

MUSIC AS A HEALTH PATTERNING MODALITY FOR PRETERM INFANTS
IN THE NICU

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Abstract

Preterm birth is on the rise causing neonatal mortality and is a major determinant of early childhood mortality and morbidity in the United States. Numerous preterm infants suffer from neurological disability including cerebral palsy; visual and hearing impairments; learning difficulties; and, psychological, behavioral, and social problems. This increasing incidence of prematurity, prevalence of significant morbidity, and burden to society, both personal and cost-related, make it *imperative to identify developmental care strategies such as music that might reduce this burden.*

This study integrates the work of music therapy, neuroscience, audiology, and medicine with nursing to address the uncertainty regarding the effect of music as a holistic health patterning modality and discover if preterm infant physiological and neurobehavioral state responses to music and ambient noise are different. The goal of this study was to establish a foundation for further research related to the use of music with preterm infants and to address the issue of safety in providing music as a health patterning modality for this population.

Forty-one clinically stable, non-ventilated, appropriate-for-gestational-age (AGA) preterm infants from 32 to 35 weeks gestation in a large, urban Midwest Children's Hospital NICU were included in this study. An interrupted time-series design with repeated measures was used to explore the health patterning responses of preterm infants to an intentionally designed music intervention of recorded piano music. The effect of the music was measured every 30-seconds before, during, and after the sound condition of music or ambient noise by observing the oxygen saturation, heart rate, and behavioral

state of randomly assigned preterm infants in the NICU in relation to a control group in which no music (only standard NICU care with recorded ambient noise) was provided.

Mixed modeling was used to look at how preterm infant responses varied over time as well as changes between music and ambient noise groups of infants. Although there were no significant differences between group responses over the three time periods, there were significant changes in individual infant oxygen saturations, heart rates, and behavioral states over time. Infant oxygen saturations did not change significantly in the 10 minutes before the sound ($p = .97$) or during the 20 minutes of sound ($p = .75$); however, preterm oxygen saturation decreased significantly in the 10 minutes after presentation of the sound conditions ($p = .004$). Infant heart rates did not change significantly before the sound ($p = .71$) or during the sound ($p = .54$); however, preterm heart rate changes after the sound conditions approached significance by increasing during the 10 minutes after the sound conditions ($p = .07$). Infant behavioral states changed significantly before the sound as infants went from a state of active sleep to quiet sleep ($p = .04$) and after the sound as infants became slightly more aroused going from quiet sleep to active sleep ($p = .05$). There were no significant preterm infant behavioral state changes over the time period during the sound conditions ($p = .22$).

Infants listening to music and those listening to ambient noise recorded from the inside of an incubator all exhibited changes in oxygen saturations, heart rates, and behavioral states during the three time periods and variability in those changes; however, these responses remained within normal limits. Findings from this study demonstrated that preterm infants in a NICU did not have adverse reactions to a carefully designed music intervention.

Table of Contents	Page
Acknowledgements	i
Abstract	ii
Table of Contents	iv
List of Tables	viii
List of Figures	ix
Chapter 1: Introduction	1
Conceptual Framework	5
The Concept of Patterning	5
Evolution of Patterning in Nursing	7
Health Patterning	8
Conceptual Model	9
Research Aim and Hypotheses	12
Background of the Study	12
The Problem of Prematurity	12
Purpose and Significance of the Study	13
Chapter 2: Literature Review	16
Research on the Impact of Infant Stimulation	17
Research on Noise and Music Interventions for Preterm Infants	21
Nursing Research on Preterm Infant Developmental Care	31
Research Related to Health Patterning in Nursing	33
Research Related to Health Patterning of Preterm Infants	35

Conclusions Drawn From Research Related to Preterm Infants and Music	38
Chapter 3: Methodology	40
Research Design	40
Design Rationale	41
Justification for the Design	47
Strengths and Weaknesses of the Design	48
Sample	49
Setting	50
Sampling and Recruitment Procedures	50
Study Protocol	52
Supply and Equipment Set-Up	52
Data Collection	53
Data Collection Methods and Rationale	54
Strengths and Limitations of Data Collection Methods	56
Data Analysis Procedures	56
Analysis of Descriptive Data	58
Analysis of Dependent Measures	58
Ethical Considerations	59
Protection of Human Subjects	60
Gender and Minority Inclusion	61

Chapter 4: Results	64
Demographic Data	64
Infant Past Medical Conditions	69
Risk Factors Related to Prematurity	70
Current Medications	73
Room Sound Level	74
Intervention Data	75
Results of Analysis by Hypotheses	76
Oxygen Saturation	76
Heart Rate	78
Behavioral State	80
Gender Differences	83
Results of Analysis by Individual Differences in Preterm Infant Responses	83
Oxygen Saturation	83
Heart Rate	84
Behavioral State	85
Examples of Individual Infant Graphs	86
Maternal Report of Music Exposure During Pregnancy	98

Chapter 5: Discussion	100
Discussion of Results by Hypotheses	100
Oxygen Saturation	101
Heart Rate	103
Behavioral State	106
Gender Differences	108
Study Limitations	108
Conclusions and Recommendations for Further Research	111
Conclusions	111
Recommendations for Further Research	112
Investigator Impressions	117
Implications for Nursing Practice	118
References	122
Appendix A: Literature Supporting Use of Music With Preterm Infants	147
Appendix B: Research Evaluation Checklist	150
Appendix C: Nursing Research Within a Nursing Model on Health Patterning Modalities	152
Appendix D: Studies Related to the Patterning of Preterm Physiological Responses (2000 to 2004)	155
Appendix E: Research Consent Form	158
Appendix F: Data Safety Monitoring Plan	161

List of Tables	Page
Table 1. Critique of Studies Using Music with Preterm Infants	4
Table 2. Stoplight: A Guide for Understanding Infant Behavioral Responses to Stimulation	44
Table 3. Sample Inclusion/Exclusion Preterm Infant Criteria	51
Table 4. Hypotheses/Data Analyses	57
Table 5. Targeted/Planned Enrollment	62
Table 6. Race/Ethnicity and Gender Data From 2006 Through March 2008	63
Table 7. Race/Ethnicity and Gender Data For Study Infants	63
Table 8. Demographic Characteristics of the Sample	68
Table 9. Past Medical Condition of the Sample	70
Table 10. Risk Factors of the Sample	73
Table 11. Current Medications of the Sample	74
Table 12. Room Sound Level of the Sample	75
Table 13. Results of t-tests Comparing Music and Ambient Noise Group Oxygen Saturation Means	77
Table 14. Results of t-tests Comparing Music and Ambient Noise Group Heart Rate Means	79
Table 15. Results of t-tests Comparing Music and Ambient Noise Group Behavioral State Means	82
Table 16. Music Exposure During Pregnancy	99

List of Figures	Page
Figure 1. Depiction of Prigogine's theory of dissipative structures	7
Figure 2. Conceptual model for music as a health patterning modality	11
Figure 3. Health patterning conceptual framework	37
Figure 4. Health patterning of preterm infants during NICU hospitalization	37
Figure 5. Design: Interrupted Time-Series Design With Repeated Measures	40
Figure 6. Graph Comparing Oxygen Saturations for Music and Ambient Noise Groups	77
Figure 7. Graph Comparing Heart Rates for Music and Ambient Noise Groups	80
Figure 8. Graph Comparing Behavioral States for Music and Ambient Noise Groups	82
Figure 9. Music Infant 04 Graph	88
Figure 10. Music Infant 12 Graph	89
Figure 11. Music Infant 30 Graph	90
Figure 12. Music Infant 41 Graph	91
Figure 13. Ambient Noise Infant 03 Graph	93
Figure 14. Ambient Noise Infant 19 Graph	94
Figure 15. Ambient Noise Infant 05 Graph	95
Figure 16. Ambient Noise Infant 39 Graph	97
Figure 17. Music Exposure During Pregnancy	99

Chapter 1

INTRODUCTION

Each year over 500,000 families in the United States (U.S.) experience the birth of a preterm infant (National Center For Health Statistics, 2005). Preterm infants are those born after the beginning of the 20th week of gestation and before the end of the 37th week. Despite significant advancements in the care of preterm infants during the past 40 years, these infants still have high rates of subnormal growth, illness, and neurodevelopmental deficits (Colvin, McGuire, & Fowlie, 2004; Martin, Hamilton, Sutton, Ventura, Menacker, & Munson, 2003).

Investigators have demonstrated that providing appropriate stimulation to preterm infants is necessary for their growth and development and that lack of appropriate infant stimulation negatively affects physiological and neurobehavioral functioning (Gardner & Goldson, 2006; Wood, Marlow, Costeloe, Gibson, & Wilkinson, 2000). Music is a form of sound stimulation that has been found to enhance physiological and behavioral health patterning in many populations including preterm infants. For example, a meta-analysis of the efficacy of music therapy for preterm infants showed an overall large, significant, consistent effect size suggesting that music has statistically significant physiological and neurobehavioral benefits for preterm infants (Standley, 2002).

One avenue of research has involved the presence and attributes of sound in the neonatal intensive care unit (NICU) and its effects on neonatal health. Studies have investigated the role of ambient sound in the NICU and the effects of deliberately introduced sound, in the form of music, on neonatal development. Although there is

general agreement that noise in the NICU should be reduced, there is controversy about the use of music as a developmental care strategy with preterm infants. Much literature supports using music with preterm infants indicating that it provides clinically important benefits for them, but some experts worry that music is overstimulating for NICU infants (Bremmer, Byers, & Kiehl, 2003; Graven, 2000; Philbin, 2000). Others maintain that music reduces stress behaviors and physiological instability (Butt & Kisilevsky, 2000; Cassidy & Standley, 1995; Coleman, Pratt, Stoddard, Gerstmann, & Abel, 1997; Collins & Kuck, 1991; Standley & Moore, 1995) and enhances the physiological and neurobehavioral functioning of these infants (Caine, 1991; Cassidy & Standley; Coleman et al.; Collins & Kuck; Standley, 1998; Standley, 2000; Standley, 2003b; Standley & Moore; Whipple, 2000). See Appendix A.

Those who caution against the use of music with preterm infants are concerned that music further increases the high levels of sound in the NICU and do not make a distinction that music is different from noise or ambient sound (environmental noise normally experienced by a preterm infant during standard care in a NICU). It is important to make distinctions between sound, noise, and music. According to the American Academy of Pediatrics (1997), sound is vibration in a medium, usually air, and has intensity (loudness), frequency (pitch), periodicity, and duration. The intensity of sound is reported in decibels (dB) and the frequency is measured in hertz (Hz), which is sound vibration in cycles per second. Hearing has been defined as the ability to discriminate between sounds of different intensities, frequencies, and duration (Hall, 2000a).

The normal range of human adult hearing is between 20 and 20,000 Hz and comfortable sound levels for adults are from about 60 to 80 dB (Gray, 2000). The auditory

range of preterm infants born in the last trimester (25 to 37 weeks gestation) is from 500 to 1,000 Hz (Roeser, 1996). Although it is not possible to determine comfortable sound levels for preterm infants, maintaining a constant sound level between 60 and 65 dB is recommended in a meta-analysis on music research with preterm infants (Standley, 2002). Researchers who advocate limiting sound levels in the NICU recommend sound levels below 55 dB (Gray).

Noise is non-patterned sound of irregular frequency containing inconsistencies of tension (build up of volume and tempo in a musical phrase), stress (emphasized beats in a measure), and configuration. In contrast, most musical sounds are rhythmic and formatted, although some music may be considered noise. Music encompasses high-frequency acoustic content and patterned sounds consistent with those in the intrauterine environment (Jourdain, 2002). Noise is a sound comprised of many frequencies that may be undesirable and annoying, and it may negatively affect preterm infants (Bremmer, Byers, & Kiehl, 2003; Graven, 2000; Gray, 2000; Philbin, 2000). Researchers specify that infant responses to patterned music are different than their responses to non-patterned noise. These researchers point to studies from music therapy, medicine, audiology, the neurosciences, and nursing, which describe the acoustic properties of music as dissimilar from noise (Griffiths, 2003; Jourdain; Patterson, Uppenkamp, Johnsrude, & Griffiths, 2002; Wagner, 1994).

Critics assert that much of the research into music intervention with preterm infants is not scientifically rigorous for reasons that involve the treatment guidelines and protocols, adequacy of data collection and analysis, failure to consider gender, and other

factors (Bremmer, Byers, & Kiehl, 2003; Graven, 2000; Morris, Philbin, & Bose, 2000; Philbin, 2000; Philbin & Klaas, 2000). See Table 1. Nevertheless, evidence that supports using music with preterm infants is substantial and must be considered and further tested.

Table 1. Critique of Studies Using Music with Preterm Infants

Critique	Study
1. Don't include adequate sample sizes	Bremmer et al., 2003; Graven, 2000; Morris et al., 2000; Philbin, 2000; Philbin & Klaas, 2000
2. Neglect to incorporate random selection	Philbin, 2000; Philbin & Klaas, 2000
3. Lack carefully controlled subject groupings	Philbin, 2000
4. Don't integrate established audiological information	Philbin, 2000; Philbin & Klaas, 2000
5. Don't report effects of stimulus on infant vital signs, movement, and behavioral state	Philbin, 2000; Philbin & Klaas, 2000
6. Neglect to describe sound levels in the NICU	Philbin, 2000; Philbin & Klaas, 2000
7. Disregard information about acoustical properties of stimulus	Philbin, 2000
8. Lack substantive theoretical basis in basic science or animal studies	Bremmer et al., 2003; Graven, 2000; Philbin, 2000; Philbin & Klaas, 2000
9. Have potential for investigator bias in data collection	Philbin, 2000
10. Include inadequate data analysis	Philbin, 2000
11. Attribute benefits not supported by data	Philbin, 2000
12. Don't investigate possible adverse effects of stimulation intervention	Philbin, 2000
13. Are isolated phenomenological reports based on the assumption that a particular kind of auditory stimulus will benefit preterm infants	Bremmer et al., 2003; Graven, 2000; Philbin, 2000; Philbin & Klaas, 2000

Carefully implemented studies regarding the use of music as a health patterning modality with preterm infants are needed with rigorous methodological designs based on research, critiques, and recommendations derived from music therapy, medicine, neuroscience, audiology, and nursing.

Conceptual Framework

The Concept of Patterning

Patterning can be used as a conceptual framework within which to view the health patterning of preterm infants as evidenced by their physiological functioning and behavioral state organization. Patterning has been associated with health, situations, ideas, information, disease, behavior, interactions, and relationships. Newman (1994) asserts that viewing a pattern within a larger pattern can help us see the whole picture or activity of the entire system. She further states that an awareness of and searching for information related to patterning is necessary before pattern identification takes place and, because patterning occurs over time, action or movement is required for recognition or knowledge of the changes in pattern (Newman, 1995). Variations that facilitate recognition of the pattern include: contrasts such as light and dark or loud and soft; time frames such as observing variations in the patterning of a patient's temperature over the course of a day or blood pressure throughout hospitalization; and increases in distance such as viewing a maze from above (Newman, 1994). Patterning may also refer to manifestations of the physical body and behavior of a person at multiple points in time (Gulick & Bugg, 1992).

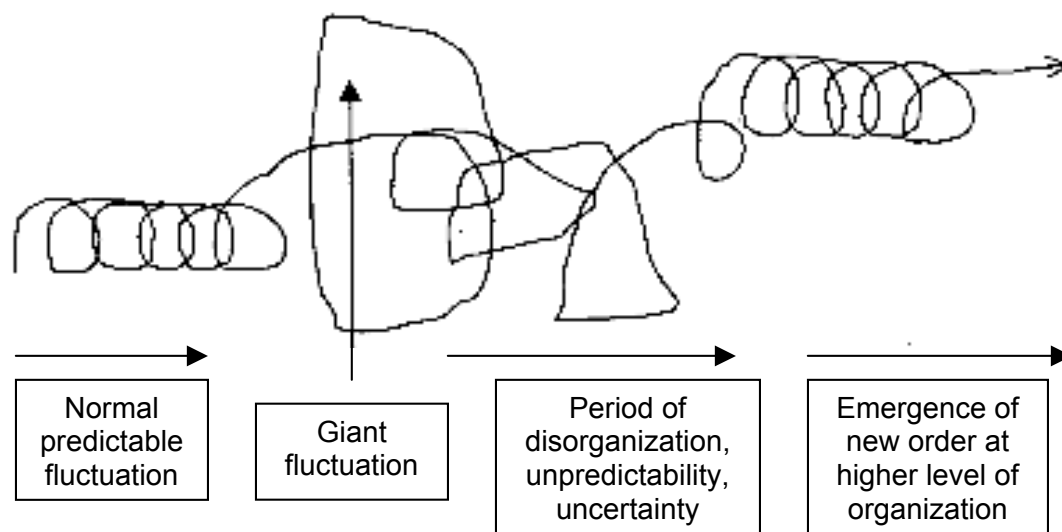
Both Rogers (1970, 1990) and Newman (1994, 1995, 2002) describe patterning of the whole person as the identifying characteristic of a person's wholeness emphasizing

that the parts cannot stand alone as separate. Separate parts may appear to be very different from each other and unrelated until they are viewed together in relation to one another.

Drawing upon the work of David Bohm (1980), Newman (1994, 1995) contends that patterning is the explicate manifestation of the underlying pattern, portrays the whole, and evolves over time. For example: patterning, as in genetic pattern, identifies enduring unique features or characteristics of particular people distinguishing them across their lifespan and directs their becoming such as in voice and movement pattern. Newman further asserts that the fundamental aspects of patterning include connectedness, context, and time with characteristics of movement, diversity, and rhythm. These basic attributes of patterning are rooted in Bateson's (1979) central thesis of the "pattern which connects" emphasizing pattern as meaning within context over time. Each pattern of the person-environment interaction is time-specific and contains information enfolded from the past that will unfold in the future. The diverse parts are constantly in motion or changing in relation to each other in a rhythmical movement. Newman suggests that recognition of this movement and its action potential provides the framework for nursing practice.

The process of patterning illustrated by Newman was drawn from the work of Ilya Prigogine (1976). According to Prigogine's theory of dissipative structures, a system continues to fluctuate in an orderly manner until some disruption occurs (e.g., stress, unrest, discomfort, pain, illness, overstimulation, disorganization, a disrupted state, restrictions in movement, etc.) from which the system begins to move in a chaotic, disrupted, seemingly random way until a point in which it transcends to a higher level of organization where it again fluctuates in an orderly manner (see figure 1).

Figure 1. Depiction of Prigogine's theory of dissipative structures



Adapted from: Newman (1994, p.38)

Evolution of Patterning in Nursing

Patterning is rooted in the discipline of nursing and follows from the historical development of nursing knowledge. Early development of nursing knowledge was primarily focused on physical environmental factors affecting the health of the patient and physical care of the patient (Newman, 2002). Florence Nightingale, the founder of modern nursing, treating the sick and improved public health by placing the individual in the best possible condition for nature to act (by manipulating the environment to promote rest, fresh air, clean room, nourishing food, etc.). In the Crimean War, she halved the mortality rate with this kind of care and her concepts of quiet, warmth, ventilation, cleanliness, and diet are still integral to nursing and health care today. Furthermore, she was the first to use music as a health patterning modality to help the recovery of sick soldiers during the war (Jonas-Simpson, 1997). Next, the emphasis was on the actions of the nurse in stabilizing and assisting patients during physical disability and the

interpersonal process of the nurse-patient relationship (Newman, 2002). A holistic, integrative approach followed in which patients were viewed as multidimensional within the context of their environment (Newman, 2002). Finally, Rogers (1970) introduced a unitary, dynamic perspective shifting the focus to a self-organizing human being (human field) embedded in a large self-organizing universe (environmental field) identified by pattern and interaction with the larger whole (Newman, Sime, Corcoran-Perry, 1991).

This shift initiated a transformative, dynamic model of nursing by a nurse theorist task force, which produced a unitary view of the pattern of person-environment interaction (Newman, 2002). In 1977, a nurse theorist group facilitated by Sister Callista Roy began work on a conceptual, organizing framework for nursing practice (NANDA International, 2005). In 1982, Dr. Roy and other prominent theorists (e.g., Margaret Newman, Martha Rogers, Dorothea Orem and Imogene King) presented the organizing framework for nursing diagnoses called Patterns of Unitary Man (Humans) to the North American Nursing Diagnosis Association (NANDA) and the Taxonomy Committee (NANDA International). Patterning was conceptualized as the basis for nursing diagnosis in the framework and the relationship between the parts or entities was identified as being of key importance (Newman, 1994, 1995, 2002). This NANDA health assessment framework rooted in unitary person-environment patterns of interaction is currently used in nursing practice as a guide for assessment that helps nurses collect data on human health responses in order to facilitate patient health pattern recognition (Carpenito-Moyet, 2008).

Health Patterning

Health patterning is defined as nurses assisting clients with changes in their health in relation to two processes: (a) pattern manifestation appraisal (or recognition), which is a

continuous process of identifying indicators of human and environmental fields related to current health events, and (b) deliberative mutual planning, whereby nurses support clients in patterning environmental fields using interventions to promote harmony related to health events (Barrett, 1988, 1990). Health patterning of individuals and groups has been associated with physiological and psychological responses and has been appraised within different health care areas such as acute care, home care, surgery, obstetrics, mental health, and oncology as well as throughout the lifespan from pediatric to gerontological care (Good, 1995; Hagemaster, 2000; Hernandez, 1998; Madrid, 1996; McBride, Graydon, Sidani, & Hall, 1999; Peck, 1997; Peck, 1998; Wiand, 1997).

A variety of modalities have been used as interventions for affecting health patterning in clients including meditation, imagery, laughter, affirmations, music imposed motion/ movement/dance, breathing/rest/relaxation approaches, descriptive dream experiences, therapeutic touch, poetry, drawing, color, light, and sound (Biley, 1996b; Good, 1995; Green, 1998; Hagemaster, 2000; Hernandez, 1998; Madrid, 1996; McBride et al., 1999; Peck, 1997, 1998; Wiand, 1997). Several recent studies point to music as an intervention that provides clinically important benefits to preterm infants in the NICU (Butt, 2000; Standley, 1998, 1999, 2000, 2002, 2003b; Whipple, 2000).

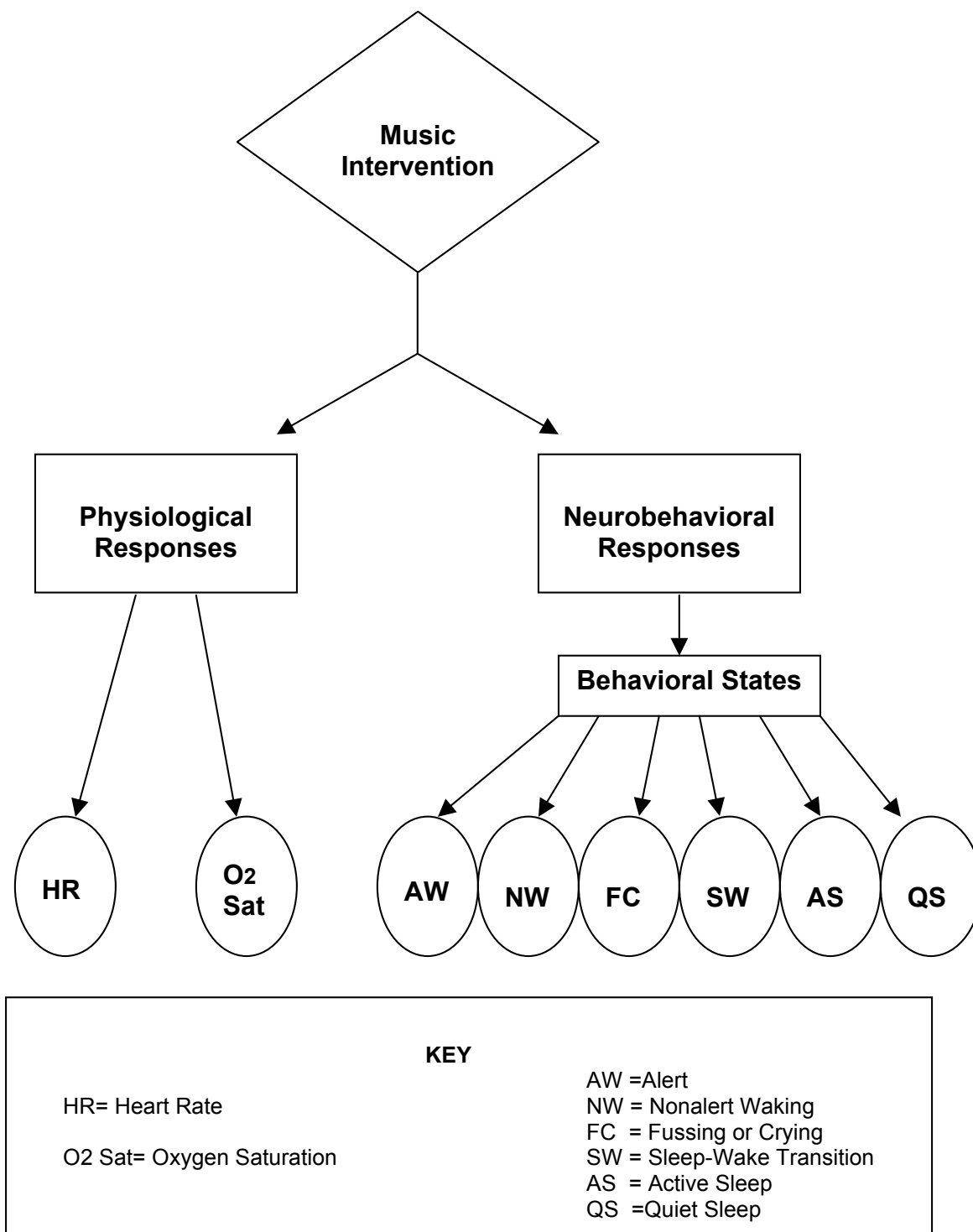
Conceptual Model

The conceptual model that will guide this study is a physiological and neurobehavioral schema based upon Newman's conceptual framework of patterning. Research from the disciplines of music therapy, neuroscience, audiology, medicine and nursing was used to design a music intervention and protocol to discover if preterm infant

responses to music and ambient noise are different. The model will be used to examine the health patterning of preterm infants in the form of physiological and behavioral state responses of the infants to a nursing intervention of recorded music. The responses of the preterm music intervention group will be compared with the responses of a preterm infant control group to recorded ambient noise to discover if the responses of the two groups of infants are similar or significantly different.

The physiological responses to be measured include two physiological characteristics and one neurobehavioral characteristic of preterm infants believed to be directly affected by the nursing intervention of music. The physiological variables include: oxygen saturation and heart rate. The neurobehavioral variable is composed of the following behavioral states from Thoman's Derived States behavioral classification scheme (1990): (a) alert, (b) nonalert waking, (c) fussing or crying, (d) sleep-wake transition, (e) active sleep, and (f) quiet sleep (see figure 2).

Figure 2. Conceptual model for music as a health patterning modality



Research Aim and Hypotheses

The specific aim of the proposed study and associated null hypotheses include:

Compare the effects of selected recorded music with the effects of ambient noise on the physiological and behavioral state responses of preterm infants in the NICU.

H₀₁: There will be no significant differences in oxygen saturations between the music intervention group and ambient noise control group

H₀₂: There will be no significant differences in heart rates between the music intervention group and ambient noise control group

H₀₃: There will be no significant differences in behavioral states between the music intervention group and ambient noise control group

Background of the Study

The Problem of Prematurity

The preterm birth rate has increased 21 percent in the U.S. in the past 16 years and is now 12.8 percent of live births (Hamilton, Martin, & Ventura, 2006). Preterm birth is currently the leading cause of neonatal mortality and the major determinant of early childhood mortality and morbidity in the U.S. (Green, Damus, Simpson, Iams, Reece, Hobel, et al., 2005; Hamilton et al., 2006). The cost (medical, educational, and lost productivity) associated with preterm birth in the U.S. was at least \$26.2 billion in 2005 (March of Dimes, 2006). Infant hospital costs related to prematurity were \$15.5 billion in 2002 (Green et al.). The period between 20 and 32 weeks after conception is especially critical as it is one of rapid brain growth and development; so illness, undernutrition, and

infection during this time may compromise neurodevelopment (Colvin, McGuire, & Fowlie, 2004).

Although the survival rate for extremely preterm infants has improved over the past decade, the overall prevalence of neurological disability (including cerebral palsy; visual and hearing impairments; learning difficulties; and, psychological, behavioral, and social problems) after preterm birth has not fallen (Colvin et al., 2004). This increasing incidence of prematurity, prevalence of significant morbidity, and burden to society, both personal and cost-related, make it imperative to identify developmental care strategies and health patterning modalities such as music that might reduce this burden. Research related to the use of music with preterm infants is necessary because of continued uncertainty regarding the safety and efficacy of using music with these infants in the NICU despite some demonstrated benefits of music in reducing the pervasiveness and severity of problems associated with prematurity.

Purpose and Significance of the Study

This study integrates the work of music therapy, neuroscience, audiology, and medicine with nursing to address the uncertainty regarding the effect of music as a holistic health patterning modality and discover if preterm infant responses to music and ambient noise are different. The focus is to compare the physiological and behavioral state responses of preterm infants from 32 to 35 weeks gestation during intentionally designed recorded music with responses during recorded ambient noise in the NICU. The objective is to address the concerns of those skeptical about the use of music with preterm infants.

The long-term goal of this study is to demonstrate the safety and efficacy of music as a health patterning modality that enhances physiological functioning and neurobehavioral organization in preterm infants. Another long-term goal is to establish a foundation for further research into the developmental impact of music in these infants. Such evidence would strengthen the case that music is not harmful and may provide physiological and neurobehavioral benefits for preterm infants in the NICU. The proposed research question is: Are there differences between the physiological and behavioral state responses of preterm infants receiving a nursing intervention of recorded music as compared to the responses of those listening to recorded ambient noise in the NICU?

This study is important because of continued uncertainty regarding the safety and efficacy of music with preterm infants in the NICU (Neal, 2008). While there is general agreement that noise in the NICU should be reduced, there is ambiguity about the use of music with preterm infants. Much literature supports the use of music with preterm infants; however, some researchers believe that music may overstimulate these infants, while others believe that it will enhance physiological and neurobehavioral functioning.

Although many studies have found that music interventions provide physiological and neurobehavioral benefits for preterm infants, much of the research has not included: (a) adequate sample sizes, (b) random selection, (c) carefully controlled subject groupings, (d) standardized guidelines for implementation of the intervention, (e) an investigation of gender differences, or (f) comprehensive utilization of scientific information from neuroscience and audiological studies. Also, many music intervention studies: (a) neglect to disclose of the medical history of subjects, (b) fail to report environmental sound levels, (c) have a potential for investigator bias, (d) lack clear description of measurement

methods, (e) include inadequate data analysis, (f) do not investigate possible adverse affects of the stimulation intervention, and (g) attribute benefits not supported by the data (Table 1).

Lack of methodological rigor in research with preterm infants may lead to unsafe practices. The danger is intensified when there are strong beliefs about practices not scientifically tested through research. This study will address shortcomings in previous research to discover if preterm health patterns (as measured by vital signs and behavioral state) are different when exposed to music as compared to infant responses to ambient noise. These findings will help to determine whether there are key physiological and behavioral state benefits of a carefully implemented music intervention with this population.

Chapter 2

LITERATURE REVIEW

Chapter One introduced the problem of prematurity and the controversy over using music with preterm infants in the NICU. Chapter One also introduced patterning as a conceptual framework within which to view the health patterning of preterm infants. Chapter Two explores the literature to provide greater depth about: (a) infant growth and development, (b) research related to infant stimulation, (c) acoustical differences between noise and music, (d) scientific knowledge about music and its impact on infants from music therapy, audiology, and neuroscience together with information pertaining to the developmental care of preterm infants from medicine and nursing, and (e) research involving the use of music as a health patterning modality with preterm infants.

Following this review, health patterning is described as a concept within nursing and a conceptual framework for health patterning of preterm infants during NICU hospitalization is detailed. Conclusions drawn from research associated with preterm infants and music will complete this chapter and are key to the methodology of research using music as a health patterning modality for preterm infants in the NICU presented in Chapter Three. The chapter is arranged as follows:

- Part One: Research on the impact of infant stimulation
- Part Two: Research on noise and music interventions for preterm infants
- Part Three: Nursing research on preterm infant developmental care
- Part Four: Research related to health patterning in nursing
- Part Five: Research related to health patterning of preterm infants

Research on the Impact of Infant Stimulation

In utero, stimulation of the fetus is continuous and key to the development and maturation of the central nervous system, one of the first systems to begin developing and one of the last to complete significant development after birth (Gardner & Goldson, 2006; Hockenberry, 2003). Brain growth and neurologic development are rapid from 20 weeks gestation to two years of age. This is the most vulnerable period of dendrite growth in the cortex (Gardner & Goldson). Fetuses develop the majority of their neurons by the third trimester, forming them at the rate of 250,000 per minute (Fischer & Rose, 1994). Risk factors related to prematurity may contribute to inadequate development of gray matter and synaptic interconnections (Curtis, Lindeke, Georgieff, & Nelson, 2002; National Research Council and Institute of Medicine, 2000). Prenatal and early life experiences also positively or negatively alter synapse development between neurons (National Research Council and Institute of Medicine).

Infant stimulation in utero occurs through tactile, vestibular, gustatory-olfactory, auditory, and visual mechanisms (Grimwade, Walker, & Wood, 1970). Fetal movement provides tactile self-stimulation through the senses of touch, temperature, and pressure (Grimwade et al.). Vestibular stimulation occurs through oscillations and movements of the fluid environment of the womb that originate from normal movements of the mother as well as activities of the fetus (Grimwade et al.). Gustatory-olfactory stimulation occurs through bathing of fetal taste and olfactory receptors in amniotic fluid swallowed by the fetus (Grimwade et al.). Even though the womb is usually dark, minimal visual stimulation also occurs under certain conditions when light is transmitted to the fetus (Grimwade et al.).

Development of the auditory system begins at around three to six weeks gestation and all major structures of the ear are in place for sound to produce physiological effects in the fetus by 25 weeks gestation (Cheour-Luhtanen, Alho, Sainio, Rinne, Reinikainen, Pohjavuori, et al., 1996; Eldredge & Salamy, 1996; Hall, 2000b; Parmelee & Sigman, 1983). Auditory functioning, demonstrated by cortical auditory evoked responses in the cerebral cortex and brainstem, is apparent by 26 to 28 weeks gestation, indicating that preterm infants beyond that point can respond to and process auditory stimulation (Eldredge & Salamy; Hall, 2000a;). At 30 to 35 weeks gestation, the fetus hears maternal sounds, responds to these sounds, and begins to discriminate among speech sounds, especially in relation to pitch and rhythm (Lecanuet, Granier-Deferre, & Busnel, 1995).

Auditory stimulation occurs within an intrauterine environment that contains rhythmic, structured, and patterned cardiovascular, intestinal, and placental sounds similar to the patterning of musical sounds. These sounds may emanate from the mother or present externally as voices and music heard above low frequency background sounds at approximately 85 dB with short bursts over 90 dB (Gardner & Goldson, 2006; Gerhardt & Abrams, 2000). Also, the sounds to which preterm infants are exposed in utero may be encoded into their memory and affect their responses to sound in the extrauterine environment (deRegnier, Wewerka, Georgieff, Mattia, & Nelson, 2002). Polverini-Rey (1992) demonstrated that fetuses responded to lullabies played during the nine weeks prior to birth and remembered them at four weeks of age.

Infant stimulation in the extrauterine environment is very different from that experienced in utero, though it occurs through the same senses as in utero (Gardner & Goldson, 2006; Rubel, 1985; Standley & Madsen, 1990). For preterm infants in the NICU,

radically altered tactile input includes exposure to air currents, cold stress, tape, instruments, handling by caregivers, and other painful stimuli. Manipulation or turning by a caregiver, and disorganized, environmentally limited spontaneous limb movement provide vestibular stimulation. Gustatory-olfactory stimulation is provided by the smells and tastes of the NICU environment, including noxious tasting medications and electrolytes. Visual stimulation comes in the form of bright overhead lights, phototherapy, and eye examinations. Typically, there is a continuous exposure to light over the 24-hour period (Gardner & Goldson).

The primary auditory stimulation infants receive in the NICU is ambient noise. Sound levels in NICUs usually vary between 50 and 80 dB with peaks over 100 dB (from motors, fans, ventilators, personnel, telephones, pagers, alarms, trash lids, doors, and so on) and frequently range between 70 and 80 dB (Thomas & Uran, 2007). Sound levels can reach up to 130 or 140 dB when the side of the incubator is struck or the porthole door is closed (Mitchell, 1984). Ambient noise is the total composite of non-patterned sounds in the environment. Ambient noise that is considered too loud may be irritating, and noise levels that are too soft may be disconcerting (Wagner, 1994). Environmental sounds present in the NICU environment are neither predictable nor organized. Some experts state that the auditory stimulation experienced by preterm infants in NICUs would be overwhelming even for healthy adults (Gardner & Goldson, 2006).

Numerous investigators have demonstrated that appropriate stimulation of infants, which is neither overstimulating nor understimulating, is necessary for their growth and development (Als & Gilkerson, 1997; Coleman et al., 1997; Gardner & Goldson, 2006; Leib, Benfield, & Guidubaldi, 1980; Parmelee & Sigman, 1983; Wood et al., 2000).

Appropriate infant stimulation, which enhances physiologic and neurobehavioral development, is essential for the development of body image and the ability to organize and sort stimuli (Gardner & Goldson). Its absence negatively affects physiologic and neurobehavioral functioning and increases the risk of physical impairment, mental retardation, or subnormal skill development (Gardner & Goldson; National Research Council and Institute of Medicine, 2000). For example, monkeys and institutionally reared infants who had minimal contact and social interaction with others have displayed significant growth and developmental delays (Beckett, Bredenkamp, Castle, Groothues, O'Connor, & Rutter, 2002; Levine & Mody, 2003).

Evidence has shown that brain function and structure are also positively affected by early experiences and developmental care in the NICU (Als, Duffy, McAnulty, Rivkin, Vajapeyam, Mulkern, et al., 2004). For example, research suggests that exposing infants to sound in utero influences later responses to sound in the extrauterine environment (deRegnier et al., 2002). A summary of recent hearing development studies found that normal binaural sound experience is required to maintain the capability of sound localization (Werner & Gray, 1998). Lack of appropriate auditory infant stimulation has been found to negatively affect physiological functioning as well (Gardner & Goldson, 2006; Nocker-Ribaupeirre, 1999; Standley, 1998; Standley, 2000; Standley, 2002; Standley & Moore, 1995; Whipple, 2000). These studies also support the claim that music is similar in acoustical properties to auditory stimulation experienced by a fetus in the womb and that appropriate auditory infant stimulation is important for normal physiologic, neurobehavioral, and hearing development.

Research on Noise and Music Interventions for Preterm Infants

Similar to nursing and medical research with adults in coronary care, oncology, surgery, and post-anesthesia recovery settings (Chlan, 2000; Halstead & Roscoe, 2002; Migneault, Girard, Albert, Chouinard, Boudreault, Provencher, et al., 2003; Nilsson, Rawal, Enqvist, & Unosson, 2003; Vollert, Stork, Rose, & Mockel, 2003), studies of music in the NICU setting have focused on minimizing noise as a stressor and using music as a rhythmic, structured, patterning of sound (Butt & Kisilevsky, 2000; Coleman et al., 1997; Graven, 2000; Philbin, 2000; Schwartz, 1997; Standley, 1998; Standley, 1999; Standley, 2000; Standley, 2002; Standley, 2003a; Standley, 2003b). Music as a clinical intervention in adults has been shown to improve health, promote sleep, and lower stress through entrainment. This process takes place through the synchronization of interacting objects vibrating at similar frequencies until they resonate at the same frequency (Jourdain, 2002). Entrainment facilitates the synchronization of body rhythms (such as heart rate and respiratory rate) with the tempo or beat of the music. For example, prolonged auditory stimulation with a regular rhythm, such as lullabies, is calming and may slow heart and breathing rates. This entrainment may similarly reduce unnecessary energy expenditure for preterm infants thus facilitating their health, growth, and development. Auditory intervention in the NICU includes efforts to both reduce ambient noise and induce patterned auditory input like that in the intrauterine environment (Gardner & Goldson, 2006).

Environmental noise is a stressor to infants in the NICU and should be minimized as it may cause sensorineural damage to developing auditory structures, contributing to later language or auditory processing disorders (Gardner & Goldson, 2006; Graven, 2000;

Maschke, Rupp, & Hecht, 2000; Philbin, 2000). Nursing, music, and medicine researchers agree that noise levels should be reduced in NICUs because noise interferes with sleep and causes physiologic stress (Graven; Maschke et al.; Philbin; Schwartz, 2003; Stewart & Schneider, 2003). Environmental noise may also result in detrimental infant responses including: low oxygen saturation levels, increases in heart and respiratory rates, and alterations in glucose consumption and intestinal peristalsis (Graven). In addition, noise may cause fatigue, hyperalerting responses and reflexive startle (Maschke et al.) as well as changes in behavioral states from alertness, quietness, or sleep to fussing and crying (Philbin; Schwartz; Standley, 2003a; Stewart & Schneider; Zahr & Balian, 1995).

Experts disagree about the use of music interventions with preterm infants. Although music has been demonstrated in some studies to provide clinically important benefits for NICU preterm infants, concern remains regarding overstimulating these infants. Some researchers have claimed that noise and auditory stimulation through music could overwhelm preterm infants and increase physiologic stress (Bremmer et al., 2003; Graven, 2000; Philbin, 2000). They caution that music adds to the high levels of sound in the NICU; however, they do not make the distinction that music is different from noise or ambient sound. They also do not cite specific evidence related to the negative effects of music. Typically, the harmful effects of environmental sound and poor methodology of existing research studies are used to discourage music utilization in the NICU (Graven; Philbin). These researchers maintain that studies asserting the benefits of music are flawed in that they do not: (a) include adequate sample sizes (Bremmer et al.; Gardner & Goldson, 2006; Graven; Morris et al., 2000; Philbin; Philbin & Klaas, 2000),

(b) incorporate random selection (Philbin, Philbin & Klaas), (c) contain carefully controlled subject groupings (Philbin); (d) integrate established audiological information regarding the presentation of aural stimuli to preterm infants (Philbin; Philbin & Klaas); (e) report the effects of the stimulus on infant vital signs, movement, and behavioral state (Philbin; Philbin & Klaas); (f) describe the ambient sound levels in the NICU research setting (Philbin; Philbin & Klaas); nor (g) provide information about the acoustical properties of the stimulus (Philbin). They also claim that studies of clinical interventions using sound stimulation: (a) lack a substantive theoretical basis in basic science or animal studies (Bremmer et al.; Graven; Philbin; Philbin & Klaas), (b) have a potential for investigator bias in data collection (Philbin), (c) include inadequate data analysis (Philbin), (d) attribute benefits not supported by the data (Philbin), (e) don't investigate possible adverse affects of the stimulation intervention (Philbin), and (f) are isolated phenomenological reports based on the assumption that a particular kind of auditory stimulus will benefit preterm infants (Bremmer et al.; Graven; Philbin; Philbin & Klaas). See Table 1.

Much of the music literature describes the acoustic properties of music as being very different from sound in the form of noise (Cassidy & Ditty, 1998; Gardner & Goldson, 2006; Leonard, 1993; Loewy, 2003; Wagner, 1994). Music is more organized, contains fewer dynamic changes in sound amplitude, and results in responses opposite to that of noise (Schwartz). In adults, soothing music can facilitate the relaxation response through stimulating the release of endorphins from the brain and decreasing sympathetic nervous system activity as evidenced by a lowering of heart rate, respiratory rate, blood

pressure, muscle tension, metabolic rate, and oxygen consumption (Everly & Benson, 1989; Kaminski & Hall, 1996).

Music has been found to calm infants (Moore, Gladstone & Standley, 1994), reduce stress behaviors (Caine, 1991; Whipple, 2000), improve the frequency and strength of non-nutritive sucking (Standley, 2000), and decrease physiological instability in preterm infants. Decreased physiologic instability is observable in physiological and behavioral indicators such as: (a) heart rate, respiratory rate, and blood pressure (Burke, Walsh, Oehler, & Gingras, 1995; Lorch, Lorch, Diefendorf, & Earl, 1994); (b) oxygen saturation (Burke et al.; Cassidy & Standley, 1995; Chou, 2003; Collins & Kuck, 1991; Standley & Moore, 1995); (c) episodes of apnea and bradycardia (Cassidy & Standley); (d) behavioral state (Butt & Kisilevsky, 2000; Coleman et al., 1997; Collins & Kuck; Kaminski & Hall, 1996); and (e) observed pain (Burke et al.; Butt & Kisilevsky). One study by Schwartz (1997), a neonatologist, discovered a trend for faster growth of head circumference for preterm infants exposed to music. Music has also been shown to enhance physiological functioning in preterm infants. Correlations with music interventions include: increased weight gain/day (Caine; Standley, 1998; Whipple); strengthened tolerance for stimulation (Standley, 1998); and a reduced or baseline return of heart rates, oxygen saturations, and behavioral states after noxious stimulation or painful procedures (Burke et al.; Butt & Kisilevsky). Preterm infants in music studies had significantly higher oxygen saturations (Cassidy & Standley; Chou; Collins & Kuck; Standley & Moore); increased formula intake (Caine; Standley, 2003; White-Traut, Nelson, Silvestri, Vasan, Littau, Meleedy-Rey, 2002); a reduction in days to discharge (Caine; Standley, 1998) and higher 6-month mental and motor scores on the Bayley Scales

of Infant Development (Leib, Benfield, & Guidubaldi, 1980). It is theorized that the cognitive processing that occurs in preterm infants during music listening promotes neurological organization and is a pleasurable activity until fatigue sets in (Standley, 2002; Wagner, 1994).

Although many music intervention studies may lack scientific rigor, the evidence in support of using music with preterm infants must be considered and further tested. Carefully implemented studies with rigorous research designs and methodologies using research available from music therapy, medicine, audiology, and neuroscience together with information from nursing are essential to address the uncertainty regarding the effect of music interventions with infants born prematurely. Two such studies have been recently published. The first carefully designed and implemented study explored the effects of live versus recorded music on preterm infant heart rates, respiratory rates, oxygen saturations, and behavioral states. Arnon, Shapsa, Forman, Regev, Bauer, Litmanovitz et al. (2006), found no significant differences in preterm infant heart rate, respiratory rate, oxygen saturation, or behavioral state before, during, or after recorded music. Arnon et al. also found no significant differences in these preterm infant responses before or during live music, but found significant differences thirty minutes after live music. A second randomized controlled trial also found no significant differences in preterm infant heart rate, respiratory rate, or oxygen saturation before, throughout, or after recorded music during kangaroo care; but found that infants in the treatment group had more occurrence of quiet sleep states and less crying (Lai, Chen, Peng, Chang, Hsieh, Huang, et al., 2006).

A meta-analysis of the efficacy of music therapy for preterm infants by Standley (2002) provides guidelines for the use of music in the NICU such as: (a) beginning music interventions around 28 weeks gestation; (b) using soothing, constant, stable, and relatively unchanging sounds to reduce alerting responses; (c) having a light rhythmic emphasis and constant rhythm; (d) including melodies in the higher vocal ranges which infants hear best; (e) assuring a maximum time of 1.5 hours per day for playing music (in short intervals of 20 to 30 minutes per session at critical periods such as at the beginning of sleep, quiet times, and immediately after stressful procedures); and (f) maintaining a constant volume with volume level in the low 70s dBC (or low 60s dBA according to Gray [2000] and Gray and Philbin [2000]). Lower frequency sounds in a C-weighted decibel scale are perceived as louder than an A-weighted scale because the C-scale discounts low frequency sounds far less than the A-scale normally used to describe sound levels as they would sound to the human ear (Morris et al., 2000).

According to Schwartz and Ritchie (1999) and Schwartz (2003), musical selections for preterm infants should be chosen for simplicity, gentle rhythms, flowing and lyrical melodies, simple harmonies, and a soft tone color. Musical characteristics that should be avoided include the following: (a) transient changes in amplitude, (b) abrupt tempo changes, (c) complex sound timbre and color, and (d) complicated combinations of different instruments. Schwartz and Ritchie have stated that lullabies may be particularly effective because they are slow (60 to 82 beats per minute); regular, monotonous, and repetitive with a lower pitch to promote relaxation; and have no exciting disruptions in rhythm and/or melody.

Audiological studies have provided much information regarding preterm infant perception of aural stimuli. The auditory range of preterm infants from 25 to 37 weeks gestation is restricted to 500-1000 Hz (Roeser, 1996). One audiological study examined research in the field of music with premature and full term infants in order to identify protocols being used in the presentation of musical stimuli to neonates. This study used knowledge gleaned from audiology as a basis for suggesting a standardized protocol for use of musical stimuli with infants as follows: (a) the minimum age for music intervention should be 28 weeks gestation when consistent responses to acoustic stimuli are reported; (b) the bass should be boosted and the treble toned down because low frequencies are perceived earlier than high frequencies; (c) the minimum decibel level necessary to cause the desired effect should be used; and (d) the sound must be adjusted to a lower volume for infants to equate with adult hearing due to smaller ear canals. However, this is less of an issue when ear cups or earphones are used with open space over the pinna to expand the size of the resonating chamber (Cassidy & Ditty, 1998).

Neuroscience research has used event-related potentials (ERPs) to study neural pathways underlying real time cognitive processing related to a discrete event such as viewing a picture or hearing a sound (deHaan & Nelson, 1997). ERPs are non-invasive, have been employed in the study of infant cognition over the last 20 years, and provide one of the only methodological techniques that allows researchers to examine the relation between brain and behavior beginning at birth without requiring verbal, motor, or behavioral responses of subjects (DeBoer, Scott, & Nelson, 2004; deRegnier, Nelson, Thomas, Wewerka & Georgieff, 2000; Nelson & Bloom, 1997). By averaging EEG signals (in which the ERP is imbedded), ERPs have been used to evaluate the cognitive

processing of music in adults and children. They have also been used to study attention, memory, and language comprehension in infants using visual or auditory stimuli, but not specifically music. ERPs have revealed preterm infant processing of auditory information such as maternal voice (Therien, Worwa, Mattia & deRegnier, 2004) and preterm auditory discrimination of pure tones (Cheour-Luhtanen et al., 1996; Cheour, Alho, Ceponiene, Reinikainen, Sainio, Pohjavuori, et al., 1998).

Neuroscience research has also used functional Magnetic Resonance Imaging (fMRI) to determine which parts of the brain are activated by physical sensation or activity such as sight and sound. fMRI studies show that noise and musical notes with a fixed pitch activate the auditory cortex differently in adults further demonstrating the perceptual differences between noise and music (Griffiths, 2003; Patterson et al., 2002). No similar fMRI studies are reported from preterm infants, although there is evidence that preterm infants from 30 to 35 weeks gestation process sound in the form of pure tones similarly to adults (Cheour et al., 1998). Moreover, the ability to process music has been studied only in children five years of age and older (Koelsch, Grossmann, Gunter, Hahne, Schroger, & Friederici, 2003).

Music therapy studies have found differences between male and female preterm infant responses to music suggesting a possible gender effect. Female infants have exhibited greater benefits from music interventions, possibly due to having more sensitive hearing than male infants (Cassidy & Ditty, 2001). Data from two studies indicate that preterm infants engaged in experimental music therapy treatment were discharged from the hospital nearly twelve days sooner than their preterm female control peers (Caine, 1991; Standley, 1998). Although the difference between experimental and control preterm

male infants was negligible, experimental preterm male infants went home 1.5 days earlier than control males.

Audiological studies using Transient Evoked Otoacoustic Emissions (TEOAE) and Spontaneous Otoacoustic Emissions (SOAE) to measure hearing have also uncovered gender differences, which may account for some of the differences noted in music therapy studies. Hearing and interpreting sounds occurs through mechanical processing in the outer, middle, and inner ears, and intricate conversion into electrical-chemical energy in the cochlea (Cassidy & Ditty, 2001). These energy impulses transfer to the brain via synapses in the auditory nerve and are received by and interpreted within the temporal lobes of the brain (Cassidy & Ditty, 2001). In TEOAE, brief sounds produced by the probe trigger movement in the outer hair cells of the cochlea producing mechanical energy within the cochlea. This energy is converted to an acoustic signal and transmitted back through the middle ear and tympanic membrane (Cassidy & Ditty, 2001). With SOAE, sounds are emitted without an acoustic stimulus (Campbell & Mullin-Derrick, 2002).

Cassidy & Ditty (2001) used TEOAE to study 350 infants randomly selected from a subject pool of 1,685 healthy term infants between 38 and 42 weeks gestation. This study found hearing to be least responsive at 1.6 kHz, and most responsive at 3.2 kHz. Responses at 2.4 kHz and at 4.0 kHz were similar. There were no significant differences between left and right ears. Males were less responsive at 4.0 kHz than at 2.4 kHz whereas females were more responsive. Both males and females had low responses at 1.6 kHz and these differences increased at each subsequent decibel level.

Morlet, Durrant, Lapillonne, Putet, Collet, & Duclaux (2003) used TEOAE to

study 1020 ears of 510 preterm neonates (postconceptional ages ranging from 34 to 39 weeks). Morlet et al. demonstrated developmental gender differences in TEOAE between right and left ears. The left ear of female preterm infants showed an increase in the TEOAE amplitude at low and medium frequencies with age, whereas differences were less dramatic in the right ear. In male infants between 34 and 39 weeks postconceptional age, TEOAE amplitude decreased in several frequency bands at high frequencies above 4 kHz and most developmental differences were found to be more dramatic in the right than in the left ear.

Morlet, Lapillonne, Ferber, Duclaux, Sann, Putet, et al. (1995) also studied 81 preterm neonates, from 30 to 40 weeks postconceptional age, using SOAEs. Prevalence, peak number, and acoustic frequencies of preterm SOAEs showed similarity with full-term neonates. Comparison of SOAE characteristics between male and female preterm infants suggested that preterm males were less advanced in peripheral auditory development than were preterm females.

Neuroscience data supports gender differences as well. Developmental differences in auditory anatomy and the manner in which hearing is processed have been established between males and females. Males have a longer cochlea than females and male children demonstrate left lateralized cognitive processing of music as compared to bilateral processing in females (Hall, 2000b; Koelsch et al., 2003). The shorter cochlea in females has been hypothesized to result in faster response times to sound and better synchronization of the neural pathways compared to males (Don, Ponton, & Eggermont, 1993). The etiology of these gender differences in response to aural stimuli is difficult to determine because, at any point in the growth process, males and females could develop

differently (Cassidy & Ditty, 2001). Identifying differences between genders is important in identifying variables that might influence preterm infant responses to music.

Nursing Research on Preterm Infant Developmental Care

Many nurse researchers focus their research on infant developmental care strategies (Brown & Heermann, 1997; Burns, Cunningham, White-Traut, Silbestri, & Nelson, 1994; Heermann & Wilson, 2000; McGrath, 2000; Neal, 1988). Developmental care is a broad category of interventions carried out by nurses, parents, and others designed to minimize the stress of the NICU environment. It includes modalities like infant stimulation, touch, music, and decreasing environmental impact through noise and light control. Most music studies involving preterm infants are found in music therapy, neuroscience, and medicine journals.

Much of the nursing research related to preterm infants is focused on reducing sound in the NICU. Nursing studies determined that noise has the following effects on preterm infants: (a) reduces oxygen saturation (Elander & Hellstrom, 1995; Zahr & Balian, 1995); (b) causes changes in behavioral state from regular sleep to fussy and crying states (Zahr & Balian); (c) results in apnea and bradycardia (Bremmer et al., 2003); (d) decreases respiratory rate (Elander & Hellstrom); and (e) increases heart rate (Elander & Hellstrom). Nurse researchers found that lowering sound levels in the NICU affected preterm infant responses by reducing crying and enhancing sleep (Strauch, Brandt, & Edwards-Beckett, 1993). Studies by nurse researchers also discovered that noise may be minimized in the NICU through: (a) educating nursing staff about the causes of noise (Philbin & Gray, 2002; Zahr & Balian); (b) renovating the physical space (Philbin & Gray); (c) applying ear covers to preterm infants (Zahr, 1995); (d) covering incubators

with blankets (Saunders, 1995); (e) minimizing conversation (Elander & Hellstrom); and (f) implementing a quiet hour (Strauch et al.).

Research has also established the feasibility of measuring key indicators related to the effect of appropriate nursing stimulation for preterm infants. Enhanced physiological functioning has been measured by nurse researchers using physical parameters (systolic blood pressure, heart rate, respiratory rate, and oxygen saturation) and demonstrated by improvement in preterm infant responses such as: (a) fewer hospitalization days (Caine, 1991; Standley, 1998; Whipple, 2000); (b) increased weight gain (Caine; Standley, 1998; Whipple); (c) higher oxygen saturations (Burke et al., 1995; Cassidy & Standley, 1995; Chou, 2003; Collins & Kuck, 1991; Standley and Moore, 1995); (d) lower than standard ranges for systolic blood pressure, heart rate, and respiratory rate (Burke et al., 1995; Lorch et al., 1994); (e) fewer apneic and bradycardic episodes (Cassidy & Standley; Neal, 1988); (f) pain reduction using standardized behavioral observation scales for analysis of symptoms of pain in infants (Burke et al.; Butt & Kisilevsky, 2000); and (g) feeding progression indicated by increased calorie consumption and formula intake (Caine; Standley, 2003; White-Traut et al., 2002). Improved neurobehavioral functioning has been measured through behavioral state scales and determined by more time spent in quiet alert states than other states (Burke et al.).

Although many benefits have been attributed to the use of developmental interventions, including music, some investigators criticize studies related to the effects of sound on term and preterm infants (Bremmer et al., 2003; Evans & Philbin, 2000; Graven, 2000; Gray & Philbin, 2000; Morris et al., 2000; Philbin, 2000; Philbin & Gray, 2002; Philbin & Klaas, 2000). Nurse researcher Philbin and psychologist Klaas offer a research

evaluation checklist for clinicians planning an auditory intervention such as music with infants. The checklist includes guidelines to evaluate the validity and reliability of such a study and promote quality research related to the effects of sound (see Appendix B).

Research Related to Health Patterning in Nursing

According to Newman (2002), patterning is an integral concept to nursing and is based on mutual, authentic relationships. Newman states that patterning “includes the focus (i.e., the client) and the environment, and its meaning permits a jump from what is seen and heard to the larger context and from the explicit to the implicit” (p. 5). She further clarifies that things considered as irreconcilable or opposites, like the crest and trough of a wave or light and dark, cannot exist without each other (Newman, 2003). Reality is the unity of these inseparable activities as are people and their experiences or wellness and illness, which are incorporated into a notion of health that spans all dimensions of life (Newman, 2003).

