

Efficacy of Yakson touch and kinesthetic stimulation on the behavioral development, pain and vitals of pre-term neonates during critical care stay: A randomized controlled trial.

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Abstract

Background: Premature infants are susceptible to various sources of stress that is compounded by stays in critical care units. The evidence to recommend stimulation to reduce such stress in neonates is limited.

Purpose: Determine effects of intervention.

Methods: 64 pre-term neonates were randomized into two groups. One group received kinesthetic stimulation including the Yakson touch technique in addition to standard care while the other received only standard care. Primary outcome measures were the differences in the sleep-wake pattern and vital parameters and the secondary outcome measures pain response of preterm. ABSS and PIPP are between baselines and immediately after an invasive procedure. Analysis was per protocol.

Result: 58 neonates completed the trials and were analyzed. In the intervention group, ABS score change from 54.8% (pre-test) to 64.4% (post-test) for sleep and 45.2% (pre) to 35.5% (post) for awake in experimental group. 70.4% (pre) to 11.1% (post) for sleep and 29.6% (pre) to 88.9% (post) in control group. In PIPP the $p=0.73$ for control group and $p=0.001$ for the experimental group. The behavioral status in experimental group with the $p\text{-value}=0.001(<0.05)$. The heart rate $p\text{-value}$ of $0.001(<0.05)$, the respiratory rate the $p\text{-value}=0.005(<0.05)$; in oxygen saturation $p\text{-value}$ $0.02(<0.05)$

Conclusion: The intervention has significant effect on management of sleep-wake pattern, stabilization of the vitals (heart-rate, respiratory-rate and oxygen saturation) and minimization of pain during the heel-prick.

Implications for Practice: Neonatal nurses can Practice for early improvement in different aspects of pre-terms.

Implications for Research: Studies can be conducted for neuro-behavioral improvement by using this therapy.

Keywords: Efficacy, Yakson, Kinesthetic, Behavioral development, Pain, Pre-term.

Accepted on July 20th, 2021

Introduction

Pre-terms infants have incomplete physiological and behavioral development. Primary needs of infants are manifested through different behaviors and responses [1-2]. Pre term has so many adjustment problems soon after the delivery.

The external world is a source of major stress. This is made worse when they are admitted to Neonatal Intensive Care Units (NICU) with various hazardous stimuli such as lights, sounds, and invasive procedures performed for diagnostic and therapeutic purposes [1]. The striking difference between the intrauterine environment and the NICU is obvious. The sensory impact of the NICU has been postulated to adversely influence the neuro-developmental outcome of the preterm infants [1-3]. Therefore finding new methods to reduce stress in preterm infants in NICU is a notable issue in the field of nursing care.

Kinesthetic stimulation techniques including the Yakson touch have proven effective in minimizing the complications and disabilities of preterm delivery. Yakson is a Korean therapeutic

touch which is given to the infants and neonates by putting one hand on the back and caressing by the other hand [4]. Other kinesthetic stimulation includes the passive movement of all the extremities singly and then together [5-7]. The Yakson touch includes the use of warm hands, gentle touch without pressure and slow movement of the hands, which are appropriate for the preterm infants [3-5].

The Yakson therapeutic touch has been shown in some studies to have an effective role on neonate's vitals, pain and behavioral response. However, a Cochrane meta-analysis has stated that the evidence is still incomplete. There is an unmet need to augment the evidence base with further studies from low and middle income countries that still have high rates of neonatal mortality and morbidity [8].

Thus, this randomized control trial was carried out to determine the effects of yak son therapeutic touch followed by kinesthetic stimulation on behavioral response, vital parameters and pain response in preterm neonates [9].

Methods

All the preterm babies admitted in an NICU of a teaching hospital in Odisha were assessed for inclusion. All neonates with low birth weight (≥ 1500 g and ≤ 2499 g), aged 26-37 weeks who were under doing any invasive procedure like heel prick were included. Neonates on ventilators or on pressor agents, those with congenital anomalies or who had any surgery were excluded.

Sample size estimation

By adopting the reduction in respiratory rate as 3.4/min among the Yakson therapeutic touch group as well as reduction rate of 5.7 heart rate/min among Yakson therapeutic touch group at 1% level of significance and 90% of minimum study power, the per group required sample size is 45.

Randomization of subjects

Enrollment of samples was done according to the inclusion criteria. The simpler random sampling method was used by taking computer assisted randomization Table. The subjects were assigned according to their bed no. The no.1 was the indicator for experimental group and no.0 was for the control group. Though it was a thesis work the data collection was done for a period of 3 month and totally 64 samples were enrolled for this study.

Statistical analysis

Statistical analysis was done by using descriptive statistics for demographic variables and parametric test (independent t-test and paired t-test) to compare the variables for pain, sleep wake cycle and vitals (heart rate, respiratory rate and oxygen saturation) of pre and post score in between two groups by using SPSS-20.

