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Comparison of Proprioceptive Nest with Standard Nesting to meet the proprioceptive needs of preterm neonates in NICU- A randomized control non-inferiority study

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We use this protocol and it's working

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Abstract

Overview and Justification

An essential component of neurodevelopment, proprioceptive stimulation begins in the foetal stage. Movements of the body can trigger sensorimotor experiences as early as the foetal stage. Proprioceptive feedback is created when the foetus moves within the uterus. The Proprioceptive Nest is a cutting-edge nesting tool made to give preterm infants comfort and age-appropriate proprioceptive stimulation. In preterm neonates under 36 weeks admitted to the NICU, the study aims to evaluate the effectiveness of the newly constructed device with standard nesting practices.

Guidelines

Discharge criteria:
Infants will be discharged
once they reach full enteral feeds and are on full Wati spoon feeds/ breast feeds and
regularly gaining weight for at least 3 consecutive days and
weight at discharge >1.3 Kg.

Following discharge, infants will be followed up in the Neonatology OPD within 48 hours
and will be monitored for feeding and weight gain.

Materials

Conventional nesting: This is the nesting practice already used in the unit. Partial nesting made of hard, nonflexible material is placed surrounding the baby in a U-shaped manner.

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Experimental group: This group will utilise a proprioceptive nest. The device is comprised of a baby-friendly, flexible material that allows for easier mobility. Because of its design, the baby will be able to get age-appropriate proprioceptive stimulation.

Troubleshooting

Safety warnings

Risk Benefit Assessment:
No added risk is involved with the use of new nesting compared with the standard nest. The standard neonatal treatment and neonatal procedures can be performed without any added risk or discomfort to the
neonates in the new nesting. There will be no limitation on the routine activities of care, including nursing care. The neonates will be monitored as per standard NICU policy, and this will not be affected using the new nesting.
The difference between the two nesting procures includes mainly providing additional proprioceptive stimulus; the new nesting would benefit in simulating the intrauterine environment better, helping develop motor patterns, promoting better midline orientation, and helping in self-regulation and coping in the stressful NICU environment.

Ethics statement

A clinical trial is approved by the Institutional Ethics Committee. The approval number is EC/OA-88/2023 Version 1.2. The clinical trial is registered as **CTRI/2024/02/062524.**

Before start

Premature birth is a common occurrence and techniques to improve outcomes for these preterm infants are increasing. One such technique is therapeutic positioning.
This has been shown to improve physiological, developmental, and neurological outcomes in preterm infants admitted in NICU settings. (Alisyn Larkin, 2019)
Proprioceptive stimulation is an integral part of neurodevelopment and starts right from the fetal period. Sensorimotor experiences evoked by bodily movements begin as early as the fetal period and enable this cortical learning. (Yamada, 2016). When the fetus moves in the uterus, that movement generates a proprioceptive feedback loop as well as organized tactile input from changes in the pressure on the skin. From 20 to 30 weeks, fetal kick strength nearly doubles from 6.5 to 10.5 pounds of force (SW, 2018).
In addition, these intrauterine movements also aid in improving bone formation and mineralization. (Miller, 2003)
In a preterm infant admitted to NICU all these proprioceptive stimulation and stimulation for bone formation get compromised in the less favorable extrauterine environment. The use of nesting in NICU has been shown to reduce this problem. Nesting promotes midline orientation, prevents the formation and development of abnormal motor patterns and by providing a physical boundary that closely mimics the maternal womb.

However, there are many positioning devices available. But it has many limitations when practically used. The problems encountered with the currently available nesting include: lack of recoiling with every movement of the baby, lack of 360-degree proprioception, lack of customisation; wear and tear with frequent sterilisation and cost.
These lacunae might lead to the development of muscle tone, the risk of osteopenia of prematurity, a lack of opportunity to self-regulate, and delay in the development of lower extremity milestones.
Proprioceptive Nest (Mumbai, Maharashtra, India Patent No. 592-1, 2022) is an innovative nesting device designed to provide preterm babies with age-appropriate proprioceptive stimulation as well as comfort. It can also be used for positioning the baby in the supine, side lying, or prone position. The principle of keeping the baby in flexion with midline orientation of the extremity needs to be followed. Additionally, this can be used during handling the baby during feeding or interacting too.
It has a unique feature to accommodate the need of critical baby by being able to change its orientation and has a provision for allowing the monitoring of the baby using a pulse oximeter probe connected to the feet to continue while the positioning is not affected. Hence this study is planned to compare the efficacy of the proprioceptive nest with standard nesting practice to meet the proprioceptive needs of preterm neonates admitted to NICU and its effect on neuromotor development and bone mineralisation.

Recruitment of Participants

1 Randomization-
Random sequences for this study will be computer generated by a statistician who will not be involved in the study. Variable Permuted block randomisation will be applied using block sizes of 2, 4, and 6.

2 Allocation concealment:
will be done using sequentially numbered sealed opaque envelopes.

3 Blinding
The study intervention cannot be blinded.
The statistician and outcome assessors will be blinded.

4 Inclusion criteria:
All preterm neonates > 28 weeks gestation that are admitted in NICU

5 **Exclusion criteria:**
Neonates with major congenital anomalies

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