Jonsdottir (1988) contends that the focus of nursing is identifying and understanding the patterns of person-environment interaction. Cowling (1990) states that the nurse is informed of patterning via the experiences, perceptions, and expression of clients including physical sensations and physically represented entities “(gait, position, activity level, posture, and sleeping behaviors, etc.) observed by the nurse” (p. 54). He further delineates that information expressed in the form of language (especially metaphors) and descriptions or pictorial representations of visualizations or images promotes pattern appraisal (Cowling). Matas (1997) proposes that “the essence of health lies in the notion of pattern” and that “health and illness are viewed as manifestations of the patterning process of human beings and their environment” (p.90). Matas believes that

the primary goal of nursing is to assist individuals in becoming aware of their unique human-environmental patterning process so that well-being can be maximized. She states that nurses accomplish this process through appraisal of the individuals' presenting pattern in order to design meaningful nursing strategies with individuals in the realization of health potentials. Pharris (1999) concludes that pattern recognition as a nursing intervention has been found to be most beneficial during times of turbulence or disorganization in the lives of clients.

Health patterning occurs when nurses assist clients with changes in their health through pattern manifestation appraisal, in which indicators of human and environmental fields related to current health events are identified, and by supporting clients in patterning environmental fields using interventions to promote health (Barrett, 1988, 1990). Cowling (1990) asserts that human energy field patterning is the basic referent of nursing practice that emerges from a human and environmental field mutual process and is the central focus for considering nursing strategies (knowledge of an individual's pattern facilitates the development of nursing interventions). Appraisal of patterning reveals information about clients and their environments and provides a focus from which to consider nursing interventions (Cowling). These intervention strategies promote harmony in the environmental field related to health events with the goal being a "substantive change in health dynamics... in the direction of health [and wellness] as defined by the client" (Cowling, p. 51).

Intervention strategies identified in the nursing literature that promote health patterning include the following: music; patterned environmental resonance; powerful, meaningful, or profound experiences; and health patterning modalities such as meditation,

innovative imagery, laughter, affirmations as expressions of intentionality, imposed motion/ movement/dance, breathing/rest/relaxation approaches, descriptive dream experiences, therapeutic touch, poetry, drawing, color, light, and sound. Therapeutic touch, imagery, and music are some of the most common modalities used as nursing interventions to affect health patterning in clients. See Appendix C.

Music as a health patterning modality in nursing research has been used to:

(a) change patient perceptions of the environment (Biley, 1996a; Edwards, 1991; Madrid, 1996), (b) facilitate healing (Brewer, 1998), (c) promote relaxation (Chlan, 2000; Good, 1995; Wiand, 1997), (d) alter perception of pain (Good; Schorr, 1993), (e) minimize anxiety (Chlan; Janelli, 1995; McBride et al., 1999; Norred, 2000; Sabo & Michael, 1996), and (f) reduce dyspnea (McBride et al.). Even when the patterning appears to be unorganized or blocked, health patterning modalities have been found to enhance the ability to comprehend the unitary nature of human beings and includes movement to a higher level of health, meaning, and organization leading to a strengthening of inner resources, wisdom, and insight (Newman, 1994, 1995).

Research Related to Health Patterning of Preterm Infants

According to Newman (1995), patterning defines a self-organizing quality of becoming more highly organized with additional information over time. This process may be illustrated with the patterning of physiological and neurobehavioral preterm responses. As preterm infants grow and develop, their autonomic nervous system (ANS) as well as other physiological systems mature. Maturation of the ANS results in a decrease in the variability of oxygen saturation and mean heart rate with progression of gestational age (DiPietro, Caughy, Cusson, & Fox, 1994). Maturation of the nervous system also results

in an increase in state organization (Gardner & Goldson, 2006; Hockenberry, 2003; Holditch-Davis, Scher, Schwartz, & Hudson-Barr, 2004; Thoman, Ingersoll, & Acebo, 1991). As described in the literature, appropriate stimulation of preterm infants is necessary to inhibit physiological and neurodevelopment deficits and improve functioning and health patterning as evidenced by stabilization of preterm physiological status and organization of preterm behavioral state.

The physiological responses of preterm infants to interventions are the explicit manifestations of their underlying health pattern. Medical and nursing research studies related to the patterning of preterm physiological responses are presented in Appendix D.

Behavioral state patterning is used to explicate the underlying neurobehavioral functioning of preterm infants because state reflects functioning of the brain and status of the central nervous system (Fischer & Rose, 1994; Gardner & Goldson, 2006; Halpern, MacLean, & Baumeister, 1995; Prechtl, 1977; Thoman, 1982, 1990; Wolff, 1987). Behavioral state refers to whether an infant is awake or asleep and may convey the neurobehavioral response of infants to developmental interventions, including music (Borghese, Minard, & Thoman, 1995; Gardner & Goldson; Gertner, Greenbaum, Sadeh, Dolfen, Sirota, & Ben-Nun, 2002; Whitney & Thoman, 1993). Also, behavioral states may connect level of consciousness with body activity and overlap with all other categories of behavioral development providing a more complete picture of the preterm infant over time (Gardner & Goldson). The process of patterning the person-environment interaction may be applied to the health patterning of preterm infants during NICU hospitalization (see figures 3 and 4).

Figure 3. Health patterning conceptual framework

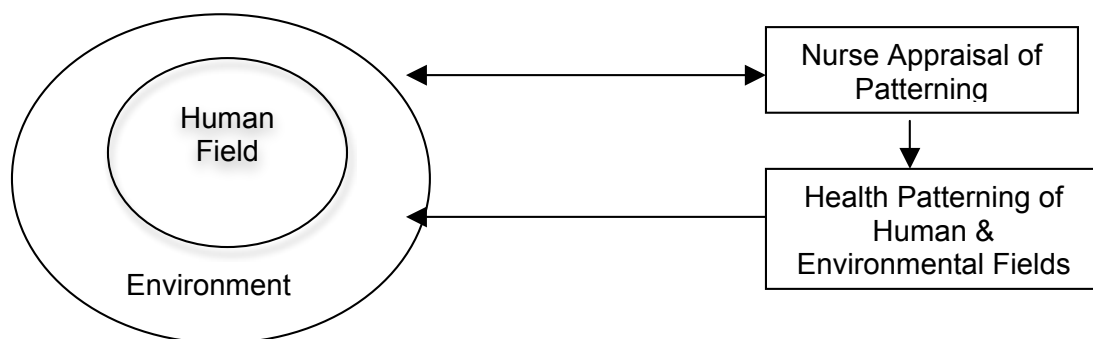
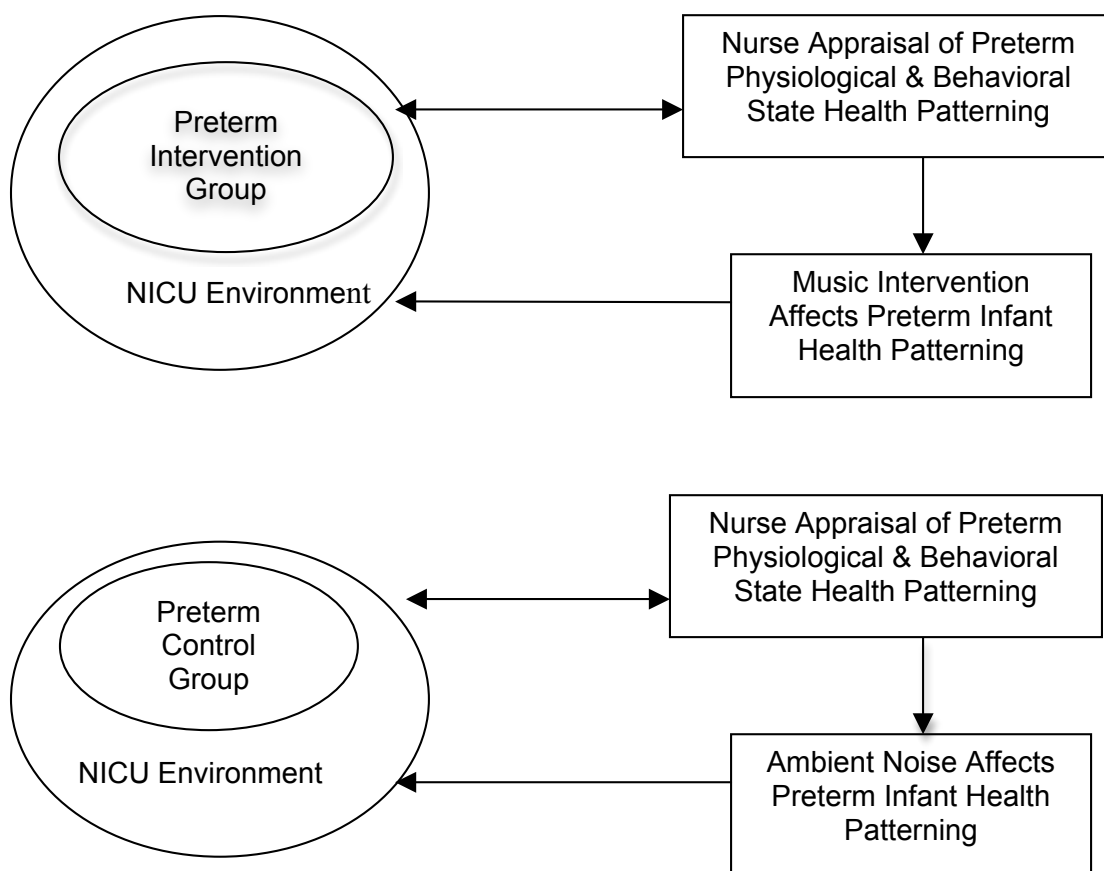


Figure 4. Health patterning of preterm infants during NICU hospitalization



Conclusions Drawn From Research Related to Preterm Infants and Music

This review of literature prompts several conclusions:

1. In utero stimulation of the fetus is continuous and key to the development and maturation of the central nervous system.
2. Attention to the nature of stimulation for preterm infants in the NICU is of great importance for the continued development of the child.
3. Since auditory function is in operation by 28 weeks, noise is a stimulus that will affect most preterm infants in a NICU and music is a stimulus that may be heard.
4. Noise is considered to be a stressor to preterm infants and should be minimized in the NICU.
5. Experts disagree about the use of music with preterm infants in the NICU.
6. Some researchers are critical of the scientific rigor of music intervention studies with preterm infants.
7. There are persuasive theories and preliminary small studies that support music intervention as an appropriate developmental care strategy for preterm infants in NICU.
8. Recent guidelines for the use of music in the NICU based upon meta-analysis of the efficacy of music therapy for preterm infants have been established, but not systematically utilized in studies that support music as an intervention with preterm infants.

9. Comprehensive neuroscience and audiological information regarding the presentation of aural stimuli to preterm infants have not been incorporated into studies that support music as an intervention with preterm infants.
10. Previous researchers have recognized a set of measures and measurement techniques that permits scientific evaluation of key questions related to the use, tolerability, and effectiveness of music intervention with preterm infants in NICU.

Chapter 3

METHODOLOGY

Research Design

An interrupted time-series randomized design with repeated measures was used to explore the physiological and neurobehavioral health patterning responses of preterm infants from 32 to 35 weeks gestation to a selection of recorded piano music in a NICU. A 20-minute session of Brahms's Lullaby with a relatively constant rhythm, volume, and pitch provided at a volume level in the low 60s dBA was the music intervention used. The effect of the music was measured every 30-seconds before, during, and after the sound condition of music or ambient noise by observing the oxygen saturation, heart rate, and behavioral state of randomly assigned intervention preterm infants in the NICU in relation to a control group in which no music (only standard NICU care with recorded ambient noise) was provided. A diagram of the interrupted time-series design is depicted in Figure 5.

Figure 5. Design: Interrupted Time-Series Design With Repeated Measures

Experimental Group (R)	O ₁ to O ₂₀ \bar{X} O ₂₁ to O ₆₀ \bar{X} O ₆₁ to O ₈₀
Control Group (R)	O ₁ to O ₂₀ ● O ₂₁ to O ₆₀ ● O ₆₁ to O ₈₀

KEY:

R = random assignment

O₁ to O₂₀ = baseline pre-music or ambient noise observation for measurement of responses

\bar{X} = 20 minute recorded music intervention

● = 20 minute recorded ambient noise condition (no music)

O₂₁ to O₆₀ = music or ambient noise observation for measurement of responses

\bar{X} = recorded music intervention removed

● = recorded ambient noise condition removed

O₆₁ to O₈₀ = post-music or ambient noise observation for measurement of responses

Design Rationale

The musical piece was played to present aural stimuli to preterm infants as recommended by Cassidy and Ditty (1998): (a) using low frequencies within the 500-1000 Hz range best heard by preterm infants, (b) boosting the bass and toning down the treble to enhance the effects of the musical stimuli, and (c) ensuring the minimum decibel level necessary to cause the desired effect. The melody of Brahms' Lullaby was played on a piano in the key of B at approximately 60 beats per minute, a tempo suggested by Schwartz and Ritchie (1999) and Schwartz (2003). The pitch range was an octave, from the B in the treble clef to the B above it, because these Bs have frequencies of 494 Hz and 987 Hz respectively. The piano's sound was recorded live in a concert hall to provide a natural reverberation. Because of this reverberation, no studio processing to the actual music was necessary. Reverberation helps absorb and moderate some of the higher sound frequencies, so in effect, it tunes down the treble and makes the music sound richer. Compared to this recording, a piano recorded in a dry sound booth would sound tinny. Recorded piano music was used because neurocognitive responses of children to piano music have been found to be clearer and more mature than responses to other tones (Trainor, Shahin, & Roberts, 2003). Brahms' Lullaby was used as the musical selection because it has soothing, stable, and relatively unchanging sounds to reduce alerting responses as well as light rhythmic emphasis and a constant rhythm as described in Standley's (2002) music therapy guidelines for the use of music in the NICU.

Recorded ambient noise like that normally experienced by preterm infants in a NICU was used to ensure a consistent input of safe sound levels. The ambient noise was

filtered using computerized software (Digital Performer 4.12) only to ensure that the infants heard a clean sample of the NICU's normal sound environment free from artifacts.

Music and ambient noise were delivered via specially designed disposable neonatal earphones to expand the resonating chamber and control for sound conditions according to the recommendations of Cassidy and Ditty (1998). Sound conditions were administered after a feeding during a time that is usually a resting period for the infant. Once the earphones and pulse oximeter were placed, the baby was undisturbed in the incubator or crib and the incubator remained closed unless it was necessary to disrupt the study for the infant's medical care or comfort (e.g., apnea spell requiring stimulation, desaturation, fussiness, emesis, etc.). Sound was faded in and out using Digital Performer 4.12 to prevent startling of the infants as recommended by researchers (Schwartz & Ritchie, 1999; Standley, 2003a; Thoman, 1990). The sound was also looped for consistency, making sure to avoid creating clicks at the loop points. Earphones presented the stimulus at the same carefully controlled decibel level (whether the infant was in an incubator or crib), attenuated ambient noise allowing for minimal volume, guaranteed binaural presentation of the stimulus, and prevented an effect on other infants in the NICU (Cassidy & Ditty, 1998; Standley, 2003a). The protocol was developed to incorporate recommendations of Cassidy and Ditty as well as Standley's (2002) music therapy guidelines for preterm infants.

Oxygen saturation and heart rate were chosen as physiological health patterning measures because they are responsive to auditory stimuli, have commonly been used in studies on the effects of music with preterm infants, and are directly affected by infants' behavioral states (Gordin, 1990; Morris et al., 2000). Behavioral state was chosen because

it characterizes the underlying functioning of the brain and reflects infants' ongoing responses to acoustic stimulation (Borghese et al., 1995; Gertner et al., 2002; Halpern et al., 1995; Thoman, 1982; Whitney & Thoman, 1993).

Behavioral state was chosen as a neurobehavioral health patterning measure of preterm infants because behavioral state is a sensitive measure of infant response to sound. Furthermore, nearly all researchers studying preterm infants include some measure of state as a critical factor in infant behavioral organization (Holditch-Davis & Edwards, 1998). The behavioral state pattern of “organization,” defined as spending more time in quiet sleep or quiet alert states than in active states or fussing and crying, is an important indicator of infant well-being (Kaminski & Hall, 1996). Energy and effort are required for the infant’s physical activity and stress responses. This competes with metabolic activity going toward growth and development. Behavioral cues are routinely used to indicate infant stress levels. Measuring behavioral state is a critical factor in determining infant behavioral organization and is important to include in preterm intervention studies (Holditch-Davis & Edwards; Lowman, Stone, & Cole, 2006). Table 2 describes neonatal behavioral stress cues and recommended caregiver responses appropriate for identifying infant responses to external events, including music (Brazelton Institute, 1999; Lowman, Stone, & Cole).

Table 2. Stoplight: A Guide for Understanding Infant Behavioral Responses to Stimulation

System	Green Light	Yellow Light	Red Light
Autonomic	<ul style="list-style-type: none"> • Good, even color • Smooth breathing • No tremors or startles 	<ul style="list-style-type: none"> • Mild color change (paling, mottling, acrocyanosis) • Grunting or rapid, shallow breathing • Few startles or tremors • Bowel movements 	<ul style="list-style-type: none"> • Substantial color change • Chest wall retractions • Labored breathing or shallow breathing with pauses • Vigorous hiccups • Gagging or spitting up • Many startles or tremors
Motor	<ul style="list-style-type: none"> • Relaxed tone • Good range of motion • Hand-to-mouth movement • Sucking • Hand grasping • Smooth movements • Postural change • Body kept calm 	<ul style="list-style-type: none"> • Jerky movements • Flaccidity or hypertonia • Uneven tone • Body held tensely 	<ul style="list-style-type: none"> • Stiffening and arching away • Disorganized activity • Flailing and frantic movements • Limpness
State and social interaction	<ul style="list-style-type: none"> • Bright-eyed alert state • Readiness for interaction • Visual/auditory locking • Self-quieting behavior • Robust sleep, alert, and crying states 	<ul style="list-style-type: none"> • Shutting out by moving into drowsy or sleep state • Irritability and difficulty being consoled • Gaze aversion • Hyperalert state 	<ul style="list-style-type: none"> • Inconsolable crying • Extreme irritability • Saccadic (twitching) eye movement • Setting sun eyes • Panicked alertness • Constant eye averting • Inability to be aroused
Examiner's response to infant cues	Continue exam.	Pause and observe: Which direction is this baby going to go? What do I have to do to facilitate?	Allow resting period until color, tone, and respirations return to normal. If the baby continues to look stressed and does not recover easily, end the exam.

Note. This table separates behavioral cues into categories that indicate the infant's level of stress and provides professionals with guidelines for responding to infants during a stimulus such as music interventions.

Adapted from: Brazelton Institute. 1999. *Neonatal behavioral assessment scale (NBAS) handbook*. Boston: Author. Reprinted by permission.

One reason for including state when assessing behavioral organization is that physically identical stimuli can produce very different responses, depending on the behavioral state of the infant during stimulation (Prechtl, 1977; Wolff, 1966). Another reason for including state is that preterm infant state has been described as a powerful determinant of other behavior. For example, an infant's behavior (e.g., respiratory pattern, eye opening, movements, muscle tone, eye movement, crying, alertness, etc.) is affected by the state he is in: (a) alert, (b) nonalert waking, (c) fussing or crying, (d) sleep-wake transition, (e) active sleep, or (f) quiet sleep (Thoman, 1990). An infant's respiratory pattern will be slow, regular, and abdominal during quiet sleep whereas it will be irregular and primarily costal during active sleep (Thoman, 1990). Also, behavioral state is a sensitive measure of infant response to sound and changes in behavioral state provide information about the neurobehavioral status of infants including the impact of interventions (Thoman, 1990).

Little agreement exists on state classifications for infant behavior and contradictory results have been reported in studies of infant states. The behavioral taxonomies of Wolff (1966), Brazelton, (1973), Prechtl (1974), and Thoman (1975) have been most widely used; however, there is neither convention nor consensus for methodologies related to state study for infants. The abbreviated version of Thoman's Primary States Taxonomy (1990), deemed appropriate for preterm infants, was utilized in this study because the behavioral state variables identified have been shown to exhibit concurrent and predictive validity as well as reliability of measurement and individual differences for preterm infants (Holditch-Davis, 1990; Holditch-Davis & Thoman, 1987). In addition, Thoman provides concrete evidence and rationale for each distinct state category. Thoman's

Derived States behavioral classification scheme (1990) rationally and systematically combines some of the Primary States into clusters. The classification scheme was used as follows:

0. Alert- the infant's eyes are open, bright, and attentive or scanning.
Motor activity is low and respirations fairly even, but the infant may be active.
1. Nonalert Waking- the infant's eyes are usually open, but dull and unfocused.
Motor activity may vary, but is usually high and respirations are even. The eyes may be closed during high-activity and fuss vocalizations may occur.
2. Fussing or Crying- fuss sounds are continuous or intermittent at low levels of intensity. Intense vocalizations occur either singly or in succession.
3. Sleep-Wake Transition (including drowse and gaze)- the infant shows behaviors of both wakefulness and sleep. Although motor activity is typically low, there is usually generalized activity that may vary. The eyes are typically closed, but they may open and close. If the infant's eyes are open, they may be heavy-lidded or glassy and immobile. Isolated fuss vocalizations may occur.
4. Active Sleep- the infant's eyes are closed. Respiration is uneven and primarily costal. Sporadic movements may occur, but muscle tone is low between movements. Rapid eye movements (REMs) occur intermittently accompanied by occasional eye opening. Other behaviors may include smiles, frowns, grimaces, sighs, mouthing, sucking, and twitching movements of the extremities. High-pitched cries may be emitted as well as straining or grunting vocalizations during large stretching movements.

5. Quiet Sleep (including active-quiet transition)- the infant's eyes are closed.

Respiration is relatively slow, regular, and abdominal. Tonic motor tone is maintained and motor activity is limited to occasional startles, sighs, or rhythmic mouthing. Limb or body movements or isolated REMs may occur.

Infants were videotaped and their behavioral state was coded every 30-seconds by an expert in behavioral assessment and a co-coder tested for interrater reliability as commonly done in studies using auditory stimulation with preterm infants. Periods with mixed signs of active and quiet sleep were scored as quiet sleep if there is transitioning into or out of quiet sleep (Holditch-Davis et al., 2004). They were scored as active sleep if they occurred within active sleep or in transition between active sleep and awake states (Holditch-Davis et al.).

Justification for the Design

This design is appropriate for the study as there is enough prior research with study variables in the preterm infant population to answer the question: Are there differences between the physiological and behavioral state patterning responses of preterm infants receiving a nursing intervention of recorded music and those listening to recorded ambient noise in the NICU? In addition, the design is justified because it involves: (a) random assignment of subjects to intervention and control groups, (b) manipulation of independent variables (auditory stimuli in the form of music and ambient noise), (c) comparison of responses for the two auditory stimuli conditions, and (d) control over extraneous variables and threats to validity through strict experimental rigor, adequate sample size, carefully controlled subject groupings, and use of standardized guidelines for the presentation of auditory stimuli.

Strengths and Weaknesses of the Design

Controls for threats to validity afforded by this design include random assignment to groups to control for selection bias, and blinding of the researcher and behavioral state coder and co-coder to manage investigator bias. Additional safeguards built into the study include: (a) use of instruments tested for reliability and validity to measure the physiological responses of preterm infants (instrument calibration per standard protocol by the hospital biomedical department); (b) pre-treatment observations of preterm physiological and neurobehavioral responses to strengthen interpretation of results; (c) post-treatment observations to decrease the potential for measurement discrepancies and reduce the risk of Type I errors; and (d) repeated measures over time added to allow effects of history to be tested between the groups. Finally, procedures for administration of the auditory stimuli to preterm infants were strictly enforced to control variance, promote treatment integrity, and enhance internal validity of the design.

Limitations or threats related to internal validity are as follows: (a) the risk of errors due to extraneous sources of variance including medical status and condition-related factors of the subjects such as the influence of medications; (b) random fluctuations such as unplanned environmental sounds (although earphones were used to control sound conditions); (c) errors of measurement or documentation of preterm infant responses; (d) technically unacceptable tests, experimental mortality, or attrition due to infants being removed from the study by parents or because of a change in health status; and (e) sensitization to testing in which preterm infants physiologically accommodate or habituate to auditory stimuli. A threat to external validity includes the interaction of setting and treatment because there may be characteristics of the particular NICU, such as

having private rooms, which interact with the treatment affecting generalizability of the findings.

Sample

The total sample recruited consisted of 42 clinically stable, non-ventilated, appropriate-for-gestational-age (AGA) preterm infants from 32 to 35 weeks gestation. Infants were within three to ten days of birth and APGAR scores were from 8 to 10 at five minutes after birth. One infant was withdrawn from the study because she was fussy and had high motor activity prior to and during the sound condition. Sample size was determined in consultation with a biostatistician. Power analysis was done using Cohen's d for studies of music with preterm infants using the same dependent variables as proposed in this study (Cohen, 1988). The sample size required for the variable with the smallest effect size of .919 for heart rate was 20 per group. This size is consistent with the .83 effect size determined by Standley's (2002) meta-analysis of the efficacy of music therapy for premature infants, which included ventilated infants, a large range of gestational ages, weights, and medical conditions, some small sample sizes, and more variables than planned for this study. Half of the infants were randomized to an experimental (music intervention) group and the other half to a control (standardized care with ambient noise) group using computer generated randomized numbers. Study completion was estimated at 20 preterm infants per group after factoring in potential attrition due to experimental mortality (e.g., infants who were discharged, became ill, or were withdrawn from the study, etc.) and technically unacceptable physiological or behavioral recording rates. The final sample size included 41 preterm infants (21 infants in the intervention group and 20 in the control group).

Setting

The setting was a newly remodeled NICU at the seventh-largest independent, not-for-profit Minnesota children's health care organization in the U.S. The NICU is the largest private-room NICU in the United States (49 private rooms). The setting was purposefully selected because it is a hospital in the Twin Cities area that includes a level III NICU with more premature and critically ill infants than any other health care provider in the Upper Midwest. Most of the patients in the NICU are preterm infants (approximately 250 infants were born at 32 to 35 weeks gestation in 2005). Also, rooms were designed to help shield neonates from noise and light in order to somewhat simulate the in utero environment.

Sampling and Recruitment Procedures

Participants were selected for the study based upon predetermined theoretical and practice-based inclusion and exclusion criteria. Preterm infants who were appropriate-for-gestational-age (AGA), from 32 to 35 weeks gestation, within three to ten days of birth, and have a 5-minute APGAR score of 8 to 10 were included in the study as they were considered to be at an appropriate age and condition to receive auditory stimulation. AGA infants from 32 to 35 weeks gestation and three to ten days of age were chosen because there are significant differences in physiological growth and development between preterm infants with large size and gestational age spans (deRegnier et al., 2002). All infants had signed parental consent and were screened for normal hearing by a NICU audiologist to ensure their ability to hear the sound stimuli.

Only infants who were clinically stable and physically able to tolerate the stimuli as determined by a neonatologist or neonatal nurse practitioner (NNP) were included. In

addition, those with comorbidities such as congenital defects, intraventricular hemorrhage (IVH), necrotizing enterocolitis (NEC), patent ductus arteriosus (PDA), sepsis, acute lung disease, or neonatal anemia (hemoglobin less than 12 gm/dl) were eliminated. Infants who were currently ventilated were excluded from the study as ventilators affect transmission of sound and would distort music used in the intervention. Infants receiving overhead phototherapy were excluded to prevent disruption of the treatment. Also, infants whose mothers had a known history of maternal drug abuse, including alcohol or illegal substances, were excluded because those substances could affect infant responses along with preterm growth and development. Infants currently receiving prescribed sedation medications were excluded as well because of the effect of sedatives on responsiveness. Sample inclusion and exclusion criteria for preterm infants are displayed in Table 3.

Table 3. Sample Inclusion/Exclusion Preterm Infant Criteria

Inclusion	Exclusion
Appropriate-for-gestational-age	Diagnosis of congenital defects, IVH, NEC, PDA, sepsis, acute lung disease, or neonatal anemia (Hgb <12 gm/dL)
32 to 35 weeks gestation	Current ventilator use
3 to 10 days of age	Known maternal drug, alcohol, or illegal substance abuse
5 minute APGAR score of 8 to 10	Currently receiving medications for sedation
Signed parental consent	Current overhead phototherapy
Passed hearing test	
Clinically stable	

Eligible preterm infants were identified by a NICU neonatologist or research associate, who then notified the principal investigator about potential subjects for the study. Parents of eligible preterm infants were initially approached by the neonatologist or research associate for permission to be contacted by the principal investigator and invited to participate in the study. Parents were assured that participation was voluntary, that refusal to take part would not jeopardize their relationship with staff in the NICU nor would it impact their child's care, and that their confidentiality would be protected.

Before data gathering was initiated, a cover letter and consent form explaining the purpose of the study was distributed to parents of eligible preterm infants by the principal investigator, neonatologist, or research associate (see Appendix E). One of these three individuals reviewed the information and consent form with the parent(s), fully explained the study, answered questions, and had parents interested in participating sign the consent form and HIPAA documentation. Mothers of study infants were also given a questionnaire to complete related to music listened to during the pregnancy. Participant parents were not paid for their child's participation in the study. A CD of lullaby music was given to parents after the study was completed.

Study Protocol

Supply and Equipment Set-Up. Prior to data collection, study equipment was set up in the hospital research laboratory. A RS232 cable from a Masimo SET[®] (signal extraction technology) pulse oximeter was connected to a Dell[™] Latitude[™] D620 laptop PC serial connector and the PC was turned on after ensuring that settings were accurate on both the pulse oximeter and PC. Next, transducers, acoustic tips and tubing, and a dual headphone adapter were used to connect two Bio-logic original foam Ear Muffin[™]

earphones to a 1 GB iPod nano. Earphones were lined with cotton to prevent them from sticking to infant ears. The decibel level transmitted from the iPod through transducer tubing was then tested using an Impluse digital sound level meter, model 2700 by Quest technologies to ensure maximum sound levels with a volume in the low 60s dBA and the iPod was locked to prevent any changes in settings. Finally, the pulse oximeter was powered up and tested, the Canon ES970A 8mm camcorder was turned on with settings adjusted to sports mode to view infant movement, and the timing counter reset to 0.

In the NICU room, the investigator set up and retested the video camera on a tripod stand, washed hands, and cleaned equipment using Cavi Wipe disinfecting towelettes. Ear Muffins™ were placed over both infant ears using a stockinette. A Masimo SET® adhesive sensor was placed on the lateral aspect of an available infant foot and shielded from light and a sign with the infant ID number was positioned next to the infant so that it was visible during videotaping. Lastly, the decibel level of the room was measured near the infant's ears within the incubator or crib

After equipment was set up, pulse oximeter and video camera recording was initiated. The music or ambient noise sound was started after 10 minutes and stopped after 20 minutes. The video camera and pulse oximeter recordings continued until 10 minutes after sound recording was stopped. Investigator hands were again washed and equipment was cleaned using the disinfectant wipes. Oxygen saturation and heart rate data were then downloaded from the pulse oximeter to the laptop computer.

Data Collection

Demographic data including gender, race/ethnicity, gestation, age, APGAR, birth weight, current weight, cause of prematurity (if known), past conditions, medications

including prenatal steroid use, sound level of the room, and risk factors related to prematurity (if known) was recorded from the hospital records of study infants and their mothers. Any prenatal and postnatal use of music prior to initiation of the study was obtained through maternal reporting of the type and length of music time to which the fetus would have been exposed prenatally. Physiological data including oxygen saturations and heart rates, and behavioral state data were collected at baseline, during, and after music and ambient noise conditions. A 20-minute session of recorded piano music using Brahms' Lullaby with a relatively constant rhythm, volume, and pitch or recorded ambient noise was provided at a volume level in the low 60s dBA. Sound levels were measured using a digital sound level meter.

Data Collection Methods and Rationale

Physiological and behavioral data were collected on preterm intervention infants and control infants by the investigator who was blinded to group assignment. Physiological data including oxygen saturations and heart rate were obtained through a Masimo SET[®] pulse oximeter (SLO2) and downloaded directly into a Dell[™] Latitude[™] D620 laptop computer. Over 100 clinical studies support the conclusion that Masimo SET[®] is the most effective pulse oximeter for overcoming problems associated with data dropouts, false alarms and inaccurate measurements due to patient motion, low perfusion and other challenging conditions. These monitoring systems allowed for continuous recording of physiological variables to determine the patterning of preterm responses over time and blinding to group assignment. Physiological parameters were recorded continuously (in 30 second increments) for 40 minutes for each infant enrolled in the study (10 minutes before the sound condition, 20 minutes during the sound condition, and

10 minutes after the sound condition). The infant was videotaped using a Canon ES970A 8mm camcorder.

Behavioral state was measured by a behavioral state coder skilled in evaluating six variables shown to exhibit reliable individual differences for preterm infants and a nurse tested for interrater reliability as follows: (a) alert, (b) nonalert waking, (c) fussing or crying, (d) sleep-wake transition, (e) active sleep, and (f) quiet sleep. The behavioral state coder and co-coder were blinded to group assignment as well and coded videotaped behavioral states in 30-second epochs during baseline, sound condition, and post-sound condition periods as is commonly done in studies using auditory stimulation with preterm infants. The video recording also allowed for analysis of the patterning of preterm responses over time.

Techniques for ensuring the accuracy and reliability of instrument measurement were employed as recommended in literature related to physiological variable measurement in preterm infants: (a) regular calibration of equipment before and after each observation session, (b) verification of an adequate CR scan tracing, and (c) minimization of oxygen saturation errors due to artifacts. Data collection and measurement procedures recommended for use with each of the physiological variables were also incorporated including: (a) continuous monitoring; (b) avoiding disruption of preterm infants, if possible, by collecting data using electrodes already in place; (c) shielding of the pulse oximeter sensor to avoid error from light interference; (d) using multiple data collection points (before, during, and after intervention); and (e) downloading data for later analysis.

Strengths and Limitations of Data Collection Methods

One strength of collecting data through continuous recording of physiological variables is the richness, abundance, and meaningful quality of patterned data to be obtained as opposed to periodic snapshots of preterm infant responses. Another strength is that blinding of the researcher to group assignment was possible. Also, the most reliable instrument for pulse oximetry was found to be the Masimo SET[®] for measurement of oxygen saturation as used in this study. A limitation of this method was the complexity of collecting continuous data. Additionally, according to findings from a critical review related to measurement of physiological variables in preterm infants, the most reliable instrument for measurement of cardiorespiratory variables was the Hewlett-Packard Neonatal-Model 78834C. Because the NICU utilized for collecting data did not have the Hewlett-Packard monitor, this is one more limitation of the data collection method used.

Besides the wealth and quality of patterned data to be obtained through videotaping preterm infants over time, strengths of collecting behavioral state data in this manner included the opportunity to establish interrater reliability and review the videotape when it was convenient to do so, the ability to recheck any questionable behavioral state coding, and the means to allow for blinding of the researcher, behavioral state coder, and co-coder to group assignment. Limitations of this method consist of the logistics in setting up the videocamera in NICU rooms, ensuring quality filming of each preterm infant, and training the behavioral state co-coder.

DATA ANALYSIS PROCEDURES

Multilevel mixed modeling through Sequence Annotated by Structure (SAS) was used for analysis of physiologic and neurobehavioral variables (SAS Institute, 2004).

Mixed modeling examines the mean averages of the intercepts and slopes to determine the observed average pattern of change. Variation in intercepts summarizes observed interindividual differences in preterm infant oxygen saturation, heart rate, and behavioral state at the beginning of each time period (before, during, and after the music or ambient noise sound conditions. Variation in slopes describes observed interindividual differences in preterm infant oxygen saturation, heart rate, and behavioral state changes over the three time periods. Level-1 submodeling describes how each infant's oxygen saturation, heart rate, and behavioral state changes over time. Level-2 modeling describes how these changes differ between infants. Physiologic and neurobehavioral study variables and further analyses are shown in Table 4.

Table 4. Hypotheses/Data Analyses

Hypothesis	Variable	Analysis
1. There will be no significant differences in oxygen saturations between the music intervention group and the ambient noise control group	Pulse oximeter measurement of oxygen saturation	Multilevel mixed modeling
2. There will be no significant differences in heart rates between the music intervention group and the ambient noise control group	Pulse oximeter measurement of heart rate	Multilevel mixed modeling
3. There will be no significant differences in behavioral states between the music intervention group and the ambient noise control group	Assessment of behavioral state using Thoman's Derived States Taxonomy	Multilevel mixed modeling

Note. Level of significance was set a priori at $p < .05$ for all inferential statistical tests.

SPSS-PC was used for analysis of inferential data to ascertain measures of central tendency (mean, median, standard deviation, and variance), to assess normality of the frequency distributions (histograms), and to detect any outliers. All data were found to be normally distributed on these measures.

Analysis of Descriptive Data

Descriptive statistics were carried out on all demographic variables (gender, race/ethnicity, gestation, age, APGAR, birth weight, current weight, cause of prematurity [if known], past conditions, medications including prenatal steroid use, and sound level of the room). Chi-square was used to assess nominal data for any significant associations between the groups. T-tests were used for normally distributed data or Mann-Whitney U tests for data not normally distributed to examine interval data for any significant differences between the groups. These test were performed because significant associations between variables, such as gender or medical condition of the infant, had the potential to impact findings differentially and would need to be controlled for statistically. For example, the responses of male and female infants to music and ambient noise were compared to determine gender differences according to the recommendations of Cassidy and Ditty (1998).

Analysis of Dependent Measures

Oxygen saturation, heart rate, and behavioral state data were analyzed using SAS for multilevel mixed modeling. Mixed modeling was used in to detect any differences between music (intervention) and ambient noise (control) infants related to these physiological and neurobehavioral measures over time (how the responses of infants varied over time) as well as the variability of those changes (how the responses of infants

varied within each time period). Dependent variables were measured every 30 seconds for 40 minutes per infant (10 minutes before, 20 minutes during, and 10 minutes after the sound conditions).

Ethical Considerations

This study was important because of continued uncertainty regarding the safety and efficacy of using music as an intervention with preterm infants in the NICU (Neal, 2008). Although studies have demonstrated that music interventions promote preterm infant health, much of the research has not been methodologically rigorous in including adequate sample sizes or carefully controlled subject groupings, accounting for gender differences, nor utilizing scientific information and standardized guidelines for implementation of the intervention. This study used carefully controlled methods to address these shortcomings to discover if preterm infant responses to music are different from those to ambient noise and to determine key physiological and behavioral state benefits of a carefully implemented music intervention with this population.

Methodological rigor in research is of key importance to ensure that optimal care for patients is fostered and harm is prevented (beneficence versus nonmaleficence). Scientific method has been determined to be the most objective, systematic way of obtaining knowledge (Nieswiadomy, 2002). Therefore, research that can greatly impact the lives of others requires objectivity, sound methodology, and tight controls over the research situation as the quality of the study depends on the quality of the measurement (Brink & Wood, 1998). Uncritical acceptance of untested practices and disregard for methodological rigor in nursing research is closely tied to the ethical issue of nonmaleficence versus beneficence. Reliable evidence regarding the risks and benefits of

clinically important outcomes for preterm infants has not been available to health care providers because most neonatal practices have not been rigorously tested (Cole, 2004). This disregard for methodological rigor in research may lead to unsafe practices that could harm infants. There is a very great danger in accepting unsupported interventions and using them in the care of preterm infants (or any patients). The danger is intensified when there are strong beliefs about practices honed through experience or when tradition, authority, or trial and error is the basis of clinical knowledge, instead of testing through research (Cole).

Protection of Human Subjects

Internal Review Board (IRB) approval for the use of human subjects in research was granted from the participating Children's Hospital NICU on February 8, 2006, with subsequent approval from the University of Minnesota on May 15, 2006. Potential risks to subjects were minimal and parental consent was obtained. Low-stimulus recorded piano music was provided to preterm infants, as was recorded ambient noise at the same decibel level as the music. The sound presentation was painless and required very little time to prepare the subject. Disposable earphones held in place with a stockinette eliminated the need for any adhesion materials.

Complementary therapies including developmental care, touch, and music have long been used in the health care field to improve outcomes of patients. Music, in particular, has had resurgence during the last several decades and has been studied in adult health care settings such as coronary care, surgery, post-anesthesia recovery, and critical care (Chlan, 2000) as well as in neonatal care. A Data Safety Monitoring Plan for the protection of study infants has been included in Appendix F.

Preterm infants may or may not have directly benefitted from participation in this study. Potential benefits, as discussed in the literature, may have included: reduced physiological instability as evidenced by higher oxygen saturations, lower heart rates, lower respiratory rates throughout the music intervention as compared with baseline measurements and improved behavioral state as evidenced by increased general quieting or alerting throughout the music intervention as compared with baseline and ambient noise condition measurements.

Data collected in this research study were managed in a manner that complies with the Department of Health and Human Services standards for confidentiality and provisions of the Privacy Act (U.S. Department of Health and Human Services, 2003). In addition, the federally mandated HIPAA law was strictly adhered to in order to insure that privacy and security standards for protected health information were followed. Each subject was assigned a code and all personal identifiers were removed from data collection sheets. Access to data was restricted to the principal investigator, the hospital sponsor, the research associate, and faculty advisors; password protected files were used; and all data with identifying information will be stored in a locked filing cabinet by the principal investigator for two years after completion of data collection. Following completion of the study, coded data and videotapes will be kept for educational purposes or further analysis for five years. The tapes will be erased and destroyed after five years.

Gender and Minority Inclusion

Over the past sixteen years, there has been a 21% increase in the incidence of preterm birth in Minnesota (Martin et al., 2003). Out of nearly 70,000 live births in Minnesota in 2005, 10.7% were preterm and almost half were female (Martin et al.;

Sutton & Mathews, 2004). During 2003-2005 (average) in Minnesota, preterm birth rates were highest for black infants (12.8% of the black population, 9.8% of all preterm infants), followed by Native Americans (12.4% of the Native American population, 2.1% of all preterm infants), Asians (10.6% of the Asian population, 6.0% of all preterm infants), whites (10.2% of the white population, 71.2% of all preterm infants), Hispanics (9.6% of the Hispanic population, 7.0% of all preterm infants) (National Center for Health Statistics, 2008). There was no report of race/ethnicity for 3.9% of all preterm infant births. Both male and female infants were included in the study. Based on this gender and race/ethnicity data, planned enrollment for the study is listed in Table 5.

Table 5. Targeted/Planned Enrollment For Study Infants

	Non-Hispanic black	Native American	Asian or Pacific Islander	Non-Hispanic white	Hispanic	Total
Female	4.5	4.5	4	3.5	3.5	20
Male	4.5	4.5	4	3.5	3.5	20
Total	9 (23%)	9 (22.3%)	8 (19.1%)	7 (18.3%)	7 (17.3%)	40 (100%)

Note. From the National Vital Statistics Report obtained in Sutton & Mathews (2004).

Data collection occurred from October of 2006 through May of 2008. All eligible preterm infants regardless of gender, race, or ethnicity were recruited for this study and there was no exclusion based on gender, race or ethnicity. Race/Ethnicity and gender data from the NICU at Children's Hospital from 2006 through March of 2008 is listed in Table 6.

Table 6. Race/Ethnicity and Gender Data From 2006 Through March 2008

	2006	2007	2008 (January through March)
White	71.7%	71.9%	70.7%
Black	15.6%	13.0%	13.2%
Asian	6.1%	7.0%	8.3%
Hispanic	5.9%	7.1%	7.0%
Native American	0.7%	1.0%	0.8%
Male	53.9%	58.0%	58.7%
Female	46.1%	42.0%	41.3%

Note. From Children's Hospital NICU (2008).

Based upon Minnesota data for 2005, the hospital's NICU sample did not have similar stratification possibly due to the change in population demographics for the years 2006 through 2008 versus 2005. Similar stratification did exist for data collected in 2004. Based upon Children's Hospital NICU data for 2006 through March of 2008, the study sample had similar stratification, although there were slightly more females (51.2%) than males (48.8%) in the study whereas the hospital's NICU data included more males than females. The largest group of study infants included white infants (73.2%), followed by blacks (14.6%), Asians (7.3), and Hispanics (4.9%). There were no Native American infants that met inclusion criteria for the study during the recruitment period. See Table 7.

Table 7. Race/Ethnicity and Gender Data For Study Infants

	October, 2006 - May, 2008 <i>n</i> (%)
White	30 (73.2)
Black	6 (14.6)
Asian	3 (7.3)
Hispanic	2 (4.9)
Native American	0 (0)
Female	21 (51.2)
Male	20 (48.8)

Note. From Children's Hospital NICU (2008).

Chapter 4

RESULTS

Demographic Data

A total of 42 clinically stable, non-ventilated, appropriate-for-gestational-age (AGA) preterm infants from 32 to 35 weeks gestation were recruited for this study from a large, newly remodeled Children's Hospital NICU. The final sample size included 41 preterm infants (21 infants in the intervention group and 20 in the control group). One control infant was withdrawn from the study due to fussiness and high motor activity prior to and during the sound condition.

Study infants were racially diverse and had similar race/ethnicity stratification in relation to the NICU site and to the latest Minnesota data for 2003 to 2005. Study infants from October 2006 through May, 2008 included 73.2% whites, followed by 14.6% blacks, 7.3% Asians, and 4.9% Hispanics. There were no Native American infants that met inclusion criteria for the study during the recruitment period. Ethnicity of the NICU site from 2006 through March of 2008 ranged from 70.7 to 71.9% white, 13.0 to 15.6% black, 6.1 to 8.3% Asian, 5.9 to 7.1% Hispanic, and 0.7 to 1.0% American Indian infants. Specific race/ethnicity rates for preterm infants in Minnesota from 2003-2005 included 71.2% white, 9.8% black, 7.0% Hispanic, 6.0% Asian, and 2.1% American Indian infants (3.9% of the preterm infants did not have reports on race/ethnicity). There were slightly more white preterm infants and slightly fewer Hispanic and American Indian preterm infants in the study sample as compared with NICU site data. There were more black preterm infants, slightly more Asian preterm infants, and fewer Hispanic and American

Indian preterm infants in the study sample as compared with data for the population of Minnesota for 2003 to 2005. This discrepancy is possibly due to the change in population demographics for the years 2006 through 2008 versus 2003 to 2005 as well as the urban setting of the study site.

There were approximately the same number of white infants in the music and ambient noise groups (16 music infants versus 14 ambient noise infants) and the same number of Hispanic infants in each group (1 Hispanic infant in each group). There were fewer black infants in the music versus ambient noise groups (1 music infant versus 5 ambient noise infants) and more Asian infants in the music versus ambient noise groups (3 music infants versus 0 ambient noise infants).

Birth weight ranges for study infants nearly doubled from 1495 to 2820 grams ($M = 2037.20$; $SD = 365.46$). This is not surprising given the range in gestational ages of nearly three weeks (32.3 weeks to 34.9 weeks with a mean gestational age of 33.66 weeks) and a range in age from 3 to 10 days of life (mean age = 7.10 days). Also, most of the study infants were in birth weight groups from 1700 to 1999 grams and over 2300 grams. There were an equal number of infants weighing less than 1700 grams in each group and approximately the same numbers of infants in the other birth weight groups as well. There were slightly more music group infants than ambient noise group infants in the two middle birth weight categories (weighing from 1700 to 1999 grams and from 2000 to 2299 grams at birth) and slightly more ambient noise group infants than music group infants in the largest birth weight category (weighing over 2300 grams at birth).

Current weight ranges for study infants nearly doubled as well from 1495 to 2820 grams ($M = 2013.85$; $SD = 343.84$). Again, this is not surprising given the range in

gestational ages and age at the time of the study. Most of the study infants were in current weight groups from 1700 to 1999 grams and from 2000 to 2299 grams. There were fewer equal numbers of infants in music and ambient noise groups with similar current weight ranges. There were again more music group infants than ambient noise group infants in the two middle current weight categories (weighing from 1700 to 1999 grams and from 2000 to 2299 grams at birth) and slightly more ambient noise group infants than music group infants in the smallest and largest current weight categories (weighing less than 1700 grams and weighing over 2300 grams at the time of the study).

Infant gestational ages ranged from 32.3 weeks to 34.9 weeks ($M = 33.76$; $SD = 0.75$). There were approximately equal numbers of infants from music and ambient noise groups in similar gestational age ranges. There were a few more music group infants than ambient noise group infants in the lowest gestational age category and a few more ambient noise group infants than music group infants in the highest gestational age categories.

Infant ages at the time of the study ranged from 3 to 10 days of life ($M = 7.10$; $SD = 2.04$). There were fewer equal numbers of similarly aged infants in music and ambient noise groups. There were 4 more ambient noise group infants than music group infants from 3 to 6 days of life at the time of the study and 5 more music group infants than ambient noise group infants from 7 to 10 days of life at the time of the study.

APGAR scores were from 8 to 10 ($M = 8.78$; $SD = 0.53$). Five minute APGAR scores met the study inclusion criteria of 8 to 10 and had a mean of 8.78. Most of the infants received an APGAR score of 9 and most of those infants were in the music group. Of infants who had received an APGAR score of 8, a few more of them were in the

music group versus the ambient noise group. There were an equal number of infants in the music and ambient noise groups who had received an APGAR score of 10 (1 in each group). A slightly larger number of infants with higher APGAR scores were in the music versus ambient noise group.

Because infants were randomly selected into groups using computer generated randomized numbers, there were equivalent distributions of race/ethnicity, gender, weight (birth weight and current weight), ages (gestational age and age at study date), and APGAR scores in music and ambient noise groups of infants so that these characteristics most likely did not influence study results. The demographic data of subjects is presented in Table 8.

Table 8. Demographic Characteristics of the Sample ($N = 41$)

		Total	Music $n = 21$	Ambient Noise $n = 20$	Test Statistic	p - value
Demographic		n (%)	n (%)	n (%)	χ^2 or t	p
Race/Ethnicity					$\chi^2 = 5.78$.08 ^a
	White	30 (73.2)	16 (39.0)	14 (34.1)		
	Black	6 (14.6)	1 (2.4)	5 (12.2)		
	Hispanic	2 (4.9)	1 (2.4)	1 (2.4)		
	Asian	3 (7.3)	3 (7.3)	0 (0.0)		
Gender					$\chi^2 = 1.21$.27
	Male	20 (48.8)	12 (29.3)	8 (19.5)		
	Female	21 (51.2)	9 (22.0)	12 (29.3)		
Birth Weight (grams)		2037.20	1997.67	2078.70	$t = .71$.49
Mean (SD)		(365.46)	(343.97)	(391.27)		
	< 1700	8 (19.5)	4 (9.8)	4 (9.8)		
	1700 – 1999	14 (34.1)	8 (19.5)	6 (14.6)		
	2000 – 2299	8 (19.5)	5 (12.2)	3 (7.3)		
	≥ 2300	11 (26.8)	4 (9.8)	7 (17.1)		
Current Weight (grams)		2013.85	2006.57	2021.50	$t = .14$.89
Mean (SD)		(343.84)	(320.41)	(375.13)		
	< 1700	7 (17.1)	2 (4.9)	5 (12.2)		
	1700 – 1999	14 (34.1)	10 (24.4)	4 (9.8)		
	2000 – 2299	11 (26.8)	6 (14.6)	5 (12.2)		
	≥ 2300	9 (22.0)	3 (7.3)	6 (14.6)		
Gestational Age (weeks)		33.76	33.66	33.87	$t = .90$.37
Mean (SD)		(0.75)	(.75)	(.76)		
	32 – 32.9	8 (19.5)	5 (12.2)	3 (7.3)		
	33 – 33.9	13 (31.7)	7 (17.1)	6 (14.6)		
	34 – 34.9	20 (48.8)	9 (22.0)	11 (26.8)		
Age at Study (days)		7.10	7.62	6.55	$t = -1.71$.10
Mean (SD)		(2.04)	(1.63)	(2.31)		
	3-6	14 (34.1)	5 (12.2)	9 (22.0)		
	7-10	27 (65.9)	16 (39.0)	11 (26.8)		
APGAR Score (5 minutes)		8.78	8.86	8.70	$t = -1.01^b$.31
Mean (SD)		(0.53)	(0.48)	(0.57)		
	8	11 (26.8)	4 (9.8)	7 (17.1)		
	9	28 (68.3)	16 (39.0)	12 (29.3)		
	10	2 (4.9)	1 (2.4)	1 (2.4)		

Note. a. Fisher Exact test

b. Mann-Whitney U test

Infant Past Medical Conditions. Although infants with major comorbidities were excluded from the study, there were some infants with past medical conditions common to preterm infants such as 1 infant in the music group requiring brief positive pressure ventilation (PPV) through an endotracheal tube (ETT) at birth and 16 with hypoglycemia as defined by a blood glucose level less than 50 mg/dL. Half of the infants diagnosed with hypoglycemia were in the music group and half were in the ambient noise group. There were also 6 infants with hyperbilirubinemia as characterized by a total serum bilirubin level of greater than 12 mg/dL. Four of the infants in the study had total bilirubin levels over 12 mg/dL (two infants had peak levels of 12.5 mg/dL and two had peak levels of 13.4 mg/dL) for which they received phototherapy prior to the study. Eleven infants total underwent phototherapy treatment prior to the study. Total bilirubin levels ranged from 2.6 to 13.4 mg/dL. One infant had a total bilirubin level of 7.9 mg/dL and received phototherapy and one had a total bilirubin level of 11.2 mg/dL and did not receive phototherapy. Of infants diagnosed with hyperbilirubinemia, 2 were in the music group and 4 were in the ambient noise group. Hypoglycemia and hyperbilirubinemia were expected diagnoses because of the preterm risk for low blood glucose and high bilirubin levels.

A nearly equal number of infants experienced other past medical conditions in the two sound groups. Past conditions included mild respiratory distress (initial mild retractions, intermittent grunting, nasal flaring, tachypnea, tachycardia, apnea, bradycardia, and desaturations), small aspirates or emesis, low grade systolic heart murmurs, and abnormal laboratory values (slightly high potassium, creatinine, and chloride levels; mild thrombocytopenia; and minimally elevated monocyte, lymphocyte,

and neutrophil counts). These comorbidities were also predictable since they are commonly seen in preterm infants. Past medical conditions of study infants are presented in Table 9.

Table 9. Past Medical Condition of the Sample ($N = 41$)

	Total	Music $n = 21$	Ambient Noise $n = 20$	Test Statistic	p - value
	n (%)	n (%)	n (%)	χ^2	p
Past Medical Condition					
PPV at Birth	1 (2.4)	1 (2.4)	0 (0.0)	$\chi^2 = .98$	1.00 ^a
Hypoglycemia (BG <50)	16 (39.0)	8 (19.5)	8 (19.5)	$\chi^2 = .02$.90
Hyperbilirubin (Hgb >12)	6 (14.6)	2 (4.9)	4 (9.8)	$\chi^2 = .90$.34
Other Past Conditions	21 (51.2)	11 (26.8)	10 (24.4)	$\chi^2 = .02$.88

Note. a. Fisher Exact test

Risk Factors Related to Prematurity. Risk factors, which may or may not have contributed to the premature birth of study infants, were reviewed as well. Identification of maternal and fetal risk factors for premature infants is a challenge because the causes of prematurity are often unknown involving interaction of numerous conditions. Most maternal risk factors were present in a small number of study infants and were fairly evenly distributed between the music and ambient noise groups.

With respect to maternal factors, the following conditions were found to be present: 2 mothers had smoked during pregnancy (1 of these infants was in the music group and 1 was in the ambient noise group), 5 mothers were over 35 years of age when they delivered their preterm infant (3 of these infants were in the music group and 2 were in the ambient noise group), 5 mothers had experienced some type of infection during pregnancy (2 of these infants were in the music group and 3 were in the ambient noise

group), 3 mothers were diagnosed with maternal hypertension (1 of these infants was in the music group and 2 were in the ambient noise group), 1 mother was found to have gestational diabetes and her infant was in the ambient noise group, 1 mother was discovered to have a placenta previa and her infant was also in the ambient noise group, 12 mothers had a history of an abortion or miscarriage (4 of these infants were in the music group and 8 were in the ambient noise group), and 4 mothers had experienced a previous preterm birth (2 of these infants were in the music group and 2 were in the ambient noise group).

In addition, 16 infants were the product of a multiple pregnancy with half of the infants in the music group and half in the ambient noise group. The high incidence of multiparity (a pregnancy of two or more fetuses) or multiple pregnancy is foreseen in that it is a risk factor for prematurity. Eighteen infants were born subsequent to premature rupturing of the membranes (PROM) with 11 of the infants in the music group and 7 in the ambient noise group. Twenty-one infants were born following preterm labor with 11 of the infants in the music group and 10 in the ambient noise group. Eight infants required preterm induction with half in the music group and half in the ambient noise group. Premature rupture of membranes precedes premature birth as does preterm labor and preterm induction; therefore, the presence of these maternal factors is not remarkable.

Other maternal factors were also present in 29 mothers such as: preeclampsia, GER, positive group B streptococcus cultures, abnormal laboratory values (high liver function and thrombocytopenia), and other chronic illnesses (asthma, a bicornate uterus, polycystic ovaries, cervical incompetence, cholestasis, hyperemesis, a single kidney, adrenal hyperplasia, hyperthyroidism, anxiety disorder, and depression). These factors

are anticipated in mothers who give birth to preterm infants since they are risk factors that affect pregnancy outcomes (Gardner & Goldson, 2006). Of these maternal factors, 14 were in the music group and 15 were in the ambient noise group.

Fetal factors related to prematurity were quite uniformly distributed between the music and ambient noise groups as well. These factors would be expected to be even more prevalent than maternal factors due to the direct impact of fetal conditions upon pregnancy outcomes. In relation to fetal factors that may have contributed to the prematurity of infants, 7 infants experienced fetal distress (typified as decelerations and a prolapsed cord) and 1 infant in the ambient noise group was born with a methicillin-resistant staphylococcus aureus (MRSA) infection. Four of the infants who had experienced fetal distress were in the music group and 3 were in the ambient noise group. Fetal distress as noted in this study is commonly assessed before preterm birth and MRSA infection is not an exceptional finding and is becoming more prevalent in hospitalized patients. Risk factors, which may or may not have contributed to the premature birth of study infants, are presented in Table 10.

Table 10. Risk Factors of the Sample ($N = 41$)

	Total	Music $n = 21$	Ambient Noise $n = 20$	Test Statistic	p - value
Risk Factors	n (%)	n (%)	n (%)	χ^2	p
Maternal Risk Factors					
Maternal Smoking	2 (4.9)	1 (2.4)	1 (2.4)	.00	1.0 ^a
Maternal Age >35	5 (12.2)	3 (7.3)	2 (4.9)	.18	.68
Maternal Infection	5 (12.2)	2 (4.9)	3 (7.3)	.29	.59
Maternal Hypertension	3 (7.3)	1 (2.4)	2 (4.9)	.41	.52
Gestational Diabetes	1 (2.4)	0 (0.0)	1 (2.4)	1.08	.49 ^a
Placenta Previa	1 (2.4)	0 (0.0)	1 (2.4)	1.08	.49 ^a
Abortion or Miscarriage	12 (29.3)	4 (9.8)	8 (19.5)	2.17	.14
Previous Preterm Birth	4 (9.8)	2 (4.9)	2 (4.9)	.00	.96
Multiple Pregnancy	16 (39.0)	8 (19.5)	8 (19.5)	.02	.90
PROM	18 (43.9)	11 (26.8)	7 (17.1)	1.26	.26
Preterm Labor	21 (51.2)	11 (26.8)	10 (24.4)	.02	.88
Preterm Induction	8 (19.5)	4 (9.8)	4 (9.8)	.01	.94
Other Maternal Factors	29 (70.7)	14 (34.1)	15 (36.6)	.34	.56
Infant Risk Factors					
Fetal Distress	7 (17.1)	4 (9.8)	3 (7.3)	.12	.73
Fetal Infection	1 (2.4)	0 (0.0)	1 (2.4)	1.08	.49 ^a

Note. a. Fisher Exact test

Current Medications. Regularly scheduled medications that infants received at the time of the study are commonly dispensed to preterm infants in the NICU and were ordered in mostly equal numbers between the music and ambient noise groups. Most of the preterm infants were not receiving medications at the time of the study. Medications ordered for infants at the time of the study included aminophylline, antibiotics, topical skin preparations, and vitamins. Aminophylline was ordered to promote respirations for 2 infants (1 of these infants was in the music group and 1 was in the ambient noise group).

One infant in the ambient noise group was still on ampicillin and gentamicin antibiotics, although blood cultures remained negative, because she was only three days old at the time of the study. Ten infants were on some other type of medication such as topical creams for perianal rashes and dry skin or vitamin supplements. Half of the infants on other medications were in the music group and half were in the ambient noise group. In addition, 21 infants had been given one or two doses of betamethasone steroids prenatally with 11 being in the music group and 10 in the ambient noise group. Current medications for study infants are presented in Table 11.

Table 11. Current Medications of the Sample ($N = 41$)

	Total	Music $n = 21$	Ambient Noise $n = 20$	Test Statistic	p - value
	n (%)	n (%)	n (%)	χ^2	p
Current Medications					
Aminophylline	2 (4.9)	1 (2.4)	1 (2.4)	.00	1.0 ^a
Antibiotics	1 (2.4)	0 (0.0)	1 (2.4)	1.08	.49 ^a
Other	10 (24.4)	5 (12.2)	5 (12.2)	.01	.93
Prenatal Steroids	21 (51.2)	11 (26.8)	10 (24.4)	.02	.88

Note. a. Fisher Exact test

Room Sound Level. Room sound levels were recorded as recommended by Philbin (2000) and Philbin and Klaas (2000). Sound levels were measured using a digital sound level meter placed near the ears of infants. Because the NICU setting for the study included private-rooms, sound levels in study rooms were very low ranging from 29.9 to 50.5 dBA ($M = 38.61$; $SD = 5.06$) when they usually vary between 50 and 80 dB in most NICUs. Most of the sound levels in rooms were below 40 dB. Of infants in rooms where the sound level was 29.9 – 40.0 dB, 11 were in the music group and 10 were in the

ambient noise group. Of infants in rooms where the sound level was 40.0 – 44.9, 7 were in the music group and 9 were in the ambient noise group. Of infants in rooms where the sound level was 45.0 – 50.5, 3 were in the music group and 1 was in the ambient noise group. Room sound levels for study infants are presented in Table 12.

Table 12. Room Sound Level of the Sample ($N = 41$)

	Total	Music $n = 21$	Ambient Noise $n = 20$	Test Statistic	p - value
	n (%)	n (%)	n (%)	t	p
Room Sound Level (dBA)					
Mean (SD)	38.61 (5.06)	38.68 (5.62)	38.53 (4.55)	-.09	.93
29.9 – 40.0	21 (51.2)	11 (26.8)	10 (24.4)		
40.0 – 44.9	16 (39.0)	7 (17.1)	9 (22.0)		
45.0 – 50.5	4 (9.8)	3 (7.3)	1 (2.4)		

Intervention Data

Because graphing of oxygen saturation, heart rate, and behavioral state data indicated changes in the time periods (before, during, and after the music or ambient noise sound conditions) and variability in those changes, multilevel mixed modeling was used for analysis of data. Mixed modeling examined the changes in data over time within infants (how the responses of infants varied over time) as well as changes between the music and ambient noise groups. Level-1 modeling demonstrated a significant amount of variability between oxygen saturations, infant heart rates, and behavioral states for intercepts (differences in preterm responses at the beginning of each time period) and slopes (differences in preterm infant response changes over the three time periods), which

warranted the second level of modeling. Also, because of the significant unexplained variability between infants, both group and gender differences were analyzed.

Results of Analysis by Hypotheses

Hypothesis #1: *There will be significant differences in oxygen saturations between the music intervention group and the ambient noise control group.*

Oxygen Saturation. There were no significant differences in infant oxygen saturations between the music and ambient noise groups, although there were significant oxygen saturation changes for preterm infants over the time period after the sound conditions. Infant oxygen saturations did not change significantly in the 10 minutes before the sound ($p = .97$) or during the 20 minutes of sound ($p = .75$); however, preterm oxygen saturation did decrease significantly in the 10 minutes after presentation of the sound conditions ($p = .004$). Oxygen saturations for infants in the music group ranged from 93 to 100% at the 10 minute landmark before the music was played ($M = 96.38$; $SD = 1.83$), from 91 to 99% at the 30 minute landmark after the music was stopped ($M = 96.43$; $SD = 2.23$), and from 91 to 100% at the 40 minute landmark after data collection was completed ($M = 95.48$; $SD = 2.42$). Oxygen saturations for infants in the ambient noise group ranged from 90 to 99% at the 10 minute landmark before the ambient noise ($M = 96.20$; $SD = 2.04$), from 92 to 100% at the 30 minute landmark after the ambient noise was stopped ($M = 96.70$; $SD = 2.16$), and from 90 to 100% at the 40 minute landmark after data collection was completed ($M = 95.90$; $SD = 2.75$).

According to mix modeling graphs, there was variability in oxygen saturations for each group, but oxygen saturations generally remained the same before and during the sound condition for infants in both groups, whereas oxygen saturations decreased after

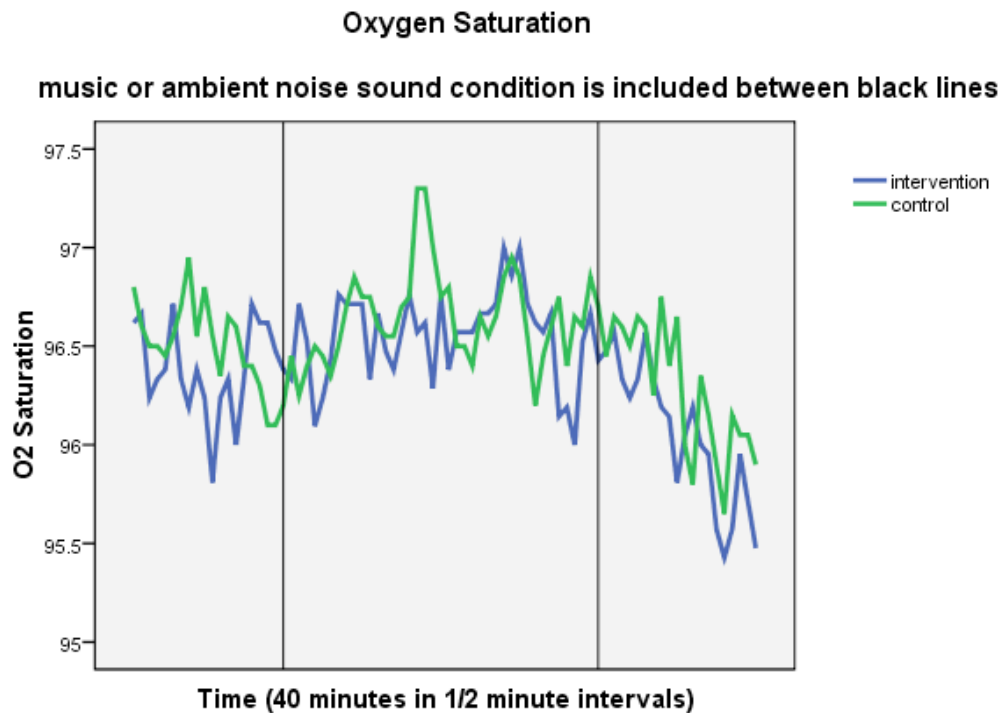
the sound for infants in both groups. Oxygen saturation means for music and ambient noise group were analyzed through *t*-tests and the results are presented in Table 13.

Table 13. Results of *t*-tests Comparing Music and Ambient Noise Group Oxygen Saturation Means ($N = 41$)

	Music $n = 21$	Ambient Noise $n = 20$	Test Statistic	p - value
Oxygen Saturation	Mean (SD)	Mean (SD)	t	p
At 10 Minutes (before sound)	96.38 (1.83)	96.20 (2.04)	-0.30	.77
At 30 Minutes (after sound)	96.43 (2.23)	96.70 (2.16)	0.40	.69
At 40 Minutes (10 minutes after sound)	95.48 (2.42)	95.90 (2.75)	0.52	.60

A graph comparing oxygen saturations for the groups is presented in figure 6.

Figure 6. Graph Comparing Oxygen Saturations for Music and Ambient Noise Groups



Hypothesis #2: *There will be significant differences in heart rates between the music intervention group and ambient noise control group.*

Heart Rate. There were again no significant differences in infant heart rates between the music and ambient noise groups, although preterm infant heart rate changes approached significance for both groups over all time periods ($p = .06$). Infant heart rates did not change significantly in the 10 minutes before the sound ($p = .71$) or during the 20 minutes of sound ($p = .54$); however, preterm heart rate changes after the sound conditions approached significance for both groups by increasing during the 10 minutes after the sound conditions ($p = .07$). Heart rates for infants in the music group ranged from 127 to 182 at the 10 minute landmark before the music was played ($M = 152.48$; $SD = 14.56$), from 123 to 181 at the 30 minute landmark after the music was stopped ($M = 148.95$; $SD = 13.20$), and from 115 to 169 at the 40 minute landmark after data collection was completed ($M = 150.10$; $SD = 12.47$). Heart rates for infants in the ambient noise group ranged from 127 to 167 at the 10 minute landmark before the ambient noise ($M = 149.10$; $SD = 12.70$), from 130 to 174 at the 30 minute landmark after the ambient noise was stopped ($M = 145.60$; $SD = 11.22$), and from 124 to 189 at the 40 minute landmark after data collection was completed ($M = 152.50$; $SD = 16.12$).

According to mix modeling graphs, there was variability in heart rates for each group. Heart rates for infants in the music group generally remained the same before the music, during the music, and after the music, whereas heart rates for infants in the ambient noise group remained relatively stable before the noise and dipped slightly during the noise, but increased steadily above baseline after the noise. Additionally, infant heart rates were significantly lower in the ambient noise group when the noise was

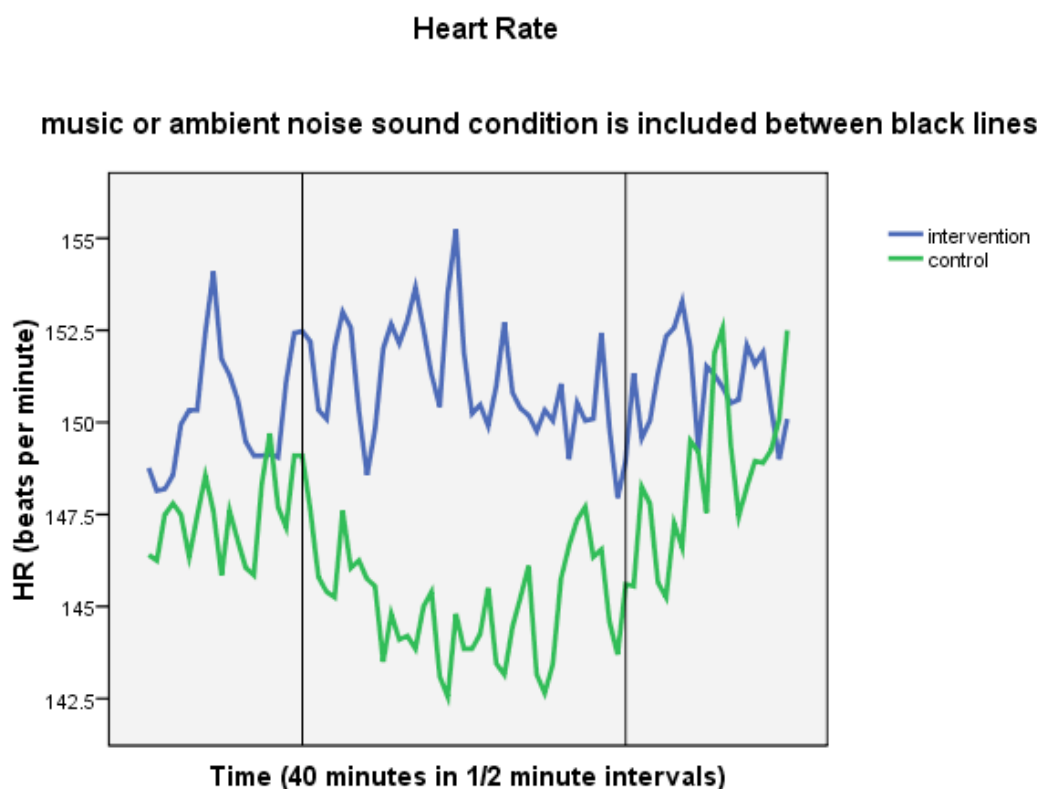
initiated as compared to the heart rates for infants in the music group when the music was started ($p = .05$). The lower ambient noise group heart rates when noise was introduced may partially account for the nearly significant preterm infant heart rate group differences ($p = .06$). Heart rate means for music and ambient noise group were analyzed through t -tests and the results are presented in Table 14.

Table 14. Results of t -tests Comparing Music and Ambient Noise Group Heart Rate Means ($N = 41$)

	Music $n = 21$	Ambient Noise $n = 20$	Test Statistic	p - value
Heart Rate	Mean (SD)	Mean (SD)	t	p
At 10 Minutes (before sound)	152.48 (14.56)	149.10 (12.70)	-0.79	.44
At 30 Minutes (after sound)	148.95 (13.20)	145.60 (11.22)	-0.87	.39
At 40 Minutes (10 minutes after sound)	150.10 (12.47)	152.50 (16.12)	0.54	.60

A graph comparing heart rates for music and ambient noise groups is presented in figure 7.

Figure 7. Graph Comparing Heart Rates for Music and Ambient Noise Groups



Hypothesis #3: *There will be significant differences in behavioral states*

between the music intervention group and ambient noise control group.

Behavioral State. There were also no significant differences in infant behavioral states between the music and ambient noise groups, although preterm infant behavioral state changes were significant over the time periods before and after the sound conditions. Infant behavioral states changed significantly in the 10 minutes before the sound as infants went from a state of active sleep to quiet sleep ($p = .04$) and in the 10 minutes after the sound as infants became slightly more aroused going from quiet sleep to active sleep ($p = .05$). There were no significant preterm infant behavioral state changes over the time period during the sound conditions ($p = .22$). Behavioral states for infants in

the music group ranged from 3 to 5 in all three time periods: at the 10 minute landmark before the music was played ($M = 4.24$; $SD\ 0.70$), at the 30 minute landmark after the music was stopped ($M = 4.10$; $SD\ 0.63$), and at the 40 minute landmark after data collection was completed ($M = 4.24$; $SD\ 0.63$). Behavioral states for infants in the ambient noise group also ranged from 3 to 5 in all three time periods: at the 10 minute landmark before the ambient noise ($M = 3.95$; $SD\ 0.61$), at the 30 minute landmark after the ambient noise was stopped ($M = 4.40$; $SD\ 0.68$), and at the 40 minute landmark after data collection was completed ($M = 4.00$; $SD\ 0.80$).

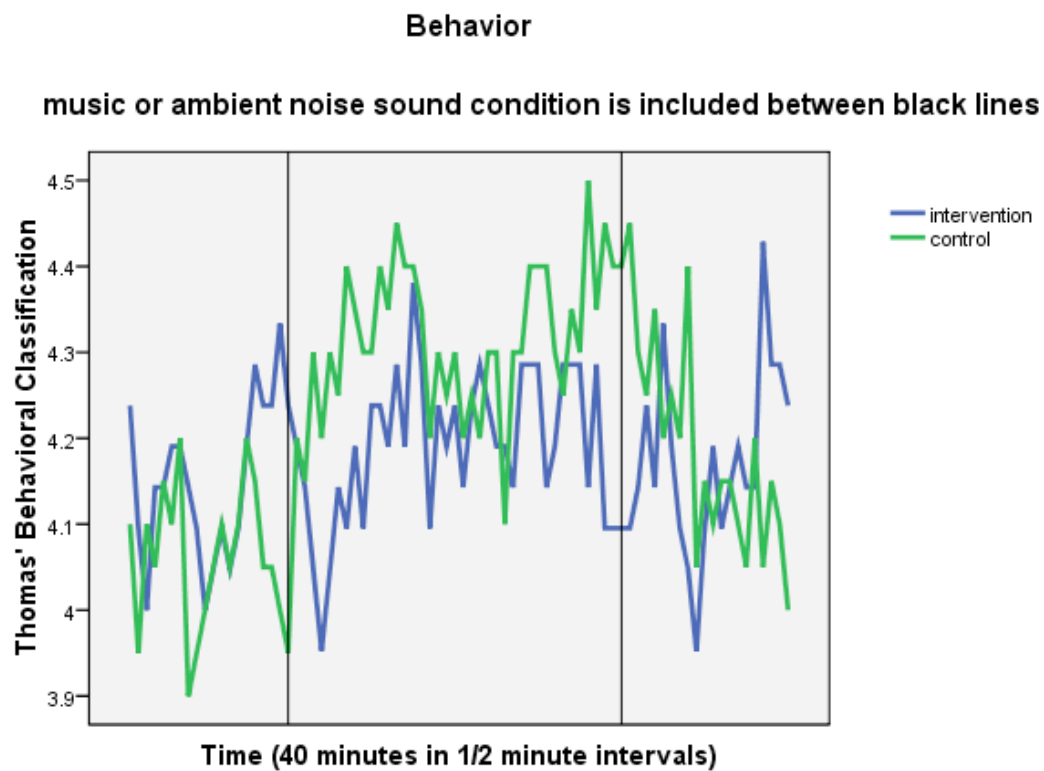
According to mix modeling graphs, there was very slight variability in behavioral states for each group. Behavioral states generally remained the same before, during, and after the sound condition for infants in both groups, although music and ambient noise group infants were generally in their deepest state of sleep during the sound conditions according to Thoman's Derived States behavioral classification scheme (1990). One exception included music group infants, who were in their deepest Thoman sleep state in the final minutes of observation following the music intervention. Behavioral state means for music and ambient noise group were analyzed through t -tests and the results are presented in Table 15.

Table 15. Results of t-tests Comparing Music and Ambient Noise Group Behavioral State Means ($N = 41$)

	Music $n = 21$	Ambient Noise $n = 20$	Test Statistic	p - value
Behavioral State	Mean (SD)	Mean (SD)	t	p
At 10 Minutes (before sound)	4.24 (0.70)	3.95 (0.61)	-1.41	.17
At 30 Minutes (after sound)	4.10 (0.63)	4.40 (0.68)	1.50	.14
At 40 Minutes (10 minutes after sound)	4.24 (0.63)	4.00 (0.80)	-1.07	.29

A graph comparing behavioral states for music and ambient noise groups is presented in figure 8.

Figure 8. Graph Comparing Behavioral States for Music and Ambient Noise Groups



Gender Differences. There were no significant gender differences between the music and ambient noise groups. The effect of gender upon oxygen saturation was not significant ($p = .47$). There was no effect of gender upon heart rate ($p = .66$) or behavioral state ($p = .87$) as well.

Results of Analysis by Individual Differences in Preterm Infant Responses

Individual differences for preterm infants within music and ambient noise groups were examined as well. Significant changes were found in individual infant oxygen saturations, heart rates, and behavioral states over the three time periods (in the ten minutes before presentation of the two sound conditions, the twenty minutes during presentation of the two sound conditions, and the last ten minutes after presentation of the two sound conditions). Significant individual preterm infant response changes and examples of individual infant graphs depicting negative and positive physiological and neurobehavioral responses to music and ambient noise will be portrayed.

Oxygen Saturation. With regard to oxygen saturations, 30 infants experienced significantly decreased oxygen saturations during at least one of the three time periods (18 of these infants were in the music group and 12 were in the ambient noise group). Of the infants who experienced significantly decreased oxygen saturations, 5 had significant oxygen saturation decreases over two of the three time periods (4 of these infants were in the music group and 1 was in the ambient noise group). Seven of the significant oxygen saturation decreases occurred in the first ten minutes before presentation of the sound (3 of the decreases were from infants in the music group and 4 were from infants in the ambient noise group). Eleven of the significant oxygen saturation decreases occurred in the second twenty minutes during presentation of the sound (8 of the decreases were from

infants in the music group and 3 were from infants in the ambient noise group).

Seventeen of the significant oxygen saturation decreases occurred in the third time period during the last ten minutes after presentation of the sound (11 of the decreases were from infants in the music group and 6 were from infants in the ambient noise group).

On the contrary, 17 infants experienced significant increased oxygen saturations during at least one of the three time periods (8 of these infants were in the music group and 9 were in the ambient noise group). Of the infants who experienced significantly increased oxygen saturations, 5 had significant oxygen saturation increases over two of the three time periods (3 of these infants were in the music group and 2 were in the ambient noise group). Seven of the significant oxygen saturation increases occurred before presentation of the sound (4 of the increases were from infants in the music group and 3 were from infants in the ambient noise group). Twelve of the significant oxygen saturation increases occurred during presentation of the sound (5 of the increases were from infants in the music group and 7 were from infants in the ambient noise group). Three of the significant oxygen saturation increases occurred after presentation of the sound (2 of the increases were from infants in the music group and 1 was from an infant in the ambient noise group).

Heart Rate. With regard to heart rates, 21 infants experienced significantly increased heart rates during at least one of the three time periods (11 of these infants were in the music group and 10 were in the ambient noise group). Of the infants who experienced significant increased heart rates, 6 had significant heart rate increases over two of the three time periods (3 of these infants were in the music group and 3 were in the ambient noise group). Eleven of the significant heart rate increases occurred before

the sound (7 of the increases were from infants in the music group and 4 were from infants in the ambient noise group). Eight of the significant heart rate increases occurred during the sound (4 of the increases were from infants in the music group and 4 were from infants in the ambient noise group). Eight of the significant heart rate increases occurred after the sound was discontinued (3 of the increases were from infants in the music group and 5 were from infants in the ambient noise group).

Alternately, 19 infants experienced significantly decreased heart rates during at least one of the three time periods (9 of these infants were in the music group and 10 were in the ambient noise group). One ambient noise group infant experienced a significant heart rate decrease over two of the three time periods. Two of the significant heart rate decreases occurred before the sound (1 of the decreases was from an infant in the music group and 1 was from an infant in the ambient noise group). Thirteen of the significant heart rate decreases occurred during the sound (5 of the decreases were from infants in the music group and 8 were from infants in the ambient noise group). Five of the significant heart rate decreases occurred after the sound (3 of the decreases were from infants in the music group and 2 were from infants in the ambient noise group).

Behavioral State. With regard to behavioral states, all of the study infants spent more time in quiet sleep or active sleep states than in a sleep-wake transition, fussing and crying, or awake states. Fourteen infants experienced significantly decreased behavioral states (defined in this study as moving from a state of quiet sleep, to active sleep, to a sleep-wake transition, to fussing and crying, to being awake or alert) during at least one of the three time periods (6 of these infants were in the music group and 8 were in the ambient noise group). One music group infant had a significant behavioral state decrease

over two of the three time periods. Five of the significant behavioral state decreases occurred prior to the sound (2 of the decreases were from infants in the music group and 3 were from infants in the ambient noise group). Four of the significant behavioral state decreases occurred during the sound (3 of the decreases were from infants in the music group and 1 was from an infant in the ambient noise group). Six of the significant behavioral state decreases occurred after the sound ended (2 of the decreases were from infants in the music group and 4 were from infants in the ambient noise group).

In contrast, 19 infants experienced significantly increased behavioral states during at least one of the three time periods (12 of these infants were in the music group and 7 were in the ambient noise group). One music group infant had a significant behavioral state increase over two of the three time periods. Eight of the significant behavioral state increases occurred before the sound condition (5 of the increases were from infants in the music group and 3 were from infants in the ambient noise group). Seven of the significant behavioral state increases occurred during the sound condition (3 of the increases were from infants in the music group and 4 were from infants in the ambient noise group). Five of the significant behavioral state increases occurred after the sound condition (5 of the increases were from infants in the music group and 0 were from infants in the ambient noise group).

Examples of Individual Infant Graphs

One infant from the music group, Infant 04, exhibited high oxygen saturations except for a small drop in oxygen saturation and a decrease in behavioral state as well as an increase in heart rate towards the very end. This infant also displayed much variability in heart rate and behavioral state with mean heart rates ranging from 140 to over 180

beats per minute and behavioral states in wave-like patterns throughout the study (figure 9).

Another infant from the music group, Infant 12, displayed somewhat more variability in oxygen saturations (91 to 99%) than Infant 04 (97 to 100%) for most of the study. There was also much variability in heart rate and little variability in behavioral state for this infant with mean heart rates ranging from nearly 155 to over 190 beats per minute. This infant displayed very stable behavioral states as well with one small decrease (from a state of sleep-wake transition to a state of fussing and crying and back) and one small increase (from a state of sleep-wake transition to a state of active sleep and back) in comparison with Infant 04 (figure 10).

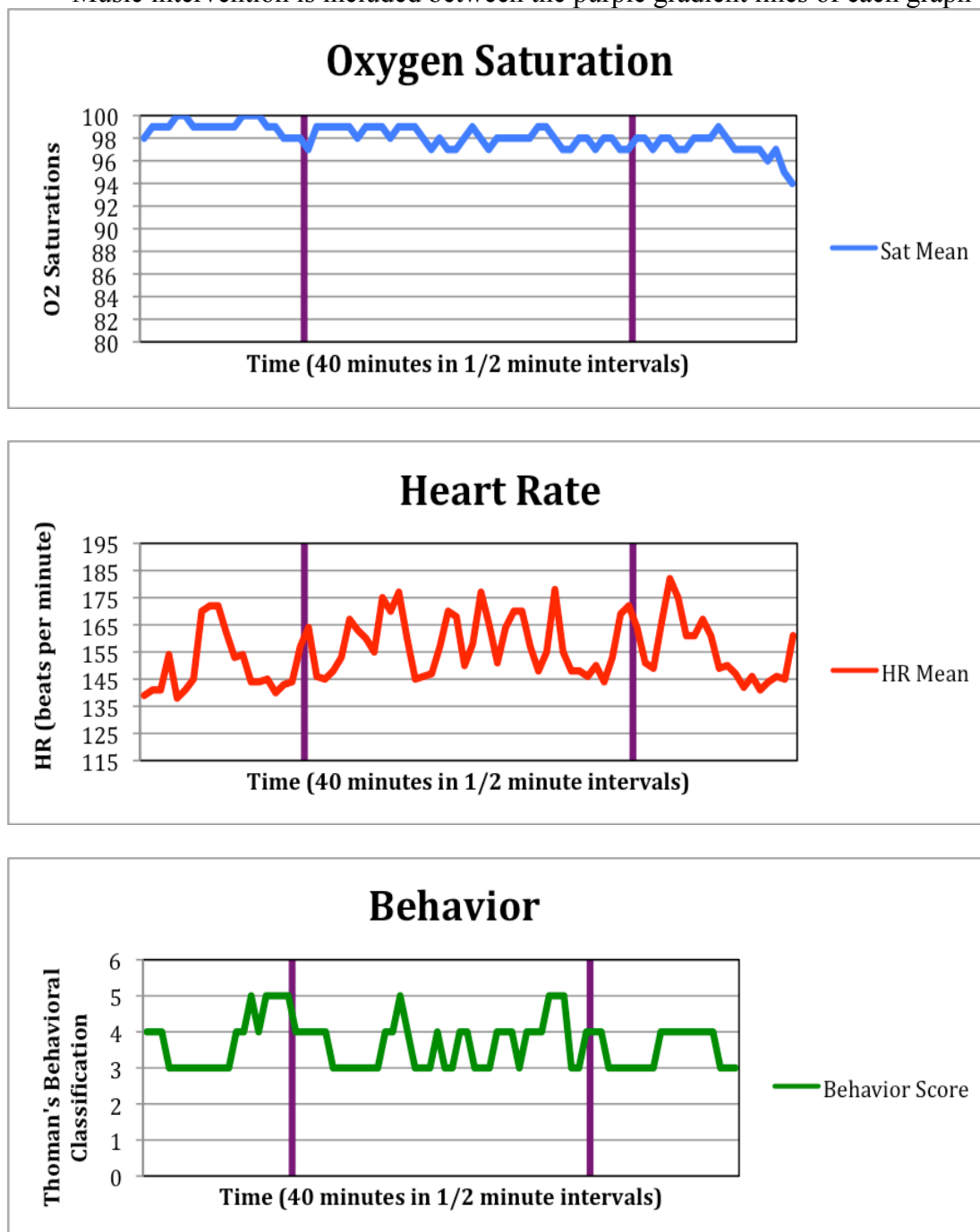
Infant 30 provided a positive portrayal of responses for the music group. Contrary to the previous music infant graph, this infant exhibited minimal variability in oxygen saturations and behavioral states. Oxygen saturations ranged mostly between 95 and 97% and behavioral states periodically vacillated between quiet sleep and active sleep. This infant also demonstrated very little variability in heart rate with lower mean heart rates ranging only from about 140 to 150 beats per minute (figure 11).

Infant 41 also positively portrayed responses for the music group. This infant illustrated a gradual sloping incline in oxygen saturation and behavioral state and a gradual decline in heart rate, which was more variable than for Infant 30. Mean heart rates ranged from less than 130 to about 165 versus about 140 to 150 beats per minute in Infant 30. Oxygen saturations ranged mostly between 96 and 99% and behavioral states again periodically vacillated, this time between active sleep and sleep-wake transition before rising to a steady quiet sleep state (figure 12).

Figure 9. Music Infant 04 Graph

Infant 04

Music intervention is included between the purple gradient lines of each graph

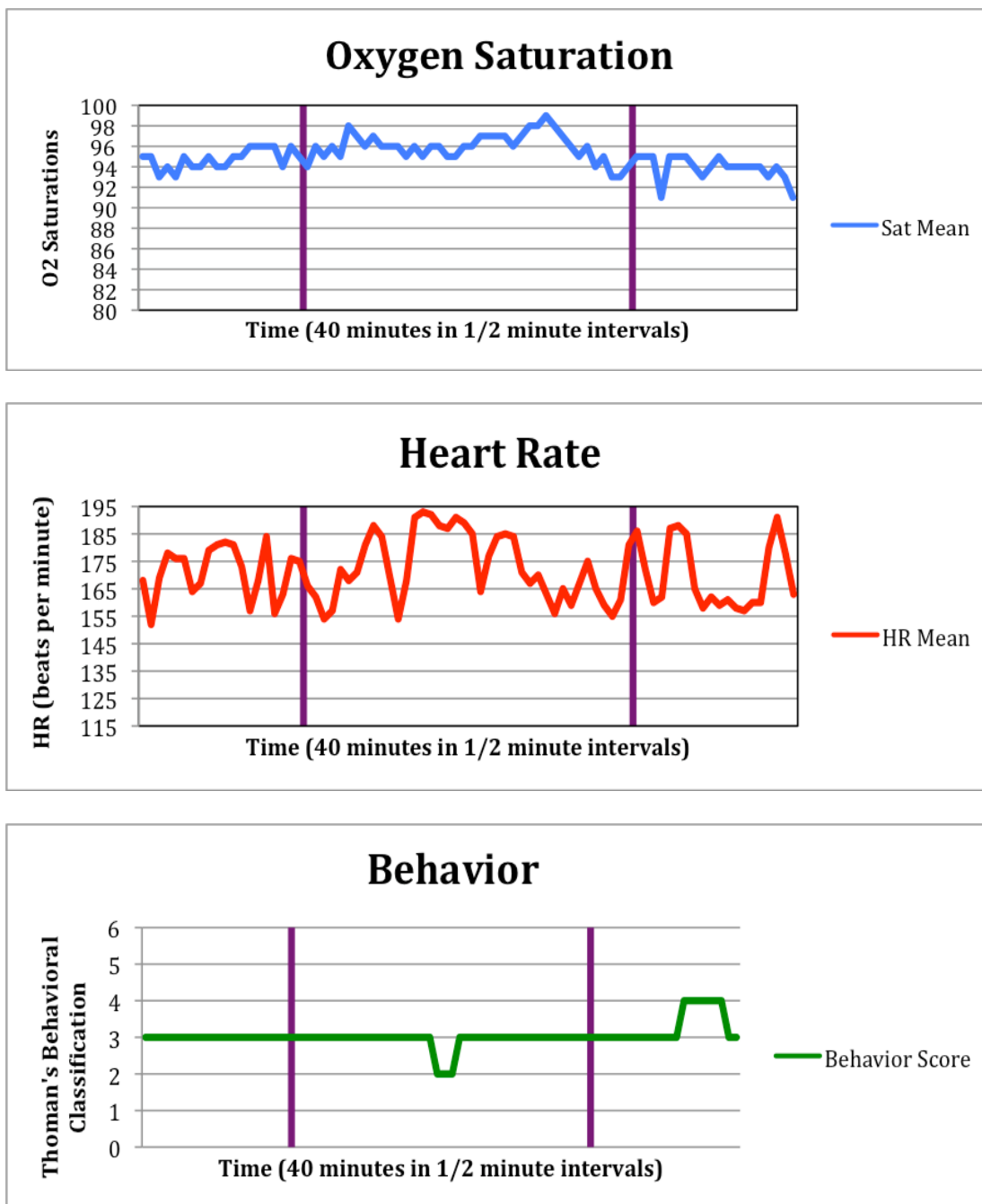


Note. Thoman's Behavioral Classification: 0 = Alert, 1 = Nonalert Waking, 2 = Fussing or Crying, 3 = Sleep-Wake Transition, 4 = Active Sleep, 5 = Quiet Sleep

Figure 10. Music Infant 12 Graph

Infant 12

Music intervention is included between the purple gradient lines of each graph

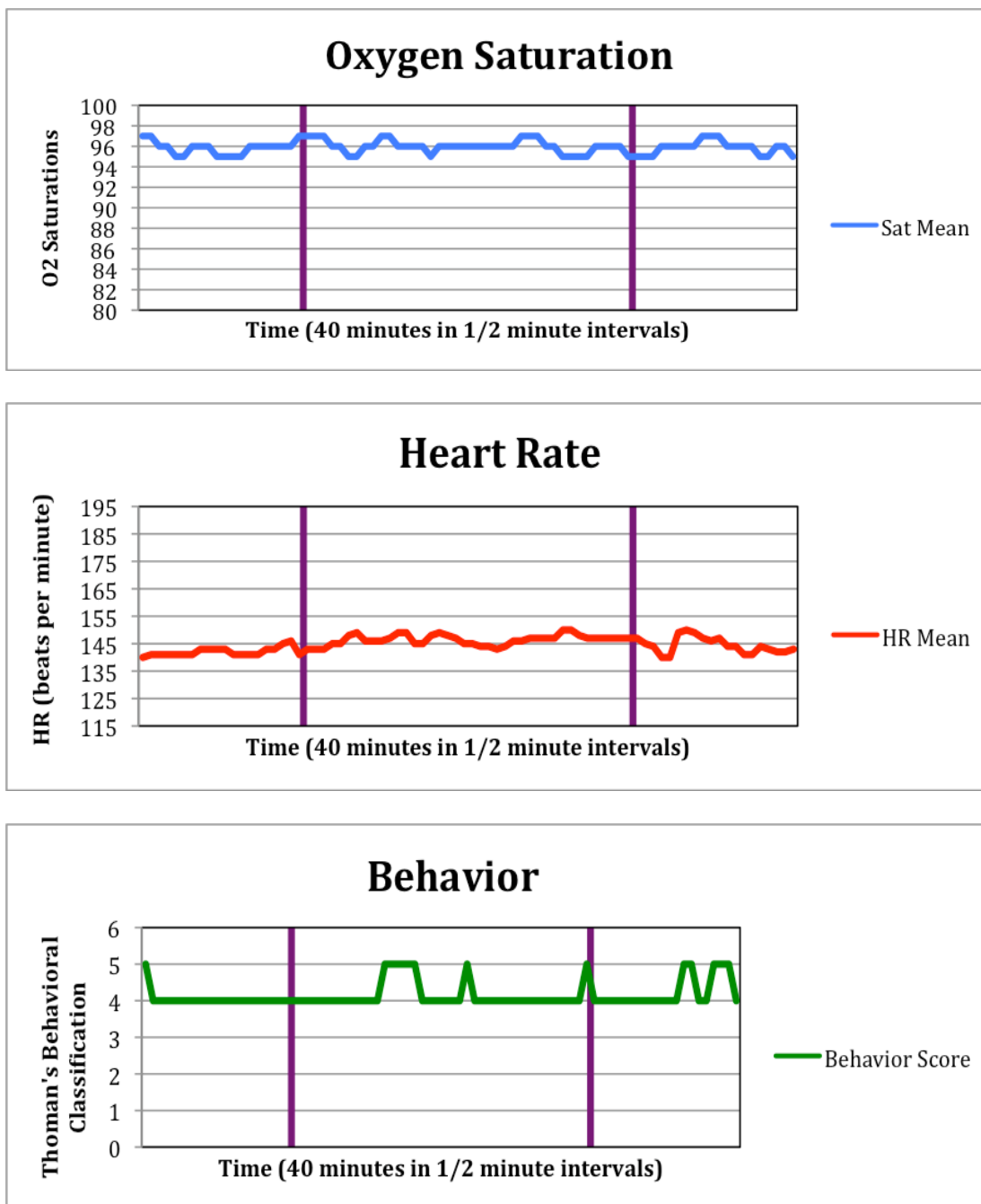


Note. Thoman's Behavioral Classification: 0 = Alert, 1 = Nonalert Waking, 2 = Fussing or Crying, 3 = Sleep-Wake Transition, 4 = Active Sleep, 5 = Quiet Sleep

Figure 11. Music Infant 30 Graph

Infant 30

Music intervention is included between the purple gradient lines of each graph

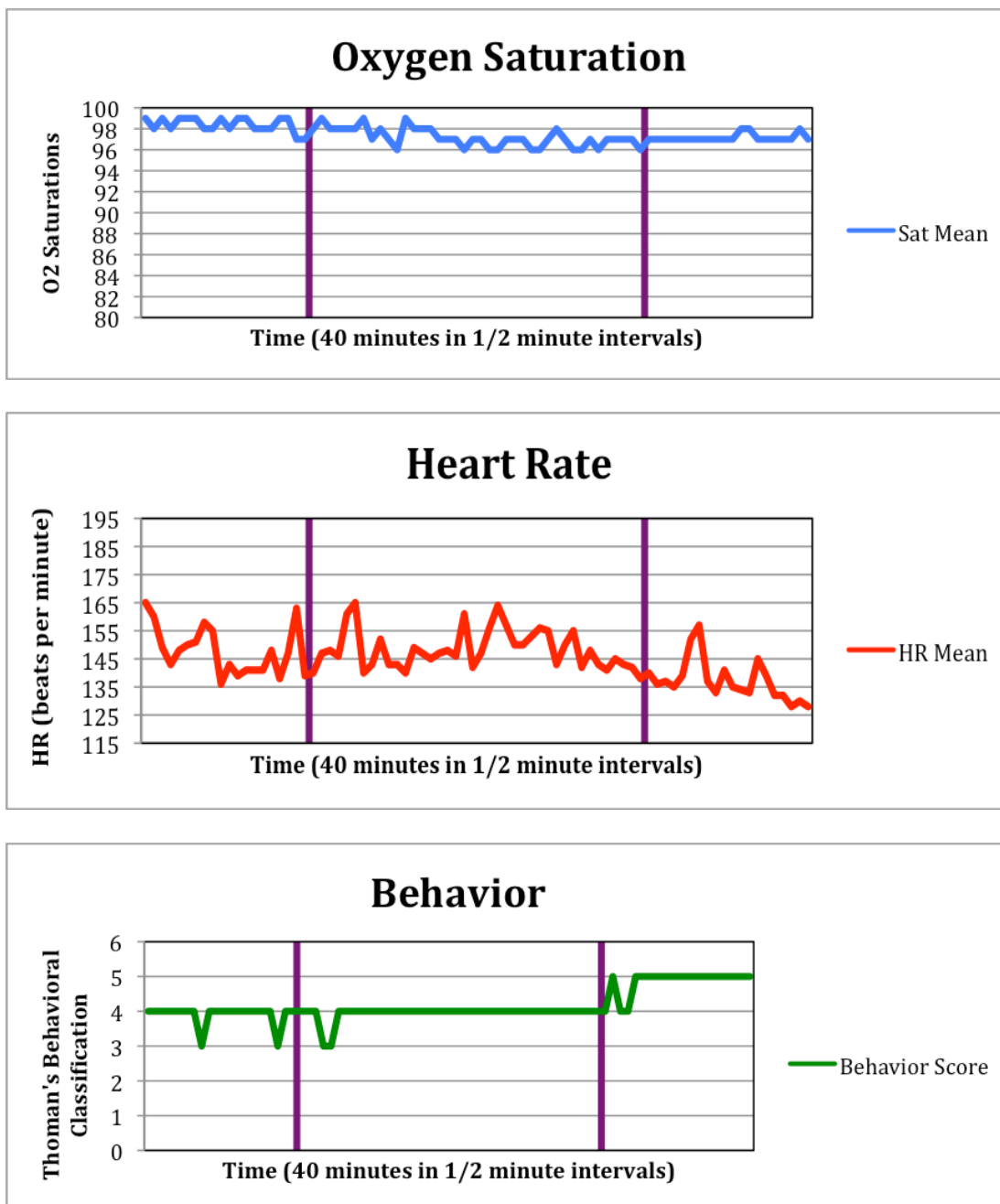


Note. Thoman's Behavioral Classification: 0 = Alert, 1 = Nonalert Waking, 2 = Fussing or Crying, 3 = Sleep-Wake Transition, 4 = Active Sleep, 5 = Quiet Sleep

Figure 12. Music Infant 41 Graph

Infant 41

Music intervention is included between the purple gradient lines of each graph



Note. Thoman's Behavioral Classification: 0 = Alert, 1 = Nonalert Waking, 2 = Fussing or Crying, 3 = Sleep-Wake Transition, 4 = Active Sleep, 5 = Quiet Sleep

Infant 03 from the ambient noise group exhibited high oxygen saturations and behavioral states in wave-like patterns throughout the study, as did Infant 04 from the music group. Infant 03 also displayed much variability in heart rate and behavioral state similarly to Infant 04. Additionally, this infant had mean heart rates ranging from about 120 to 185 beats per minute as compared with the Infant 04 range of 140 to over 180 beats per minute (figure 13).

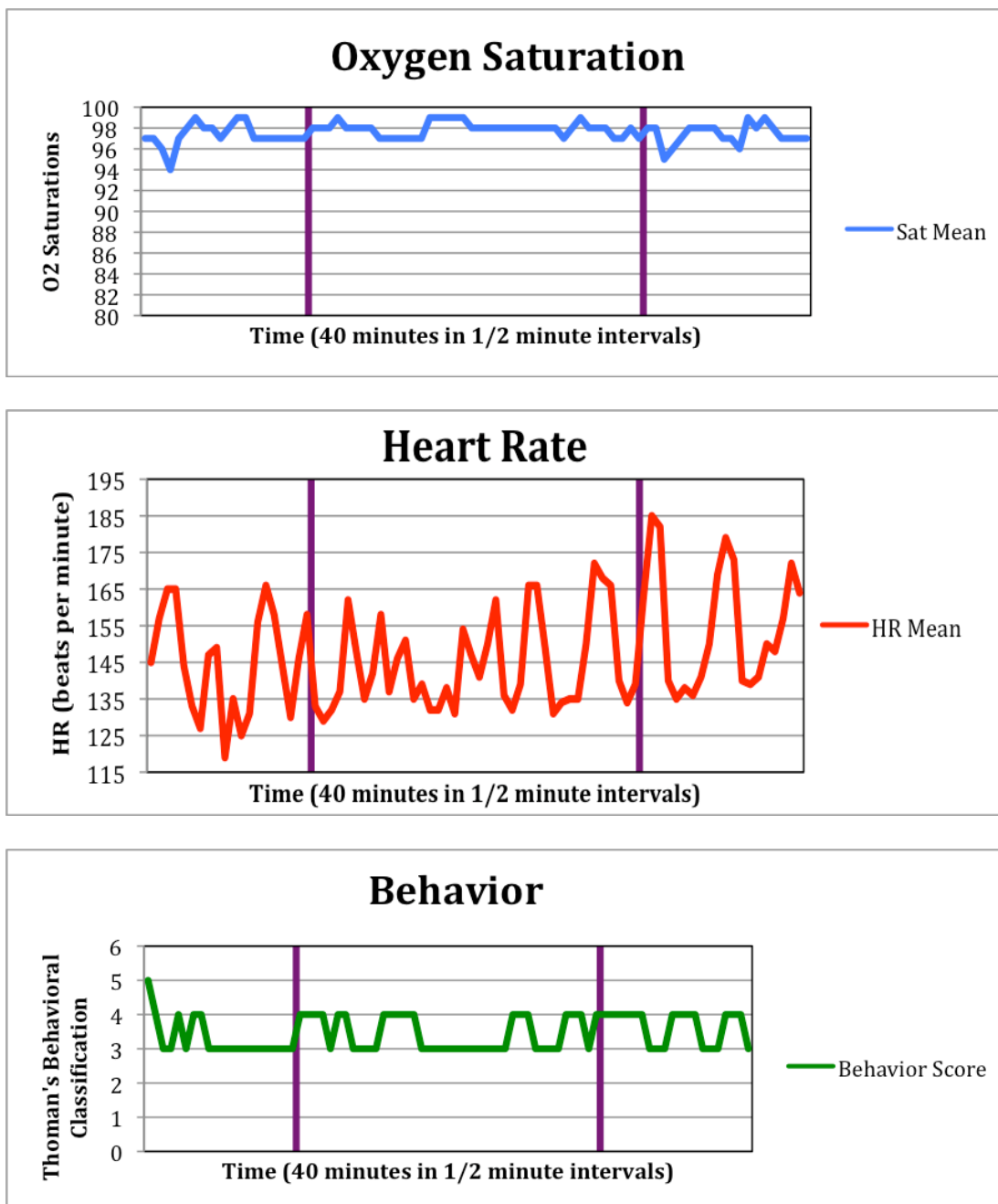
Another infant from the ambient noise group, Infant 19, exhibited relatively high oxygen saturations and behavioral states throughout the study, as did Infants 03 and 04. Dissimilarly, this infant presented with two brief dips in oxygen saturation, although the last dip occurred at the very end of the study. Infant 19 also displayed more variability in heart rate with mean heart rates ranging from about 115 to nearly 190 beats per minute as compared with the other two infants. Behavioral state for this infant remained fairly stable with minimal state changes from active sleep to quiet sleep (figure 14).

Infant 05 positively portrayed responses for the ambient noise group similarly to Infant 41 for the music group, except for having very steady high oxygen saturation levels (lingering at 100%) instead of a gradual sloping incline in saturations. Moreover, instead of a gradual decline in heart rate as depicted by the graph for Infant 41, the graph for Infant 05 showed a gradual, but shallow incline in heart rate. Also, mean heart rates had a greater range for Infant 05 (from just over 115 to about 155 beats per minute versus about 140 to 150 beats per minute for Infant 41). Behavioral states for Infant 05 were much like those for Infant 30 in that they periodically vacillated between quiet sleep and active sleep before rising to a steady quiet sleep state as for Infant 41 (figure 15).

Figure 13. Ambient Noise Infant 03 Graph

Infant 03

Ambient noise is included between the purple gradient lines of each graph

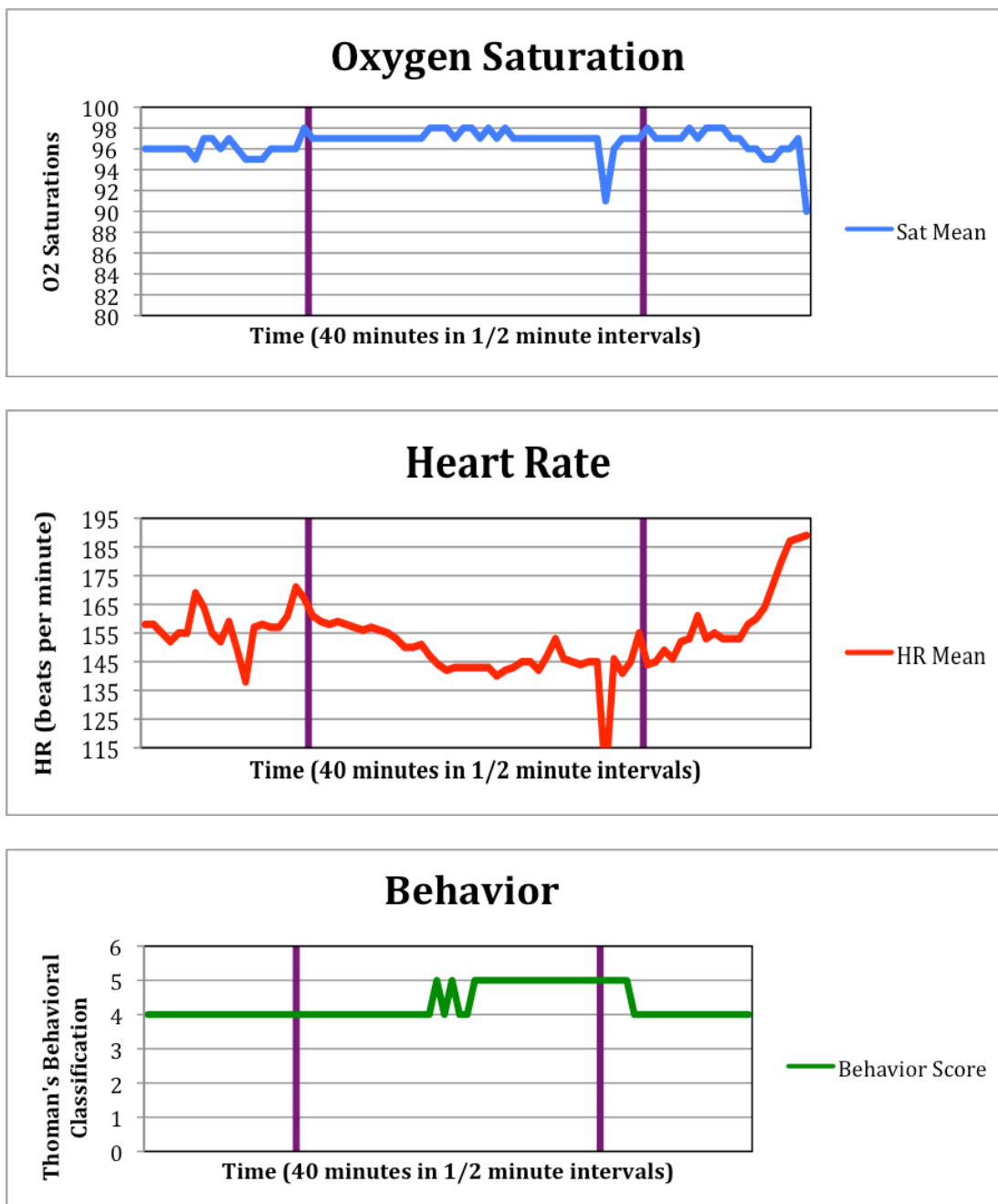


Note. Thoman's Behavioral Classification: 0 = Alert, 1 = Nonalert Waking, 2 = Fussing or Crying, 3 = Sleep-Wake Transition, 4 = Active Sleep, 5 = Quiet Sleep

Figure 14. Ambient Noise Infant 19 Graph

Infant 19

Ambient noise is included between the purple gradient lines of each graph

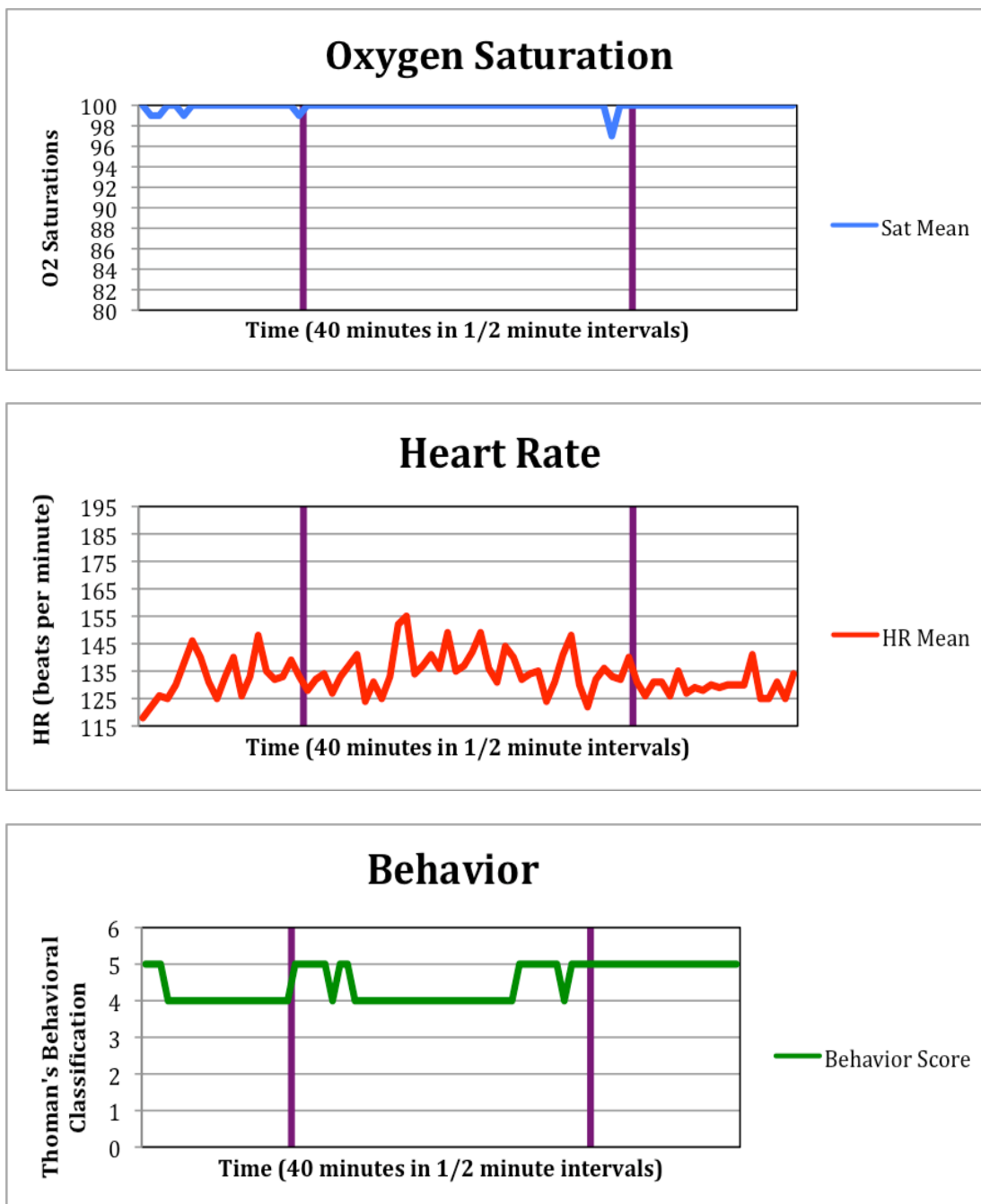


Note. Thoman's Behavioral Classification: 0 = Alert, 1 = Nonalert Waking, 2 = Fussing or Crying, 3 = Sleep-Wake Transition, 4 = Active Sleep, 5 = Quiet Sleep

Figure 15. Ambient Noise Infant 05 Graph

Infant 05

Ambient noise is included between the purple gradient lines of each graph



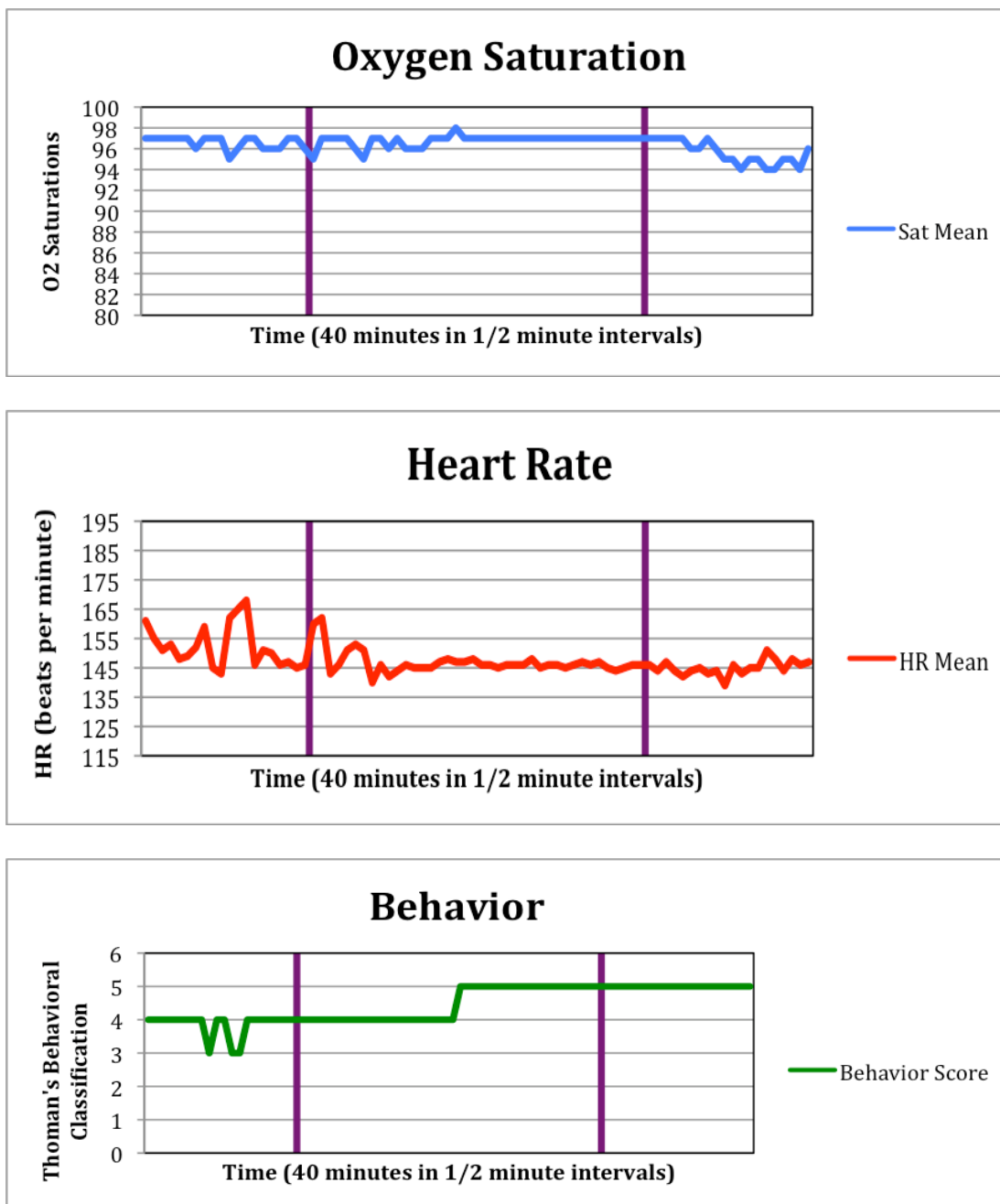
Note. Thoman's Behavioral Classification: 0 = Alert, 1 = Nonalert Waking, 2 = Fussing or Crying, 3 = Sleep-Wake Transition, 4 = Active Sleep, 5 = Quiet Sleep

Infant 39 also provided a positive portrayal of responses for the ambient noise group exhibiting minimal variability in oxygen saturations, heart rates, and behavioral states nearly mimicking responses observed in music group Infant 30. Oxygen saturations ranged mostly between 94 and 97%, whereas they were from 95 to 97% in Infant 30. Mean heart rates for Infant 39 were higher and exhibited a greater range initially (before introduction of the ambient noise) than those for Infant 30 (about 140 to almost 170 versus 140 to 150 beats per minute). Mean heart rates for Infant 39 then became less variable ranging identically to those for Infant 30 after the noise was introduced. Behavioral states periodically vacillated between quiet sleep and active sleep as for Infant 30, the only exception being that behavioral states rose to a steady quiet sleep state as they did for Infant 41 (figure 16).

