

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

Comparison of the effectiveness of oral and motor-intervention with multisensory stimulation in nutritive sucking in premature infants admitted to the neonatal intensive care unit: RCT

Protocol summary

Study aim

Comparison of the effectiveness of oral motor intervention in preterm infants and its combined methods with multisensory stimulation in nutritional sucking in preterm infants admitted to the intensive care unit

Design

Clinical trial, with control group, with parallel groups, one-way blind, randomized, on 90 patients

Settings and conduct

Neonatal Intensive Care Unit

Participants/Inclusion and exclusion criteria

Inclusion criteria for preterm infants in this study include: Fetal age between 28 to 34 weeks, birth weight between 1000 and 2000 grams Receiving tube feeding, physiological stability, absence of congenital anomalies, absence of genetic syndromes, absence of neonatal obstruction, absence of untreated blood infection, absence, presence of pink cranial malformations, absence of untreated respiratory disease Exclusion criteria of this study include: Physiological instability at the beginning and during interventions of nutritional stimuli, infant death

Intervention groups

Intervention group: Combined methods (PIOMI with multisensory stimulation) For this group, in addition to performing oral movement therapy in premature infants, multisensory stimulation will also be performed. In this way, for 5 days a week, multi-sensory stimulation, which includes auditory stimulation, tactile stimulation, visual stimulation and vestibular stimulation, will be performed for 12 minutes. Touch stimulation by massaging the baby's limbs for 3 minutes, auditory stimulation By playing a lullaby in the incubator for 3 minutes, visual stimulation by hanging black and white cards inside the incubator for 3 minutes and vestibular stimulation by vertical and horizontal shaking of the baby for 3 minutes.

Main outcome variables

Determining the effectiveness of combination therapies on oral nutrition in premature infants

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211215053422N1**

Registration date: **2021-12-25, 1400/10/04**

Registration timing: **registered_while_recruiting**

Last update: **2021-12-25, 1400/10/04**

Update count: **0**

Registration date

2021-12-25, 1400/10/04

Registrant information

Name

Sara Abedini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5250 3788

Email address

abedini.s@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-22, 1400/10/01

Expected recruitment end date

2022-02-20, 1400/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of oral and motor-intervention with multisensory stimulation in nutritive sucking in premature infants admitted to the neonatal intensive care unit: RCT

Public title

Comparison of the effectiveness of oral and motor-intervention with multisensory stimulation in nutritive sucking in premature infants admitted to the neonatal intensive care unit: RCT

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

The inclusion of premature infants in this study includes gestational age between 28 and 34 weeks Birth weight between 1000 and 2000 grams Tube feeding Physiological stability at the onset of nutritional stimulation Absence of congenital anomalies Absence of genetic syndromes Absence of oppression in infancy Absence of untreated blood infection Absence of craniofacial deformities Absence of untreated respiratory disease

Exclusion criteria:

Exclusion criteria of this study include: Physiological instability at the beginning and during nutritional stimulation interventions Infant death

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: 90

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization: Individuals are divided into two groups completely randomly based on the method of 4 random blocks. The site at sealedenvelope.com is used for randomization. If we call two groups A and B. The logic of randomization is that from 6 blocks BAAB, BBAA, ABBA, ABAB, AABB and BABA, we select enough samples by placement (ie $n / 4$) to get the sample size.

Blinding (investigator's opinion)

Single blinded

Blinding description

Blinding: The patient has no knowledge of how to be in

groups. Only those who do the intervention know how patients are grouped. The rest of the people involved in the study have no knowledge of the assignment of individuals to groups. People who do the job of measuring response variables are different from people who do the job of intervention.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Ahwaz Jundishapur University of Medical Sciences

Street address

Golestan Highway, Student Dormitory of the Sisters of the Revolution

City

Ahwaz

Province

Khouzestan

Postal code

6135815751

Approval date

2021-12-11, 1400/09/20

Ethics committee reference number

IR.AJUMS.REC.1400.563

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

Premature Infants

ICD-10 code

R63.3

ICD-10 code description

Feeding difficulties

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

Fetal age, time of transition from tube feeding to independent oral feeding, feeding progress (oral recovery interval), mean weight gain, feeding efficiency (oral volume), type of intervention, POFRAS test score, duration of neonatal hospitalization

Timepoint

The beginning of the intervention and the end of the intervention

Method of measurement

Premature Oral Feeding Readiness Scale

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Combined methods (PIOMI with multisensory stimulation) For this group, in addition to performing Premature Infant Oral Motor Intervention (PIOMI), multisensory stimulation will also be performed. Thus, daily and for 5 days a week, multisensory stimulation, which includes auditory stimulation, tactile stimulation, visual stimulation, and vestibular stimulation, will be performed for 12 minutes. Touch stimulation by massaging the baby's limbs for 3 minutes, auditory stimulation By playing the lullaby in the incubator for 3 minutes, visual stimulation by hanging black and white cards inside the incubator for 3 minutes, and vestibular stimulation by vertical and horizontal shaking of the baby for 3 minutes. In this group, the treatments will be performed by the researcher in order, so that first the multisensory treatment is performed and then the PIOMI method. The mother or the nurse of the baby are not involved in the intervention and are unaware of all the treatments received.

Category

Treatment - Other

2**Description**

Control group: receiving Premature Infant Oral Motor Intervention (PIOMI) This treatment consists of 8 steps: 1. C-shaped stimulation or traction of the cheek 2. Rolling the lips 3. Lip curl Or Lip stretch 4. Gum massage 5. Lateral wall of tongue / cheek 6. The middle blade of the tongue / palate 7. Extract a suction 8. Support for non-nutritional sucking.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Khomeini Hoapital

Full name of responsible person

Dr. Majid Soltani

Street address

Imam Khomeini Medical Center of Ahvaz, Azadegan Ave, Ahwaz

City

Ahwaz

Province

Khouzestan

Postal code

6193673111

Phone

+98 61 3222 2922

Email

s.abedini.slp@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Dr. Ali Ahmadi Moghadam

Street address

Ahvaz University City, Vice Chancellor for Research and Technology Ahvaz Jundishapur University of Medical Sciences and Health Services, Ground Floor

City

Ahwaz

Province

Khouzestan

Postal code

6135715794

Phone

+98 61 3336 2414

Email

itc@ajums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Ahvaz 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**

Ahvaz University of Medical Sciences

Full name of responsible person

Majid Soltani

Position

Associate Professor of Speech Therapy

Latest degree

Ph.D.

Other areas of specialty/work

Speech therapy

Street address

Ahvaz Jundishapur University of Medical Sciences,
Golestan Blvd ,Ahwaz, Iran

City

Ahwaz

Province

Khouzestan

Postal code

61375-15794

Phone

+98 61 3311 0000

Email

info@ajums.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Majid Soltani

Position

Associate Professor of Speech Therapy

Latest degree

Ph.D.

Other areas of specialty/work

Speech therapy

Street address

Ahvaz Jundishapur University of Medical Sciences,
Golestan Blvd ,Ahwaz, Iran

City

Ahwaz

Province

Khouzestan

Postal code

61375-15794

Phone

+98 61 3311 0000

Email

info@ajums.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Majid Soltani

Position

Associate Professor of Speech Therapy

Latest degree

Ph.D.

Other areas of specialty/work

Speech therapy

Street address

Ahvaz Jundishapur University of Medical Sciences,
Golestan Blvd ,Ahwaz, Iran

City

Ahwaz

Province

Khouzestan

Postal code

61375-15794

Phone

+98 61 3311 0000

Email

info@ajums.ac.ir

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

No - There is not 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

No - There is not a plan to make this available