

Title:

The effects of recorded sedative music on the physiology and behaviour of premature infants with a respiratory disorder

Author(s):

[Jacinta Calabro](#) , [Helen Shoemark](#) and [Rory Wolfe](#)

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Abstract

This study tested the safety of using recorded sedative music (RSM) with 34-week-old premature infants with a respiratory disorder. Data was collected to measure the effect of RSM on the physiological stability and behaviours of these infants. Twenty-two infants were randomly assigned to one of two groups, the music group or control group. The music group received 20 minutes of recorded music per day for 4 days. The control group received no music for 4 days. Each infant was observed for a total of 45 minutes each day for the 4 days that they participated. The data collectors were unaware of group allocation and listened to masking music when conducting observations. Data measures were heart rate, respiration rate, oxygen saturation, and infant behaviours. The use of RSM had no negative effect on the physiology or behaviour of the infants in the music group. There were no significant differences between the groups with regard to heart rate, respiration rate, or oxygen saturation. Behavioural results also showed no significant differences between the behavioural states of the two groups. The lack of significant results is attributed to a number of factors including a potentially skewed sample and insufficient exposure to the music to establish an effect.

Introduction

Before the modern trend of evidence-based practice, the traditional tenet of medicine was to "do no harm". So it should be for the provision of music therapy. This study examines the safety of providing programmed recorded music for premature infants with respiratory disorders.

The technological developments in medicine now ensure that many of the most fragile infants survive. Medical therapy has been increasingly effective in reducing mortality at the expense of an increasing number of preteen survivors with chronic lung disorders (Copeland, 2002). Assisted ventilation, antenatal steroids, and surfactant replacement therapy have provided life-preserving assistance to the immature lungs of premature infants, enabling them to survive through early critical phases (Kennedy, 1999). The Australian & New Zealand Neonatal Network Report (Donoghue, 2002) stated that, of the infants who survive, 25.3% will suffer from chronic lung disorders. These may cause physiological instability, disorganised behavioural states, prolonged hospital stays, and a variety of persistent respiratory conditions throughout the infants' lives (Quayle & Williams, 2001; Als et al., 1986). Until the incidence of chronic lung disorders can be significantly diminished, care protocols must address the physiological and behavioural outcomes of these disorders.

Chronic lung disease includes infants receiving invasive and noninvasive oxygen therapy for general respiratory distress, Respiratory Distress Syndrome (RDS), or Bronopulmonary Dysplasia (BPD). RDS is a lung disease resulting from inadequate

surfactant in the lungs of newborns, commonly due to prematurity and low birthweight (Kennedy, 1999). Infants with RDS experience a rise in respiration rate, laboured breathing, expiratory grunt, increased apnoea episodes, and irritability (Vulliamy & Johnston, 1987). It is the most frequent respiratory cause of death and morbidity in children under one year of age (Copeland, 2002). Untreated, around 25% of babies with RDS born before 28 weeks gestation will die within 28 days of birth, and another 25% will develop BPD (Bonn, 1996). BPD develops as a result of long-term oxygen support and/or mechanical ventilation, which damages the ability of the lungs to maintain adequate oxygenation and creates a chronic pulmonary condition (Myers et al., 1992). Aside from chronic respiratory difficulty, infants with BPD experience a hypervigilant, pervasive state of panic and oversensitivity to environmental stimuli such as light, touch, and noise (Als et al., 1986). The increased work of merely breathing can leave these infants exhausted with no oxygen reserves available when they become stressed (Mitchell, 1996).

In a study by Myers et al. (1992), respiratory illness was found to have a negative effect on the behavioural organisation of premature infants. Specifically, the infants had difficulty organising interactive, motor, stress reduction, and self-consoling behaviours. Kenner (1998) also stated that infants with chronic lung disorders have great difficulty in behaviour organisation and regulatory control, and are not able to keep heart and respiratory rates stable when exposed to stress. Stressful events include interaction with caregivers and medical and nursing interventions which may trigger bronchospasm or hypoxic seizures (Mitchell, 1996). These stressors also raise the oxygen saturation requirement for the infant, which can contribute to further lung damage (Als et al., 1986). The infant does not function in isolation. The environment which we provide is significant not only in their survival, but in their development also.