Figure 16. Ambient Noise Infant 39 Graph

Infant 39

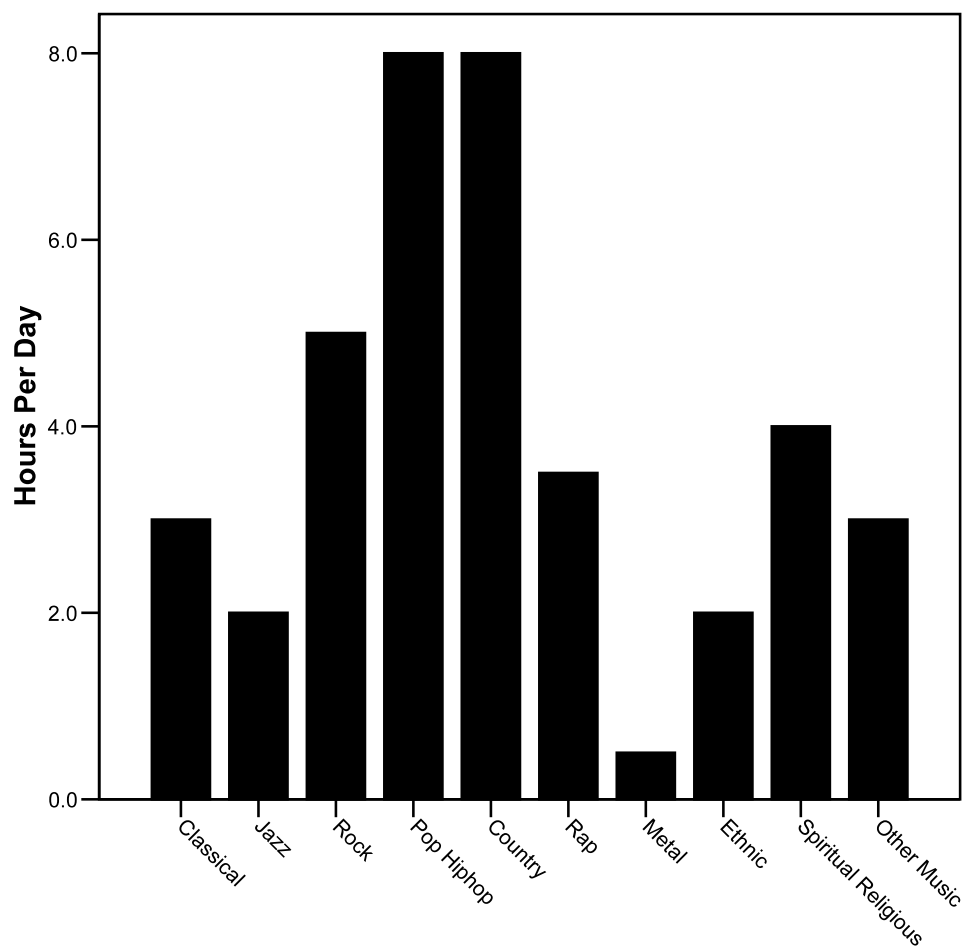
Ambient noise is included between the purple gradient lines of each graph



Note. Thoman's Behavioral Classification: 0 = Alert, 1 = Nonalert Waking, 2 = Fussing or Crying, 3 = Sleep-Wake Transition, 4 = Active Sleep, 5 = Quiet Sleep

Maternal Report of Music Exposure During Pregnancy

Because sounds to which preterm infants are exposed in utero may be encoded into their memory and affect their responses to sound in the extrauterine environment (deRegnier et al., 2002; Polverini-Rey, 1992), mothers of study infants were given a questionnaire to complete related to music listened to during their pregnancies. Each mother recorded the type and length of music time to which the fetus was exposed prenatally in number of hours per day. The types of music listened to for the most hours per day by mothers included pop/ hip-hop and country (8.0 hours/day each). The next most frequent type of music was rock (5.0 hours/day), followed by spiritual (4.0 hours/day), rap (3.5 hours/day), classical and other types of music including lullabies, children's music from the Wiggles television show, and music from the 1980s (3.0 hours/day each), jazz and ethnic (2.0 hours/day each), and metal (0.5 hours/day). In response to data related to prenatal exposure to music, no conclusions could be made. Results of maternal reporting of prenatal exposure to music are displayed in figure 17 and Table 16.

Figure 17. Music Exposure During Pregnancy (N = hours per day)Table 16. Music Exposure During Pregnancy ($N = 41$)

Type of Music	Number of Mothers $n = 41$	Number of Hours/Day (total for all mothers)
Metal	2	1.0
Ethnic	3	5.0
Rap	7	8.0
Jazz	11	11.5
Other	8	13.0
Classical	11	13.5
Spiritual/ Religious	8	17.0
Rock	25	38.5
Country	22	45.5
Pop/ Hip Hop	23	62.0

Chapter 5

DISCUSSION

This chapter includes a discussion of the findings from this study in relation to the hypotheses and the health patterning conceptual framework as described in chapter 2, figures 3 and 4. Limitations of this study, along with conclusions, recommendations for further research, and implications for nursing practice will be delineated as well.

Discussion of Results by Hypotheses

Patterning as referring to manifestations of the physical body and behavior of a person at multiple points in time (Gulick & Bugg, 1992), was used as the conceptual framework for this study. Because pattern is used to represent meaning within context over time (Bateson, 1979), patterning of preterm physiologic and neurobehavioral responses was used to explicate manifestations of the underlying neurophysiology of these infants in order to portray the wholeness of those responses as well as their evolution over time (Bohn, 1980; Newman, 1994; Newman, 1995). Preterm infant oxygen saturations, heart rates, and behavioral states were measured every thirty seconds for ten minutes before, twenty minutes during, and ten minutes after music and ambient noise sound conditions. The frequent measurements provided a detailed and in depth depiction of infant response patterns to music and ambient noise over time to assist in determining if music may be used to promote preterm infant health.

Hypothesis #1: *There will be significant differences in oxygen saturations between the music intervention group and the ambient noise control group.*

Oxygen saturation. Oxygen saturations varied within a 10% range and the average saturation was close to 96% during each of the three time periods (before, during, and after presentation of the two sound conditions) for both music and ambient noise groups of preterm infants. Although there were no significant differences in oxygen saturations between the infant groups, there were significant oxygen saturation changes for preterm infants over the time period after the sound conditions ($p = .004$).

Significant decreases were found in individual oxygen saturations for 30 infants over the three time periods. Most of the significant oxygen saturation decreases occurred after presentation of the two sound conditions and most of those decreases were seen in music group infants. The next most frequent significant oxygen saturation decreases occurred during the presentation of sound and those decreases were mostly from music group infants as well. There was one more ambient noise group infant than music group infant with significant oxygen saturation decreases occurring before any sound was initiated.

A steady decline in oxygen saturation occurred for both groups of preterm infants during the time period after presentation of the sound condition. One possible reason for this was because oxygen saturations decrease as infants become sleepier and their breathing becomes increasingly shallow. According to Thoman (1989), an infant's respiratory pattern will be slow, regular, and abdominal during quiet sleep whereas it will be irregular and primarily costal during active sleep. Therefore, infants will most likely have lower oxygen saturations during a state of quiet sleep than during active sleep.

Another possibility is that infants recognized that there was no more sound and began breathing more shallowly or not as frequently as a result of this awareness. This was an interesting finding in relation to the literature related to the use of music as a nursing intervention for preterm infants and correlated with study behavioral state findings, which found that music group infants were in their deepest Thoman sleep state in the final minutes of observation following the music intervention (Arnon et al., 2006).

Significant increases were also found in individual oxygen saturations for 17 infants and these increases were nearly evenly distributed between music and ambient noise group infants over each of the three time periods. Most of the significant oxygen saturation increases occurred during the presentation of sound and most of those increases were seen in ambient noise group infants (2 more ambient noise than music group infants). The next most frequent significant oxygen saturation increases occurred in the time period before sound was introduced and those increases were mostly from music group infants (1 more music than ambient noise group infant). There was also one more music group infant than ambient noise group infant with significant oxygen saturation increases occurring after presentation of the sound. It is interesting to note that both groups of infants were fairly similar with regard to significant changes in oxygen saturations before sound was introduced to them.

Study findings were similar to those of Arnon et al. (2006) and Lai et al., (2006) who found no significant differences in preterm infant oxygen saturations before, during, or after recorded music. These results did not corroborate other investigator's findings of significantly higher preterm infant oxygen saturations in response to a music intervention (Burke et al., 1995; Cassidy & Standley, 1995; Collins & Kuck, 1991; Standley &

Moore, 1995) nor significantly lower preterm infant oxygen saturations in response to noise (Elander & Hellstrom, 1995; Zahr & Balian, 1995). A rationale explanation for the contradiction with noise studies is that the ambient noise used in this study was soothing and did not compare with loud or unpleasant types of NICU environmental noise.

The lack of substantiation with some previous findings may also have to do with the brief time frame for presentation of music, the short length of time for measurement of responses after sound presentations, or the subtle nature of the ambient noise comparison group. Preterm infants in both groups similarly experienced significant increases and decreases in oxygen saturation throughout the three periods of time, but none of the mean oxygen saturations decreased below 86% (and that occurred in only 2 infants, 1 from each group, for a very brief amount of time). Most of the oxygen saturations remained above 90% (only 41 brief episodes of mean oxygen saturation less than 90% occurred in the 3280 thirty second time periods). Oxygen saturations were usually above 95% throughout the study (85% of the oxygen saturations remained above 95%). Additionally, oxygen desaturations are common in preterm infants. In any case, neither music nor ambient noise appeared to be associated with any adverse effects for preterm infants in this study.

Hypothesis #2: *There will be significant differences in heart rates between the music intervention group and ambient noise control group.*

Heart Rate. Heart rates ranges were fairly similar during each of the three time periods for both music and ambient noise groups, although infant heart rates were significantly lower in the ambient noise group when the noise was initiated as compared to the heart rates for infants in the music group when the music was started ($p = .05$).

Heart rates for infants in the music group generally remained the same before, during, and after the music; whereas heart rates for infants in the ambient noise group remained relatively stable before the noise and dipped slightly during the noise, but increased steadily above baseline after the noise. Again, there were no significant differences in heart rates between the infant groups, even though preterm infant heart rate changes approached significance over the time period after the sound conditions ($p = .07$).

Significant increases were found in individual heart rates for 21 infants over the three time periods. Most of the significant heart rate increases occurred in the time period before sound was introduced and a few more of those increases were seen in music than ambient noise group infants. There were 8 significant heart rate increases that occurred in the time periods during and after the presentation of sound. These increases occurred equally in both groups during presentation of the sound and occurred in 2 more ambient noise group infants than music group infants after the sound condition. There was 1 more ambient noise group infant than music group infant with significant heart rates increases occurring in the first time period before sound was introduced.

Significant decreases were also found in individual heart rates for 19 infants and these decreases were again nearly evenly distributed between music and ambient noise group infants over each of the three time periods. Most of the significant heart rate decreases occurred during the presentation of sound and most of those decreases were seen in ambient noise group infants (3 more ambient noise than music group infants). The next most frequent significant heart rate decreases occurred in the time period after sound was introduced and those decreases were mostly from music group infants (1 more music than ambient noise group infants). There were only 2 infants (1 from each group) with

significant heart rate decreases occurring before presentation of the sound. It is interesting to note that both groups of infants were fairly similar with regard to significant changes in heart rates.

While infants in the music group had mean heart rates that were lower than infants in the ambient noise group after the sound conditions, this difference was very small and not statistically or clinically significant. These lower heart rates did correlate again with study behavioral state findings, which found that music group infants were in their deepest Thoman sleep state in the final minutes of observation following the music intervention. Lower heart rates are also associated with other investigator's findings, although results from this study were not significant (Burke et al., 1995; Chou, 2003; Lorch et al., 1994).

Study findings were again similar to those of Arnon et al. (2006) and Lai et al., (2006) who found no significant differences in preterm infant heart rates before, during, or after recorded music. Arnon et al. also found no significant differences in these preterm infant heart rates before or during live music, but found significant differences thirty minutes after live music. The results of this study are not consistent with other investigator's findings of significantly lower preterm infant heart rates in response to a music intervention (Burke et al., 1995; Chou, 2003; Lorch et al., 1994). The results were also not supported by investigator findings that noise increases heart rates in preterm infants (Elander & Hellstrom, 1995), although the ambient noise used in this study was not comparable to some types of NICU environmental noise.

Hypothesis #3: *There will be significant differences in behavioral states between the music intervention group and ambient noise control group.*

Behavioral State. As with the physiologic measures, infant behavioral states varied similarly and modestly between active sleep and quiet sleep (a “within sleep transition” according to Thoman, 1989) during each of the three time periods for both music and ambient noise groups. Again, there were no significant differences in infant behavioral states between the infant groups, even though preterm infant behavioral state “within sleep transition” changes were significant over the time periods before and after the sound conditions.

Significant decreases were found in individual behavioral states for 14 infants over the three time periods. Significant behavioral state decreases occurred in nearly the same numbers for each of the three time periods. Most of the decreases occurred after presentation of the sound and were seen in 2 more ambient noise group infants than music group infants. The next most frequent significant behavioral state decreases occurred before presentation of the sound and those decreases were mostly from ambient noise group infants as well (occurring in 1 more ambient noise than music group infant). There were 2 more music group infants than ambient noise group infants with significant behavioral state decreases occurring during presentation of the sound condition.

Significant increases were also found in individual behavioral states for 19 infants over the three time periods. Most of the significant behavioral state increases occurred before presentation of the sound condition and most of those increases were seen in music group infants (5 more music than ambient noise group infants). The next most frequent significant behavioral state increases occurred during presentation of the sound condition and those increases were mostly from ambient noise group infants (1 more infant from the ambient noise than music group). There were 5 infants with significant

behavioral state increases occurring after presentation of the sound and none of these infants were from the ambient noise group.

The range in behavioral state was from 3 to 5 indicating that infants remained in a sleep state throughout the study (state 2 or fussing and crying was only noted 6 times out of 3280 possible behavioral states during the entire study). In fact, both groups of study infants were usually in an active state of sleep as evidenced by a category state of 4, which corresponds with the literature describing active sleep as the most common preterm infant behavioral state (Thoman). According to Thoman, the mean percentage of time that infants spent during the portion of the day when they were alone in each of the derived behavioral states is as follows: 6.7% of the time in state 0 or an alert state, 2.8% of the time in state 1 or a nonalert waking state, 3.4% of the time in state 2 or a fussing or crying state, 6.7% of the time in state 3 or a sleep-wake transition state, 52.3% of the time in state 4 or an active sleep state, and 28.1% of the time in state 5 or a quiet sleep state. Also, study infants were generally in their deepest state of sleep according to Thoman's Derived States behavioral classification scheme (state 5 or a quiet sleep state) during the sound conditions. One exception included music group infants who were in their deepest Thoman sleep state in the final minutes of observation following the music intervention.

Once more, study findings were similar to those of Arnon et al. (2006) and Lai et al., (2006) who found no significant differences in preterm infant behavioral states before, during, or after recorded music. Arnon et al. also found no significant differences in these preterm infant behavioral states before or during live music, but found significant differences thirty minutes after live music when infants were in their deepest sleep states according to Als (1984). Lai et al. did find that infants in the music group had a

significantly greater occurrence of quiet sleep states and less crying when integrated with kangaroo care. These findings are not consistent with those of other investigators describing preterm infant behavioral state as more time spent in quiet alert states than other states or as moving towards a decreased state of arousal following music (Burke et al., 1995; Butt & Kisilevsky, 2000; Coleman et al., 1997; Collins & Kuck; Kaminski & Hall, 1996). The results were also not supported by investigator findings that noise causes changes in behavioral state from regular sleep to fussy and crying states (Zahr & Balian, 1995), although the ambient noise used in this study was again not analogous to some types of NICU environmental noise.

Gender Differences. Although music therapy studies have found differences between male and female preterm infant responses to music suggesting a possible gender effect (Caine, 1991; Cassidy & Ditty, 2001; Standley, 1998), there were no significant gender differences between the music and ambient noise groups in this study. A possible reason for a lack of gender effect in this study may have to do with the use of earphones, which provided a binaural presentation of sound as well as a reduction of additional environmental sound.

Study Limitations

There are limitations to this study. The limited number of subjects, few minority subjects recruited, and urban Midwest location of the setting precludes generalizations to other diverse populations and locations. Although sample size was determined by power analysis, the least number of subjects required were included in the study. Also, recruited infants were racially diverse and had similar race/ethnicity stratification in relation to the NICU site and to the latest Minnesota data, nearly three-quarters of them were white and

there were no Native American infants enrolled in the study. Random fluctuations such as variations in room sound levels or unplanned environmental sounds might be considered as limitations as well, except that there were again equal distributions of music and ambient noise preterm infants in these sound level categories and all infants were provided with earphones to control sound conditions and had private rooms designed to help shield them from noise and light.

There were other study limitations, which may have threatened the internal validity of the study. Errors of measurement or documentation of preterm infant responses was possible although oxygen saturation and heart data were downloaded directly from a Masimo SET[®] pulse oximeter into a Dell[™] Latitude[™] D620 laptop PC. Behavioral state data was videotaped and coded by by a behavioral state coder skilled in evaluating the six variables shown to exhibit reliable individual differences for preterm infants and a nurse (the investigator) tested for interrater reliability. These factors assisted in limiting potential errors of measurement. Another potential error of measurement was associated with ensuring the quality of filming each preterm infant. Videotaping preterm infants was a challenge in that each NICU room had different lighting issues depending upon whether or not there were windows in the room and the location and type of lighting. Also, glare from lighting on infant isolettes posed additional challenges to the quality of the videotaping. Furthermore, the amount of clothing worn by infants in cribs affected coding proficiency in that it was difficult to count respirations and identify fine motor activity such as twitching of the extremities in infants who were clothed.

There was also a potential for documentation error by coders who individually wrote down behavioral states every thirty seconds for forty minutes for each infant (80

data points per infant). Coders met in person initially and discussed subsequent coding over the phone to compare results. Together, the coders checked data for each infant at least twice to prevent possible errors. Another limitation was the potential for technically unacceptable tests, experimental mortality, or attrition due to infants being removed from the study by parents or because of a change in health status. There were no technically unacceptable tests or experimental mortality; however, one infant was withdrawn from the study by the investigator due to fussiness and high motor activity prior to and during the sound condition. A final limitation, which had the potential to threaten internal validity of the study, was sensitization to testing in which preterm infants physiologically accommodate or habituate to auditory stimuli. Habituation is a decreasing response to a repeated stimulus and is a fundamental type of learning that may influence behavioral responses (Philbin, 2000; Thompson & Spencer, 1966). This was a real possibility in that infants listened to each sound condition for twenty minutes.

Additional limitations to the study included the brief time frame for presentation of music, the short length of time for measurement of responses after sound presentations, and the subtle nature of the ambient noise comparison group.

One threat to external validity includes the interaction of the setting and treatment. Because the NICU used in the study had private rooms, this may have affected infant responses to the music and ambient noise thereby affecting generalizability of the findings. The use of earphones to control sound conditions served to reduce the impact of this threat.

Conclusions and Recommendations for Further Research

Conclusions

The goal of nursing research is to expand the body of knowledge, which forms the foundation of the discipline of nursing. Nursing knowledge is primarily focused on care related to human responses affecting the actual or potential health of people. Preterm birth causes neonatal mortality and is a major determinant of early childhood mortality and morbidity in the U.S. Numerous preterm infants suffer from neurological disability including cerebral palsy; visual and hearing impairments; learning difficulties; and, psychological, behavioral, and social problems. Providing nursing care to preterm infants through patterning of the NICU environment using interventions such as music may provide some benefits in reducing the pervasiveness and severity of problems associated with prematurity.

Although there were no significant differences in infant responses between music and ambient noise groups over time, there were significant changes in individual infant oxygen saturations, heart rates, and behavioral states over the three time periods (in the ten minutes before presentation of the two sound conditions, the twenty minutes during presentation of the sound, and the ten minutes after presentation of the sound). These significant individual preterm infant responses provide some indication that the infants were reacting to the music and ambient noise sound conditions. Fortunately, findings from this study showed that preterm infants in a NICU did not have adverse reactions to a carefully designed music intervention. Infants listening to Brahms' Lullaby and those listening to ambient noise recorded from the inside of an incubator all exhibited changes in oxygen saturations, heart rates, and behavioral states during the three time periods and

variability in those changes; however, these responses remained within normal limits. There were also no significant gender differences in oxygen saturations, heart rates, or behavioral states between the music and ambient noise groups in this study, but that does not indicate a definitive lack of gender effect in preterm infants for whom an intervention of music is provided. Nursing, medicine, music therapy, audiology, and neuroscience studies have found differences between male and female preterm infant responses to music suggesting a possible gender effect and the potential for this effect should continue to be investigated.

Given that music was provided to preterm infants for only one twenty minute session, no conclusions may be made as to the long-term effect of music interventions with this population. Also, even though there were no significant differences in infant responses between music and ambient noise groups over time and there was statistical significance for individual infant responses to the sound conditions, evidence of clinical or practical significance was not conclusive. In light of this study's finding that a carefully designed music intervention is not clinically harmful to preterm infants from 32 to 35 weeks gestational age and the potential benefits of music to reduce the pervasiveness and severity of problems associated with prematurity and improve neonatal health, further interdisciplinary research implementing controlled, rigorous studies is needed to determine the long-term effects and clinical significance of music interventions with preterm infants in the NICU.

Recommendations for Further Research

There were no significant differences in infant responses between music and ambient noise groups over time; however, findings from this study showed that preterm

infants in a NICU were not detrimentally affected by a carefully designed music intervention. The brief time frame for presentation of music, short length of time for measurement of responses after sound presentations, and subtle nature of the ambient noise comparison group might have all contributed to the lack of significant findings between these preterm infant groups. Future studies might implement multiple sessions of music interventions over a longer period of time (weeks or months), measure infant responses for a longer length of time after sound presentations, investigate the pattern of interaction between parents and their preterm infants during music alone (not with other modalities), and incorporate quiet live singing or soft soothing instrumental music while integrating a no music control group for comparison of preterm infant responses. Furthermore, because of unexplained variances as uncovered in the first level of mixed modeling for this study, further research should continue to look for covariates that might affect infant responses such as group and gender. Analysis of other covariates including maternal factors like nutritional status of the mother during pregnancy or medical condition of the infant should be carried out as well to assist in explaining these differences.

Nurse researcher Kathleen Philbin and psychologist Patricia Klaas offer a research evaluation checklist for clinicians planning an auditory intervention such as music with infants (2000). This investigator found the following components of the guidelines to be most useful in evaluating the validity and reliability of the current research study and highly recommends them to promote high-quality research related to the effects of sound in future research:

1. Sample size is determined through power analysis.
2. Subjects reflect the population of interest, detailed demographics and medical information are collected and described (race/ethnicity, gender, weight at birth and testing, age at birth and testing, medical history, and so on), and group inclusion (a passed hearing test) and exclusion criteria (not receiving medication for sedation) are clearly stated.
3. The method of subject selection is reported, and subjects are randomly assigned to groups and stratified into homogeneous subgroups.
4. Protocols and procedures for the administration of interventions are carefully and rationally determined, clearly described, and systematically carried out (sound level measurements include a weighting scale and meter response times, intervention conditions and procedures are clearly described and controlled, and infant condition is controlled); and investigators are skillful and reliable in the method of determining state.
5. Investigators, caregivers, data collectors, and analyzers are blinded or masked, or there is a placebo condition along with a nontreatment control condition.
6. All relevant information about subject responses to the intervention is reported; undesirable responses and long-term consequences are evaluated; and measurements are standardized, consistently applied, and logically related to the intervention.
7. Presentation and analysis of data are clear, discrepancies between planned and actual numbers of subjects are explained, descriptive measures are identified for all important variables, appropriate statistical tests are employed, results are interpreted accurately, and important hazards and limitations are assessed.

8. Recommendations for practice are clear and consistent with results and negative findings or failures to obtain results are reported.

Additionally, future research should include comprehensive utilization of scientific information from research studies, incorporate standardized guidelines for the intervention, and study differences between genders. Controls should also be built into the study, such as:

- Use of instruments tested for reliability and validity of measurement (instrument calibration per standard protocol by the hospital biomedical department)
- Pretreatment observations of preterm infant responses to strengthen interpretation of results
- Posttreatment observations to decrease the potential for measurement discrepancies and reduce the risk of Type I errors
- Repeated measures over time added to allow effects of history to be tested between the groups

Procedures for administering auditory stimuli to preterm infants should be strictly enforced to control variance, promote treatment integrity, and enhance internal validity of the design. Measurements of key indicators of infant responses to sound such as heart rate, oxygen saturation, and behavioral state are also needed to determine the effects of specific music selections (Kaminski & Hall, 1996). Using a classification system such as the abbreviated version of Thoman's Primary States Taxonomy, deemed appropriate for preterm infants, is especially valuable because it characterizes the underlying functioning of the brain and reflects infants' ongoing responses to acoustic stimulation. Also, the behavioral state variables identified in Thoman's Taxonomy have been shown to exhibit

concurrent and predictive validity as well as reliable individual differences for preterm infants (Holditch-Davis, 1990; Holditch-Davis & Thoman, 1987).

Musical selections should be played to present aural stimuli to preterm infants as recommended by Cassidy and Ditty (1998): (a) using low frequencies within the 500-1000 Hz range best heard by preterm infants, (b) boosting the bass and toning down the treble to enhance the effects of the musical stimuli, (c) ensuring the minimum decibel level necessary to cause the desired effect, and (d) utilizing specially designed disposable neonatal earphones to expand the resonating chamber and control for sound conditions.

Additionally, administering music with a tempo of approximately 60 beats per minute as suggested by Schwartz and Ritchie (1999) and Schwartz (2003) and choosing musical selections with soothing, stable, and relatively unchanging sounds to reduce alerting responses as well as a light rhythmic emphasis and a constant rhythm as described in Standley's (2002) music therapy guidelines for the use of music in the NICU is crucial. Also, because of the differences in preterm hearing physiology and the preponderance of study data describing gender differences, gender effect should continue to be examined in future research studies. Because research suggests that exposing infants to sound in utero influences later responses to sound in the extrauterine environment (deRegnier et al., 2002), prenatal exposure to music and the longterm impact is another area to continue to evaluate. Finally, further research that is rigorously designed, incorporating guidelines to evaluate the validity and reliability of the study, and including comprehensive utilization of scientific information to promote high-quality results is needed to assess the long-term effect of music on the development of preterm infants.

