

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Effect of spiritual care on posttraumatic growth mothers of preterm neonate, post discharge of NICU

Protocol summary

Study aim

Determining the effect of spiritual care on the overall score of post-traumatic growth

Design

Clinical trial with control group, with parallel, randomized, phase 3 groups on 60 mothers. Lottery was used for randomization.

Settings and conduct

Neonatal Intensive Care Unit of UmolBanin , Imam Reza, Ghaem and Hashemi nejad Hospitals

Participants/Inclusion and exclusion criteria

A mother with a baby between 28 and 32 weeks of gestation

Intervention groups

After obtaining the consent of mothers of premature infants admitted to the neonatal intensive care unit of Imam Reza, Ghaem, Umm Al-Banin, Hasheminejad hospitals, spiritual care based on Richards & Bergin intervention method with Islamic approach during 8 sessions of 30 to 60 minutes for mothers of neonates The intervention will be performed. Mothers in the control group receive routine ward care. Post-traumatic growth is measured three times, once before the intervention, once immediately after the intervention, and once two weeks after the infant is discharged from the hospital.

Main outcome variables

posttraumatic growth

General information

Reason for update

Acronym

Neonatal intensive care unit

IRCT registration information

IRCT registration number: **IRCT20210627051721N1**

Registration date: **2021-08-14, 1400/05/23**

Registration timing: **prospective**

Last update: **2021-08-14, 1400/05/23**

Update count: **0**

Registration date

2021-08-14, 1400/05/23

Registrant information

Name

Zahra Kariznoei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3859 1511

Email address

kariznoeiz982@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-23, 1400/07/01

Expected recruitment end date

2021-12-22, 1400/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of spiritual care on posttraumatic growth mothers of preterm neonate, post discharge of NICU

Public title

Effect of spiritual care on posttraumatic growth

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

A mother with a neonate between 28 and 32 weeks of

gestation Mothers of neonates without congenital anomalies and chromosomal abnormalities Mother of the baby without severe asphyxia The mother should not use anti-anxiety and anti-depressant drugs before and during the study No addiction of the mother Lack of experience of a serious accident or serious family disputes in the last 6 months The presence of the mother in the ward Belief in Islam and Shiite religion The mother does not already have a history of a premature baby alive

Exclusion criteria:

Maternal withdrawal from further study Death or transfer of the baby to other centers Clearance earlier than 12 days Duration of hospitalization more than 4 weeks Lack of cooperation of the mother to participate in more than two sessions

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling will be available and for allocating mothers of premature infants to intervention and control groups, first two hospitals will be selected by lot for sampling in the control group and two hospitals will be selected for sampling in the intervention group.

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

School of Nursing and Midwifery, Ebne Sina St.

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Approval date

2021-07-06, 1400/04/15

Ethics committee reference number

IR.MUMS.NURSE.REC.1400.036

Health conditions studied

1

Description of health condition studied

prematurity

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Posttraumatic growth

Timepoint

Before the intervention, after the end of the intervention, two weeks after the discharge of the baby

Method of measurement

Tedeschi and Calhoun Post Traumatic Growth Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Spiritual care based on Richards & Bergin intervention method with Islamic approach will be done in 8 sessions of 30 to 60 minutes for mothers of newborns in the intervention group. In addition to spiritual care, the mothers of the intervention group benefit from the usual actions of the ward.

Category

N/A

2

Description

Control group: This group will receive NICU routine care, including daily visits by the mother and cuddling.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Zahra Kariznoee

Street address

Ebne Sina Street

City

MASHHAD

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 3854 3031

Email

Kariznoeiz982@mums.ac.ir

2**Recruitment center****Name of recruitment center**

Ghaem Hospital

Full name of responsible person

Zahra Kariznoee

Street address

Ahmad Abad Street

City

Mashhad

Province

Razavi Khorasan

Postal code

9176699199

Phone

+98 51 3840 0001

Email

Kariznoeiz982@mums.ac.ir

3**Recruitment center****Name of recruitment center**

Ommolbanin Hospital

Full name of responsible person

Zahra Kariznoee

Street address

Corner of Ayatollah Behjat 16, Zarrineh Crossroads

City

Mashhad

Province

Razavi Khorasan

Postal code

91447347667

Phone

+98 51 3223 1061

Email

Kariznoeiz982@mums.ac.ir

4**Recruitment center****Name of recruitment center**

Hasheminezhad Hospital

Full name of responsible person

Zahra Kariznoee

Street address

Moftteh Street, at the end of Abu Reihan Blvd

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Phone

+98 51 3273 7011

Email

Kariznoeiz982@mums.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Robab Latifnejad Roodsari

Street address

Ebne Sina Street

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Phone

+98 51 3859 1511

Email

latifnejadr@mums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Mashhad 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**

Mashhad University of Medical Sciences

Full name of responsible person

Zahra Kariznoei

Position

Master Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery
Street address
Ebne Sina street
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913199
Phone
+98 51 3859 1511
Email
Kariznoeiz982@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Naghmeh Razaghi
Position
faculty member
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Ebne Sina Street
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913199
Phone
+98 51 3859 1511
Email
razaghin@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences
Full name of responsible person
Naghmeh Razaghi
Position
Faculty member of university
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Ebne Sina Street
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913199
Phone
+98 51 3859 1511
Email
razaghin@mums.ac.ir

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