Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Nov 2026

The effect of environmental and behavioral interventions on physiological and behavioral responses of preterm infants candidate for intravenous catheterization in neonatal intensive care units

Protocol summary

Summary

41 preterm infants whose parents agreed with their participation in the present study, were selected. The infants were randomly assigned into two experimental and control groups. In the experimental group, demographic, basic and physiological information questionnaire was completed with NIPS & EDIN Scale before implementing any intervention. Then, environmental and behavioral interventions such as closing the infants' eyes to reduce the light using eye pad, closing the infants' ears to reduce auditory simulations using ear plugs and placing the baby in an embryonic state to reduce environmental simulations using the nests prepared by the researcher, were implemented by researcher. 30 minutes after intervention, while the intervention was going on, intravenous catheter placement was performed by a qualified nurse. At the same time, a graduate student who knew how to fill the measuring tools and had at least one year working experience in the neonatal ward, filled the related checklist at the times of 2 minutes before, during and 5 minutes after intravenous catheter placement. Then, 30 minutes after intravenous catheter placement, while the intervention was going on, the physiologic information form and related checklists were filled again and the infant was removed from the study after an hour. No environmental and behavioral interventions were implemented on the infants in the control group, but, like the first time, all the stages of collecting information and filling the checklists were performed and recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017011231892N1**

Registration date: **2017-09-24, 1396/07/02**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-09-24, 1396/07/02

Registrant information

Name

Anahita Masoumpoor

Name of organization / entity

Martyr Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 8865 5366

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Recruitment status

Recruitment complete

Funding source

Researcher

Expected recruitment start date

2017-02-19, 1395/12/01

Expected recruitment end date

2017-05-22, 1396/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of environmental and behavioral interventions on physiological and behavioral responses of preterm

infants candidate for intravenous catheterization in neonatal intensive care units

Public title
The effect of environmental and behavioral interventions on physiological and behavioral responses of preterm infants candidate for intravenous catheterization in neonatal intensive care units
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria; gestational age of 30-37 weeks;admission to neonatal intensive care unit; requiring administration of intravenous fluids and catheter; constant positive airways pressure (N-CPAP); no use of sedatives، anticonvulsants، or anesthetics; no comorbidities such as congenital abnormalities, neurological problems, or cerebral intra-ventricular hemorrhage and seizures and;fully conscious infant; Exclusion criteria; parents withdrawing participation of their infant; failure to insert intravenous catheter in two attempts; critical illness of infant in the process of its disease interfering with interventions; lack of response to N-CPAP .
Age
From **1 day** old to **1 day** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **82**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Using colored beads

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Martyr Beheshti University of Medical Sciences
Street address
Tehran, Vali Asr intersection of prayer, the Heart Hospital Rajai martyr, martyr Beheshti University of Medical Sciences
City
Tehran
Postal code
1985717443
Approval date
2016-11-13, 1395/08/23
Ethics committee reference number
IR.SBMU.RETECH.REC.1395.587

Health conditions studied

1

Description of health condition studied
Premature infants
ICD-10 code
p07.3
ICD-10 code description
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
physiological responses
Timepoint
2 minutes before venipuncture, during venipuncture, 5 and 30 minutes after venipuncture
Method of measurement
Pulse monitoring, observation

Secondary outcomes

1

Description
Behavioral responses
Timepoint
2 minutes before venipuncture, during catheter insertion, 5 and 30 minutes after venipuncture
Method of measurement
NIPS scale & EDIN scale

Intervention groups

1

Description
The intervention implemented in the experimental group: “environmental and behavioral interventions such as closing the infants’ eyes to reduce the light using eye pad, closing the infants’ ears to reduce auditory simulations using ear plugs and placing the baby in an embryonic state to reduce environmental simulations using the nests prepared by the researcher, are implemented by researcher. 30 minutes after intervention, while the intervention is going on, intravenous catheter placement is performed by a

qualified nurse. At the same time, a nurse who knows how to fill out the measuring tools and has at least one year working experience in the neonatal ward, fills out the related checklist at the time of 2 minutes before, during and 5 minutes after intravenous catheter placement. Then, 30 minutes after intravenous catheter placement, while the intervention is going on, the physiologic information form and related checklists are filled out again and the infant is removed from the study after an hour."

Category

Behavior

2

Description

The intervention implemented in the control group: "no environmental and behavioral interventions, except for routine cares, are implemented on the infants in the control group, but all the stages of collecting information and filling out the checklists are done and recorded like the first time."

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Hospital Al zahra Isfahan

Full name of responsible person

Shohreh Taheri Karchegani , Nursing Graduate Student newborns

Street address

Hospital Alzahra, Sofe Blvd, Isfahan

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Martyr Beheshti University of Medical Sciences

Full name of responsible person

Shohreh Taheri Karchegani

Street address

School of Nursing and Midwifer, The intersection of prayer, Valiasr Street, The martyr Rajai Hospital Tehran, Iran

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Martyr Beheshti 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

Martyr Beheshti University of Medical Sciences

Full name of responsible person

Shohreh Taheri Karchegani

Position

Master's student nursing specialist neonates

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Anahita Masoumpoor

Position

Phd

Other areas of specialty/work

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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