

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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

4

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

Nursing and midwifery of Shiraz University of Medical Sciences, Namazee Square, Zand Street, Shiraz

City

Shiraz

Postal code

Phone

+98 71 3647 4258

Fax

Email

mitraedraki@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mitra Edraki

Position

Master degree

Other areas of specialty/work

Street address

Nursing and Midwifery of Shiraz University of Medical Sciences, Namazee Square, Zand Street, Shiraz

City

Shiraz

Postal code

Phone

+98 71 3647 4258

Fax

Email

mitraedraki@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mitra Edraki

Position

Master degree/ Faculty member

Other areas of specialty/work

Street address

Nursing and midwifery of Shiraz University of Medical Sciences, Namazee Square, Zand Street, Shiraz

City

Shiraz

Postal code

Phone

+98 71 3646 4254

Fax

+98 71 3647 4252

Email

mitraedraki@yahoo.com

Web page address

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