Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of Waimala and Field infant massage by mothers on self-esteem, maternal self-efficacy, and perceived social support in primiparous mothers of preterm infants.

Protocol summary

Study aim

Determining the effect of Vaimala and Field massage of premature infants by mothers on self-esteem, maternal competence and perceived social support in primiparous mothers

Design

A clinical trial with one control group and two intervention groups on 90 patients, using a block randomization method.

Settings and conduct

90 mothers of premature infants hospitalized in Ayatollah Rouhani Hospital in Babol will be included in the study. Mothers will be selected from the available samples and randomly divided into three groups (each group of 30): A) Control group without massage B) Field massage group C) Waimala massage group. After teaching the massage techniques to the mothers, in the intervention groups each mother will massage her infant with odorless olive oil for 5 consecutive days and daily, and for 15 minutes each day in three sessions. Then, information will be collected through questionnaires of self-esteem , maternal competence and perceived social support on the first and fifth days of the intervention

Participants/Inclusion and exclusion criteria

Inclusion criteria for mothers and infants: Mothers not employed in healthcare and medical environments, mother not addicted, mothers literate, singleton pregnancy No experience in participating in massage classes, mothers not suffering from mental illness Intrauterine age 36-28 weeks, no congenital anomalies or severe respiratory disease, no skin infections or rashes, no coagulation problems Exclusion criteria include mother's unwillingness to continue participating in the study, early discharge of the infant or death of the infant, and no massage for two consecutive days

Intervention groups

Control group without massage, field massage intervention group, and Waimala massage intervention group

Main outcome variables

maternal self-esteem, maternal competence, and perceived social support

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250707066394N1**
Registration date: **2025-08-10, 1404/05/19**
Registration timing: **registered_while_recruiting**

Last update: **2025-08-10, 1404/05/19**
Update count: **0**

Registration date

2025-08-10, 1404/05/19

Registrant information

Name

Mehri Zamzam

Name of organization / entity

Country

Iran (Islamic Republic of)

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m.zamzam@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-08-08, 1404/05/17

Expected recruitment end date

2026-08-09, 1405/05/18

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of Waimala and Field infant massage by mothers on self-esteem, maternal self-efficacy, and perceived social support in primiparous mothers of preterm infants.

Public title
Studying the effect of massage on premature infants by mothers
Purpose
Health service research
Inclusion/Exclusion criteria
Inclusion criteria:
1) Intrauterine age 36-28 weeks 2) No congenital abnormalities or severe respiratory disease 3) No infection or skin rash for infant massage 4) Infant should not have coagulation problems or any problems that may provoke bleeding
Exclusion criteria:
1) Mothers working in healthcare and medical environments 2) Mothers addicted to drugs and alcohol 3) Mothers are literate 4) Having experience in massage classes 5) Mothers suffering from mental or chronic illness based on the patient's file
Age
From **196 days** old to **252 days** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
This study is a parallel randomized controlled trial, given that not all infants and toddlers will be enrolled at the same time, and the researchers cannot predict in advance which group each infant entering the study will belong to.The three groups will be assigned using the Block Randomization method. In order to conceal the random assignment, the codes generated by the software will be placed in opaque envelopes so that it is not clear which group the next person will be placed in. Randomization is the cornerstone of a good intervention study. One of the most important biases that we face in such studies is selection bias, which can best be controlled by using randomization. With this randomization method, we can eliminate the effects of variables that play a role as confounders in examining the study objectives and we have identified these variables, and this method is also able to eliminate the effects of confounders that were not measured or identified. In this study, eligible male participants will be randomly assigned to one of three control and intervention groups in a 1:1:1 ratio in blocks of 6, after receiving informed consent, in a manner that the researcher cannot predict which intervention group the next person will be placed in. The codes will be placed in opaque envelopes, and with each new person entering, the envelope will be opened and the person's belonging to the relevant group will be determined.
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 Babol University of Medical Sciences
Street address
Zirab, Azadi St., Shahid Kamil Imani Blvd., Zirab Martyrs Hospital
City
zirab
Province
Mazandaran
Postal code
4781779718
Approval date
2025-06-30, 1404/04/09
Ethics committee reference number
IR.MUBABOL.REC.1404.089

Health conditions studied

1

Description of health condition studied
Premature babies
ICD-10 code
P07.2
ICD-10 code description
Extreme immaturity of newborn

Primary outcomes

1

Description
1- self-esteem
Timepoint

Questionnaires are given on the first and fifth days of the intervention.