The nursery environment can be unpredictable, overstimulating, and stretch the limited ability of the premature infant to cope (D'Apolito, 1991). Environmental noise levels in the newborn nursery contribute to their increased stress, decreased sleep times, and disorganised behavioural and physiological systems (Standley & Moore, 1995; Kaminski & Hall, 1996). Philbin (2000) described nursery noise as "generally loud and chaotic, (and] lacking in pattern or rhythm" (p. S77). Noise levels may be caused by infant crying, staff, telephones, and frequent equipment alarms, which can peak at 80-90 decibels even inside an isolette (Cassidy & Standley, 1995). Recorded music may be introduced into this environment as a more predictable and stable source of stimulation, which can mask intermittent and unpredictable sounds, therefore decreasing the amount of stress and interruption experienced by the infant (Standley, 2002; Cassidy & Ditty, 1998).

Music may also positively affect an infant's physiology. Physiological entrainment occurs when an infant's unstable physiological systems, such as heart and respiration rates, synchronise to the consistent and regulated rhythm of sedative music (Koepchen et al., 1992; Taylor, 1997). Anecdotally, the use of music for the external regulation of hospitalised infants with a respiratory disorder has been observed by the first author and unit staff to be a behaviourally positive and non-invasive intervention.

Music is a potent stimulus with great variability in its many elements. To achieve the objective of maintaining homeostasis in the premature infant, the music must provide continuous support through careful containment of the musical elements. Such music is referred to as sedative music. Gaston (1951) described sedative music as having sustained melodic passages that lack percussive or strong rhythm. Rebollo

Pratt (1999) further noted that sedative music has little dynamic variance and is performed by instruments with a soft tone colour and medium to low frequency range, such as guitar, harp, flute, and string instruments. The therapeutic benefits of sedative music include the masking effect of music on environmental noise (Standley & Moore, 1995), cardio-respiratory entrainment (Taylor, 1997), and the emotionally soothing quality of the melodic contour (Unyk, Trehub, Trainor, & Schellenberg, 1992).

Lullabies are the appropriate sedative music selection for infants. Infant music preference research has highlighted newborn preference for lullabies. Lullabies traditionally contain lyrical, predictable, and tonic oriented melodies of around eight bars in length with a steady rhythm of 60-80 beats per minute (Unyk et al., 1992). Unyk et al. (1992) also found that the melodic contours of lullabies reflect the typical features of infant directed speech (IDS), which is also known as "motherese" or "babytalk". Lullaby music and IDS both feature higher pitch, wide pitch range, and short melodic phrases followed by long pauses, slow pace, smooth, simple and highly modulated intonation contours, and much repetition (Unyk et al., 1992; Bloom, 1990). As infants are capable of recognising these musical elements (Trehub & Trainor, 1990), it is speculated that the IDS-like features of lullaby melodies contribute greatly to the emotionally soothing effect of lullabies.

Some music and nursing research indicated positive **effects** when **recorded** sedative music (RSM) was used with premature infants (Kaminski & Hall, 1996; Leonard, 1993; Schwartz, Ritchie, Sacks, & Phillips, 1999; Burke, Walsh, Oehler, & Gingras, 1995; Gardner & Lubchencho, 1998). While the results demonstrated that recorded music may be used safely with infants, the studies varied greatly in sample size, bias, subject selection, data analysis, age/diagnosis, and design. This disparity makes it difficult to make definitive statements about safe implementation (Philbin, 2000).

