

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jul 2026

### Comparative Study of the Effect of Oral Stimulation and Non-Oral Stimulation Intervention in Premature Infant on start time, the Time of Independent Oral Nutrition, Weight Gain and length of stay in hospital

#### Protocol summary

##### Study aim

Comparison of the effect of oral and non-oral intervention of preterm infants on the time of achieving independent oral feeding, weight gain and time of hospital discharge

##### Design

This study is a RCT. The study population was premature infants aged 28-32 weeks. The method of selecting the subjects after applying the entry and exit criteria is random allocation. The personal and medical information of the subjects is recorded in the prepared questionnaire based on the medical records available in the neonatal intensive care unit and by asking questions from the parents.

##### Settings and conduct

This study is performed in NICU of Om Al-Banin Hospital.

##### Participants/Inclusion and exclusion criteria

1. Be born between 28-32 weeks of gestation. 2. Receive nutrition through the tube 3. Their birth weight is between 1000-2000 grams 4. Have physiological stability (stability in spo<sub>2</sub>, Hr, RR) at the beginning of nutritional stimuli. 5. Oral irritation and the onset of feeding in these infants do not alter the autonomic system [skin color, heart rate, or respiration rate]. 6. Apgar score above 6 in 5 minutes 7. Newborns without congenital anomalies and obvious chromosomal abnormalities 8. No oral lesions such as candidiasis 9. No lip and mouth abnormalities such as cleft lip and palate

##### Intervention groups

Oral stimulation group with the method: PIOMI. The non-oral stimulation group with FIELD technique is another group that will be performed by field massage every day. Control Group: Will receive NICU Routine Care.

##### Main outcome variables

The timing of the onset of oral feeding and reach 8 independent oral feedings in infants in the intervention and control groups will be assessed. The weight of the

newborns and age of hospital discharge will be assessed on a daily basis and the average will be compared in the intervention and control groups

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210224050479N1**

Registration date: **2021-03-03, 1399/12/13**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-03-03, 1399/12/13**

Update count: **0**

##### Registration date

2021-03-03, 1399/12/13

##### Registrant information

##### Name

najme zabihi torbati

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3605 9029

##### Email address

zabihitn1@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-02-28, 1399/12/10

##### Expected recruitment end date

2021-08-01, 1400/05/10

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparative Study of the Effect of Oral Stimulation and Non-Oral Stimulation Intervention in Premature Infant on start time, the Time of Independent Oral Nutrition, Weight Gain and length of stay in hospital

**Public title**

Comparative Study of the Effect of Oral Stimulation and Non-Oral Stimulation Intervention in Premature Infant on start time, the Time of Independent Oral Nutrition, Weight Gain and length of stay in hospital

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

1. Be born between 28 and 32 weeks of gestation.2. Receive nutrition through the tube3. Their birth weight is between 1000-2000 grams4. Have physiological stability (stability in spo<sub>2</sub>, Hr, RR) at the beginning of nutritional stimulation.5. Oral stimulation and the onset of feeding in these infants do not alter the autonomic system [skin color, heart rate, or respiration rate].6. Apgar score above 6 in 5 minutes7. Newborns without congenital anomalies and obvious chromosomal abnormalities8. No oral lesions such as candidiasis9. No lip and mouth abnormalities such as cleft lip and palate

**Exclusion criteria:**

1. NPO of the baby in case of symptoms such as fever, respiratory distress, muscle stiffness, frequent vomiting for one day and more2. Diagnosis of cases such as intraventricular hemorrhage, necrotizing enterocolitis, open arterial duct, sepsis, acute lung disease or severe anemia by a physician during the days of interventions3. The need for surgery during the days of interventions4. Transfer the baby to other centers5. Infant death6. Lack of cooperation of the mother in performing the interventions7. Maternal addiction8. Physiological instability (spo<sub>2</sub>, Hr, RR) during a day and night so that he can not receive one pumice massage or two field massage.

**Age**

No age limit

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Data analyser

**Sample size**

Target sample size: 90

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

It was used to allocate infants to intervention and control groups by random block method with a volume of 3

(numbers 1 to 90) according to the lottery in closed envelopes. Random block sampling is a method of randomization that ensures that at almost every point in a study, an almost equal number of participants are assigned to all comparison groups.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

The analyst will be unaware of the intervention and control groups.

