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The Effects of Recorded Lullabies on Infants Receiving Phototherapy

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THE EFFECTS OF RECORDED LULLABIES ON INFANTS RECEIVING PHOTOTHERAPY

By

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ABSTRACT

The purpose of this study was to explore the effects of recorded lullabies on infants undergoing phototherapy. Infants undergo phototherapy to treat hyperbilirubinemia, more commonly known as neonatal jaundice. This study was a pre-test post-test design with participants (N=24) randomized by gender into two groups (n=6 males, 6 females per group), experimental and control. The music intervention consisted of 20 minutes of recorded lullabies at a random time in the morning and afternoon. Dependent variables included bilirubin levels, days of hospitalization and phototherapy, behavioral observation on crying, a nurse survey on infant behavior state, and a post treatment parent survey on infant characteristics. A two-tailed Mann Whitney U test revealed that the experimental group had significantly greater scores for the average rating of behavior state as measured by nurse surveys. No significant differences were found on any of the other measures either by group or by gender. Implications for future research are discussed.

CHAPTER 1
INTRODUCTION AND
LITERATURE REVIEW

Bringing Home Baby

Many will argue that few experiences in life are better than bringing home a newborn baby. About 4 million newborns are welcomed into the world each year in the United States (www.cdc.gov). After months of baby's development in the womb, and months of anticipation from the mother and father, the baby is born. If the baby is born in a hospital, he or she will probably be brought home soon after birth. Recent articles cite data from 1995, when the average length of stay in the hospital following birth decreased to just 1.1 days (Farhat & Rajab, 2011). In 1996, legislation was passed that required insurance companies offering maternity coverage to pay for at least 48 hours of hospital stay following a healthy vaginal delivery, and 96 hours following a Cesarean delivery (www.cdc.gov). Beyond this, coverage is not guaranteed and thus many families return home within this time, so long as their baby is healthy and does not require further medical assistance. Unfortunately, not all births are so easy.

Extended Hospital Care

Newborns are often required to stay in the hospital for extended periods of time if anything is complicating their development. Of course, infants born prematurely frequently receive extended care in the Neonatal Intensive Care Unit (NICU), sometimes for weeks or months at a time. About 12.8 percent of births are premature in the United States (Mally, Bailey, & Hendricks-Muñoz, 2010). Other reasons for extended hospital stay include hyperbilirubinemia (jaundice), drug withdrawal, congenital abnormalities, trauma, and hypothermia (Ellatar, Selamat, Robson, & Loughney, 2008). Hyperbilirubinemia is a leading cause of extended hospital stay and alleviating some of its adverse effects is the primary concern of this study.

Hyperbilirubinemia

Hyperbilirubinemia is a common syndrome in newborns that results from an imbalance between bilirubin production and elimination. It is so common in fact that all babies are likely to have some level of hyperbilirubinemia in the first week after birth (Stevenson, Vreman, & Wong, 2011). The infant's body naturally resolves the high levels of bilirubin as it matures, making uptake and elimination more manageable. Normally, changes in bilirubin level are so predictable that it can be compared to an hour-specific nomogram (See Appendix E). It is when levels increase beyond this chart's predictions that the pediatrician must consider treatment. If early intervention is necessary, phototherapy is almost always used to assist the body in gradually decreasing bilirubin levels. Severe cases that require an immediate elimination of bilirubin may require blood transfusions. Although hyperbilirubinemia is a common condition in full-term, near full-term, and premature infants, if left unchecked it could cause serious consequences to child development.

To understand hyperbilirubinemia, one must first understand the presence of bilirubin in the body. Bilirubin is an orange-yellow pigment that results from the normal destruction of red blood cells ("Bilirubin test," n.d.). When red blood cells are broken down, unconjugated bilirubin passes through the body until it reaches the liver. At the liver, the unconjugated bilirubin becomes conjugated when it attaches to certain types of sugars. It is then stored in the gallbladder as bile until it is eliminated from the body through the stool. High levels of bilirubin in infants can indicate an underdeveloped liver or an increased breakdown in red blood cells. Detection of bilirubin levels can be done through a blood sample, or heel stick. The presence of bilirubin in the body is normal and appropriate levels can be reached as the body matures during the first week of life.

Phototherapy Treatment for Hyperbilirubinemia

Modern treatment of hyperbilirubinemia finds its origins in Essex, England in the 1950s. Dobbs and Crèmer (1975) recount the discovery that sunlight aids jaundiced infants by decreasing levels of bilirubin. According to their story, an observation was made that a heavily jaundiced infant had experienced improved color after spending time in the sunlight. Where most of the infant's body was now a pale yellow, a portion of it that had been covered by a

sheet, and thus hidden from the sun, had remained its original dark yellow. Not long after, it was discovered in the hospital's laboratory that blood samples that had been exposed to the sun exhibited much lower bilirubin levels than expected. Upon testing a second sample that had not been exposed to sun, bilirubin levels read very high. It was through these observations and further trial and error that phototherapy became the normal method of treatment in countries outside the United States. Ten years later, the United States "rediscovered" phototherapy and began using it in its own hospitals. Phototherapy has since replaced blood transfusions as the most common method of treatment for hyperbilirubinemia.

Phototherapy has proved to be an effective tool in decreasing levels of bilirubin in the body. Although it is commonly thought that phototherapy utilizes ultraviolet light, the bigger wavelengths of blue light are more effective in penetrating skin and other tissue (Maisels & McDonagh, 2008). Blue light that passes through the body's tissue is absorbed by bilirubin. Once light has been absorbed, its energy breaks bilirubin down into smaller molecules that are more readily eliminated from the body. Factors that may increase the intensity of treatment include the distance of the infant from the light source and the amount of skin exposed. Usually, the infant is placed in a crib with light fixed above wearing only a diaper and eye patches. The eye patches are necessary to protect the newborn's retina from exposure to the light. It is recommended that infants that present at 1 to 2 milligrams per deciliter (mg/dL) or more above the normal range of bilirubin for their age receive treatment. Phototherapy is used until bilirubin levels decrease to an appropriate level for that infant's age, measured in hours. A rebound of 1 to 2 mg/dL is possible, so the infant's bilirubin levels are again measured twenty-four hours after treatment is discontinued. Phototherapy has proven so effective that the use of blood transfusions for the purpose of decreasing bilirubin levels is now very rare.

Consequences of Untreated Hyperbilirubinemia

Untreated hyperbilirubinemia can have profound effects on an infant. When a high amount of bilirubin exists in the body, it begins to collect in the brain's tissue, causing a neurological condition known as kernicterus ("Kernicterus," 2011). Kernicterus presents quite a few symptoms in its early, middle, and late stages. At its worse, kernicterus is recognized as brain damage that causes hearing loss, mental retardation, muscle rigidity and movement

disorders, issues in speech, seizures, and death. Fortunately, kernicterus is a rare condition that can easily be prevented with phototherapy.

Adverse Effects of Phototherapy

Not much is said in research about the adverse effects of phototherapy. The reason for this may be that most professionals consider the side effects so mild that the benefits of phototherapy outweigh the risks. However, if the side effects can be controlled at the same time that the infant receives the benefits of phototherapy, then it is important to consider how both may be accomplished. In a 2011 article, researchers note that some of the immediate side effects include decreased maternal interaction, water loss, electrolyte imbalance, and disturbed sleep cycle, the latter of which has been known to induce "frequent crying and jitteriness" (Xiong, Qu, Cambier, & Mu). Because of all this, phototherapy may provide a very discomforting environment for infants. Although these issues are minor compared to the consequences of not addressing hyperbilirubinemia with phototherapy, it seems impractical that they be ignored altogether. Thus it is necessary that a technique for comforting infants undergoing phototherapy be explored.

Discomfort in the Hospital

Painful procedures. The current hospital environment is often far from comforting. A baby admitted into the NICU will likely experience 115 painful procedures during a two-week period (Badr et al., 2010). Another article reports this number much higher, at 224 painful procedures during a two-week period (Lago et al., 2009). While the procedures are considered routine and necessary, it is apparent that they can have a negative impact on infant development. A study by Barker and Rutter (1995) that followed newborn infants admitted into the NICU found that 56 percent of painful procedures were heel sticks, a process in which the skin of the heel is broken to produce blood for sampling. This is a common practice that all infants in the hospital encounter after birth. Although it is routine and necessary, the heel stick is painful. Many nurses squeeze the heel after the procedure to produce more blood samples. The process of squeezing is also common but can cause bruising and be more painful than the heel stick itself (Morrow, Hidinger, & Wilkinson-Faulk, 2010). Heel sticks are done for a number

of reasons and some populations are more susceptible to them than others. Babies with hyperbilirubinemia receive an increased number of heel sticks because this is the method by which many hospitals collect and analyze bilirubin levels. While babies in the NICU are at greater risk for hyperbilirubinemia, many term and otherwise healthy babies stay at the hospital to treat hyperbilirubinemia alone. These infants are also susceptible to frequent and recurring heel sticks. Other sources of discomfort in the hospital may include the absence of pleasant touch and the presence of constant adverse sounds.