A pilot study by Collins and Kuck (1991) observed 17 agitated infants, aged 24-37 weeks gestation, 10 minutes before and 10 minutes after recorded music was presented in their isolettes. The infants' oxygen saturation levels were significantly increased during the sedative music. It was assumed in this study, however, that preteen infants experience the same stressors as adult ICU patients and that their auditory perception and behavioural responses are also similar, which is not supported in the literature (Philbin, 2000). Caine (1991) observed the effect of music on the behaviours of low birth weight infants and found that vocal music (lullabies and children's songs), played at 70-80 decibels, had a significant effect on stress behaviours, weight gain, increased formula and caloric intake, and shortened hospital stay by 5 days. This study was limited, however, to premature infants in isolettes only, regardless of differing diagnosis or age.

In a study by Cassidy and Standley (1995), sedative music had a dramatic effect on 24-30 week old oxygenated infants in the Neonatal Intensive Care Unit (NICU). Heart rate, respiration rate, and infants' oxygen saturation levels were all significantly affected by the music, with no negative results found. The music was presented over 3 days and recorded by a time sampling observation method. Unfortunately, no behavioural data was observed. Coleman, Rebollo Pratt, Stoddard, Gerstmann, and Abel (1999) used an independent groups model with a complex cross-over design to present multiple treatments over 4 days to 33 premature infants. Music's effect on the heart rate, oxygen saturation, and distress behaviours were examined. The music was presented at 65-75 decibels and speakers were placed 3 to 5 inches behind the infant's head. A 10 minute baseline observation was

completed, followed by 20 minutes of music, then 20 minutes post observation, and repeated three times. Music lowered heart rate, increased oxygen saturation, reduced distress behaviours, increased caloric intake and weight gain, and shortened NICU stay by 3 days.

This study sought to replicate the successful protocol of Coleman et al. (1999) with minor adaptations for the study's context. Current concerns about the possible effect of environmental auditory stimuli above 80 decibels (C weighting scale) includes physiologic instability, interrupted sleep, hearing loss, and difficulties with habituation (Philbin, 2000; Graven, 2000). For this study, decibel levels were reduced to the lowest volume necessary to mask environmental noise. Also, the RSM was only presented once daily due to constraints on the availability of data collectors.

This is the first study of RSM for premature infants in Australia. Given that NICU and special care environments vary around the world, it was important to gather local data which recognised this particular context. The study was conducted as a pilot to assess the safety of providing a controlled program of RSM for 34 week gestation infants in an Australian tertiary level NICU and special care nursery. Data was also gathered to evaluate the impact of the 4 day music program on the infants' stress behaviours, heart rates, respiration rates, and oxygen saturation levels.

Hypotheses

The hypotheses for this study were that:

1. The presentation of RSM will have no negative effect on the physiological and behavioural stability of 34 week gestation infants with oxygen dependency and/or chronic lung problems.
2. Infants receiving RSM will show more regular heart rates, respiration rates, and oxygen saturation levels than control subjects.
3. Infants receiving RSM will display fewer disorganised behaviours than the control subjects.

Method

Prior to commencement, approval from the hospital's Human Research Ethics Committee was granted for this study.

Design. This study was a randomised controlled trial consisting of a control group who received no music intervention and a music group that received RSM.

Length/duration. Each infant participated over 4 consecutive days. The total data collection period was 7 months.

Subjects. Twenty-two premature infants were recruited from the clinical population in the newborn services unit of a large general hospital. Criteria for inclusion in the study were (a) a gestational age of 34 weeks, (b) a diagnosis of a chronic lung disorder and/or oxygen dependency, and (c) availability for 4 consecutive days. Exclusion criteria included infants who (a) did not have a primary diagnosis of chronic lung problems, (b) had a diagnosed hearing impairment, (c) were not connected to a pulse oximeter and cardiac monitor, (d) were to undergo a surgical procedure within the 4 days, or (e) were withdrawing from a substance addiction.