Method of measurement

1-Questionnaire Rosenberg Self-Esteem Scale

2

Description

2-Gibaud-Wallston Parental Competence

Timepoint

Questionnaires are given on the first and fifth days of the intervention.

Method of measurement

2-Gibbaud-Wallston Parental Competence Questionnaire)

3

Description

3-Zimmet Perceived Social Competence Questionnaire

Timepoint

Questionnaires are given on the first and fifth days of the intervention

Method of measurement

3- Questionnaire perceived social support

Secondary outcomes

empty

Intervention groups

1

Description

.Intervention group: Vaimala massage: Various pressure and movements are used on the soft tissues of the body and help reduce pain, relieve muscle tension, and calm the mind. 2) Vaimala technique: The massage is performed in two phases for 15 minutes as follows: Phase 1: In the supine position. 1) Face: From the forehead to the sides of the face. Then in front of the ears and jaw with circular movements. 2) Chest: From the center of the chest outward along the ribs and then in the reverse direction. 3) Arms and hands: From the shoulder to the wrist and fingers on both hands with circular movements (Indian milking). 4) Abdomen: (I Love You method) From the upper left side of the abdomen (under the ribs) downwards, from the right side and lower abdomen upwards and then across the abdomen to the left and then repeat the first stage, continuously. 5) Legs: From the thighs to the knees and calves on both legs (Indian milking). The second phase in the prone position: The hands move perpendicular to the spine, from the waist to the neck and vice versa. The movement of the hands is with medium pressure while the baby's body is smeared with olive oil. Each mother will massage her baby with odorless olive oil for 5 consecutive days, daily, and for 15 minutes each day, three times. The olive oil used for all samples will be from Utab Teb Company. After teaching the massage techniques to the mothers, in the intervention groups, each mother will massage her baby with unscented olive oil for 5 consecutive days, daily, for 15 minutes three times a day. Then, data will be collected through questionnaires of self-esteem (Rosenberg), maternal competence (Gibaud-Wallston), and perceived social support (Zimt) on the first and fifth days of the intervention

Category

Treatment - Other

2

Description

Two-field intervention group: This technique, based on pressure contacts and stretching movements, has several effects on the mother's mental health. 2) Vaimala technique: Massage is performed in two phases for 15 minutes as follows: First phase in the supine position: 1) Face: From the forehead to the sides of the face. Then in front of the ears and jaw with circular movements. 2) Chest: From the center of the chest outward along the ribs and then in the reverse direction. 3) Arms and hands: From the shoulder to the wrist and fingers on both hands with circular movements (Indian milking). 4) Abdomen: (I Love You method) From the upper left side of the abdomen (under the ribs) downwards, from the right side and lower abdomen upwards and then across the abdomen to the left and then repeat the first stage continuously. 5) Legs: From the thighs to the knees and calves on both legs (Indian milking). The second phase in the prone position: The hands move perpendicular to the spine, from the waist to the neck and vice versa. The movement of the hands is with medium pressure while the baby's body is smeared with olive oil. Each mother will massage her baby with odorless olive oil for 5 consecutive days, daily, and for 15 minutes each day, three times. The olive oil used for all samples will be from Utab Teb Company. After teaching the massage techniques to the mothers, in the intervention groups, each mother will massage her baby with unscented olive oil for 5 consecutive days, daily, for 15 minutes three times a day. Then, data will be collected through questionnaires of self-esteem (Rosenberg), maternal competence (Gibaud-Wallston), and perceived social support (Zimt) on the first and fifth days of the intervention.

Category

Treatment - Other

3

Description

Control group: Control group: A control group in which no intervention is performed.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Babol Rohani Hospital

Full name of responsible person
Dr. Parvin Aziznejad Roshan
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Babol University of Medical Sciences, Faculty of Nursing and Midwifery, Department of Pediatric Nursing and Health
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
dokter ghdimi
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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
Babol 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
Babol University of Medical Sciences
Full name of responsible person
Dr. Parvin Aziznejad Roshan
Position
PhD in Nursing and Faculty Member and Associate Professor of the Nursing Department
Latest degree
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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

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available