# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Nov 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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**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
**Age**
From **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,
**City**
Zanjan
**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 It is 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**
Mahmoud Khodadoost

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Chamran Highway, Yemen St., Parvaneh St., next to Taleghani Hospital, Shahid Beheshti University of Medical Sciences and Health Services, Building No. 1, Fifth Floor, Deputy of Management and Resources Development

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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

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**Position**
Nursing Graduate Student

**Latest degree**
Bachelor

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Nursery

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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