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Effects Of Music Therapy On Preterm Infants In The Neonatal Intensive Care Unit

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EFFECTS OF MUSIC THERAPY ON PRETERM INFANTS IN THE NEONATAL INTENSIVE CARE UNIT

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NURSING

ABSTRACT

The study purpose was to examine the effects of a 15-min live-music therapy intervention on heart rate, oxygen saturation, level of motor activity, behavioral distress, and behavioral state levels in premature infants in the neonatal intensive care unit. The convenience sample included 20 infants born at 26 to 29 weeks' gestational age who were hospitalized in a large teaching hospital in the southern United States. In a 1-group repeated-measures crossover design, infants were randomly assigned order of music versus no-music conditions. Data were collected on 4 occasions over a 2- to 4-week period beginning when the infants were 1 to 2 weeks old. On 2 occasions, the infants received 15 min of live music provided by a music therapist; on the other 2 occasions, the infants did not receive the music intervention. Study variables were measured for 10 min (baseline), for 15 min during the music intervention or control period (during), and for 10 minutes after the during period (post). A 2-factor repeated-measures ANOVA was used to test differences among means for statistical significance for the 2 hypotheses. Results did not support the hypothesis that, during and for 10 min after exposure to a 15-min live-music intervention, infants would exhibit a greater decrease from baseline in heart rate, level of motor activity, and signs of behavioral distress than they would exhibit after exposure to a no-music condition. Results did not support the hypothesis that infants would exhibit a greater increase from baseline in oxygen saturation during and for 10 min after exposure to a 15-min live-music intervention than they would exhibit after a no-music condition. No deleterious effects of the music therapy were identified. Music is a noninvasive, nonpharmaceutical, and relatively low-cost intervention that can be implemented at the infant's bedside. Further research is needed to determine whether effects noted in previous studies can be consistently replicated in diverse settings and with diverse groups of preterm infants. Additional testing of the conceptual framework is proposed for this study is needed to more specifically examine the mechanisms by which music may positively affect the physiologic and behavioral outcomes in infants in the neonatal intensive care unit.

DEDICATION

I dedicate this dissertation to my children, Amanda and Colton Segars, who lovingly shared their mother with this research for 4 years, and to my stepson, Cater Wood, who joined this adventure with a smile. I thank my husband, Jerry “Bogie” Wood, for his never-ending patience and support especially during the late night typing hours. My parents, Robert and Nancy Hodges, have always been supportive and proud of all of my accomplishments; I love them both. My sister, Erin Schrimsher, will forever be the wind beneath my wings.

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CHAPTER 1

INTRODUCTION

Overview of the Problem

Infants born before 37 weeks' gestational age are considered preterm, and infants born before 32 weeks' gestational age are considered very preterm. Despite decades of research, scientists have not yet developed effective ways to help prevent premature delivery. The number of preterm births has increased nearly 20% since 1990 (National Center for Health Statistics, n.d.). In 2005, there were 525,000 infants born prematurely in the United States; this figure represents 12.7% of live births (March of Dimes, 2007). Preliminary data from the National Center for Health Statistics indicate that the preterm birth rate for 2006 was slightly higher at 12.8% of live births, or 543,000 infants.

Medical and technological advances in the care of the preterm infant have greatly increased infant survival over the past decade; however, researchers have noted that medical and nursing procedures and the excessive noise and other stimulation in the neonatal intensive care unit (NICU) environment are stressful for the preterm infant (Caine, 1991; Field, T., 1990; Peters, K., 1992; Peters, K.L., 1998; Schanberg & Field, 1987). The focus of the highly trained staff in the NICU has been body system physiologic support, as well as neuroprotective strategies and neurodevelopmental support; however, in comparison with full-term controls preterm infants have been found to consistently experience a higher rate of sensory impairments (Aucott, Donohue, Atkins, & Allen, 2002).

Effects of the NICU Environment on Stress Responses
of Preterm Infants

Over the past 2 decades, a number of studies have documented the excessive stimulation provided in NICUs, and noting the adverse effects of excessive noise, light, and handling on preterm infants; such effects include increased stress responses, masking of speech input, disturbances in sleep, and increased risk of cochlear damage that may lead to hearing loss produced by certain drugs commonly used with preterm infants (American Academy of Pediatrics, 1997; Graven, 2000; Philbin, 2000b). Excessive noise has also been correlated with a decrease in oxygen levels as well as with an increase in heart rate (HR) and sleep disturbances in infants hospitalized in the NICU (Kellman, 2002; Zahr & de Traversay, 1995). The American Academy of Pediatrics recommended that ambient environmental noise levels in the NICU not exceed 45 dB (Scale A).

Much emphasis has been placed on techniques for reducing environmental stress and stimuli, such as keeping isolettes dark and quiet and minimizing handling of babies (Aucott et al., 2002; Graven, 2000). More recently, the use of structured stimuli (e.g., music therapy) has been encouraged as a means of reducing environmental stress (Aucott et al.; Kemper, Martin, Block, Shoaf, & Woods, 2004; Standley, 2002). Other stress reduction techniques that have been employed to minimize environmental stress include clustering of nursery activities, positioning or swaddling of preterm infants, touch/massage therapy, kangaroo care, oral sucrose, nonnutritive sucking, and music therapy (Arnon et al., 2006; Fearon, Kisilevsky, Hains, Muir, & Tranmer, 1997; Harrison, Williams, Berbaum, Stem, & Leeper, 2000; Lai et al., 2006; Schanberg & Field, 1987; Standley, 2003; Symington & Pinelli, 2003).

Results of studies of music therapy with older infants, children, and adults suggest that music therapy can reduce pain, stress, and stimulus deprivation during illness (Standley, 2003). Philbin (2000b) described the NICU as “generally loud and chaotic, lacking in pattern and rhythm” (p. 77). Some researchers have suggested that music serves as a distracter, a more predictable and stable source of stimulation that ameliorates the chaos of the NICU environment; therefore, this distraction may decrease the amount of stress and interruption experienced by the infant (Cassidy & Ditty, 1998; Standley, 2002). Hillecke, Nickel, and Bolay (2005) and Lambert (1992) referred to this distraction as attention modulation and suggested that in comparison with other sensory stimuli, music is more effective in attracting attention.

Findings from studies of the effects of music on preterm infants have been inconsistent, and many of these studies have failed to account for extraneous variables such as characteristics of the infant (e.g. morbidity, gestational age, amount of stimulation received in the hours before the music), characteristics of the NICU (e.g., ambient noise, light levels, number of infants and visitors in the unit), and characteristics of the music itself. Therefore, the focus of this exploratory pilot study was to examine the effects of a live music therapy intervention on preterm infants in the NICU. To control for characteristics of the infant that might influence responses to music, I designed the study in such a way that each infant served as his or her own control. To examine environmental characteristics that might influence the infants’ responses to music, I collected data on noise levels, numbers of staff/visitors in the unit during the music intervention, and amount of stimulation provided to the infant during the 2 hr before the music.

Use of Music to Reduce Stress of Preterm Infants

Music therapy was first used by Florence Nightingale to aid in the recovery of soldiers during the Crimean War (Jonas-Simpson, 1997). This therapy is defined as "the prescribed use of music and musical interventions to restore, maintain, and improve emotional, physiological, and spiritual health and well-being" (Guzzetta, 1995, p. 672)and is described as "a behavioral science that uses specific music to produce desired changes in behavior, emotions, and physiology" (Guzzetta, p. 672). According to the American Music Therapy Association (2007), "Music Therapy is the clinical and evidence-based use of music interventions to accomplish individualized goal," (What is music therapy, ¶ 1)

Standley (2003) summarized findings from studies of music interventions with preterm infants that have been conducted over the past 20 years in a book published by the American Music Therapy Association. In her book, Standley (2003) suggested that "music shows promise for soothing and nurturing premature infants, reducing stress, stabilizing physiological functions and behavior states thus enhancing maturation during this critical final stage of fetal development under medical treatment" (p. 2). She also acknowledged that "early intervention with music during the premature infant's NICU stay is still developing and long-term benefits are not yet documented by research" (Standley, 2003, p. 36).

Although there have been a number of studies examining the effects of music on preterm infants over the past 35 years, the exact mechanism by which preterm infants positively respond to this stimulus is not known. Questions remain about which infants might benefit from music interventions, what types of music are appropriate for hospitalized preterm infants, when to initiate sensory stimulation or music interventions, and how music might exert beneficial effects (Hillecke et al., 2005; Lickliter, 2000; Philbin, 2000b; Standley, 2003).

Conceptual Framework

The conceptual framework that was used to guide this study incorporated concepts from the theory of stress proposed by Selye (1976) and from Als' synactive theory of development (1986); also included in the framework was identification of characteristics of the music, the preterm infant, and those of the environment that might influence responses to a particular music intervention. In addition, components of the relaxation response theory (Benson, 1975) were used to explain the mechanism by which music may influence stress in the premature infant.

Stress

Selye (1976) defined stress as a biologic response of the body to any demand/stressor. A stressor is anything that causes stress. Selye categorized stressors by the manner in which they cause stress: physical, chemical, emotional, and thermal. Selye proposed that individuals vary in their responses to stressors of the same potency and that these depend on the individual's inherent strengths and weaknesses. The process of adapting to stress depends partly on the nature of the stressor and the mechanisms available in each individual. Adults' responses to environmental stimuli are profoundly determined by their symbolic interpretation of the stimuli. The individual's perception of the stimulus/stressor primarily determines the way in which an individual will respond (stress response). Building upon research related to adult responses to stressors, researchers began to study the ways in which infants respond to and cope with stressors such as aversive procedures and stimulation (Brazelton, 1984; Gunnar, Malone, Vance, & Fisch, 1985). In this study, it was assumed that preterm infants experience a variety of stressors caused by factors internal and external to the infant (level of prematurity creating vulnerability to internal and external stimuli, morbidity factors, characteristics of the NICU environment, and caregiving activities). These stressors create a stress response in the infant that is manifested both physiologically and behaviorally.

Als' Synactive Theory of Development

Als' (1986) synactive theory of infant development provides a framework for understanding infant physiologic and behavioral responses to stressors. The infant's responses are grouped according to five subsystems of functioning. The five subsystems are classified by Als as motor (motor tone, movement, activity, and posture), autonomic nervous system (skin color, tremors/startles, heart rate, and respiratory rate), state organizational system (levels of arousal that range from being quiet or actively sleeping to being drowsy, awake/alert to fussing/crying), attention and interaction system (availability of the infant for interacting, alertness of the infant and robustness of the interaction), and self-regulatory balancing system (presence and success of the infant's efforts to achieve and maintain a balance of the other four subsystems). Although often described independently, each subsystem functions in relation to the other subsystems. Synaction is the process of subsystem interaction (the ways in which the five subsystems work together or influence each other). In Als' synactive theory of development proposes that infant development is influenced by the interaction of the five subsystems and the environment.

In healthy full-term infants, these systems generally work in tandem. In the preterm infant, these systems are not fully mature; therefore, the preterm infant's behaviors are often characterized by disorganization and signs of stress (stress response). The synactive theory involves the proposition that observation of responses in these five subsystems should guide the type and amount of stimulation that is provided to fragile preterm infants.

The signs of stress for four of the subsystems are given here.

- Autonomic nervous system - Color changes such as pallor, flushing (turning red), and cyanosis (turning blue); changes in vital signs such as HR, respiratory rate, blood pressure (BP), and oxygen saturation; visceral responses such as vomiting, gagging, hiccups, and passing gas; sneezing; and yawning.
- Motor system - Generalized hypotonia (limpness, decreased resistance to moving of the infant's extremities), flailing movements, finger splaying (holding fingers spread wide apart), and hyperextension of extremities (arms or legs extended straight out almost in a locked position).
- State system - diffuse sleep states (lots of twitching, grimacing, and lack of rest), glassy-eyed look (appears to be "tuning out"), gaze aversion (cut eyes to the side avoiding lookong at what is in front of them), staring (a locked gaze, eyes usually wide open), and irritability (hard to console).
- Attention/interaction system – Inability of infant to integrate with other sensory input (cannot look at and face an object or person, listen to talking, and suck a bottle at the same time.

Behaviors observed in the self-regulatory system reflect attempts by the infant to deal with stress and regain control. These behaviors include change in position, hand-to-mouth behaviors, grasping, sucking, visual locking, and hand clasping.

The behaviors noted above in the self-regulatory system are considered to be indicators of adaptive responses to stressors. The behaviors noted above in the other four systems are generally considered to indicate maladaptive responses to stressors, or negative stress cues.

The physiologic and behavioral outcomes related to stress result in increased demands on the cardiovascular and muscular systems (Butt & Kisilevsky, 2000), on the endocrine system (Anand, 1993), and on the respiratory systems (Als, 1986). These demands result in increased energy expenditure and deplete the available energy needed for growth and development (Butt & Kisilevsky). The infant's stress response results in an increased release of adrenocorticotropic hormones such as cortisol (Chou, Wang, Chen, & Pai, 2003). Gunnar (1989) reported that repeated episodes of increased cortisol levels may weaken the infant's immunological status and increase susceptibility to infection. Thus, it is important to identify strategies with which to minimize stressors and maladaptive stress responses in fragile preterm infants.

On the basis of the synactive theory of development, physiologic indicators of stress in the preterm infant that were measured in this study included increased or decreased HR and decreased oxygen saturation level (Butt & Kisilevsky, 2000; Field, T., 1990; Long, J., Lucey, & Phillip, 1980; Peters, 1992). Behavioral indicators of stress that were examined in this study included hiccup, facial grimace, finger splay, clenched fists, crying, fussing, spitting, vomiting, and changes in sleep/wake patterns (Als, 1986;

Brazelton, 1984; Calabro, Wolfe & Shoemark, 2003; Coleman, Pratt, Stoddard, Gerstmann, & Abel, 1997; Fitzgerald & Anand, 1993; Grunau & Craig, 1990; Hiniker & Moreno, 1994; Johnson, Stevens, & Craig, 1993; Shoemark, 1999; Taddio, Nulman, Koren, Stevens, & Koren, 1995).

Relaxation Response

In this study, the relaxation response mechanisms of distraction and entrainment were incorporated into the conceptual framework to explain mechanisms by which music might reduce the stress responses of preterm infants in the NICU. Benson (1975) suggested that relaxation quiets the sympathetic nervous system (SNS) and is a voluntary reaction to the fight-or-flight response. This response results in decreased BP, HR, and respiratory rate. Kaminski and Hall (1996) suggested that exposure to soothing music helps facilitate the relaxation response and thus decreases the amount of time spent in high arousal states. Distraction and entrainment are two mechanisms that may invoke the relaxation response.

Distraction provides an alternative focal point that is comforting and pleasant. The stressful stimulus is then diminished in importance (Chlan, 1998; McCaffrey & Locsin, 2002). Music may provide distraction by drawing the attention of the premature infant away from mechanical sounds and other aversive auditory stimuli (Coleman et al., 1997).

Another mechanism by which music may decrease the stress response is entrainment. Entrainment is the synchronization of natural body rhythms with a different rhythm. In adults this occurs when a rhythm that is physiologically close to the participant's innate HR rhythm is introduced. This rhythm is slowly changed and thus changes the innate rhythm (Chlan, 1998; Taylor, 1981). In infants, physiological entrainment may occur when unstable physiological systems such as HR synchronize to the consistent rhythm of sedative music (Calabro et al., 2003).

Music, acoustically different from other sound, produces sound with harmonics. Harmonics are the "overtones whose frequencies are multiples of the original sound" (Standley, 2003, p. 47). Ambient noise (all noise in the environment) may result in fatigue and stress in the listener and can produce irritation. Therefore, music may be used to mask aversive sound (Standley, 2003). Thomas and Martin (2000) suggested that environmental sound in the NICU serves as a stressor. Glass (1994) suggested that prolonged exposure to ambient noise levels in the NICU could contribute to impaired language development.

Effects of Music on Physiologic and Behavioral Stress Indicators of Preterm Infants

Chou et al. (2003) suggested that music can cause alterations in reactions of the autonomic nervous system in the thalamus and result in regulation of the nervous impulse conductions of the limbic system and reticular activating system and that this regulation, in turn, leads to a decrease in the release of adrenocorticortropic hormone and in adrenergic activity, as well as to an increased tolerance to pain. Chronically elevated cortisol levels can exert harmful effects such as suppression of the immune response (Avers, Ambika, & Kamat, 2007). Prior research by Block, Jennings, and David (2003) showed that music reduces release of the stress hormone, cortisone, during invasive procedures with adults and children. Block et al. also found that exposure of preterm infants to live harp music resulted in a significant decrease in salivary cortisol levels and in lower respiratory rates.

Several studies documented other positive changes in behavioral and physiological indicators of preterm infants after a music intervention, such as decreases in HR, respiratory rate, BP, metabolic rate, and oxygen consumption (Cassidy & Standley, 1995; Coleman et al., 1997; Kaminski & Hall, 1996).

Characteristics of Music That Might Affect Physiologic and Behavioral Responses of Preterm Infants

Response to a particular musical stimulus is influenced by many characteristics of the music itself, including the melody, rhythm, harmony, pitch, dynamics, and timbre of the music (Philbin & Klaas, 2000; Standley, 2003). Individual factors also influence perception of a particular piece of music, including previous learning and the resulting emotional associations to the music, as well as individual preferences. The comparative effects of live versus recorded music on infants' well-being are not well known. Arnon et al. (2006) suggested that, in comparison with recorded music, live music has a greater impact on adults and children because of the social interaction and responsiveness involved.

Arnon et al. (2006) found that preterm infants exposed to live-music lullabies demonstrated no physiologic or behavioral responses during the 30 min of music therapy, although they demonstrated a significant decrease in HR and behavioral score during the 30 min after the music. The behavioral score was assigned as defined by Als' (1986) numerical score for infant state, including deep sleep, light sleep, drowsy, quiet awake or alert, actively awake and aroused, highly aroused/upset or crying, and prolonged respiratory pause greater than 8 s. Infants in a no-music and recorded-music group did not exhibit changes in physiologic or behavioral responses at any interval (Arnon et al.). Block et al. (2003) reported that live harp music was shown to be beneficial to premature infants by lowering cortisol levels and respiratory rates; however, the study protocol did not include a recorded-music comparison.

Scheve (2004) reported that live music may have intrinsic sound qualities that are not present in recorded music. According to Arnon et al. (2006), other benefits to live music are the ability of the musician to maintain a certain decibel level by altering his or her voice in response to fluctuating noise in the nursery. Also, the musician can adjust the music intervention based on the infant's response.

Stewart and Schneider (2000) noted the potential carryover effect and nurturing qualities of live music. Courtnage (2000) suggested that live music sounds more caring and is distinguishable from recorded music.

Recorded music may be more favorable in some situations in which cost is a concern. If a music therapist is not available (whether because of cost is a constraint or because music is desired on the night shift), recorded music is the next option. In addition, recording the parent's singing and playing the recording for the infant increases the infant's awareness of parental voice and possibly improves mother/infant bonding. Recorded music can be placed directly in the isolette, with the doors closed to minimize other sounds from within the nursery. When space is a problem and when the nursery is crowded, recorded music may be preferred over live music. During feedings, the bedside may be crowded, and space may not be adequate. If the mother is breast-feeding, she may want to play recorded music during the feeding and may feel that a live-music therapist would be intrusive.

Calabro et al. (2003) suggested that sedative music should be used in the NICU. Gaston (1951) described sedative music as having sustained melodic passages that lack percussive or strong rhythm. This music is performed by instruments with a soft tone color and medium- to low-frequency range, such as a guitar (Pratt, 1999). However, Standley (2003) wrote that “there is no piece of music that can be consistently labeled stimulative or sedative. Rather, research shows this is a learned perception of the listener” (p. 48).

Environmental Factors That Might Affect Preterm Infants’ Physiologic and Behavioral Responses to Music

Environmental factors that could affect the response to music include noise level in the nursery, number of visitors at the bedside, amount of light in the nursery, number of infants in the nursery, and number of visitors/staff in the nursery (Abromeit, 2003; Gardner & Lubchenco, 1998). Environmental noise in the nursery contributes to increased stress, decreased sleep times, and disorganized behavioral systems (Calabro et al. 2003; Kaminski & Hall, 1996; Standley & Moore, 1995). The NICU environment frequently provides excessive visual, auditory, and tactile stimulation for preterm infants (Lorch, Lorch, Diefendorf, & Earl, 1994). Loudness and noise in the NICU often exceed safe levels (White-Traut, 1993). This environment can create stress and inhibit normal development (Caine, 1991).

Characteristics of the Neonate that Might Affect Responses to Music

At 23 to 25 weeks' gestation, the human fetus is mature enough for sound to produce physiologic effects (Graven, 2000). Much is known about these physiologic effects in the full-term infant; however, these effects may be different for the preterm infant because the infants' capacity for tolerating and responding to stimuli is limited (Philbin & Klaas, 2000). Each preterm infant's responses may vary and depend on individual factors such as gestational age, chronological age, morbidity status, prenatal and postnatal music exposure, race, gender, medications, feeding method, and hunger (Lewis, Thomas, & Worobey, 1990; Porter, Grunau, & Anand, 1999; Wilson, Megel, Fredrichs, & McLaughlin, 2003).

According to Standley (2003), appropriate auditory guidelines (including various types of sounds) for preterm infants are not clearly defined. At 25 to 27 weeks' gestation, the premature infant has a consistent startle response to sound. Between 28 to 30 weeks' gestation, hearing is fully developed; however, auditory thresholds (such as decibel requirement) are high. Philbin and Klaas (2000) reported that less mature infants require greater intensity and pitch for discrimination. At 30 to 32 weeks' gestation, the preterm infant is mature enough for auditory learning to occur (Philbin & Klaas). Field, Dempsey, Hatch, Ting, and Clifton (1979) found that in comparison with preterm infants, full-term infants were more likely to demonstrate HR habituation to sound and tactile stimulation. Als (1986) suggested that preterm infants have more motor, autonomic, and state changes in response to auditory, tactile, visual, and social stimulation than full-term infants do. Despite these increased responses, preterm infants have problems differentiating patterns of sound, especially if ambient noise is loud; therefore, it is unclear whether preterm infants can discriminate music from background (ambient) noise (Gray & Philbin, 2004).

Purpose

The purpose of this study was to examine the effects of a 15-min live-music therapy intervention on HR, oxygen saturation, level of motor activity, behavioral distress, and behavioral state levels in premature infants in the NICU. The study tested two hypotheses.

Hypotheses

1. Infants will exhibit a greater decrease from baseline in HR, level of motor activity, and signs of behavioral distress during and for 10 min after exposure to a 15-min live-music intervention than they will exhibit during and for 10 min after exposure to a no-music condition.
2. Infants will exhibit a greater increase from baseline in oxygen saturation during and for 10 min after exposure to a 15-min live-music intervention than they will exhibit during and for 10 min after exposure to a no-music condition.

Study Questions

In addition to the two study hypotheses, the following study questions were included to provide data about internal infant characteristics and environmental characteristics that might influence infants' responses to the music intervention:

1. What were the gestational ages and resuscitation requirements at birth of infants enrolled in the study?
2. Were there differences in the mean sound levels and numbers of staff and visitors before, during, and after the music therapy and control periods, comparing the music therapy and control sessions?
3. Were there differences in the mean morbidity levels, weights, and quantity of stimulation scores of infants during the music and control conditions?
4. Was there a difference in the mean percentages of time in each of the seven behavioral states before, during, and after the music therapy or control periods, comparing the music therapy and control sessions?

Definition of Terms

Five key terms were defined conceptually and operationally for this study. The terms were music therapy, sound, behavioral state, motor activity level, and behavioral distress.

Music therapy is the prescribed use of music and musical interventions to restore, maintain, and improve emotional, physiologic, and spiritual health and well being (Guzzetta, 1995). Music therapy is “the clinical and evidence-based use of music interventions to accomplish individualized goals within a therapeutic relationship by a credentialed professional who has completed an approved music therapy program” (American Music Therapy Association, n.d., What is music therapy, ¶ 1). For the purposes of this study, a music intervention was viewed as the actual act of providing the music stimulation. Music therapists incorporate individualized needs, as well as theory and evidence-based practice, to guide the actual music intervention. The term music therapy intervention was used in this study because a board-certified music therapist sang to one infant at a time and adjusted the level of her singing according to infant response and to ambient noise level in the NICU.

Music therapy in this study consisted of live music performed by a board-certified music therapist who sang lullabies while providing guitar accompaniment. Appendix A contains a list of the songs that were performed. According to Standley (2003), lullabies place an emphasis on vowels and on rising and falling phrases. Theses songs are soothing, constant, and stable. Lullabies typically have a single accompanying instrument, a light rhythmic emphasis, and constant rhythm and volume. The music therapist sat on a stool approximately 2 to 4 ft from the infant's bed and sang with guitar accompaniment for 15 min. The nurse generally opened the portholes to the infant's isolette unless doing so was contraindicated by temperature instability.

Sound is harmonic pressure variations that can be heard in air (Gray, 2000). Sound levels were measured in decibels at the infant's head and outside the isolette. The decibel scales are logarithmic, and the decibel is one tenth of a log unit (Gray; Morris, Philbin, & Bose, 2000). Decibels are useful for measuring sound because ears respond to percentages of change and because decibels are equal percentages.

Behavioral state was conceptually defined as level of behavioral arousal, including Quiet Sleep, Active Sleep, REM Sleep, Drowsy, Alert Inactive, Awake Active, and Fuss/Crying (Brazelton, 1984). Operational definitions are included in Appendix B.

Motor activity level refers to the amount of observed physical movement. Motor activity results in energy expenditure. The following motor activities were coded: single limb, multiple limb, and gross body movement; head turn, and startle. Operational definitions are included in Appendix B.

Behavioral distress was defined conceptually as subtle and potent behavioral manifestations associated with responses of preterm infants to stressors. The following stress responses were coded: hiccup, facial grimace, finger splay, clenched fists, crying, fussing, spitting, and vomiting. Operational definitions are included in Appendix B.

Assumptions

The study was based on five underlying assumptions:

1. Premature infants experience stressors.
2. Stress responses in premature infants include physiological responses (HR and oxygen saturation) and behavioral responses (behavioral state, motor activity, and signs of behavioral distress).
3. Modulation of the stress response in premature infants may reduce energy demands and enhance recovery.
4. In the NICU, characteristics of auditory stimulation provided by music differ from those of other types of auditory stimulation.
5. Preterm infants respond differently to music than to other random NICU noise.

Summary

The NICU is an environment of bright lights, noise, and tactile stimulation, all of which might be potential stressors for the preterm infant. Findings from previous studies have suggested that music is effective in decreasing the stress response in the preterm infant. Many of these studies have failed to control for important extraneous variables, including characteristics of the infant (e.g., morbidity, gestational age, amount of stimulation received in the hours before the music), characteristics of the NICU (e.g., ambient noise, light levels, number of infants and visitors in the unit), and characteristics of the music itself. This study contributed to the growing body of research examining the effects of music on preterm infants, and by having infants serve as their own controls as a means of controlling effects of internal infant characteristics that might influence response to music. The study also provided a description of environmental variables that might influence the infants' responses to the music (e.g. number of visitors in the NICU, level of noise in the NICU, amount of stimulation during the 2 hours prior to the music intervention, and infant morbidity status and gestational age).

CHAPTER 2

REVIEW OF LITERATURE

Introduction

A major focus for health care professionals caring for premature infants in the NICU is the identification of best practices for promoting optimal neurological/ behavioral development of these vulnerable infants. Some have argued that the NICU does not provide premature infants with appropriate types and amounts of sensory stimulation at critical periods of neurological development and have recommended providing supplemental auditory, tactile, visual, vestibular, and/or kinesthetic stimulation (Burns, Cunningham, White-Traut, Silvestri, & Nelson, 1994; Schanberg & Field, 1987; White-Traut & Tubeszewski, 1986). Others have asserted that the NICU environment provides excessive stimulation and that it is important to reduce stimulation in order to minimize stress and promote growth and healing (D'Agostino & Clifford, 1998; Gottfried, Hodgman, & Brown, 1984; Graven, 2000).

The use of music in medicine is not a new concept. In 1914, the *Journal of the American Medical Association* published a report regarding the use of music for patients undergoing regional or local anesthesia (Kane, 1914). During this time, Duke University hospitals were using music in operating and recovery rooms (Avers et al., 2007). The discipline of medical music therapy began after World War II when community musicians went to Veterans Hospitals around the country to play for the thousands of veterans suffering both physical and emotional trauma. The patients' notable physical and emotional responses to music led the doctors and nurses to request the hiring of musicians by the hospitals (Davis, Gfeller, & Thaut, 1992). During the early 1950s, studies showed beneficial effects of music in surgical patients, such as increased cardiac output and decreased HR, respiratory rate, and BP (Light, Love, Benson, & Morch, 1954). The study of music on the preterm infant has been championed by the American Music Therapy Association, which was founded in 1998 through the merging of the National Association for Music Therapy (founded in 1950) and the American Association for Music Therapy (founded in 1971; American Music Therapy Association, n.d.).

Researchers in the 1970s began evaluating the behavioral responses of preterm infants to stimulation. Katz (1971) was the first to publish findings indicating that premature infants in the NICU benefit from auditory stimulation. During that same time, Segall (1971) reported that postnatal auditory stimulation promoted a cardiac response. When the infant was crying, the HR decreased in response to auditory stimulation; during the quiet state, the infant's HR increased in response to auditory stimulation (Segall). Over the next decade, Chapman (1978) and Malloy (1979) published results from similar studies but were unable to support the findings reported by Katz and Segall. Not until the early 1990s did researchers begin to include physiologic outcome variables such as HR, BP, oxygen saturation, and respiratory rate (Burke, Walsh, Oehler, & Gingras, 1995; Butt & Kisilevsky, 2000; Cassidy & Standley, 1995; Coleman et al., 1997; Collins & Kuck, 1991; Lorch et al., 1994; Standley & Moore, 1995; White-Traut, Nelson, Silvestri, Patel, & Kilgallon, 1993). Interest in examining the effects of different types of music, as well as those of different modes of delivery, was also evident in reports published beginning in the 1990s (Coleman et al.; Lorch et al.; Standley & Moore).

This review of literature presents a summary of research that has been focused on the effects of music, auditory stimulation, or music therapy provided to premature infants in the NICU. Studies were included in this review if they met the following criteria: (a) included premature infants (less than 37 week' gestational age at birth) in the NICU, (b) evaluated responses to music during the NICU period, and (c) evaluated the effects of music on the infant's physiologic or behavioral responses. Studies were identified through a search of Medline and CINAHL databases by using the search terms of preterm infant, neonate, music, sensory intervention, stress, and auditory stimulation. Additional studies were identified by reviewing reference lists and keywords of reviewed studies and including music therapy, preterm infant, neonatal intensive care, therapeutic intervention, singing, and music. The final sample included 29 studies published from 1971 through 2007. A summary of these 29 studies appears in Appendix C. The summary provides information on study design, gestational age, sample size, use of control group, randomization, music type and delivery method, duration, decibel measurement, and significant results.

A variety of behavioral and physiologic dependent variables were examined in these studies: auditory and visual function, motor and tactile/adaptive maturation, limb movement, maturation at discharge, stress behaviors, arousal state, weight gain, calorie intake, feeding rate, length of hospital stay, HR, BP, respiratory rate, oxygen saturation, and parent-infant interaction. The studies varied in sample size and characteristics, procedures for selection of study participants, design, and methods of data analysis. These variations made it difficult to make definitive statements about guidelines for safe implementation of music in the NICU. This review of literature is organized first into descriptions of studies of recorded music and then into a discussion of studies of live music. The recorded-music studies are further organized by the type of music provided (vocal speech, vocal singing, instrumental, and pacifier-activated lullabies [PAL]). Vocal-music studies also include music with kangaroo care, as well as music as a component of multimodal stimulation (ATVV). Within each section, the studies are further organized by whether music was provided during a potentially stressful procedure and by the type of outcome (physiologic or behavioral) measured.

Research Involving Recorded Music for the Preterm Infant

Recorded Speech

Katz (1971) and Segall (1971) were the first to publish findings from studies comparing preterm infants' responses to auditory stimulation provided by a prepared monologue of the mother's voice compared to routine ambient noise. Katz presented recorded maternal speech for 5 min, six times per day in 2-hr intervals beginning on the 5th day of life and continuing until 36 weeks' post-conceptual age. Segall presented recorded maternal speech for 30 min each day until 36 weeks' post conceptual age; the infant's age when the intervention began was not reported. The Katz and Segall studies included 60 and 62 infants, respectively, who were 28 to 32 weeks' gestational age at birth. Each researcher used a two-group experimental design in which on group was a control (routine nursery care) group. Segall reported random assignment of infants to group but no blind ing of researchers, and Katz failed to report whether random assignment was used but indicated blinding of researchers.

Katz (1971) reported an increase in auditory and visual function and in motor and tactile/adaptive maturation. Both Katz and Segall (1971) concluded that preterm infants were responsive to auditory stimulation. Adding to these findings, Segall reported that preterm infants had different HR responses to auditory stimulation and that these differences depended on behavior state. When the infant was crying, the HR decreased when the infant was exposed to the mother's voice; when they were not crying, infants exposed to the mother's voice head increased HRs (Segall).

Recorded Music

The most common type of music used in research involving the preterm infant has been recorded female singing combined with instrumental music. Fifteen studies utilized a variety of types of recorded music (Burke et al., 1995; Butt & Kisilevsky, 2000; Caine, 1991; Calabro et al., 2003; Cassidy & Standley, 1995; Chapman, 1978; Chou et al., 2003; Coleman et al., 1997; Collins & Kuck, 1991; Johnston, Filion, & Nuyt, 2007; Kaminski & Hall, 1996; Lai et al., 2006; Lorch et al., 1994; Malloy, 1979; Standley & Moore, 1995).

Of the 15 studies of recorded music, 7 included vocal music (Butt & Kisilevsky, 2000; Caine, 1991; Cassidy & Standley, 1995; Coleman et al., 1997; Johnston et al., 2007; Lai et al., 2006; Standley & Moore, 1995), 3 included *Transitions,* a combination of digital samples of actual womb sounds and barely discernable synthesized female vocal harmonies (Burke et al., 1995; Chou et al., 2003; Collins & Kuck, 1991), and 5 included instrumental music only (Calabro et al., 2003; Chapman, 1978; Kaminski & Hall, 1996; Lorch et al., 1994; Malloy, 1979).Table 1 includes a summary of the characteristics of the music and the samples in these 15 studies.

Table 1

Summary of Recorded-Music Studies

First author	Description of the music 1. Vocalist 2. Accompanying sounds 3. Music style/selection 4. Decibel	Duration and timing of music exposure	Sample Characteristics 1. Sample size 2. Birth gestational age 3. Birth weight
		Vocal	
Butt	1. Female singing versus piano 2. None 3. "Brahms' Lullaby" 4. 76 dBA (average)	10 min x 2 after heel lance (started after infant had been in NICU at least 24 hrs; specific infant criteria for when ended NR)	1. *N* = 14 2. 28-36 weeks 3. 590–2,280 g
Caine	1. NR 2. NR 3. Lullaby/Children's songs 4. 70-80 dB[a]	30 min music alternating with 30 min routine auditory stimulation, total music 1.5 h once/day (began 4th day of life or 1st day in isolette, continued until infant was dis-charged from the NICU)	1. *N* = 52 2. NR 3. E mean = 1,675.77 g C mean = 1,678.85 g

Table 1 (Continued)

First author	Description of the music 1. Vocalist 2. Accompanying sounds 3. Music style/selection 4. Decibel	Duration and timing of music exposure	Sample Characteristics 1. Sample size 2. Birth gestational age 3. Birth weight
Cassidy (1995)	1. Female singing 2. Orchestral 3. Lullaby 4. 80 dB[a]	5 segments of 4 min each of silence alternating with 4 segments of 4 min of music, total 36 min across 3 days (specific infant criteria for when intervention began and ended NR)	1. *N* = 20 2. 24–30 weeks 3. NR
Coleman	1. Female alternating w/male singing versus spoken 2. NR 3. Lullaby 4. 65-75 dB[a]	20 min for each of 3 intervention periods, 20-min breaks between each intervention for 4 successive days (specific infant criteria for when intervention began/ended NR)	1. *N* = 66 2. 25–35 weeks 3. NR
Johnston	1. Maternal singing and speaking 2. None 3. Singing or speaking nursery rhymes/baby talk 4. 60-70 dBA	10 min 3x/day for 48 hrs, then at next two heel lance procedures played 1 min before heel lance and during until heart rate and O_2 returned to baseline (enrolled within first 10 days of life)	1. *N* = 20 2. 32–36 weeks 3. Mean = 1,985 g
Lai	1. NR 2. Instrumental 3. Lullaby 4. NR	60 min/day x 3 consecutive days during kangaroo care (specific infant criteria for when intervention began and ended NR)	1. *N* = 30 2. <37 weeks 3. NR

Table 1 (Continued)

First author	Description of the music 1. Vocalist 2. Accompanying sounds 3. Music style/selection 4. Decibel	Duration and timing of music exposure	Sample Characteristics 1. Sample size 2. Birth gestational age 3. Birth weight
Standley (1995)	1. Female singing versus speaking 2. NR 3. Lullaby 4. 65-70 dB[a]	20 min x 3 days (specific infant criteria for when intervention began and ended NR)	1. *N* = 20 2. NR 3. 25–57 oz
	"Transitions"		
Burke	1. Female singing 2. Womb sounds 3. "Transitions" 4. 65 dB[a]	15 min after suctioning *Infant A:* vibrotactile and auditory conditions – six 15-min trials each; five 15-min no-music conditions. *Infants B, C, D:* six 15-min trials each of three conditions (specific infant criteria for when intervention began and ended NR)	1. *N* = 4 2. Infant A: 25 weeks Infant B: 28 weeks Infant C: 31 weeks Infant D: 35 weeks 3. Infant A: 575 g Infant B: 1,600 g Infant C: 1,100 g Infant D: 2,270 g
Chou	1. Female singing 2. Womb sounds 3. "Transitions" 4. 60 dB[a]	During suctioning (time variable; specific infant criteria for when intervention began and ended NR)	1. *N* = 30 2. 28–36 weeks 3. Weight = 728-1,980g (not clear whether this was birth weight)
Collins	1. Female singing 2. Womb sounds 3. "Transitions" 4. 80 dB[a]	10 min baseline followed by 10 min music (age at time of intervention was 1-14 days; number of sessions, specific infant criteria for when intervention began and ended NR)	1. *N* = 17 2. 24–37 weeks 3. 705–3,290 g

Table 1 (Continued)

First author	Description of the music 1. Vocalist 2. Accompanying sounds 3. Music style/selection 4. Decibel	Duration and timing of music exposure	Sample Characteristics 1. Sample size 2. Birth gestational age 3. Birth weight
	Instrumental		
Calabro	1. NA 2. Instrumental (small orchestral ensemble) 3. “Brahms’ Lullaby”, “Sandman” 4. 60-70 dBC	20 min, 1x/day x 4 consecutive days (specific infant criteria for when intervention began and ended NR)	1. *N* = 22 2. 34 weeks 3. NR
Chapman	1. Maternal speech 2. Orchestral 3. “Brahms’ Lullaby” 4. NR	5 min, 6x/day, 2 hr intervals (began on 5th day of life and continued until infant weight 1,843 g)	1. *N* = 153 2. 26–33 weeks 3. 3 lb, 2 oz
Kaminski	1. NA 2. Orchestral 3. Sonata, symphony, “Brahms’ Lullaby”, concerto 4. 35 dB (pillow speaker)[a]	One session - C-2 hr followed by E-2 hr (conducted when infant was 24–72 hr old)	1. *N* = 20 2. 36–42 weeks 3. 2,860 – 4,160 g
Lorch	1. NA 2. Instrumental 3. “Moonlight Sonata” versus “Sabre Dance” 4. 76 - 80 dB[a]	20 min on 2 consecutive days (specific infant criteria for when intervention began and ended NR)	1. *N* = 10 2. 32–36 weeks post-conceptual age 3. NR
Malloy	1. Maternal speech 2. Instrumental 3. “Brahms’ Lullaby” 4. NR	5 min, 6 x/day, 2-hr intervals (began on 5th day of life and continued until infant weighed approximately 2,000 g and was ready for discharge	1. *N* = 127 2. 27– 33 weeks 3. NR

Note. NICU = neonatal intensive care unit; NR = not reported.
[a]Scale not reported.

The decibel levels of the music provided in 14 of these 15 studies were relatively consistent, and ranged from 60 dB to 80 dB, although one study reported a dB level of only 35. However, the scale of measurement was often not reported. This limitation makes it difficult to compare the effects of the volume of music used. Kaminski and Hall (1996) reported a set level of 35 dB through use of a speaker pillow placed under the infant. Other researchers reported using speakers placed near the infant's head or using insert and phonopad earphones to deliver the music. Speakers were placed 3 to 20 inches from the infant's head, and whether the decibel level was measured at the infant's ear, was generally not reported.

The number of subjects per study ranged from 4 to 153 infants. Burke et al. (1995) enrolled 4 infants at postconceptual ages 25, 28, 31, and 35 weeks. Earlier studies by Chapman (1978) and Malloy (1979) involved 153 and 127 infants, respectively. The remaining studies had sample sizes of 10 to 52 infants, with eight studies having 17 to 30 infants.

Gestational age at birth ranged from 24 weeks to 42 weeks. Kaminski and Hall (1996) included infants 36 to 42 weeks' gestational age at birth. Lorch et al. (1994) reported postconceptual ages ranging from 32 to 36 weeks at enrollment. All other studies included infants 24 to 37 weeks' gestational age at birth.

Physiologic outcomes such as HR, mean arterial pressure, oxygen saturation, and/or respiratory rate were examined in several studies evaluating the effects of recorded music (Burke et al., 1995; Butt & Kisilevsky, 2000; Caine, 1991; Calabro et al., 2003; Cassidy & Standley, 1995; Chou et al., 2003; Coleman et al., 1997; Collins & Kuck, 1991; Johnston et al., 2007; Lorch et al., 1994; Standley & Moore, 1995).

Effects of Recorded Music on Oxygen Saturation

Researchers from six of seven studies of the effects of recorded music on oxygen saturation reported that music resulted in increased oxygen saturation levels (Burke et al., 1995; Cassidy & Standley, 1995; Chou et al., 2003; Coleman et al., 1997; Collins & Kuck, 1991; Standley & Moore, 1995). Authors from one study (Johnston et al., 2007) reported a decreased oxygen saturation level after a music intervention.

Collins and Kuck (1991) reported statistically significant increases in oxygen saturation from a mean of 89% at baseline to a mean of 92% after exposure to a 10-min intervention with *Transitions* among infants who were 24 to 37 weeks' gestational age at birth. Burke et al. (1995) reported that *Transitions* music played for 15 min after suctioning resulted in an increase in oxygen saturation among 3 of 4 infants who were included in the study and who were 25, 28, and 35 weeks' gestational age at birth; however, no statistical analyses were reported to support these conclusions. In their study of 30 infants born at 28 to 36 weeks' gestational age, Chou et al. (2003) found that mean oxygen saturation levels during 30 min after suctioning were higher in the experimental group than in the control group and that the mean time in minutes to recovery of oxygen level to baseline was shorter in the experimental group than in the control group; however, the amount of time that the music was provided varied, and the range of time was not clearly reported. Coleman et al. (1997) reported a statistically significant increase in oxygen saturation during a 20-min lullaby intervention provided for 4 consecutive days among infants who were 25 to 35 weeks' gestation at birth. The precise levels of oxygen saturation were presented in graphic format only.

Cassidy and Standley (1995) reported that, in comparison with recorded maternal speech, a 30-min lullaby intervention among infants who were 24 to 37 weeks' gestation resulted in an increase in mean oxygen saturation from 83.8% to 95.8% on Day 1. In the 30-min intervention, five segments of 4 min each of silence alternated with four segments of 4 min of music across 3 days. On Study Days 2 and 3 during the final observation period, oxygen levels in infants exposed to recorded lullaby were lower than those in infants in the recorded maternal speech group.

Standley and Moore (1995) compared the effects of recorded lullabies sung by a female vocalist with those of recorded maternal speech and found that the lullaby group's mean oxygen saturation increased on Study Day 1 only; sung recorded lullaby intervention was provided for 20 min on each of 3 days. However, precise levels of oxygen saturation were presented in the article in graphic format only.

Results of one study of the effects of music on oxygen saturation revealed that the oxygen saturation level after a music intervention among infants from 32 to 36 weeks' gestation was lower than the level found for a routine care group in the same age range (Johnston et al., 2007). The music intervention included recorded maternal voice (singing and speaking nursery rhymes) provided for 10 min three times per day for 2 days, provided for 1 min before two different heel lance procedures and continuing until the infant's HR and oxygen saturation returned to baseline. Johnston et al. concluded that the volume of the recording (60 to 70 dBA) and the placing of the speakers in the isolette may have been aversive.

Effects of Recorded Music on HR

Three of four studies of the effects of recorded music on HR yielded reports of a decreased HR after exposure to the music intervention (Burke et al., 1995; Butt & Kisilevsky, 2000; Calabro et al., 2003; Coleman et al., 1997). Butt and Kisilevsky tested 14 infants under two recorded “Brahms’ Lullaby” music conditions: sung a capella versus instrumental (piano). The intervention was provided for 10 min after two separate heel lance procedures. A significant decrease in HR was reported in infants more than 31 weeks’ postconceptual age but not in infants less than 31 weeks’ postconceptual age. One possible explanation for the difference between the findings for the two gestational age groups is that infants who were less than 31 weeks’ postconceptual age did not show as much stress or pain during the heel lance as the infants more than 31 weeks’ postconceptual age. Butt and Kisilevsky proposed that, because the younger infants’ response to the heel lance was not as pronounced, it was possible that those infants could not mount and maintain as much of a stress response; thus any return to baseline was not statistically significant. No difference was found between types of music (vocal versus instrumental). Coleman et al. (1997) reported that, after a singing music intervention, HR was statistically significantly lower than the HR found after a speaking condition; however, specific HR levels were not presented. Burke et al. (1995) reported a decrease in HR after suctioning among infants in the music condition but did not report results of statistical analyses. Calabro et al. (2003) used recorded instrumental music with a small ensemble playing “Brahms’ Lullaby” and “Sandman” for 20 min, once per day for 4 consecutive days to 11 infants in the experimental group born at 34 weeks’ gestation; these authors reported no effect of music on HR.

Effects of Recorded Music on BP

Lorch et al. (1994), the only researchers who reported the effects of recorded music on BP, compared responses of infants who were 32 to 36 weeks' conceptual age to a recorded sedative-music intervention and to stimulating music. The authors reported that in comparison with baseline, levels of systolic BP were higher and more variable during stimulative music than during sedative music; however, sedative music resulted in a more variable HR.

Effects of Recorded Music on Behavioral Responses

Behavioral outcomes, although reported frequently as significant, were occasionally vaguely defined. Caine (1991) reported an increase in *nonstress behaviors* for infants exposed to recorded lullabies for 30 min of music alternating with 30 min of routine auditory stimulation, for a total of 1.5 hr of music once per day and continued until discharge. However, the term *nonstress behaviors* was not defined. The favorable behavioral results most often reported to have occurred during or immediately after a music intervention were an increase in quiet alert states and quiet sleep states or a decrease in high arousal time (Burke et al., 1995; Butt & Kisilevski, 2000; Coleman et al. 1997; Lai et al., 2006; Kaminski & Hall, 1996).

Kaminski and Hall (1996) reported a lower amount of time in high arousal states during the 2-hr music intervention than during the 2-hr control period in a sample of 20 infants born from 36 to 42 weeks' gestational age. The study was conducted when the infants were 24 to 72 hr of age. Butt and Kisilevski (2000) found that, after undergoing a heel lance procedure, infants who were more than 31 weeks' postconceptual age demonstrated a more rapid return to behavioral stability after exposure to recorded music than they showed after exposure to the absence of music. Behavioral stability was defined as a return to baseline measures of HR, oxygen saturation, and behavioral state score; the behavioral state scores were calculated by using Brazelton's (as cited in Butt and Kisilevski) categories of state of arousal and facial expressions of pain. Collins and Kuck (1991) reported improved behavioral states; the authors defined *behavioral states* as changing from being agitated or fussy to being asleep or awake, although they did not clearly describe the means by which these states were measured.

Johnston et al. (2007) found no significant differences in behavioral indicators of pain (facial actions and neurobehavioral state as defined in the Premature Infant Pain Profile) among preterm infants (32 to 36 weeks' gestation) divided into an experimental group and a control group. The infants in the experimental group were exposed to recorded maternal singing and speech 1 min before, during, and after heel lance; those in the control group received routing care before, during, and after the heel lance.

Effects of Recorded Music on Other Outcome Variables

Findings from several studies suggested that exposure to recorded music might have beneficial effects on other variables, including length of hospital stay, caloric intake, and weight gain. Malloy (1979) studied a total of 127 infants, gestational age 27 to 33 weeks at birth, who received recorded instrumental "Brahms' Lullaby", recorded maternal speech, or routine care. The recorded-music interventions were provided for 5 min six times per day in 2-hr intervals beginning on the 5^{th} day of life and continuing until the infant was ready for discharge. Malloy reported that infants exposed to the recorded instrumental music were 9.9 days younger at discharge than those in the routine-care group were found to be. In comparison with infants in the routine-care group, those exposed to recorded maternal speech were 6.2 days younger at discharge.

A decrease in length of hospital stay was also reported by Caine (1991) for infants exposed to recorded lullabies for 30 min of music alternating with 30 min of routine auditory stimulation for a total of 1.5 hr of music once per day; this procedure continued until discharge. The mean length of hospitalization for infants in the intervention group was 26 days, whereas that for infants in the routine-are control group was 31 days. Coleman et al. (1997) also reported that, in comparison with the length of stay for infants 25 to 35 weeks' gestational age at birth who were placed in a routine-care control group, that for infants of the same gestational ages who were exposed to recorded sung and instrumental lullabies provided for 20 min for each of three intervention periods, with 20-min breaks among interventions for 4 days, was found to be shorter (38.2 days vs. 35.7 days, respectively). An increase in caloric intake was also reported by both Caine and Coleman et al. with increased weight reported as significant by Coleman et al. only.

Recorded Music Combined With Kangaroo Care

In a study of 30 infants less than 37 weeks' gestational age at birth, Lai et al. (2006) compared the influences of a no-music condition with those of a condition involving recorded lullabies during kangaroo care provided for 60 min per day for 3 days on maternal anxiety and preterm infants' responses, includingHR, oxygen saturation, respiratory rate, and behavioral state. Kangaroo care is a method of holding an infant in skin-to-skin contact and upright. Mothers were allowed to choose the type of music from three options: Western vocal, instrumental lullaby, or aboriginal Taiwanese lullaby. There were no significant differences noted between the physiologic measures of infants in the kangaroo care/music group and those of infants in a control group who received usual care. However, infants in the intervention group had more quiet sleep states and less crying; these two variables were measured every 10 min for a total of 60 min beginning 1 hr after the previous feeding.

Vocal Music (Recorded and Live) With ATVV Stimulation

Six studies included vocal stimulation (recorded or live) as a component of ATVV stimulation (Standley, 1998; White-Traut & Nelson, 1988; White-Traut & Tubeszewski, 1986; White-Traut et al., 1993, 1997, 2002). The ATVV intervention provides female human voice auditory stimulation, tactile stimuli through moderate touch stroking, visual stimuli in the form of eye-to-eye contact, and rocking stimuli as vestibular stimulation (University of Illinois at Chicago, 2007). In one study, Whipple (2000) evaluated the effects of parent training in music and multimodal ATVV stimulation. Table 2 includes a summary of the characteristics of these studies.

Table 2

Summary of Vocal Music (Recorded and Live) With Auditory, Tactile, Visual, and Vestibular Stimulation Studies

First author	Description of the music 1. Vocalist 2. Accompanying sounds 3. Music style/selection 4. Decibel	Duration and timing of music exposure	Sample Characteristics 1. Sample size 2. Birth gestational age 3. Birth weight
Standley (1998)	1. NR 2. NR	15–30 min 1-2x/week (began after infant's 10th day of life	1. $N = 40$ 2. 26–34.5 weeks

Table 2 (Continued)

First author	Description of the music 1. Vocalist 2. Accompanying sounds 3. Music style/selection 4. Decibel	Duration and timing of music exposure	Sample Characteristics 1. Sample size 2. Birth gestational age 3. Birth weight
Standley (1998)	3. Live "Brahms' Lullaby" (hummed) 4. NR	and continued for 2-3 weeks)	3. 700–2,030 g
Whipple	1. Parent (gender NR) 2. NR 3. Live (style NR) 4. NR	NR (specific infant criteria for when intervention began and ended not reported)	1. *N* = 20 2. 25–36 weeks 3. 630–2,500 g
White-Traut (1986)	1. NR 2. NR 3. Talking or singing (style NR) 4. NR	15 min 1x/day for 10 days or until discharge (intervention began when infant's weight was 1,750 g)	1. *N* = 33 2. 29–35 weeks 3. <1,800 g
White-Traut (1988)	1. Mother 2. NR 3. Live talking or singing (style NR) 4. NR	15 min during the following post birth periods: 24-36 hr, 37-48 hr, 49-60 hr, 61-72 hr (started after infant was 24 hr old)	1. *N* = 33 2. 28–35 weeks 3. Mean = 1,923 g
White-Traut (1993)	1. Female 2. NR 3. NR 4. NR	15 min 1x/day for 4 consecutive days (enrolled at 33 weeks' postconceptual age)	1. *N* = 40 2. 30–32 weeks 3. Mean = 1,757 g
White-Traut (1997)	1. Female 2. NR 3. Recorded voice (style NR) 4. NR	15 min 1x/day for 4 consecutive days (specific infant criteria for when data collection began NR; sample mean postconceptual age at entry into study was 33 weeks)	1. *N* = 54 2. Mean = 32 weeks 3. 1,200–2,353 g

Table 2 (Continued)

First author	Description of the music 1. Vocalist 2. Accompanying sounds 3. Music style/selection 4. Decibel	Duration and timing of music exposure	Sample Characteristics 1. Sample size 2. Birth gestational age 3. Birth weight
White-Traut (2002)	1. Female 2. NR 3. Live infant-directed talk 4. NR	15 min before first three oral feedings (entered into study at 33–35 weeks corrected age)	1. *N* = 22 2. 29–33 weeks 3. E mean = 1,571 g C mean = 1,726 g

Note. NR = not reported.

None of the studies of ATVV stimulation reported decibel levels of the auditory stimulation or described whether there were any accompanying instruments. The gestational ages at birth of infants enrolled in these studies ranged from 25 to 36 weeks. The sample size of each study varied from 20 to 54. The most frequently reported finding in the ATVV studies was that, in comparison with the routine-care group, the intervention group demonstrated increased alert state or state of arousal both during the intervention and for 30 min after the intervention (White-Traut et al., 1993, 1997, 2002).

White-Traut et al. (1993) studied 40 infants 30 to 32 weeks' gestational age at birth who were exposed either to ATVV with a female voice 15 min once per day for 4 consecutive days or to routine nursery care; the authors reported that, in comparison with infants in the routine-care group, those in the intervention group showed an increase in HR (149 bpm to 155.5 bpm, respectively) and a decrease in oxygen saturation (96.4% to 95.7%, respectively). These authors also noted an increased alert state during the intervention and for 30 after the intervention (White-Traut et al., 1993). In a subsequent study, White-Traut et al. (1997) studied infants with a mean gestational age at birth of 32 weeks who were exposed either to ATVV with a female voice 15 min once per day for 4 consecutive days or to routine nursery care; inn this study, White-Traut et al. (1997) included 54 infants and found that any group exposed to a protocol that contained a tactile component demonstrated increased arousal, HR, and respiratory rate during the actual stimulation. Standley (1998) compared the effects of live lullaby singing (humming of “Brahms’ Lullaby” without words) paired with ATVV with the benefits of routine care on weight gain/day, tolerance to stimulation, and days to discharge in 40 infants who were, 26.0 to 34.5 weeks’ gestational age at birth. The females receiving the ATVV intervention for 15 to 30 min once or twice per week were discharged an average of 11.8 days earlier than those females in the routine-care group were discharged. There was no difference between days to discharge for males in the intervention and those for males in the control group. However, males and females in the intervention group exhibited a higher weight gain per day than both genders in the control group did (Standley, 1998).

The effects of infant-directed talk via a live female voice paired with ATVV versus those of routine care were compared by White-Traut et al. (2002) in 22 infants with gestational ages of 29 to 33 weeks at birth. The infants in the experimental group received 15 min of the intervention just before to the first three oral feedings. The authors found that the experimental group’s alert state during the intervention was higher than that of the control group. In addition, in comparison with infants in the control group, those in the experimental group demonstrated higher levels of five of eight feeding-readiness behaviors during the intervention. Despite the increase in feeding-readiness behaviors in the experimental group, the feeding volume and duration of feeding of this group were not significantly different from those of the control group.

Whipple (2000) evaluated the effects of parent training in music and ATVV multimodal stimulation in 20 infants 25 to 36 weeks' gestational age at birth on (a) parent-neonate interaction, (b) weight gain, and (c) length of NICU stay. Parents were encouraged to read and sing to infants and to provide appropriate tactile stimulation. Appropriate parent scores were not clearly defined in the publication; however, parent scores were reported as significantly higher for the experimental group. There were no significant differences for weight gain or length of stay. The effects of music on the preterm infant in this study are unclear because of numerous uncontrolled extraneous variables. Music listening was intermittent, and there was no description of the kind of music or of the noise level. In addition, parents were told of music benefits before the study, and parents in both the music and multimodal stimulation groups provided music (Whipple).

PAL

Three studies consisted of evaluations of the effects of PALs (Cevasco & Grant, 2005; Standley, 2000, 2003). Table 3 includes a summary of these studies.

Table 3

Summary of Pacifier-Activated Lullaby (PAL) Studies

First author	Description of the music 1. Vocalist 2. Accompanying sounds 3. Music style/selection 4. Decibel	Duration and timing of music exposure	Sample Characteristics 1. Sample size 2. Birth gestational age 3. Birth weight
Cevasco (2005)	1. Child or Music Therapist (solo/duet) 2. Keyboard	PAL (each suck activated lullabies for a 10-s interval, each resulting in suck reset at the 10-s interval). Each	1. *N* = 62 2. 32–36 weeks 3. NR

Table 3 (Continued)

First author	Description of the music 1. Vocalist 2. Accompanying sounds 3. Music style/selection 4. Decibel	Duration and timing of music exposure	Sample Characteristics 1. Sample size 2. Birth gestational age 3. Birth weight
Cevasco (2005)	3. Lullaby 4. 65 dBC/58 dBC	subject had the opportunity to use PAL for 15 min per trail, with a total of 4 trials (specific infant criteria for when intervention began and ended NR).	
Standley (2000)	1. Female 2. NR 3. Lullaby 4. 65–70 dB	PAL (each suck activates lullabies for a 10-s interval, each resulting in suck reset at the 10-s interval) 5 min x2 with 2-min silence between (began when infant at least 34 weeks' postconceptual age, specific infant criteria for when intervention ended NR)	1. *N* = 12 2. 24–32 weeks 3. 677–1,616 g
Standley (2003)	1. Female 2. NR 3. Lullaby 4. 65 dBC/58 dBA	PAL (each suck activates lullabies for a 10-s interval, each resulting in suck reset at the 10-s interval) 15–20 min approximately 1 hr before late-afternoon feeding x 2 occurring within 1 week of referral to study (specific infant criteria for when intervention began and ended NR)	1. *N* = 32 2. 24–40 weeks 3. 620–2,640 g

Note. NR = not reported.

Standley (2000, 2003) and Cevasco and Grant (2005) investigated the effects of the PAL on nonnutritive sucking, feeding rates, and weight gain. The PAL uses lullabies as contingent reinforcement for sucking, and is set so that a suck of predetermined strength activates the music (Standley, 2000). Standley (2000) found that sucking rates were significantly greater in the experimental period than at baseline. In her 2003 study, Standley found that there was no difference between the morning feeding rates of the experimental group and control group. The afternoon feeding rate was significantly higher for the experimental group than for the control group; however, clinical significance was questionable. Additionally, the confounder of nurse feeding techniques was not addressed (Standley, 2003).

To evaluate the effects of PAL on weight gain, Cevasco and Grant conducted a post hoc analysis on data from a study of 62 premature infants. Results showed that the number of PAL trials completed (1 to 4) did not influence infant weight gain and that, although there was a trend toward greater weight gain with PAL use, individual variability within groups was greater than group differences were to be found.

Research Involving Live Music and the Preterm Infant

Two studies utilized live music (Arnon et al., 2006; Blumenfeld & Eisenfeld, 2006). Table 4 includes a summary of these two live music studies.

Table 4

Summary of Live-Music Studies

First author	Description of the music 1. Vocalist 2. Accompanying sounds 3. Music style/selection 4. Decibel	Duration and timing of music exposure	Sample Characteristics 1. Sample size 2. Birth gestational age 3. Birth weight
Arnon	1. Female singing 2. Frame drum with harp 3. Lullaby 4. 55 – 70 dBA	30 min x 3 consecutive days (began after 32 weeks' post-conceptual age)	1. $N = 31$ 2. 25–34 weeks 3. 650–1,737 g
Blumenfeld	1. Mother 2. NR 3. Maternal choice 4. 60 – 79 dB	23 min $\pm$ 9 min, 2 feedings on 2 consecutive days vs. 2 feedings with no singing (specific infant criteria for when intervention began and ended NR)	1. $N = 11$ 2. 23–34 weeks 3. NR

Note. NR = not reported.

Blumenfeld and Eisenfeld (2006) measured the effects of mothers' live singing on HR, respiratory rate, duration of feeding, and feeding volume. Arnon et al. (2006) examined effects of live-music lullabies versus those of the same lullabies recorded on physiologic measures, including HR, respiratory rate, oxygen saturation, and behavioral parameters. Although Blumenfeld and Eisenfeld found no significant results, Arnon et al. reported that in the 30 minutes after the live-music intervention, HR and behavioral score (deeper sleep) were significantly lower and higher, respectively, than those found for the control period. The mean HR was 150 beats per minute at baseline and decreased to a mean of 127 beats per minute after the intervention.

One possible reason for the different findings reported from these studies (Arnon et al., 2006; Blumenfeld and Eisenfeld, 2006) involves the sample size of 11 in the study by Blumenfeld and Eisenfeld, who discussed the difficulty that they encountered when recruiting infants for the study. Only 20% of mothers who agreed to participate followed through with the study. This small sample size could have led to the inability to detect significant differences. Other possible explanations include the choice of music and other stimulation surrounding the intervention. In the Arnon et al. study, infants were exposed to lullabies sung by a female vocalist and included an accompanying instrument. Blumenfeld and Eisenfeld allowed mothers to choose the type of music that they wanted to sing, and options varied from nursery rhymes to contemporary pop. In addition, the researchers had no control over the tempo and volume of the music, positioning of the baby, or other procedures performed during the day, whereas Arnon et al. placed all infants in the supine position, controlled the decibel level of the music, imposed control over the environmental noise, and carried out all interventions 1 hr after completion of feeding.

Meta-Analysis of Studies of Music Interventions With Preterm Infants

Standley (2002) published a meta-analysis of 10 studies of music therapy for preterm infants. These 10 studies were published from 1991 to 2000, with sample sizes ranging from 9 to 66 participants. Nine of the studies included recorded music, and only one study had live music as the intervention. All 10 studies included lullabies as the type of music used. The music intervention was compared with routine auditory stimulation in

5 studies and with white noise in one study. Two studies involved the evaluation of lullabies contingent on pacifier activation.

On the basis of findings from this meta-analysis, Standley (2002) recommended that music in the NICU should be nonalerting, with a constant volume and rhythm. She also recommended (a) that vocal music should be provided by a female or child, with a maximum of one accompanying instrument; (b) that volume level for music be in the low 70 dBC range (never greater than 75 to 80 dBC); (c) that music be provided in short intervals of 20 to 30 min throughout the day; and (d) that live singing be steady, constant, quiet, soothing, and infant directed. Music classified as a lullaby generally meets these criteria for music selection (Standley, 2003).

Summary

Evaluating studies about music, music interventions, and music therapy in the preterm infant was difficult because of the wide variations in music type, music delivery mode, music volume, music duration, other types of stimulation, and gestational ages of subjects. Nonetheless, several recurring themes across studies could be identified.

Of greatest concern were the wide range of decibel levels (35–80 dB), failure to report the scale of decibel measurement, and inconsistency in means of music delivery. In several cases, infants wore earphones; in other studies, music was provided through speakers inside the isolette that were placed 3 to 20 inches from the infant's head. There was inconsistency in the duration and frequency of the music intervention that was provided, and no authors reported a rationale or justification for the selected duration. Reported results were often questionable because of poorly described data collection methods, lack of environmental description, failure to blind data collectors, and vaguely defined variables. Despite these concerns, aspects of the studies provide direction for further research such as comparison of duration and frequency of a music intervention, development of a conceptual framework for music therapy with the neonatal population, evaluation of various decibel levels of the music, comparison of different gestational age groups at different developmental levels, and additional studies using live music.

The most significant limitation of research involving music in the preterm infant consisted of the lack of a conceptual framework that adequately addressed the many characteristics that may have affected infants' responses to music, as well as addressing possible mechanisms by which music might affect the infant. Additional limitations included lack of information on morbidity levels of the infants during data collection sessions; failure to measure the actual decibel level of music at the infant's ear; poorly defined variables; and failure to measure possible extraneous variables such as ambient noise, number of visitors/staff in nursery, and other stimulation received by the infant. Another potential confounder was the lack of discussion about the timing of the intervention or data collection. Few reports indicated consistency in the time of day at which data were collected. Sample sizes were often small and acknowledged as a limitation; however, very few authors reported a power analysis and/or why a specific sample size was chosen.

This study was designed and implemented to address these limitations and to provide an opportunity to further study live music with premature infants. The use of a music therapist providing a music therapy intervention was another unique aspect of this study. There was randomized assignment to a session order of two music therapy sessions and two no-music control sessions. This crossover design provided another control not addressed in many of the earlier studies. Both the conceptual framework developed during this study and the study results will contribute to development of further research involving larger sample sizes and the evaluation of both immediate benefits and long-term effects of live music therapy in the NICU.

CHAPTER 3

METHODS

The purpose of this study was to examine the effects of a 15-min live-music therapy intervention on HR, oxygen saturation, level of motor activity, behavioral distress, and behavioral state levels in premature infants in the NICU. The study tested the following hypotheses by using repeated-measures ANOVAs:

1. Infants will exhibit a greater decrease from baseline in HR, level of motor activity, and signs of behavioral distress during and for 10 min after exposure to a 15-min live-music intervention than they will exhibit during and for 10 min after exposure to a no-music condition.

2. Infants will exhibit a greater increase from baseline in oxygen saturation during and for 10 min after exposure to a 15-min live-music intervention than they will exhibit during and for 10 min after exposure to a no-music condition.

In addition to the two study hypotheses, the following study questions were included to provide data about internal infant characteristics and environmental characteristics that might influence infants' responses to the music intervention:

1. What were the gestational ages and resuscitation requirements at birth of infants enrolled in the study?

2. Were there differences in mean sound levels and numbers of staff and visitors before, during and after the music therapy and control periods, comparing the music therapy and control sessions?
3. Were there differences in the mean morbidity levels, weights, and quantity of stimulation scores of infants during music and control conditions?
4. Was there a difference in mean percentage of time in each of the seven behavioral states before, during, and after the music therapy or control periods, comparing the music therapy and control sessions?

The design used in this study was a one-group repeated-measures crossover design. The sample included 20 preterm infants who were hospitalized in a NICU in the southern United States. Infants served as their own controls. Data were collected on four occasions over a 2- to 4-week period beginning when the infants were 1 to 2 weeks old. On two occasions, the infants received 15 min of live music provided by a music therapist; on the other two occasions, the infants did not receive the music intervention. Because the music therapy was part of the standard of care in the NICU in which the study was conducted, it was not possible to use an experimental design in which infants were assigned randomly to an experimental group or to a control group. During each data collection period, data on HR, oxygen saturation, motor activity, behavioral state, and behavioral distress were collected every 30 s for 10 min before to the music intervention or control period, every 30 s for the 15 min during the music intervention or control period, and every 30 s for 10 min after the music intervention or control period.

Sample and Setting

A convenience sample of preterm infants (*N* = 22) in the NICU was initially enrolled in the study. To conduct a power analysis to project the needed sample size for this study, I reviewed the sample sizes in eight previously published studies in which one-group designs were used to evaluate the effects of music in the NICU on preterm infants. The sample sizes in these studies ranged from 4 to 31, with an average of 17.87 subjects. Standley (2002) reported a mean effect size ($d = 0.83$) for the variables of oxygen saturation, HR, behavioral state, weight gain, days in hospital, feeding rate, and non-nutritive sucking rate in her meta-analysis of studies of the effects of music therapy in preterm infants. In Standley's (2002) meta-analysis, there were two studies for which HR effect sizes were reported as 0.9190 and 0.4555. The effect sizes for oxygen saturation ranged from 0.6971 to 1.2887. Behavioral state effect sizes ranged from 0.7283 to 1.9528.

A significance level of 0.05 was set a priori. If a repeated-measures ANOVA is used, the final sample size of 20 subjects would allow an effect size of 0.63 to be detectable (Cohen, 1988) for the variables oxygen saturation, HR, and behavioral state.

The directional hypotheses were considered justifiable based on the literature that indicaated that HR and oxygen saturation levels decreased or did not change when a music therapy intervention was administered (Standley, 2000). In addition, Collins and Kuck (1991) and Arnon et al. (2006) reported positive effects on preterm infants' physiological and behavior states with music therapy provided during a heel lance.

The final sample included 20 preterm infants who met the following inclusion criteria: (a) were 26–29 weeks' gestational age at birth, (b) had no congenital anomalies, (c) had not undergone surgery, (d) were not receiving pancuronium or other medication to induce muscle paralysis, (e) were being cared for in an isolette at the time of data collection, (f) were eligible to receive music therapy as part of their standard of care in the NICU, and (g) had received at least one previous session of music therapy. Before discharge, each infant was administered an auditory brain stem response (ABR) procedure by an audiologist to ensure that audiological responses were consistent with normal hearing. All but one infant successfully passed the ABR procedure on the first attempt. The one remaining infant received a "need repeat ABR" notation on the chart because the findings were questionable. This infant was discharged before the second test was done, and information about a postdischarge ABR procedure was not available.

Protection of Human Subjects

The study was approved by the University of Alabama at Birmingham Institutional Review Board for Human Use (IRB; see Appendix D). Because the music therapy intervention that was evaluated was part of the standard of care at the NICU in which this study was conducted, the infants were not exposed to any additional stimulation or risk. Data were collected on physiologic responses of the infants by using the monitors that were already in place on the infants, so additional monitors were not needed. If it was necessary for the infant's nurse to handle the infant during the 35-min observation period or to intervene because of infant instability, the observation was discontinued and scheduled for another day.

My position as a part-time staff nurse in the study NICU enabled me to consult with the NICU staff at least twice per week to identify potential participants. Parents were invited to participate in the study when their infants were medically stable and at least 2 to 4 days old. Once the staff nurse received an indication of interest from the mother, I would discuss the project with the mother and then contact her 24 hr after the initial discussion to invite her to sign the informed consent form (see Appendix E). No mother refused to participate in the study. Twenty-two infants were initially enrolled in the study. Two infants enrolled did not complete at least two sessions in the study: One infant was moved to an open crib after one music therapy session, and one infant became unstable and was placed on the ventilator after two sessions.

Instruments

Data on the main dependent variables for this study (oxygen saturation, HR, behavioral state, motor activity, and behavioral distress) were recorded on a Physiologic and Behavioral Coding Sheet (PBCS; see Appendix F) that was completed by me or by the research assistant (RA). These date were recorded every 30 s with the use of a time-sampling system consisting of observing the infant for 15 s and then recording observations during the subsequent 15 s.

Oxygen saturation and HR levels were recorded after viewing the infants' bedside monitors. Behavioral state, motor activity, and behavioral distress were recorded based on observations of the infants. Appendix B contains a copy of the definitions for the behavioral state, motor activity, and behavioral distress variables. A check mark was made for each observation during the 15 s. There were seven behavioral states (quiet sleep, active sleep, REM sleep, drowsy, alert inactive, awake active, and fuss/cry); the infant could only be in one behavioral state at a time. Motor activity included five items (single limb, multiple limb, gross body movement, head turn, and startle); an infant could demonstrate anywhere from zero to five movements at a time. At the end of data collection for each of the three periods (baseline, intervention, postintervention) the numbers of motor activity were totaled. During the baseline and postintervention periods (20 data collection points each), motor activity scores could range from 0 to100 per period. During the music (or during the control condition) period (30 data collection points), motor activity scores could range from 0 to 150.

Behavioral distress scores included eight items (hiccup, facial grimace, finger splay, clenched fists, crying, fussing, spitting, and vomiting). An infant could demonstrate anywhere from zero to eight signs of behavioral distress at a time. At the end of data collection for each of the three periods (baseline, intervention, postintervention) the numbers of behavioral distress were totaled. During the baseline and postintervention periods (20 data collection points each), behavioral distress scores could range from 0 to 160 per session. During the music (or control condition) period (30 data collection points), the behavioral distress score could range from 0 to 240 session.

Data were also recorded every 30 s on sound level in the infant's isolette with the use of a Center 322 Sound Level Meter (Center Technology Corp., Taipei, Taiwan)**.** Sound level outside the isolette was measured at the same intervals by placing an ATEX Model 2800 Impulse Integrating Sound Level Meter (Quest Technologies, Oconomowoc, WI) on top of the infant's isolette. At the end of each observation period, data were also recorded on the number of staff in the nursery and on the number visitors at the bedside.

In this study, Scale A was used to measure both sound in the nursery and sound in the isolette during music and no-music conditions. According to The University of New South Wales School of Physics in Sydney Australia (2006), the human ear does not respond equally to all frequencies. The human ear is much more sensitive to sounds in the frequency range of about 1 kHz to 4 kHz than to very low- or high-frequency sounds. For this reason, sound meters are usually fitted with a filter that responds to frequency a bit like the human ear. The A scale filters out these low- and high-frequency sounds and is therefore the easiest and most widely used sound filter. Low-frequency sounds such as those produces by machinery are much more likely to affect the C scale than to affect the A scale. According to J. Wolfe (personal communication, February 1, 2008), it is not possible to convert decibel levels measured on Scales A or C unless the spectrum of the sound is known. For example, for a pure tone at 1 kHz, there is no difference between the scales. At 200 Hz, there is approximately a 10 dB difference.

One meter was placed on top of the infant's isolette to measure sound outside the isolette. A second meter was placed within the isolette, with the microphone approximately 2 cm from the infant's head to determine sound level within the isolette. The sound meters were calibrated before each data collection period by an employee of the university's Department of Occupational Health and Safety.

Additional data were also collected to describe characteristics of the infants in the study. Data on variables of infant gender, gestational age, race, birth order (singleton or multiple), birth weight, delivery method, Apgar score at 1 and 5 min, a measure of the resuscitation requirements at birth, and maternal age were recorded by me on a Demographic Data Sheet (DDS; see Appendix G); these data were obtained from the infant's medical record. The question about resuscitation requirements was included based on the assumption that more vigorous resuscitation at birth may reflect a higher level of neonatal morbidity and risk. In addition, I interviewed the mother to gather information about whether the infant had been prenatally exposed to music stimulation. All mothers stated that, while pregnant, they had listened to music via radio or on television. A variety of music was reported, including country, pop, rock, easy listening, and rap.

Data on infant weight and morbidity status were collected fro the infant's medical record during each of the 4 days of data collection and were recorded on a Daily Data Collection (DDC) form (see Appendix H). The neonatal morbidity score was calculated by using the Revised Neonatal Morbidity Scale (Minde, Whitelaw, Brown, & Fitz-hardinge, 1983). The content validity of this revised scale was reported by Harrison, Leeper, and Yoon (1990). In the current study, four infant charts (20%) were reviewed by the faculty mentor and by me. The mean interrater reliability for the DDC was 93%.

The Quantity of Stimulation Scale (QSS; see Appendix I) was completed by me; information was used to complete this scale was obtained from the nurse's flow sheet before each data collection period. The QSS was used to document the amount of stimulation that the infant received during the 2 hr preceding each data collection period. Content validity of this scale was established by Harrison et al. (1990). In the current study, four infant charts (20%) were reviewed by the faculty mentor and by me. The mean interrater reliability for the QSS was 99%.

Interrater reliability of the measures of physiologic and behavioral variables was assessed on a random sample of four music therapy observations and four no-music therapy observations by comparing percentage of agreement of responses of at least two data collectors (the RA, my dissertation advisor, or me). Calculated as a percentage of agreement between two raters, the mean interrater reliability scores for individual variables are presented in Table 5.

Table 5

Mean Interrater Reliabilty Score for Individual Dependent Variables

Variable	% Agreement
Heart rate	95
Oxygen saturation	97
Behavioral state	84
Motor activity	85
Behavioral distress	93
Sound levels	95

Description of the Music Intervention

The music therapy consisted of lullabies that were sung by a music therapist who also included various finger picking guitar accompaniments that involved alternating bass patterns (bass and adjacent strings) and was seated approximately 3 ft from the infant's isolette. The music therapist altered her playing and singing on the basis of other noise within the nursery and/or on the basis of distress cues displayed by the infant. The target volume in the isolette during the music therapy was between 55 and 70 dB and was not to exceed 75 dB (Scale A). Standley (2002) suggested that the volume of music not exceed 75 to 80 dBC. Songs utilized during the study are listed in Appendix A.

To enable the infant to hear the music, the nurses opened one of the portholes of the isolette during the music therapy intervention (while providing additional covering to maintain the infant's body warmth). Other than incidental sound throughout the nursery, no additional live acoustic stimulation was received by the infants during this intervention. However, it is not known whether infants received other music stimulation from visitors. The sound throughout the nursery was measured before, during, and after the intervention with the use of the meters provided. This information was recorded on the

PBCS in the section identified as *Sound Level*. All alarms were silent unless they reached the specified alarm limits for bradycardia and/or decreased oxygen saturations.

Before the initiation of the intervention, the music therapist confirmed with nurses in the nursery that there were no infants who should not receive the therapy, and I confirmed with the infant's nurse that no interventions were scheduled. If any other intervention was required during the intervention, the observation was discontinued. I assessed whether the infant needed to be repositioned or required a diaper change by inspecting the diaper. If so, the infant's diaper was changed, and the infant was repositioned into the center of the isolette and returned to either the supine or the prone position. This position was determined by the position in which the infant was found. Nurses follow a positioning pattern and rotation schedule. I ensured that this pattern was not changed or disturbed. The stimulation was noted on the QSS, and of at least 10 min were allowed to pass before baseline data were collected.

The infants were observed by the (RA or me) for adverse reactions that included elevated HR, decreased oxygen saturation, and signs of behavioral distress (hiccps, facial grimace, finger splay, clenched fists, crying, fussing, spitting, and vomiting). The observer utilized her nursing judgment to determine whether the infant was responding negatively to the music. If the infant began to show any of the above adverse reactions to the intervention, the music therapy was stopped per standard of care. This effect was noted on the PBCS. Music therapy was discontinued on one infant because of infant agitation (increased HR above 200 beats per minute, crying, finger splay, facial grimace).

Procedure for Data Collection

After written informed consent was obtained, I reviewed the infant's medical record and completed a DDS with information such as gestational age, Apgar scores, and birth weight (Appendix G). The infant was then assigned the next identification (ID) number and the corresponding randomly assigned order of conditions. Before enrollment was begun, each of 24 numbers (101-124) was randomly assigned to one of six possible orders of condition. For each of the six possible condition orders 4 ID numbers were assigned. In the condition orders, *0* represented no music and *1* represented music in the condition orders: 1 (1100), 2 (1010), 3 (1001), 4(0110), 5 (0101), and 6 (0011).

All data collection was scheduled for Tuesdays and Thursdays because these were the days when the music therapist was available to provide the music intervention. The time of data collection was between 10:00 a.m. and 2:00 p.m. It was necessary to change 6 infants' assigned order of conditions because of changes in the music therapist's schedule: Five of the infants (112, 113, 114, 115, and 117) received music only on Thursdays because of the schedule change, and the order was changed from the assigned order of 1 or 4 to the actual order of 5; one infant (122) was changed from an assigned order of 1 to an actual order of 6 because the therapist was available on Week 2 instead of Week 1 of data collection. A total of 18 of 20 infants received all four music/control sessions. Two infants (106 and 107) received only three sessions (two music and one control) because they were transferred out of the unit before the fourth session took place. Table 6 illustrates the assigned condition order, actual condition order, total number of music and control sessions received, and other condition order information.

Table 6

Participant Condition Order and Number of Sessions Received

ID	Assigned Order	Actual Order	Total Number of Music/ Control Sessions Received	Additional Condition Information
101	6	6	4	
102	2	2	4	
103	6	6	4	
104	3	3	4	
105	5	5	4	
106	2	2	3	Session 4 not conducted, infant transferred
107	4	4	3	Session 4 not conducted, infant transferred
109	5	5	4	
110	5	5	4	
111	3	3	4	
112	4	5	4	Because of music therapist's schedule,
113	1	5	4	required to remove Tuesday music collec-
114	1	5	4	tion; music therapy on Thursday only
115	4	5	4	(Sessions 2 and 4) for infants 112, 113, 114, 115
117	4	5	4	Because of music therapist's schedule, required to remove Tuesday music collection; music therapy on Thursday only (Sessions 2 and 4)
118	5	5	4	
119	3	3	4	
120	6	6	4	
121	6	6	4	
122	1	6	4	Because of music therapist's schedule, required to move music therapy from 1st week of data collection to 2nd week

Note. Assigned orders (1=music; 0=no music): 1 (1100), 2 (1010), 3 (1001), 4 (0110), 5 (0101), 6 (0011).

The immediate effects of the music therapy intervention were assessed by recording measures of infant HR, oxygen saturation level, oxygen requirement, behavioral state, behavioral distress, and motor activity for 10 min before the 15-min music intervention, throughout the intervention, and for 10 min after the conclusion of the intervention. The assessments were made on 4 separate days (2 days when the infant received the music intervention and 2 days when the infant did not receive the music intervention).

I completed the QSS and the DDC before each data collection session. Data about the infant's morbidity score, weight, and medications were gathered from the infant's medical record and used to complete the DDC.

The RA who was blinded as to whether the infant was receiving music in a given data collection session, collected baseline data every 30 s on the PBCS for 10 min before the 15-min music therapy or control period and then every 30 s for the 10 min after the music therapy or control period. The RA left the nursery during the 15-min music (or control) period, during which time I collected the data on HR, oxygen saturation, motor activity, behavioral state, and behavioral stress every 30 s. A time-sampling observation system was used in which the RA and I observed infant responses for 15 s, and then re-corded the responses during the subsequent 15-s interval.

CHAPTER 4

PRESENTATION AND ANALYSIS OF DATA

The purpose of this study was to examine the effects of a 15-min live-music therapy intervention on HR, oxygen saturation, level of motor activity, and behavioral distress in premature infants in the NICU. The study tested the following hypotheses:

1. Infants will exhibit a greater decrease from baseline in HR, level of motor activity, and signs of behavioral distress during and for 10 min after exposure to a 15-min live-music intervention than they will exhibit during and for 10 min after exposure to a no-music condition.

2. Infants will exhibit a greater increase from baseline in oxygen saturation during and for 10 min after exposure to a 15-min live-music intervention than they will exhibit during and for 10 min after exposure to a no-music condition.

To examine these hypotheses, I calculated descriptive statistics for each dependent variable by measurement period (baseline, during, and after) and condition (music therapy, no-music therapy); and means were then plotted by period and condition. A two-factor repeated-measures ANOVA was used to test differences among means for statistical significance. The first factor, labeled Period, represented the three measurement periods; the second factor, labeled Music, represented the music therapy or no-music therapy condition. A separate ANOVA was conducted for each dependent variable, and Mauchly's Sphericity Tests were conducted to test the sphericity assumption for the Interaction and Period main effects required for repeated-measures ANOVA procedures. Mauchly's Tests were not required for the main effect of Music, because this factor has only two levels. Statistically significant Interaction and Period main effects were followed up by testing the differences among pairs of means for statistical significance; a paired *t* test with the Bonferroni adjustment for multiple comparisons was used in this procedure. An alpha level of .05 was selected as the criterion for statistical significance in all analyses. The unit of analysis was Infant within Condition instead of Infant within Session and Condition. There were two reasons for deciding to use Infant within Condition as the unit of analysis. First, it could be argued that the mean of two measurements under the same intervention or control condition would be more reliable than one measurement alone would be likely to be. This is particularly true if the two interventions occur within a short period, as was the case in this study; all measures were taken over a 2- to 4-week period. The second reason for deciding to use Infant within Condition as the unit of analysis was that this method allowed me to use data for all infants instead of deleting from the analysis infants who had missing data. Because there were missing data on 13% of the data collection sessions, it would have been necessary to delete infants with missing data from one of the two sessions for each condition if Session had been included as a unit of analysis. To explore whether results would have differed if Session was included as a unit of analysis, I conducted separate analyses in which data from only one session with complete data for each condition were analyzed; no differences in results were obtained when Infant within Condition was used as the unit of analysis. Therefore, the decision was made to use Infant within Condition as the unit of analysis and to use the mean of the two sessions for each condition. The method for handling missing data is described later in this chapter.

The levels of motor activity and behavioral distress were calculated by summing the numbers for each of the separate motor activity items (single limb movement, multiple limb movement, gross body movement, head movement, and startle) and behavioral distress items (hiccup, facial grimace, finger splay, clenched fists, crying, fussing, spitting, and vomiting). Because the music/no-music period (During) lasted 15 min and the baseline and after periods lasted 10 min, the music/no-music period was standardized to 10 min by dividing the sums by 15 and multiplying by 10. The resulting measure was called Number of Movements/Signs per 10 Min.

In addition to the two study hypotheses, the following study questions were included in order to provide data about internal infant characteristics and environmental characteristics that might influence infants' responses to the music intervention:

1. What were the gestational ages and resuscitation requirements at birth of infants enrolled in the study?
2. Were there differences in mean sound levels and numbers of staff and visitors before, during and after the music therapy and control periods, comparing the music therapy and control sessions?
3. Were there differences in the mean morbidity levels, weights, and quantity of stimulation scores of infants during music and control conditions?
4. Was there a difference in mean percentage of time in each of the seven behavioral states before, during, and after the music therapy or control periods, comparing the music therapy and control sessions?

To address Study Question 1, I calculated descriptive statistics. Study Questions 2 and 4 were addressed by using the same data analysis procedures used to examine the hypotheses. Study Question 3 was addressed by calculating descriptive statistics for each dependent variable by session (one or two) and condition (music therapy, no-music therapy), and then plotted means by session and condition. A two-factor repeated-measures ANOVA was used to test differences among means for statistical significance. The first factor, labeled Session, represented the two sessions; the second factor, labeled Music, represented the music therapy or no-music therapy condition. A separate ANOVA was conducted for each dependent variable.

Data Entry Validation

Data entry was checked and validated for accuracy by the faculty mentor and by me. I read aloud the data recorded on the original data collection forms while the faculty mentor verified accuracy in the computerized data file. Eight participants (40% of the sample) were randomly selected, as were 10% of the sessions (Session 1, 2, 3, or 4). Because there were 20 participants and a total of 78 completed sessions, 8 sessions were checked and validated for data entry accuracy. The three periods, baseline, during (music/control), and after intervention, were checked for the session selected. The following data were verified: sound at head, sound outside isolette, oxygen saturation, HR, behavioral state, motor activity, behavioral distress, visitors/staff, and demographic data. The data entry validation results are presented in Table 7 as the percentage of agreement between data on data collection forms and data in the computerized data file.

Table 7

Data Entry Accuracy Results

Variable	% Agreement
Sound at head	98
Sound outside isolette	98
Oxygen saturation	99
Heart rate	99
Behavioral state	98
Motor activity	99
Behavioral distress	99
Visitors/staff	100
Demographic data	100

Two of the 20 infants were discharged before the fourth session, so there were only 3 days of data collection (for a total of 18 data sessions). For 18 of the 20 infants, there were baseline, music/control, and postintervention data collection periods for each of four sessions (two with music and two without music), or a total of 12 sessions per infant (total 216 sessions). For all 20 infants, including the 2 who were discharged after three sessions, there were a total of 234 data collection sessions.

Missing Data

Missing data were identified in 13% (31) of the 234 possible data sessions. Most of the missing data were oxygen saturation level data. Of the 234 possible oxygen saturation data collection sessions, 27 sessions were missing some or all oxygen saturation data. Of these 27 (12%), 21 sessions were missing oxygen saturation data because these infant's oxygen saturation levels were no longer being monitored. Two sessions were missing because the data collector failed to document the levels, 2 sessions were missing because the mother stimulated the infant, 1 session was missing because the nurse stopped the recording to feed the infant, and 1 session was missing because data collection was stopped when then infant became irritable. The 1 infant who became irritable had completed one previous music day and one previous no-music data collection day; on Data Collection Day 3, music day, the music was discontinued after 12.5 min of the scheduled 15 min because the infant's HR increased above 200 beats per min for 2 min and because the level of motor activity and behavioral distress cues also increased during the 2 min of the elevated HR. The infant's behavioral state changed from quiet and active sleep to awake active and fuss/cry. The oxygen saturation remained at 100% on room air. The music was discontinued; after 7 min the infant's HR returned to less than 200 beats per minute, the level of motor activity and behavioral distress cues decreased, and the infant returned to quiet sleep.

Three options were considered for handling the missing data. The first option was to use all of the available data. If an infant had two sessions of music and one session of no-music, this method would involve use of the mean of the two music sessions and the single session of no-music. This method assumes that the mean of the missing no-music session would be the same as that of the single non-missing session. The second option was to use only one session per infant; this approach would have been the cleanest and most conservative but would have resulted in loss of a significant amount of data. The third option was to use the mean of the two sessions for infants with data for all four sessions and to use only one session of data for infants with data for fewer than four sessions. The data were analyzed by using these three methods, and all provided the same conclusions; therefore, the decision was made to use the first approach that involved the use of all available data so that no cases were excluded.

Demographic Profiles

All 20 mothers who were in the study indicated that they had listened to music while pregnant. They reported music delivery methods such as the car radio and home compact disc players. Mothers' ages at the time of delivery ranged from 16 to 42 years, with a mean of 26.25 (*SD* = 6.65). Tables 8 and 9 present data describing the demographic characteristics of the infants in the study.

Table 8

Gender, Race, Delivery Method, and Birth Order

Variable	No.	%
Gender		
Female	13	65
Male	7	35
Race		
White	12	60
Black	7	35
Other	1	5
Delivery Method		
Caesarian section	14	70
Vaginal Delivery	6	30
Birth Order		
Singleton	19	95
Twin	1	5

Table 9

Apgar Scores and Birth Weight

Variable	*M*	*SD*	Minimum	Maximum	No.
1-min Apgar score	5.05	2.1392	1	8	20
5-min Apgar score	7.00	1.9467	1	9	20
Birth weight (g)	844.4	200.21	540	1160	20

Research Hypotheses

Hypothesis 1

Hypothesis 1 was as follows: Infants will exhibit a greater decrease from baseline in HR, level of motor activity, and signs of behavioral distress during and for 10 min after exposure to a 15-min live-music intervention than they will exhibit during and for 10 min after exposure to a no-music condition. Results related to this hypothesis are presented here.

HR

Table 10 presents descriptive statistics by music condition and period. These findings are shown graphically in Figure 1.

Table 10

Descriptive Statistics for Heart Rate by Music Condition and Period

Condition and Period	*M*	*SD*	Minimum	Maximum	No.
No Music					
Baseline	163.39	10.79	137.85	180.08	20
During	161.77	11.89	131.40	181.12	20
After	162.29	11.95	130.13	175.55	20
Music					
Baseline	160.53	10.01	141.38	176.70	20
During	162.47	12.95	133.50	185.65	20
After	161.67	12.10	140.90	184.50	20

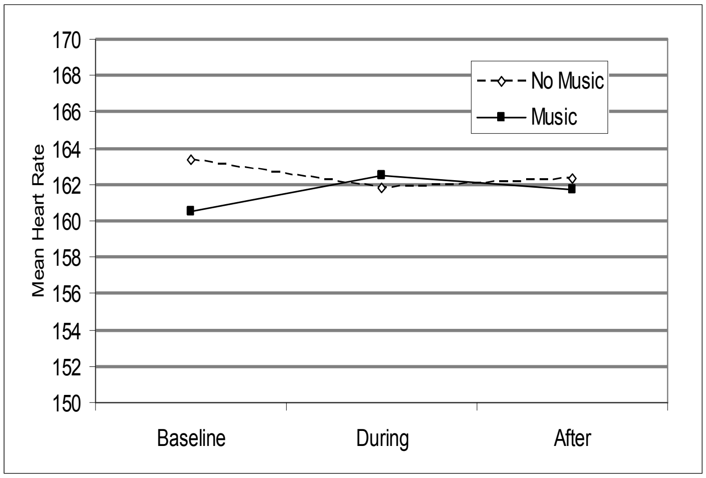

Figure 1. Mean heart rate by music condition and period.

Mauchly's Test was not statistically significant for the main effect of Period, $\chi^2(2) = 1.079$, $p = .583$ or for the interaction of Period and Music, $\chi^2(2) = 2.161$, $p = .339$; these findings indicate that the sphericity assumption was not violated. ANOVA results are shown in Table 11. The interaction of Period and Music was not statistically significant; therefore, the pattern of means for HR across periods did not differ for the Music and No-Music conditions. The main effects for Period and Music were also not statistically significant.

Table 11

ANOVA Results for Heart Rate

Source	*df*	*F*	*p*	Effect size[a]
Period	2, 38	0.210	.979	0.001
Music	1, 19	0.245	.626	0.013
Period x Music	2, 38	1.664	.203	0.203

[a]Partial eta-squared.

Motor Activity

Table 12 presents descriptive statistics by music condition and period for the motor activity variable. Means are presented graphically in Figure 2.

Table 12

Descriptive Statistics for Motor Activity by Music Condition and Period

Condition and Period	*M*	*SD*	Minimum	Maximum	No.
No Music					
Baseline	21.33	8.95	10.00	39.00	20
During	19.65	9.23	7.00	42.67	20
After	20.45	11.09	2.50	37.00	20
Music					
Baseline	20.88	9.85	3.50	39.50	20
During	19.36	8.70	5.67	35.27	20
After	21.30	8.85	7.00	36.50	20

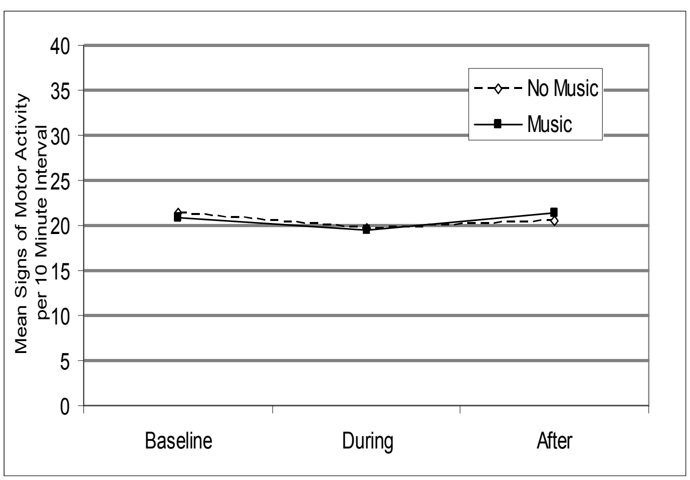

Figure 2. Mean motor activity by music condition and period.

Mauchly's Test was not statistically significant for the main effect of Period, $\chi^2(2) = 1.874$, $p = .392$, or for the interaction of Period and Music, $\chi^2(2) = 2.620$, $p = .270$;

these findings indicate that the sphericity assumption was not violated. ANOVA results are shown in Table 13. The interaction of Period and Music was not statistically significant; therefore, the pattern of means for motor activity across periods did not differ for the Music and No-Music conditions. The main effects for Period and Music were also not statistically significant.

Table 13

ANOVA Results for Motor Activity

Source	*df*	*F*	*p*	Effect size[a]
Period	2, 38	0.495	.632	0.024
Music	1, 19	0.440	.985	0.000
Period x Music	2, 38	5.010	.924	0.004

[a]Partial eta-squared.

Behavioral Distress

Table 14 presents descriptive statistics by music condition and period for behavioral distress. Means are presented graphically in Figure 3.

Table 14

Descriptive Statistics for Behavioral Distress by Music Condition and Period

Condition and Period	*M*	*SD*	Minimum	Maximum	No.
No Music					
Baseline	2.38	2.59	.00	9.00	20
During	2.48	2.13	.00	9.33	20
After	1.53	2.01	.00	7.50	20
Music					
Baseline	2.43	2.01	.00	7.50	20
During	1.79	2.33	.00	9.13	20
After	1.25	1.48	.00	4.50	20

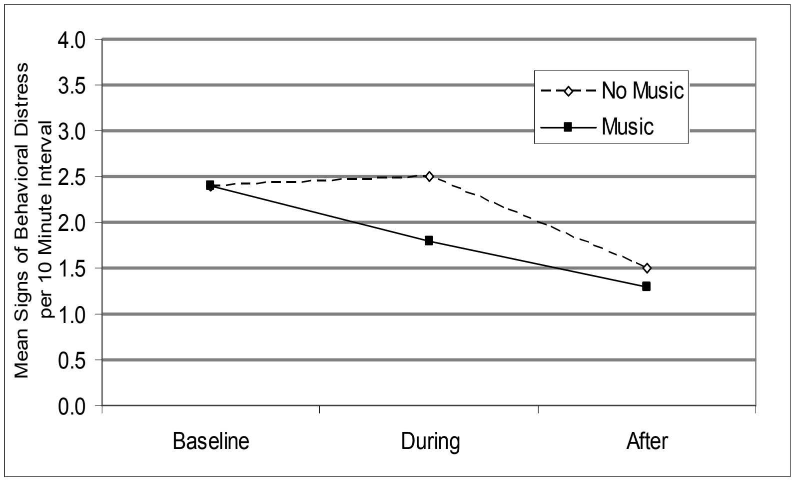

Figure 3. Mean behavioral distress by music condition and period.

Mauchly's Test was not statistically significant for the main effect of Period, $\chi^2(2) = 3.300$, $p = .192$, or for the interaction of Period and Music, $\chi^2(2) = 4.178$, $p = .124$; these findings indicate that the sphericity assumption was not violated. ANOVA results are shown in Table 15. The interaction of Period and Music was not statistically significant; therefore, the pattern of means for behavioral distress across periods did not differ for the Music and No-Music conditions although the mean level of behavioral distress decreased during the Music and increased during the No-Music condition. The main effect for Period was statistically significant; this finding indicates that, when ignoring the music factor, there was a difference among Period means. Pairwise comparisons showed a statistically significant difference between the Baseline mean (2.40, *SD*=2.30) and the During mean (2.14, *SD*=2.23) and a statistically significant difference between the During mean and the After mean (1.39, *SD*=1.75). These comparisons are summarized in Table 16.

Table 15

ANOVA Results for Behavioral Distress

Source	*df*	*F*	*p*	Effect size[a]
Period	2, 38	5.806*	.006	0.234
Music	1, 19	0.465	.504	0.024
Period x Music	2, 38	0.494	.614	0.025

[a]Partial eta-squared.
*Statistically significant at $p<.05$.

Table 16

Pairwise Comparisons for the Main Effect of Period on Behavioral Distress

(I) Period	(J) Period	Mean Difference (J-I)	*SE*	p^a
Baseline	During	-0.26	.341	1.000
	After	-1.01*	.336	0.021
During	After	-0.75*	.237	0.015

[a]Adjustment for multiple comparisons: Bonferroni.
*Statistically significant at $p<.05$ (2 tailed).

Hypothesis 1 stated that infants would exhibit a greater decrease from baseline inHR, level of motor activity, and signs of behavioral distress during and for 10 min after exposure to a 15-min live-music intervention than they would exhibit during and for 10 min after exposure to a no-music condition. This hypothesis was not supported.

Hypothesis 2

Hypothesis 2 was as follows: Infants will exhibit a greater increase from baseline in oxygen saturation during and for 10 min after exposure to a 15-min live- music intervention than they will exhibit during and for 10 min after exposure to a no-music condition. Results related to this hypothesis are given here.

Table 17 presents descriptive statistics for oxygen saturation by music condition and period. Means are presented graphically in Figure 4.

Table 17

Descriptive Statistics for Oxygen Saturation by Music Condition and Period

Condition and Period	*M*	*SD*	Minimum	Maximum	No.
No Music					
Baseline	96.16	2.73	90.05	99.30	18
During	96.17	2.59	90.42	99.07	18
After	95.79	2.92	89.23	98.70	18
Music					
Baseline	96.83	2.68	91.48	100.00	18
During	96.87	2.49	91.58	100.00	18
After	97.02	2.23	92.95	100.00	18

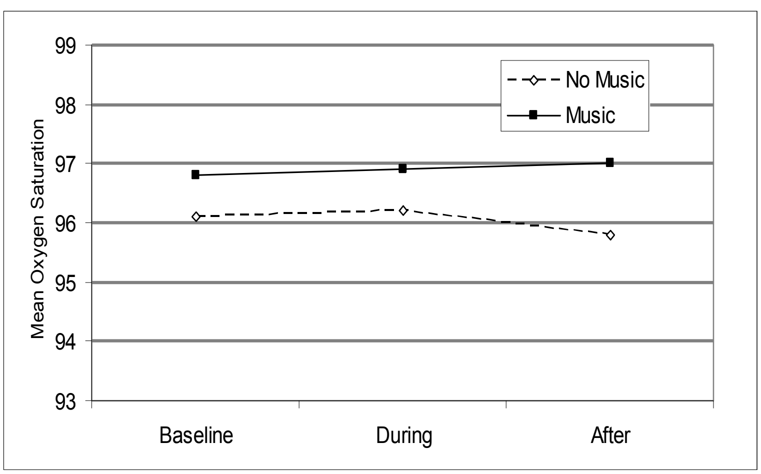

Figure 4. Mean oxygen saturation by music condition and period.

Mauchly's Test was not statistically significant for the main effect of Period, $\chi^2(2) = .385$, $p = .825$, or for the interaction of Period and Music, $\chi^2(2) = 5.580$, $p = .061$; these findings indicate that the sphericity assumption was not violated. ANOVA results are shown in Table 18. The interaction of Period and Music was not statistically significant; therefore, the pattern of means for oxygen saturation across periods did not differ for the Music and No-Music conditions. The main effects for Period and Music were also not statistically significant.

Table 18

ANOVA Results for Oxygen Saturation

Source	*df*	*F*	*p*	Effect size[a]
Period	2, 34	0.209	.812	0.012
Music	1, 17	3.245	.089	0.160
Period x Music	2, 34	0.651	.528	0.037

[a]Partial eta-squared.

Hypothesis 2 sated that infants would exhibit a greater increase from baseline in oxygen saturation during and for 10 min after exposure to a 15-min live-music intervention than they would exhibit during and for 10 min after exposure to a no-music condition. This hypothesis was not supported.

Study Questions

Study Question 1

This question was worded as follows: What were the gestational ages and resuscitation requirements at birth of infants enrolled in the study? This section contains a discussion of results related to Study Question 1.

Infants enrolled in the study were required to meet the criteria of having been 26.0 to 29.6 weeks' gestational age at birth. For the 20 infants enrolled in this study, the minimum gestational age at birth was 26.10 weeks, and the maximum gestational age was 29.20 weeks; the mean was 27.54 weeks.

When the infant was enrolled in the study, a 3-point scale was used to record resuscitation requirement at birth (see Appendix G). Lower scores reflected lower resuscitation requirements. Of the 20 infants, 18 had a resuscitation requirement score of 1; that is, that the infant required resuscitation (including supplemental oxygen) at or soon after birth, but the 5-min Apgar score was greater than 5. Two infants had a resuscitation requirement score of 3; in other words, the infant was in cardiac arrest or required prolonged attempts at resuscitation at birth or during transfer, and the 5-min Apgar score was less than 5. Table 19 presents data on gestational age and resuscitation requirements at birth for the study infants.

Table 19

Gestational Age and Resuscitation Requirement at Birth

Variable	*M*	*SD*	Minimum	Maximum	No.
Gestational age (weeks)	27.54	0.9023	26.1	29.2	20
Resuscitation requirement	1.20	0.6156	1	3	20

Study Question 2

Study Question 2 was as follows: Were there differences in mean sound levels and numbers of staff and visitors before, during and after the music therapy and control periods, comparing the music therapy and control sessions? Results related to this study question are presented here.

Sound level included ambient sound in the nursery. When the music was being played, sound level included sound from the music, as well as ambient nursery sound.

Sound Level at Infant's Head

Table 20 presents descriptive statistics for sound level at the infant's head by music condition and period. Means are presented graphically in Figure 5.

Table 20

Descriptive Statistics for Sound Level (dB) at Infant's Head by Music Condition and Period

Condition and Period	*M*	*SD*	Minimum	Maximum	No.
No Music					
Baseline	47.81	1.96	45.45	51.55	20
During	48.20	3.00	45.50	59.03	20
After	47.33	1.64	45.18	50.10	20
Music					
Baseline	47.40	1.83	44.50	59.03	20
During	53.50	1.98	50.03	57.15	20
After	47.58	2.02	43.85	52.00	20

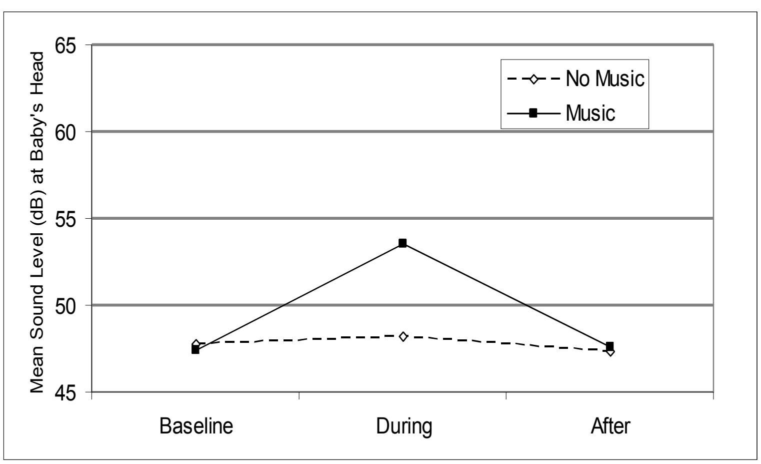

Figure 5. Mean sound level at infant's head by music condition and period.

Mauchly's Test was statistically significant for the main effect of Period, $\chi^2(2) = 13.175$, $p = .001$, and for the interaction of Period and Music, $\chi^2(2) = 8.022$, $p = .018$; these findings indicate that the sphericity assumption was violated. To address this violation, the degrees of freedom were adjusted using the Huynh-Feldt correction. ANOVA results are shown in Table 21. The interaction of Period and Music was statistically significant; therefore, the pattern of means of sound levels measured at the infant's head across Periods differed for the Music and No-Music conditions. For the Music condition, pairwise comparisons showed a statistically significant difference between the Baseline mean (47.40, *SD*=1.83) and the During mean (53.50, *SD*=1.98), as well as a statistically significant difference between the During mean and the After mean (47.58, *SD*=2.02). For the No-Music Condition, pairwise comparisons showed no statistically significant differences among any of the Period means. Pairwise comparisons are summarized in Table 22. The main effects of Period and Music were also statistically significant, but these effects are not meaningful because the interaction effect was statistically significant. Table 23 summarizes the pairwise comparisons between music conditions by period. For the During period, there was a statistically significant difference between the No-Music (48.20, *SD*=3.00) and Music (53.50, *SD*=1.98) conditions; this finding indicates that, as expected, the sound level measured at the infant's head was higher during the music condition.

Table 21

ANOVA Results for Sound Level at Infant's Head

Source	*df*	*F*	*p*	Effect size*
Period	1.376, 26.144[a]	72.027[b]	<.001	0.791
Music	1, 19	14.485[b]	.001	0.433
Period x Music	1.564, 29.721[a]	27.762[b]	<.001	0.594

[a]Adjusted with Huynh-Feldt correction. [b]Partial eta-squared.
*Statistically significant at $p<.05$.

Table 22

Pairwise Comparison of Period Means for Music and No Music Conditions

Music Condition	(I) Period	(J) Period	Mean Difference (J-I)	*SE*	*p**
No Music	Baseline	During	0.39	.722	1.000
		After	-0.48	.356	.572
	During	After	-0.88	.478	.246
Music	Baseline	During	6.10[a]	.581	<.001
		After	0.18	.336	1.000
	During	After	-5.92[a]	.584	<.001

[a]Adjustment for multiple comparisons: Bonferroni.
*Statistically significant at $p<.05$ (2 tailed).

Table 23

Pairwise Comparison of Music and No-Music Condition Means by Period

Period	(I) Music	(J) Music	Mean Difference (J-I)	*SE*	*p**
Baseline	No Music	Music	-.410	.519	.439
During	No Music	Music	5.301[a]	.914	<.001
After	No Music	Music	.256	.454	.579

[a]Adjustment for multiple comparisons: Bonferroni.
*Statistically significant at $p<.05$ (2 tailed).

Sound Level Outside the Isolette

Table 24 presents descriptive statistics by music condition and period. Means are presented graphically in Figure 6.

Sound level included ambient sound in the nursery and, when the music was being played, included sound from the music in addition to the ambient nursery sound.

Table 24

Descriptive Statistics for Sound Level (dB) Outside Isolette by Music Condition and Period

Condition and Period	*M*	*SD*	Minimum	Maximum	No.
No Music					
Baseline	58.67	3.13	53.22	64.35	20
During	58.60	3.93	46.27	65.78	20
After	59.01	3.13	53.83	63.65	20
Music					
Baseline	57.71	3.44	49.50	65.28	20
During	60.91	6.40	35.67	65.77	20
After	56.71	6.70	30.55	62.50	20

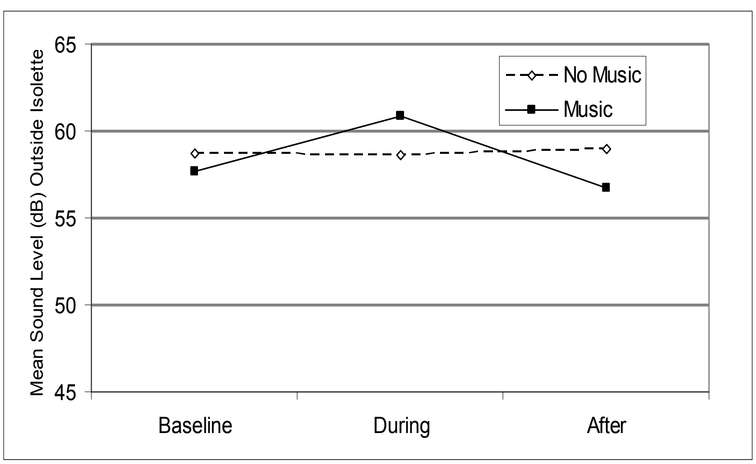

Figure 6. Mean sound level outside the isolette by music condition and period.

Mauchly's Test was not statistically significant for the main effect of Period, $\chi^2(2) = 1.696$, $p = .428$, or for the interaction of Period and Music, $\chi^2(2) = 1.251$, $p = .535$; these findings indicate that the sphericity assumption was violated. ANOVA results are shown in Table 25. The interaction of Period and Music was statistically significant; therefore, the pattern of means across periods differed for the Music and No-Music conditions, but there was no statistically significant difference between any corresponding periods in the Music and No-Music conditions. For the Music condition, pairwise comparisons showed a statistically significant difference between the Baseline mean (57.71, *SD*=3.44) and the During mean (60.91, *SD*=6.40), as well as a statistically significant difference between the During mean and the After mean (56.71, *SD*=6.70). For the No-Music Condition, pairwise comparisons showed no statistically significant differences among any of the period means. Pairwise comparisons are summarized in Tables 26 and 27. The main effect of Period was also statistically significant, but this effect is not meaningful because the interaction effect was statistically significant. The main effect of Music was not statistically significant.

Table 25

ANOVA Results for Sound Level Outside the Isolette

Source	*df*	*F*	*p*	Effect size[a]
Period	2, 38	5.690*	.007	0.230
Music	1, 19	0.047	.830	0.002
Period x Music	2, 38	8.591*	.001	0.311

[a]Partial eta-squared.
*Statistically significant at $p<.05$.

Table 26

Pairwise Comparison of Period Means for Music and No-Music Conditions

Music Condition	(I) Period	(J) Period	Mean Difference (J-I)	*SE*	*p**
No Music	Baseline	During	-0.06	.695	1.000
		After	0.34	.543	0.572
	During	After	0.40	.981	0.246
Music	Baseline	During	3.20[a]	1.061	<0.001
		After	-1.00	1.078	1.000
	During	After	-4.20[a]	.326	<0.001

[a]Adjustment for multiple comparisons: Bonferroni.
*Statistically significant at $p<.05$.

Table 27

Pairwise Comparison of Music and No-Music Condition Means by Period

Period	(I) Music	(J) Music	Mean Difference (J-I)	*SE*	p^a
Baseline	No Music	Music	-0.955	1.201	.436
During	No Music	Music	2.309	1.691	.188
After	No Music	Music	-2.299	1.813	.220

[a]Adjustment for multiple comparisons: Bonferroni.

Number of Staff and Visitors

Table 28 presents descriptive statistics by music condition and period. Means are presented graphically in Figure 7.

Table 28

Number of Staff and Visitors by Music Condition and Period

Condition and Period	*M*	*SD*	Minimum	Maximum	No.
No Music					
Baseline	3.48	1.92	0	10	20
During	3.65	1.84	0	9	20
After	3.50	1.44	0	9	20

Table 28 (Continued)

Condition and Period	*M*	*SD*	Minimum	Maximum	No.
Music					
Baseline	2.83	1.38	0	8	20
During	3.13	1.47	0	8	20
After	3.35	1.84	0	8	20

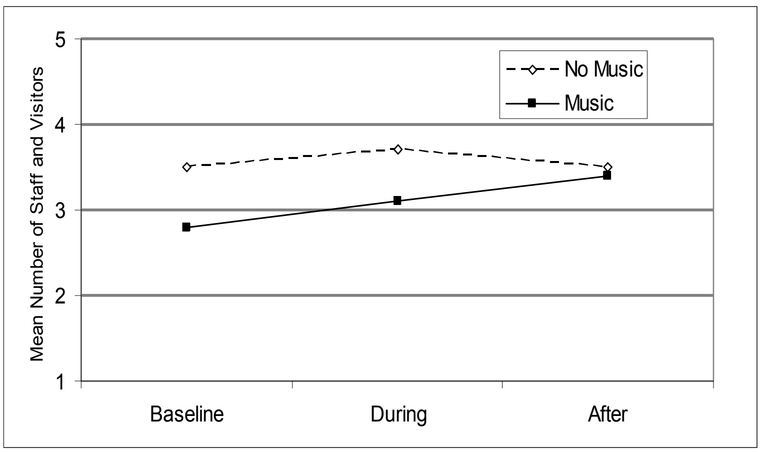

Figure 7. Mean number of staff and visitors by music condition and period.

Mauchly's Test was not statistically significant for the main effect of Period, $\chi^2(2) = 3.977$, $p = .136$, or for the interaction of Period and Music, $\chi^2(2) = 2.256$, $p = .324$; these findings indicated that the sphericity assumption was not violated. ANOVA results are shown in Table 29. The interaction of Period and Music was not statistically significant; therefore, the pattern of means across periods did not differ for the Music and No-Music conditions. The main effects for Period and Music were also not statistically significant.

Table 29

ANOVA Results for Number of Staff and Visitors

Source	*df*	*F*	*p*	Effect size[a]
Period	2, 38	0.683	.511	0.035
Music	1, 19	2.068	.167	0.098
Period x Music	2, 38	0.573	.569	0.029

[a]Partial eta-squared

The findings related to Study Question 2 suggest that the infants should have been able to hear the music during the music condition because the mean sound level at the infant's head increased from baseline to the music period and then decreased after the music period. Similarly, the sound level outside the isolette increased during the music condition from baseline to the music period and then decreased after the music period. There were no significant differences in the number of staff and visitors before, during, and after the music therapy period and those before, during, and after the control period. These findings indicate that the number of staff and visitors was not an extraneous variable that may have affected infants' responses to the music condition or no-music condition.

Study Question 3

Study Question 3 was stated as follows: Were there differences in the mean morbidity levels, weights, and quantity of stimulation scores of infants during music and control conditions? This section contains a discussion of results related to this study question.

Morbidity

Table 30 presents descriptive statistics for morbidity by music condition and session. Means are presented graphically in Figure 8.

Table 30

Descriptive Statistics for Morbidity by Music Condition and Session

Music Condition and Session	*M*	*SD*	Minimum	Maximum	No.
Morbidity (Music 1)	0.47	0.70	0	2	19
Morbidity (Music 2)	0.32	0.75	0	3	19
Morbidity (No Music 1)	0.42	0.69	0	2	19
Morbidity (No Music 2)	0.47	0.84	0	3	19

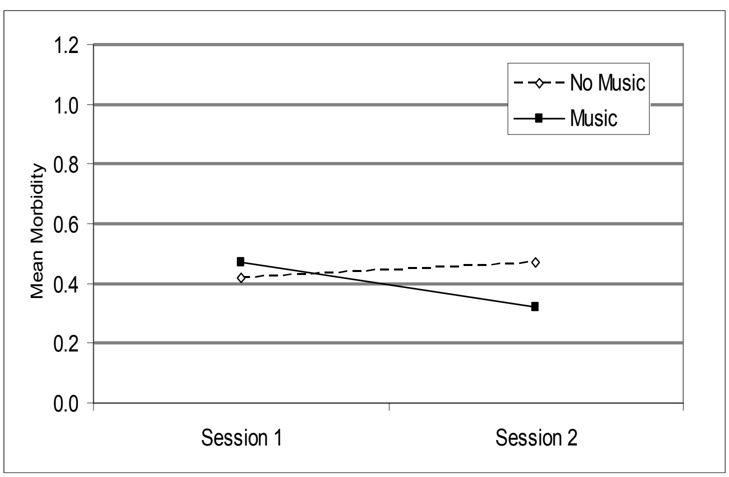

Figure 8. Mean morbidity by music condition and session.

ANOVA results are shown in Table 31. The interaction of Music and Session was not statistically significant; therefore, the pattern of means for morbidity scores across sessions did not differ for the Music and No-Music conditions. The main effects for Session and Music were also not statistically significant.

Table 31

ANOVA Results for Morbidity

Source	*df*	*F*	*p*	Effect size[a]
Music	1, 18	0.321	.578	0.018
Session	1, 18	0.321	.578	0.018
Music x Session	1, 18	2.118	.163	0.105

[a]Partial eta-squared.

Weight

Table 32 presents the descriptive statistics for weight by session and music condition. Means are presented graphically in Figure 9.

Table 32

Descriptive Statistics for Weight by Music Condition and Session

Music Condition and Session	*M*	*SD*	Minimum	Maximum	No.
Weight (Music 1)	1,178.11	295.40	699	1,870	18
Weight (Music 2)	1,423.44	294.74	927	2,029	18
Weight (No Music 1)	1,068.28	252.59	637	1,782	18
Weight (No Music 2)	1,284.28	311.08	781	2,135	18

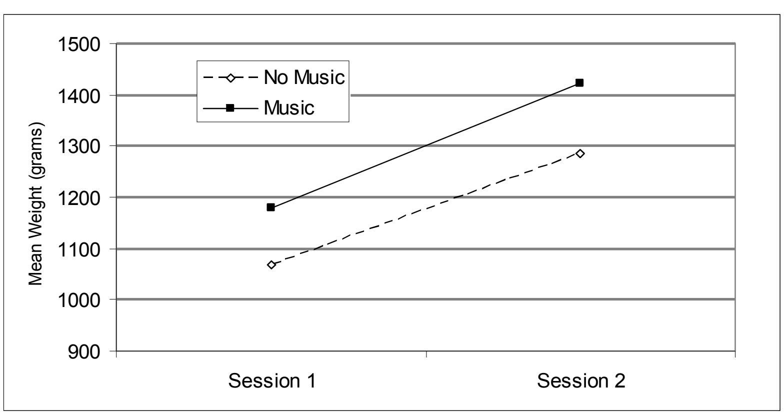

Figure 9. Mean weight by music condition and session.

ANOVA results are shown in Table 33. The interaction of Music and Session was not statistically significant; this finding indicates that the pattern of means for weight across sessions did not differ for the Music and No-Music conditions. The main effect for Session was statistically significant; this finding indicates that, when the Music factor was ignored, there was a statistically significant difference between the overall Session 1 mean (1,123.20, *SD*=273.00) and the overall Session 2 mean (1,353.86, *SD*=302.91). The main effect for Music was statistically significant; this finding indicates that, when the session factor was ignored, there was a statistically significant difference between the overall music mean (1,300.78, *SD*=295.07) and the overall no-music mean (1,176.28, *SD*=281.84).

The difference in mean weight between the music condition and the no-music condition may be explained by the order in which the measurements were taken. The infants weighed more in later sessions because they were older; in addition, only 5 of the 20 infants were in the music condition for Session 1 whereas 17 of 20 were in music condition for Session 4. Correlations between weight and the outcome measures (HR, oxygen saturation, motor activity, and behavioral distress) were run at baseline for the first session for each infant. Correlations are presented in Table 34. The results show that weight was not linearly related to the outcome measures.

Table 33

ANOVA Results for Weight

Source	*df*	*F*	*p*	Effect size*
Music	1, 17	21.153[a]	<.001	0.554
Session	1, 17	73.932[a]	<.001	0.813
Music x Session	1, 17	0.231	.637	0.013

[a]Partial eta-squared.
*Statistically significant at p<.05.

Table 34

Correlations for Weight and Outcome Measures

Measure	Results	
Oxygen	Pearson correlation	.140
	p (2 tailed)	.557
Heart rate	Pearson correlation	-.038
	p (2 tailed)	.875
Motor activity	Pearson correlation	-.033
	p (2 tailed)	.889
Behavioral distress	Pearson correlation	.038
	p (2 tailed)	.873

Note. n = 20.

QSS

Table 35 presents descriptive statistics for the QSS by music condition and session. Means are presented graphically in Figure 10.

Table 35

Descriptive Statistics for Quantity of Stimulation Scale by Music Condition and Session

Music Condition and Session	*M*	*SD*	Minimum	Maximum	No.
QSS (Music 1)	1.56	0.78	0	3	18
QSS (Music 2)	1.67	0.77	0	2	18
QSS (No Music 1)	1.83	0.62	1	3	18
QSS (No Music 2)	1.61	0.98	0	3	18

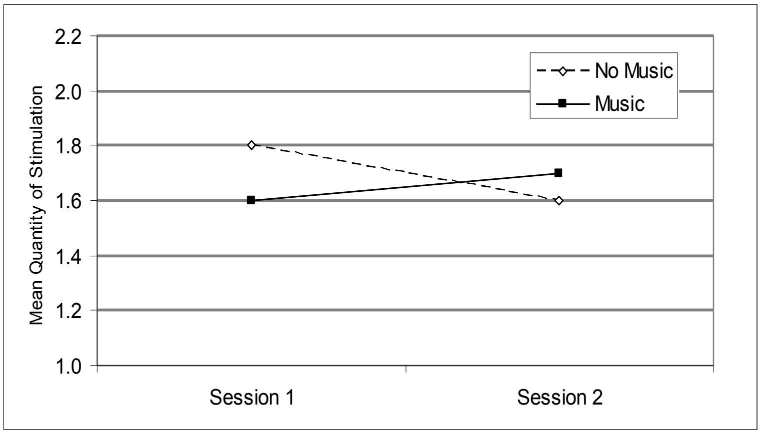

Figure 10. Mean score on Quantity of Stimulation Scale by music condition and session.

ANOVA results are shown in Table 36. The interaction of Music and Session was not statistically significant; this finding indicates that the pattern of means for the QSS across sessions did not differ for the Music and No-Music conditions. The main effects for Session and Music were also not statistically significant.

Table 36

ANOVA Results for Quantity of Stimulation Scale

Source	*df*	*F*	*p*	Effect size[a]
Music	1, 17	0.430	.521	0.025
Session	1, 17	0.050	.826	0.003
Music x Session	1, 17	1.000	.331	0.056

[a]Partial eta-squared.

The findings related to Study Question 3 suggest that infant morbidity level and the quantity of stimulation received during the 2 hr before the music sessions did not differ from those during the 2 hr before the no-music control sessions and were not extraneous variables that may have affected study outcomes. Although there were differences between infant weight in the music conditions and infant weight in the no-music conditions, the finding that weight was not linearly related to the outcome measures suggests that infant weight was not an extraneous variable affecting study outcomes.

Study Question 4

This question was states as follows: Was there a difference in mean percentage of time in each of the seven behavioral states before, during, and after the music therapy or control periods, comparing the music therapy and control sessions? A discussion of findings related to Study Question 4 is contained in this section.

Table 37 presents descriptive statistics of behavioral states by music condition and period. Means are presented graphically in Figures 11 to 17.

Table 37

Descriptive Statistics for Behavioral States by Music Condition and Period

Behavioral State	Condition and Period	Mean %	*SD*	Minimum %	Maximum %	No.
Quiet	No Music					
Sleep	Baseline	50.13	24.20	5.00	90.00	20
	During	45.50	25.77	.00	85.00	20
	After	42.92	24.77	2.50	100.00	20
	Music					
	Baseline	50.50	22.85	10.00	95.00	20
	During	45.88	24.13	5.00	97.50	20
	After	46.63	19.72	12.50	85.00	20
REM Sleep	No Music					
	Baseline	14.12	14.29	.00	55.00	20
	During	17.00	13.39	.00	40.00	20
	After	11.38	14.41	.00	50.00	20
	Music					
	Baseline	13.13	14.62	.00	47.50	20
	During	16.13	15.70	.00	50.00	20
	After	15.50	13.61	.00	47.50	20

Table 37 (Continued)

Behavioral State	Condition and Period	Mean %	*SD*	Minimum %	Maximum %	No.
Alert Inactive	No Music					
	Baseline	3.25	6.54	.00	22.50	20
	During	3.75	9.65	.00	42.50	20
	After	3.25	5.07	.00	15.00	20
	Music					
	Baseline	1.63	5.08	.00	22.50	20
	During	4.00	8.79	.00	30.00	20
	After	2.13	4.31	.00	12.50	20
Fuss/Cry	No Music					
	Baseline	0.88	3.91	.00	17.50	20
	During	0.38	1.22	.00	5.00	20
	After	0.38	1.68	.00	7.50	20
	Music					
	Baseline	0	0	.00	.00	20
	During	0	0	.00	.00	20
	After	0.50	2.24	.00	10.00	20
Active Sleep	No Music					
	Baseline	17.63	11.14	.00	37.50	20
	During	24.63	15.20	.00	65.00	20
	After	19.96	12.46	.00	42.50	20
	Music					
	Baseline	18.75	11.37	2.50	42.50	20
	During	27.00	16.97	.00	65.00	20
	After	19.13	14.47	2.50	52.50	20
Drowsy	No Music					
	Baseline	9.38	10.32	.00	37.50	20
	During	3.25	5.57	.00	17.50	20
	After	16.25	14.72	.00	40.00	20
	Music					
	Baseline	10.13	17.33	.00	67.50	20
	During	3.75	7.97	.00	35.00	20
	After	13.00	16.73	.00	52.50	20
Awake Active	No Music					
	Baseline	4.63	10.68	.00	42.50	20
	During	5.50	11.55	.00	40.00	20
	After	3.38	9.71	.00	42.50	20
	Music					
	Baseline	5.88	12.41	.00	50.00	20
	During	3.25	5.07	.00	15.00	20
	After	3.13	8.15	.00	30.00	20

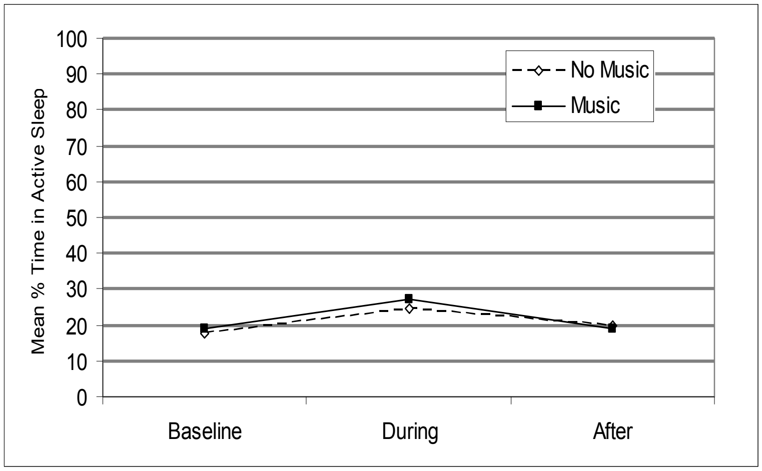

Figure 11. Mean percentage of time in active sleep by music condition and period.

