Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the impact of educate mothers, auriculotherapy on mothers and infant's massage by mothers on mother's anxiety symptoms in preterm labour

Protocol summary

Study aim

The birth of every infant is a challenging, and sometimes stressful, point in the life of the mother and the family. Now, if some pregnancy complications occur, such as early delivery and the birth of a premature baby, conditions for parents and especially the mother will be more anxious. Concerns about how to care for a premature baby and, finally, the health condition of the baby causes these conditions. The purpose of this research is to apply and test solutions that can be used to reduce the anxiety of mothers and increase self-esteem and self-efficacy and improve the quality of care for premature infants.

Design

Clinical trial with control group, with parallel groups, blind and randomized, and random sampling with estimated sample size of 96 people.

Settings and conduct

Participants and analyst are blind about study and intervention groups. The place of research is in Bahar Hospital, Shahroud

Participants/Inclusion and exclusion criteria

The inclusion criteria was satisfaction of mothers to participate in the research, the ability to speak Persian, reading and writing skills, ages 18 to 35, lack of mental or physical illness or mental problems that require the intervention of a third person in caring It is related to the baby, the baby in the age range of 28 weeks to 36 weeks is able to breastfeed from the breast or stomach. Exclusion criteria include the baby's malaise and maternal cessation, the death of the baby, and the mother's reluctance to continue caring.

Intervention groups

Interventions include the training of appropriate information in the care of premature infants, effective acupressure techniques to reduce anxiety and make skin contact with the baby through touch and massage. The control group has no intervention until the end of the sampling

Main outcome variables

Measurement of maternal anxiety with standard, valid and reliable questionnaire

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180108038265N2**
Registration date: **2018-10-08, 1397/07/16**
Registration timing: **registered_while_recruiting**

Last update: **2018-10-08, 1397/07/16**
Update count: **0**

Registration date

2018-10-08, 1397/07/16

Registrant information

Name

Niloofar Rabiee

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-02, 1397/07/10

Expected recruitment end date

2019-03-01, 1397/12/10

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

Scientific title
Comparison of the impact of educate mothers, auriculotherapy on mothers and infant's massage by mothers on mother's anxiety symptoms in preterm labour

Public title
Comparison of the impact of educate mothers, auriculotherapy on mothers and infant's massage by mothers on mother's anxiety symptoms in preterm labour
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Mothers' satisfaction and cooperation to participate in research Ability to speak Persian and have reading and writing skills Age 18 to 35 years old The infant is in the range of 28 weeks to 36 weeks. There is the possibility of breastfeeding from the breast or ng tube
Exclusion criteria:
Having a specific mental or physical illness or problem that requires the involvement of a third person in the care of the baby Newborn sickness and maternal cessation of care Infant death Mother's dissatisfaction with continued caring
Age
From **18 years** old to **35 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **96**
Randomization (investigator's opinion)
Randomized
Randomization description
At first, the blocks are set to eight, they are divided into intervention and control groups according to the design blocks. The random allocation sequence is determined by the statistics expert by the software. The intervener puts each assignment in a white sealed envelope and numbers them. Eligible applicants will be registered by the intervener in order of entry into the study and receive the code. Before receiving the intervention, the basic questionnaires are filled in. Then for each individual, according to his code, an envelope is opened and the person to be assigned to the specified group.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, the mothers participating in the study, the person who assesses the outcomes, and Statistics Consultant are blind to the intervention and control groups.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahroud University of Medical Sciences
Street address
7 Tir Square, Shahroud
City
Shahroud
Province
Semnan
Postal code
36147-73947
Approval date
2018-08-28, 1397/06/06
Ethics committee reference number
IR.SHMU.REC.1397.122

Health conditions studied

1

Description of health condition studied
Mother's anxiety
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Mother's anxiety
Timepoint
Before intervention, immediately after the intervention and before discharge from the NICU
Method of measurement
This result will be measured using the standard, valid and reliable questionnaire of Spilberger's apparent and hidden anxiety, which includes 20 questions about apparent anxiety and 20 questions about hidden anxiety that questions with Likert scale rating with very few options, Low, high and very high scores. Each of the options in the direct statements are in the order of points

1 to 4 and in reverse expressions, respectively, are points 4 to 1. The total score of the questionnaire is between 20 and 80.