Separation. Infants experience painful or uncomfortable experiences repeatedly, but it is the absence of pleasant touch that has perhaps one of the greatest consequences on infant development. Many new parents find the transition to parenthood difficult, especially when extended hospitalization occurs (Hutchinson, Spillett, & Cronin, 2012). According to Coppola and Cassibba (2010), interviews with parents of neonates tend to reveal a sense of helplessness and insecurity when it comes to providing care for their child. This often has lasting effects on the parents' care-giving behavior and ultimately impedes regular infant development. This problem can be magnified by the severity of the infant's medical condition and their location and position during hospital visits. Certain arrangements inhibit physical closeness and contact, like the placement of the infant in an isolette or phototherapy bed. Fegran, Helseth, and Fagermoen (2008) write that there are three important characteristics of attachment in a mother and infant relationship: proximity, reciprocity, and commitment. Proximity deals with touch and visual contact, reciprocity with the parents' ability to decode the infant's signals, and commitment with the enduringness of the relationship. The placement of a child under phototherapy can affect at least two out of these three attachment characteristics; proximity because the infant must remain under the phototherapy lights with blinds over the eyes, and reciprocity because the mother probably lacks experience communicating with her child. In contrast, parents that regularly practice close contact with their children experience fewer instances of rehospitalization, greater confidence in their own parenting ability, and feelings of connectedness with their child (Hutchinson, Spillett, & Cronin, 2012; Hunt, 2008).

Noise. The typical hospital environment is filled with noise. Conversation, crying babies, ringing phones, humming machines, and alarms are all types of sounds a baby hears during hospitalization. An interesting study analyzed noise in the NICU environment over 16 hours

(Caskey, Stephens, Tucker, & Vohr, 2011). Most of this time, 59 to 68 percent, was consumed with monitor sounds and background noise of ventilators, isolettes, and similar instruments. There was silence for 27 to 39 percent of the time, and a mere 2 to 5 percent consisted of language. This small amount of conversation directed toward the infant is a testimony to what little early socialization experience a child in the hospital receives. With parents present, the infant's own vocalizations increased 129 percent. The potential for language development at home is much greater than that in the hospital. Unfortunately, the main problem with noise in the hospital is that at times it is loud and unpredictable, causing both physiological and behavioral stress responses from the infant. Infants react to their stressful environment with physiological changes in heart rate, respiration rate, blood pressure, oxygen saturation, intracranial pressure, skin blood flow, and sweat (Peng et al. 2009). Behavioral responses may include an arched back, splayed fingers, leg extensions, kicking, and arm waving. The American Academy of Pediatrics recommends that sound levels in the NICU remain below 45 decibels (dB) on Scale A, but some researchers report sound levels averaging between 50 and 90 dB (Wachman & Lahav, 2011). Besides the stress responses that occur when sounds are too frequent, too intense, too long, or too complex, noise and light in the NICU can also disturb regular sleep cycles.

Light. Babies that are required to stay in the hospital for an extended period of time are typically exposed to continuous artificial lighting. This lasting exposure to light can disrupt the biological clock and circadian sleep cycles (Ohta, Mitchell, & McMahon, 2006). Sudden illumination of an overhead light source, like those used during procedures and phototherapy, can suppress respiratory rate and oxygen saturation. It is recommended that the best practice to maintain regular sleep cycles in newborns is to turn lights on and off to imitate day and night, and to use a dimmer to introduce gradual light changes (White, 2011; Ozawa, Sasaki, & Kanda, 2010). This recommendation seems best suited for infants that are not undergoing phototherapy in the hospital. It is usually necessary to keep the infant under phototherapy lights even at nighttime. The eyes of infants under phototherapy are protected from the bright artificial lights using eye patches. However, even with an absence of constant artificial light, infants with eye covers cannot differentiate the practice of turning lights on and off to imitate

night and day. The result may be a disturbed sleep cycle, which can lead to poor weight gain and disrupted brain development (Ohta, Mitchell, & McMahon, 2006; Liu et al., 2007).

Comforting Newborns

While the subject of comforting infants receiving phototherapy has not been the primary focus of research in the past, articles have discussed the comfort of infants under other conditions. White (2011) writes that an appropriate environment is essential to nurturing early development during the first weeks of life. Factors that are apparently beneficial to an infant in the hospital environment include pleasant touch, light cycles imitating night and day, and an absence of "noxious" noise. Probably the greatest comfort to a newborn is pleasant interaction with other humans, especially with mother and father.

There is great benefit for infants that receive frequent mother contact. Many studies tout the benefits of "kangaroo mother care" or "skin-to-skin care" (KMC/STS), a process in which the bare-chested baby is laid on the bare chest of the mother (Ludington-Hoe & Golant, 1993). In a study, 75 infants were monitored for brain activity using Electroencephalography (EEG) tests during eight weeks of KMC/STS. Infants in the experimental group receiving KMC/STS showed accelerated brain maturation compared to control groups receiving no KMC/STS (Scher, et al., 2009). Infants receiving KMC/STS also showed significantly fewer pain responses to routine heel sticks than infants with no intervention at all (Kostandy et al., 2008; Deringer-Kohorst, 2011; Morrow, Hidinger, & Wilkinson-Faulk, 2010). Further benefits include stabilized or increased oxygen saturation levels, decreased agitation and thus decreased motor activity, relaxed breathing, and improved mother-infant relationship. KMC/STS can also strengthen the parent-child bond by giving parents an increased confidence in their parenting skills, improved perception of NICU experience, and a feeling of connectedness with their child (Hunt, 2008). This improved development has lasting effects throughout at least the first year of life (Ohgi et al., 2002; Hunt, 2002). Benefits are said to occur even when KMC/STS is executed by someone other than the mother and when both parent and child are fully clothed (White, 2011). To counterbalance and reduce the consequence of the great number of painful and uncomfortable procedures, pleasant touch is essential in the hospital environment.

Discomfort During Phototherapy

Phototherapy provides an uncomfortable experience for the infant but is a common treatment for jaundice. Infants undergoing phototherapy receive one to two heel sticks each day to monitor the blood for changing bilirubin levels (Barker, Latty, & Rutter, 1994). When a heel stick is performed, it is regular practice for the nurse to squeeze the heel to procure more blood for sampling. The act of breaking the skin and squeezing the heel is a painful procedure for infants and occurs frequently during phototherapy treatment. Close contact with the mother and other significant caregivers is essential to infant development (Anderson et al., 2003). However, phototherapy treatment requires that the infant lay in a crib positioned under lights for hours or days at a time. The mother typically doesn't hold the infant except when breastfeeding and the opportunities for skin-to-skin contact for the baby are very limited. Noise in the hospital frequently reaches levels that are inappropriate for infant development (Cabrera, 2000). Loud and startling background noise can pause neurological development and may have lasting effects as the infant matures. The absence of regular light cycles also impacts growth, as it disturbs regular sleep cycles necessary for development (Miller, White, Whitman, O'Callaghan, & Maxwell, 1995). During phototherapy, the intense lights are on for hours or days at a time while hospital staff attempts to decrease bilirubin levels. Biliband® eye patches are used to cover the infant's eyes to protect the retinas from the light. Whether the infant is left in total lightness or darkness, the detection of night and day cannot occur. Disturbed sleep cycles can alter growth, feeding regularity, and behavior states. While some form of eye protection is necessary under phototherapy lights, focus group complaints have arisen about the Biliband® eye-patch (Yongmei, 2008). On an active baby, eye protectors are frequently displaced, leaving the eyes uncovered. Infants' heads are changing rapidly in the days after birth, and the fit of the Biliband® may change, leaving openings where light enters or further reasons for concerns about displacement. The displaced Biliband® may end up over the infant's nose or mouth which may not only be uncomfortable, but dangerous as well. Individuals within focus groups have tried to remedy the problem by tightening the Biliband®, only to find that it causes bruising around the eyes. Needless to say, eye protectors are also a source of discomfort for babies being treated with phototherapy.

Music in the NICU

Music therapy has already been successfully integrated into NICU programs around the United States and a growing amount of research supports the practices used by board certified music therapists (MT-BCs). Music therapy for the neonates begins with an understanding of the auditory system during this fragile time. Auditory development begins in the womb (Graven & Browne, 2008). For the first 20 weeks of fetal development, the structural components of the ear are just developing. Between 25 and 29 weeks, the ear becomes fully functional, and the infant begins experiencing auditory stimulation. Amazingly, the baby begins to recognize voices, melodies, and other meaningful sounds around 30 weeks gestational age. These experiences are necessary to fetal auditory development because without meaningful sounds, neuron connections are lost and the infant will have difficulty later differentiating between frequencies. A newborn at 40 weeks that has not been exposed to meaningful sounds (or these sounds were masked by background noise 60 decibels and higher) will already be 2 months delayed in language development. A caution from researchers Graven and Browne note that it is important for anyone that considers introducing music to an infant to never place headphones directly on the mother's abdomen. Decibel levels are doubled in the womb when emerging from two separate sources directed toward the fetus. Studies in music outline the most appropriate music interventions at each stage of the infant's development.

In two separate articles, Standley and Gooding (2001; 2010) lay out current music therapy protocols that are appropriate to the NICU setting. Oxygen saturation, sleep, behavior state, and weight gain all improved through various music therapy interventions. Some of these interventions, like multimodal stimulation to increase tolerance to stimuli and nonnutritive sucking using the pacifier-activated-lullaby system (PAL) to improve feeding performance, are probably not particularly beneficial to jaundiced infants who are otherwise developing normally. However, other interventions typical to the NICU setting may be of use to babies with hyperbilirubinemia.

Non-nutritive sucking for the purpose of reducing pain responses in low birth weight infants has proven effective, but adding music through the PAL system produces even greater results. The PAL system provides music contingent on sucking (Standley et al., 2010). When a baby uses the system, the act of sucking puts pressure on a compatible pacifier, which sends

electrical signals to activate a music player. A music therapist can adjust the settings on the music player to respond to sucking with a brief period of music. Within minutes, infants can learn the cause and effect relationship between sucking and music. The PAL system makes the transition to nipple feeding easier and promotes weight gain in neonates. Although the PAL is best known for its success in improved nipple feeding, Whipple (2008) used the PAL system to test the effects of three separate conditions on infant pain responses before, during, and after heel sticks. Non-nutritive sucking using the PAL system had the greatest effect on behavioral pain responses over non-nutritive sucking without music as a reinforcer and no contact during the procedure at all. The PAL group had significantly positive results in the following domains: pain responses during the heelstick, time spent in "undesirable states," during- and post-heel stick stress levels, and behavior state and stress level differences between recorded intervals. Also, the score for pre-heel stick stress was significantly lower than the no-contact group. Although Whipple examined the NICU population, infants with jaundice are tested one or two times daily through heel stick for bilirubin levels and could benefit from this research.

Music listening for inconsolable crying is also an effective application of music therapy to the NICU. Keith, Russell, and Weaver (2009) tested the effects of recorded music on infants that reached the point of inconsolable. An inconsolable infant was defined in this study as one that continued a lasting, intense cry five minutes beyond a nurse's efforts to console the infant through "patting, swaddling, a change of diaper, a change of position, or presenting a pacifier." Each infant was enrolled in the study for four days, alternating days with music therapy and days without. On days without music therapy, there were an average of 7 occurrences of inconsolable crying for each infant, lasting approximately 23 minutes. On days with music therapy, there were only 4 occurrences of inconsolable crying, lasting 5 minutes. The differences in occurrences, duration, and physiologic responses in heart rate, respiratory rate, and oxygen saturation were significant.

Literature on kangaroo mother care and skin-to-skin contact (KMC/STS) has presented many positive outcomes for mothers and their premature infants. A Taiwanese study determined that KMC/STS paired with recorded music also has great effects on this population (Lai et al., 2006). In this study, 30 mother-infant dyads were enrolled. The experimental group

(n=15) practiced 60 minutes of KMC/STS with preferred recorded music for three consecutive days while the control group (n=15) received routine incubator care. Mothers receiving music chose among Western vocal music, instrumental music, or Taiwanese lullabies. Infants in the music group experienced more quiet sleep states and less crying than those in the control group. Mothers in this group had significantly lower scores for maternal anxiety than the control group. The researcher notes that other studies on KMC/STS resulted in greater feelings of paternal "mastery," feelings of crisis resolution, positive attitudes toward the infant, feelings of pregnancy completion, increased duration of breastfeeding, and heart rate and temperature increases that were still within the normal range for the infant. Furthermore, KMC/STS can enhance the bond between parent and child when physical detachment occurs in the NICU or during phototherapy.

Music for lactation support may be beneficial to mothers that have started breastfeeding and is not limited to use in the NICU. Procelli (2005) found new mothers (N=60) that experienced a music therapy intervention prior to breastfeeding showed fewer anxious behaviors, more relaxed behaviors, and more smiling, talking, and laughing toward their infant. The music therapy intervention consisted of ten or more minutes of live music performed by a music therapist in the genre of the mother's choice. Music was paired with active listening, relaxation techniques, and counseling techniques. While infants did not show a difference between groups on behavior state, successful breastfeeding can aid the mother and child bond. Procelli mentions that breastfeeding encourages closeness through "frequent touching, holding, and eye-to-eye contact." For infants undergoing phototherapy, the opportunity for touching, holding, and eye contact is greatly reduced. It could be helpful to the parent and child to have a music therapist present during breastfeeding to improve the quality of time that the family is able to spend in close contact.

It is important to discuss the practice of music therapy in the NICU when considering music therapy for infants with jaundice. Infants in the NICU are more susceptible to jaundice than term infants because they are generally at a younger gestational age. At a younger gestational age, the organs needed for ridding the body of bilirubin are less developed than in term infants (Gouyon, Iacobelli, Ferdynus, & Bosante, 2012). Music therapy research done in the NICU can be applied, with special considerations to age and developmental

appropriateness, to infants outside of the NICU. Likewise, findings from research on term and near-term infants with hyperbilirubinemia can be transferred over to the NICU population. Thus it is important to explore the benefits of music therapy in both populations.

Purpose of this Study

The purpose of this study is to determine whether music therapy can benefit infants undergoing phototherapy. The participants in this study were full-term or near-term jaundiced infants that were considered otherwise healthy but needed extended hospitalization to treat hyperbilirubinemia. Considering the research that exists, phototherapy is a very necessary but uncomfortable and perhaps developmentally disruptive procedure for newborns with hyperbilirubinemia. Because of music therapy's ability to improve conditions for infants in the NICU, it is appropriate to consider its benefits in similar populations. The factors being examined in this study are the effects of recorded music on crying, infant behavior state, bilirubin levels, duration of phototherapy, and length of hospitalization.

CHAPTER 2

METHOD

Participants

This study was approved by the Florida State University Human Subjects Committee and the Tallahassee Memorial Healthcare Institutional Review Board (see Appendix A & B). The participants were 24 full-term and near-term infants admitted into the Family Care Unit or Pediatric Unit of a hospital in the Southeastern United States. All participants presented with hyperbilirubinemia and were undergoing phototherapy at the time of this study. The infants were otherwise healthy and remained in the hospital only to receive phototherapy treatment. All participants required a signed consent form from the mother or father to participate in the study (see Appendix C). Once a consent form was signed, participants were randomly assigned to the control or experimental group.

Table 1. Participant background

Participant number	Group	Male/Female	Birth Weight (g)	Gestational age (weeks)
1	Control	Male	3160	39.29
2	Control	Male	3771	39.00
3	Control	Male	3295	39.71
4	Control	Male	3010	40.00
5	Control	Male	3300	40.86
6	Control	Male	2807	37.29
7	Control	Female	3830	40.71
8	Control	Female	3600	40.00
9	Control	Female	3545	37.86
10	Control	Female	2860	38.43
11	Control	Female	3400	39.43
12	Control	Female	2499	Unknown*
13	Experimental	Male	3147	39.57

Table 1. Participant background (continued)

Participant number	Group	Male/Female	Birth Weight (g)	Gestational age (weeks)
14	Experimental	Male	3160	39.71
15	Experimental	Male	4360	38.86
16	Experimental	Male	2170	37.71
17	Experimental	Male	3742	39.71
18	Experimental	Male	3771	38.29
19	Experimental	Female	2520	36.00
20	Experimental	Female	4050	39.00
21	Experimental	Female	3460	37.29
22	Experimental	Female	3360	38.29
23	Experimental	Female	3544	40.86
24	Experimental	Female	3345	39.14
Means for control group			**3256.42**	**39.33**
Means for experimental group			**3385.75**	**38.70**

*One baby in this study was born at home and came into the hospital the following day for phototherapy treatment. No information on gestational age at birth was found in this baby's medical record.

Design

This study used a pre-test post-test experimental control group design randomized by group (N=24) and by gender (n=6 males, 6 females per group). The dependent variables were bilirubin levels, days on phototherapy and in the hospital, behavioral observation on crying and interaction status, a nurse survey on infant behavior state, and a post treatment parent survey on infant characteristics.

Setting

Nearly all sessions took place in the infant's assigned hospital room. Mothers were also in the room with the infant 24 hours a day, even after they were officially discharged from the hospital. Infants stayed in a rolling crib that could be wheeled under the phototherapy light source. Lights hung over the crib and were draped with a hospital sheet, apparently to block the light from filling the room. Although this was not confirmed with the nurses at the hospital, research has shown that white sheets can intensify phototherapy treatment (Blackwell, 2003). Infants wore only a diaper and Biliband® eye patches. Physicians recommended a certain amount of time for each patient to receive phototherapy. Patients were usually only removed from under the lights to feed, have a diaper changed, or receive any other procedures or testing required by the treatment staff.

Only one session took place in a location other than the mother's room. In this case, the mother was taking a shower and so the infant was brought to a nursery behind the nurse's station. This room was a large room that only one other child occupied it at the time. This child had just undergone a circumcision procedure and was crying at the time of the session.

Materials

A USB Snowball microphone by Blue was used to record the music therapist's voice to Garageband, a Macintosh music editing software. The track was saved as an mp4, and then converted to a format for use in iTunes. From iTunes, the track was downloaded onto an iPod. In sessions, the iPod was connected to two speakers that were placed on either side of the crib. A Radioshack decibel reader was then used to measure the decibel level at each ear of the infant. The music that was recorded and played on the iPod consisted of ten popular lullabies. The music used in this research was chosen and recorded in consideration of the guidelines set forth by Standley (2010) regarding appropriate music style for premature infants. Because the infants in this study were term and near-term infants that are more developmentally advanced than those in the NICU, there was less concern for taking precautionary measures to avoid overstimulation. While overstimulation is always a concern for clients in music therapy, it was determined by the researcher to be developmentally appropriate to include a more harmonically complex lullaby like "Edelweiss" on the music

recording. Still, other precautions were taken. The recordings included lullabies to encourage language development, a female voice, a slow tempo, voice with guitar accompaniment only, and a simple plucking pattern on the guitar strings. For a list of songs used in the recording, see Appendix F.

Assessment tools

Observation sheet (Appendix G). Observation periods were conducted at every session. Infants in the experimental group were observed following twenty minutes of music and infants in the control group were observed with no previous music. Periods of observation lasted five minutes with repeating intervals of ten seconds for observation and five seconds for recording (Madsen & Moore, 1978). There were 20 total observe-record intervals, measured with a stopwatch. The following information was recorded: (1) crying/not crying, (2) parent interaction, (3) nurse or physician interaction, and (4) other comments needed for data analysis. To score the infant on episodes of crying or not crying, the researcher analyzed each observe-record interval. If the infant had cried at all during the ten-second observe interval, a "+" was circled during the five-second record interval. If no crying had taken place, a" 0" was circled. The researcher counted every observe interval that was marked "0" and divided it by the total number of observe intervals (20) to yield a percentage of time spent not crying. For example, if the infant cried during 10 observe intervals, the infant received a score of 50 percent.

Nurse survey (Appendix H). Nurses were asked to complete a brief survey regarding the infant's primary behavior state during their shift. Both daytime and nighttime shifts completed the single-question survey that asked the nurse to circle the primary behavior state of the infant during their shift. The nurses were asked to begin the process of answering survey questions when phototherapy was first initiated and then continue until the patient was discharged from phototherapy. The options listed on the nurse survey were derived from Brazelton and Nugent's (1995) list of the various states used to describe infant behavior: deep sleep, light sleep, drowsy, quiet alert, active alert, and crying. The definitions of each behavior state are as follows. Deep sleep is referred to as closed eyes, regular breathing, no activity, and no eye movement. Light sleep is referred to as closed eyes but perhaps moving under the

lid, minimal activity, and more frequent startles than during deep sleep. Drowsy is referred to as eyes closed or “heavy-lidded,” eyes dazed when open, light activity, and delayed reactions. Quiet alert is referred to as eyes open and fixed on people or objects, minimal activity, and an occasionally dazed look that can easily be broken to grab attention. Active alert is referred to as eyes open, a lot of activity, thrusting arms and legs, reactive to environment, and with some occasional vocalizations or fussing. Crying is referred to as an intense cry from the infant and high activity. Scores in this survey were determined by assigning each behavior state a number, on a Likert scale. Deep sleep was considered most favorable and scored as a 6. Crying was considered least favorable and scored as a 1.

Parent survey (Appendix I). Parents were asked to provide either an e-mail or mailing address at the time that consent was given. The music therapist sent a brief survey to each parent two to five weeks after the infant’s discharge from the hospital. The survey was adapted from a previous study by Standley (1991) that examined the development of babies at 6 to 9 months of age that had received music therapy in the NICU as newborns. In the study, a survey was sent out to parents that asked them to compare seven characteristics of their infant to other infants of the same age. Crying, sleeping, cheerfulness, yawning, and jitteriness are all considered indicators of how well the baby is progressing developmentally and were included in this researcher’s parent survey. The first five survey questions were rated 1 through 5, with 5 being the most favorable behavior and 1 being the least favorable behavior. Overall scores were then calculated by adding the score of the first five questions. A higher score indicates better behavior. The final question in the survey regarding number of children in the family was not included in the score.

Medical record data collection (Appendix J). Some basic information about each child was collected from medical records after the child had been discharged. This data included birth date, gestational age at birth, weight at birth, discharge date, weight at discharge, number of days on phototherapy, and all bilirubin levels recorded.

Intervention Procedures

The music therapist called the Family Care Unit and Pediatric Unit at approximately nine o’clock every morning during the time of data collection. The purpose of this phone call was to

gather information regarding (1) whether any babies were under phototherapy at that time and (2) how the music therapist could best contact the parent. The therapist would then visit the hospital as soon as possible to contact the parent in person and request consent for their child to be a part of this study. When parent consent was given, the music therapist immediately initiated the first intervention or observation period (dependent on whether the child was randomly assigned to the experimental or control group, respectively). Infants in the experimental group listened to twenty minutes of recorded lullabies during each session. To prepare the infants in this group, the music therapist disinfected all equipment needed for the session, including iPod, speakers, and decibel reader. The speakers were then set at either side of the crib near the head or the foot of the infant. The speakers were connected to the iPod and the music therapist began the music. Immediately after the music began, the music therapist used the decibel reader to ensure that the music loudness was at an appropriate level, between 55 and 65 dB using Scale C, as recommended by guidelines set forth by Standley (2010). The music therapist left the room and returned just before the music track ended. When the track ended, the observation period began. Following the observation, the music therapist picked up the equipment and the session ended. In the event that a child was still under phototherapy that afternoon (or the following morning if the first session took place in the afternoon), the music therapist returned for a second session. The control group received no music and was observed at a randomly selected time.

CHAPTER 3
RESULTS

This was a unique research study that sought to answer questions regarding the possible benefits of music therapy for infants undergoing phototherapy. Statistical analyses were conducted on a range of items (see Appendix K). Factors that were considered included the effects of recorded music on crying, duration of phototherapy, length of hospitalization, bilirubin levels, and behavior state. Twenty-four participants were enrolled in this study and randomly assigned to two groups, experimental and control. Data were collected through observing the infant in his or her room, conducting nurse and parent surveys, and finding information in medical record charts.

Previous research has suggested that recorded music reduces crying and fussiness in newborns. In this study, crying was observed as a post-test and the statistical significance of the data was calculated using a two-tailed Mann Whitney U test. There was no statistical significance between groups. The control group and experimental group received a U score of 75 and 69, respectively (n_1=12, n_2=12, $\propto$=0.05, critical U=37). To further explore the effects of recorded lullabies on crying, statistical significances between the male and female participants were examined. Again, there were no significant differences between groups, as males received a U score of 79 and females received a U score of 65 (n_1=12, n_2=12, $\propto$=0.05, critical U=37). Although these results cannot be declared statistically significant, the means for the two groups favored the experimental group. Babies that received music were content (not crying) 94.17 percent of the time while babies that received no music were content just 84.47 percent of the time. Implications of these findings are discussed in the following chapter.

There were no significant differences between groups regarding the number of days spent in the hospital. The researcher determined the total number of days that each participant was in the hospital by examining medical records. Both the day of admission and the day of discharge were counted as one day each, regardless of what time the infant was born and what time he or she went home. The control group received a U score of 92 and the

experimental group received a U score of 60 (n_1=12, n_2=12, $\propto$=0.05, critical U=37). An analysis of number of hospital days for males and females was also calculated, and with a U score of 84 for males and 60 for females, there was no statistical significance (n_1=12, n_2=12, $\propto$=0.05, critical U=37).

The experimental and control groups also spent a similar amount of time undergoing phototherapy. The number of days under phototherapy was determined by searching through medical records for dates in which the doctor ordered phototherapy to begin and end. Regardless of the time at which the infant began or ended phototherapy, each counted as one day. With a U score of 88.5 for the control group and 55.5 for the experimental group, there was no statistical significance (n_1=12, n_2=12, $\propto$=0.05, critical U=37). Males and females had a U score of 61 and 83 respectively, which was not statistically significant (n_1=12, n_2=12, $\propto$=0.05, critical U=37).

Understandably, the initial bilirubin levels that were taken before consent was signed and participation began were not statistically significant. Bilirubin levels were found by looking at lab results included in the infant's medical chart. The initial bilirubin level was considered the bilirubin level recorded just before phototherapy began, within 12 hours. The control group received a U score of 77.5 and the experimental group a score of 66.5 (n_1=12, n_2=12, $\propto$=0.05, critical U=37). There were no significant differences between groups regarding initial bilirubin levels immediately before phototherapy began. No statistically significant differences were found for the males versus females, with respective scores of 40.5 and 103.5 (n_1=12, n_2=12, $\propto$=0.05, critical U=37).

