Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jun 2026

Effectiveness of Premature Infant Oromotor Intervention by mother on the situation of mood in mothers of premature infants

Protocol summary

Study aim

We measure the effect of oral movement intervention of premature babies by the mother on their mood.

Design

The clinical trial has a control group, with parallel groups of a blind strain and is performed on 74 patients. Two hospitals are chosen by lottery for control and intervention groups.

Settings and conduct

Mothers of premature babies who meet the inclusion criteria fill out the questionnaire at the beginning of the study and 10 days later in the neonatal intensive care unit at Al-Zahra and 17 Shahrivar Hospitals in Rasht. In the intervention group, the intervention will be done by the mothers.

Participants/Inclusion and exclusion criteria

Entry criteria for mothers: 1) Not having a history of infertility-Uncomplicated pregnancy-Desire of pregnancy-No history of physical and mental illness- No addiction-The absence of accidents during the past three months (according to the participant's statement) Exit criteria: Mother's unwillingness to continue participating in the study_Early discharge of the baby with the personal consent of the parents_Transferring the baby to another treatment center_Not having the ability to intervene_incompleteness of 20% of the completed information of the forms

Intervention groups

Premature infant oromotor intervention is performed in premature babies to strengthen sucking and swallowing. which is done by the mother in the intervention group, and in the control group it is done by a nurse or speech therapist according to the ward routine.

Main outcome variables

Improving the mood of mothers Increasing participation of mothers in care

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230423057977N1**
Registration date: **2023-06-20, 1402/03/30**
Registration timing: **prospective**

Last update: **2023-06-20, 1402/03/30**
Update count: **0**

Registration date

2023-06-20, 1402/03/30

Registrant information

Name

sahar Hosseinzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-22, 1402/04/01

Expected recruitment end date

2023-09-22, 1402/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of Premature Infant Oromotor Intervention by mother on the situation of mood in mothers of premature infants

Public title
The effect of premature infant oral motor intervention by the mother on mothers' mood
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
For mothers, entry conditions include: no history of infertility Uncomplicated pregnancy Desire to be pregnant No history of physical and mental illness No addiction Lack of accidents during the last three months (according to the participant) The conditions for the inclusion of infants in the study include: 1) infants with a gestational age of 29-34 weeks, 2) having physiological stability and no stress symptoms at the time of stimulation, 3) without cleft palate, cleft lip, and temperament abnormalities, 4) infants with an Apgar score of 5 or more than 7
Exclusion criteria:
Mother's unwillingness to continue participating in the study Early discharge of the baby with the personal consent of the parents Transferring the baby to another treatment center Not having the ability to intervene Incompleteness of 20% of the completed information of the forms The conditions for the exclusion of infants from the study: 1) sepsis 2) heart disease 3) necrotizing enterocolitis 4) grade 3 and 4 intraventricular hemorrhage (according to sonography that is routinely performed in the first week) 5) severe asphyxia
Age
No age limit
Gender
Female

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **74**
Randomization (investigator's opinion)
Randomized
Randomization description
Two hospitals of Al-Zahra and 17 of Shahrivar were selected by lottery to collect samples for the control and intervention groups.
Blinding (investigator's opinion)
Single blinded
Blinding description
In order to prevent the exchange of information between the mothers of the two control and intervention groups, from the two hospitals of 17 Shahrivar and Al-Zahra Rasht, one control group and the other intervention group will be collected by lottery. The intervention group is selected from 17 Shahrivar Hospital in Rasht and the control group is selected from Al-Zahra Hospital.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Working Group / Ethics Committee in Research Faculty of Nursing, Midwifery and Rehabilitation Facult
Street address
Dr. Mirkhani St (East Nusrat), Tawheed Square
City
Tehran
Province
Tehran
Postal code
1419733171
Approval date
2023-04-16, 1402/01/27
Ethics committee reference number
IR.TUMS.FNM.REC.1402.002

Health conditions studied

1

Description of health condition studied
Mood
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Mood score in POMS standard questionnaire
Timepoint
Measuring the mood score at the beginning of the study (before the intervention) and 10 days after the intervention
Method of measurement
Standard Mood Questionnaire (POMS)

Secondary outcomes

1

Description
Participation
Timepoint
The questionnaire will be filled at the beginning of the study and 10 days later.

Method of measurement
Questionnaire POMS

Intervention groups

1

Description
Intervention group: The mood questionnaire will be filled in at the beginning of the study by the mother, who both herself and her baby meet the inclusion criteria. And oral motor intervention of the premature baby is taught to the mother by the researcher on the doll and educational videos. Then, after appropriate feedback, this intervention will be performed by the mother on her baby under the supervision of the researcher and speech therapy for 10 days. And the mood questionnaire will be completed again by the mother after 10 days of intervention.
Category
Rehabilitation

2

Description
Control group: The mood questionnaire will be completed at the beginning of the study by mothers who both themselves and their babies meet the entry criteria. And 10 days later, this questionnaire is filled again by mothers. During these 10 days, the baby will be cared for according to the department's routine.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Zahra Hospital
Full name of responsible person
Sahar Hosseinzadeh
Street address
Al-Zahra Hospital, Namjoo Blvd
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2

Recruitment center
Name of recruitment center
17 Shahrivar hospital
Full name of responsible person
Sahar hosseinzadeh
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17Shahrivar hospital, Shahid siadati Blvd, Namjoo Blvd
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Akbar fotoohi
Street address
Tawheed Square, Dr. Mirkhani St. (East Nusrat).
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fnm@tums.ac.ir
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
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

Tehran University of Medical Sciences

Full name of responsible person
Sahar Hosseinzadeh

Position
Master's student of neonatal special care nursing

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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NICU, Dr Pirooz hospital, Keshavarz Blvd

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Position
MSC student of neonatal intensive care nursing

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Person responsible for updating data

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Master's student neonatal intensive care nursing

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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
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
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