Parents were contacted by the chief investigator after referral from medical, nursing, or allied health staff. They received a plain English information sheet and consent forth. Subjects were randomly allocated to either the control or music group using blocked allocation with the Moses-Oakford algorithm and table of random numbers (Moses & Oakford, 1963). Eleven infants were allocated to the music group and eleven infants to the control group. Of these, five infants were not included in analysis ($n = 2$ control, $n = 3$ music). One infant was discharged before completing the study and four infants were diagnosed with a hearing impairment. All infants were required to pass an oto-acoustic emissions test conducted by an audiologist to detect any hearing impairment. Any infant showing an impairment was referred to the hospital audiology department for further tests. Due to time shortage and issues with the audiology equipment the infants' hearing tests were conducted after their participation in the study.

Justification of sample size. A sample size of 20 subjects was calculated on the primary outcome of oxygen saturation level. Ten subjects per treatment group were required to detect a 5% difference in oxygen saturation (effect size of 1.3) at a significance level of 0.05 and a power of 80%.

Materials. The chief investigator selected two instrumental lullabies, "Brahms Lullaby" and "Sandman" (Ross, 1995), totalling approximately 20 minutes, from the commercially recorded "Music for Dreaming" compact disk. These arrangements were chosen for their adherence to the key sedative parameters of "minimum range and minimum change" in tonality, tempo, register, timbre, volume, and attack. The instrumentation included a small ensemble of acoustic orchestral instruments (violins, viola, 'cello, harp, and flute), and remained consistent throughout both tracks.

Both tracks were dubbed sequentially onto both sides of SA-X90 TD K cassette tapes. Each tape included 10 minutes silence before the two tracks and 15 minutes silence after (total 45 minutes). Blank tapes were provided for the infants in the control group. The tapes were played on a Sony Walkman portable radio/cassette player, WM-FX373, and presented via Panasonic Mini-speakers, RP-SP30, which were enclosed in small plastic bags and secured for infection control purposes. The portable cassette player was connected to a Musicway AC/DC Adaptor, Cat.#MACK 595. Decibel levels were tested using a Dawe D-1405E Digital sound survey meter.

Placement of materials. The enclosed mini-speakers were sterilised using HC-20 disinfectant and placed in opposite corners 15-20cm behind each infant in the isolette or crib and rotated slightly inward. The speakers were connected to each other via a single lead and connected to the cassette player containing the cassette tape via another single lead. The cassette player was located outside the crib or isolette and placed either underneath the isolette/crib or on the shelf behind. The cassette player was connected via a single lead to the AC/DC adaptor, which was plugged into the closest power point, and turned on. The data collector was required to turn on the cassette player before commencing data collection. When one side of the tape finished the cassette player automatically turned off and the tape changed direction when turned on the next time.

Presentation of music. Ambient environmental noise levels in the unit were periodically noted to vary between 65-90 decibels (C) throughout the day. The location of the speakers meant that the stimulus source was more immediate than almost all other sounds, therefore, the recorded music was presented at 60-65

decibels (C) for music infants in an isolette, 65-70 (C) decibels for music subjects in an open crib, and 0 decibels for control infants. The adjustment in decibel level between isolette and open crib was necessary to mask the extra environmental noise for infants in an open crib. The increase in decibel level was behaviourally assessed by the chief investigator to be effective in masking most of the fluctuating environmental noise while remaining within safe levels.

The chief investigator set the appropriate volume on each infant's cassette player at the commencement of the 4 day period. The decibel levels were tested at the subject's ear using a sound level meter, and the volume level on the cassette player was then fixed and covered to avoid accidental unsafe changes in volume. The tapes were presented to each infant once per day (for 4 days) during the 45 minute data collection period.

Measures/data collection. Two experienced nurse researchers collected the data. They were educated by the chief investigator regarding equipment use, data collection protocol, and classification/identification of infant behaviours. Inter-rater reliability was tested at 98% prior to the study commencing. Data collectors were available for one period of data collection each day between 8.30am to 4.30pm. The chief investigator advised them to liaise with the infant's primary care nurse each day to select an appropriate time for data collection after medical, nursing, or parent contact with the infant had ceased.

