

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

The effect of massage on compliance with maternal role in mothers with premature infants admitted to the intensive care unit

Protocol summary

Study aim

The effect of massage on compliance to parental role of mothers of premature infants hospitalized in NICU

Design

This is a quasi-experimental study with a control group with parallel groups. the sequential method will be used with non-random Allocation to groups. The sample size is 90 mothers who will be divided equally into two groups.

Settings and conduct

This study will be done in the neonatal intensive care unit of Amol city. The researcher will teach infant massage to the mothers of intervention group in two sessions . Mothers will done massage their child daily for 15 minutes for 5 consecutive days. The mothers of both groups will be completed questionnaire before, in the fifth and 14 days after completing the intervention for massage group.

Participants/Inclusion and exclusion criteria

Inclusion criteria for mothers of preterm infants (32-37 weeks gestation): no history of physical and mental illness and history of infertility. Inclusion criteria for preterm infants: clinical condition stability of baby's and no respiratory distress or congenital abnormalities.

Intervention groups

The infants in the intervention group will be massaged by the mother from the third day of hospitalization for 5 consecutive days. Compliance with Mather's role before the intervention will be re-measured on the fifth and 14th days. At the same time, mothers in the control group also responded to Compliance with Mather's role questionnaire, but only routine care would be provided for them.

Main outcome variables

Compliance with motherhood role

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160119026104N11**

Registration date: **2020-02-27, 1398/12/08**

Registration timing: **registered_while_recruiting**

Last update: **2020-02-27, 1398/12/08**

Update count: **0**

Registration date

2020-02-27, 1398/12/08

Registrant information

Name

Mahnaz Shoghi

Name of organization / entity

Iran university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 4687 1192

Email address

shoghi.m@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-22, 1398/10/01

Expected recruitment end date

2020-08-22, 1399/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of massage on compliance with maternal role in mothers with premature infants admitted to the intensive care unit

Public title

The effect of massage on compliance with maternal role in mothers with premature infants

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Gestational age 32 to 37 weeks Stability of the baby's clinical condition and lack of respiratory distress or congenital abnormalities Having no history of infertility

Exclusion criteria:

Mother's addiction Maternal history of physical and mental illness

Age

From **1 day** old to **14 days** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Not 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 Iran University of Medical Sciences

Street address

School of Nursing and Midwifery, Rashid Yasimi St., Vali-e-Asr Ave.

City

Tehran

Province

Tehran

Postal code

1996713883

Approval date

2019-03-11, 1397/12/20

Ethics committee reference number

IR.IUMS.REC.1397.700

Health conditions studied

1

Description of health condition studied

compliance with maternal role

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

compliance with maternal roles

Timepoint

The day before the intervention, the fifth day of the intervention and the 14th day after the intervention

Method of measurement

Compliance to maternal role

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Massage will be performed by the mother from the third day of hospitalization, if the baby is stable, once a daily for 15 minutes for 5 consecutive days. questionnaire will be completed by the mothers before the beginning of the intervention and on the 5th and 14th day after the intervention. .

Category

Behavior

2

Description

Control group: Neonates in this group will receive routine care in the ward and questionnaire will be completed by this mothers in first day, fifth day and 14 days after .

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Ali hospital

Full name of responsible person

Mahnaz Shoghi

Street address

Noor Road to Chamestan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Doctor Masoud Naseri
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University of Nursing and Midwifery, Shahid yasemi,
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1449614535
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pr@iums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Mahnaz Shoghi
Position
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Latest degree
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Other areas of specialty/work
Nursery

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Data is encoded to make the profile of individuals unrecognizable and confidential

When the data will become available and for how long

From the end of sampling 1398 to 6 months after the article was published

To whom data/document is available

University Ethics Committee, Project Review Committee, Paper Review Committee, other researchers

Under which criteria data/document could be used

Perform systematic or meta-analysis tasks with a document

From where data/document is obtainable

Mahnaz shoghi shoghi@iums.ac.ir

What processes are involved for a request to access data/document

The request will be sent by academic email, and information files will be made available to people no later than one week.

Comments