

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Investigating training effects of spiritual self care on psychological interpenetration & life quality of mothers with preterm neonates admitted in NICU

Protocol summary

Summary

Aim of this research is investigating training effects of spiritual self care on psychological interpenetration & life quality of mothers with preterm neonates admitted. In this study 60 mother with preterm neonate were selected randomly and were divided to two groups of intervention and control. Mothers in both groups completed short scale life quality questionnaire of WHO(WHOOL- BERF). Mothers in both group were informed a bout condition of their babies 15 minutes everyday for 14 days. In intervention group moreover than superior program spiritual self care training 45 minutes daily for 6 sessions was implemented. Followup performed by calling 2 times a week for two weeks. Finally we wanted the mother ta attend the hospital. The baby was visited free by neonatologist and mothers were asked to complete short scale life quality questionnaire. Including criterion: Satisfaction for participating in the study; preterm neonate with gestational age between 28 to 36 weeks; Iranian nationality; Muslim; At least five class literacy; Attending 14 days in ward; No depression; No addiction to drugs; No previous record of preterm baby. Excluding criterion: Congenital malformation; No propensity to continue the study; Neonatal discharge earlier than 14 days; Neonatal death; Twin birth

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201308018314N2**

Registration date: **2013-09-11, 1392/06/20**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-09-11, 1392/06/20

Registrant information

Name

Mohammad Heidarzadeh

Name of organization / entity

Health Ministry

Country

Iran (Islamic Republic of)

Phone

+98 21 6670 7313

Email address

heidarzadeh@health.gov.ir

Recruitment status

Recruitment complete

Funding source

vice chancellor for research, Mashhad University of Medical science

Expected recruitment start date

2013-08-23, 1392/06/01

Expected recruitment end date

2013-12-21, 1392/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating training effects of spiritual self care on psychological interpenetration & life quality of mothers with preterm neonates admitted in NICU

Public title

Investigating training effects of spiritual self care on psychological interpenetration & life quality of mothers

with preterm neonates admitted in NICU

Purpose
Supportive

Inclusion/Exclusion criteria
Including criteria:Satisfaction for participating in the study;preterm neonate with gestational age between 28 to 36 weeks;Iranian nationality:Muslim:At least five class literacy:Attending 14 days in ward:No depression:No addiction to drugs:No previous record of preterm baby.Excluding criteria:Congenital malformation:No propensity to continue the study:Neonatal discharge earlier than 14 days:Neonatal death:Twin birth .

Age
No age limit

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

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

Ethics committee of Mashhad University of Medical Sciences

Street address

Mashhad University of medical sciences,Fakori street,Mashhad,Khorasan Razavi,Iran

City

Mashhad

Postal code

Approval date

2013-03-13, 1391/12/23

Ethics committee reference number

911012

Health conditions studied

1

Description of health condition studied

Psychologic reaction to stress

ICD-10 code

F43.9

ICD-10 code description

Reaction to severe stress

Primary outcomes

1

Description

Psychologic Interpenetration

Timepoint

Initial 5 days neonatal admission in NICU &14 days after i

Method of measurement

Score achieved by mother from tolerable agitated questionnaire

2

Description

Life Quality

Timepoint

Initial 5 days neonatal admitted in NICU &14 days after intervention

Method of measurement

Score achieved by mother from life quality questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

In intervention group spiritual self care program training 45 minutes daily for 6 sessions was implemented.Followup performed by calling2 times a week for two weeks.Finally we wanted the mother to attend the hospital.The baby was visited free by neonatologist and mothers were asked to complete short scale life quality questionnaire.

Category

Behavior

2

Description

Mothers in control group were informed a bout condition of their babies 15 minutes everyday for 14 days,Then completed short scale life quality questionnaire of WHO.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Omolbanin Hospital

Full name of responsible person

Mohammad Heidarzadeh

Street address

Ommolbanin hospital, Ayatollah Behjat
street, Mashhad, Khorasan Razavi, Iran

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

vice chancellor for research, Mashhad University of
Medical science

Full name of responsible person

Mrs Reihani

Street address

Mashhad University of medical sciences, Fakori
street, Mashhad, Khorasan Razavi, Iran

City

Mashhad

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, Mashhad University of
Medical science

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

Mashhad University of medical sciences

Full name of responsible person

Sekhvatpor

Position

Master of science

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Health Ministry

Full name of responsible person

Dr. Mohammad Heidarzadeh

Position

Subspecialist of neonate

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Health Ministry

Full name of responsible person

Mohammad Heidarzadeh

Position

Subspecialist of neonate

Other areas of specialty/work

Street address

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City

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Fax

Email

heidarzadeh@health.gov.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