Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Nov 2026

The effect of nutrition education based on neonatal behavioral symptoms of nurses on short-term health outcomes in preterm infants.

Protocol summary

Study aim
The purpose of this study was to determine the effect of nutrition education on neonatal behavioral symptoms to nurses on the short-term health outcomes of preterm infants.

Design
Clinical trial with control group without educational intervention and intervention group with educational intervention.

Settings and conduct
Neonatal of intensive care unit of Yas hospital in Tehran and train nurses.

Participants/Inclusion and exclusion criteria
The criteria for entry include preterm infants from 28 to 36 weeks of gestational age, whose intravenous feeding period is completed and intravenous fluids stoped and have an autonomic stability and for starting oral feeding should be weight above 1500g or over 34 gestational age and be insid the incubator. The exit criteria of neonates include the need for invasive respiratory protection, patients with grade 3 and4 interaventricular hemorrhage, necrotic enterocolitis, and which after the onset of the study reduced or decreased weight gain 3 consecutive days or serum-therapy and stop of nutrition. Nurses' entry criteria including at least 6 months of work experience with the newborn, participation in the training course and the willingness to participate in project.

Intervention groups
Starting of study is with 30 infant in control groups that according to the physician's order, every two to three hours without regard to the infant's demand are fed, and information is collected in the checklist, and then hold a training course for the health care staff. Study started in two shifts of 12-hour day and night on infants is based on CBF protocols and information from each infant is entered into the checklist, thus the short-term health outcomes of the preterm infants in both groups are compared.

Main outcome variables
Short-time health outcomes of preterm infant incloud duration of hospitalization,weight gain,Apnea times.

General information

Reason for update

Acronym
CBF

IRCT registration information
IRCT registration number: **IRCT20170828035962N2**
Registration date: **2018-05-27, 1397/03/06**
Registration timing: **registered_while_recruiting**

Last update: **2018-05-27, 1397/03/06**
Update count: **0**

Registration date
2018-05-27, 1397/03/06

Registrant information

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Babol University of Medical Scienes

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Recruitment status
Recruitment complete

Funding source
Babil University of Medical Sciences, Amirkola Non-Communicable Disease Research Center

Expected recruitment start date
2017-06-26, 1396/04/05

Expected recruitment end date

2018-07-21, 1397/04/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of nutrition education based on neonatal behavioral symptoms of nurses on short-term health outcomes in preterm infants.

Public title
The effect of CBF on short-term health outcomes of infants

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Preterm infants from 28 to 36 weeks of pregnancy that complete intestinal feeding, and their intravenous feeding period was complete, when they could eat milk to the 120 ml / kg / day, and we can stop intravenous fluids. At this time, only infants who weigh over 1500 grams or older than 34 weeks of gestation can begin their oral feeding, or the physiological stability of the autonomic system (skin color, heart rate and respiration) The infants should be transferred to incubator and be sure to monitor the heart. The inclusion criteria of the nurses in the study include: having at least 6 months work experience in neonatal intensive care units, participating in the curriculum score and willingness of nurses to participate in the project,

Exclusion criteria:
Premature infants requiring respiratory support by invasive and non-invasive mechanical ventilation (but oxygen therapy with other methods such as oxy hood, canola and free oxygen at the incubator level, interfering with our intervention) Infant with interaventricular hemmorhage grade 3 and 4 Infant with necrozan entrocolitis Infant with Broncho Pulmonary Dysplasia Infant with Congenital disorder Infant with Surgical Disorder Iinfant with sepsis Infants who receive sedative and sedative drugs such as phenobarbital, midazolam, fentanyl, or morphine Infants who lose weight or lack of weight gain for 3 consecutive days after the start of the study. Infant wih mothers are addicted to alcohol or narcotics Do any other supportive interventions, such as therapeutic touch and music therapy during the study. The criteria for leaving nurses are reluctance to participate in the plan

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Short-term health outcomes include the duration of infant access to oral nutrition, duration of hospitalization, weight gain, apnea and O2Sat loss rates.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Babol University of Medical Sciences

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Babol Univercity of Medical Sciences, Gangafrooz Ave., Babol, Mazandaran.

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4717647745

Approval date
2017-06-25, 1396/04/04

Ethics committee reference number
MUBABOL.HRI.REC.1396.4

Health conditions studied

1

Description of health condition studied
Infant feeding of Cue Based : CBF

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Neonate weight gain

Timepoint
At the begining of the shift in morning

Method of measurement
In gram by using digital scale

Secondary outcomes

empty

Intervention groups

1

Description
To begin the study, at first, the control group samples were evaluated with a sample size of 30 neonates. The group was routinely administered on an hourly basis (every two hours or three hours), regardless of the demand of the baby and with any nutrition
Category
Behavior

2

Description
After taking samples in the control group, they began organizing workshops, distributing educational pamphlets, and installing nutrition protocols on request based on posters. The teaching materials for nurses in the workshops were: Definition of NIDCAP a
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Yas hospital
Full name of responsible person
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Sponsors / Funding sources

1

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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
Babol 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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
No more information.
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