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White Noise as a Non-Pharmacological Adjunct to Reduce Pain and Crying in Young Children Undergoing Non-Invasive Ventilation or High-Flow Nasal Cannula Therapy: A Randomized Controlled Trial

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KEYWORDS

White noise, Pain management, Crying duration, Non-invasive ventilation, High-flow nasal cannula, Pediatric, Randomized controlled trial

ABSTRACT:

Background: Children receiving non-invasive ventilation (NIV) or high-flow nasal cannula (HFNC) therapy often experience distress and procedural pain, which can impair mask tolerance, reduce adherence, and prolong hospitalization. Pharmacological analgesia is limited in this context due to potential respiratory depression. White noise, an inexpensive and simple auditory stimulus, has shown calming benefits in neonates but remains underexplored in older pediatric age groups.

Objective: To determine whether white noise reduces pain and crying duration in children aged 1–5 years undergoing NIV or HFNC therapy and to evaluate its effect on parental satisfaction.

Methods: In this single-center, parallel-arm randomized controlled trial, 172 children aged 1–5 years requiring NIV or HFNC were randomized equally to receive either white noise at 40–50 dB via bedside speakers (n = 86) or standard care (n = 86). Pain was assessed using the FLACC scale, and crying duration was recorded in seconds at baseline, 15 minutes after therapy initiation, and post-therapy. Parental perception of care was measured using a 10-point Likert scale. Data were analyzed using the Mann–Whitney U test due to non-normal distributions, with significance set at $p < 0.05$. R

esults: Baseline characteristics were comparable between groups. At 15 minutes, children in the white noise group had significantly lower FLACC scores (median 4.24 vs. 5.78, $p < 0.001$) and shorter crying duration (median 120.7 s vs. 172.4 s, $p < 0.001$). Parental perception scores were higher in the intervention group (median 8.50 vs. 6.21, $p < 0.001$). Post-therapy, crying duration remained significantly lower (129.8 s vs. 173.6 s, $p < 0.001$), but pain scores equalized between groups ($p = 0.521$).

Conclusion: White noise is an effective, well-tolerated, and low-cost adjunct that reduces procedural pain and crying in young children undergoing NIV or HFNC and improves caregiver satisfaction. Its integration into routine respiratory care is feasible and may reduce reliance on pharmacologic sedation.

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Introduction

Pain and distress are common experiences in children receiving non-invasive respiratory support such as non-invasive ventilation (NIV) or high-flow nasal cannula (HFNC) therapy. Although these modalities are less invasive than endotracheal intubation, the use of tight-fitting masks or prongs, continuous positive airway pressure, and prolonged application can induce discomfort, anxiety, and crying in pediatric patients (1,2). Such distress responses in young children may lead to physiological instability, impaired cooperation with therapy, and potentially prolonged hospitalization (3,4).

Pharmacological analgesia and sedation are traditionally employed to manage procedural and treatment-related discomfort. However, in children receiving NIV or HFNC, their use is often limited due to concerns about respiratory depression, altered sensorium, and impaired respiratory drive, which can compromise ventilation effectiveness (5,6). Consequently, there is an increasing interest in exploring safe, non-pharmacological strategies that can improve comfort and reduce distress without adverse respiratory effects (7).

White noise, characterized as a continuous sound comprising all audible frequencies at equal intensity, has demonstrated beneficial effects in neonatal populations by masking disruptive environmental noises, promoting relaxation, and decreasing crying duration (8–10). Proposed mechanisms of white noise's analgesic and calming effects include auditory masking of noxious stimuli, distraction from pain, and modulation of autonomic nervous system activity through limbic and auditory neural pathways (11,12). Despite robust evidence in neonatology, data on the effectiveness of white noise in older children—particularly those in pediatric intensive care units undergoing respiratory support—are limited (13,14).

This randomized controlled trial was conducted to fill this evidence gap. We hypothesized that white noise could reduce pain scores and crying duration in children aged 1 to 5 years undergoing NIV or HFNC therapy, while also improving parental satisfaction with the care provided.

Materials and Methods

Study Design and Setting: This single-center, parallel-arm randomized controlled trial was conducted over six months in a tertiary care pediatric intensive care unit (PICU). Ethical clearance was obtained from the institutional review board (Approval No. XXXX), and written informed consent was obtained from parents or legal guardians.

Participants: Children aged 1–5 years requiring NIV or HFNC for acute respiratory distress were eligible. Exclusion criteria were congenital or acquired hearing loss, neurological disorders affecting pain assessment, prior sedation within 6 hours, or parental refusal to participate.