The data collectors were unaware of group allocation and listened to recorded music themselves (using a portable cassette tape player and headphones) during data collection to ensure they did not hear whether the infant was receiving music or silence. The data collectors' tapes contained 45 minutes of music taken from the commercially released compact disc "Mariner" (O'Connor, 2001), provided by the chief investigator. The music selection was instrumental and reflected the elements of sedative music as discussed earlier (Gaston, as cited in Taylor, 1997; Rebollo Pratt, 1999). An electronic beep was superimposed over the recorded music each minute to cue data collection.

Data collection began once the data collectors started the infants' and their own cassette players. The data collection was divided into 45 one-minute time samples. After hearing the first beep the data collector would record the infant's heart rate, respiration rate and oxygen saturation level as displayed on the pulse oximeter and cardiac monitor. For the remainder of the minute the nurse researcher recorded the infant's behavioural state which was taken from 22 possible behaviours listed on the Physiological and Behavioural Assessment Form (adapted from Als, 1986, Hiniker & Moreno, 1994, and Shoemark, 1999a. See Appendix). Behaviours were divided into eleven categories that indicated positive organised states and eleven categories that indicated negative disorganised states. Organised behaviours included quiet alert, active sleep, quiet sleep, open face, cooing/smiling, smooth limb movement, hand to mouth, sucking, trunk tucking, foot anchor/hand clasping, and grasp inglholding on. The disorganised behaviours included crying/whining, low level alertness/drowsy, fussing/struggling, finger splay/halt hands, facial grimace/frowning, gaze aversion, startle, panicked/worried look, tongue thrusts/protrusion, hiccups/yawning, and spitting/vomiting. These were listed numerically on the assessment form to easily categorise and record the infant's state. At the end of the minute, the data collector would also indicate on the assessment form whether the infant's state was positive or negative overall, as time values were not allocated to the behaviour scores and infants could display both positive and negative behaviours within each minute.

Data safety and monitoring. The data collector was responsible for monitoring each infant's response during the data collection. The safety protocol (approved by the ethics committee) indicated that if at any time the data collector observed negative cues, she believed were in response to the research protocol, she would turn off the cassette player and continue to observe the infant for 10 minutes. If this occurred again at the next daily data collection the infant would be withdrawn from the study. This did not occur.

Data Analysis

During each session of data collection, heart rate, respiratory rate, oxygen saturation, and number of organised behaviours were averaged (using means) over the initial baseline (10min), music/silence (20min), and post observation (15min) periods. Total number of disorganised behaviours were calculated for each period and expressed as number of disorganised behaviours per 10 minutes. For primary analysis, the groups were compared during the music/silence period and post observation for any changes from baseline, using robust standard errors to account for correlation between the four values (one per day for 4 days) from each infant. Secondary analyses involved comparison of mean changes between days and between males and females. Also a secondary analysis was performed on disorganised behaviours which excluded those behaviours that occurred as isolated events, and thus are not considered inherently negative, for example, yawning occurring without other negative behaviours. A P-value was considered significant if it was less than 0.05. All analyses were performed in Stata 7 statistical software (StataCorp, 2001).

Results

The primary analysis for the second hypothesis (Table 1) illustrates the difference in baseline respiration rates between the music group (mean = 46) compared to control group (mean = 54). The groups were otherwise balanced for weight, type of oxygen therapy/diagnosis, average heart and oxygen saturation rates, and sex (data not shown). The positive trend for oxygen saturation was reduced when comparing the music/silence period to the post silence period (Table 1), and there were no significant effects for any other measure for any day. Secondary analysis divided by sex showed no significant effect, and there were no differences within the music group for any measure over the 4 days (data not shown).

The primary analysis for the third hypothesis compared the mean number of disorganised and organised behaviours between the groups at baseline and over the 4 days. The number of disorganised behaviours at baseline was higher in the music group with a mean of 2.8 in the first 10 minutes compared to 0.6 for controls (Table 1). The groups were matched for number of positive behaviours. There were no significant differences between groups for any particular behaviour for any day. Secondary analysis divided by sex and adjusted disorganised behaviour measures also showed no significant effect for any behaviour for any day (data not shown).

