Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of body massage on the premature Infants' mothers' attachment behaviors in the Neonatal ICU of Shahid Sadoughi and Afshar Yazd Hospitals

Protocol summary

Study aim
Determining the effect of body massage on attachment behaviors of mothers of premature infants in Neonatal Intensive Care Unit

Design
A randomized, pre-and post-test clinical trial with two groups of control and test, 60 mothers and infants hospitalized in Neonatal Intensive Care Unit, double blind

Settings and conduct
For massage training to mothers in the test group: 1- Presentation of a booklet on massage. 2- A two-part training session is held for one hour. 3. Massage training film is performed. In order to blind the control group and not to know about massage therapy, the control group is in another hospital. . To assess the attachment behaviors in the test and control group before the intervention, days 3 and 5, after the intervention, when the mother of the infant's bedside is offered, during the time period determined by the researcher who is unsure about the objectives and method of implementing the plan, Observing the attachment behaviors of the mother for 15 minutes and checking the behavioral checklist Madrkhvahd tag payment.

Participants/Inclusion and exclusion criteria
Newborns with gestational age 34 to 37 weeks that are feed with breast milk or milk powder, 3-5 days after birth, mother should be Persian speaker and must be able to read and write, with a single and wanted pregnancy.

Intervention groups
Experimental group: premature infants' mothers trained for massage technique. They applied massage to their infants once a day for 5 consecutive days (15 minutes). Control group: received only usual care.

Main outcome variables
Maternal attachment

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180621040184N1**
Registration date: **2019-07-07, 1398/04/16**
Registration timing: **retrospective**

Last update: **2019-07-07, 1398/04/16**
Update count: **0**

Registration date
2019-07-07, 1398/04/16

Registrant information

Name
Zahra Kargar Shooroki

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-07-23, 1397/05/01

Expected recruitment end date
2018-10-22, 1397/07/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of body massage on the premature Infants' mothers' attachment behaviors in the Neonatal ICU of Shahid Sadoughi and Afshar Yazd Hospitals

Public title
The effect of body massage on the attachment behaviors of premature Infants' mothers

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Age of birth is from 34 weeks of pregnancy to 37 weeks of pregnancy Nutrition with breast milk or milk powder 3 to 5 days from the birth of the baby Mother should be Persian speaker Mother must be literate at least to read and write Mother should have a wanted, single pregnancy

Exclusion criteria:
Neonates with cardio-pulmonary and neuro-muscular disorders require intubation and care at level three Infant born by IVF method or born after several years of infertility Mothers dissatisfaction with the sex of the baby Having a history of high-risk behaviors in mother or spouse (prison record, drug addiction, alcohol use) Maternal addiction to drugs and alcohol Use of antidepressants by mother Mother's education in psychology and counseling

Age
From **3 days** old to **7 days** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **54**
More than 1 sample in each individual
Number of samples in each individual: **2**
MotherAnd premature baby

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description
Two researchers who assess the attachment behaviors of mothers in both control and test groups are not aware of the goals and method of the plan. At the morning shifts, when the mother presents to the infant's bedside to feed her infant with milk or interact with her baby, They observe the attachment behaviors of the mother without the mother awareness for 15 minutes then note it on the related checklist.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Shahid Sadoughi of University of Medical Sciences

Street address
Ghadir Alley 18, Ghadir Street,Imam Street

City
Mybod

Province
Yazd

Postal code
8964155345

Approval date
2018-06-26, 1397/04/05

Ethics committee reference number
IR.SSU.REC.1397.048

Health conditions studied

1

Description of health condition studied
Mothers of preterm infants

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Attachment

Timepoint
Before the intervention, the third day and the fifth day after the intervention

Method of measurement
Observation questionnaire on maternal attachment behaviors

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: To do massage, the hands are washed in accordance with the WHO Handbook of Hygiene provided to the mothers, and after drying hands, rubbing several times to warming hands using some palm oil, massage are done (sweet almond oil is used for all samples from a commercial brand called

FADAK). Massage technique (field technique) consisted of three 5-minute steps and lasted a total of 15 minutes are applied. In the first and third stages, the baby is placed in the abdomen and massage is done as follows: 1- Upper head to neck and vice versa, 2- From neck to shoulders and vice versa, 3- From top to back and vice versa, 4- From shoulders to hand, then in reverse direction in both hands, 5- From thigh to ankle and foot then back in both legs. Massage is performed in each of the areas mentioned in 12 seconds. In the second stage, the baby is placed in an open arched position, and the inactive movements of the flexion and extension of the arms and legs separately, both legs together, in 5 stages of a minute, each containing 6 steps of 10 seconds , is done. In the test group, in addition to receiving regular care, each mother carries out massage for her baby for 24 hours, once daily for 30 to 40 minutes after lactation, when the baby is pricked for 5 days.

Category
Behavior

2

Description
Control group: In the control group, mothers and infants receive only the usual care of the department. This care includes: doctor's examination, daily baby weighing, medication, serum therapy, teaching breastfeeding to mothers, controlling the absorption and discharge of the baby, and evaluating the correct nutrition of the baby. Attachment assessment is performed on the first, third and fifth day when the mother is on the infant's bedside to feed her baby, being with or interact with her baby.

Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Sadoughi Hospital, Yazd

Full name of responsible person
Zahra kargar Shooroki

Street address
Shahid Qandi Boulevard, Avicenna St., Shahid Sadoughi Hospital

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2

Recruitment center

Name of recruitment center
Afshar Hospital in Yazd

Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yazd University of Medical Sciences

Full name of responsible person
Dr Masoud Mirzaei

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Yazd 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

Name of organization / entity
Yazd University of Medical Sciences

Full name of responsible person
Zahra Kargar Shooroki
Position
Student
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable