

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Comparison of kangaroo mother care and tactile-kinesthetic stimulation on weight gain of late preterm infants in hospitalized in neonatal intensive care units in the Mousavi hospital affiliated to Zanjan University of Medical Sciences. 2020. :A Randomized Clinical Trial.

Protocol summary

Study aim

Determining and comparing the method of tactile-kinetic stimulation and maternal kangaroo care on weight gain in infants of late prematurity admitted to the neonatal intensive care unit.

Design

A randomized clinical trial with the control group, with intervention and control groups, on 80 infants of late prematurity admitted to the neonatal intensive care unit

Settings and conduct

The study site of the neonatal intensive care unit of Ayatollah Mousavi Hospital in Zanjan is affiliated to Zanjan University of Medical Sciences

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Fetal age 37-34 weeks 2. Hemodynamic stability 3. Nutrition through digestion (oral or digestive tube) with breast milk or formula 4. Staying in the neonatal intensive care unit for at least one week 5. The birth of an only child 6. Iranian nationality 7. The presence of the biological mother, who is literate and willing and able to perform interventions correctly in the hospital Exclusion criteria: 1. Having a diagnosis of genetic, cardiac, respiratory, central nervous system problems (acquired and congenital) 2. The need for any surgery 3. Having a history of intrauterine growth retardation 4. History of substance abuse in the mother

Intervention groups

30 babies in the control group and 30 babies in the intervention group with tactile stimulation. and 30 babies will be in the intervention group with mother's kangaroo care. These interventions will be performed three times a day for 60 minutes in the kangaroo mother care group and 15 minutes in the tactile-kinetic stimulation group for one week.

Main outcome variables

In case of the positive effect of the studied interventions

on the weight of infants in late prematurity, training to use these methods as auxiliary interventions in weight gain of these infants.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210109049974N1**

Registration date: **2023-02-11, 1401/11/22**

Registration timing: **retrospective**

Last update: **2023-02-11, 1401/11/22**

Update count: **0**

Registration date

2023-02-11, 1401/11/22

Registrant information

Name

Soheila Mirlou

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 24 3352 9480

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-21, 1400/01/01

Expected recruitment end date

2021-10-22, 1400/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of kangaroo mother care and tactile-kinesthetic stimulation on weight gain of late preterm infants in hospitalized in neonatal intensive care units in the Mousavi hospital affiliated to Zanjan University of Medical Sciences. 2020. :A Randomized Clinical Trial.

Public title

Comparison of kangaroo mother care and tactile-kinesthetic stimulation on weight gain of late preterm infants in hospitalized in neonatal intensive care units.

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Fetal age 34-37 weeks Hemodynamic stability Feeding through the digestive system (oral or digestive tube) with breast milk or formula Staying in the neonatal intensive care unit for at least one week Birth of a singleton Iranian nationality The presence of the biological mother, who is literate and willing and able to perform interventions correctly in the hospital

Exclusion criteria:

Discharge the baby before the end of the intervention Transfer to another department before the end of the intervention Having a diagnosis of genetic, cardiac, respiratory, central nervous system problems (acquired and congenital) The need for any surgery Having a history of intrauterine growth retardation History of substance abuse in the mother

AgeFrom **238 days** old to **259 days** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **80****Randomization (investigator's opinion)**

Randomized

Randomization description

The function of random numbers was used to randomize and assign people to groups; Randomization using Excel software is as follows: First, in one column, the groups are entered as A, B, c and below; Because the number of samples in each group is set to 30 (including sample loss), therefore, 30, B, A c should be entered in order. In the opposite column, random numbers are generated using the RAND command. In the next step, using the sort command, the generated random numbers are sorted from small to large or vice versa, which changes the order of the groups, i.e. c A, B. Using the new order, people are assigned to different groups.

Blinding (investigator's opinion)

Not 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 Shahid Beheshti University of Medical Sciences

Street address

no.3,7th floor,block6,The residential complex of Farhang Town sepehr,

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Province

Zanjan

Postal code

4519949858

Approval date

2020-11-15, 1399/08/25

Ethics committee reference number

IR.SBMU.RETECH.REC.1399.696

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

Maternal kangaroo care and kinetic tactile stimulation

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Weight

Timepoint

Before study, during study, after study

Method of measurement

Digital baby measuring scales

Secondary outcomes

empty

Intervention groups

1

Description

The first intervention group: in the tactile-kinetic stimulation intervention group, late preterm infants will receive tactile-kinetic stimulation three times a day (morning, noon, night) for 15 minutes for 7 days. This intervention will be performed by mothers on babies in three 5-minute stages. The stages of the intervention will be as follows:- The first stage: (touch stage) which was done in the palm position and relatively strong tactile stimuli applied by the palms of the baby's mother on the baby's head, neck, shoulders and back. It was found that these stimulations lasted for 5 seconds in each turn of tactile stimulation and the duration of this stage was 5 minutes. The firmness that is applied by the palms of the baby's mother on the forehead, cheeks, chest, abdomen, upper and lower limbs, palms and feet of the baby. This stage should last 5 minutes. The third stage: (Kinetic stage) This stage of tactile stimulation will be done in the open arch position and includes passive movements of bending and straightening the upper limbs in the shoulder and elbow joints and the lower limbs in the location of the hip, knee and ankle joints. These passive movements will be performed 5 times in each joint, each movement will last 2 seconds and the total time for this step will be 5 minutes.

Category

Other

2

Description

The second intervention group: In the mother's kangaroo care intervention group, the late preterm babies will be placed on the mother's chest by the relevant nurse for 7 days and 3 times a day for 60 minutes, and there will be skin contact between the mother and the baby. The nude that is in a stable physiological condition will be established.

Category

Other

3

Description

Control group: In this research, the control group will be late premature babies who are hospitalized in the neonatal intensive care unit and receive the usual nursing interventions.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Mousavi Hospital affiliated to Zanjan University of Medical Sciences

Full name of responsible person

Soheila Mirloo

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Soheila Mirloo

Position

Nursing Graduate Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available