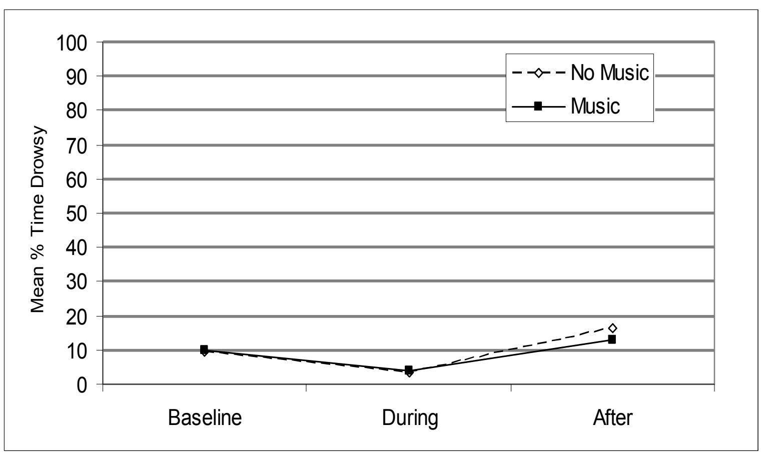

Figure 12. Mean percentage of time in drowsy state by music condition and period.

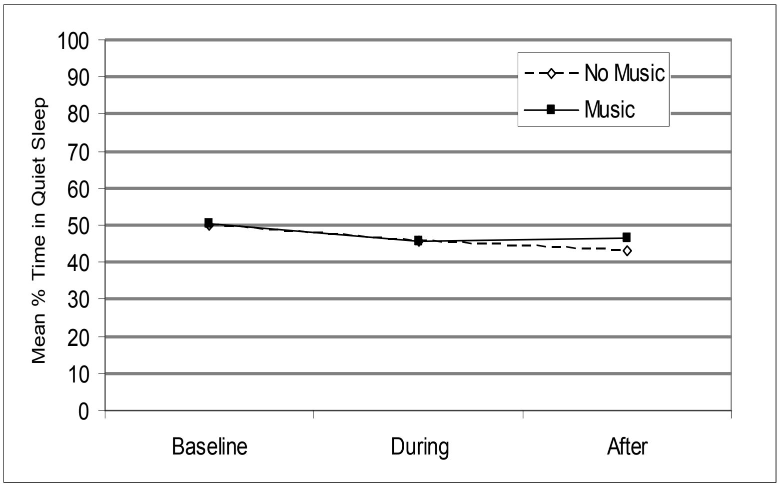

Figure 13. Mean percentage of time in quiet sleep by music condition and period.

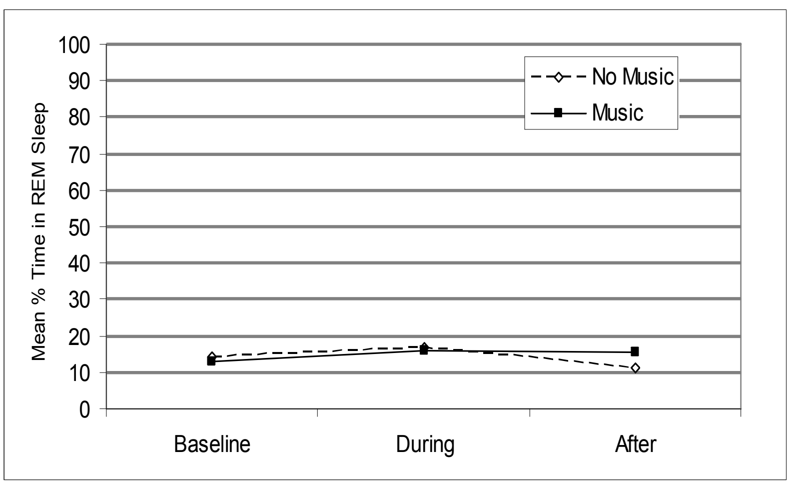

Figure 14. Mean percentage of time in REM sleep by music condition and period.

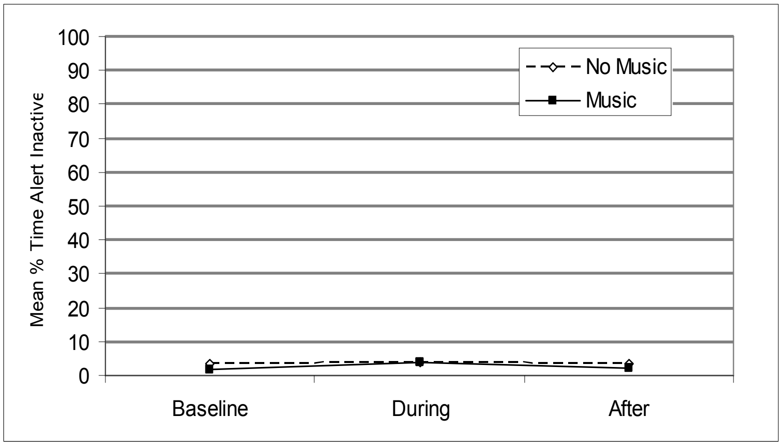

Figure 15. Mean percentage of time in alert inactive state by music condition and period.

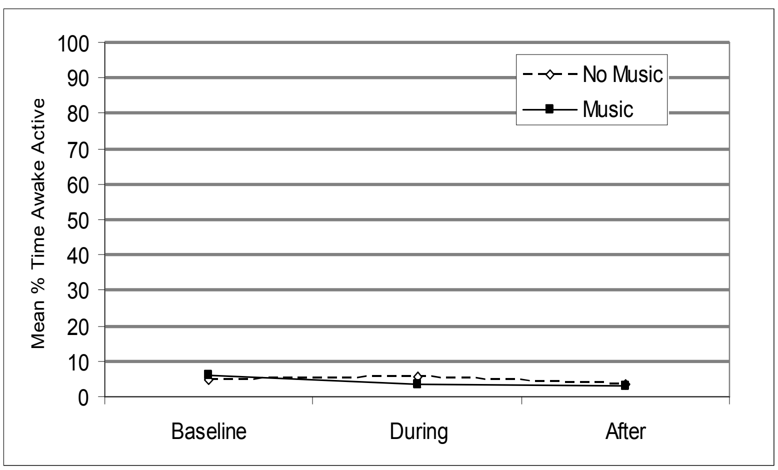

Figure 16. Mean percentage of time in awake active state by music condition and period.

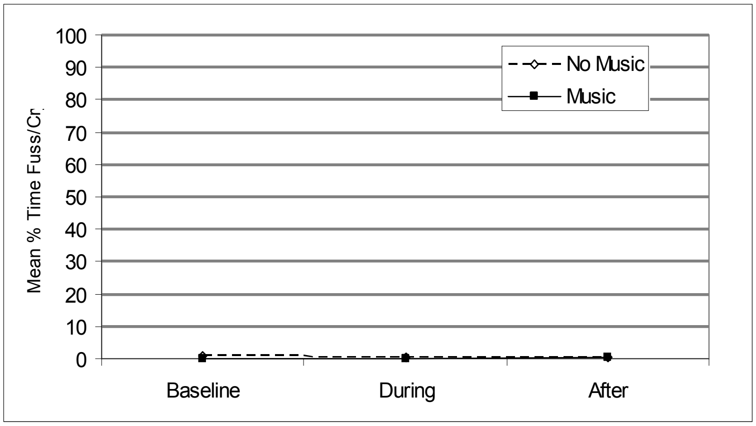

Figure 17. Mean percentage of time in fuss/cry state by music condition and period.

Results of Mauchly's Test are summarized in Table 38. Mauchly's Test was statistically significant for Alert Inactive, Awake Active, and Fuss/Cry; these findings indicate that the sphericity assumption was violated. The degrees of freedom were adjusted by using the Huynh-Feldt correction. Mauchly's Test was not statistically significant for Quiet Sleep, Active Sleep, REM Sleep, and Drowsy.

Table 38

Mauchyl's Test Results by State for Period Main Effect/Period by Music Interaction

	Period			Period x Music		
State	χ^2	*df*	*p*	χ^2	*df*	*p*
Quiet Sleep	.160	2	.923	1.840	2	.399
Active Sleep	1.563	2	.458	.437	2	.804
REM Sleep	.950	2	.622	.847	2	.224
Drowsy	.807	2	.145	.947	2	.614
Alert Inactive	9.945*	2	.007	6.444*	2	.040
Awake Active	9.864*	2	.007	8.893*	2	.012
Fuss/Cry	--[a]	2	--[a]	46.324*	2	<.001

[a]Could not be computed because Mauchly's W = 0.
*Statistically significant at $p<.05$.

ANOVA results are shown in Table 39. There were no significant effects for Period, Music, or the Interaction between Period and Music for five of the seven behavioral state variables (Quiet Sleep, REM Sleep, Awake Inactive, Awake Active, or Fuss/Cry). For the Active Sleep variable, the Interaction of Period and Music was not statistically significant; this finding indicates that the pattern of means across Periods did not differ for the Music and No-Music conditions. The main effect of Music was not significant. The main effect of Period was statistically significant; this finding indicates that, when ignoring the Music factor, there was a difference in level of Active Sleep among Periods. Pairwise comparisons showed a statistically significant difference between the mean level of Active Sleep at Baseline (18.19, *SD*=11.25) and During (25.81, *SD*=16.08); however, neither differed from the After mean (19.55, *SD*=13.47).

For the Drowsy behavioral state, the interaction of Period and Music was not statistically significant; this finding indicates that the pattern of means across Periods did not differ for the Music and No-Music conditions. The main effect of Period was statistically significant; this finding indicates that, when ignoring the Music factor, there was a difference in the level of Drowsy behavioral state among Periods. Pairwise comparisons showed a statistically significant difference between the Baseline mean (9.75, *SD*=13.82) and the During mean (3.50, *SD*=6.77), as well as a statistically significant difference between the During mean and the After mean (14.62, *SD*=15.72). These comparisons are summarized in Tables 40 and 41. The interaction of Period and Music was not statistically significant for Quiet Sleep, REM sleep, Alert Inactive, Awake Active, and Fuss/Cry; therefore, the pattern of means across Periods does not differ for the Music and No-Music conditions. The main effects for Period and Music were also not significant.

Table 39

ANOVA Results for Behavioral States

Source	*df*	*F*	*p*	Effect size[a]
		Quiet Sleep		
Period	2, 38	0.758	.476	0.038
Music	1, 19	0.101	.754	0.005
Period·Music	2, 38	0.087	.917	0.005
		Active Sleep		
Period	2, 38	4.100*	.024	0.177
Music	1, 19	0.065	.801	0.003
Period·Music	2, 38	0.221	.803	0.012
		REM Sleep		
Period	2, 38	0.844	.438	0.043
Music	1, 19	0.111	.742	0.006
Period·Music	2, 38	0.414	.664	0.021
		Drowsy		
Period	2, 38	9.408*	<.001	0.331
Music	1, 19	0.077	.784	0.004
Period·Music	2, 38	0.393	.678	0.020
		Alert Inactive		
Period	1.482, 28.161	0.497	.559	0.025
Music	1, 19	0.548	.468	0.028
Period·Music	1.646, 31.278	0.363	.554	0.019
		Awake Active		
Period	1.485, 28.220	0.665	.479	0.034
Music	1, 19	0.075	.787	0.004
Period·Music	1.525, 28.974	0.307	.586	0.016
		Fuss/Cry		
Period	1,19	0.603	.447	0.031
Music	1,19	1.263	.275	0.062
Period·Music	1.046,19.881	0.958	.344	0.048

[a]Partial eta-squared.
*Statistically significant at $p<.05$.

Table 40

Pairwise Comparisons for the Effects of Period and Music on the Active Sleep Behavioral State

(I) Period	(J) Period	Mean Difference (J-I)	p[a]
Baseline	During	7.625*	.018
	After	1.354	.581
During	After	- 6.271	.059

[a]Adjustment for multiple comparisons: Bonferroni.
*Statistically significant at $p<.05$ (2 tailed).

Table 41

Pairwise Comparisons for the Effects of Period and Music on the Drowsy Behavioral State

(I) Period	(J) Period	Mean Difference (J-I)	p[a]
Baseline	During	-6.250*	.013
	After	4.875	.329
During	After	11.125	.002

[a]Adjustment for multiple comparisons: Least Significance Difference.
*Statistically significant at $p<.05$ (2 tailed).

Summary of Findings

The demographic data for the sample of preterm infants showed that most of the infants in the sample were female (65%) and that most were White (60%), with 35% being Black. Also, 70% of the babies were delivered via caesarian section. The mean maternal age was 26.25 years, and the mean gestational age at birth was 27.54 weeks.

The findings related to the first hypothesis indicated that infants did not exhibit a significant decrease from baseline in HR or motor activity levels during and after the music intervention. Ignoring the Music factor, there was a significant difference between the level of behavioral distress in the Baseline period and that in the During period, as well as between the level of distress in the During period and that in the After period. The findings did not support the first hypothesis that infants would exhibit a greater decrease from baseline in HR, level of motor activity, and behavioral distress during and for 10 min after the music intervention than they would exhibit during and for 10 min after to the no-music condition. The level of behavioral distress decreased from Baseline to During for the Music condition and increased from Baseline to During for the No-Music condition, although the difference was not significant for condition effects. There was an overall decrease in behavioral distress across both conditions when Baseline, During, and Post means were compared.

The findings related to the second hypothesis indicated that infants did not exhibit a significant decrease from baseline in oxygen saturation during and after the music intervention. Therefore, the findings did not provide support for the second hypothesis that infants would exhibit a greater increase from baseline in oxygen saturation during and for 10 minutes after the music intervention compared to the no-music condition.

The findings related to Study Question 1 indicated that most the infants ranged from 26.1 to 29.2 weeks' gestational age at birth (M = 27.5 weeks) and that 18 of the 20 infants required resuscitation after birth but had 5-minute Apgar scores greater than 5. However, two of the infants required prolonged resuscitation and had 5-minute Apgar scores less than 5.

The findings related to Study Question 2 suggested that the infants should have been able to hear the music during the music condition because the mean sound level at the infant's head increased from baseline to the music period and then decreased after the music period. Similarly, the sound level outside the isolette increased during the music condition from baseline to the music period and then decreased after the music period. There were no significant differences between the number of staff and visitors before, during, and after the music therapy and control periods, comparing the music therapy and control sessions. These findings indicate that the number of staff and visitors was not an extraneous variable that may have affected infants' responses to the music or no-music conditions.

The findings related to the third study question indicated that there were no significant differences between the levels of morbidity or between the amount of stimulation received by the infant during the 2 hr before the Music condition and those during the 2 hr before the No-Music condition. However, there were differences between the mean weight across the two conditions. This difference between weights may be explained by the order in which the measurements were taken. The infants weighed more in later sessions because they were older; in addition only 5 of the 20 infants were in the music condition for Session 1, whereas 17 of 20 were in the music condition for Session 4. Correlations between weight and the outcome measures (HR, oxygen saturation, motor activity, and behavioral distress) were run at baseline for the first session for each infant. The results showed that weight was not linearly related to the outcome measures.

The findings related to the fourth study question examining differences between percentages of time in each of the seven behavioral states before, during, and after the music period and those before, during, and after the control period indicated that there were no effects for five of the seven behavioral state variables (Quiet Sleep, REM Sleep, Awake Inactive, Awake Active, and Fuss/Cry). Regardless of which condition (music or no-music) was involved, the levels of Active Sleep were significantly higher for the During period than for the Baseline period. Regardless which condition (music or no-music) was involved, the levels of Drowsy were significantly lower for the During period than for the Baseline period. The factors that may have contributed to these differences are not known.

CHAPTER 5

DISCUSSION

Summary of Findings

The purpose of this study was to examine the effects of a 15-min live-music therapy intervention on HR, oxygen saturation, level of motor activity, behavioral distress, and behavioral state levels in premature infants in the NICU. Physiological (HR and oxygen saturation) and behavioral (level of motor activity, behavioral distress, and behavioral state) outcomes were measured, and the study findings indicated that there were no significant physiological effects of the music therapy intervention. Findings for behavioral outcomes of motor activity, behavioral distress, and percentage of time in each of the behavioral states were not statistically significant, with two exceptions: (a) an increased mean percentage of time in the active sleep state from the Baseline mean to the During mean and (b) a decreased percentage of time in the drowsy state from the Baseline mean to the During mean, followed by an increase on this state from the During Mean to the After mean. This chapter contains a discussion of the findings in comparison with findings from previously reported research and as they relate to the conceptual framework that was proposed for this study. This chapter concludes with discussions of study strengths and limitations and of recommendations for research and practice.

Relationship of Results With Literature

Research Findings Related to Effects of Music on Physiological Outcomes

Oxygen saturation. A total of nine studies were identified that evaluated the effects of music on oxygen saturation levels in preterm infants. Six of the nine studies reviewed reported an increase in oxygen saturation during or after exposure to a music intervention (Burke et al., 1995; Cassidy & Standley, 1995; Chou et al., 2003; Coleman et al., 1997; Collins & Kuck, 1991; Standley & Moore, 1995). There were wide variations across these six studies in type, duration, and decibel level of music; gestational age of the infants; and sample size. However, all six studies used recorded female singing, and none of the studies blinded the researchers to group assignment. There were few similarities between the six studies and the current study other than the use of female vocals.

Burke et al. (1995) reported that *Transitions* music played for 15 after suctioning resulted in an increase in oxygen saturation among 3 of 4 infants (25-35 weeks' gestation). Collins and Kuck (1991) reported statistically significant increases in oxygen saturation after exposure to a 10-min intervention with *Transitions* among infants who were 24 to 37 weeks' gestational age at birth. Chou et al. (2003) found that, in a sample of 30 infants born at 28 to 36 weeks' gestation age, mean oxygen saturation levels during 30 min after suctioning were higher in the experimental group than in the control group and that the mean time in minutes to recovery of oxygen level to baseline was shorter in the experimental group than in the control group; the amount of time that the music was provided varied, and the range of time was not clearly reported. Cassidy and Standley (1995) reported an increase in mean oxygen saturation during a 30-min lullaby intervention among infants who were 24 to 37 weeks' gestation on only Day 1 and made no report of significant effects on oxygen saturation during Days 2 and 3. Standley and Moore (1995) found an increase in mean oxygen saturation on only Study Day 1 only during a sung recorded lullaby intervention provided for 20 min on each of 3 days. Coleman et al. (1997) reported a statistically significant increase in oxygen saturation during a 20-minute lullaby intervention provided for 4 consecutive days among infants who were 25 to 35 weeks' gestation at birth.

The investigators in two studies (Johnston et al., 2007; White-Traut et al., 1993) reported a decrease in oxygen saturation during a music intervention. Johnston et al. played recorded maternal voice (speaking, singing or saying nursery rhymes, or talking baby talk in a singsong voice) for 10 min three times per day for 48 hr and then for 1 min before and then throughout heel lance on two occasions; the sample consisted of 20 infants born at 32 to 36 weeks' gestational age. The investigators suggested that the decrease in oxygen saturation could have resulted from the fact that, when the infants were exposed to the heel lance stressor, the addition of the music could have served as additional stimulation instead of as distraction (Johnston et al.). White-Traut et al. (1993) provided a female voice as one component of ATVV stimulation. Auditory stimulation included a live female voice (whether singing or speaking was not reported) provided for 15 min once per day for 4 consecutive days to an experimental group of 20 infants born at 30 to 32 weeks' gestational age. Although the decrease reported by White-Traut et al. (1993) was statistically significant, the clinical significance was questionable because the mean level decreased only 1.3%; the investigators suggested that the decrease in oxygen saturation could have been caused by other aspects of the stimulation and not by the auditory stimulation, but it was unclear whether there was more than one intervention period.

The findings from one of the nine studies (Calabro et al., 2003) were consistent with this study's findings that there was no effect of music on oxygen saturation levels. Calabro et al. used recorded instrumental music with a small ensemble playing "Brahms' Lullaby" and "Sandman" for 20 min; the intervention was provided once per day for 4 consecutive days to 11 infants in the experimental group who were born at 34 weeks' gestation.

HR. A total of nine studies involved examining the effects of music interventions on preterm infants' HRs; in four of these studies (three with recorded music and one with live music), infant HR decreased after the music. Three of four studies in which recorded music was used as the intervention yielded findings of a decreased HR after the music intervention (Burke et al., 1995; Butt & Kisilevsky, 2000; Coleman et al., 1997). One of two studies that involved using a live-music intervention reported a decreased HR after exposure to the music (Arnon et al., 2006). Coleman et al. reported a decrease in HR during recorded sung and spoken lullabies provided to 33 preterm infants (25-35 weeks' gestation) for 20 min per day for 4 days; researchers were not blinded to group assignment. Arnon et al. reported a decrease in HR during the 30 min after a live female wordless music intervention that included an accompanying instrument and was provided at 55-70 dB for 30 min for 3 consecutive days to a sample of 31 infants born between 25 and 34 weeks' gestational age; researchers in the study were blinded to intervention order.

In the studies that used multimodal (ATVV) stimulation, researchers reported increased HRs in response to the stimulation (White-Traut et al., 1993, 1997). However, this increase was not necessarily an undesirable outcome; the intention was to increase alert states and feeding-readiness behaviors and not to soothe and decrease alert states. Nevertheless, White-Traut et al. (1993, 1997) did state that HRs greater than 180 beats per minute among fragile preterm infants may be cause for concern.

One group studying recorded music reported no effect on HR (Calabro et al., 2003), and two researchers investigating live music reported no effect on HR (Blumenfeld & Eisenfeld, 2006); these findings are consistent with those from the present study. Both the Calabro et al. and the Blumenfed and Eisenfeld studies had sample sizes (11 and 22 infants, respectively), and included infants ranging from 23 to 34 weeks' gestational age at birth. Calabro et al. used recorded instrumental music with a small ensemble playing "Brahms' Lullaby" and "Sandman". Blumenfeld and Eisenfeld used live maternal singing during consecutive feedings on 2 consecutive days. Researchers were blinded to group assignment in the study by Calabro et al. and in the current study, but Blumenfled and Eisenfeld did not blind researchers to music condition.

Research Findings Related to Effects of Music on Behavioral Responses

Twelve studies were identified that involved evaluating behavioral responses to a music intervention. Ten of these resulting in reports of significant effects (Arnon et al., 2006; Burke et al., 1995; Caine, 1991; Chapman, 1978; Coleman et al., 1997; Collins & Kuck, 1991; Johnston et al., 2007; Kaminski & Hall, 1996; Lai et al., 2006; White-Traut et al., 1993, 1997, 2002).

In the 10 studies yielding reported behavioral effects of the music intervention, infants ranged from 24 to 42 weeks' gestational age; the interventions included *Transitions* or other recorded lullabies, live lullabies, and ATVV. Authors in 5 of these studies reported that, in comparison with results obtained during the control period, those obtained during the intervention period revealed a decrease in highly aroused states or in an increase in sleep or quiet awake and quiet alert states (Arnon et al., 2006; Burke et al, 1985; Collins & Kuck, 1991; Coleman et al. 1997; Kaminski & Hall, 1996). In these 5 studies, gestational ages at birth and sample size varied. There was no consistency in the type of music provided, duration of music (10 min to 2 hr), or decibel level (35–80 dB). Two studies involved using *Transitions*, one included recorded instrumental lullabies, and the other involved playing recorded sung lullabies by both a male and female. In one of the 5 studies were researchers blinded to group or condition assignment. Caine (1991) reported an increase in nonstress behaviors for infants exposed to recorded lullabies for 30 min of music alternating with 30 min of routine auditory stimulation for a total of 1.5 hr of music once per day and continued until discharge. Authors of the three studies evaluating the effects of the ATVV intervention reported an increase in alert or arousal states either during or after the intervention (White-Traut et al., 1993, 1997, 2002).