The lack of significant results for hypotheses 2 and 3 supports the first hypothesis that the presentation of RSM will have no negative effect on the physiological and behavioural stability of 34 week gestation infants with oxygen dependency and/or chronic lung programs.

Discussion

The primary purpose of this study was to determine the safety of using RSM by documenting its impact on the cardio-respiratory systems and behavioural states of premature infants with chronic lung disorder and/or oxygen dependency. In the protocol as presented, there was no effect on the physiology or behaviour of the subjects. Therefore it presented no risk and was safe for the subjects.

Despite observing a (non-significant) positive effect on oxygen saturation the results of this study do not support previous research with similar methodologies. Collins and Kuck (1991) found that 24-37 week (gestational age) infants in an agitated state had significantly increased oxygen saturation and improved behavioural state after only one presentation of music for 10 minutes. Butt and Kisilevsky (2000) found that infants aged 31 weeks and older obtained homeostasis after a stressful event quicker in the presence of music after only one trial. In both studies, infants were in a heightened state of distress at the commencement of the music, so a wider range of response could occur. In this study, infants were behaviourally stable at the commencement of the protocol, perhaps resulting in a more modest effect.

The results do, in part, support the recent research of Abromeit (2002). Nine infants aged around 31 weeks were exposed to standard care, RSM, and sensory stimulation with live singing. Although the infants received 24 episodes of RSM (with standard care and sensory stimulation counterbalanced) over 6 to 8 weeks, there were no significant changes in respiration rate, heart rate, stress behaviours, or self-regulatory behaviours. Furthermore, when receiving RSM the infants showed an initial increase in stress behaviours, which decreased over the 24 trials.

Many factors contributed to the outcome of the present study. Perhaps most significantly, since the study's completion, it has been suggested that past research has been too conservative in the frequency of music presentation, and that premature infants as young as 26 weeks may benefit from sedative music administered several times daily throughout their hospital stay (J. M. Standley, personal communication, August 9, 2002). Infants may also need a period of time to build a psychological association with music as a positive stimulus (Shoemark, 1999; Tims, as cited in Standley, 1991). The first author's clinical experience certainly indicates that the effect of music may be greater once the infant has had time to experience RSM while in a positive state and has learnt to associate it with homeostasis. Certainly, the infants in this study were relatively stable physiologically and behaviourally, and may have tolerated music more frequently, therefore increasing the potential for an effect to occur.

Another factor which may have contributed to the lack of significant effect was the small and potentially skewed sample. Despite random allocation the groups were not evenly matched at baseline. Because of the scheduling and equipment restriction of hearing tests, 19% of the enrolled infants were diagnosed with a hearing impairment after they had participated. The resulting sample for the analysis was small and not a good representation of the population. The sample size was only adequate to detect a relatively large difference between the two groups and it may be that positive, smaller differences exist but could not be detected. The results did indicate that music was not harmful to these infants and that greater potential benefit was possible over time.

The lack of negative physiological and behavioural outcomes for this study was sufficient assurance for a clinical program to commence in this unit. The protocol has been modified in the duration and frequency of music presentation. Each infant is assessed to determine their response to RSM and their tolerance for the duration of

music before specifically programmed tapes or CDs are provided. It is recommended that the RSM be used after an infant's nursing care cluster (feed, nappy change, etc.), approximately every 3 to 4 hours. These modified clinical applications of RSM offer promising anecdotal evidence of positive effect for regulation of cardiorespiratory systems, transitioning between disorganised to organised behavioural states, and masking disruptive environmental noise.

RSM is useful in the initial and ongoing stages of music therapy intervention (based on the infant's assessed tolerance) and is easily accessible by staff and parents. This provides a positive music experience "on tap" for the infant which is carefully assessed, designed, and monitored by the music therapist. The needs of premature infants with respiratory disorders and their families are complex however, and varying music therapy interventions are needed to address them. Incorporating the listening preferences of infants and their parents is an important part of a family centred music therapy program. Methods which are respectful of and responsive to the cues of the individual infant, such as music adapted multimodal (sensory) stimulation, have proven highly effective in increasing infants' tolerance for stimulation and reducing their hospital stay by up to 11 days (Standley, 1998).

Previous research justifies further inquiry into the area of premature infants and music therapy. A replication of this study with adjustments to the frequency of music presentation and a larger sample size would certainly be beneficial. Further research on how to best meet the complex individual needs of these infants could include or compare RSM with other music therapy methods. Music therapy methods which aim to reduce distress, facilitate development, promote homeostasis, and reduce length of hospital stay should be investigated.

Appendix

Physiological and Behavioural Assessment

Appendix

Physiological and Behavioural Assessment

Attach Bradma Here

Instructions

- 1 Attach Bradma
- 2 Record Date and Time
- 3 Put on and begin own music headphones
- 4 Press PLAY on infants walkman (turn tape over or change direction if necessary)
- 5 Commence observation and record data below after each beep
- 6 Complete form and return to research folder
- 7 Note observation and time in patient file

Date:

Time:

Min	Heart	Resp	Ox Sat	Behavioural State	O'all+-	Behavioural Assessment
1						Organise Behaviour
2						1 Quiet alert
3						2 Active sleep
4						3 Quiet sleep
5						4 Open face
6						5 Cooing/smiling
7						6 Smooth limb movement
8						7 Hand to mouth
9						8 Sucking
10						9 Trunk tucking
11						10 Foot anchor/hand clasping
12						11 Grasping/holding on
13						Disorganised Behaviour
14						12 Crying/whining
15						13 Low level alertness/drowsy
16						14 Fussing/struggling
17						15 Finger splay/halt hands
18						16 Facial grimace/frowning
19						17 Gaze aversion
20						18 Startle
21						19 Panicked/worried look
22						20 Tongue thrusts/protrusion
23						21 Hiccups/yawning
24						22 Spitting/vomiting

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Glossary

C weighting scale: a minimal filter used by the sound level meter to better replicate the frequencies heard by the human ear.

Jacinta Calabro BMus(Hons) RMT, Monash Medical Centre, Melbourne

Rory Wolfe PhD BSc, Monash University, Melbourne

Helen Shoemark MME BMus RMT, Royal Children's Hospital, Melbourne

Table 1
Comparison of physiological and behavioural outcomes for music and control groups

Outcome measure	Baseline period on Day 1		Change from baseline period to music/silence period	
	Control Mean	Music Mean	Difference in mean change (95% CI)	P-value
Heart rate (bpm)	156	165	-0.9 (-5.0, 3.2)	0.64
Respiratory rate (bpm)	54	46	1.8 (-2.4, 6.0)	0.38
Oxygen saturation (%)	94.2	95.5	0.7 (-0.9, 2.3)	0.36
Organised behaviours (per min)	1.7	1.8	0.0 (-0.2, 0.2)	0.78
Disorganised behaviours (per 10 min)	0.6	2.8	0.1 (-0.9, 1.1)	0.83
Outcome measure	Change from baseline period to post observation			
	Difference in mean change (95% CI)	P-value		
Heart rate (bpm)	-0.1 (-7.8, 7.6)	0.98		
Respiratory rate (bpm)	0.1 (-4.3, 4.5)	0.96		
Oxygen saturation (%)	0.4 (-1.3, 2.0)	0.62		
Organised behaviours (per min)	0.1 (-0.2, 0.3)	0.63		
Disorganised behaviours (per 10 min)	-0.2 (-1.7, 1.3)	0.74		

Note. Positive values in the "Difference in mean change"

columns indicate a greater within-infant increase (or smaller within-infant decrease) in the Intervention group than in the Control group.

Calabro, Jacinta^Wolfe, Rory^Shoemark, Helen

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