Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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Mahnaz Shoghi

Name of organization / entity
Iran university of medical sciences

Country
Iran (Islamic Republic of)

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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
City
Amol
Province

Mazandaran
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47646-76893
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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
Street address
University of Nursing and Midwifery, Shahid yasemi, Kordestan highway
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1449614535
Phone
+98 21 86701
Email
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
Associate Professor
Latest degree
Ph.D.
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