Secondary outcomes

empty

Intervention groups

1

Description

First Intervention group: is the mothers' education group. In this group, the mothers are related to the cause of the newborn's condition, strategies for coping with the infection, how to change the position of the premature baby, how to breast feed through breast or ng tube, maintaining the temperature, how to feed and keep milk, how to bathe And changing the nappies, disinfecting hands, and the like in the earliest possible time after the baby is admitted to the NICU, and become steady in the condition of the mother and the baby. Data were collected at two periods of time, 24 hours after admission to the NICU, before the start of the training session (as a preliminary test), second time (post test 1) after the intervention, and the third load (post test 2), at the time of discharge of the infant The intensive care unit will be assessed and compared using the relevant tool.

Category

Other

2

Description

second Intervention group:The mother's massage group is the mother. Massage therapy will begin at the first time after the admission of a newborn in NICU and the condition of the baby will be physically and physically and mentally prepared for the baby, and will continue for 5 consecutive days and every 5 minutes. The first massage is done one hour after the morning feeding, the second half hour after the middle day and the third time 45 minutes after the second turn is completed. Each massage session will include 5 minutes of stimulation. To massage the baby into the abdomen (prone mode).The mother will warm her hands and be quiet and quiet during the work. Massage is done slowly and with the soles of the fingers. Massage is divided into five sections of one minute and each section divided into six episodes of ten seconds. The first part involves massage from the top of the head to the back of the neck and again from the back of the neck to the top of the head. Part II and III massage from the back of the neck to the shoulders and from the shoulders to the back of the neck. Part IV, massage from the back of the shoulders to the buttocks and back from the buttocks to the shoulders, but the contact with the beads is avoided.The fifth part involves simultaneous massage in two legs from the pelvic floor to the sole of the foot and backward from the bottom up. The sixth part involves both hands simultaneously from the shoulders to the wrists and back to the top. In fact, the steps of each massage cycle take five minutes, including five times a one minute massage, 10 seconds of head and neck massage, 20 seconds of shoulder massage, 20 seconds of back massage and 10 seconds massage of both legs. Data were collected at two time intervals, the first time before the beginning of massage sessions (as pretest) and the second time (as posttest 1) after the end of massage sessions and for the third time at the time of discharge of the baby (as a post-test 2) The ICT will be compared and evaluated using the relevant tools.

Category

Other

3

Description

Third Intervention group: is acupressure (uriculotherapy) that takes place on the mother. The onset of intervention will be after the baby's and mother's status. The points used in both the left and right ears are symmetric and include the points of "Sunnan, muscle relaxation and tension point and anxiety point". The researcher, using a pointer, first intersperses these points in the right ear in circular motion, pressing for 60 seconds for each point (4 cycles for 4 minutes each). Then the same thing will be done in the other ear. This intervention will be carried out 12 times (twice a day). The data are measured at two time points, the first time before the intervention (as a pre test) and the second time (post test 1), after the intervention, and the third load (post test 2) at the time of discharge of the baby with the relevant tools.

Category

Other

4

Description

Control group: The only group was to check the absence of interventions and compare them with intervention groups. For these mothers, after the completion of the sampling, the training sessions will be similar to group 1.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Bahar hospital

Full name of responsible person

Nahid Bolbol haghighi

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahroud University of Medical Sciences
Full name of responsible person
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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
Shahroud 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
Shahroud University of Medical Sciences
Full name of responsible person
Niloufar rabiee
Position
Student
Latest degree
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Other areas of specialty/work
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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
Not applicable

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

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

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

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