Investigator Impressions

The intention of this investigator was to carry out a well-designed, carefully implemented study to address shortcomings in previous research and discover if preterm health patterns (as measured by oxygen saturation, heart rate, and behavioral state) are different when exposed to music as compared to infant responses to ambient noise. It was believed that the findings would help determine whether there are key physiological and behavioral state benefits of a carefully implemented music intervention with this population. The patterning identified through individual preterm infant graphs revealed a variety of patterns for responses as well as similarities in patterns for the two groups for which no definitive conclusions could be drawn. Additionally, this study and two others did not find statistically significant results using oxygen saturation, heart rate, and behavioral state as responses to recorded music. This may be due to numerous factors as those cited as limitations, or there may be another key indicator in relation to preterm infant cognitive processing.

Furthermore, although the objective was to identify the pattern of preterm responses to music using a holistic, integrative approach, this investigator realized that only a partial representation of the whole emerged. The variability in infant responses to music was still not explained, even when looking at the interaction of groups and gender. Something was missing. Originally, the plan was to look at preterm infant cognitive processing of music using event-related potentials (ERPs) as done by Koelsch, but that path was blocked because of the departure of a faculty member, whose expertise would have been crucial in such an endeavor. ERPs are one of the only methodological techniques that allows researchers to examine the relation between brain and behavior

beginning at birth without requiring verbal, motor, or behavioral responses of subjects (DeBoer, Scott, & Nelson, 2004; deRegnier, Nelson, Thomas, Wewerka & Georgieff, 2000; Nelson & Bloom, 1997). ERPS have been used to evaluate the cognitive processing of music in adults and children, but have not been studied in any children under five years of age (Koelsch, Grossmann, Gunter, Hahne, Schrõger, & Friederici, 2003). In hindsight, the lack of ability to pursue ERP measurement would not have been wise because research related to ERPs with music is in initial stages and has not yet been performed on term or preterm infants.

This investigator believes that the the most important contribution made by this research study to the body of nursing knowledge is related to the intentionally designed music intervention of recorded piano music using knowledge obtained from a variety of disciplines. Also, obtaining measurements related to the effect of the music every 30-seconds before, during, and after music or ambient noise provided a rich, detailed description of preterm infant responses. Other important contributions are associated with addressing the concerns of those skeptical about the use of music with preterm infants including: the incorporation of detailed demographics and medical information to control variance; random assignment to control for selection bias; careful implementation of protocols, procedures, and measurements to promote treatment integrity and enhance internal validity of the design; direct downloading of physiologic data and blinding of the researcher and behavioral state coder to manage investigator bias.

Implications for Nursing Practice

The focus of nursing is identifying and understanding the patterns of person-environment interaction for consideration of interventions to use in caring for others

(Cowling, 1990; Jonsdottir, 1988). Nurses accomplish this process through appraisal of the individuals' presenting pattern in order to design meaningful nursing strategies with individuals to promote health and wellness (Matas, 1997). The appropriateness of providing music within the discipline of nursing to promote preterm infant health was explored in this study. The research findings can be used by nurses to enhance their understanding of the effects of music on preterm infants in neonatal intensive care units and in designing future music research with this population.

The inspiration for this study came from a dear friend and colleague, whose daughter delivered triplets at 25 weeks gestation. Both mother and grandmother have strong opinions on the importance of providing music to preterm infants in the NICU because music played a significant role during their hospitalization in the NICU and continues to be important in the lives of these children who are now healthy and nearly seven years old. According to the grandmother who is a nurse educator: "This comforting sound needs to be part of the atmosphere in the NICU. The nurses who allowed or suggested I play some music were my favorites." The grandmother also stated the following: "Each of the triplets had trouble eating when we got them home - no strong sucking and it was hard to get them started. We learned very early that each had a favorite tune and if we sang that tune each time we fed them, they latched on right away... they would only do it really well for their particular tune." The mother of the triplets, a health care provider, provided further insight:

Music was definitely soothing for the kids and for the nurses as well.

There was less crying [in the NICU]. I play the same CD that we used in the NICU and they go to bed with it every night. It was really helpful to be

able to turn it on in the middle of the night when they woke up [because] they would go right back to sleep again. They were able to self soothe. We never had to worry about needing to lay down with them in their beds to help them sleep as we did with our other son...this is really hard for some parents [to deal with] at night. I also use music for naps, in the car, and on vacations. They just know that the music signals it is time to wind down and take a nap. Sometimes they even hum the music to themselves.

Additionally, while observing their preterm infants during the study, several parents commented that they believed their child “liked” the music and that it was “good” for them. One father in particular never moved from his position next to his daughter’s incubator during the entire forty minutes of the study. He frequently made comments about how cute she was while she listened to the music, discussed how he felt music was really important for her, and declared that he planned to continue providing music for her when she was finally able to come home.

In summary, using appropriate music such as lullabies as a nursing intervention with preterm infants is important because of some demonstrated benefits and evidence that it may reduce the pervasiveness and severity of problems associated with prematurity. From a nursing practice perspective, music interventions are not time-consuming for nurses to integrate into a busy shift caring for infants in the NICU or expensive to implement. In fact, providing music interventions may actually reduce the amount of time nurses spend consoling distressed infants. Furthermore, music may be a non-invasive normalizing activity for families in that it sets up patterns of interaction between parents and infants and it has been shown to reduce of anxiety for staff as well.

Although studies carried out thus far cannot yet conclusively endorse using music as a nursing intervention with preterm infants, further research implementing controlled, rigorous methodologies is needed to definitively test this promising intervention.

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Appendix A

Literature Supporting Use of Music With Preterm Infants

Table A1

Music Studies Demonstrating Decreased Physiologic Instability in Preterm Infants

Decreased Physiologic Instability	Study, Description, and Effect
Higher baseline oxygen saturations	<p><u>Cassidy & Standley, 1995</u>: Quasi-experimental study to ascertain the effect of an intermittent schedule of music stimulation (4 minutes on and 4 minutes off) on the physiologic responses of 20 low birth weight preterm infants from 24 to 30 weeks gestational age with normal hearing in the first week of life in the NICU. Effect: Oxygen saturation = 1.1885.</p> <p><u>Collins & Kuck, 1991</u>: Descriptive study to evaluate the effects of taped intrauterine sounds with synthesized female vocal singing on the heart rate, mean arterial pressure, oxygen saturations, and behavioral state of 17 agitated, intubated, preterm infants. Effect: Oxygen saturation = 0.6971, behavior state = 1.2559, heart rate = 0.4555.</p> <p><u>Standley & Moore, 1995</u>: Quasi-experimental study using a repeated measures design to ascertain the effect of 20 minutes of music listening across 3 days on oxygen saturation levels and occurrences of oximeter alarms for 20 premature oxygenated infants in the NICU and to contrast these effects with responses to recordings of the mother's voice. Effect: Oxygen saturation = 1.0280.</p>
Fewer episodes of apnea and bradycardia	<u>Cassidy & Standley, 1995</u>
Less observed pain	<u>Butt & Kisilevsky, 2000</u> : Exploratory study with experimental and controlled conditions to evaluate physiologic and behavioral effects of music during recovery from heel lance in preterm infants tested during music and during a no-music control. Effect: No effect size calculated.
Increased resting behavioral states (more quiet alert or sleeping states than active awake or fussing/crying states), which results in decreased oxygen consumption and caloric requirements so that more calories are available for growth or healing	<p><u>Butt & Kisilevsky, 2000</u></p> <p><u>Coleman et al., 1997</u>: Quasi-experimental study to determine the effect of 20-minute segments of auditory stimulation composed of males and females singing lullabies versus males and females speaking lullabies versus ambient sounds on 66 preterm infants in an NICU. Effect: Oxygen saturation = 0.8636, behavior state = 1.9528, heart rate = 0.9190, days in hospital = 0.4915, weight gain = 0.4915.</p> <p><u>Collins & Kuck, 1991</u></p>

Note. The effect size information was estimated for independent variables and reported as Cohen's *d* as obtained from Standley (2002).

Appendix A

Literature Supporting Use of Music With Preterm Infants

Table A2

Music Studies Demonstrating Enhanced Physiologic Functioning in Preterm Infants

Enhanced Physiologic Functioning	Study, Description, and Effect
Increased daily weight gain	<p><u>Caine, 1991</u>: Descriptive study to evaluate and compare the effectiveness of music on selected stress behaviors, weight, caloric and formula intake, and length of hospital stay of preterm and low birth weight neonates in an NICU. Effect: Days in hospital = 0.5045, weight gain = 0.8375.</p> <p><u>Standley, 1998</u>: Quasi-experimental study to test a music-enhanced procedure for stimulation and reinforcement of preterm infants' acquisition of developmental behaviors in the areas of sensory, social, and motor skills through examination of visual and aural attending, social bonding, differentiated vocal responses, and reaching/grasping motor behavior. Effect: Days in hospital = 0.5489, weight gain = 0.8102.</p> <p><u>Whipple, 2000</u>: Quasi-experimental study to determine the effects of parent training in music and multimodal stimulation on the quantity and quality of parent-neonate interactions, weight gain, and length of hospitalization of premature and low birth weight infants in the NICU. Effect: No effect size calculated.</p>
Strengthened tolerance for stimulation	<u>Standley, 1998</u>
Higher oxygen saturations	<p><u>Cassidy & Standley, 1995</u>: Quasi-experimental study to ascertain the effect of an intermittent schedule of music stimulation (4 minutes on and 4 minutes off) on the physiological responses of 20 low birth weight preterm infants from 24 to 30 weeks gestational age with normal hearing in the first week of life in the NICU. Effect: Oxygen saturation = 1.1885.</p> <p><u>Collins & Kuck, 1991</u>: Descriptive study to evaluate the effects of taped intrauterine sounds with synthesized female vocal singing on the heart rate, mean arterial pressure, oxygen saturations, and behavioral state of 17 agitated, intubated, preterm infants. Effect: Oxygen saturation = 0.6971, behavior state = 1.2559, heart rate = 0.4555.</p> <p><u>Standley & Moore, 1995</u>: Quasi-experimental study using a repeated measures design to ascertain the effect of 20 minutes of music listening across 3 days on oxygen saturation levels and occurrences of oximeter alarms for 20 premature oxygenated infants in the NICU and to contrast these effects with responses to recordings of the mother's voice. Effect: Oxygen saturation = 1.0280.</p>

Table A2 (Continued)

Music Studies Demonstrating Enhanced Physiologic Functioning in Preterm Infants

Increased formula intake	<u>Caine, 1991</u> <u>Standley, 2003b</u> : Experimental study in which nonnutritive sucking and nipple feeding rates pre- and posttreatment were assessed for 32 infants referred as poor feeders who were provided music reinforcement using a pacifier-activated lullaby. Effect: No effect size calculated.
Improved frequency and strength of nonnutritive sucking	<u>Standley, 2000</u> : Quasi-experimental study to assess music as reinforcement for nonnutritive sucking of 12 preterm infants born at an average gestation of 29.3 weeks and an average birth weight of 1,111.9 g. Effect: Nonnutritive sucking rate = 0.7334.
Reduction in days to discharge	<u>Caine, 1991</u> <u>Standley, 1998</u>

Note: The effect size information was estimated for independent variables and reported as Cohen's *d* as obtained from Standley (2002).

Appendix B

Research Evaluation Checklist

1. The purpose of the study is clearly stated, intervention and outcome variables logically follow from the purpose, and no commercial interests are likely to influence the research.
2. The experimental design is thoroughly described; the data collection was planned before initiation of the study and the rationale for subject selection is clear, logical, and related to the outcome measure.
3. Sample size is determined by power analysis and the conditions are controlled.
4. Subjects reflect the population of interest, demographics are described (e.g., age at birth and testing, race, sex, medical history, etc.), and group inclusion and exclusion criteria are clearly stated.
5. The method of subject selection is reported and subjects are randomly assigned to groups and stratified into homogenous subgroups.
6. Group assignments are randomized and clearly described.
7. Procedures for intervention administration are clearly described; informed consent is obtained; sound level measurements include a weighting scale and meter response times; nonlinear pressures are not averaged over time; intervention conditions and procedures are clearly described and controlled (e.g., background room and intervention sound levels measured at the infant's ear, length of the intervention, frequency range and temporal characteristics of the sound, etc.); infant condition is controlled (e.g., behavioral state, use of stimulant medications, hours of sleep, time since last sleep cycle and feeding,

etc.); investigators are reliable in state determination method; and indications for initiating, modifying, or discontinuing the intervention are clear.

8. Investigators, caregivers, and data collectors/analyzers are blinded or masked or there is a placebo condition along with a non-treatment control condition.
9. There are predefined conditions for removing subjects from the study, subject attrition is described, and the effect of losses is analyzed.
10. All relevant clinical information about subject responses to the intervention are reported, undesirable responses and long-term consequences are evaluated (e.g., behavioral state, motor function, physiology, general development, etc.), measurements are standardized and consistently applied, measurements are logically related to the study purpose(s) and intervention, and relevant intervention costs are described.
11. Presentation and analysis of data are clear, discrepancies between planned and actual numbers of subjects are explained, descriptive measures are identified for all important variables (e.g., subject background information, intervention effects, results, etc.), appropriate statistical tests are employed, results are interpreted accurately, and important hazards and/or limitations are assessed.
12. Recommendations for practice are clear and consistent with results, negative findings or failures to obtain results are reported, and reservations about the use of the intervention are stated.

Appendix C

Nursing Research Within a Nursing Model on Health Patterning Modalities

Table C1

Nursing Research Within a Nursing Model on Therapeutic Touch (TT)

1st Author (Yr)	Research Topic	Finding	Model
Biley, F.C. (1996b)	Subjective experience of phantom pain & TT.	Qualitative Case Study	Rogers
Green, A.C. (1998)	Subjective experience of giving & receiving TT for pain & associated anxiety.	Qualitative Case Study	Rogers
Hagemaster, J. (2000)	TT, Mimic TT, & mental health, family/social relationships, & abstinence in substance-abuse.	Improvement in outcome variables in TT group.	Rogers
Meehan, T.C. (1993)	TT, Mimic TT, narcotic analgesic, & postoperative pain.	Hypothesis not supported.	Rogers
Peck, S.D.E. (1997)	TT, progressive muscle relaxation, & pain in elders with degenerative arthritis.	Hypothesis partially supported.	Rogers
Peck, S.D.E. (1998)	TT, progressive muscle relaxation, & functional ability in elders with degenerative arthritis.	Hypothesis partially supported.	Rogers
Quinn, J. (1993)	TT & psychological & immune status on practitioners & bereaved recipients.	Provided affirmation of the unitary perspective.	Rogers
Samarel, N. (1992)	TT & psychological & immune status on practitioners & bereaved recipients.	Provided affirmation of the unitary perspective.	Rogers
Samarel, N. (1998)	TT & preoperative & postoperative anxiety, mood, & pain with breast cancer surgery.	Hypothesis supported for preoperative anxiety.	Rogers

Note. The information in Table A1 was obtained from Madrid & Windstead-Fry (2001).

Table C2

Nursing Research Within a Nursing Model on Imagery

1st Author (Yr)	Research Topic	Finding	Model
Hernandez, N.E. (1998)	Relaxation techniques of breathing & guided imagery on anxiety in primary caregivers of chronically ill children.	Hypotheses not supported.	King
Speck, B.J. (1990)	Guided imagery & anxiety in baccalaureate nursing students performing their first injections.	Hypothesis partially supported.	Neuman
Thompson, M.B. (1994)	Guided imagery & anxiety & movement with magnetic resonance imaging.	Hypotheses supported.	Rogers
Troesch, L.M. (1993)	Guided imagery, perception of chemotherapy experience, & side effects of nausea & vomiting in patients receiving chemotherapy.	Hypothesis partially supported.	Orem

Note. The information in Table A2 was obtained from Madrid & Windstead-Fry (2001).

Table C3

Nursing Research Within a Nursing Model on Music

1st Author (Yr)	Research Topic	Finding	Model
Biley, F.C. (1996a)	The effects of background music on patients & their perception of the environment.	Qualitative Case Study	Rogers
Brewer, J.F. (1998)	Healing sounds.	Hypotheses supported.	Guzzeta

Table C3 (Continued)

Nursing Research Within a Nursing Model on Music

1st Author (Yr)	Research Topic	Finding	Model
de Sevo, M.R. (1991)	Temporal experience & the preference for musical sequence complexity.	Hypotheses partially supported.	Rogers
Edwards, J.V. (1991)	The relationship of contrasting selections of music & human field motion.	Hypotheses supported.	Rogers
Good, M. (1995)	Comparison of the effects of jaw relaxation & music on postoperative pain.	Hypothesis partially supported.	Orem
Madrid, M. (1996)	The participating process of human field patterning in an acute-care environment.	Qualitative Case Study	Rogers
McBride, S. (1999)	The therapeutic use of music for dyspnea & anxiety in COPD patients living at home.	Hypotheses partially supported.	Rogers
Norred, C.L. (2000)	Integrative caring-healing therapies that may minimize preoperative anxiety.	Hypotheses supported.	Watson
Sabo, C.E. (1996)	The influence of personal message with music on anxiety & side effects of chemo.	Hypotheses partially supported.	Neuman
Schorr, J.A. (1993)	The use of music as a unitary-transformative means of altering the perception of chronic pain among women with rheumatoid arthritis.	Hypothesis supported.	Newman
Wiand, N.E. (1997)	Relaxation levels achieved by Lamaze-trained pregnant women listening to music & ocean sound tapes.	Hypotheses partially supported.	Rogers

Note. The information in Table A3 was obtained from a CINAHL search of peer-reviewed nursing journals specifying the conceptualization of music within a nursing model.

Appendix D

Studies Related to the Patterning of Preterm Physiological Responses (2000 to 2004)

First Author (Year)	Title	Preterm Response	Database
Al-Hathlol, K. (2000)	A study of breathing pattern and ventilation in newborn infants and adult subjects.	Respiratory rate	MEDLINE & CINAHL
Anastasiadis, P.G. (2001)	Fetal heart rate patterns in normal & ritodrine-treated pregnancies, detected by magnetocardiography.	Heart rate	MEDLINE & CINAHL
Bohnhorst, B. (2001)	Skin-to-skin (kangaroo) care, respiratory control, and thermoregulation.	Respiratory rate	MEDLINE & CINAHL
Courtney, S.E. (2001)	Lung recruitment and breathing pattern during variable versus continuous flow nasal continuous positive airway pressure in premature infants.	Respiratory rate	MEDLINE & CINAHL
Elgellab, A. (2001)	Effects of nasal continuous positive airway pressure on breathing pattern in spontaneously breathing premature newborn infants.	Respiratory rate	MEDLINE
Galinkin, J.L. (2001)	A randomized multicenter study of remifentanyl compared with halothane in neonates & infants undergoing pyloromyotomy: Periop breathing patterns in neonates & infants with pyloric stenosis.	Respiratory rate	MEDLINE
Hanna, B.D. (2000)	Heart rate variability in preterm brain-injured and very-low-birth-weight infants.	Heart rate	MEDLINE
Harrison, L.L. (2000)	Factors associated with vagal tone responses in preterm infants.	Heart rate	MEDLINE & CINAHL
Magnenant, E. (2004)	Dynamic behavior of respiratory system during nasal continuous positive airway pressure in spontaneously breathing premature infants.	Respiratory rate	MEDLINE

Studies Related to the Patterning of Preterm Physiological Responses (2000 to 2004)
(Continued)

First Author (Year)	Title	Preterm Response	Database
Matsuda, Y. (2003)	The critical period of non-reassuring fetal heart rate patterns in preterm gestation.	Heart rate	MEDLINE
Maynard, V. (2000)	Effect of positioning on respiratory synchrony in non-ventilated pre-term infants.	Respiratory rate	MEDLINE & CINAHL
Pandit, P.B. (2000)	Lung resistance and elastance in spontaneously breathing preterm infants: Effects of breathing pattern and demographics.	Respiratory rate	MEDLINE
Payer, C. (2003)	Apnea associated with hypoxia in preterm infants: impact on cerebral blood volume.	Heart rate	MEDLINE
Razi, N.M. (2002)	Periodic breathing and oxygen saturation in preterm infants at discharge.	Respiratory rate	MEDLINE
Rieger-Fackeldey, E. (2003)	Effect of body temperature on the pattern of spontaneous breathing in extremely LBW infants supported by proportional assist ventilation.	Respiratory rate	MEDLINE
Sawnani, H. (2004)	The effect of maternal smoking on respiratory & arousal patterns in preterm infants during sleep.	Respiratory rate	MEDLINE
Thoyre, S.M. (2003a)	Occurrence of oxygen desaturation events during preterm infant bottle feeding near DC.	Oxygen saturation	MEDLINE
Thoyre, S.M. (2003b)	Preterm infants' behavioural indicators of oxygen decline during bottle feeding.	Respiratory rate	MEDLINE & CINAHL
Van Iddekinge, B. (2003)	Visual interpretation of the effect of maternal betamethasone on the fetal heart rate pattern.	Heart rate	MEDLINE

Studies Related to the Patterning of Preterm Physiological Responses (2000 to 2004)
(Continued)

First Author (Year)	Title	Preterm Response	Database
Verklan, M.T. (2002)	Physiologic variability during transition to extrauterine life.	Heart rate	CINAHL
von Poblitzki, M. (2003)	Effects of theophylline on the pattern of spontaneous breathing in preterm infants less than 1000 g of birth weight.	Respiratory rate	MEDLINE
Weintraub, Z. (2001)	The morphology of periodic breathing in infants and adults.	Respiratory rate	MEDLINE
White-Traut, R.C. (2004)	Developmental patterns of physiological response to a multisensory intervention in extremely premature and high-risk infants.	Oxygen saturation, heart rate, & respiratory rate	MEDLINE & CINAHL

Appendix E

CHILDREN'S HOSPITALS AND CLINICS OF MINNESOTA- ST. PAUL

345 N. Smith Ave.
St. Paul, MN 55102

RESEARCH CONSENT FORM

INTRODUCTION

Before agreeing that your child will take part in this research study, it is important that you read and understand the following explanation. It describes the purpose, treatment plan, benefits, risks and discomforts of the study, and the safeguards that will be taken. It also describes the other options available and the right to withdraw from the study at any time.

BACKGROUND

You are invited to enroll your child in a research study that evaluates the effects of music on preterm infants in a neonatal intensive care unit (NICU). This study is being conducted by Diana Neal, M.S., R.N., a doctoral candidate in the School of Nursing at the University of Minnesota. Your child was selected as a possible participant because of premature birth, age of 32 to 35 weeks gestation, and good health in the NICU. We hope to learn if there differences between the responses of preterm infants receiving recorded music as compared to the responses of infants listening to recorded ambient noise in the NICU.

RESEARCH PURPOSE

The purpose of the study is to learn more about the responses of a preterm infant to recorded lullaby music and compare them with responses to recorded ambient noise (the noise heard continuously by the infant in the NICU environment that will be recorded to control the sound level). It is important to learn about the responses of preterm infants to music to find out if music may help calm and relax these infants in the NICU.

RESEARCH PROCEDURES

If you agree to have your child participate in this study, your (the mother's) medical record and your child's medical record will be reviewed. Your course of pregnancy, labor, and delivery will be recorded. Your child's race, gender, APGAR score, gestational age, weight, medical diagnoses, medications will be documented as well. All information will be kept private. You will be asked if your child experienced any music while you were pregnant or afterwards in the NICU. You will also be asked about the the type and length of the music experience. If your child meets the criteria of the study, she or he will be randomly assigned by chance "like the flip of a coin" to the recorded music group or the recorded ambient noise group where standard NICU care is provided, but no music.

Twenty minutes of sound will be delivered after regular nursing care to prevent disrupting your child's sleep through specially designed infant earphones. These earphones will assure that the sound is presented at a carefully controlled level and reduce the interference of other sounds allowing for minimal volume. Brahms' Lullaby will be used as the musical selection because it has been determined to be appropriate for preterm infants in that it has soothing, constant, stable, and relatively unchanging

sounds as well as a light rhythmic emphasis and constant rhythm as directed by published guidelines for the use of music in the NICU. Your child's oxygen saturation, heart rate, respiratory rate, and behavioral state will be measured before, during, and after presentation of the sound. Your child will be videotaped in order for a skilled behavioral state coder to determine behavioral states.

Before the study begins, your child will be checked for normal hearing. Preparing your child for the sound presentation requires very little time. Disposable infant earphones will be placed over your child's ears using a soft stockinette so that there is no need for any sticky materials. The sound that your child will hear will be faded in and out and carefully monitored so that it is within the range of comfort for the child's ears. The music or ambient noise presentation will be painless. When the study is finished, the stockinette and earphones will be removed.

RISKS

Potential risks to subjects are minimal. Some infants may become fussy while listening to the music or ambient noise. Strict safety protocols and research-based guidelines will be used to minimize risks. A nurse will monitor your child's responses to the music or ambient noise. If your child becomes fussy, s/he will be given a short break. If s/he is still fussy, the session will end and be rescheduled at a later time.

BENEFITS

Music may or may not have direct benefits to your child. For some preterm infants, music has been found to lower stress, promote sleep, improve feeding, and increase calming and relaxation. It is expected that the results of this study will provide information about the effects of music on preterm infants, which may help children in the future.

ALTERNATIVES

Non-participation is the alternative to participation in this study.

HOW TO GET ANSWERS TO YOUR QUESTIONS:

You are encouraged to ask questions both before you agree to be in the study and also at any time you need information.

If you have any questions about this study please contact the researcher, Diana Neal, M.S., R.N., at 952-250-4604 or co-investigator, Jill Therien, M.D. at 651-220-6210 (NICU). You may also contact the researcher's advisor, Linda Lindeke, Ph.D., R.N., C.N.P., School of Nursing, University of Minnesota at 612-626-1133 or the researcher's co-advisor, Susan O'Conner-Von, D.N.Sc., R.N., School of Nursing, University of Minnesota, at 612-624-6647. If you participate in the study and have questions at a later date please also feel free to ask at any time.

If you have any questions about your rights as a research participant or any complaints that you feel you cannot discuss with the investigators, you may call Elizabeth Kipp Campbell, Ph.D., Children's Hospitals and Clinics of Minnesota IRB Administrator at 651-220-5818.

If you have any questions or concerns that you feel you would like to discuss with someone who is not on the research team, you may also call the Family Relations Liaison in St. Paul at 651-220-6888.

CONFIDENTIALITY

Records of patients enrolled in this research are private, and any knowledge that is gained that can be used to identify patients will not be given to anyone other than immediately involved study personnel and by the investigator's research advisors. Knowledge that is gained from this study may be published in scientific journals without identifying the patient. Following conclusion of the study, coded data and videotapes will be kept for educational purposes or further analysis for five years. The tapes will be erased and destroyed after five years.

FINANCIAL ISSUES**Costs for participation in study**

You will not be charged for any research-related procedures, nor will you be paid for your child's participation in the study. A CD of lullaby music will be given to you after the study is completed.

OTHER INFORMATION:

You have been told about the research plan, about the side effects and benefits to be expected, and have had the other choices described to you. Taking part in this research is completely voluntary. By signing this Consent Form, you agree to take part in this research study. You are free to withdraw from this research study at any time without prejudice of any kind. If you have any questions at any time, they will be answered. If you choose to not have your child take part, you will still be offered the best care for the patient's needs.

In the event that this research activity results in an injury, please contact the NICU physician at 651-220-6210 (NICU). Treatment will be available, including first aid, emergency treatment and follow-up care as needed. Payment for any such treatment must be provided by you or your third party payer, if any (such as health insurance, Medicare, etc.). By signing this Consent Form, you are not waiving any rights that you otherwise may have. In the event that you are not covered by insurance please call the patient relations liaison at 612-813-7393, who will help you with your rights.

Your signature below means that you have read the above information, that you have discussed this study with your doctor and his or her staff, and that you have decided to take part based on what you have read and discussed.

You will be provided a copy of this form.

Parent/Guardian Signature	Date
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Parent/Guardian Signature	Date
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I have fully explained this research study to the participants, and in my judgment there was sufficient information regarding risks and benefits, to make an informed decision. I will inform the participant in a timely manner of any changes in the procedure or risks and benefits if any should occur.

Researcher's Signature	Date
------------------------	------

IRB #: 0601-002

IRB Approval Date: May, 25, 2006

Appendix F

Data Safety Monitoring Plan

Planned procedures for the protection of subjects against risks include the following: Recorded music and ambient noise will be provided to preterm infants using stringent safety protocols, research-based guidelines, and inspected instrumentation. A nurse will monitor infant physiological and behavioral responses to the sound conditions throughout the study. Standley's (2002) guidelines for the use of music in the NICU will be strictly adhered to as previously described and recorded music and ambient noise will be played using earphones as recommended by Cassidy and Ditty (1998) and Standley (2002).

All instrumentation including tubing, wires, recorders, and sound meters will be cleaned using Cavacide spray disinfectant and inspected by hospital biomedical engineers. In the event that this research activity results in an injury, treatment will be available, including: first aid, emergency treatment, and follow-up care as needed. Care for such injuries will be billed in the ordinary manner to subject parents or their insurance company. Parents will be instructed to immediately notify a NICU neonatologist if they believe that their child has suffered a research related injury.

In addition, data collected in this research study will be managed in a manner that complies with the Department of Health and Human Services standards for confidentiality and provisions of the Privacy Act. The federally mandated HIPAA law will be strictly adhered to in order to insure that privacy and security standards for protected health information are followed. Each subject will be assigned a code and all personal identifiers will be removed from data collection sheets and videotapes. Access to data will be

restricted to the Principal Investigator, Children's Hospital Sponsor, Children's Hospital Research Associate, and faculty advisors; password protected files will be used; and all data with identifying information will be stored in a locked filing cabinet by the Principal Investigator for two years after data collection is completed. Following completion of the study, coded data and videotapes will be kept for educational purposes or further analysis for five years. The tapes will be erased and destroyed after five years.