

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

The effect of massage by mothers on the baby's weight and perceived Self-efficacy of mothers who have low birth weight babies in neonatal intensive care unit

Protocol summary

Study aim

The effect of maternal infant massage on neonatal weights and perceived self-efficacy of mothers with low birth weight infants.

Design

The present study is a semi-experimental clinical trial. There is a control group. Sampling was done randomly and blocked. The sample size in each intervention group was 40 and control group.

Settings and conduct

This is a quasi-experimental clinical trial. Research environment Using random allocation, two hospitals are selected as intervention and control in educational centers in Ahwaz. In the intervention group, the babies are given massage for sixty days. The control group is only routine care.

Participants/Inclusion and exclusion criteria

Maternal entry criteria: - The mother of Iran, the presence of the mother with the baby in all the days prescribed for massage, mothers of drugs and alcohol addiction is not addictive. - The mother has no contagious skin disease in her hands. - Mother's pregnancy is wanted on its own. Neonatal Criteria: - The baby is asked for a pregnancy, the birth weight of the infant is 2499-1500 grams. - The gestational age of babies is between 30 and 36 (32) weeks. The incidence of intrauterine gestational age is considered to be 32 weeks, however, if the number of babies born in 32 weeks is low, neonates will be sampled from 30 to 36 weeks. - The baby has no contagious skin disease and genetic and congenital anomalies. - The baby has constant clinical conditions. - The baby does not have an interventional treatment such as chest tube and surgery. - At least ten days in hospital.

Intervention groups

The baby's intervention group is massaged for sixty days by the mother who has been trained. In the control

group, mothers and infants will receive only the usual care of the department.

Main outcome variables

Baby weight gain and self-efficacy of mothers with low birthweight.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090405001788N19**

Registration date: **2018-04-08, 1397/01/19**

Registration timing: **registered_while_recruiting**

Last update: **2018-04-08, 1397/01/19**

Update count: **0**

Registration date

2018-04-08, 1397/01/19

Registrant information

Name

Leili Borimnejad

Name of organization / entity

Iran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-21, 1397/01/01

Expected recruitment end date

2018-09-22, 1397/06/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of massage by mothers on the baby's weight and perceived Self-efficacy of mothers who have low birth weight babies in neonatal intensive care unit

Public title
The effect of massage by mothers on the baby's weight and perceived Self-efficacy of mothers who have low birth weight babies in neonatal intensive care unit

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Neonatal Criteria: The baby is asked for a pregnancy. The birth weight of the infant is 2499-1500 grams The gestational age of the infants is between 30 and 36 (32) weeks. The baby has no contagious skin disease and genetic and congenital anomalies. The baby has constant clinical conditions. The baby does not have an interventional treatment such as chest tube and surgery. At least ten days in hospital. Maternal Entry Criterion: The presence of the mother with the baby on all the days prescribed for massage. Mother of iran. Mother has no contagious skin disease in her hands. Pregnancy is your mother's will. Mothers are not addicted to drugs and alcohol.
Exclusion criteria:

Age
To 60 days old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: 80

Randomization (investigator's opinion)
Randomized

Randomization description
Using random allocation, two hospitals in Ahvaz educational centers will be selected as intervention and control, then newborns with entry criteria will be studied.

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 Seinces

Street address

Hemmat Highway

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Tehran

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1449614535

Approval date

2017-12-26, 1396/10/05

Ethics committee reference number

IR.IUMS.REC1396.9411451012

Health conditions studied

1

Description of health condition studied

Premature infants

ICD-10 code

P07.1

ICD-10 code description

Other low birth weight newborn

Primary outcomes

1

Description

Baby weight

Timepoint

Weight gain on days 3, 10 and 60.

Method of measurement

Weight of newborns using the German Seca digital scale with a precision of $10 \pm \text{g}$.

2

Description

Self-efficacy of mothers with preterm infants

Timepoint

At the end of the 2nd month of the baby

Method of measurement

Farsi version of the Self-efficacy Questionnaire (PMP S-E) Barnes and Adamson-Macedo (2007) will use maternal self-efficacy measurements.

Secondary outcomes

empty

Intervention groups

1

Description

In order to evaluate the effect of massage on weight loss in low birthweight and self-efficacy of mothers, massage will be performed for 60 days. Sampling is done in randomized blocks and participants will be asked to fill out the informed consent form, then the mothers who will be satisfied with the participation in the study will be selected. Interviews include: a) Presenting a booklet And a training DVD that is provided by the Neonatal Health Department and the Ministry of Health and Medical Education, 2015, with the collaboration and participation of the Neonatal Health Department of the Ministry of Health and Medical Education (Massage of Infants and Infants). It should be noted that the way the massage steps are performed on the DVD will be explained by the researcher in a comprehensible language for mothers. B) Presentation of massage training for mothers; c) conducting 2 one-hour training sessions by the researcher; d) practicing a mother in the presence of a researcher on a simple neonatal model that is available for routine training at the nursing school. An occupational therapist, along with a researcher, will be available to massage and confirm the correct way of massage at all stages of massage. If the mother needs more sessions and more hours for massage training, these trainings will be continued by the researcher until a proper massage is completed. Performing good massage and ensuring that all mothers have the right impression of massage therapy will be controlled by the researcher and occupational therapist through the observation of the massage performed by the moms on the moth. In all phases of film play for massage therapy and practical massage practice, the researcher will be presenting more explanations and solving the problems and questions of mothers along with them. The researcher's contact number is also available to answer questions from mothers 24 hours a day. Massage from the head to the tip of the baby while the baby's body is uncovered or if it has only a cover. Each mother will massage her baby with olive oil for 15 minutes (used for all samples of a commercial type), the study will continue for 60 days.

Category

Behavior

2

Description

In the control group, mothers and newborns will receive only the usual care of the department (these include: physician's examination, daily weighting of the baby, drug therapy, serum therapy, training on the correct breast feeding to mothers, controlling the absorption and excretion of the baby, training and follow up Vaccination, training for the discharge of the baby and assessment of the correct nutrition of the infant).

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Khomeyni hospital

Full name of responsible person

Dr.Kambiz Masomi

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Vice chancellor for research, 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
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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

After Data coding In order to keep confidentiality of the participants in the research

When the data will become available and for how long

the end of sampling till six month after article publishing.

To whom data/document is available

ethical , reviewer and editorial committees, researchers

Under which criteria data/document could be used

systematic review and meta analysis or secondary analysis citation

From where data/document is obtainable

Leili Borimnejad , borimnejad.l@iums.ac.ir

What processes are involved for a request to access data/document

After sending request by academic email, we will send them data files up to one week.

Comments