Variables controlled

Covariates-socio demographic variables such as mother's age during pregnancy, maternal education status, history of high risk pregnancy, method of delivery, gender of the neonate, birth weight in gram, APGAR Score in 5 min, birth order of the baby, gestational age of the baby and age of the neonate.

Ethics statement

As in this study the participants were human subjects, the clearance has been taken from the Ethics committee of Kalinga Institute of Medical Sciences, KIIT Deemed to be University, Bhubaneswar, Odisha. The entire study was done as per the latest ethics recommendation of the Helsinki Declaration. The trial was registered under the clinical trial.gov with registration no CTRI/2019/04/018817. Informed written consent had taken from the parents of the babies before the enrollment of the trial.

Procedure

Anderson Behavioural State scale (ABSS), Premature-Infant-Pain-Profile scale (PIPP) and the existing vitals(heart-rate,

SPO2 and respiratory rate) was first assessed. Universal precautions were maintained and sterile conditions were taken.

In the experimental group, Yakson therapy followed by kinaesthetic stimulation of the limbs was given 5 minutes prior to starting the painful procedures like heel-stick and routine screening. First both the hands were warmed with a radiant warmer. With the neonate being in supine position, Yakson therapy was administered for 15 minutes. This was divided into resting the hands, caressing gently, and further resting the hands, each lasting for 5 minutes. Fingers and palm of the therapist was in constant contact with literally no pressure on the infant.

Resting the hands for 5 minutes on the chest and abdomen of the neonate, with the other hand supporting the back, caressing was carried out in the same position of the hands for 5 min. In kinaesthetic stimulation there were 6 passive movements each of the movement lasted for approximately 10 seconds. The movements were done by the following order: Right arm, left arm, right leg, left leg, and both legs simultaneously involving the full range of motion in major joints such as shoulder and hip joints [10]. The control group received only routine care. The post test was done in both groups after the heel-stick and routine screening test using the same Scales.

Results

Maximum numbers of mothers were age <20 years which comprise of 11(40.7%) in control group and 22 years-26 years 10(32.3%) in experimental group. In education level of mothers 13(48.1%) in control group and 15(48.4%) in the experimental group. In control group 14(51.9%) mothers and 17(54.8%) in experimental group mothers were in the history of high risk pregnancy. In the method of delivery 14(51.9%) are having the vaginal delivery in control group and 19(61.3%) caesarean section delivery in experimental group. majority of neonates 15(55.6%) male in control group and 21(67.7%) in experimental group [11,12].

Maximum pre-term neonates were 16(59.3%) in between the birth weight 1501-2000 gm in control group and 18(58.1%) in experimental group. In APGAR score 5 min 2(7.4%) were less than 3 and 11(40.7%) were more than 7 in control group and 17(54.8%) in experimental group. Majority of babies 15(55.6%) with the birth order three/more than three were in control group and 19(61.3%) with the first order in the experimental group. Maximum 14(51.9%) in control group were 28-32 weeks of gestational age and 10(32.3%) in experimental group were 33-37 weeks of gestational age of the pre-term neonates [13-16]. The study reveals that majority 13(48.1%) in control group and 21(67.7%) in experimental group having more than 3 days of postnatal age.

The pre-test behavioral score in control group was 3.9(SD=2.01) and in the experimental group was 4.5(SD=0.242) the calculated p-value was 0.296. In posttest the behavioral score was 8.56(SD=3.17) in control group and 3.94(SD=1.48) in experimental group with p value of 0.0001(<0.05) which was statistically significant (Table 1).

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| ABSS Score | Control group (Mean ± SD) | Experimental group (Mean ± SD) | Independent 't' test p-value |
|---------------------------|---------------------------|--------------------------------|------------------------------|
| Pretest behavioral score | 3.9 ± 2.01 | 4.5 ± 0.242 | 0.296 |
| Posttest behavioral score | 8.56 ± 3.17 | 3.94 ± 1.48 | 0 |

Table 1. Difference of pre-test and post-test score of behavioral status in experimental group. N=58(n₁=27, n₂=31).

In heart rate the pre-test score for control group was 2.0(SD=0.8) and in experimental group was 1.19(SD=0.7) with calculated p value was 0.001 and in posttest control group average 2.4(SD=0.7) and in experimental group it was

0.38(SD=0.49) with the p-value 0.001 which is also statistically significant. But in the post test the mean value is decreasing in experimental group than the control group. So it is clinically more significant (Table 2 and Figure 1).

| Characteristics | Control | | | | Experimental | | | |
|-----------------|---------|--------|-------|--------|--------------|--------|-------|--------|
| | Sleep | | Awake | | Sleep | | Awake | |
| | f | % | f | % | f | % | f | % |
| Pretest score | 19 | 70.40% | 8 | 29.60% | 17 | 54.80% | 14 | 45.20% |
| Post test score | 3 | 11.10% | 24 | 88.90% | 20 | 64.40% | 11 | 35.50% |

Table 2. Frequency and percentage distribution of behavioral status of neonates in experimental and control group. N=58(n₁=27, n₂=31).



