Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effect of Massage by Mother on the Situation of Mood Admitted to the NICU of the Afzalipour Hospital of Kerman University of Medical Sciences in 2016

Protocol summary

Summary

Objectives: Birth of premature infant and hospitalization in neonate intensive care unit causes mood changes, for parents,especially mothers as anxiety, depression, fatigue, confusion, irritability and lack of ability to care for premature infants. Therefore some strategies are needed to reduce mood changes in mothers.So, in this study considering premature infant massage as on intervention for reducing the likelihood of mothers with premature infants whose the time of discharge from the neonatal intensive care unit is near will be investigated in this study. Design:This Study is of the type of intervention studies. That the research sample contain 52 mothers with premature infants admitted to the NICU of the Afzalipour Hospital of Kerman University of Medical Sciences that 26 patients will be blocked randomly in the control group and 26 in case group. Participants including major eligibility criteria: The mothers inclusion criteria include: the ability to speak Persian, having at least the literacy of reading and writing,and will be excluded if they have chronic mental illness. And 30 to 37 weeks premature infants who don’t have congenital anomaly or severe respiratory illness not requiring ventilator will be enrolled in the study.The data will be collected using:(1) the demographic data questionnaire and 2- POMS questionnaire. The control group are mothers which no intervention on their infant. And the intervention group are mothers that after obtaining the necessary training in three stages(elementary, middle and final) do massage for their infants as follow. To do the infant massage, initially hands are washed and heated by being rubbed together and massage will be done from head to the tip of infants foot while the babys body is naked and it has only diapers. It Will be tried that the infant is given massage by the mothers at certain hours (7 am to 7 pm) on five consecutive days for at least 15 minutes. Each 15-minute massage turn will consist of three 5-minute phases, which at the first phase, the infant will be in prone position.And massage will be given with gentle pressure by the smooth and soft part of the fingers of both hands on the areas desired. And in the middle and final phase,the infant is given massage in supine position.The method of doing massage:For doing massage on infant, at first hands are washed and rubbed together to be heated and the infant is placed in prone position. Massage will be done from head to the tip of infants foot while his body is naked having wear just diapers. It will be tried that massage is given by the mother at certain hours (7 am to 7 pm) on five consecutive days for at least 15 minutes in the following way. Each 15-minute massage turn will consist of three 5-minute phases which at the first phase,the infant will be on prone position.And massage will be given with a gentle pressure by the smooth and soft part of fingers of both hands on the areas desired. In the initial phase, massage will be done on one of the five areas below in each minute respectively. A:12 massage move (every 5 seconds a move) from head downward on both sides of the face till the neck and vice versa B:12 massage move (every 5 seconds a move) From the back of the neck toward across the shoulders and vice versa. C:12 massage move (every 5 seconds a move) from the upper back downward to the waist and vice versa. D:12 massage move (every 5 seconds a move) from the thighs down to the ankles and vice versa E:12 massage move (every 5 seconds a move) from shoulder to wrist, and vice versa. In the middle Phase infant is put in flat position lying on his back (supine). And in each minute the massage is given on one of the five following areas respectively. A: 12 massage moves (every 5 seconds a move) touching the areas of the face and cheeks. B: 12 massage moves (every 5 seconds a move) Touching the chest. C: 12 massage moves (every 5 seconds a move) palpation of the abdomen. D: 12 massage moves (every 5 seconds a move) palms. E: 12 massage moves (every 5 seconds a move) Touching the soles of the feet. In final

phase,the baby is put in a flat supine position and 6 passive extension and flexion movements (every 10 seconds one)will be given respectively on this 5 areas (shoulders, elbows, knees, wrists, and ankles). Both group will complete the mood questionnaires before and after the intervention. Interventions: A: Acts before Massage: 1. – Providing an educational massage therapy pamphlet based on the massage therapy book produced by the Bureau of Infant Health 2 –Showing massage educational film for mothers 3- holding a 30-minute massage training session for the mothers on the dolls and then on infant and if the mother needs to be more trained,This training continues until proper learning. Also before applying massage on infant by the mother,implantation of the correct techniques of infant massage by the mother will be controlled by applying massage on the doll by the researcher. Main outcome measures: Mood NICU routine care will be done for the control group infants.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016092824919N2**
Registration date: **2017-03-04, 1395/12/14**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-03-04, 1395/12/14

Registrant information

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Name of organization / entity

Kerman Medical University of Sciences

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Recruitment status

Recruitment complete

Funding source

Private

Expected recruitment start date

2016-03-19, 1394/12/29

Expected recruitment end date

2016-12-21, 1395/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Massage by Mother on the Situation of Mood Admitted to the NICU of the Afzalipour Hospital of Kerman University of Medical Sciences in 2016

Public title

The Effet of Massage on Premature infant on Mood of Mother

Purpose

Supportive

Inclusion/Exclusion criteria

Mothers inclusion criteria: the ability to speak Persian; the minimum literacity of reading and writing Infant inclusion criteria :preterm infants (30-37Hfth) Infant exclusion criteria : having a congenital anomaly; risk of severe or intense respiratory illness or infants; requiring ventilatior. Mothers exclusion criteria : having chronic mental or physical illness

Age

To **1 month** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **52**

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

1

Registry name

-

Secondary trial Id

-

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Kerman University of Medical Sciences

Street address

Pardize Oloompezashki, Haft Bagh e Alavi Kerman Kerman Iran, Islamic Republic Of

City
Kerman
Postal code
Approval date
2016-08-31, 1395/06/10
Ethics committee reference number
Ir.kmu.res.1395.117

Health conditions studied

1

Description of health condition studied
Mood
ICD-10 code
F39
ICD-10 code description
Unspecified mood [affective] disorder

Primary outcomes

1

Description
Mood
Timepoint
Before Intervention and after Intervention
Method of measurement
POMS questionnaire(profile of mood state)

Secondary outcomes

1

Description
-
Timepoint
-
Method of measurement
-

Intervention groups

1

Description
Participants in the intervention group at certain hours (7 am to 7 pm) on five consecutive days for 15 minute massage their babies in trained ways.
Category
Behavior

2

Description
NICU routine care will be done for the control group infants.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Afzalipour Hospital of Kerman University of Medical Sciences
Full name of responsible person
Batoul Lotfalipour
Street address
Emam Highway
City
Kerman

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor Of Research, Kerman University of Medical Sciences
Full name of responsible person
Abbas Pardakhty Ph.D
Street address
Pardize Oloompezeshki, Haft Bagh e Alavi Kerman
City
Kerman
Grant name
00
Grant code / Reference number
00
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor Of Research, Kerman 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
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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