Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Investigating the effect of parent education on communication skills of preterm infants

Protocol summary

Study aim
Determining the effect of parent training on the development of communication skills in preterm infants

Design
It is a single-group study that will be implemented on 7 preterm infants.

Settings and conduct
This study will be conducted at the Afarinesh Clinic of Shahid Akbarabadi Hospital in Tehran, involving a sample of seven preterm infants identified as being at risk for developmental communication delays. Given the nature of this research as a single-group experimental design, randomization and blinding procedures are not applicable.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Preterm infants with a gestational age of maximum 32 weeks at birth, weight less than 1500 grams at birth; Exclusion criteria: Infant suffering from congenital anomalies and syndromes, infant suffering from specific medical diseases or conditions including cardiovascular and respiratory diseases

Intervention groups
The intervention consists of three individual, in-person counseling and training sessions for mothers of preterm infants, held at the infant's 1st week, 3rd month, and 6th month of age. Each session lasts 45–60 minutes. Session Content: Session 1: Skin-to-skin contact, visual stimulation (colorful toys), maternal verbal/facial interaction during breastfeeding, responding to infant cues, infant massage, and singing lullabies. Session 2: Mimicking infant facial expressions and vocalizations, narrating daily activities, mirror play, and repeating simple phonemes (e.g., "ba-ba," "ma-ma"). Session 3: Labeling body parts, animal identification/sounds, and singing nursery rhymes. To reinforce learning and ensure adherence, summarized educational brochures corresponding to each session will be sent to the mothers via the Rubika messaging platform.

Main outcome variables
Infant's communication skills; Speech and Language Environmental Richness

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260318069002N1**
Registration date: **2026-06-26, 1405/04/05**
Registration timing: **registered_while_recruiting**

Last update: **2026-06-26, 1405/04/05**
Update count: **0**

Registration date
2026-06-26, 1405/04/05

Registrant information

Name
Zeinab Hedayati abkoohi ravari

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-04-20, 1405/01/31

Expected recruitment end date
2027-01-20, 1405/10/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of parent education on communication skills of preterm infants

Public title
The effect of parent education on preterm infant growth

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Preterm infants with gestational age of maximum 32 weeks at birth Birth weight less than 1500 grams Parental willingness to participate in this study

Exclusion criteria:
Medical diseases or special conditions in the newborn; including cardiovascular and respiratory diseases Congenital anomalies or syndromes in the newborn

Age
From **1 day** old to **10 days** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **7**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Iran University of Medical Sciences

Street address
Iran University of Medical Sciences (IUMS), Shahid Hemmat Highway, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1449614535

Approval date
2025-06-30, 1404/04/09

Ethics committee reference number
IR.IUMS.REC.1404.374

Health conditions studied

1

Description of health condition studied
Preterm infant

ICD-10 code
P07

ICD-10 code description
Disorders of newborn related to short gestation and low birth weight, not elsewhere classified

2

Description of health condition studied
Speech and language disorders

ICD-10 code
F80

ICD-10 code description
Specific developmental disorders of speech and language

3

Description of health condition studied
Prevention of developmental disorders

ICD-10 code
Z13.4

ICD-10 code description
Encounter for screening for certain developmental disorders in childhood

Primary outcomes

1

Description
Infant's communication skills

Timepoint
Data collection will occur at three distinct time points: Baseline assessment: conducted during the first session, prior to the administration of counseling and educational interventions to the mother. Post-intervention assessment I: conducted at the conclusion of the second counseling and education session. Post-intervention assessment II: conducted at the conclusion of the third counseling and education session.

Method of measurement
Rosetti infant-toddler scale

2

Description
Speech and Language Environmental Richness

Timepoint
At the beginning of the intervention (at birth) and then at

the end of the intervention

Method of measurement

Speech and Language Environmental Richness Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group: This is a single-subject study consisting of one intervention group. The intervention will be delivered through face-to-face counseling and educational sessions for mothers of preterm infants. The intervention will consist of three individual sessions conducted when the infant is 1 week, 3 months, and 6 months of age. Each session will last approximately 45–60 minutes. Session 1: Mothers will be encouraged to engage in daily skin-to-skin contact with their infant, hold and gently touch the infant, position their face at an appropriate distance from the infant, expose the infant to colorful and sound-producing toys, maintain eye contact with the infant during feeding, smile and talk to the infant, pay attention to signs of hunger and other infant cues and respond promptly to the infant's needs, use crib mobiles, gently massage the infant's arms, legs, and body, and sing songs and lullabies to the infant. Session 2: Mothers will be encouraged to imitate the infant's facial expressions and vocalizations, talk to the infant about daily activities and events, look through picture books and simple illustrated books with the infant and read the stories aloud, use facial expressions that correspond to the content of their speech when interacting with the infant, show the infant his or her reflection in a mirror together with the mother's reflection, provide supervised tummy time and place toys within the infant's reach, and repeat simple syllables such as "ba-ba-ba," "ma-ma-ma," and "da-da-da" while allowing the infant to observe the mother's mouth movements. Session 3: Mothers will be encouraged to sing songs and nursery rhymes to the infant, look at picture books and read stories together with the infant, name body parts while simultaneously pointing to the corresponding body parts on themselves and the infant, use toy animals to introduce animal names and sounds while creating simple stories, and engage in ball-playing activities with the infant. Following each intervention session, the educational content will be provided to the mothers in the form of an electronic brochure via the Rubika application to reinforce learning and reduce the likelihood of forgetting the educational materials.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Akbarabadi Hospital

Full name of responsible person

Maryam Tarameshlu

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Ferdows Garden Station, Molavi Avenue , Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Majid Safa

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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

Iran 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
Iran University of Medical Sciences

Full name of responsible person
Zeinab Hedayati abkoohi ravari

Position
Master's student

Latest degree
Bachelor

Other areas of specialty/work
Speech therapy

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Person responsible for scientific inquiries

Contact

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Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
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Person responsible for updating data

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Position
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Other areas of specialty/work
Speech therapy

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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
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