

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Comparison of effect of tele health- nursing and multimedia education of mothers on the growth and developmental indexes of infants, Compared with mothers who received training of health care workers

Protocol summary

Summary

Objective: Comparison of effect of tele health- nursing and multimedia education of mothers on the growth and developmental indexes of infants (6-12 months). The study population: Infants 6-12 months and their mothers. Sampling procedure: Random stratified sampling method was used. At first 3 health care centers were selected by random cluster sampling and then they allocated into 3 groups including: tele health- nursing, multimedia education and control by simple random sampling (43 subject in each group). Blindness is not carried out due to educational interventions. Inclusion criteria: Mother is willing to cooperate in this project, literate and with capability of mental, hearing and visual for participating in study and having a phone. Exclusion criteria: At the time of the study children go to kindergarten and become ill or chronic disease. Intervention: at the first intervention necessary educations were presented by phone calls. They were also given a phone number for further and necessary consults. The second intervention group was educated by lecture, film and pamphlet. Control group no received specific intervention. Intervention time: Developmental indexes at 6,8,10 and 12 months and growth indexes at 6, 7, 9 and 12 months measured. Primary outcomes: weight, length, head circumference, communication, gross motor, fine motor, problem solving and personal-social.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016030225127N2**
Registration date: **2016-03-25, 1395/01/06**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-03-25, 1395/01/06

Registrant information

Name

Elham Farahnak

Name of organization / entity

Yasuj University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Yasuj University of Medical Sciences

Expected recruitment start date

2015-06-20, 1394/03/30

Expected recruitment end date

2015-11-22, 1394/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of effect of tele health- nursing and multimedia education of mothers on the growth and developmental indexes of infants, Compared with mothers who received training of health care workers

Public title

The Effect of education on The indexes of growth and development of 6-12 months infants

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: mother is willing to cooperate in this project; mother has direct responsible for child's feeding; the father and mother be literate (at least secondary education is completed); the mother does not express certain mental problem; no graduates or studying in sciences or psychology or medicine; children at the time of the study not have defects, acute illness or not systematic; children have normal growth at baseline (is not Under 3 percentile); parents are both still alive; having a home phone or mobile phone. Exclusion criteria: at the time of the study children go to kindergarten; children become ill or chronic disease; the child get single parent; the child's father become unemployed; the child's mother begin studying the medical sciences or psychology; parents cancel to continue working with more than two absences researcher training sessions or care.

Age

From **6 months** old to **12 months** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **129**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Factorial

Other design features

Blindness is not carried out due to educational interventions

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Yasuj University of Medical Sciences

Street address

Yasuj University of Medical Science, Shahid Motahari street

City

Yasuj

Postal code

Approval date

2015-05-22, 1394/03/01

Ethics committee reference number

IR.YUMS.REC.1394.2

Health conditions studied

1

Description of health condition studied

Infants growth & development

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Weight

Timepoint

At the end of 6, 7, 9 and 12 months

Method of measurement

By Scale

2

Description

Length

Timepoint

At the end of 6, 7, 9 and 12 months

Method of measurement

Length measured with meters

3

Description

Head circumference

Timepoint

At the end of 6, 7, 9 and 12 months

Method of measurement

Head circumference measured with meters

4

Description

Development

Timepoint

At the end of 6, 8, 10 and 12 months

Method of measurement

By using Ages and Stages Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

In the first intervention group (long distance-tele- health nursing education method), procedures of surveying, education, orientation and suggestion were performed and used. For 6-8 months age children, phone connections were performed once a week regarding to Nutrition Education Protocol suggested by the Health Ministry of Iran according to items mentioned in children development profiles, assigned at 6, 7, 9 and 12 months of children age. Necessary educations were presented as weekly phone calls and the questions of parents were answered and were consulted if required. Contents of the next week were educated in each phone call and previous efforts were also checked and emphasized if were not obeyed. Two phone calls were performed for children with age of 9 months and more per week and the mother were referred to reserved physician if medical intervention was required. They were also given a phone number for further and necessary consults.

Category

Behavior

2

Description

In the second intervention group (multi media education method), the education process was based on lectures in group sessions according to an educational program. These educational sessions were formed at 6,8,10 and 12 months of children ages regarding to the time of Ages and Stages questionnaire filling. Because of the dissipation of children ages and large number of people in a group, children born at the first half of month were educated at the beginning of the corresponding month and children born at the second half of month were educated at the last days of month by multimedia method. Also an educational film containing items about supplementary nutrition, use of iron supplementary droplets, emotional relations performance with the suckle, quality and modality of games at different ages and protection of the baby against accidents was shown to the mothers. Duration of each session was an hour. Educational pamphlets containing the issues of next 2 months according to the phone educations were given to the participants at the end of each session and they were asked to read the contents of each next week at corresponding week time. All educational contents and concepts were similar in both intervention groups. These educations were presented besides and apart of educations and recommendations offered by health personnel of mentioned health and medical centers.

Category

Behavior

3

Description

In the control group, only educations through the health care personnel were presented. ages and stages questionnaires were filled at the end of 6, 8, 10 and 12 months during interviews by the mothers

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Ashrafi Martyr, Health Center

Full name of responsible person

Elham Farahnak, Master of Nursing

Street address

Ave. Imam Khomein, Sharafabad town

City

Yasuj

2

Recruitment center

Name of recruitment center

Shafiei Martyr, Health Center

Full name of responsible person

Elham Farahnak, Master of Nursing

Street address

Yas street, Shahid salari boulevard

City

Yasuj

3

Recruitment center

Name of recruitment center

Dastgheib Martyr Health Center

Full name of responsible person

Elham Farahnak, Master of Nursing

Street address

Next to blood transfusion center, Jihad Blvd.

City

Yasuj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Yasouj University of Medical Sciences .

Full name of responsible person

Mohammad Mousavi

Street address

Yasouj University of Medical Science, Motahari Bolvar, Yasouj

City

yassouj

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Yasouj 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

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Full name of responsible person

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Position

Nursing Graduate Student

Other areas of specialty/work

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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