

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 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 Spielberger 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 Spielberger 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

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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

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Person responsible for scientific inquiries

Contact

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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