The average rate of change in daily bilirubin levels was also analyzed. The results should be considered with some care, as different levels of bilirubin are appropriate for infants at different ages. For data purposes, a decrease in bilirubin levels was considered most favorable. In reality, there are some cases in which no change, or even a small increase, is appropriate for the baby. For example, a baby may have experienced no change in bilirubin levels from 12 to 24 hours of age, but at 24 hours, the body may be able to tolerate that amount of bilirubin better than it did at 12 hours. Additionally, bilirubin levels were drawn for the lab at various times and ages (hours) of the infant's life, which made data difficult to compare among subjects. The control group received a U score of 69.5 and the experimental a score of

74.5, neither of which was statistically significant (n_1=12, n_2=12, $\propto$=0.05, critical U=37). Males and female comparisons also came out not statistically significant. The U score for males was 98.5 and the U score for females was 45.5, revealing no significant differences (n_1=11, n_2=11, $\propto$=0.05, critical U=30).

Nurses of the day and night shift were asked to complete a survey regarding the infant's primary behavior state during every shift for the duration of their phototherapy treatment. The first score completed was analyzed for statistical significance. There were no significant differences between groups regarding behavior state as reported by initial nurse surveys. The control group received a U score of 70.5 while the experimental group received a score of 50.5 (n_1=11, n_2=11, $\propto$=0.05, critical U=30). Further analysis revealed that there was also no significant difference between males and females, with a score of 68.5 and 52.5 respectively (n_1=11, n_2=11, $\propto$=0.05, critical U=30).

Interestingly, there was a significant difference between groups regarding average scores for behavior state as reported by nurse surveys. All completed surveys were averaged for each infant. The nurses were not aware of which babies received music. The control group yielded a U score of 98.5 and the experimental group a score of 22.5 (n_1=11, n_2=11, $\propto$=0.05, critical U=30). Males yielded a U score of 72.5 and females a U score of 48.5 (n_1=11, n_2=11, $\propto$=0.05, critical U=30), also not statistically significant.

Table 2. Table of means

	Control	**Experimental**
Time spent not crying*	87.42	94.17
Hospital days	4.17	4.33
Phototherapy days	2.92	3.00
Initial bilirubin (mg/dL)	11.73	12.27
Daily bilirubin change (mg/dL)	-0.61	-1.05
Initial nurse score*	4.55	4.91
Mean nurse score*	4.33	5.04

*Higher score indicates the more desired behavior

All parents agreed to complete a brief parent survey several weeks after they returned home from the hospital. The parents provided either a physical mailing address or an e-mail address to receive the survey. Of the 24 parent surveys sent, only seven were returned. The researcher concluded that there were not enough parent surveys to run a statistical analysis. However, all of the surveys (which included the parents of two control babies and five experimental babies) averaged a score of 17.86. The highest possible score on the parent surveys was a score of 25 and the lowest possible score was a score of 5. While not much can be said statistically, it is interesting to note that the parents of babies that received music returned a majority of the surveys.

CHAPTER 4
DISCUSSION

The purpose of this study was to examine the effects of recorded lullabies on infants receiving phototherapy. Factors that were examined in this research included observed crying, behavior state rated by parent and nurse surveys, number of days in hospital and under phototherapy, and changes in bilirubin levels. This study did not yield any significant differences on the factors considered except for mean scores for nurse surveys. On average, nurses rated infants in the experimental group as being in primarily more desirable behavior states than infants in the control group. Nurses were not made aware of which patients were receiving music, so it is not possible that they purposely reported higher scores to favor the music therapy group. With a lack of statistically significant scores in the other areas, it cannot be concluded that music therapy does not benefit infants undergoing phototherapy. A closer look at possible reasons for all of these outcomes and their implications for future research must be made.

Limitations of the Study

When designing the study, it was the intention of the researcher to visit the infant at totally random times in the morning and the afternoon. If the researcher returned at various times throughout the day, the samples of observation could be completely random and a fair representation of the infant's overall behavior. As it turns out, the researcher's time of arrival became more predictable than intended. Nine o' clock was the time at which the researcher called the charge nurse (the nurse that oversees everything on the unit). After the phone call, it took the researcher approximately 20 minutes to drive to the hospital. No visitors were allowed from one to three o'clock. The researcher did not visit after six o' clock. All of this left very small windows of opportunity to visit the infant. There were many times when the researcher had to wait for the infant because the mother did not want the researcher around while breastfeeding, the infant was being seen by the doctor, or other uncontrollable circumstance occurred. Thus the music and observation times were not totally random and the researcher often saw the

infant on a predictable schedule. If the researcher regularly saw the infant after a feeding, then the infant was probably sleeping or content. This could affect the data, as the researcher would not have had a chance to see the infant in a more active state. Similarly, if the researcher regularly observed immediately before feeding, the infant was likely to be irritable and fussy. This same issue occurred again and again for many of the participants, as mothers are instructed not to go more than three hours without feeding the infant.

Another note regarding feeding must be made. The randomization of the participants into control and experimental groups randomly assigned the researcher to several control infants in a row (see Appendix L). In an attempt to make observations truly random, the researcher began the study allowing observation of the control babies during breastfeeding. By the time the researcher saw the first experimental baby of the study, it was realized that because music could not be played during breastfeeding, the infant would also not be observed during breastfeeding. Although the mother was told to act as she normally would without the researcher there, the mothers would usually delay feeding to allow the researcher to observe uninterrupted. The outcome of this was that there were possibly enough content control babies and, in contrast, enough hungry experimental babies to affect the outcome of the research. An assumption about this cannot be firmly made, but future research should certainly consider this when designing a follow-up study.

Another limit of this research was a small participant number (N). Twenty-four infants being treated for hyperbilirubinemia with phototherapy were included in this study. It took two full months to get this number of participants enrolled from two units in a large regional hospital. Twenty participants (83 percent) resided in the family care unit, which is the unit that the infant and parents are assigned after delivery. Only four participants (17 percent) resided in the pediatric unit, readmitted due to an appearance of symptoms of hyperbilirubinemia. Future researchers that are interested in this population should keep this in mind and allow more time for data collection or cover multiple locations to increase enrollment.

As time went by, it became clear that babies require different amounts of time under phototherapy treatment. The original design of this study had the researcher visiting the infant twice daily for the duration of phototherapy. However, some infants were only on phototherapy long enough to participate in one research trial, whereas some others were seen over several

days. For the sake of keeping data consistent, it was decided that the researcher would change the design mid-study to visit the infant up to two times.

The researcher committed a lot of time to visiting infants in this study, which may not be so easy for those interested in a follow-up study. The design required that the researcher see the experimental group infants for 25 minutes. The time it took to visit each infant was probably actually closer to 35 or 40 minutes, including the time it took to explain the study, obtain consent, disinfect equipment, and set up. The researcher used only one set of iPod and speakers, which made it impossible to see more than one experimental infant at a time. There were days when the researcher was scheduled to see several patients within the limited hours of the morning or afternoon, but had to wait for one or more patients due to a procedure or feeding. It was by luck that the researcher did not have to exclude any babies from the study due to an inability to visit consistently.

Implications for Future Research

Music therapists that wish to follow up with this line of research should seek a larger number of participants (N), either by allowing more time for research or spreading the research over multiple locations. He or she should consider altering the study procedures to free up more time for the researcher. One possibility might be that the parents are given an iPod and speaker set to play the music as directed by the music therapist. The researcher could then instruct parents to play the music at a particular time, perhaps halfway between feedings. Although this study employed recorded music, live music has shown to have a greater effect on patients than recorded music (Standley, 2002), so this is something else that should be considered.

This study involved term and near-term infants, but premature infants in the NICU are more susceptible to jaundice. This study or another may be more effective on this population. A note of precaution: any music therapist that wishes to pursue research in the NICU should be well trained on the premature infant and understand the responsibility that comes with bringing music and music interventions to this fragile population. Music therapists that practice in the NICU should be certified through the National Institute for Infant and Child Music Therapy (www.music.fsu.edu/Music-Research-Centers/NICU-MT). At this time, it is the only

organization that offers training to music therapists wishing to pursue practice in the NICU. To be certified in NICU Music Therapy (NICU-MT), a person must have first completed a four year accredited music therapy program and six-month internship, as well as earned a credential of board certified music therapist (MT-BC) from the national Certification Board of Music Therapists (www.cbmt.org).

Music therapists may be able to greatly benefit infants undergoing phototherapy by facilitating greater parent and child interaction. It was stated in the literature review that phototherapy impedes the physical contact and closeness of parent and child. It appeared to this researcher that this statement was true; mothers and fathers typically only touched and talked to the infant when the infant cried. Understandably, parents use these techniques to soothe and comfort the child. However, the parents are reacting to the behavior rather than trying to prevent it. A music therapist might design an intervention to facilitate appropriate parent and child interaction while the baby remains under phototherapy lights, even when he or she is not presently crying.

Infants with hyperbilirubinemia experience multiple heel sticks during their hospitalization. Nurses draw blood one or two times a day to measure levels of bilirubin in the infant's body. The process of sticking the heel and squeezing it to produce more blood for sampling is a painful but necessary practice that produces a jump in the infant's stress level. Research in music therapy has already shown that music interventions can help infants cope with the pain (Whipple, 2008). For infants receiving music, the return to a normal baseline was faster than infants that received no music. Research should be done to see how multiple heel sticks affect a jaundiced newborn over time, and how music therapy can help improve the procedure.

Infants under phototherapy are more likely to have episodes of inconsolable crying. The environment that phototherapy provides is discomforting and impedes normal parent and infant interaction. Recorded music has helped newborns by shortening crying episodes and making them less frequent (Keith, Russell, & Weaver, 2009). Music therapists should pursue this line of research to see how this can further help infants with hyperbilirubinemia. This study provided music for infants regardless of whether the infant was crying before the music was turned on. Music therapists may wish to examine whether it is better practice to use the music

in a reactive or proactive manner; responding to a baby that is crying or playing music before the baby begins crying.

Regarding data collection on crying, there are other possibilities than what the researcher chose for this study. In this study, the researcher visited the infant twice in a day to measure observed crying. In hindsight, this was not the most effective way to learn an infant's overall behavior. Instead, future researchers may wish to have the parent keep a running tally of the number of times their infant cried in a day. The researcher would have to stress to the parent the importance of accurate responses, and would probably need to check in on the parent to make sure all the parents' questions are answered and that they are keeping the report up-to-date.

It was an issue in this study to have parent surveys returned weeks after the parents left the hospital. A future researcher that wishes to conduct a parent survey may wish to do so before the infant is discharged from the hospital. Once the parents have left the hospital, the researcher is out of sight and out of mind, and there is little incentive to continue participation.

Conclusion

In this study, the experimental group yielded statistically greater nurse survey scores regarding primary behavior state than the control group. Although this study did not yield any other statistical significance, there is reason to pursue music therapy with infants undergoing phototherapy. Similar populations with similar experiences have benefited from music therapy in the past. More studies should be conducted to try to capture the true benefit of music interventions with newborns hospitalized for hyperbilirubinemia.

APPENDIX A

TALLAHASSEE MEMORIAL HEALTHCARE

INSTITUTIONAL REVIEW BOARD APPROVAL FORM

Office of Research
Institutional Review Board 1300 Miccosukee Road
Tallahassee, Florida 32308

(850) 431-5676
(850) 431-6052 Fax

Tallahassee Memorial HealthCare

January 25, 2012

Michelle Strutzel
445 Appleyard Drive
A2-5
Tallahassee, FL 32304

Dear Ms. Strutzel:

Following your presentation to the Institutional Review Board (IRB) at Tallahassee Memorial HealthCare (TMH) on January 24, 2012, IRB # 2011-48 Titled: The of Recorded Lullabies on Infants Receiving Phototherapy was unanimously approved with the provision that modifications may be submitted to the IRB Chair for consideration using expedited review guidelines. The approval expires on January 23, 2013.

IRB # 2011-48 The of Recorded Lullabies on Infants Receiving Phototherapy
Principal Investigator: Michelle Strutzel
Informed Consent: Approved as presented. Version 2
Partial Waiver of HIPAA Authorization for Screening /Recruitment of Subjects: Approved effective 1/24/2012 through 1/23/13 only for those patients who are patients of the physicians who have agreed to allow their patients to be approached for the study.
Protocol: V 1, December 20, 2011
Other materials approved: Attending Physician Study Contact Authorization Sheet, Data Collection Sheet, Observation Sheet, Recruitment Flyer, Nurse Survey, and Parent Survey.
Reporting Requirements:

- Report to the IRB any planned change in the study or informed consent and do not implement any change without receiving prior approval, except to eliminate immediate hazard;
- Report to the IRB any unanticipated problems involving risks to subjects;
- Report to the IRB any new information on the project that adversely influences the risk/benefit ratio;
- Report to the IRB any serious or unexpected adverse events;
- Report to the IRB any major protocol violations with in ten days. Minor protocol deviations may be reported at the time of the Study Progress Report (Application for Renewal). Maintain a log throughout the year and establish a plan of correction to minimize the deviations.

- Report to the IRB when the study is terminated or completed and submit a summary of the study findings.

Please request approval for advertising copy, recruitment flyers, publications, that appear in any medium prior to use.

Supplemental Reporting Requirements: None
Expiration Date: January 23, 2013
Continuation Review Date: January 23, 2013
Continuation Review Requirements: At the time of renewal please check the Office of Research/IRB intranet site to ensure that you have the most current edition of the IRB Forms. The investigator must submit a completed Study Progress Report Application and supporting documentation packet to the Office of Research/IRB one month prior to the approval expiration date. Please note the expiration date of the study and compare it to the IRB Meeting Schedule to ensure timely review and processing of the study file prior to the fully convened IRB meeting and inclusion of your request for renewal on the appropriate agenda. If you have any questions about the forms or submitting them, please contact Mary Sandell, Regulatory Readiness Coordinator, at (850) 431-5676.

As the principal investigator you are responsible for ensuring compliance with the study protocol, the applicable IRB at TMH Guidelines and Code of Federal Regulations set forth by the Department of Health and Human Services. The IRB Guidelines and forms required to comply with reporting requirements are available on the TMH Intranet.

Enclosed are copies of the materials which were reviewed and approved by the board and have the IRB approval stamp for this year.

Sincerely,

[redacted]

Cynthia Blair
Administrative Liaison/IRB

APPENDIX B
FLORIDA STATE UNIVERSITY HUMAN SUBJECTS COMMITTEE APPROVAL FORM

Office of the Vice President For Research
Human Subjects Committee
Tallahassee, Florida 32306-2742
(850) 644-8673 · FAX (850) 644-4392

APPROVAL MEMORANDUM

Date: 2/20/2012

To: Michelle Strutzel

Address: [redacted]
Dept.: MUSIC SCHOOL

From: Thomas L. Jacobson, Chair

Re: Use of Human Subjects in Research
The Effect of Recorded Lullabies on Infants Receiving Phototherapy

The application that you submitted to this office in regard to the use of human subjects in the research proposal referenced above has been reviewed by the Human Subjects Committee at its meeting on 12/14/2011. Your project was approved by the Committee.

The Human Subjects Committee has not evaluated your proposal for scientific merit, except to weigh the risk to the human participants and the aspects of the proposal related to potential risk and benefit.

This approval does not replace any departmental or other approvals, which may be required.

If you submitted a proposed consent form with your application, the approved stamped consent form is attached to this approval notice. Only the stamped version of the consent form may be used in recruiting research subjects.

If the project has not been completed by 12/12/2012 you must request a renewal of approval for continuation of the project. As a courtesy, a renewal notice will be sent to you prior to your expiration date; however, it is your responsibility as the Principal Investigator to timely request renewal of your approval from the Committee.

You are advised that any change in protocol for this project must be reviewed and approved by the Committee prior to implementation of the proposed change in the protocol. A protocol change/amendment form is required to be submitted for approval by the Committee. In addition, federal regulations require that the Principal Investigator promptly report, in writing any unanticipated problems or adverse events involving risks to research subjects or others.

By copy of this memorandum, the Chair of your department and/or your major professor is reminded that he/she is responsible for being informed concerning research projects involving human subjects in the department, and should review protocols as often as needed to insure that the project is being conducted in compliance with our institution and with DHHS regulations.

This institution has an Assurance on file with the Office for Human Research Protection. The Assurance Number is FWA00000168/IRB number IRB00000446.

Cc: Jayne Standley, Advisor
HSC No. 2011.7442

APPENDIX C

CONSENT TO PARTICIPATE

Title of Project: The Effect of Recorded Lullabies on Infants Receiving Phototherapy

Principal Investigator: Michelle Strutzel, MT-BC, NICU-MT

Other Investigators:

Participant's Printed Name: _____

This is a research study. Research studies include only people who want to take part. This form gives you information about this research, which will be discussed with you. It may contain words or procedures that you do not understand. Please ask questions about anything that is unclear to you. Discuss it with your family and friends and take your time to make your decision.

1. **Purpose of the Research**
   The purpose of this research is to examine the effect of recorded lullabies on infants receiving phototherapy. Phototherapy is a procedure in which infants are exposed to light to treat high levels of bilirubin in the body. Bilirubin is a substance in the body that is created through the breakdown of red blood cells and hemoglobin. High levels of bilirubin in newborns can lead to jaundice if it is not treated. Your infant is invited to participate in this research study that examines the effect of music on crying, bilirubin levels, duration of phototherapy, and length of stay in the hospital. You are being offered this opportunity because your infant is receiving phototherapy. There will be approximately 64 infants participating in this study.

2. **Procedures to Be Followed**
   After you have given consent for your infant to participate in the study, your infant will be assigned to a randomized list (similar to flipping a coin) generated before the study begins. This list will determine whether your infant is placed in the experimental group (receiving music) or control group (receiving no music). The principal investigator will begin visiting your child twice per day for the duration of his or her phototherapy treatment. If your infant is randomly assigned to the experimental group, he or she will receive 20 minutes of recorded music in the morning (before 12:00 p.m.) and in the afternoon (after 12:00 p.m.). Following the recorded music, the principal investigator will observe the behavior of the infant for five minutes to measure crying. If your infant is randomly assigned to the control group, the principal investigator will visit your infant twice per day to measure crying during a five-minute period. The visits will occur in the morning (before 12:00pm) and in the afternoon (after 12.00 p.m.). No music will be played. Following your infant's discharge from the hospital, the principal investigator will examine medical records to obtain data on your infant's daily bilirubin levels, duration of phototherapy, and length of stay in the hospital.