Figure 1. Post-test mean score of heart rate in control and experimental group.

The pre-test average respiration rate in the control group was 51.5 ± 1.6 and in the experimental group was 51.8 ± 3.5 and the p-value was 0.75; but in the post test the average mean for

control group was 54.2 ± 3.5 and in experimental group was 51.3 ± 3.8 and the p-value was 0.005(<0.05) which was statistically significant (Table 3).

| Respiratory rate | Control-group | Experimental-group | Independent 't' test 'p' value |
|----------------------------|---------------|--------------------|--------------------------------|
| Pre-test respiratory-rate | 51.5 ± 1.6 | 51.8 ± 3.5 | 0.75 |
| Post-test respiratory-rate | 54.2 ± 3.5 | 51.3 ± 3.8 | 0.005 |

Table 3. Respiratory rate pre-test and post-test score in experimental and control group. N=58(n₁=27, n₂=31).

The pre-test average oxygen saturation in control group was 0.519 ± 0.5 and in experimental group was 0.548 ± 0.5 with calculated p value 0.82(>0.05) which is not significant. But the post-test oxygen saturation for control group was 0.778 ± 0.5 and in experimental group 452 ± 0.5.

The calculated p-value was 0.02(<0.05) which shows statistically a little significant in posttest after intervention (Table 4 and Figure 2).

| Oxygen saturation | Control-group | Experimental-group | Independent 't' test 'p' value |
|-----------------------------|---------------|--------------------|--------------------------------|
| Pre-test oxygen saturation | 0.519 ± 0.5 | 0.548 ± 0.5 | 0.82 |
| Post-test oxygen saturation | 0.778 ± 0.5 | 0.452 ± 0.5 | 0.02 |

Table 4. Oxygen saturation pre-test and post-test score in experimental and control group. N=58(n₁=27, n₂=31).

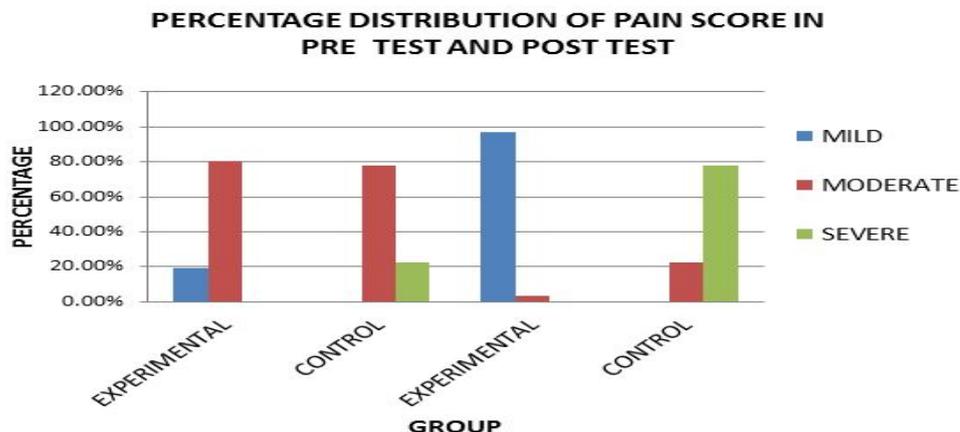


Figure 2. Percentage of pain scores in experimental and control group.

In the level of pain; in control group pre and posttest mean was 11.7 ± 2.03 and 14 ± 1.94 with the p value 0.073(>0.05) which was statistically not significant (Table 5).

In experimental group the pre and posttest mean was 8.25 ± 1.8 and 4.93 ± 1.43 with the p-value 0.001(<0.05) which was statistically significant (Figure 3).

| | Control group | | | | Experimental group | | | |
|-----------------|---------------|----|---------|---------|--------------------|----|---------|---------|
| | Mean ± S.D | df | t-Value | p-value | Mean ± S.D | df | t-Value | p-value |
| Pre-test score | 11.7 ± 2.03 | 26 | -6.288 | 0.073 | 8.25 ± 1.8 | 30 | 11.005 | 0 |
| Post-test score | 14 ± 1.94 | | | | 4.93 ± 1.43 | | | |

Table 5. Difference of level of pain in between control & experimental group in pre-test & post-test. N=58(n₁=27, n₂=31).

which was statistically significant and in pre-test sleep score in the control group was 70.4% and in the experimental group was 54.8%. After intervention on Yakson therapy and kinesthetic stimulation the post test sleep score in control group was 11.1% and in experimental group was 64.4%. So the intervention was effective on behavioral status for management of sleep-wake cycle after the painful procedures like heel prick and vein puncture in NICU.

