

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

Effect of PIOMI combined with music therapy on feeding progression of premature infants

Protocol summary

Study aim

To investigate the combined effect of music therapy and PIOMI on the feeding progression of preterm infants of 26 to 30 gestational age

Design

A clinical trial with a control group, parallel, blinded, randomized groups on 58 premature infants

Settings and conduct

The intervention is performed individually, once a day for 10 days. In the intervention group, 5 minutes of PIOMI and 10 minutes of Mozart music are performed daily, and in the control group, only 5 minutes of PIOMI is presented. In the final stage of PIOMI (non-nutritive sucking lasting 2 minutes), Mozart's music is played and continues for another 8 minutes. The music is played by a disinfected speaker inside the incubator at distance of 30 cm from the infants' ear with a intensity of 45 dB. Before, during, and after the stimulation, the researcher monitors vital signs using a monitor, and if any symptoms of infant intolerance occurs through the number of breath, facial expressions, and gestures, the stimuli stop. Assessments are performed by a nurse.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1.gestational age between 26 and 30 weeks at birth 2.physiological stability and lack of stress symptoms with stimulation 3. Apgar score 7 and above in 5 minutes after birth 4. Parental consent 5. Infants without congenital anomalies 6. Infants without any chronic medical problems such as asphyxia or fetal distress at birth, ... 7. Failure to get gavage before the end of the 30th week of gestational age. Exclusion criteria: Parents refuse to continue or transfer to other centers

Intervention groups

In the intervention group, 5 minutes of PIOMI and 10 minutes of Mozart-music and in the control group 5 minutes of PIOMI are presented

Main outcome variables

Gestational age Weight Oral feeding Average weight gain

Hospitalization days in the NICU

General information

Reason for update

Acronym

PIOMI

IRCT registration information

IRCT registration number: **IRCT20210502051155N1**

Registration date: **2021-09-18, 1400/06/27**

Registration timing: **registered_while_recruiting**

Last update: **2021-09-18, 1400/06/27**

Update count: **0**

Registration date

2021-09-18, 1400/06/27

Registrant information

Name

Elmira Shokri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-06, 1400/05/15

Expected recruitment end date

2021-10-07, 1400/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of PIOMI combined with music therapy on feeding progression of premature infants

Public title

Effect of PIOMI combined with music therapy on feeding of premature infants

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Post-menstrual age between 26 and 30 weeks at birth
Physiological stability and lack of stress symptoms when presenting stimuli Apgar score 7 and above in 5 minutes after birth
Obtaining written consent from parents in order to participate in the research
Absence of any congenital anomalies and chronic medical problems such as asphyxia , neonatal seizures, grade 3 and 4 intraventricular hemorrhage, necrotizing enterocolitis, bronchopulmonary dysplasia, jaundice, and hearing loss.
Infants who have started gavage feeding by the end of the 30th week of pregnancy.

Exclusion criteria:

Parental disapproval or transfer to other health center

Age

From **182 days** old to **210 days** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **58**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation will be done based on the sequence created by the computer or using the site, the second step is to hide the random allocation, which is done using opaque and sealed envelopes, and Sequences will be recorded on the cards. At the time of registration, the envelopes are opened according to the order of entry of the envelopes and the allocation group is determined. People who are in random allocation and the person who assigns participants will be different.

Blinding (investigator's opinion)

Single blinded

Blinding description

The intervention is presented by the researcher and the outcome assessment is performed by a trained nurse using the POFRAS index.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of university of social welfare and rehabilitation sciences

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University of social welfare and rehabilitation science, Kodakyar Ave., Daneshjo Blvd.,Evin,,Tehran,Iran

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Approval date

2021-07-17, 1400/04/26

Ethics committee reference number

IR.USWR.REC.1400.106

Health conditions studied**1****Description of health condition studied**

preterm infants

ICD-10 code

P92.9

ICD-10 code description

Feeding problem of newborn, unspecified

Primary outcomes**1****Description**

Feeding progression

Timepoint

Before the intervention and day 5 and 10 of the intervention

Method of measurement

Preterm Oral Feeding Readiness Assessment Scale(POFRAS)