3. **Discomforts and Risks:**
   There are no foreseeable risks for participating in this study.

4. **Possible Benefits:**
   a. **Possible benefits to the participant:**
   The possible benefit your infant may experience from the music described in this research includes decreased crying. There is no guarantee that you or your child will benefit from being in this research.

   b. **Possible benefits to others:**

The results of this study may benefit others by expanding the music therapy research literature. The knowledge obtained in this research may help guide music therapists in the future treating infants receiving phototherapy.

5. **Other Options that Could be Used Instead of this Research:**
You do not have to take part in this research study.

6. **Time Duration of the Procedures and Study:**
Participation in this study does not require any additional time on your part with the exception of a brief survey that will be emailed or mailed to you after your infant is discharged from the hospital. The estimated time that this survey will take is approximately ten minutes. The principal investigator will visit your infant twice daily for the duration of his or her phototherapy treatment. The amount of time spent with your infant will be 5 minutes twice per day for those in the control group and 25 minutes twice per day for those in the experimental group.

7. **Statement of Confidentiality:**
Privacy and confidentiality measures for the use of private health information:

Health information about your child will be collected if you choose to be part of this research study. Health information is protected by law as explained in the TMH Privacy Notice. If you have not received this notice, please request a copy from the researcher. Your information will only be used or shared as explained and authorized in this consent form or when required by law. It is possible that some of the other people/groups who receive your health information may not be required by Federal privacy laws to protect your information and may share it without your permission.

To participate in this research you must allow the researcher to use your health information. If you do not want your protected health information used, your child may not participate in this research.

Your permission for the use, retain, and share of your identifiable health information will expire expire upon completion of the research study. At that time, the research information not already in your medical record will be retained for 3 years after the study is completed as required by federal law. Any identifying information that links you and your infant to the research results will be destroyed immediately upon completion of the study. Any research information in your medical record will be kept indefinitely.

If you choose to participate, you are free to withdraw your permission for the use and sharing of your child's health information at any time. You must do this in writing. Write to Michelle Steutzel and let her know that you are withdrawing from the research study. Her mailing address is [redacted]

If you withdraw your permission:
- The investigator will no longer use or share medical information about you for this research study, except when the law allows us to do so.
- The investigator is unable to take back anything we have already done or any information we have already shared with your permission.

- The investigator may continue using and sharing the information obtained prior to your withdrawal if it is necessary for the soundness of the overall research.
- The investigator will keep her records of the care provided to you as long as the law requires.

The investigator will use the following sources of health information:

- Bilirubin levels
- Duration of phototherapy
- Length of hospital stay
- Weight
- Name
- Gender
- Hospital room number
- Telephone number
- Email address or mailing address
- Nurse observation questionnaire
- Parent observation questionnaire
- Observed crying

Representatives of the principal investigator, Michelle Strutzel, may use your health information and share it with other specific groups in connection with this research study.

The principal investigator may share your health information with the following people/groups for their use in connection with this research study. These groups, while monitoring the research study, may also review and/or copy your original TMH medical and research records.

- The Office of Human Research Protections in the U. S. Department of Health and Human Services
- The Institutional Review Board at Tallahassee Memorial Health Care
- The FSU Human Subjects Protection Office

We will do our best to make sure that the personal information in your medical record will be kept private. However, because of the need to release information to the above parties, absolute confidentiality cannot be guaranteed. Once your personal health information is released, it may be redisclosed and no longer protected by federal privacy regulations. Your personal information may also be given out if required by law and in rare circumstances may be subpoenaed by a court.

In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

8. Costs for Participation:

a. Costs:

There is no cost for you to participate in this study.

b. Treatment and compensation for injury:

Every effort to prevent injury as a result of your participation in this research study will be taken. In the event of an injury resulting directly from your child's participation in this research study,

medical treatment is available but will be provided at the usual charge. Provision of such medical care does not imply any negligence or other wrongdoing on the part of the Hospital or any of the nurses or other personnel involved in this study. Where applicable, the Hospital reserves the right to seek payment from third-party vendors for any medical care or services rendered. The Hospital has no program to provide you with any additional compensation as a result of any such injuries. You will not lose legal rights by signing this form.

9. **Compensation for Participation:**
You will not receive any compensation for being in this research study.

10. **Research Funding:**
The institution and investigators are not receiving any funds to support this research study.

11. **Voluntary Participation:**
Taking part in this research study is voluntary. You do not have to participate in this research. If you choose to take part, you have the right to stop at any time. If you decide not to participate or if you decide to stop taking part in the research at a later date, please let Michelle Strutzel know in writing at [redacted]. There will be no penalty or loss of benefits to which you are entitled. The principal investigator may take you out of the research study without your permission. This consent and authorization expires upon completion of this study.

12. **Contact Information for Questions or Concerns:**
You have the right to ask any questions you may have about this research. If you have questions, complaints or concerns or believe you may have developed an injury related to this research, contact Michelle Strutzel at [redacted] You may also contact her academic supervisor, Dr. Jayne Standley, at [redacted]

If you have questions regarding your rights as a research participant or you have concerns or general questions about the research, contact FSU Chair of the Human Subjects Committee, Institutional Review Board, through the office of the Vice President of Research, at [redacted] or the research protection advocate Cynthia Blair, Administrative Liaison/IRB, Tallahassee Memorial HealthCare [redacted]. You may also call this number if you cannot reach the research team or wish to talk to someone else.

Signature and Consent/Permission to be in the Research

Before making the decision regarding enrollment in this research you should have:

- Discussed this study with an investigator,
- Reviewed the information in this form, and
- Had the opportunity to ask any questions you may have.

Your signature below means that you have received this information, have asked the questions you currently have about the research and those questions have been answered. You will receive a copy of the signed and dated form to keep for future reference.

Participant's Legally Authorized Representative: By signing below, you indicate that you give permission for the participant to take part in this research.

Signature of Participant's Legally Authorized Representative	Date	Time	Printed Name

(Signature of Participant's Legally Authorized Representative is required for people unable to give consent for themselves.)

Description of the Legally Authorized Representative's Authority to Act for Participant

Person Explaining the Research: Your signature below means that you have explained the research to the participant/participant representative and have answered any questions he/she has about the research.

Signature of person who explained this research	Date	Time	Printed Name

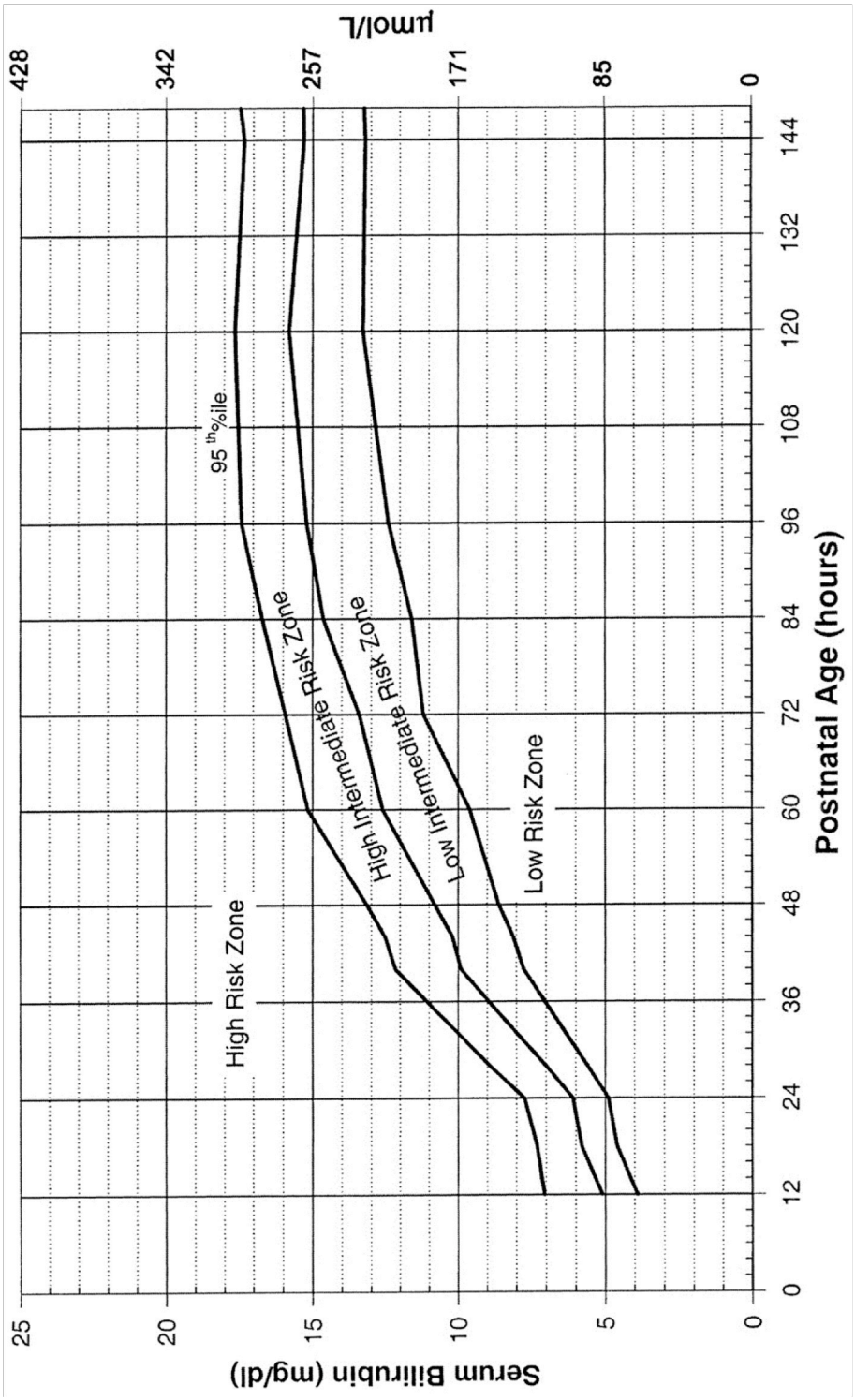
(Only approved investigators/research coordinators and those trained in obtaining research informed consent and familiar with this research may explain the research and obtain informed consent.)