**Placebo**

Not used

**Assignment**

Other

**Other design features****Secondary Ids**

empty

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

Ethics Committee of Mashhad University of Medical Sciences

**Street address**

Doktora Crossroads-School of Nursing and Midwifery

**City**

mashhad

**Province**

Razavi Khorasan

**Postal code**

91778-99191

**Approval date**

2021-01-28, 1399/11/09

**Ethics committee reference number**

IR.MUMS.NURSE.REC.1399.081

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

The study is about premature infants and the importance of achieving independent oral nutrition and weight gain.

**ICD-10 code**

p07

**ICD-10 code description**

اختلالانی که به کوتاه بودن دوران حاملگی یا وزن کم زمان تولد مربوط باشد

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

The timing of the onset of oral feeding in infants in the intervention and control groups will be assessed.

**Timepoint**

When to start oral feeding for the first time

#### **Method of measurement**

Record the age of the infant at the time of starting oral feeding in a questionnaire

## **2**

#### **Description**

The time of reach to independent oral feedings in the infants of the intervention and control groups will be evaluated.

#### **Timepoint**

Time to reach 8 times independent oral feeding

#### **Method of measurement**

Record the age of the infant at the time of reaching 8 times of independent oral feeding in a questionnaire

## **Secondary outcomes**

## **1**

#### **Description**

The weight of the newborns will be assessed on a daily basis and the average will be compared in the intervention and control groups.

#### **Timepoint**

The weight during the study on a daily

#### **Method of measurement**

Weight will measure with scales

## **2**

#### **Description**

The age of hospital discharge in infants in the intervention and control groups will be compared.

#### **Timepoint**

The time of discharge

#### **Method of measurement**

Record the age of the infant at the time of discharge in a questionnaire

## **Intervention groups**

## **1**

#### **Description**

Intervention group: Oral stimulation group with PIOMI method: "Oral stimulation before feeding" program is a five-minute oral-motor intervention. In this program, stimuli are applied to oral structures including cheeks, gums, lips, tongue. It is served by gavage once a day before feeding. Oral ostomy intervention for 7 consecutive days without interruption for each infant is performed first by the researcher and after education to the mother by the mother. The 5-minute stimulation program includes 3 minutes of stretching and cheek massage and 2 minutes (non-nutritional sucking (NNS)).

#### **Category**

Rehabilitation

## **2**

#### **Description**

Intervention group: Non-oral stimulation group with FIELD technique is another group that will be performed by field massage method per day. Each 15-minute period (before feeding) consists of three 5-minute phases in which the infant is placed in a supine position on the abdomen at the beginning and end, and the fingers of both hands are touched with a gentle pressure with the smooth part of the fingers. In these two phases, one of the following five areas is touched every minute (12 touches in 5 seconds): from the tip of the head down to the sides of the face to the neck and vice versa, from the back of the neck across the shoulders and vice versa, from the upper back to the bottom to the waist and vice versa, from the thighs down to the ankles and vice versa, from the shoulders to the wrists and vice versa. In the middle phase, the infant was lying flat on its back and 6 passive extension-flexion movements (one every 10 seconds) were given to these five areas, respectively: right arm, left arm, right leg, left leg, and both legs. This protocol lasts for 7 days

#### **Category**

Rehabilitation

## **3**

#### **Description**

Control group: NICU routine care including non-nutritional sucking and kangaroo care will be given to the baby twice a day.

#### **Category**

N/A

## **Recruitment centers**

## **1**

#### **Recruitment center**

##### **Name of recruitment center**

Om Al Banin hospital

##### **Full name of responsible person**

Najme Zabihi Torbati

##### **Street address**

Behjat18 street

##### **City**

Mashhad

##### **Province**

Razavi Khorasan

##### **Postal code**

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##### **Phone**

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##### **Email**

zabihitn1@mums.ac.ir

## **Sponsors / Funding sources**

## **1**

#### **Sponsor**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr Mohsen Tafaghodi

**Street address**

Doktora crossroad

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**Province**

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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**

Mashhad 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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr Naghme Razaghi

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

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Doktora crossroad

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

Mashhad University of Medical Sciences

**Full name of responsible person**

Najme Zabihi Torbati

**Position**

Nurse

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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

Mashhad University of Medical Sciences

**Full name of responsible person**

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**Position**

Nurse

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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**Province**

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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**  
Not applicable  
**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**  
Publish as an article  
**When the data will become available and for how long**

After publishing the article  
**To whom data/document is available**  
Researchers working in academic institutions  
**Under which criteria data/document could be used**  
Use of data and results with reference  
**From where data/document is obtainable**  
Correspondence with the project manager Dr. Naghmeh Razaghi  
**What processes are involved for a request to access data/document**  
Request via email  
**Comments**