynab Noeizad
Position
Neonatal Intensive Care Nursing Master of Science Student
Other areas of specialty/work
Street address
Hazrat-e-Fatemeh Nursing and Midwifery Faculty, Namazi Square, Shiraz
City
Shiraz
Postal code
Phone
00
Fax
Email
noeizad@sums.ac.ir
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty