## Research

# White Noises and Parental Voices Against Noises Damage in preterm babies: a randomised trial's protocol

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**Abstract**

**Introduction**. Adaptation to extrauterine life is challenging for preterm babies. Environmental stimuli, like noises, could lead to adverse health outcomes, causing instability in vital parameters and neurodevelopment impairment. American Academy of Pediatrics recommends a maximum environmental noise ≤ 45 decibels (dB) in the Newborn Intensive Care Units (NICUs). We hypothesise that listening to white noises and parental voices could mitigate the adverse outcomes caused by noises > 45 dB on preterm babies.

**Methods**. A randomised controlled trial (ClinicalTrials.gov, NCT06150404) aimed to include preterm babies of ≥31 weeks gestation, meeting the specific inclusion criteria. Data regarding environmental noises and vital parameters will be collected from all patients enrolled from the day of enrollment till their discharge. In addition, data regarding language and hearing development will be collected respectively after three years and three months from discharge. A soundtrack with white noises and parental voices will be administered to preterm babies enrolled in the intervention group through an mp3 device.

**Expected Results.** If our hypothesis is confirmed, this study could benefit preterm babies by reducing adverse outcomes linked to excessive environmental noise, such as vital parameters instability and language and hearing impairment. Study results could also affect care practices in NICU settings to ensure patient safety, even if the null hypothesis is confirmed. The data collected will be utilised to understand environmental noise levels in our NICU and implement improvement projects in their management.

**Keyword:** Nursing, Parents, Randomized Controlled Trials as Topic, Infant, Premature, Noise, Voice

## Introduction

Preterm births are a global health issue: 1 in 10 babies is born preterm (<37 weeks gestation), approximately one every two seconds. Their survival rate depends on where their birth came from: in high-income countries, 9 in 10 extremely preterm babies (<28 weeks gestation) will survive, but in low-income countries, only 1 in 10 will survive[1]. These patients are admitted to Newborn Intensive Care Units (NICUs), where the environment has to be adequately structured to support their neurodevelopment[2]. Even if, in the last decades, the survival rate of these patients has increased, there is a disproportionate growth in disability and healthcare needs in preterm babies compared to the general pediatric population[3]. This growth in disability and healthcare needs is also caused because preterm babies in NICU settings are exposed to numerous environmental stresses that are harmful to their neurodevelopment. Among the environmental stressors, the most ordinary and most challenging to control are environmental noises[4,5]. The American Academy of Pediatrics (AAP) have since 1997 established that the environmental noise level has to be ≤45dB to be safe and not adversely affect the neurodevelopment of preterm babies[6]. Despite this recommendation, the noise level in NICUs remains a significant problem worldwide, regardless of the efforts made on this topic[7].

Preterm babies in NICUs are constantly exposed to noises derived, for example, from incubator motors, ventilators, air flushes, incubator doors slamming, human talk, or the crying of other babies[8]. In addition, it has been known for more than 45 years that patients in NICUs are often treated with potentially ototoxic antibiotics, increasing the risk of hearing impairment[9]. Moreover, exposure to these noises led to different adverse outcomes, like tachycardia, tachypnoea, increased blood pressure, apnoea and bradycardia episodes, or increased oxygen consumption that could cause desaturation and reduced energy available to the baby's growth[10]. Noises also impact the circadian rhythm, causing a discontinuity in the sleep. This discontinuity is a very different characteristic compared to intrauterine life, where babies are asleep 80% of the time[11]. In the end, the excessive noise could cause damage to the cochlea of preterm babies in NICUs[12], with direct consequences also on language development, because could cause a retarding in hearing and language development[13]: a recent study has shown how the noise attenuated by the incubator could have a negative effect in the language development because it also reduces the perception of the human talk[14].

Given the adverse outcomes caused by NICU stay, some researchers have tried to maintain noise ≤45 dB by creating the ideal environment – such as Single Family Rooms - where preterm babies can adequately grow and develop[15-19]. However, where the NICUs are still organized as open-bay, environmental noise remains a big issue, considering that the principal studies available in the literature show no effectiveness in maintaining noise levels low during the years[5, 20-24]. In addition, some noises that exceed the safe limits of 45 dB are not eliminable, nor would it be wise to attempt to do so. For example, in the case of alarm devices, healthcare personnel must be alerted urgently from the vital parameters monitor of a potentially life-threatening condition. However, the adjacent patient could be damaged by hearing these alarms.

Therefore, the hypothesis under this study is that the most efficient intervention to reduce adverse outcomes caused by the hearing of excessive noises could be to reduce only the environmental noises heard by the preterm babies, maintaining an adequate perception of noises from the healthcare personnel.

The literature has shown that continuous noises, like white noises, can improve some of these adverse outcomes. White noises are less likely to cause sleep disruption than intermittent and sudden noises (e.g., intravenous pump alarms)[11] because they have an equal intensity to every frequency audible from the human ear[9]; consequently, they help newborns sleep[25-28]. Some evidence also shows that white noises could help preterm babies control pain or gain weight[29,30].

In addition to white noises, the effect of maternal voices has been recognised to have benefits for preterm babies' development and stability[31]: recent studies showed how listening to a recorded maternal voice could help preterm babies in their physical development[32], and how the mothers singing and speaking improve the preterm babies general movement and neurobehavioral development[33]. Ultimately, the exposition to adult languages promotes vocalisation in preterm babies and is associated with better cognitive and language outcomes[34]. Exposure to parental voices could isolate newborns from sudden NICU environmental noises, reducing the possibility of being awake during and immediately after a high level of noise[11].

Considering this information, our study's research question is: could the combined use of white noises and parental voices reduce the adverse effects of exposure to environmental noises >45dB on preterm babies admitted to NICUs?

## Methods

### *Aims*

The study aims to evaluate the efficacy — in reducing the frequency of tachycardia, tachypnoea, desaturation, and apnoea caused by exposure to environmental noises > 45dB — of an intervention based on the listening of white noises and parental voices by preterm babies in NICUs. The secondary aim is to evaluate the potential longitudinal effects of this intervention on the hearing and language development of preterm babies enrolled.

### *Design and randomisation*

This study is a randomised controlled trial (RCT) (ClinicalTrials.gov NCT06150404) conducted without intervention blinding procedures. Eligible participants will be randomly assigned in equal numbers to intervention or control groups using sealed envelopes prepared by a nurse not involved in the research group. The research members and the nurses providing care to the patients enrolled will be aware of the patient group assignment. Data analysis will be performed by an independent researcher – a statistician – blinded to group allocation and not involved in the intervention. The trial protocol conforms to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT)[35], and the trial results will be reported in compliance with the Consolidated Standards of Reporting Trials (CONSORT) Statement[36].

### *Participants and Study Setting*

The RCT will be conducted in a 22-bed III-level NICU at a major children's Hospital in Italy. This NICU does not have protocols or guidelines for noise control. For the sample size calculation, a preliminary observational phase will be conducted to identify the frequency of tachycardia, tachypnoea, and desaturation events — during a specific amount of time — that occur when the environmental noises are > 45 dB. The sample size calculation will be conducted following the method proposed by Cundill and De Alexander[37]. Preterm babies that meet the inclusion criteria will be enrolled consecutively.

### *Inclusion criteria*

Preterm babies will be eligible if they have a gestational age ≥ 31 weeks (because at this age, sound perception is ≥40dB[38], and there is predictable clinical stability that could ensure the intervention delivery without much interruption) and are monitored with one of the following devices for vital parameters monitoring: Masimo rainbow SET™ (Masimo); Infinity® Delta (Draeger); Infinity® Acute Care System (Draeger); or Efficia CM (Philips).

### *Exclusion criteria*

Preterm babies will be excluded if they have meningitis, severe brain insult[27], brain congenital anomalies, congenital syndrome with the suspected or known brain dysfunction, hypoxic-ischemic encephalopathy, airway abnormalities with an alteration in the breath during sleep[11]. In addition, preterm babies with terminal illnesses, faces, ears, cranium or brain abnormalities, congenital infection, and hearing cognitive impairment will be excluded[39]. Lastly, preterm babies with parents or legal guardians who refuse participation in the study will be excluded[40], parents followed by social services, parents who do not understand the Italian language, and patients already enrolled in other clinical trials.

### *Study procedures*

A form about demographical data will be completed for every patient enrolled. The demographic data collected will be about gestational age, weight (both at birth and at the time of enrolment and discharge), gender, date of birth, date of admission to NICU, date of enrolment and date of discharge.

Every day – from the day of enrolment until discharge – a recording of environmental noises (with professional sound level meters - Sounds Level Meters PCE-322A) and vital parameters (with the use of a video camera) will be performed for the length of the intervention (see subsequent paragraph for its details) for both intervention and control group. During these recordings, the nurses dedicated to the patient will complete a "report form" to indicate the eventual patient's respiratory support and when nursing care or other procedures (i.e. blood sample collection, medical care, feeding, etc.) will be performed – to control the confounding variables during data analysis.

Nurses can stop the recording or the intervention delivery in any emergency, excessive stimulation (such as instability in vital parameters, respiratory alteration, abnormal body movement, abnormal skin colour, crying or excitement that is challenging to contain), or unit

necessity. This interruption must be reported in the "report form."

To achieve the secondary objective of this study, after the discharge, parents or legal guardians of the enrolled patient will be contacted by the research members as follows:

- Three months after discharge, after the execution of audiometer exams that every patient discharged by this NICU will perform to evaluate the results of tests about hearing development.
- Three years after discharge to evaluate the results of eventual tests performed by patients about language development.

Parents or legal guardians will be asked for personal data (like telephone number and name) to collect and analyse data correctly. These data will be anonymised entirely at the end of the study and during data analysis, and only research members will have access to the study repository.

*Intervention group*

Parents or legal guardians of preterm babies enrolled in the intervention group will be asked to record their voices for 10 minutes. Parents or legal guardians will decide who will talk during the record (mother, father or both) and determine what record (telling a story, singing a song). The research members will indicate which characteristics the record has to have: the place in which the record will be done needs to be quiet, without background noises; the parents or legal guardian has to talk in their mother tongue if it is desired; the voice tone has to be sweet, stable and regular during the time; the voice tone has not to be changed if there are different characters when telling a story because babies have not to be excited or extra stimulated by the record hearing. The parents or legal guardians send this record to the study's Principal Investigator, who will ensure that the record adheres to the guidelines provided and assemble the soundtrack of 5 hours in length. This soundtrack will be settled at 45 dB on an mp3 device and administered to preterm babies in the intervention group. The soundtrack will be composed as follows (according to music therapy guidelines in NICUs[41]): 1 hour and 30 minutes of white noises (recording with the use of sound machine Dreamegg Sound Noise Machine), 30 minutes of parental voices (the recording of 10 minutes length of parental voices will be repeated 3 times, to achieve the total of 30 minutes length), 1 hour stopped, 1 hour and 30 minutes of white noises, and 30 minutes of parental voices. The environmental noises will not be managed, according to the hypothesis under this study.

*Control group*

Preterm babies enrolled in the control group do not receive the intervention. They will receive the usual nursing care provided in the unit and be exposed to the usual environmental noises in the NICU.

The vital parameters and environmental noises of babies in this group will also be recorded to achieve the study's aim and compare the outcomes of the two groups.

***Data handling***

Data related to demographic characteristics, vital parameters, and environmental noises will be downloaded to a specific repository for further data analysis. A database will be created (using Microsoft Excel software). Both the repository and database will be accessible only to research group members.

*Other and confounding variables*

Data about the following confounding variables will be collected to minimise interpretative bias in study results: nursing care provided during registration hours, drugs administered during study enrolment that could impact vital parameters stability or hearing development (e.g., caffeine, ototoxic drugs), respiratory support if present, kangaroo-mother care performed, the patient's placement in an incubator or open bed, and the choice performed by parents in what to say to their babies (singing a song or telling a story).

***Outcomes measures***

*Primary outcomes*

The primary outcomes of the study are:

- Reduction in the frequency, in patients enrolled in the intervention group compared to the control group, of tachycardia episodes during the timing of data collection;
- Reduction in the frequency, in patients enrolled in the intervention group compared to the control group, of tachypnoea episodes during the timing of data collection;
- Reduction in the frequency, in patients enrolled in the intervention group compared to the control group, of desaturation episodes during the timing of data collection;
- Reduction in the frequency, in patients enrolled in the intervention group compared to the control group, of apnoea episodes during the timing of data collection.

*Secondary outcomes:*

The secondary outcomes of the study are:

- Reduction in patients enrolled in the intervention group compared to the control

group of language test results as negative or not completely passed at patients' three years old.
- Reduction in patients enrolled in the intervention group compared to the control group of hearing test results as negative or not completely passed at the patient's three months old (according to our hospital procedures).

**Data analysis**

Descriptive statistics analysis will be conducted on environmental noise level, vital parameters and sample demographic characteristics. Vital parameters will be analysed to identify their variation with noise levels > 45 dB. We hypothesise that patients in the intervention group will have less frequent alterations in vital parameters.

Then, statistical inferential analysis will be conducted to discover if there are statistically significant differences between the two groups. A Student's *t*-test of the independent sample will be performed to evaluate the difference in the mean of vital parameters frequency alterations. Pearson's *r* coefficient will be analysed to understand the strength of the association between the noises' intensity and vital parameter frequency alterations. A *p*-value <0,05 will be considered statistically significant.

All available data will be analysed using an intention-to-treat approach. If patients drop out and complete only part of the study, their data will be analysed as far as possible.

*Ethical considerations*

The study was approved by the Regional Ethics Committee – Liguria Region, on March 14, 2022, with protocol number 417/2021 – DB ID 11651. To parents or legal guardians of preterm babies that meet the inclusion criteria, an "Information sheet" will be given with all the information needed to understand the proposed study and provide consent to study participation. Parents or legal guardians will be given an appropriate time to read the "Information sheet" and express eventual doubt or clarifications directly to the researchers. They will also be given the Principal Investigator's contact information to express doubts or questions that may arise during the study. A signature on the "Consent form" of both parents or legal guardians will be asked to proceed with the study.

Study participation is voluntary. Parents or legal guardians can withdraw their consent without needing clarification. No compensation or reimbursement will be given to those participating in the study. All data collected will be treated strictly, adhering to GDPR EU Regulation 2016/679 on privacy concerning data treatment. The study will follow the Declaration of Helsinki and Good Clinical Practice guidelines.

**Expected Results**

Given the rationale at the bottom of this study, it is plausible that administering white noises and parental voices, which could mitigate the hearing of the environmental noises of NICUs, could positively affect preterm babies' neurodevelopment. This intervention could reduce the frequency of adverse outcomes caused by noises > 45 dB. In addition, as the literature suggests, this intervention could have a long-term positive effect, improving language and hearing development. If our hypothesis is confirmed, we can imagine that white noise can be primarily utilised in NICUs worldwide because it is a cheap and feasible intervention.

The study's results will be used to modulate the care given to this population, even if the null hypothesis will be confirmed. Data collection will help us understand the noise level in our NICU and raise awareness of noise among healthcare personnel.

***Limitations***

The principal limitation of this randomised study is that researchers cannot be blinded to which patients will be enrolled in the intervention or control group. However, by adopting blindness during data analysis, we can minimise this risk of bias. Another limitation is the impossibility of understanding, which can be a source of noises > 45 dB. This can reduce the intervention's efficacy estimate. The last limitation is that this study was conducted in only one NICU, which can make evaluating secondary outcomes difficult because our NICU admitted many patients from outside our region.

**Conclusion**

The study will provide valuable information on the safety and efficacy of using white noise and human voices in NICUs for preterm babies. Its results could have important implications for the clinical care of premature infants and demonstrate how nursing care — intended as environmental management to ensure patient safety — can directly impact some critical patient outcomes.

**References**


1. World Health Organization. Born too soon: decade of action on preterm birth. Geneva, 2023 Licence: CC BY-NC-SA 3.0 IGO. (https://creativecommons.org/licenses/ by-nc-sa/3.0/igo/
2. Altimier L, Phillips RM. The neonatal ıntegrative developmental care model: Seven neuroprotective core measures for family-centered developmental care. Newborn & Infant Nursing Reviews. 2013; 13, 9– 22. https://doi.org/10.1053/j.nainr.2012.12.002
3. VandenBerg KA. Individualised developmental care for high-risk newborns in the NICU: A practice guideline. Early Hum. Dev. 2007; 83, 433–442. https://doi.org/10.1016/j.earlhumdev.2007.03.008
4. Liao, JH et al. The noise and light level in the neonatal intensive care unit. J. Nurs. Sci. 2018; 33, 11–13. doi:10.3870/j. issn.1001-4152.2018.08.021
5. Garrido Galindo, AP, Camargo Caicedo, Y, Velez-Pereira, AM. Noise level in intensive care units of a public university hospital in Santa Marta (Colombia). Med. Intensiva, 2016; 40(7), 403–410. doi:10.1016/j. medin.2015.11.01)
6. American Academy of Pediatrics. Noise: A hazard for the fetus and newborn. Pediatrics. 1997; 100, 724–727. https://doi.org/10.1542/peds.100.4.724
7. Andy L, Fan H, Valerie S, Jing W. Systematic review of environmental noise in neonatal intensive care units. Acta Paediatr. 2025;114(1):35-50. doi:10.1111/apa.17445
8. Fernández Zacarías F, Beira Jiménez JL, Bustillo Velázquez-Gaztelu PJ, Hernández Molina R, Lubián López S. Noise level in neonatal incubators: A comparative study of three models. Int. J. Pediatr. Otorhinolaryngol. 2018; 107, 150–154. https://doi.org/10.1016/j.ijporl.2018.02.013
9. Falk S. Noise Pollution; Neonatal Aspects. Pediatrics. 1974; 54
10. Wachman EM, Lahav A. The effects of noise on preterm infants in the NICU. Arch Dis Child Fetal Neonatal Ed. 2011;96(4):F305-F309. doi:10.1136/adc.2009.182014
11. Shellhaas RA, Burns JW, Barks JDE, Hassan F, Chervin RD. Maternal voice and infant sleep in the neonatal intensive care unit. Pediatrics. 2019; 144. https://doi.org/10.1542/peds.2019-0288
12. National Health System. Guideline for consideration of Noise on the Neonatal Unit. 2019; 1–13.
13. Zimmerman E, Lahav A. Ototoxicity in preterm infants: effects of genetics, aminoglycosides, and loud environmental noise. J. Perinatol. 2013; 33, 3–8. https://doi. org/10.1038/jp.2012.105.
14. Monson BB, Rock J, Cull M, Soloveychik V. Neonatal intensive care unit incubators reduce language and noise levels more than the womb. J. Perinatol. 2020; 40, 600–606. https://doi.org/10.1038/s41372-020-0592-6
15. Jobe AH. A risk of sensory deprivation in the neonatal intensive care unit. J Pediatr. 2014; 164, 1265–7
16. Monson BB, Rock J, Cull M, Soloveychik V. Neonatal intensive care unit incubators reduce language and noise levels more than the womb. J. Perinatol. 2020; 40, 600–606. https://doi.org/10.1038/s41372-020-0592-6)
17. Ahamed MF, Campbell D, Horan S, Rosen O. Noise Reduction in the Neonatal Intensive Care Unit: A Quality Improvement Initiative. Am. J. Med. Qual. 2018; 33, 177–184. https://doi.org/10.1177/1062860617711563;
18. Wang, D, et al. Examining the effects of a targeted noise reduction program in a neonatal intensive care unit. Arch. Dis. Child. Fetal Neonatal Ed. 2014; 99, 203–209. https://doi.org/10.1136/archdischild-2013-304928;
19. Calikusu Incekar M, Balci S. The effect of training on noise reduction in neonatal intensive care units. J. Spec. Pediatr. Nurs. 2017; 22. https://doi.org/10.1111/jspn.12181;
20. Pineda R, Durant P, Mathur A, Inder T, Wallendorf M, Schlaggar BL. Auditory exposure in the neonatal intensive care unit: room type and other predictors. J Pediatr. 2017; 183, 56-66.e3.
21. Smith SW, Ortmann AJ, Clark WW. Noise in the neonatal intensive care unit: A new approach to examining acoustic events. Noise Heal. 2018; 20, 121–130. https://doi.org/10.4103/nah.NAH_53_17
22. Hernández-Salazar AD, Gallegos-Martínez J, Reyes-Hernández J. Level and Noise Sources in the Neonatal Intensive Care Unit of a Reference Hospital. Investig. y Educ. en Enfermería. 2020; 38, (3):e13. Doi: 10.17533/udea.iee.v38n3e13.
23. Parra J, de Suremain A, Audeoud F, Ego A, Debillon T. Sound levels in a neonatal intensive care unit significantly exceeded recommendations, especially inside incubators. Acta Paediatr. 2017; 106, 1909–1914. https://doi.org/10.1111/ijlh.12426;
24. Sibrecht G, Wróblewska-Seniuk K, Bruschettini M. Noise or sound management in the neonatal intensive care unit for preterm or very low birth weight infants. Cochrane Database Syst Rev. 2024;5(5):CD010333. Published 2024 May 30. doi:10.1002/14651858.CD010333.pub4
25. Suna Dağ Y, Yayan EH. The effect of facilitated tucking and white noise on stress and sleep of newborns receiving nasal continuous positive airway pressure. J Pediatr Nurs. 2024;77:e442-e449. doi:10.1016/j.pedn.2024.05.008
26. Spencer JAD, Moran DJ, Lee A, Talbert D. White noise and sleep induction. Arch. Dis. Child. 1990; 65, 135–137. https://doi.org/10.1136/adc.65.1.135;
27. Forquer LAM, Johnson CM. Continuous white noise to reduce resistance going to sleep and night wakings in toddlers. Child Fam. Behav. Ther. 2005; 27, 1–10. https://doi.org/10.1300/J019v27n02_01
28. Düken ME, Yayan EH. The effects of massage therapy and white noise application on premature infants'

sleep. Explore (NY). 2024;20(3):319-327. doi:10.1016/j.explore.2023.09.002
29. Zhang Q, Huo Q, Chen P, Yao W, Ni Z. Effects of white noise on preterm infants in the neonatal intensive care unit: A meta-analysis of randomised controlled trials. Nurs Open. 2024;11(1):e2094. doi:10.1002/nop2.2094
30. Kim MH, Song JE, Ahn JA, You MA. Effect of White Noise on Pain Response, Heart Rate, and Oxygen Saturation During Heel Puncture in Premature Infants: A Randomized Controlled Trial. J Perinat Neonatal Nurs. 2024;38(3):297-305. doi:10.1097/JPN.0000000000000779
31. Filippa, M, et al. Systematic review of maternal voice interventions demonstrates increased stability in preterm infants. Acta Paediatr. 2017; 106, 1220–1229. https://doi.org/10.1111/ijlh.12426;
32. Qi M, Gong J, Xie Z, et al. Effects of recorded maternal voice on anthropometric parameters and heart rate in premature infants: A pilot randomised controlled trial. J Pediatr Nurs. 2023;72:e122-e129. doi:10.1016/j.pedn.2023.06.018
33. Filippa M, Filippa G, Della Casa E, et al. Maternal singing and speech have beneficial effects on preterm infant's general movements at term equivalent age and at 3 months: an RCT. Front Psychol. 2025;16:1536646. Published 2025 Jan 29. doi:10.3389/fpsyg.2025.1536646
34. Caskey M, Stephens B, Tucker R, Vohr B. Importance of parent talk on the development of preterm infant vocalisations. Pediatrics. 2011; 128(5), 910-6. doi: 10.1542/peds.2011-0609
35. Chan, AW et al. SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials. BMJ 346, e7586–e7586 (2013).
36. Altman, DM CONSORT 2010 guideline. (2010)
37. Cundill B, Alexander ND. Sample size calculations for skewed distributions. BMC Med Res Methodol. 2015 2;15:28. doi: 10.1186/s12874-015-0023-0.
38. Lary S, Briassoulis G, de Vries L, Dubowitz LM, Dubowitz V. Hearing threshold in preterm and term infants by auditory brainstem response. J Pediatr. 1985; 107(4), 593-9. doi: 10.1016/s0022-3476(85)80030-5.
39. Williams AL, Sanderson M, Lai D, Selwyn BJ, Lasky RE. Intensive care noise and mean arterial blood pressure in extremely low-birth-weight neonates. Am. J. Perinatol. 2009; 26, 323–329. https://doi.org/10.1055/s-0028-1104741
40. Cardoso, S.M.S., Kozlowski, L. de C., de Lacerda, A.B.M., Marques, J.M., Ribas, A., 2015. Newborn physiological responses to noise in the neonatal unit. Braz. J. Otorhinolaryngol. 81, 583–588. https://doi.org/10.1016/j.bjorl.2014.11.008
41. Detmer MR, Whelan ML. Music in the NICU: The role of nurses in neuroprotection. Neonatal Netw. 2017; 36, 213–217. https://doi.org/10.1891/0730-0832.36.4.213