APPENDIX D

RECRUITMENT FLYER

APPENDIX E

BILIRUBIN NOMOGRAM



APPENDIX F

RECORDED LULLABIES

1. You Are My Sunshine
2. Twinkle Twinkle Little Star
3. I'm a Little Teapot
4. The Alphabet Song
5. Itsy Bitsy Spider
6. Mary Had a Little Lamb
7. Are You Sleeping?
8. Rock-a-bye Baby
9. Wheels On the Bus
10. Edelweiss

APPENDIX G

OBSERVATION FORM

Observation sheet

Infant name _____
Location _____
Date _____
Time start _____
Time end _____
Observation-record ratio _____
Experimental/control group _____

Minute			Record		Record		Record		Record	Comments
1	Infant	Observe	+ 0	Observe	+ 0	Observe	+ 0	Observe	+ 0	
	Parent		0 T H Z		0 T H Z		0 T H Z		0 T H Z	
	Nurse		0 T H Z		0 T H Z		0 T H Z		0 T H Z	
2	Infant	Observe	+ 0	Observe	+ 0	Observe	+ 0	Observe	+ 0	
	Parent		0 T H Z		0 T H Z		0 T H Z		0 T H Z	
	Nurse		0 T H Z		0 T H Z		0 T H Z		0 T H Z	
3	Infant	Observe	+ 0	Observe	+ 0	Observe	+ 0	Observe	+ 0	
	Parent		0 T H Z		0 T H Z		0 T H Z		0 T H Z	
	Nurse		0 T H Z		0 T H Z		0 T H Z		0 T H Z	
4	Infant	Observe	+ 0	Observe	+ 0	Observe	+ 0	Observe	+ 0	
	Parent		0 T H Z		0 T H Z		0 T H Z		0 T H Z	
	Nurse		0 T H Z		0 T H Z		0 T H Z		0 T H Z	
5	Infant	Observe	+ 0	Observe	+ 0	Observe	+ 0	Observe	+ 0	
	Parent		0 T H Z		0 T H Z		0 T H Z		0 T H Z	
	Nurse		0 T H Z		0 T H Z		0 T H Z		0 T H Z	

Codes

Infant

+	Crying
0	No crying

Parent

0	No interaction
T	Talking
H	Holding or touching
Z	Other action, including changing diaper or breastfeeding

Nurse

0	No interaction
T	Talking
H	Holding or touching
Z	Other action, including changing diaper or breastfeeding

APPENDIX H

NURSE SURVEY

Nurse Survey

Infant name______________________
Room number______________________

Date____

Nurses, please answer this question if you are in charge of this baby during your work shift. More than one nurse can complete this questionnaire in a day.

Time____

Rate the **primary** behavior-state of this baby today during your shift:

Deep sleep	Light sleep	Drowsy	Quiet alert	Active alert	Crying
1	2	3	4	5	6

Time____

Rate the **primary** behavior-state of this baby today during your shift:

Deep sleep	Light sleep	Drowsy	Quiet alert	Active alert	Crying
1	2	3	4	5	6

Time____

Rate the **primary** behavior-state of this baby today during your shift:

Deep sleep	Light sleep	Drowsy	Quiet alert	Active alert	Crying
1	2	3	4	5	6

When this questionnaire is complete, please place it in the box labeled "Music therapy questionnaire" located behind the front desk of the unit.

APPENDIX I

PARENT SURVEY

Parent Survey

Thank you for allowing your infant to be a part of this research. Answers can be made by double-clicking on a box and then changing the "Default value" to "Checked". Please check just ***one*** *box for every question.*

1. Compared to other infants, how often does your baby cry?

Much less	Somewhat less	About the same	Somewhat more	Much more
☐	☐	☐	☐	☐

2. Compared to other infants, how much does your baby sleep?

Much less	Somewhat less	About the same	Somewhat more	Much more
☐	☐	☐	☐	☐

3. Compared to other infants, how cheerful is your baby?

Much less	Somewhat less	About the same	Somewhat more	Much more
☐	☐	☐	☐	☐

4. Compared to other infants, how often does your baby yawn?

Much less	Somewhat less	About the same	Somewhat more	Much more
☐	☐	☐	☐	☐

5. Compared to other infants, how jittery is your baby?

Much less	Somewhat less	About the same	Somewhat more	Much more
☐	☐	☐	☐	☐

6. Including your newborn, how many children do you have?

1	2	3	4	5 or more
☐	☐	☐	☐	☐

APPENDIX J

DATA COLLECTION SHEET

Data collection sheet

Infant name_____

Room number_____

Gender_____

Race_____

Gestational age_____

Date of birth_____

Weight at birth_____

Discharge date_____

Weight at discharge_____

Daily bilirubin levels

Day	1	2	3	4	5	6	7	8	9	10
Date										
Photo	Y N	Y N	Y N	Y N	Y N	Y N	Y N	Y N	Y N	Y N
Infant age (hours)										
Bili levels (mg/dl)										

Total number of days on phototherapy_____

APPENDIX K

TABLES OF RAW DATA

Table 3. Average score for percentage of time spent not crying

Participant number	Control	Experimental
1	68	93
2	50	100
3	85	100
4	100	78
5	100	88
6	100	100
7	93	93
8	100	100
9	100	100
10	100	90
11	100	88
12	53	100

Table 4. Raw data for a range of dependent variables

Participant number	Group	Gender	Hospital days	Photo-therapy days	Initial bili-rubin Level (mg/dL)	Daily bilirubin change (mg/dL)	Initial RN score	Mean RN score
1	Control	Male	4	2	10.3	0.7	5	4
2	Control	Male	7	7	6.4	.55	3	3
3	Control	Male	5	3	19.8	-3.35	5	3
4	Control	Male	3	2	15.8	-1.5	3	4.33
5	Control	Male	4	3	11.9	-1.4	6	6
6	Control	Male	3	3	8.1	1.33	4	4
7	Control	Female	4	2	12.5	-0.5	5	5
8	Control	Female	3	2	5.8	1.25	6	4.75
9	Control	Female	3	3	10.7	-0.6	5	5
10	Control	Female	5	3	7.4	2.3	2	4
11	Control	Female	4	2	10.9	-0.3	5	4.5
12	Control	Female	5	3	21.1	-5.8	None*	None*
13	Experimental	Male	6	3	14.7	-3.55	5	5.2
14	Experimental	Male	4	3	28.8	-9.25	None*	None*
15	Experimental	Male	4	3	12.1	-0.15	6	5.67
16	Experimental	Male	5	3	10.9	-1.15	5	5
17	Experimental	Male	4	4	8.6	0.67	3	4.33
18	Experimental	Male	4	3	13.7	-2.2	5	5
19	Experimental	Female	4	4	9.8	-0.2	5	5
20	Experimental	Female	5	4	7.8	1.33	5	5.2
21	Experimental	Female	4	2	13.4	0.2	5	5
22	Experimental	Female	4	4	6.7	0.25	5	5
23	Experimental	Female	5	3	11.2	0.5	5	5
24	Experimental	Female	3	2	9.5	0.9	5	5

*No nurse (RN) survey was filled out for this participant.

APPENDIX L

RANDOM GROUP ASSIGNMENT

Males	Group	Females
	CONTROL	
	CONTROL	
	EXPERIMENTAL	
	CONTROL	
	CONTROL	
	EXPERIMENTAL	
	EXPERIMENTAL	
	CONTROL	
	EXPERIMENTAL	
	EXPERIMENTAL	
	EXPERIMENTAL	
	CONTROL	

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