

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 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

###### Name

Zohreh Farsi

###### Name of organization / entity

Tehran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

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###### Email address

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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 groups 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

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#### ICD-10 code description

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## Primary outcomes

### 1

#### Description

attachment

#### Timepoint

Before massage and the day 5 after massage

#### Method of measurement

Calculated by taking the average frequency of 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 researcher. 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 telephone 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

**Street address**

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

**City**

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**Grant name**

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**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**

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Msc in Nursing

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**Web page address****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*