Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

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

Protocol summary

Summary

Aim of this study is to compare the effect of infant massage by mothers on maternal attachment behavior among infants hospitalized in neonatal 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 more and gestational age of 37 weeks or more; infants are clinically stable condition. 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 infants hospitalized in neonatal 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 1, 3 and 5 after massage

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014031116937N1**
Registration date: **2014-04-27, 1393/02/07**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-04-27, 1393/02/07

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

2014-02-20, 1392/12/01

Expected recruitment end date

2014-06-22, 1393/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

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

Public title

The effect of infant massage on mother attachment

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Iranian mother; the baby is the result of a single pregnancy; infants 2500 gm birth weight or more and gestational age of 37 weeks or more; 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
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Council of Tehran University of Medical Sciences
Street address
Sixth Floor, Central University, Qods St, Keshavarz Blvd, Tehran, Iran
City
Tehran
Postal code
Approval date
2013-10-06, 1392/07/14
Ethics committee reference number
1426/130//92/ص

Health conditions studied

1

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

Primary outcomes

1

Description
attachment
Timepoint
Before massageand and the day 1,3 and 5
Method of measurement
Calculated by taking the average frequencyof attachment behavior

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 in 1, 3, and 5 days after starting the infants 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 then in 1, 3 and 5 days after starting the 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 1st, 3rd, and 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 1st and 3rd and 5th days.

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

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Doctor Taghizadeh

Street address

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

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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Soroor Sohrabi

Position

Msc in nursing

Other areas of specialty/work

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Phone

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Email

soroor.soh@gmail.com

Web page address

Person responsible for updating data

Contact

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