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# A Randomized Controlled Trial on Investigating the Effectiveness of Earplugs on Physiological and Behavioral Responses and Weight Gain in Preterm Neonates

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***Abstract***

*A randomized controlled trial was conducted to assess the effectiveness of earplugs on selected physiological and behavioral responses among preterm neonates, and their association with weight gain, using block randomization with computer-generated random numbers and the sealed envelope technique to recruit 223 preterm neonates born between 30 to less than 37 weeks of gestation, with a birth weight between 1000 grams and less than 2500 grams. A pair of earplugs was applied to each preterm infant in the study group in the SNCU. Heart rate, oxygen saturation, sleep duration, and behavioural responses were measured four times a day for five consecutive days. The statistical significance of these parameters was determined by repeated measures ANOVA, and Regression models. The mean heart rate of preterm neonates in the study group was statistically not significant during the intervention period. However, the application of earplugs improved oxygen saturation levels, increased sleep duration, and enhanced behavioural responses. There was a statistically significant ($p<0.05$) increase in weight gain during the intervention and similar trends were noted during the 2nd and 4th-week follow-up. It was determined that earplugs were effective in maintaining higher oxygen saturation, increasing sleep duration, enhancing behavioural responses, and were associated with weight gain. Non-invasive, cost-effective noise control measures, such as earplugs, can be recommended to improve physiological parameters like oxygen saturation, sleep duration, behavioural patterns, and weight gain in preterm neonates.*

***Keywords***: *Ear Plugs, Noise Control, Physiological and Behavioral Response, Preterm, SNCU.*

## Introduction

The quality of maternal and child health is a sensitive indicator of a country's development. According to the World Health Organization's "*Born Too Soon: Decade of Action on Preterm Birth"* report, India recorded the highest number with 3.2 million preterm births globally in 2020 [1, 2] The global preterm birth rate was 9.9% in 2020, while India's preterm birth rate was 13%. Out of the 7.5 million babies born with low birth weight (less than 2500 grams) in India, 40% are preterm [3].

Preterm infants spend their early days in the sensory-atypical environment of the Neonatal Intensive Care Unit (NICU), which is

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primarily composed of procedural touch, loud alarm noises, and bright lights [4]. The transition from the secure, optimal intrauterine environment to the relatively hostile NICU environment compounds the exposure to adversities for preterm neonates and affects the developing brain. The medical care for sick babies should be as close to the nurturing environment of the womb as possible, especially through the critical period of early brain development [5]. Key components of neurodevelopmental care include developmentally supportive activities of daily living, positioning, Kangaroo Mother Care (KMC), feeding, protected sleep, pain management, and control of external stimuli like noise [6,7].

Noise is defined as "an undesirable sound that interferes with communication or causes pain or disturbance in the ear" [8]. Sound levels in NICUs were often exceeding the maximum acceptable level of 45 dB recommended by the American Academy of Pediatrics and ranged from 7 dB to 120 dB. In India, NICU noise levels range from 60 dB to 90 dB [9]. The investigator noted that noise levels in the Special Newborn Care Unit (SNCU) at the study setting, as measured by a decibel meter, ranged between 75-80 dB.

Several studies have shown that exposure to high levels of noise during the critical growth stage affects the auditory development of neonates and leads to physiological instabilities, including fluctuations in heart rate, blood pressure, oxygen saturation, increased intracranial pressure, and changes in corticosteroid production. Noise has physiological effects with both short- and long-term implications on newborns [10]. The Committee on Environmental Health in 1997 reported that the prevalence of hypoxemia (low blood oxygen levels), behavioural abnormalities (in sleep, wakefulness, crying, etc.), and hearing loss were related to continuous noise exposure among preterm neonates cared for in the NICU [11]. There is evidence of the deleterious effects of high levels of sound pressure on neonates, including higher oxygen consumption and increased heart rate [12]. Increased pathophysiologic events such as apnea, bradycardia and disrupted sleep in hospitalized neonates have been associated with the adverse acoustic environment of the NICU [13].

Multiple approaches have been adopted to reduce noise exposure in NICUs, including hearing protection devices, modifications to incubator design, adjustments in caregiver activities, and architectural renovations, such as alterations of existing NICUs, and construction of single-family, single-bed rooms. Each of these approaches varies in complexity, effectiveness, and cost. Research has found that noise reduction enhances behavioral responses, including improved sleep quality and an increased amount of quiet sleep time in preterm neonates [12].

Wearing earplugs can reduce noise levels by [7–12]. Decibels A-weighted (dBA), equivalent to a 50% reduction in sound pressure. Noise level reduction in NICUs using earplugs has been shown to improve preterm physiological stability with lower heart and respiratory rates and higher mean arterial oxygen saturation and behavioural states, measured by the Anderson Behavioral State Scale (ABSS) [10]. Interventions such as earplugs, to protect preterm neonates from noise in the NICU, are beneficial in optimizing outcomes [13]. The study aimed to find the effectiveness of earplugs on the physiological and behavioral responses of preterm neonates and analyze the association between selected physiological and behavioral responses of preterm neonates using earplugs and their weight gain

## Materials and Methods

### Study Design

A randomized controlled trial design was adopted and was conducted in a children's speciality teaching hospital with 1400 beds, having the facilities for level III NICU, and providing health care services to mothers and children in and outside of Telangana.

### Sample and Size

Preterm neonates admitted at SNCU. Assuming a 95% confidence interval with 80% power and SD of weight on the last day of intervention was 240 grams and the expected difference was 96.91 grams, the required sample size was 97 per group; considering 15% of attrition, the sample size was 112 per group. (Considered as 115 per group, and the total size was 230).

### Sampling Technique

A simple random technique with block randomization was used to select 230 preterm neonates available at SNCU, by computer-generated randomized numbers in the sealed opaque envelope. After randomization, 114 preterm neonates were assigned to the study group and 109 to the control group and seven (7) preterm were shifted to level II NICU after randomization.

### Inclusion and Exclusion Criteria

Preterm born between 30 weeks and 36 6/7 weeks gestation, with a birth weight of 1000 grams to < 2500 grams, admitted in SNCU at inborn and outborn units of study setting, stable, and available for one week before the discharge were included in the study. Preterm with congenital anomalies and those admitted from places other than Telangana, discharged before the completion of the intervention, long distance of residence, and non-responsiveness to phones were excluded from the study.

The study was carried out in accordance with the guidelines of the consort of recruitment, depicted in Figure 1.

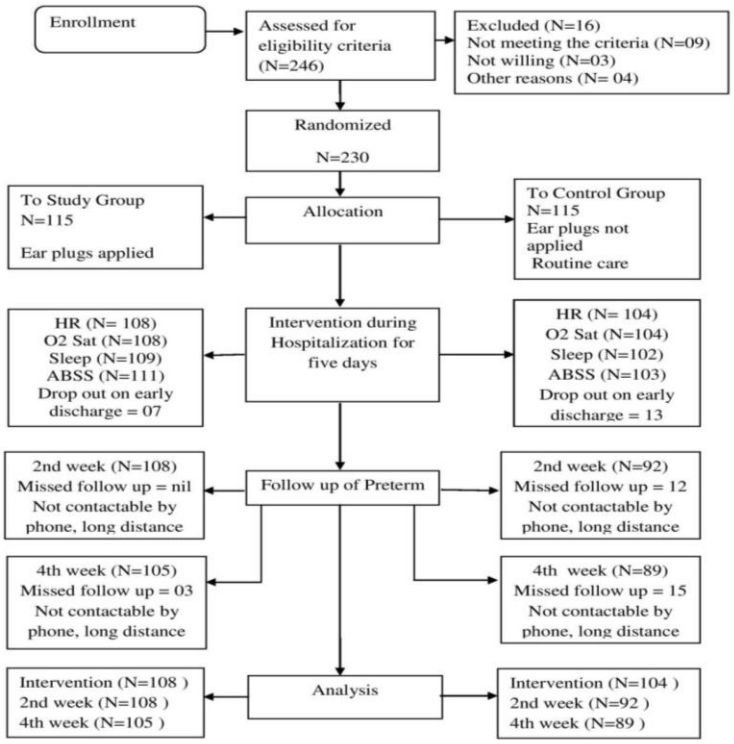


**Figure 1.** Consort Flow Diagram of Study Recruitment

**Data Collection Procedure**

The principal investigator recruited and trained two registered graduate nurses to measure and record the physiologic and behavioral responses of preterm neonates. In consultation with the in-charge neonatologists at SNCU, the tentative date for the discharge of the preterm was noted. On the day of recruitment, eligible and hemodynamically stable preterm were listed as per the date of admission and were randomized. The mother or significant family member was explained about the intervention and obtained informed consent.

Baseline data of the preterm was recorded in the proforma as per the case sheet. SNCU nurses on duty were blinded by the subjects under study. A head cap attached with ear flaps and an eye shield was provided to each preterm neonate placed in the crib for both groups. A pair of earplugs were applied to each preterm in the study group. Ear plugs were commercially available as "Disposable PU Foam EAR-PLUG" by KARAM Industries at C-35, Phase III, E.S.I.P., Sitargunj, U.Nagar, Uttarakhand, India-262405, made up of soft silicon material, pliable, corded, coded as EP 2, with a noise reduction rate (NRR) of 32 dB and a signal-to ratio (SNR) of 37 dB. The mother or significant family member was instructed to keep the earplugs in both ears for as much time as possible. Selected physiological parameters, that is, heart rate and oxygen saturation were recorded from the electronic monitors attached to the preterm with a probe and documented in the structured proforma. Duration of sleep was documented as per the verbal statement of the mother. Behavioural responses were measured by adopting ABSS, a standardized tool [14] and documented in the structured proforma.

Heart rate, oxygen saturation, and Behavioral responses were measured in the study group four times a day from 9 a.m. to 4 p.m. for five consecutive days, that is, before applying ear plugs, after two hours of applying ear plugs with an interval of two hours, and after 15 min of removing ear plugs. The duration of sleep was recorded in two divided timings, i.e., 9 am to 3 pm and 3 pm to 9 am, as per the verbal statement of the mother or significant family member available during the time of data collection. The preterm in the control group were provided with similar care except ear plugs. Heart rate, oxygen saturation, duration of sleep, and behavioural response were measured without earplugs in similar duration and frequency. A pilot study was conducted from 12.11.2021 to 26.11.2021 in two spells at SNCU and follow-up was completed in February 2022. Reliability was tested by using Pearson's and Cronbach's alpha formulas, which was 0.86. The study period was 12 months (from November 2021 to October 2022).

**Statistical Analysis**

Statistical analysis was carried out by using SPSS version 24. The p-value was considered significant if it equals or is less than 0.05. Preterm demographic variables and physiological parameters were computed by measures of central tendency, a t-test for comparing the differences between the groups at different time points, and ANCOVA was used whenever the initial differences were noted between groups. Effect size was also calculated to compare the magnitude of standardized mean differences between groups. A regression model was used to identify the association of weight gain as a dependent variable with physiological responses i.e., heart rate, oxygen saturation, sleep duration, and behavioural response measured by ABSS and group as independent variables.

## Results

A total of 223 preterm were randomized for the study and allocated 114 preterm to the study group and 109 to the control group, out of which, 105 in the study group and 89 in the

control group could complete 4th-week follow-up after discharge. Data was presented in the tables and figures.

**Table 1.** Characteristics of Preterm Neonate

| Variable | Distribution | Study Group N= 114 | Control Group N= 109 | $\chi 2$ | p |
|---|---|---|---|---|---|
| | | F (%) | F (%) | | |
| **Gender** | Female | 57 (50) | 62 (56.9) | 1.060 | 0.303 |
| | Male | 57 (50) | 47 (43.1) | | |
| **Gestational Age at birth in weeks** | 30 -31 | 29 (25.5) | 32 (29.4) | 5.360 | 0.252 |
| | 32 -33 | 60 (52.6) | 47 (43.1) | | |
| | 34 -35 | 16 (14) | 24 (22) | | |
| | 36 -<37 | 9 (7.9) | 6 (5.5) | | |
| **Weight in Grams** | 1000 -1250 | 27 (23.7) | 30 (27.5) | 1.090 | 0.896 |
| | 1251-1500 | 44 (38.6) | 39 (35.8) | | |
| | 1501 -1750 | 24 (21.1) | 21 (19.3) | | |
| | 1751 -2000 | 13 (11.4) | 15 (13.8) | | |
| | 2001 -2250 | 06 (5.3) | 4 (3.7) | | |
| **Order of birth** | One | 65 (57) | 60 (55) | 2.306 | 0.805 |
| | Two | 30 (26.3) | 29 (26.6) | | |
| | Three | 16 (14) | 16 (14.7) | | |
| | Four | 3 (2.6) | 2 (1.8) | | |
| | Five | 0 (0) | 1 (0.9) | | |
| | Six and above | 0 (0) | 1 (0.9) | | |

Details in Table 1 show that the demographic characteristics of preterm were statistically not significant across the groups.

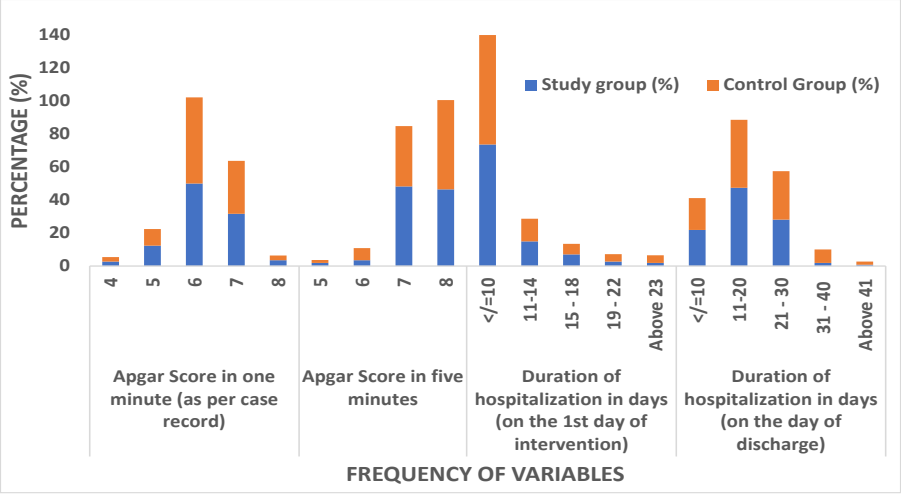


**Figure 2.** Characteristics of Preterm Neonate

It was evident from Figure 2, that the majority of preterm in both groups had less than 10 days of hospitalization on the 1st day of the intervention.

**Table 2.** Mean ± SD of Physiologic Parameters, Behavioral Responses and Weight of Preterm During Intervention

| Variable | Time | Study group (With earplugs) | | Control group (no earplugs) | | t | p | Effect Size |
|---|---|---|---|---|---|---|---|---|
| | | N | Mean & S.D. | N | Mean & S.D. | | | |
| Heart Rate | Before applying earplugs | 108 | 138.8 ± 9.90 | 104 | 139.64 ±11.68 | 0.856 | 0.393 | |
| | After Applying earplugs | | 138.5 ± 7.63 | | 140.11 ± 10.29 | 1.280 | 0.202 | |
| | After the removal of Earplugs | | 138.9 ± 0.43 | | 140.18 ± 10.05 | 0.939 | 0.349 | |
| Oxygen Saturation | Before applying earplugs | 108 | 94.70 ± 1 72 | 104 | 94.74 ± 1.76 | 0.169 | 0.866 | |
| | After applying earplugs | | 95.62 ± 1.52 | | 94.62 ± 1.62 | 4.634 | 0.000 | |
| | After the Removal of earplugs | | 95.07 ± 1.77 | | 94.69 ± 1.69 | 1.590 | 0.113 | |
| Sleep in Hours | 9 am-3 pm | 109 | 4.9 ± 0.25 | 102 | 4.3 ± 0.28 | 15.14 | 0.000 | 0.232 |
| | 3 pm-9 am | | 16.2 ± 0.48 (16.0)* | | 14.6 ± 1.06 (14.8)* | 14.48 | 0.000 | |
| | Total | | 21.1 ± 0.53 (20.8)* | 86 | 18.7 ± 0.93 (19.1)* | 21.73 | 0.000 | 0.399 |
| Behavioural response (ABSS) | Before applying earplugs | 111 | 4.6 ± 0.99 | 103 | 4.2 ± 0.81 | 2.88 | 0.005 | |
| | After applying earplugs | | 3.7 ± (3.6)* 0.95 | | 4.3 ± (4.4)* 0.73 | 4.657 | 0.000 | 0.343 |
| | After the Removal of earplugs | | 3.9 ± (3.8)* 0.81 | | 4.1 ± (4.2)* 0.81 | 1.868 | 0.063 | 0.092 |
| Weight during intervention | on 1st day | 114 | 1.39 ± 0.26 | 109 | 1.37 ± 0.25 | 0.636 | 0.032 | 0.028 |
| | On 5th day | 109 | 1.44 ± 0.27 (1.43)* | 92 | 1.39 ± 0.23 (1.40)* | 1.365 | | |

**Note**: *Mean Values of Sleep Hours, Behavioral Response and Weight Have Been Adjusted to Baseline Using ANCOVA.

Table 2 shows that there was a statistically significant association towards oxygen saturation ($p<0.05$), duration of sleep and ABSS score ($p=0.000$) in the study group compared to the control group after application of ear plugs, but statistically not significant towards heart rate across the groups. Preterm neonates showed 50 grams of weight gain in the study group and 20 grams in the control group during the statistically significant intervention period ($p<0.05$).

**Table 3**. Mean & SD of Selected Physiologic Parameters of Preterm Neonate During 2nd and 4th Week Follow-Up

| Variable | Time (week of follow-up) | N | Study group | N | Control group | t | p |
|---|---|---|---|---|---|---|---|
| | | | Mean & S.D. | | Mean & S.D. | | |
| Heart Rate | 2nd | 108 | 143.1 ± 9.44 | 92 | 139.1 ± 11.09 | 2.752 | 0.006 |
| | 4th | 105 | 138.2 ± 7.12 | 89 | 134.6 ± 11.58 | 2.517 | 0.010 |
| Oxygen Saturation | 2nd | 108 | 96.99 ± 1.41 | 92 | 95.5 ± 1.73 | 6.662 | 0.000 |
| | 4th | 105 | 97.7 ± 1.48 | 89 | 96.1 ± 1.81 | 6.889 | 0.000 |

Table 3 denotes that the mean heart rate in the study group was statistically significant ($p<0.05$) during the 2nd and 4th week follow-up. The mean Oxygen saturation level in the study group was highly significant ($p=0.000$).

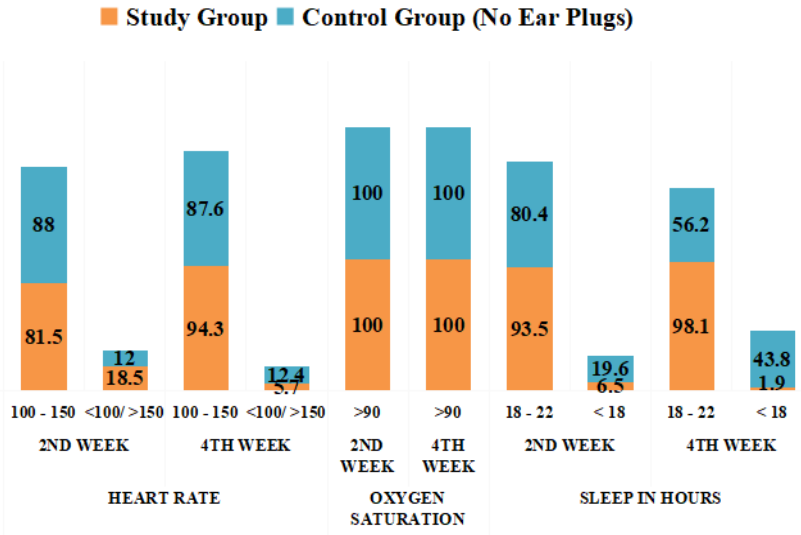


**Figure 3.** Distribution of Preterm Neonates According to Selected Physiologic Parameters During 2nd and 4th Week Follow-Up

Figure 3 depicts that the Preterm neonates who had heart rates less than 100 or more than 150 bpm during the 2nd-week follow-up were 18.5%, reduced to 5.7% during the 4th-week follow-up in the study group.

**Table 4.** Comparison of Preterm by Physiologic & Behavioral Responses During Intervention

| Variable | Time of Applying earplugs | Category (Beats per minute) | Study Group (with earplugs) | | Control Group (No Ear Plugs) | | $\chi^2$ | p |
|---|---|---|---|---|---|---|---|---|
| | | | N | F(%) | N | F(%) | | |
| Heart Rate | Before | 100 - 150 | 108 | 96 (88.9) | 104 | 84 (80.8) | 2.725 | 0.09 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | application | <100/>150 | | 12 (11.1) | | 20 (19.2) | | 9 |
| | After application | 100 - 150 | 108 | 102 (94.4) | 104 | 89 (85.6) | 4.668 | 0.031 |
| | | <100/>150 | | 6 (5.6) | | 15 (14.4) | | |
| | After Removal | 100 - 150 | 108 | 100 (92.6) | 104 | 88 (84.6) | 3.358 | 0.067 |
| | | <100/>150 | | 8 (7.4) | | 16 (15.4) | | |
| Oxygen Saturation | Before application | >90 | 108 | 108 (100) | 104 | 104 (100) | -- | -- |
| | After application | >90 | 108 | 108 (100) | 104 | 103 (99) | 1.043 | 0.307 |
| | | <90 | | 0 | | 1 (1) | | |
| | After Removal | >90 | 108 | 108 (100) | 104 | 103 (99) | 1.043 | 0.307 |
| | | <90 | | 0 | | 1 (1) | | |
| Sleep in Hours per day. | | 18-22 | 105 | 105 | 86 | 72 (83.7) | 18.445 | 0.000 |
| | | <18 | | 0 | | 14 (16.3) | | |
| ABSS (Behavioral Response) | Before application | Quite | 111 | 97 (87.4) | 103 | 99 (96.1) | 5.284 | 0.022 |
| | | Alert | | 14 (12.6) | | 4 (3.9) | | |
| | After application | Quite | 111 | 110 (99.1) | 103 | 100 (97.1) | 1.179 | 0.278 |
| | | Alert | | 1 (0.9) | | 3 (2.9) | | |
| | After Removal | Quite | 111 | 110 (99.1) | 103 | 102 (99) | 0.003 | 0.958 |
| | | Alert | | 1 (0.9) | | 1 (1) | | |

It was observed from Table 4 that there was a statistical significance in the normal range of heart rate and sleep of 18–22 hours per day ($p < 0.05$) during the intervention period, after the application of earplugs in the preterm. However, the association between oxygen saturation >90% and behavioural responses after the application of earplugs, measured by ABSS, was statistically not significant.

**Table 5.** Regression Model for Weight Gain in Preterm

| **Best variables(after application of earplugs)** | **Preterm neonate weight gain at 4th-week follow-up** | | | |
|---|---|---|---|---|
| | **B Coefficient** | **P** | **$R^2$(%)** | **F** |
| Constant | -4.354 | 0.002 | 29.3 | 24.037 |
| Oxygen saturation | 0.051 | 0.000 | | |

| | | | | |
|---|---|---|---|---|
| Behavioural response measured by ABSS | -0.065 | 0.013 | | |
| Group (Study group) | -0.177 | 0.000 | | |

Table 5 presents the Regression model analysis of the weight gain in the preterm neonates (29.3%) at the 4th-week follow-up (dependent variable) with the best 3 independent variables i.e., oxygen saturation, Behavioral response measured by ABSS after application of ear plugs and the group were statistically highly significant ($p< 0.05$).

## Discussion

This was one of the very few randomized controlled trial studies in India, carried out on 223 preterm neonates to identify the association of earplugs with weight gain. Most other studies available in open-access journals were noted to be crossover studies with limited sample sizes. The present study revealed that there was a high statistical significance in oxygen saturation, sleep duration, and behavioural responses measured by ABSS and weight gain, at different times after the application of earplugs ($p < 0.05$). The majority of preterm had less than 10 days of hospitalization on the first day of the intervention. It was noted that hospital stays were comparatively reduced in the study group. A few characteristics of preterm babies, such as gestational age, birth weight, and Apgar score, were similar to the results of a study conducted by Eman [12].