Authors of 2 of the 10 studies in which behavioral effects of music interventions were examined reported no such effects. Johnston et al. (2007) found no significant differences between behavioral indicators of pain (facial actions and neurobehavioral state as defined in the Premature Infant Pain Profile) among preterm infants (32 to 36 weeks' gestation) exposed to recorded maternal singing and speech 1 min before, during, and after heel lance and those indicators among infants in the same age range who were exposed to a routine-care condition. Only one other study was found that yielded reports of effects of a music intervention on motor activity (Chapman, 1978). Chapman compared infants' responses to recorded maternal speech, instrumental music, and routine care. The sample included 153 infants between 26 and 33 weeks' gestational age. The auditory stimulation was provided for 5 min, six times per day from the 5th day of life until a weight of 1,843 g was obtained. Chapman found no significant differences in limb movement among infants in the three groups; that finding is consistent with those from this study.

Summary of Relationship to Previous Studies

There were few similarities between previously published studies and this current study. Duration and frequency of the music intervention varied from study to study. In the current study, music was provided for 15 min once per day on 2 different days. Of the studies resulting in reports of significant effects in physiologic outcomes, music was provided for anywhere from 5 min alternating with 4 min of quiet, for a total of 36 min once a day, to 60 min once a day. Frequency of exposure was once per day for 3 days to once or twice per week for 2 to 3 weeks. In the studies yielding significant findings for physiologic outcomes with the use of one group, the sample size ranged from 10 to 31, with a mean sample size of 20.3. One of the two studies producing nonsignificant results and incorporating a one-group design had a sample size of 11, and the other had a sample size of 20. Of the two live-music intervention studies reviewed, one resulted in a report of significant physiologic outcomes for the 30 min after the intervention. Failure to identify significant physiologic findings in the current study may have been caused by the short observation time after the music intervention. In the current study, infants were observed for only 10 min after the intervention.

Failure to identify an effect of music on HR or oxygen saturation in this study may have resulted from the duration and frequency of exposure to the music intervention and from the dose of the intervention. Infants in this study were measured after only two 15-min music interventions. The decibel level during the music intervention was only 6 dB higher than that during the baseline and post-music intervention periods. It is possible that infants may not have responded to this small increase in decibel level over the level of ambient sound in the nursery. It should also be noted that more than half of the infants were in a state of quiet sleep or REM sleep during the music condition; thus they may not have been in an optimal state to mount a physiologic or behavioral response to the music intervention.

The sample size in this study was consistent with the mean sample size in similar studies. However, effect sizes in the current study were smaller for HR (0.203) and oxygen saturation (0.037) than those reported in Standley's (2002) meta-analysis. Standley (2002) reported that the effect size for HR in two previous studies was 0.4555 and 0.9190 and that the effect size for oxygen saturation in six previous studies ranged from 0.6971 to 1.2887.

Three studies involving single-subject designs and yielding significant effects of music interventions on behavioral outcomes also varied in duration and frequency of the music intervention and in sample size (Arnon et al., 2006; Collins & Kuck, 1991; Kaminski & Hall, 1996). In their study, Collins and Kuck provided a recorded music intervention for 10 min (the number of sessions was not clear) to a group of 17 infants born at less than 37 weeks' gestation; the authors reported that , in comparison with the behavioral state found during the 10-min baseline period, that found during the intervention was improved. An improved behavioral state was defined in the Collins and Kuck study as agitation or fussy changing to sleep or awake. Kaminski and Hall provided a recorded-music intervention for 2 hr to a group of 20 infants born between 36 and 42 weeks' gestational age; the authors reported less time in high arousal states during the 2-hr intervention period then during the 2-hr baseline period. In the third study, Arnon et al. counter-balanced a live-music intervention, a recorded-music intervention, and routine care for one group of 31 infants born between 25 and 34 weeks' gestational age; 30 min of each condition were provided on 3 consecutive days. The authors found that the infants' behavioral score was higher (deeper sleep) during the 30 min after a live-music intervention than during the 30 min after routine care (Arnon et al.).

Discussion of Results in Relation to Conceptual Framework

As presented in the conceptual model for this study, characteristics of the music, the environment, and the neonate may influence both physiologic and behavioral responses to a music intervention. The expected effects of music on physiologic outcomes (HR and oxygen saturation) on behavioral outcomes (motor activity and behavioral stress indicators) were not supported. Live music was used in this study, and the music therapist could control volume and tempo by altering her voice in response to both the noise in the nursery and the infant's reaction. There were no significant differences found when a number of potential extraneous variables in the music condition were compared with the same variables in the no-music condition; these variables included infant morbidity level, number of visitors or staff in the nursery, and quantity of stimulation received during the

2 hr before the intervention. This finding suggests that these variables did not influence physiologic or behavioral responses.

The relaxation response mechanisms of distraction and entrainment were proposed to be the mechanisms by which music might reduce the stress response of preterm infants in the NICU. This relaxation response was suggested as a means for quieting the SNS and therefore for decreasing HR and amounts of time spent in high arousal states. Music may provide distraction by drawing the infant's attention away from aversive auditory stimulation. Entrainment may work by synchronizing the infant's natural rhythm to another, more soothing rhythm. Physiological entrainment of infants may occur when an infant's elevated HR is lowered through synchronization to a constant rhythm of lullabies or sedative music. The mechanisms of distraction and entrainment were not specifically tested in this study.

The study was based partially on the synactive theory of development. This theory involves the proposition that observation of responses in the five subsystems should guide the type and amount of stimulation that is provided to fragile preterm infants. Although the music therapist in this study did modify her intervention if she noted distress in the infants, many of the infants were asleep when the intervention was initiated. More optimal benefits might have resulted if the intervention had been provided only to infants in a more alert or awake state.

Of the 29 studies reviewed, only 3 discussed any theoretical underpinnings to explain the effect of music within the study. In the current study, a conceptual framework was proposed that may begin to explain the preterm infant's responses to stressors and to interventions designed to reduce stressors. Further research is needed to test the specific mechanisms by which music may influence preterm infants' physiological and behavioral responses.

Study Strengths

There were many strengths to this study. A live-music therapy intervention was provided by a board-certified music therapist; thus, the music could be adjusted for volume and tempo on the basis of environmental noise and infant response. All songs met the tempo criteria for a lullaby and were sung by a solo female vocalist with one accompanying instrument (guitar). Data were collected during the same 4 hr interval on each data collection day, and activity patterns in the nursery and infant circadian rhythms were taken into consideration. The RA collecting data during the baseline and after-intervention/control periods were blinded to the music condition for that day.

A homogenous sample of infants 26 to 29 weeks' gestational age at birth who had no congenital anomalies and were in an isolette in the step down nursery were enrolled in this study. Of the 22 infants enrolled in the study, 18 infants completed four sessions within a 2- to 4-week time period. Two of the 4 remaining infants completed three sessions within a 2- to 4-week time period.

The music intervention which was noninvasive, did not require that additional monitors be attached to the infant. All infants were also required to have had at least one music therapy intervention before initiation of the study. No apparent deleterious effects were noted on infant HR, oxygen saturation, or behavioral state. One infant did become agitated during the music intervention, and the intervention was stopped. This infant had completed one previous music data collection day and one previous no-music data collection day. On Data Collection Day 3, music day, the music was discontinued after 12.5 min of the scheduled 15 min because this infant's HR increased above 200 beats per minute for 2 min; the level of motor activity and the behavioral distress cues also increased during the 2 min of the elevated HR. The infant's behavioral state changed from quiet and active sleep to awake active and fuss/cry. The oxygen saturation remained at 100% on room air. The music was discontinued; after 7 min, the infant's HR returned to less than 200 beats per minute, the level of motor activity and the behavioral distress cues decreased, and the infant returned to quiet sleep.

Study Limitations

All infants were relatively stable, with minimal levels of motor activity or behavioral distress, and with minimal variation in levels of HR or oxygen saturation. As a result, these infants may have had low levels of stress and been less responsive to an intervention such as music than less stable and more stressed infants may have been found to be.

All infants were in isolettes. Parents could bring in sources of auditory stimulation for the infants if desired, such as tape recorders and stuffed animals that played music; although none of the infants in this study had these items in their isolettes during the study sessions, it is possible that they received music at times when I was not present. During the 35 min in which the data were being collected on music and no-music days, there was no supplemental music stimulation. However, I could not control for staff or parents who may have sung to the infants during times that I was not present.

Although infants were randomly assigned to order of intervention, the schedule for music therapy was occasionally altered because of the music therapist's schedule. As a result, the order of interventions was changed for five infants. This change resulted in 85% of the last (fourth) sessions' being music condition days. This study used a convenience sample, and the sample size was relatively small. Although large effect sizes were reported in the literature, effect sizes in this study were small.

Recommendations

Implications for Practice

The research hypotheses proposed for this study were not supported, although no deleterious effects of the music therapy were identified. However, more research is needed before music therapy can be recommended for use with preterm infants in the NICU. The findings from this study do not support the possibility that benefits result from this intervention. Music is a noninvasive, nonpharmaceutical, and relatively low-cost intervention that can be implemented at the infant's bedside. Further research is needed to determine whether effects noted in previous studies can be consistently replicated in diverse settings and with diverse groups of preterm infants.

Future Research

Further testing of the conceptual framework proposed for this study is needed to more specifically examine the mechanisms by which music may positively affect the physiologic and behavioral outcomes in infants in the NICU in order to further test the conceptual framework proposed for this study. Future research is needed to determine whether live music may be of benefit to preterm infants classified as more unstable, such as ventilator-dependent infants.

Music therapy interventions may need to be even further individualized. Morris et al. (2000) suggested that there is a threshold intensity that evokes a response and that this threshold varies among individuals. Comparisons of this study with other investigations indicate that music therapy interventions provided for a longer period and with increased frequency may also be of benefit. Because some of the significant results were noted in other studies 30 min after the intervention, infants in future research may need to be observed for a longer period after the intervention. Infants may also need to be exposed to music at a higher decibel level. In the current study, mean decibel difference from baseline to the intervention period in the music condition was 6 dB. The minimum detectable difference is 1 dB under ideal conditions, and a change of 5 dB is clearly perceptible (Gray, 2000). There are very few studies of the infant's ability to discriminate sound intensity. Sinnott and Aslin (1985) reported that infants could discriminate changes in decibel level as low as 3 dB. Bull, Eilers, and Oller (1984) reported that infants could discriminate intensity in 2- to 6-dB increments. However, in both cases, these were term infants 5 to 11 months old. Further research needs to be done to determine appropriate decibel levels for music therapy in preterm infants.

The current study did not require infants to be in a certain behavioral state before initiation of the data collection. In this study, infants were most often in a sleep state. It is unclear whether infants were in the most appropriate state for study. Infants may be more responsive to auditory stimulation when in an awake or agitated state. Additionally, it may be less desirable to expose sleeping preterm infants to a stimulus that may lead to an awake state. Philbin (2000a) reported that results of studies involving healthy full-term infants suggest that most are disturbed or wakened from sleep in hospital nurseries at sound levels between 50 and 75 dB. Although these studies included full-term infants, preterm infants can be expected to show the same or greater sensitivity to sound (Philbin).

Qualitative research would also enhance the understanding of other benefits of music therapy in the NICU. Examples include studies of nurse perception and parent perception of the music therapy intervention.

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APPENDIX A

LIST OF SONGS PERFORMED DURING THE MUSIC THERAPY SESSIONS

Appendix A

Song	Key	Tempo (bpm)	Meter
"Annie's Song"	G	96	3/4
"Every Breath You Take"	C	84	4/4
"Here Comes the Sun"	D	92	2/4
"Hushabye"	C	84	4/4
"I Can See Clearly Now the Rain Has Gone"	D	88	4/4
"I Hope You Dance"	A	108	4/4
"Lay Me Down Gently"	D	76	3/4
"No One Like You"	G	65	4/4
"Sing! "	G	108	4/4
"Stand By Me"	C	84	4/4
"This Little Light of Mine"	E	92	4/4
"Twinkle Twinkle Little Star"	D	76	4/4
"What a Wonderful World"	C	58	2/4
"When You Say Nothing At All"	D	76	4/4
"You Are My Sunshine"	D	96	4/4

APPENDIX B

DEFINITIONS OF SLEEP STATE, MOTOR ACTIVITY, AND BEHAVIORAL DISTRESS

Appendix B

I. Behavioral State

- Quiet sleep–The infant's eyes are closed and still. There is little or no motor activity, except for an occasional startle, limb movement, or non-rhythmic mouthing. Breathing should be smooth and regular.
- Active sleep w/o REM–The infant's eyes are closed and still. Either motor activity is noted throughout most of the interval or deep, gasping, irregular respirations are present.
- REM sleep–The infant's eyes are closed (may open briefly). Darting or rolling of the eyes can be detected through closed or open eyelids. Motor activity may or may not be present. Generally, eyebrow movements in this state are part of REM sleep and are not coded as grimace.
- Drowsy–The infant's eyes may be opening and closing or may be opened but have a dull, glazed appearance and are not darting or rolling. There is little or no motor activity, except for an occasional startle, single limb movement, or mouthing.
- Alert inactive–The infant's eyes are wide open and bright. The infant is relatively inactive, although slight movements may occur in conjunction with looking/tracking behaviors.
- Awake active–The infant's eyes are open but are not bright and are not darting or rolling. Motor activity is present for the major part of the interval.

- Fussing/Crying–Fussing sounds or negative vocalization is present. Body movements may or may not be present. Mouthing or grimace cannot occur at the same time.

II. Motor Activity

- Single-limb movement–Movement of only one arm or leg at a time. If the infant has several single-limb movements in an episode, they are coded as single-limb movement.
- Multiple limb movement–Movement of two or more limbs simultaneously.
- Gross body movement–Movement of the buttocks and/or trunk. Visible contracting of the muscles. Jerky movements of the trunk or body tremors.
- Head turn–Movement, turn, lift, or raising of the head in any direction.
- Startle–Rapid, jerky extension and then flexion of arm or leg.

III. Behavioral Distress Cues

- Subtle Disengagement Cues
    - Hiccups – Spasmodic inhalation with closure of the glottis.
    - Facial grimace–Contraction of facial muscles.
    - Finger splay-Extension and spreading apart of fingers.
    - Clenched fists–Hands are held in a tightly closed position.
- Potent Disengagement Cues
    - Crying–Persistent negative vocalization.
    - Fussing–Intermittent negative vocalization.
    - Spitting–Small amount of regurgitation of stomach contents.
    - Vomiting–Forceful regurgitation of more than 20 cc of stomach contents.

APPENDIX C

SUMMARY OF REVIEWED STUDIES

Appendix C

1. Author 2. Design 3. Population (gestational age at birth) 4. Sample Size (N-total, E-experimental, C-control) 5. Control Group 6. Random Assignment 7. Blinding of researchers to group assignment	1. Music Type 2. Delivery Method 3. Music Duration 4. Volume of music 5. Actual volume measured at infants ear	Results
1. Katz (1971) 2. Experimental – 2 group 3. 28–32 weeks 4. *N* = 62 (E-31, C-31) 5. Yes 6. No 7. Yes	1. Recorded maternal speech (prepared monologue) vs. routine care 2. audiocassette (8 in from infant's ear) 3. 5 min, 6x/day, 2-hr intervals (began the 5th day of life and continued until age 252 days (36 weeks' gestation) 4. 70 dBC 5. Yes	E-↑ auditory and visual function at 36 weeks of age ↑ motor and tactile/adaptive maturation (as measured by the Rosenblith Test)
1. Segall (1971) 2. Experimental – 2 group 3. 28–32 weeks 4. *N* = 60 (E-30, C-30) 5. Yes 6. Yes 7. No	1. Recorded maternal speech vs. routine care 2. audiocassette (6-8 inches from infant's ear) 3. 30 min/day until 36 weeks' gestation (when intervention began NR) 4. 83 dBC 5. Yes	E - During rest ↑HR, during exposure to white noise, ↓HR during exposure to mother's recorded voice and/or unfamiliar recorded female voice. E - ↓HR during crying when exposed to mother's voice recording and/or unfamiliar recorded female voice.

Appendix C (Continued)

1. Author 2. Design 3. Population (gestational age at birth) 4. Sample Size (N-total, E-experimental, C-control) 5. Control Group 6. Random Assignment 7. Blinding of researchers to group assignment	1. Music Type 2. Delivery Method 3. Music Duration 4. Volume of music 5. Actual volume measured at infants ear	Results
1. Chapman (1978) 2. Experimental – 3 group 3. 26-33 weeks 4. *N* = 153 (E1-50 mother's voice; E2-51 lullaby; C-52) 5. Yes 6. Yes 7. No	1. E1 - recorded maternal speech vs. E2 - recorded orchestral arrangement of "Brahms' Lullaby" vs. routine care 2. audiocassette 3. 5 min, 6x/day, 2-hr intervals (began on 5th day of life and continued until infant weight 1,843 g) 4. NR 5. NR	No significant differences in limb activity between 3 groups.
1. Malloy (1979) 2. Experimental – 3 group 3. 27-33 weeks 4. *N* = 127 (E1-40 mother's voice, E2-44 "Brahms' Lyllaby", C- 43) 5. Yes 6. Yes 7. Yes	1. E1-recorded maternal speech vs. E2- recorded "Brahms' Lullaby" vs. routine care 2. audiocassette 3. 5 min, 6x/day, 2-hr intervals (began 5th day of life, continued until infant weight 2,000 g and infant was ready for discharge) 4. NR 5. NR	E1 – 6.2 days younger at discharge compared to routine care control group E2 – 9.9 days younger at discharge compared to routine care control group E1 and E2 – Gained weight faster than those infants in the control group

Appendix C (Continued)

1. Author 2. Design 3. Population (gestational age at birth) 4. Sample Size (N-total, E-experimental, C-control) 5. Control Group 6. Random Assignment 7. Blinding of researchers to group assignment	1. Music Type 2. Delivery Method 3. Music Duration 4. Volume of music 5. Actual volume measured at infants ear	Results
1. White-Traut & Tubeszewski (1986) 2. Experimental–2 groups 3. 29-35 weeks 4. *N* = 33 (E-17, C-16) 5. Yes 6. Yes 7. Physician who discharged infant was blinded	1. Talking or singing (ATVV) by examiner vs routine care 2. Live 3. 15 min 1x/day for 10 days or until discharge (began when infant's weight was 1,750 g) 4. NR 5. NR	No statistically significant results noted for length of stay and weight gain.
1. White-Traut & Nelson (1988) 2. Experimental–3 group 3. 28-35 weeks 4. *N* = 33 (E1–11 talking, E2 – 11 RISS, C – 11) 5. Yes 6. Yes 7. Yes	1. E1 – unstructured talking (mother spoke or sang) vs. E2 – RISS (mother administered tactile-vestibular stimulation with talking and eye contact) vs. routine care 2. Live 3. 15 min when : 24-36 hr, 37-48 hr, 49-60 hr, 61-72 hr old (start when infant was 24 hr old) 4. NR 5. NR	E2 - ↑maternal behavior scores as compared to control for maternal sensitivity toward infant, ↑maternal behavior as compared to control and talking group for cognitive growth fostering behavior subscale

Appendix C (Continued)

1. Author 2. Design 3. Population (gestational age at birth) 4. Sample Size (N-total, E-experimental, C-control) 5. Control Group 6. Random Assignment 7. Blinding of researchers to group assignment	1. Music Type 2. Delivery Method 3. Music Duration 4. Volume of music 5. Actual volume measured at infants ear	Results
1. Caine (1991) 2. Quasi-experimental–2 group 3. NR 4. *N* = 52 (E-26, C-26) 5. Yes 6. Matched (11 male/15 female each group) 7. No	1. Recorded vocal music including lullabies and children's music vs. routine auditory stimulation 2. audiocassette (10-20 inches from infant's head) 3. 30 min of music alternating with 30 min of routine auditory stimulation for a total of 1.5 hr of music 1x/day (began on 4th day of life or the 1st day in the isolette if stable medical status was achieved after the infant was 5 days old and continued until infant was discharged from the NICU) 4. 70–80 dB 5. NR	E-↑nonstress behaviors (not clearly defined); ↓ length of stay compared to control (26 days vs. 31 days)

Appendix C (Continued)

1. Author 2. Design 3. Population (gestational age at birth) 4. Sample Size (N-total, E-experimental, C-control) 5. Control Group 6. Random Assignment 7. Blinding of researchers to group assignment	1. Music Type 2. Delivery Method 3. Music Duration 4. Volume of music 5. Actual volume measured at infants ear	Results
1. Collins & Kuck (1991) 2. Experimental–one group 3. ≤ 37 weeks 4. *N* = 17 5. No 6. No 7. No	1. Recorded lullabies "Transitions" vs. no music 2. audiocassette (3 inches from ear) 3. 10 min baseline followed by 10 min music (number of sessions, specific infant criteria for when intervention began and ended NR) 4. 80 dB 5. Yes	During music intervention: ↑oxygen saturation (mean oxygen saturation pre intervention -89%, mean oxygen saturation during music intervention-92%); improved behavioral state (agitation or fussy changing to sleep or awake)
1. White-Traut, Nelson, Silvestri, Patel & Kilgallon (1993) 2. Experimental–2 group 3. 30-32 weeks 4. *N* = 40 (E – 20, C – 20) 5. Yes 6. Yes 7. No	1. Female voice (ATVV) vs. routine care 2. Live 3. 15 min 1x/day for 4 consecutive days (enrolled at 33 weeks' postconceptual age) 4. NR 5. NR	E - ↑alert state during intervention and for 30 min after intervention; ↓mean oxygen saturation during intervention for E (96.4% decreased to 95.7%) compared to C; ↑ mean HR during intervention for E (149 increase to 155.5) compared to C

Appendix C (Continued)

1. Author 2. Design 3. Population (gestational age at birth) 4. Sample Size (N-total, E-experimental, C-control) 5. Control Group 6. Random Assignment 7. Blinding of researchers to group assignment	1. Music Type 2. Delivery Method 3. Music Duration 4. Volume of music 5. Actual volume measured at infants ear	Results
1. Lorch, Lorch, Diefendorf, & Earl (1994) 2. Experimental–one group 3. 32-36 weeks PCA 4. *N* = 10 5. No 6. Counterbalanced order of music 7. No	1. Recorded sedative "Moonlight Sonata" vs. recorded stimulative " Sabre Dance" vs. baseline 2. audiocassette 3. 20 min on 2 consecutive days (specific infant criteria for when intervention began and ended not reported) 4. 78dB ± 2 dB 5. Yes	During the music sessions the mean systolic BP appeared to be more variable during stimulative music; there was more variation in HR during sedative music; respiratory rate was about the same for both music selections; as compared to baseline, systolic BP was higher and more variable during stimulative music; as compared to baseline, HR was more variable during sedative music

1. Author 2. Design 3. Population (gestational age at birth) 4. Sample Size (N-total, E-experimental, C-control) 5. Control Group 6. Random Assignment 7. Blinding of researchers to group assignment	1. Music Type 2. Delivery Method 3. Music Duration 4. Volume of music 5. Actual volume measured at infants ear	Results
1. Burke, Walsh, Oehler, & Gingras (1995) 2. Experimental –one group (4 case studies) 3. 33, 34, 35, & 57 weeks' PCA 4. *N* = 4 5. No 6. No 7. No	1. Recorded lullabies "Transitions" (via Somatron mattress with vibrotactile stimulation vs. played via cassette tape placed 65 cm from infant at foot of bed) vs. isolation room noise 2. audiocassette vs. Somatron mattress 3. 15 min after suctioning *Infant A:* vibrotactile and auditory conditions – six 15-min trials of each; five 15-min no-music conditions. *Infants B, C, D:* six 15-min trials of each of three conditions (specific infant criteria for when intervention began and ended NR. Range of days to completion - 8-21 days. 4. 65 dB 5. NR	The following results were not supported statistically in the report. During music observed greatest relaxation response (sleep); ↓ HR, ↑oxygen saturation levels; ↓highly aroused state; ↑quiet alert state. *Somatron:* Facilitated a higher number of minutes spent in quiet alert state during music.

Appendix C (Continued)

1. Author 2. Design 3. Population (gestational age at birth) 4. Sample Size (N-total, E-experimental, C-control) 5. Control Group 6. Random Assignment 7. Blinding of researchers to group assignment	1. Music Type 2. Delivery Method 3. Music Duration 4. Volume of music 5. Actual volume measured at infants ear	Results
1. Cassidy & Standley (1995) 2. Experimental–2 group 3. 24-30 weeks 4. *N* = 20 (E-10, C-10) 5. Yes 6. Balanced groups 7. No	1. Recorded lullabies (female vocal with orchestral accompaniment) vs. routine care 2. audiocassette (earphones) 3. 5 segments 4 min silence alternating with 4 segments 4 min music. Total 36 min over 3 days (specific infant criteria for when intervention began and ended NR) 4. 80 dB 5. No	E- ↑oxygen saturation levels (mean 93.8% increased to 95.8%) during intervention on Day One of music compared to control group
1. Standley & Moore (1995) 2. Experimental–2 group 3. NR 4. *N* = 20 (E1-10, E2- 10) 5. No 6. NR 7. No	1. E1- Recorded lullabies (female vocal) vs. E2- mother speaking 2. audiocassette (earphones) 3. 20 min x 3 days (specific infant criteria for when intervention began and ended NR) 4. 65 – 70 dB 5. Yes	E1-↑oxygen saturation Day 1 of intervention during 2nd 10-min intervention period compared to E2; no significant differences Day 2 or 3. E1-↓oxygen saturation Day 2 and 3 during final observation compared to E2

Appendix C (Continued)

1. Author 2. Design 3. Population (gestational age at birth) 4. Sample Size (N-total, E-experimental, C-control) 5. Control Group 6. Random Assignment 7. Blinding of researchers to group assignment	1. Music Type 2. Delivery Method 3. Music Duration 4. Volume of music 5. Actual volume measured at infants ear	Results
1. Kaminski & Hall (1996) 2. Pre-experimental–one group 3. 36-42 weeks 4. *N* = 20 5. No 6. No 7. No	1. Recorded lullabies (classical orchestral – “Brahms’ Lullaby” and “Beethoven’s Moonlight Sonata”) vs. routine care 2. audiocassette (pillowspeaker) 3. One session - C-2 hr followed by E-2 hr (conducted when infant was 24-72 hours old) 4. 35 dB 5. NR	E-↓time in high arousal states during intervention compared to control period.
1. Coleman, Pratt, Stoddard, Gerstmann, & Abel (1997) 2. Experimental–2 group 3. 25-35 weeks 4. *N* = 66 (E-33, C-33) 5. Yes 6. E and C groups matched E- 3 randomly ordered periods of music type 7. No	1. Recorded sung lullabies (male baritone/female mezzo soprano) vs. spoken lullabies vs. routine care 2. audiocassette 3. 20 min, 3x over 4 days, 20 min breaks (specific infant criteria for when intervention began/ended not reported) 4. 65 - 75 dB 5. NR	E- ↑calorie intake, ↑weight gain, ↓length of stay compared to C. E-↓HR and ↑oxygen saturation in singing vs. speaking group during intervention; behavior scores moved toward restful state in singing group during intervention

1. Author 2. Design 3. Population (gestational age at birth) 4. Sample Size (N-total, E-experimental, C-control) 5. Control Group 6. Random Assignment 7. Blinding of researchers to group assignment	1. Music Type 2. Delivery Method 3. Music Duration 4. Volume of music 5. Actual volume measured at infants ear	Results
1. White-Traut, Nelson, Silvestri, Cunningham, & Patel (1997) 2. Experimental -5 group 3. *M* = 33 weeks 4. *N* = 54 (C-14, A-9, T-10, ATV-11, ATVV-10) 5. Yes 6. Yes 7. Yes	1. Recorded female voice in A, ATV, ATVV groups vs. no additional auditory stimulation other than regular ambient noise in the T and C groups 2. audiocassette 3. 15 min 1x/day for 4 consecutive days (specific infant criteria for when data collection began NR) 4. NR 5. NR	Any group with tactile component - ↑arousal, ↑HR, ↑respiratory rate during stimulation
1. Standley (1998) 2. Quasiexperimental-2 group 3. 26-34.5 weeks 4. *N* = 40 (E-20, C-20) 5. Yes 6. No –Matched groups (10 male/10 female per group 7. No	1. Live “Brahms’ Lullaby” hummed/no words (ATVV) vs routine care 2. live 3. 15-30 min/1- 2x/week (began 10th day of life x 2-3 weeks 4. NR 5. NR	E- ↑weight gain/day in males and females compared to control group; ↓days to discharge (11.9 days earlier) for females only compared to control group

Appendix C (Continued)

1. Author 2. Design 3. Population (gestational age at birth) 4. Sample Size (N-total, E-experimental, C-control) 5. Control Group 6. Random Assignment 7. Blinding of researchers to group assignment	1. Music Type 2. Delivery Method 3. Music Duration 4. Volume of music 5. Actual volume measured at infants ear	Results
1. Butt & Kisilevsky (2000) 2. Experimental–1 group 3. 29-36 weeks' PCA 4. *N* = 14 5. Yes 6. Type of music counterbalanced 7. No	1. All subjects tested under 2 conditions: recorded "Brahms' Lullaby" sung a capella vs. recorded "Brahms' Lullaby" instrumental (piano) 2. audiocassette (speakers) 3. 10 min x 2 after heel lance (started after infant had been in NICU at least 24 hr; specific criteria for when ended NR) 4. 76 dBA 5. NR	Infants greater than 31 weeks' PCA had ↓HR, rapid return of behavioral state after heel lance, rapid return of normal facial expressions after heel lance No difference was found between type of music (vocal vs. instrumental)
1. Standley (2000) 2. Quasi-experimental-one group 3. 24-32 weeks 4. *N* = 12 5. No 6. No 7. No	1. Recorded lullabies – female 2. audiocassette (at feet) 3. PAL (began when infant at least 34 weeks' PCA, specific infant criteria for when intervention ended NR) 4. 65 – 70 dB 5. NR	During periods of contingent music - ↑nonnutritive sucking as compared to baseline sucking rates

Appendix C (Continued)

1. Author 2. Design 3. Population (gestational age at birth) 4. Sample Size (N-total, E-experimental, C-control) 5. Control Group 6. Random Assignment 7. Blinding of researchers to group assignment	1. Music Type 2. Delivery Method 3. Music Duration 4. Volume of music 5. Actual volume measured at infants ear	Results
1. Whipple (2000) 2. Quasi-experimental-2 group 3. 25-36 weeks 4. *N* = 20 (E-10, C-10) 5. Yes 6. No 7. No	1. Live (E -Parent training in music and multimodal stimulation; C – usual parent training) music type NR 2. live 3. NR(specific criteria for when intervention began and ended NR) 4. NR 5. NR	E-↑appropriate parent scores (not clearly defined) compared to control group
1. White-Traut, Nelson, Silvestri, Vasan, Patel, & Cardenas (2002) 2. Experimental-2 group 3. 29-33 weeks 4. *N* = 22 (E-12, C-10) 5. Yes 6. Yes 7. Yes	1. Infant directed talk via female voice (ATVV) vs. routine care 2. live 3. 15 min before the first 3 oral feedings (entered into study when 33-35 weeks corrected age) 4. NR 5. NR	E-↑alert state, ↑ in 5 of 8 feeding-readiness behaviors during intervention compared to control group

Appendix C (Continued)

1. Author 2. Design 3. Population (gestational age at birth) 4. Sample Size (N-total, E-experimental, C-control) 5. Control Group 6. Random Assignment 7. Blinding of researchers to group assignment	1. Music Type 2. Delivery Method 3. Music Duration 4. Volume of music 5. Actual volume measured at infants ear	Results
1.Calabro, Wolfe, & Shoemark (2003) 2. Experimental -2 group 3. 34 weeks 4. *N* = 22 (E-11, C-11) 5. Yes 6. Yes 7. Yes	1. Recorded instrumental with small orchestral ensemble ("Brahms' Lullaby" and "Sand-man") vs. no music 2. audiocassette (speakers placed 15-20 cm behind infant) 3. 20 min 1x/day for 4 days (specific criteria for when inter-vention began and ended NR) 4. 60-65 dBC in isolette/ 65-70 dBC in crib 5. Yes	No statistically significant findings.
1. Chou, Wang, Chen & Pai (2003) 2. Pre-experimental-one group 3. 28-36 weeks 4. *N* = 30 5. No 6. No 7. No	1. Recorded lullabies "Transi-tions" vs. routine care 2. audiocassette 3. during suctioning (time vari-able; specific criteria for when intervention began and ended NR) 4. 60 dB 5. NR	E- Mean oxygen satura-tion during 30 min after suctioning was higher compared to the control group. Mean time in min-utes of recovery of oxy-gen level to baseline less than control group.

Appendix C (Continued)

1. Author 2. Design 3. Population (gestational age at birth) 4. Sample Size (N-total, E-experimental, C-control) 5. Control Group 6. Random Assignment 7. Blinding of researchers to group assignment	1. Music Type 2. Delivery Method 3. Music Duration 4. Volume of music 5. Actual volume measured at infants ear	Results
1. Standley (2003) 2. Experimental-2 group 3. 24-40 weeks 4. *N* = 32 (E-16, C-16) 5. Yes 6. Yes 7. Nurses administering feedings were blinded	1. Recorded lullabies (female vocals) vs. control group (no pacifier activated lullaby training) 2. audiocassette (placed 20cm from ear) 3. PAL (each suck activates lullabies for a 10 s interval and each resulting in suck reset a the 10 s interval) 15-20 min approximately 1 hr before late afternoon feeding x 2 occurring within 1 week of referral to study (specific criteria for when intervention began and ended NR) 4. 65 dBC/ 58 dBA 5. No	E- late afternoon feeding in cc/min increased compared to control group.

Appendix C (Continued)

1. Author 2. Design 3. Population (gestational age at birth) 4. Sample Size (N-total, E-experimental, C-control) 5. Control Group 6. Random Assignment 7. Blinding of researchers to group assignment	1. Music Type 2. Delivery Method 3. Music Duration 4. Volume of music 5. Actual volume measured at infants ear	Results
1. Cevasco & Grant (2005) 2. Post-hoc analysis-one group (4 trials) 3. 32-36 weeks 4. *N* = 62 5. No 6. No 7. No	1. Recorded lullabies (child with keyboard, lullabies from around the world, or other vocal or instrumental solo/duet by music therapy students) 2. compact disc (placed at corner of bed near infant's head) 3. PAL (each suck activates lullabies for a 10 s interval and each resulting in suck reset a the 10 s interval) Each subject had opportunity to use PAL for 15 min/trial with a maximum of 1 trial/day for a total of 4 trials (specific criteria for when intervention began and ended NR) 4. 65 dBC/ 58 dBA 5. NR	No significant difference in weight gain between trials.

Appendix C (Continued)

1. Author 2. Design 3. Population (gestational age at birth) 4. Sample Size (N-total, E-experimental, C-control) 5. Control Group 6. Random Assignment 7. Blinding of researchers to group assignment	1. Music Type 2. Delivery Method 3. Music Duration 4. Volume of music 5. Actual volume measured at infants ear	Results
1. Arnon, Shapsa, Forman, Regev, Bauer, Litmanovitz, & Dolfin (2006) 2. Experimental-one group (3 within subjects) 3. 25-34 weeks 4. *N* = 31 5. No 6. Counterbalanced 7. Yes	1. E1 - Live music lullabies (wordless blend sung by a female, with frame drum,an accompanying instrument such as the harp) vs. same lullabies recorded vs. routine care 2. live vs. audiocassette 3. 30 min x 3 consecutive days (began after 32 weeks' PCA) 4. 55-70 dBA 5. Yes	E1 - During 30 min after music intervention, ↓HR (150 bpm during baseline decreased to 127 bpm after intervention), improved behavioral score (deeper sleep) compared to control period
1. Blumenfeld & Eisenfeld (2006) 2. Pre-experimental -one group 3. 23-34 weeks 4. *N* = 11 5. No 6. Counterbalanced 7. No (mothers blinded to outcome measure)	1. Live maternal singing (music type was maternal choice) vs. no singing 2. live 3. 23 min $\pm$ 9 min, 2 feedings, 2 consecutive days vs. 2 feedings of no singing (specific criteria for when began and ended NR) 4. 60 – 79 dB 5. Yes	No significant benefits or deterrents were noted when measuring HR, respiratory rate, duration of feeding, volume of fluid intake, feeding velocity and percent of feeding goal during singing versus no singing feedings

Appendix C (Continued)

1. Author 2. Design 3. Population (gestational age at birth) 4. Sample Size (N-total, E-experimental, C-control) 5. Control Group 6. Random Assignment 7. Blinding of researchers to group assignment	1. Music Type 2. Delivery Method 3. Music Duration 4. Volume of music 5. Actual volume measured at infants ear	Results
1. Lai, Chen, Peng, Chang, Hsieh, & Huang (2006) 2. Experimental-2 group 3. <37 weeks 4. *N* = 30 (E-15, C-15) 5. Yes 6. Block randomization stratified by gender 7. No	1. Recorded lullaby with kangaroo care vs. routine care 2. compact disc 3. 60 min/day x3 days during kangaroo care (specific criteria for when intervention began and ended NR) 4. NR 5. NR	E-↑quiet sleep, ↓crying on Day 2 compared to control group, ↓maternal anxiety compared to control group (measured by STAI)
1. Johnston, Filion, & Nuyt (2007) 2. Experimental-1 group 3. 32-36 weeks 4. *N* = 20 5. No 6. Crossover design, random ordering of conditions 7. No	1. Recorded maternal voice (singing/saying nursery rhymes) vs. routine care 2. audiocassette 3. 10 min, 3x/day x48 hr, 2 heel lance procedures, played 1 min before and during heel lance until HR and oxygen returned to baseline (enrolled within first 10 days of life) 4. 60 – 70 dBA 5. Yes	E- ↓oxygen saturation in voice condition versus control condition after heel lance procedure

Note. NR = Not Reported. PCA = Postconceptual age. E = Experimental Group. C = Control Group. HR = Heart Rate

APPENDIX D

INSTITUTIONAL REVIEW BOARD FOR HUMAN USE APPROVAL FORM

Appendix D

THE UNIVERSITY OF ALABAMA AT BIRMINGHAM

Institutional Review Board for Human Use

Form 4: IRB Approval Form
Identification and Certification of Research
Projects Involving Human Subjects

UAB's Institutional Review Boards for Human Use (IRBs) have an approved Federalwide Assurance with the Office for Human Research Protections (OHRP). The UAB IRBs are also in compliance with 21 CFR Parts 50 and 56 and ICH GCP Guidelines. The Assurance became effective on November 24, 2003 and expires on September 19, 2010. The Assurance number is FWA00005960.

Principal Investigator: WOOD, ASHLEY HODGES

Co-Investigator(s):

Protocol Number: F050405012

Protocol Title: *Effects of Music Therapy on Preterm Infants, Parents, and Neonatal Intensive Care Unit Nurses*

The IRB reviewed and approved the above named project on 1/16/2008. The review was conducted in accordance with UAB's Assurance of Compliance approved by the Department of Health and Human Services. This Project will be subject to Annual continuing review as provided in that Assurance.

This project received FULL COMMITTEE review.

IRB Approval Date: 1/15/2008

Date IRB Approval Issued: 01-23-08

Identification Number: IRB00000726

Albert Oberman, M.D., MPH
Vice Chair of the Institutional Review
Board for Human Use (IRB)

Investigators please note:

The IRB approved consent form used in the study must contain the IRB approval date and expiration date.

IRB approval is given for one year unless otherwise noted. For projects subject to annual review research activities may not continue past the one year anniversary of the IRB approval date.

Any modifications in the study methodology, protocol and/or consent form must be submitted for review and approval to the IRB prior to implementation.

Adverse Events and/or unanticipated risks to subjects or others at UAB or other participating institutions must be reported promptly to the IRB.

470 Administration Building
701 20th Street South
[illegible]
Fax 205 934 1301
[illegible]

The University of
Alabama at Birmingham
Mailing Address:
AB 470
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APPENDIX E

INFORMED CONSENT

Appendix E

TITLE OF RESEARCH: "Effects of Music Therapy on Preterm Infants, Parents, and Neonatal Intensive Care Nurses"
INVESTIGATOR: Ashley Hodges Wood, MSN, RNC, MA
FACULTY SPONSOR: Lynda Harrison, PhD, University of Alabama at Birmingham, School of Nursing

> For Minors (persons under 19 years of age) participating in this study, the use of the term "You" refers to "You or Your Child" and addresses both the participant and the parent or legally authorized representative.

<u>Explanation of Procedures</u>

You are being asked to participate in a study to evaluate the effects of a music therapy intervention for premature infants hospitalized in a newborn intensive care unit (NICU). The purpose of the project is to learn whether providing music therapy during the infant's stay in the NICU will reduce stress and have immediate effects on infant behavior, heart rate, oxygen saturation level, and oxygen requirements. Another purpose is to assess parent's and nurse's responses to music therapy. However, the findings from previous research about the benefits of music therapy have not been consistent, and therefore we need to do this study to find out whether providing music therapy in the NICU has benefits for the baby.

At present, infants in the NICU are receiving music therapy as part of their care. If you agree to participate in this project, your child will continue to receive the same music therapy that he/she is already receiving but will be observed at four different times by a research nurse. Regardless of your decision, there will be no change in the NICU policies regarding family visits or regarding the type of interaction that family members might provide to their babies.

1. On two different days your baby will be observed for 35 minutes. Your baby will be observed for 10 minutes before the start, during the 15 minutes, ten minutes after the completion of the music therapy.
2. On two other days your baby will be observed for 35 minutes while there is no music therapy in session.
3. Before any music therapy is started, the music therapist checks with the nurse to make sure there are no babies that cannot have the music therapy.
4. A researcher will record your baby's behaviors during the 35 minutes of observation. At the same time, your infants' heart rate, oxygen saturation level, and need for oxygen will be recorded. A researcher will record information from the baby's medical record.

Parent/Legally Authorized Representative Initials ____

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5. You will be asked to participate in a one time 15-30 interview with the researcher either in person or by phone. The researcher will contact you to discuss how you feel about the music therapy that your baby has received. This interview will be taped so that your answers can be written down exactly as you say them.

Risks and Discomforts

We will be collecting data from observation that is already part of your baby's care in the NICU, so we will not be exposing your baby to any additional stimulation or risk. We will collect information about your baby's responses using the monitors that are already in place on the baby, so will not have to attach any additional monitors or use any tape to secure the monitors.

Benefits

There is a possibility that babies who receive music therapy may benefit by having reduced activity levels, increased oxygen saturation levels, and a decrease in oxygen requirements. It is possible that participants may not personally benefit from participating in this research study.

Alternatives

You have the alternative to not participate in this observation study. However, music therapy will continue as a part of your baby's care.

Confidentiality

All information collected for this project will be treated confidentially. No names will be recorded on any data that are collected. Audiotapes and other data collection materials will be stored in a locked cabinet in the University of Alabama School of Nursing and destroyed 3 years after the end of the study. This informed consent document will be placed in and made part of your baby's permanent medical record at the University of Alabama at Birmingham Hospital. All records related to this study could be reviewed by the UAB Institutional Review Board (IRB).

New Findings

If any significant new findings are identified during the course of the study related to the risks and benefits of music therapy, you will be notified of these findings. Significant new findings that develop during the course of the research that may relate to your willingness to continue your participation in this study will be provided to you.

Withdrawal Without Prejudice

Your decision about whether to take part in this study is voluntary and will not affect your baby's hospital care. You may withdraw from this project at any time.

Parent/Legally Authorized Representative Initials ____

Costs of Participation in Research

There will be no cost to you for participating in this research. The costs of standard medical care for your baby will be billed to you and/or your insurance company.

Payment for Participation in the Research

No payment will be made for participation in this study.

Payment for Research-Related Inquires

UAB makes no provision for monetary compensation in the event of physical injury resulting from the research and in the event of such injury, medical treatment is provided, but is not provided free of charge.

Questions

If you have any questions about the research or a research related injury, Ashley Hodges Wood, MSN, RNC, MA, or Lynda Harrison, RN, PhD will be glad to answer them. You may reach Mrs. Wood or Dr. Harrison at (205) 934-6787. If you have any questions about your rights as a research participant, you may contact Ms. Sheila Moore, Director of the Office of Institutional Review Board for Human Use (IRB). Ms. Moore may be reached at (205) 934-3798 or 1-800-822-8816, press the option for an operator/attendant and ask for extension 4-3789 between the hours of 8:00 a.m. and 5:00 pm CT, Monday through Friday.

Parent/Legally Authorized Representative Initials ____

Legal Rights

I understand that I am not waiving any of my legal rights by signing this consent form.

AGREEMENT

I have received a signed copy of this participation agreement form. My signature below indicates I agree to participate in this study.

The assent of the child, ____________________(name of child) was waived because of age.

____________________________________ ____________
Signature of Parent or Legally Authorized Representative Date

____________________________________ ____________
Signature of Investigator or Person Obtaining Consent Date

____________________________________ ____________
Signature of Witness Date

University of Alabama at Birmingham
tion for Use/Disclosure of Health Information
for Research

What is the purpose of this form? You are being asked to sign this form so that UAB may use and release your health information for research**.** Participation in research is voluntary. If you choose to participate in the research, you must sign this form so that your health information may be used for the research.

Participant name: ______________________
UAB IRB Protocol Number: F050405012
Research Protocol: Effects of Music Therapy on Preterm Infants, Parents, and Nurses
Principal Investigator: Ashley Hodges Wood, MSN, RNC, MA
Sponsor**:** UAB School of Nursing

What health information do the researchers want to use? All medical information and personal identifiers including past, present, and future history, examinations, laboratory results, imaging studies and reports and treatments of whatever kind related to or collected for use in the research protocol.

Why do the researchers want my health information? The researchers want to use your health information as part of the research protocol listed above and described to you in the Informed Consent document.

Who will disclose, use and/or receive my health information? The physicians, nurses and staff working on the research protocol (whether at UAB or elsewhere); other operating units of UAB, HSF, The Children's Hospital of Alabama, Callahan Eye Foundation Hospital and the Jefferson County Department of Public Health, as necessary for their operations; the IRB and its staff; the sponsor of the research and its employees; and outside regulatory agencies, such as the Food and Drug Administration.

How will my health information be protected once it is given to others? Your health information that is given to the study sponsor will remain private to the extent possible, even though the study sponsor is not required to follow the federal privacy laws. However, once your information is given to other organizations that are not required to follow federal privacy laws, we cannot assure that the information will remain protected.

How long will this Authorization last? **Your authorization for the uses and disclosures described in this Authorization does not have an expiration date.**

Can I cancel the Authorization? **You may cancel this Authorization at any time by notifying the Director of the IRB, in writing, referencing the Research Proto-**

col and IRB Protocol Number. If you cancel this Authorization, the study doctor and staff will not use any new health information for research. However, researchers may continue to use the health information that was provided before you cancelled your authorization.

Can I see my health information? **You have a right to request to see your health information. However, to ensure the scientific integrity of the research, you will not be able to review the research information until after the research protocol has been completed.**

Signature of participant: ____________________________

Date:

or **participants' legally authorized representative:______________________**

Date:

Printed Name of participant's representative: _______________________

Relationship to the participant: _____________________________________

Revision Date: April 25, 2005

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APPENDIX F

PHYSIOLOGIC AND BEHAVIORAL CODING SHEET

Appendix F

Today's Date:____
Infant Code___________ Intervener: Code________
Session Number (1, 2, 3 or 4) _____Time at Beginning of Baseline _______
Session : _____No Music _____ Music
Period (Check One) ____ Baseline ____ Music (Control) ____ Post ____
Number of Visitors at Bedside ______
Number of Staff in Nursery Area at End of Obs _____

	0.5	1.0	1.5	2.0	2.5	3.0	3.5	4.0	4.5	5.0	5.5	6.0	6.5	7.0	7.5	8.0	8.5	9.0	9.5	10	T %
Sound Level at Baby's Head																					
Sound Level Outside Isolette																					
Oxygen Concentration																					
Oxygen Saturation																					
Heart Rate																					
I. Behavioral State (√ one only)																					
1. Quiet																					
2. Active Sleep																					
3. REM Sleep																					
4. Drowsy																					
5. Alert Inactive																					
6. Awake Active																					
7. Fuss/Cry																					
II. Motor Activity (√ all)																					
1. Single Limb Movement																					
2. Multiple Limb Movement																					
3. Gross Body Movement																					
4. Head Turn/Movement																					
5. Startles																					
III. Behavioral Distress (√all)																					
1. Hiccough																					
2. Facial Grimace																					
3. Finger Splay																					
4. Clenched Fists																					
5. Crying																					
6. Fussing																					
7. Spitting																					
8. Vomiting																					

APPENDIX G

DEMOGRAPHIC DATA SHEET

Appendix G

Infant Code: ______

Birth date: ______

Gestational Age at Birth (weeks): _____

Birth weight (grams): _________ Mother’s Age: ____

Apgar: 1 minute ____ 5 minutes _____ C-section:___ Yes ____ No

Infant's Gender: ___ Female ____ Male

Infant's Race: ____ White ___ Black ___Other

Birth Order: __ Singleton ____Twin ____Triplet ___Other

Did parents provide auditory stimulation prenatally? Yes___ No___

Resuscitation Requirement at Birth:

3 - Cardiac arrest or prolonged attempts at resuscitation at birth or during transfer, with APGAR less than 5 at age 5 minutes.

2 - Baby experienced some respiratory difficulty at or soon after birth, but was easily resuscitated. APGAR was less than 5 at age 5 minutes.

1 - Baby required resuscitation (including supplemental oxygen) at or soon after birth, but 5-minute APGAR was greater than 5.

APPENDIX H

DAILY DATA COLLECTION (DDC) SHEET

Appendix H

Infant Code: ________

DATE _______

Total Morbidity Score: ___________

Infection (√ if yes) (culture pos) ___________

Weight Today: (grams) ___________

Sedatives (√ if yes) ___________

Antibiotics (√ if yes) ___________

Steroids (√ if yes) ___________

Aminophylline/Caffeine (√ if yes) ___________

Apnea w/brady episodes: ___________
(indicate number in past 24 hours prior to observation)

Apnea episodes without brady: ___________
(indicate number in past 24 hours prior to observation)

APPENDIX I

QUANTITY OF STIMULATION SCALE (QSS)

Appendix I

(Check no. of occurrences for each procedure during the 2 hr prior to the intervention).
Code # __________________ Date ____________________

Stimulus	Check each Occurrence
1. Suctioning (endotracheal, oral, or nasopharyngeal)	___________
2. X-ray taken	___________
3. Umbilical artery catheter inserted	___________
4. Needle stick (e.g. for venipuncture, heel stick, or injection)	___________
5. NG/OG tube inserted	___________
6. Lumbar puncture performed	___________
7. Infant reintubated	___________
8. Chest physiotherapy performed	___________
9. Infant stimulated because of apnea or bradycardia	___________
10. Chest tube inserted or removed	___________
11. IV removed	___________
12. EEG, echocardiogram, or ultrasound performed	___________
13. Infant circumcised	___________
14. Infant weighed and/or bathed	___________
15. OT intervention	___________
16. Physical examination	___________
17. Held	___________
18. Feeding	___________
TOTAL SCORE	___________