Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Clinical trial the study of premature infant massage by mothers on maternal attachment behavior among infants hospitalized in neonatal intensive care unit

Protocol summary

Summary

Aim of this study is to compare the effect of premature infant massage by mothers on maternal attachment behavior among premature infants hospitalized in neonatal intensive care units between case and control group. Inclusion criteria is Iranian mother; the baby is the result of a single pregnancy; infants 2500 g birth weight or less and gestational age of 37 weeks or less. Exclusion criteria is infants discharged before end of intervention; collide stability and general condition of the baby and mother. The population of the study are all mothers and premature infants hospitalized in neonatal intensive care units. Sample size is, 80 infants and mothers, hospitalized in neonatal care units. 40 mothers were trained with educational massage films. Mothers massage her infants for 5 days, each day one turn in 15 minutes. The attachment of the mothers on their infants was assessed in before massage and the days 5 after massage. During 5 days of testing, the level of maternal attachment in the intervention group was highly significant in compare with the control group. It is noticeable that, there was no significant difference in demographic data base on statistical analysis. According to the significance of statistical difference between the level of maternal attachment on the intervention group and the control group, we can conclude that massaging infants is an effective approach to improve the maternal attachment from one side, and to cure and recover the infants from the other side. So this kind of caring can be expanded in neonatal units especially in neonatal intensive care units.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014071216937N3**

Registration date: **2015-02-21, 1393/12/02**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-02-21, 1393/12/02

Registrant information

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Zohreh Farsi

Name of organization / entity

Tehran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2014-03-21, 1393/01/01

Expected recruitment end date

2014-07-20, 1393/04/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial the study of premature infant massage by mothers on maternal attachment behavior among infants

hospitalized in neonatal intensive care unit

Public title
The effect of premature infant massage on mother attachment
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: Iranian mother; the baby is the result of a single pregnancy; infants 2500 gm birth weight or less and gestational age of 37 weeks or less; infants are clinically stable condition. Exclusion criteria: infants discharged before end of intervention; collide stability and general condition of the baby and mother
Age
From **1 day** old to **28 days** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Statistics were performed using a table of random numbers reference book. Less than 81 were selected and participated in the study. 80 samples were divided in two qroups number 1 to 40 represents the experimental group and the numbers 41 to 80, representing the control group were classified.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Sciences
Street address
Sixth Floor, Central University, Qods St, Keshavarz Blvd, Tehran, Iran
City
Tehran
Postal code
Approval date
2010-09-23, 1389/07/01
Ethics committee reference number
1426/130//92/ص

Health conditions studied

1

Description of health condition studied
The effect of premature infant massage by mother on attachment behavior
ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
attachment
Timepoint
Before massageand and the day5 after massage
Method of measurement
Calculated by taking the average frequencyof attachment behavior By maternal attachment observation form

Secondary outcomes

empty

Intervention groups

1

Description
After selecting the samples for starting the research and having enough and clear explanations for mothers about the goals and the type of the research by researcher, and also to clarify the attachment evaluation procedure and to express their attachment behavior to their infants is measured by the researcher before starting massage and the days 5 after massage. Acquiring written satisfaction, and are attendant in this project. In the experimental group a book with a training CD that is prepared by infants health office about massage training will be given to mothers. The massage is done from the tip of the infants toes in the way that the infant is without coverage or is just diapered. The massage training movie is played by the researcher for mothers. Massage training classes is hold in the two hospitals of conference saloon of hospitals.These saloons are equipped with the perfect audio visual system and the manipulation is done with the related authorities in the two hospitals to allow using this equipments. Training classes will be performed during 1 hour in 2 sessions, mothers will learn the massage practically and by face to face training, by the researche. They will practice on the maquette with attendance of the researcher. (The researcher will apply personally for massage training and also evaluation of attachment samples and she will not

use the colleague). In the case that mother needs sessions and more hours for training,these training will be continued till the correct massage learning. The researcher control the research by observation of the massage by mothers on the maquette have a correct insight from the massage training. The exact performance of massage and having a correct insight of the massage training by mothers is controlled by the researcher by mothers observation of the maquette.in all stages of the massage training film, and in practical exercise of the massage, the researcher will be present beside mothers for fixing their problems and answering to their questions. (The researcher has received the massage certificate formerly). (Also the researcher telephon number is accessible to them all the time). First massage of the infant by the mother is done by researcher attendance. Every mother massage her infant by odorless olive oil once in 24 hours. For 15 minutes. (used olive oil is of the same trade mark for all samples). Massage is done for 5 days on the infants by their mothers. Evaluation of attachment of mothers in experimental group is done before the massage and the days 5 after massage. The evaluation is done by the researcher regarding spatial time allocation of 1 hour after massage. Attachment evaluation is started by the time the mother is on the infant's bed and is ready to feed her infant and the evaluation would continue during this feeding, that is if the mother feed or contact her infant less than 15 minutes, the evaluation wouldn't be accepted and will postpone to other time. (This point of evaluation will be concerned in both the control and experimental group). In order to measure mothers attachment by attachment evaluation scale, 15 minutes interaction between mother and the infant constantly evaluate; in every minute in the first 30 second the mother behavior to the infant evaluated and in 2nd 30 second the behavior is recorded. Counting of seconds is done by counting watch. Before doing massage of the infant, the evaluation then is done in 5th days after starting the massage.

Category

Prevention

2

Description

In control group mothers and infants will receive only routine care; (this caring contains doctor visit, daily weighting newborns, serum therapy, training of correct breast feeding to infant, intake and output control, needed training for discharge of the infant, their attachment assess after confirming the needed situations for entering the research, and getting the one turn written satisfactory and then it will be assess in 5th days after massage.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Ali Asghar Hospital

Full name of responsible person

Soroor Sohrabi

Street address

Hazrat Ali Asghar Hospital - Vahid Dastgerdi St - Modare Highway

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Tehran University of Medical Sciences

Full name of responsible person

soroor sohrabi

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Sixth Floor, Central University, Qods St, Keshavarz Blvd, Tehran, Iran

City

Tehran

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 of Tehran 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

Name of organization / entity

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Full name of responsible person

Soroor Sohrabi

Position

Msc in Nursing

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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