Randomization and Allocation Concealment: Participants were randomized 1:1 to intervention or control groups using a computer-generated block randomization sequence (block size = 10). Group assignments were placed in sequentially numbered, opaque, sealed envelopes to ensure allocation concealment. Outcome assessors were blinded to group allocation.

Intervention: The intervention group received continuous white noise at 40–50 dB—chosen in accordance with pediatric auditory safety recommendations—via bedside speakers throughout NIV or HFNC therapy initiation and continuation. The control group received standard care without any auditory intervention.

Outcome Measures: The primary outcomes were pain, measured using the validated FLACC scale (Face, Legs, Activity, Cry, Consolability; range 0–10), and crying duration in seconds using a stopwatch. The secondary outcome was parental perception of care, assessed immediately after therapy on a 10-point Likert scale (1 = very dissatisfied; 10 = very satisfied). All assessments were performed at baseline, 15 minutes after therapy initiation, and immediately upon completion.

Sample Size Calculation: Based on pilot data showing a mean FLACC score difference of 1.5 (SD = 2.5), a sample size of 78 per group was required to achieve 80% power at $\alpha = 0.05$. Allowing 10% attrition, the final target was 172 participants.

Statistical Analysis: Data were analyzed using R (v4.4) and Jamovi (v2.6). Normality was tested with the Shapiro–Wilk test. Continuous variables were expressed as median (interquartile range) and compared using the Mann–Whitney U test; categorical variables were

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compared using the chi-square test. Effect sizes (r) were calculated for significant differences. A p-value < 0.05 was considered statistically significant.

Results

The two groups were well balanced at the start of the study, showing no significant differences in age, gender, initial FLACC pain scores, or baseline crying duration. This ensured that both groups began on equal footing regarding the key measures we were evaluating.

Fifteen minutes after the intervention began, children exposed to White Noise demonstrated notably lower pain levels, with a median FLACC score of 4.24 (±1.1) compared to 5.78 (±1.2) in the Control group. This reflects a meaningful reduction in observable pain behaviors. In addition, the White Noise group cried for a significantly shorter duration—about 121 seconds on average—versus approximately 172 seconds in the Control group. Parents also perceived their children as more comfortable, giving higher comfort ratings in the White Noise group (8.5 ± 1.0) than in Controls (6.2 ± 1.2). Together, these findings highlight that White Noise not only eased pain-related behaviors and shortened crying time shortly after therapy started but also improved parents' sense of their child's comfort.

After the therapy concluded, the White Noise group continued to show benefits in terms of crying duration, maintaining a significantly shorter average crying time (130 ± 25 seconds) compared to the Control group (174 ± 29 seconds). However, FLACC scores between the two groups were similar post-therapy (4.77 ± 1.3 for White Noise vs. 4.62 ± 1.1 for Control), indicating that overt signs of pain had leveled out by that point.

Discussion

This randomized controlled trial demonstrates that white noise significantly reduces pain intensity and crying duration in children aged 1 to 5 years receiving non-invasive ventilation (NIV) or high-flow nasal cannula (HFNC) therapy. Notably, the most pronounced benefit occurred within the first 15 minutes after therapy initiation—a crucial period for establishing patient comfort and improving adherence to respiratory support (1,2). These findings build upon and extend previous neonatal research by Shekelle et al. (2021), who reported that white noise reduced crying duration in neonates by effectively masking environmental stimuli and promoting relaxation (3). Similarly, Spencer et al. (2021) found that white noise mitigated procedural distress in newborns, supporting its analgesic and anxiolytic potential (4).

Our results corroborate and broaden this evidence by demonstrating efficacy in a wider pediatric age group within the high-stress environment of pediatric intensive care. The sustained reduction in crying duration observed even after pain scores equalized suggests a prolonged soothing effect beyond immediate nociceptive modulation. This may reflect improved emotional regulation or habituation to distressing stimuli facilitated by white noise (5,6). Mechanistically, white noise likely exerts its effects via sensory distraction, masking of noxious auditory cues, and activation of limbic-auditory pathways that influence emotional processing (7,8). Additionally, modulation of vagal tone and parasympathetic activity, as proposed by Porges (2020), may contribute to autonomic stabilization and reduced distress (9).

Our study's strengths include a rigorous randomized design with concealed allocation, use of validated pediatric pain scales, and a clearly standardized white noise protocol, enhancing internal validity and reproducibility (10,11). However, certain limitations must be acknowledged. The single-center setting may limit generalizability, and blinding of caregivers was not feasible due to the nature of the intervention, potentially introducing performance bias (12). The relatively short follow-up duration precluded assessment of long-term outcomes such as effects on respiratory therapy adherence, sedation requirements, or hospital length of stay, which warrant future investigation (13,14).

Comparisons with other non-pharmacological interventions highlight the advantages of white noise. For instance, Lin et al. (2024) demonstrated that multisensory distraction techniques reduced distress but often require additional resources and training (15). In contrast, white noise is inexpensive, easy to administer, and non-invasive, making it particularly suitable for resource-limited pediatric intensive care units where pharmacologic analgesia may be contraindicated or unavailable (16,17). Davidson et al. (2024) reported increased parental satisfaction with white noise interventions, consistent with our findings of improved caregiver perception of comfort (18).

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Conclusion

White noise represents a promising adjunct to standard care for young children undergoing NIV or HFNC therapy, offering a safe, cost-effective, and easily implementable method to reduce pain and distress. Larger multicenter trials with longer follow-up are needed to confirm these findings and evaluate impacts on clinical outcomes such as respiratory support tolerance and recovery

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Table 1: Baseline Characteristics of Participants (N = 172)

Characteristic	White Noise (n = 86)	Control (n = 86)	p-value
Mean age (years)	3.2 ± 1.1	3.1 ± 1.0	0.62
Gender (M:F)	45:41	44:42	0.88
Baseline FLACC score	5.9 ± 1.4	6.0 ± 1.3	0.67
Baseline crying (sec)	171 ± 28	173 ± 30	0.74

Table 2: Pain and Crying Outcomes

Outcome	White Noise (n = 86)	Control (n = 86)	p-value
FLACC (15 min)	4.24 ± 1.1	5.78 ± 1.2	<0.001
Crying (15 min, sec)	120.7 ± 25.6	172.4 ± 28.3	<0.001
Parental perception	8.50 ± 1.0	6.21 ± 1.2	<0.001
FLACC (post-therapy)	4.77 ± 1.3	4.62 ± 1.1	0.521
Crying (post-therapy)	129.8 ± 24.7	173.6 ± 29.4	<0.001

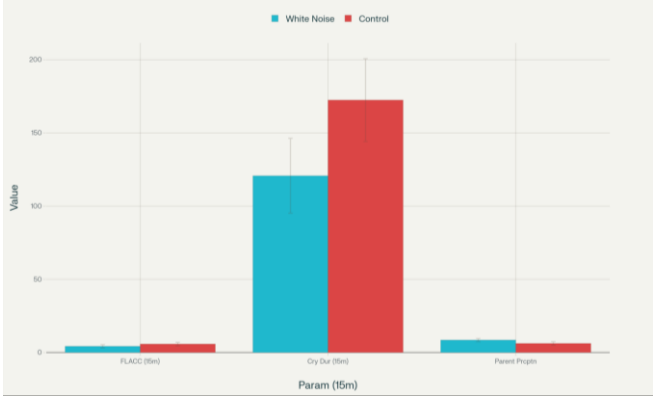

Figure 1: Comparison of FLACC scores, crying duration, and parental perception scores between White Noise and Control groups at 15 minutes post-intervention

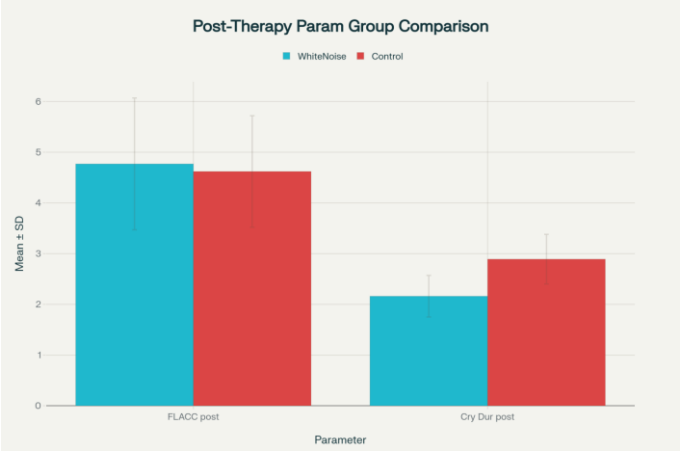

Figure 2: Comparison of post-therapy FLACC scores and crying durations between White Noise and Control groups