

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jun 2026

### Comparison between the effect of home visit training program and routine care on growth and development of preterm infants

#### Protocol summary

##### Summary

The present study aimed to investigate the effect of home visit training program on preterm infants' growth and development within 6 months. In this double blind and clinical trial study, preterm infants were randomly divided into an intervention (N=30) and a control group (n=30). The person who collected the study outcomes remained blind to the outcome measures. Moreover, the researcher who train mothers was blinded to the aim of the study. In addition, the statistician who performed the data analysis was kept blinded to the allocation, as well. The inclusion criteria of the study were gestational age under 37 weeks; being fed orally; and living in Shiraz. On the other hand, the exclusion criteria of the study were suffering from brain disorders; congenital cardiovascular diseases; metabolic or endocrine disorders; and known genetic and chromosomal abnormalities. The intervention group received home visit training program for 6 months, while the control group only received the hospital's routine care. Then, the infants' growth indexes, including weight, height, and head circumference, and development criteria such as following moving objects with the head, social laughing, keeping the head stable when changing position from lying to sitting, making "Agha" sound, taking objects by the hand, and laughing were compared in the first, second, third, and sixth months.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014082013690N3**  
Registration date: **2014-09-27, 1393/07/05**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2014-09-27, 1393/07/05

##### Registrant information

###### Name

Masoume Rambod

###### Name of organization / entity

Shiraz University of Medical Science

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 1647 4258

###### Email address

rambodm@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor for Shiraz University of Medical Sciences

##### Expected recruitment start date

2009-03-20, 1387/12/30

##### Expected recruitment end date

2010-03-20, 1388/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison between the effect of home visit training program and routine care on growth and development of preterm infants

##### Public title

Effect of home visit training program on growth and development of preterm infants

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

The inclusion criteria of the study were gestational age under 37 weeks; being fed orally; and living in Shiraz. On the other hand, the exclusion criteria of the study were suffering from brain disorders; congenital cardiovascular diseases; metabolic or endocrine disorders; and known genetic and chromosomal abnormalities.

**Age**

From **1 day** old to **6 months** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

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

empty

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

Ethics Committee of Shiraz University of Medical Sciences

**Street address**

Research Vice Chancellor, 7th floor, Central building of Shiraz University of Medical Sciences, Beside Helale Ahmar, Zand street, Shiraz

**City**

Shiraz

**Postal code****Approval date**

2008-09-22, 1387/07/01

**Ethics committee reference number**

ICR-87-4275

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

preterm infants

**ICD-10 code**

P05.1

**ICD-10 code description**

Small for gestational age

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

weight

**Timepoint**

First, second, third, and sixth month after birth

**Method of measurement**

gr

**2****Description**

Height

**Timepoint**

First, second, third, and sixth month after birth

**Method of measurement**

Meter (cm)

**3****Description**

Head circumference

**Timepoint**

First, second, third, and sixth month after birth

**Method of measurement**

Meter (cm)

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

Following moving objects with the head

**Timepoint**

First, second, third, Fourth, fifth, and sixth month after birth

**Method of measurement**

Yes; No

**2****Description**

Social laughing

**Timepoint**

First, second, third, Fourth, fifth, and sixth month after birth

**Method of measurement**

Yes; No

**3****Description**

Keeping the head stable when changing position from lying to sitting

**Timepoint**

First, second, third, Fourth, fifth, and sixth month after birth

**Method of measurement**

Yes; No

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##### **Description**

Making "Agha" sound

##### **Timepoint**

First, second, third, Fourth, fifth, and sixth month after birth

##### **Method of measurement**

Yes; No

#### 5

##### **Description**

Taking objects by the hand

##### **Timepoint**

First, second, third, Fourth, fifth, and sixth month after birth

##### **Method of measurement**

Yes; No

#### 6

##### **Description**

laughing

##### **Timepoint**

First, second, third, Fourth, fifth, and sixth month after birth

##### **Method of measurement**

Yes; No

## **Intervention groups**

#### 1

##### **Description**

Intervention group: Home visit program included familiarity with the differences between term and preterm infants, how to take care of a preterm infant, how to take care of umbilical cord, advantages of breastfeeding, how to hold the infant, and infant's nutrition, and training about how to bath the infants and take care of them before and after bathing.

##### **Category**

Other

#### 2

##### **Description**

Control group: No predefined program was executed in this group. They received the routine care and each mothers' questions were answered.

##### **Category**

Other

## **Recruitment centers**

#### 1

##### **Recruitment center**

**Name of recruitment center**

Hafez

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

Mitra Edraki

##### **Street address**

##### **City**

Shiraz

#### 2

##### **Recruitment center**

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

Hazrat Zynab

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

Mitra Edraki

##### **Street address**

##### **City**

Shiraz

#### 3

##### **Recruitment center**

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

Namaze

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

Mitra Edraki

##### **Street address**

##### **City**

Shiraz

## **Sponsors / Funding sources**

#### 1

##### **Sponsor**

##### **Name of organization / entity**

Vice Chancellor for Shiraz University of Medical Sciences

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

Dr Ali Postfroush

##### **Street address**

Research Vice Chancellor, 7th floor, Central building of Shiraz University of Medical Sciences, Beside Helale Ahmar, Zand street, Shiraz

##### **City**

Shiraz

##### **Grant name**

##### **Grant code / Reference number**

##### **Is the source of funding the same sponsor organization/entity?**

Yes

##### **Title of funding source**

Vice Chancellor for Shiraz University of Medical Sciences

##### **Proportion provided by this source**

100

##### **Public or private sector**

*empty*

##### **Domestic or foreign origin**

*empty*

##### **Category of foreign source of funding**

*empty*

##### **Country of origin**

##### **Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Mitra Edraki

**Position**

Faculty member

**Other areas of specialty/work**

**Street address**

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## Person responsible for scientific inquiries

### Contact

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Master degree

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## Person responsible for updating data

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**Other areas of specialty/work**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*