Secondary outcomes**1****Description**

days of NICU hospitalization

Timepoint

daily

Method of measurement

Counting the days

2

Description

Average weight gain

Timepoint

daily

Method of measurement

scale-gramme

3

Description

weight

Timepoint

daily

Method of measurement

scale-gramme

4

Description

gestational age

Timepoint

daily

Method of measurement

Number of days

Intervention groups

1

Description

Intervention group: 5 minutes daily intervention of motor-oral intervention of preterm infants PIOMI and 10 minutes of presentation of Mozart music. It has 8 steps as follows: cheek stretch, lip roll, lip stretch, gum massage, lateral border of tongue and cheek, middle of tongue and palate, elicit a suck, support for non-nutritive sucking. The intervention is presented by a trained researcher and before stimulation, the hands are washed with disinfectant liquid and latex gloves are used. explanations about the intervention methods are provided to the parents and written consent is obtained from them. Personal and medical information, age and birth weight are recorded in the NICU based on the NICU file or by asking parents questions. The baby's daily weight is measured by a nurse on a scale and recorded on a daily information form. Stimulation takes place inside the incubator without leaving the infant. The intervention is performed individually, once a day for 10 days. If infants have physiological stability and did not show symptoms such as skin discoloration, slow heart rate, respiratory arrest, and stress symptoms (assessed by the POFRAS scale) we start intervention. The diagnosis is made by a pediatrician about the onset of oral feeding and how many times a day. Oral nutrition in this study means bottle feeding or breastfeeding and the criterion for achieving independent oral nutrition is eight oral feedings per day. In the final stage of PIOMI intervention, non-nutritional sucking (which lasts for 2 minutes), Mozart's music is played and lasts for another 8 minutes, with a final presentation of 10 minutes. The music is played by a disinfected speaker inside the

incubator at a distance of 30 cm from the baby's ear with a intensity of 45dB. During interventions, ambient temperature and noise are kept constant, and doors are closed to minimize noise. Before, during, and after the stimulation is presented to the infant, the researcher monitors vital signs using a monitor, and if any symptoms of infant intolerance occur through the number of breaths, facial expressions, and gestures, the stimuli are stopped immediately. Technique: 1. Cheek C stretch: One finger in the cheek and one outside cheek. Slide and stretch tissue front to back toward the ear, & back to front. Move slowly. Do both cheeks twice. 2. Lip roll: Gently roll the lip between your thumb and finger (like rolling a pea). Roll both sides of upper lip once. Roll both sides of lower lip once. 3. Lip curl or lip stretch: Compress lip between thumb and finger, and curl downward. Curl both sides of upper lip once, and both sides of lower lip once. If lip is too small to grip for the curl, do the Lip Stretch: Lay finger across upper lip, gently compress and stretch side to side. Repeat on lower lip. 4. Gum massage: Use finger to put gentle pressure on outside of upper gum. Move finger slowly around upper gum to other side of mouth. (Be sure to touch outer gum surface, not biting surface.) Repeat on lower gum. 5. Lateral border of tongue/cheeks: Put finger beside tongue and push to the middle. Then move finger back into cheek, stretching it. Repeat on the other side of tongue/cheek. 6. Midblade of tongue/palate: Use finger to put pressure on roof of mouth for 3 seconds. Move finger down to tongue and gently press tongue down. Move finger back up to hard palate. Repeat these movements twice. 7. Elicit a suck: Put finger or pacifier on tongue and gently stroke to allow sucking. 8. Support for non nutritive sucking: Allow sucking on finger or pacifier for 2 minutes.

Category

Rehabilitation

2

Description

Control group: 5 minutes of PIOMI intervention is provided. It has 8 steps as follows: cheek stretch, lip roll, lip stretch, gum massage, lateral border of tongue and cheek, middle of tongue and palate, elicit a suck, support for non-nutritive sucking. The intervention is presented by a trained researcher and before stimulation, the hands are washed with disinfectant liquid and latex gloves are used. explanations about the intervention methods are provided to the parents and written consent is obtained from them. Personal and medical information, age and birth weight are recorded in the NICU based on the NICU file or by asking parents questions. The baby's daily weight is measured by a nurse on a scale and recorded on a daily information form. Stimulation takes place inside the incubator without leaving the infant. The intervention is performed individually, once a day for 10 days. If infants have physiological stability and did not show symptoms such as skin discoloration, slow heart rate, respiratory arrest, and stress symptoms (assessed by the POFRAS scale) we start intervention. The diagnosis is made by a pediatrician about the onset of oral feeding and how many times a day. Oral nutrition in this study means bottle feeding or breastfeeding and the

criterion for achieving independent oral nutrition is eight oral feedings per day.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam khomeini hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

University of social welfare and rehabilitation 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

University of social welfare and rehabilitation sciences

Full name of responsible person

Elmira Shokri

Position

Master student

Latest degree

Bachelor

Other areas of specialty/work

Speech therapy

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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

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

Title and more details about the data/document

There is no more information

When the data will become available and for how long

There is no more information

To whom data/document is available

There is no more information

Under which criteria data/document could be used

There is no more information

From where data/document is obtainable

There is no more information

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

There is no more information

Comments