

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

The effect of Home Visit Program based on the Continued kangaroo Mother Care on Maternal Resiliency and Development of Premature Infant

Protocol summary

Study aim

Determine the effect of home-based home visit program on maternal and neonatal care on maternal resilience and development of premature infants.

Design

This study is a randomized clinical trial with control group. In this research, sampling is carried out in a non-randomized manner. The allocation of the research units was based on randomized blocking method; that is, six scenarios are created for a four-block allocation in the first place, and then drawing lots is performed in order to arrange the blocks. The study population consisted 25 mothers in either group with premature 26-32 week old, who were hospitalized in the NICU ward of Omolbanin Hospital in Mashhad and met the inclusion criteria of the study.

Settings and conduct

Sampling in the NICU section of Omolbanin hospital. One Blind study

Participants/Inclusion and exclusion criteria

Neonates 26-32 weeks weighing more than 1000 gr, stable clinical status, inability to receive oxygen in an invasive way, no anomaly based, Lack of grade III and IV IVH, Lack of advanced recovery in the history

Intervention groups

Premature babies are 26-32 weeks old weighing more than 1000 gr. They are admitted to the neonatal intensive care unit, and after the removal of the newborn from advanced mechanical ventilation and finding the conditions for caring for kmc up to the min daily clearance 3 times Kmc surveillance takes, and they continue to care for a month at the home after a discharge. At the beginning of the arrival of the mothers, will be completed by the maternity ward, the time of discharge, and one month after the discharge of the Conor Davidson resiliency scale. At 2 months of age, the modified age of the newborn will be evaluated evolutionally. In the control group, after the discharge, they receive routine care.

Main outcome variables

Maternal resilience, Connor and Davidson questionnaire, neonatal development ASQ

General information

Reason for update

Acronym

KMC

IRCT registration information

IRCT registration number: **IRCT20181121041718N1**

Registration date: **2019-02-16, 1397/11/27**

Registration timing: **registered_while_recruiting**

Last update: **2019-02-16, 1397/11/27**

Update count: **0**

Registration date

2019-02-16, 1397/11/27

Registrant information

Name

marziyeh ghazi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3859 1511

Email address

ghazim3@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-10, 1397/10/20

Expected recruitment end date

2019-08-23, 1398/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Home Visit Program based on the Continued kangaroo Mother Care on Maternal Resiliency and Development of Premature Infant

Public title

The effect of Home Visit Program based on the Continued kangaroo Mother Care on Maternal Resiliency and Development of Premature Infant

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Infant: Weight greater than or equal to 1000 g
Gestational age 26 to 32 weeks Stable clinical situation
Failure to receive oxygen in an aggressive way No anomaly based on the file Non intraventricular hemorrhage grade 3 or 4 No need for advanced neonatal resuscitation during hospitalization Mother: No known mental disorders Resident in Mashhad or Mashhad suburb Not addiction based on self-declaration There is no significant family challenge with the husband, based on self-declaration. Do not have twin or multiple delivery There is no history of premature baby birth

Exclusion criteria:

Infant: Respiratory instability and need for aggressive mechanical ventilation Baby death Occurrence of significant stressful events during research Having chronic physical or mental illness

AgeFrom **1 day** old to **7 days** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample sizeTarget sample size: **50****Randomization (investigator's opinion)**

Randomized

Randomization description

This study is a randomized clinical trial with control group. In this research, sampling (inclusion of mothers and their neonates in the study) is carried out in a non-randomized manner. The allocation of the research units to intervention and control groups was based on randomized blocking method; that is, six scenarios are created for a four-block allocation in the first place, and then drawing lots is performed in order to arrange the blocks

Blinding (investigator's opinion)

Single blinded

Blinding description

The analyst will be unaware of the intervention and control groups

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

The Ethics Committee of Mashhad University of Medical Sciences

Street address

University Street, Avicenna Street, Faculty of Nursing and Midwifery

City

mashhad

Province

Razavi Khorasan

Postal code

9137913199

Approval date

2019-01-01, 1397/10/11

Ethics committee reference number

IR.MUMS.NURSE.REC.1397.074

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

Maternal resilience and the development of preterm infants receiving maternal and neonatal care through home visits

ICD-10 code

P07.3

ICD-10 code description

Other preterm infants - 28 completed weeks or more but less than 37 completed weeks (196 completed days but less than 259 completed days) of gestation.

Primary outcomes**1****Description**

Resilience of mothers of premature infants

Timepoint

The newborn is admitted to the infant's care unit, when the baby is given discharge, one month after the discharge

Method of measurement

Connor Davidson Questionnaire(2003)

2

Description

Premature infants development

Timepoint

2 months old corrected age

Method of measurement

Development questionnaire ASQ

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Premature babies are between 26-32 weeks old weighing more than 1000 grams. They are admitted to the neonatal intensive care unit and have criteria for entering the study, and after the removal of the newborn from advanced mechanical ventilation and finding the conditions for caring for kmc up to the minimum daily clearance Three times kmc surveillance takes place for 30-40 minutes, and they continue to care for a month at the home after a discharge. At the beginning of the arrival of the mothers, the intervention group will be completed by the maternity ward, the time of discharge, and one month after the discharge of the Conor Davidson resiliency scale. At 2 months of age, the modified age of the newborn will be evaluated evolutionally.

Category

Prevention

2

Description

Control group: Premature babies are between 26-32 weeks old weighing more than 1000 grams. They are admitted to the neonatal intensive care unit and have criteria for entering the study, and after the removal of the newborn from advanced mechanical ventilation and finding the conditions for caring for kmc up to the minimum daily clearance Three times, they perform kangaroo care for 30-40 minutes and receive routine care after discharge. At the beginning of the arrival of the mothers, the intervention group will be completed by the maternity ward, the time of discharge, and one month after the discharge of the Conor Davidson resiliency scale. At 2 months of age, the modified age of the newborn will be evaluated evolutionally.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Omolbanin hospital

Full name of responsible person

Marziye ghazi

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Bahjat 16,Ayatollah Behjat Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Tafaghodi Mohsen

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University St, Facing University Street 18, Deputy of University Technology and Research

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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

Mashhad 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

Mashhad University of Medical Sciences
Full name of responsible person
Marziye ghazi
Position
Nursing Student
Latest degree
Bachelor
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Title and more details about the data/document

The total potential data can be shared after unidentifiable people

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

Only for researchers working in academic and scientific institutions

Under which criteria data/document could be used

The data can be used for other human research and health centers

From where data/document is obtainable

Library of the School of Nursing and Midwifery of Mashhad, ghazim3@mums.ac.ir

What processes are involved for a request to access data/document

Visit the Library of Nursing and Midwifery Faculty of Mashhad

Comments