In heart rate the pre-test average was 2.0(SD=0.8) and 1.19(SD=0.7) in control and experimental group respectively with calculated p value was .000 and in post-test control group average 2.4(SD=0.7) and 0.38(SD=0.49) in experimental group with the p-value 0.000 which is also statistically significant. The mean value is decreasing in experimental group than the control group. So it is clinically more significant.

The pre-test the average respiration rate in control group was 51.5 ± 1.6 and in experimental group was 51.8 ± 3.5 and the p-value was .75; but in the post test the average means for control group was 54.2 ± 3.5 and in experimental group was 51.3 ± 3.8 and the p-value was 0.005 which was statistically significant.

The pre-test average oxygen saturation in control group was 0.519 ± 0.5 and in experimental group was 0.548 ± 0.5 with calculates p value 0.82(>0.05) which is not significant. But the post-test oxygen saturation for control group was 0.778 ± 0.5 and in experimental group 0.452 ± 0.5. The calculated p-value

ASSIGNMENT OF PARTICIPANTS INTO EXPERIMENTAL AND CONTROL GROUPS

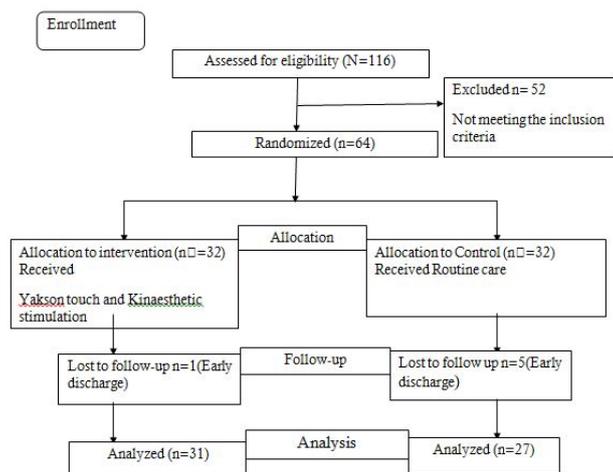


Figure 3. Consort flow diagram of intervention.

Discussion

In improvement of behavioral status the post-test the behavioural score 8.56(SD=3.17) in control group and 3.94(SD=1.48) in experimental group with p-value of 0.000

was $0.02 (<0.05)$ which shows statistically a little significant in post-test after intervention.

In the level of pain; in control group pre and post-test mean was 11.7 ± 2.03 and 14 ± 1.94 with the p value $0.073 (>0.05)$ which was statistically not significant. In experimental group the pre and post-test mean was 8.25 ± 1.8 and 4.93 ± 1.43 with the p-value $0.000 (<0.05)$ which was statistically significant.

In pre-test 80.6% in experimental group and 77.8% in control group having moderate pain and 19.4% having mild pain in experimental group and in Post-test 96.8% having mild pain in experimental group and 3.2% and 22.3% having moderate pain level in experimental group and control group respectively.

Parasar and others conducted a study on Yakson touch and kinesthetic stimulation on the development of the high risk neonates in neonatal Intensive care units: A randomized control trial. The aim of the study was to investigate the efficacy of Yakson touch in combination with kinesthetic stimulation on the development of high risk neonates. There were no significant differences between the groups ($p > 0.05$) but large effect size index was seen in the experimental group.

Eshghi et al. conducted a study on Effects of Yakson therapeutic touch on the behavioral response of premature infants. This study aimed to compare the effects of Yakson therapeutic touch and routine nursing care on the behavioral response of premature infants. This quasi-experimental study was conducted on 60 premature infants aged 26-34 weeks, admitted at the neonatal intensive care unit. The mean scores of ABSS in preterm infants of the intervention and control groups were 4.83 ± 0.14 and 10.63 ± 0.14 , respectively. Moreover, there was a significant difference between the scores of behavioral response after the intervention between the groups ($p = 0.001$).

Conclusion

The study results indicated that the Yakson therapeutic touch and the kinesthetic stimulation have the positive outcomes on the improvement of the pre-term neonates during the staying in NICU. We recommend this similar type of practice in the newborn set-up for early improvement and discharge of the pre-term neonates from the hospital.

Conflicts of Interest

Thankful to research and ethical committee (KIMS, KIIT DU IOE) for allowing me to conduct this study in NICU set-up, Received the grant from CTRI with registration number "CTRI/2019/04/018817".

Acronyms and abbreviations

NICU: Neonatal Intensive Care Unit; PIPP: Premature-Infant-Pain-Profile scale; ABSS: Anderson Behavioural State scale; SPO₂: Oxygen Saturation.

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