The mean heart rate was not statistically significant during the intervention period in the study group, but it became statistically significant ($p < 0.05$) during the 2nd and 4th week follow-up. In the control group, 14.4% of preterm recorded a heart rate <100 or >150 bpm, whereas it was 5.6% in the study group after the application of earplugs. There was a statistical significance ($p < 0.05$) in the normal range of heart rate range among preterm neonates during the intervention after the application of earplugs, but this was not statistically significant during the 2nd and 4th-week follow-up. Although the mothers of the study group subjects were informed to continue using the earplugs at home after discharge (not included in the study), it cannot be confirmed that they did so. These results were matching to a study by Abujarira et al [15], in which the observed linear increase in heart rate was significantly reduced in the earmuff group (139 vs. 146 bpm for the control group, $p < 0.001$). However, these results contrast with those of Deswinda et al. [16], where the heart rate in the earplug group was lower ($138.15 \pm 15.91$) than in the control group ($147.53 \pm 6.94$).

There was a statistical significance ($p = 0.000$) in the mean oxygen saturation level in the study group after the application of earplugs. The mean oxygen saturation in the study group during the 2nd and 4th-week follow-up was also statistically significant ($p = 0.000$). These results were similar to the studies by Nasrin et al. and Abdeyazdan et al. [11,17], which found that when earplugs were applied to neonates, they had significantly higher oxygen saturation ($p < 0.001$). Similarly, a study by Howayda et al. [18] revealed that oxygen saturation was higher in the earplug group than in the control group ($96.13 \pm 0.81$ vs. $93.31 \pm 1.25$, respectively).

The data about sleep duration was obtained through verbal statements from the mother or significant family members available with preterm. The mean sleep hours in the study group during the five days of intervention were statistically significant ($p = 0.000$). Most

of the preterm in the control group were recorded as having slept less than 18 hours per day at the 4th-week follow-up. Preterm in the study group had slept between 18 and 22 hours per day at the 2nd week ($p < 0.005$) and 4th-week ($p = 0.000$) follow-up, which was highly statistically significant. It was inferred that the application of earplugs would reduce noise and thereby increase sleep hours.

The mean ABSS score in the study group after the application of earplugs indicated a quiet state of behavioural response and was statistically significant ($p = 0.000$). The findings of this study matched with a study conducted by Nasrin et al. [11], that the preterm with earmuffs had lower ABSS scores and better sleep compared to those without earmuffs ($2.38 \pm 0.47$ vs. $4.8 \pm 0.97$, $p < 0.05$). It has been shown that noise reduction enhances behavioural responses, including sleep quality and the duration of quiet sleep in preterm.

There was a medium effect size for total hours of sleep and behavioural patterns measured by ABSS, after the application of earplugs, and a small effect size for hours of sleep from 3 p.m. to 9 a.m. and behavioural patterns measured by ABSS after the removal of earplugs. The average weight gain of 50 grams in the study group preterm on the 5th day of intervention against 20 grams of weight gain in the control group preterm showed that the earplugs had a significant impact. The association between oxygen saturation, ABSS, and weight gain in preterm was evident from the multiple regression model that 29.3% of weight gain in preterm was associated with three independent variables i.e., group, oxygen saturation, and ABSS, which was highly significant ($p < 0.000$). The effect size was not reported in previous studies. More evidence is required to understand the association of these physiological parameters with weight gain in the initial months of life.

The majority of findings in this study i.e., the difference in the mean heart rate, sleep pattern and oxygen saturation were similar to a study done by Yojana Parmar et.al [19]. Amanpreet et al. hypothesized that the application of earplugs to preterm, nursed in incubators in the NICU, would reduce spikes and fluctuations in their physiological parameters [20]. Earplugs could protect preterm averse to noise, resulting in increased duration of sleep, maintain the selected physiological parameters within normal range, enhance behavioural response to a quiet state, and also improve weight gain.

## Conclusion

The application of earplugs can maintain physiological parameters in the normal range and enhance the behavioral responses among preterm neonates. Earplugs are cost-effective, non-invasive, safe and easy-to-use devices among preterm neonates admitted to SNCU, helpful for growth.

## Ethical Approval

Ethical approval was obtained by

1. IEC of Osmania Medical College (Parent medical college of Nilofer Hospital), vide No. ECR/300/Inst/AP/2013/RR- 19 dt. 29.06.2020

2. IEC of SRIHER: Lr. No. IEC-N1/20/SEP/75/67 Dt. 19.01.2021

## Conflicts of Interests

The authors declare no conflicts of Interest.

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