

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

Effect of Tactile Kinesthetic Stimulation by mother on anthropometric measurements of discharged preterm newborns, with home visit program

Protocol summary

Summary

Tactile kinesthetic stimulation (TKS) in newborns has been shown to be effective in many studies, but applying this method by their mothers has adequately not been studied. Due to the role of mother in care of her neonate, effect of TKS on anthropometric measurements of preterm infants, with home visit, will be evaluated in this study. In a randomized controlled trial, in Shahid Akbarabadi treatment & education center, 60 Iranian preterm infants who will be discharged from neonatal intensive care unit (NICU) to home, will be allocated to control or intervention group. Each mother will be directly trained by researcher at the time of discharge, and guideline book will be given to them. TKS will be performed by trained mother from the time of discharge until term corrected age. Home visiting program will be done twice weekly by researcher. Weight, height, head and chest circumference measurements of newborns in time of discharge will be compared to these measurements at term corrected age. All measurements will be taken before and after intervention in two groups, on the same equipment and by the same blind observer.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138903092324N5**

Registration date: **2011-01-30, 1389/11/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-01-30, 1389/11/10

Registrant information

Name

Maryam Keshavarz

Name of organization / entity

Iran University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

School of Nursing and Midwifery, Tehran University of Medical Sciences

Expected recruitment start date

2010-07-14, 1389/04/23

Expected recruitment end date

2010-09-14, 1389/06/23

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Tactile Kinesthetic Stimulation by mother on anthropometric measurements of discharged preterm newborns, with home visit program

Public title

Effect of Tactile Kinesthetic Stimulation by mother, on anthropometric measurements of preterm newborns

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: 1) Birth weight >1500 g and/or gestational age \geq 32 weeks; 2) Appropriate for gestational age (AGA); 3) Exclusive breastfeeding. 4) Apgar score \geq 7 at 1 and 5 minutes with no resuscitation

required at birth; 5) no congenital anomalies; 6) single pregnancy; 7) No history of addiction in mother; Exclusion criteria: 1) Existing medical or surgical problem during intervention and hospitalization; 2) No given stimulation for two times in a couple of days; 3) no exclusive breast feeding.

Age

To **1 year** 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

School of Nursing and Midwifery, Tehran University of Medical Sciences

Street address

Rashid Yasami St. Valiasr Ave, P.P. Box: 19395-4798

City

Tehran

Postal code

Approval date

2010-05-31, 1389/03/10

Ethics committee reference number

1725812

Health conditions studied

1

Description of health condition studied

anthropometric measurements of preterm infants

ICD-10 code

P07.3

ICD-10 code description

Other preterm infants

Primary outcomes

1

Description

weight

Timepoint

Term corrected age

Method of measurement

Weight will be taken without clothes on an electronic weighing scale with an accuracy of ± 10 grams.

2

Description

Head circumference

Timepoint

Term corrected age

Method of measurement

Head circumference will be measured with a non-stretchable cloth-tape

3

Description

chest circumference

Timepoint

Term corrected age

Method of measurement

chest circumference will be measured with a non-stretchable cloth-tape

4

Description

Height

Timepoint

Term corrected age

Method of measurement

Height will be measured with an infant meter

Secondary outcomes

empty

Intervention groups

1

Description

The intervention is provided for three 20 min periods per day. Intervention comprises three phases. During the tactile stimulation in phase 1 and 3 (8 min in each phase), the infant is placed in a left and right lateral position and stroked with moderate pressure. Six strokes at approximately 10 s per stroking motion over each region in the following body region: (a) Head (b) shoulder (c) hand (d) back (E) leg. During the Kinaesthetic stimulation phase, the infant is placed in a supine position, then legs and arms are flexed and extended. (a) right arm, (b) left arm, (c) right leg, (d) left leg, Six motions at approximately 10s for each flexion and extension.

Category
Prevention

2

Description
TKS will not be taken for control group.

Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Akbarabadi treatment & education center
Full name of responsible person
Maryam Keshavarz
Street address
Molavi Street
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
School of Nursing and Midwifery, Tehran University of Medical Sciences
Full name of responsible person
Vice chancellor for research
Street address
Rashid Yasami St. Valiasr Ave, P.P. Box: 19395-4798
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Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
School of Nursing and Midwifery, Tehran 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

Nursing and Midwifery, Tehran University of Medical Sciences

Full name of responsible person
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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