THESIS

THE EFFECT OF MUSIC THERAPY ON INFANTS BORN WITH GASTROSCHISIS

Submitted by

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ABSTRACT

THE EFFECT OF MUSIC THERAPY ON INFANTS BORN WITH GASTROSCHISIS

Gastroschisis is a congenital anomaly characterized by a hole in the abdominal wall. Through this hole intestines and abdominal organs protrude requiring these infants to have surgery shortly after birth. Both preoperatively and postoperatively, infants born with gastroschisis require pain medications and ventilator support, intravenous feedings and endure long hospital stays. These infants often continue to experience constant discomfort, difficulty in eating, and may develop bowel problems and other complications such as sepsis. Music therapy is an established mode of treatment to promote individual wellness, healing and change. Live lullaby style music was provided on the guitar and / or reverie harp with humming and vocals to infants with gastroschisis postoperatively up to three times a week for 25 minutes followed by 30 minutes of quiet time. The infant's physiological parameters of heart rate, respiration and oxygen saturation were measured pre, during and post music therapy along with a behavioral and pain assessment tool, the CRIES scale. Seven infants were enrolled in the study and 29 music therapy sessions were conducted. The average heart rate, respiratory rate and the CRIES score between pre and post music therapy was compared using the paired t-test. A two-sided p-value < 0.05 was used as the significance level. With physiological parameters and CRIES both at .05 ($p<0.05$) respectively, statistical significance was found only for respiration rate during the post intervention 30 minutes of quiet time $p=0.0047$. Statistical significance on the effect of music therapy for parameters of heart rate, saturation and CRIES was not found on infants born with gastroschisis. If a caregiver was present for the music therapy session, a Likert-type scale survey was provided to rate the experience of the live music for the parent and their perception of

benefit to their child. Caregivers observed only four sessions and each completed survey had been awarded the maximum of 30 points, therefore, the perception was high that music therapy had positive benefits for both the infant and the caregiver. More research in the effect of music therapy on infants is needed. Within the gastroschisis population, no other study is available, and this data may provide a small foundation toward further study. While overall statistical significance was not found, acute effects were noted in behavioral changes of these medically compromised infants.

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I need to thank the physicians, nurses and the child life and research staff at Children's Hospitals and Clinics of Minnesota for welcoming music therapy onto the NICU and ICC units.

I would also like to thank my graduate committee for their interest and support of this complex project and Dr. Blythe LaGasse for always reminding her students "take a deep breath - everything will be okay."

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CHAPTER ONE: INTRODUCTION

A new parent may start dreaming months before their baby is born of the day they will take their new infant home. The dream, of course, is that their baby is healthy and whole and perfect in every way possible. A parent does not dream of their new precious infant having an incomplete body, requiring surgery so soon after birth, or delaying their homecoming by months in the hospital. A parent does not dream of the constant pain and discomfort their baby will experience as they struggle to eat and sleep. However, for some parents, this is their reality if their baby is born with gastroschisis.

Gastroschisis is a congenital anomaly characterized by a hole in the abdominal wall. Through this hole, intestines and abdominal organs protrude requiring these infants to have surgery shortly after birth to return the intestines to the abdominal cavity (Abdullah et al., 2007). In some cases, infants require a "silo," a plastic covering that is attached to the abdominal wall. This silo contains the exposed intestine until it can be gently and slowly pushed back into the abdominal cavity. This silo is used for up to 14 days and requires a second surgery. Both preoperatively and postoperatively, infants with gastroschisis require pain medications and ventilator support. In addition to the surgical repair of this condition, many of these infants cannot eat normally for many weeks, and often need to remain in the hospital, requiring intravenous feedings for nutrition (MN Neonatal Physicians PA, 2010).

Complications, such as sepsis and ileus, can extend the length of stay for infants born with gastroschisis (Abdullah et al., 2007). The average length of hospital stay for an infant with gastroschisis is just over one month (MN Neonatal Physicians PA, 2010). Due to the nature of this anomaly, infants with gastroschisis can develop bowel problems and many of these infants

return for treatment for up to three years of life (MN Neonatal Physicians PA, 2010). There is a great deal discomfort throughout the first months and even first years of life for an infant born with gastroschisis. Alternative therapeutic methods should be considered to aid in reducing the perception of pain, promoting positive physiological states for optimal recovery and development and helping to reduce the amount of time spent in the hospital.

Music therapy by definition is the clinical and evidence-based use of music interventions to accomplish individualized goals within a therapeutic relationship. Music therapy interventions have many medicinal benefits (AMTA, 2010). In the Neonatal Intensive Care Unit (NICU), music therapy is an established mode of treatment and its interventions can be used to promote wellness, manage stress and alleviate pain. It is commonly prescribed for preterm infants due to the number of research studies that report physiological, behavioral and developmental benefits for the premature infant with the absence of negative side effects (Standley & Walworth, 2010). However, infants born with gastroschisis are usually born at full-term or near term and are admitted to the NICU shortly after birth. The length of hospital stay may be correlated with the amount of stress to which an infant is exposed. Music therapy can significantly reduce the stress behaviors of infants in the NICU environment and may reduce their length of stay (Caine, 1991). Caine (1991) also found that music therapy promoted a deeper sleep in stable preterm infants for up to 30 minutes after music therapy had ended. Although researchers have demonstrated that music therapy has a positive effect for infants who are preterm, there are no studies on infants born with gastroschisis. The purpose of this study is to provide knowledge regarding the effect of music therapy on this population.

This study will be a mixed method, single group pre and post intervention measurement clinical trial. The research questions for this study are:

1. Does music therapy have beneficial effects on physiologic parameters, behavioral states, and pain scale evaluations in infants with gastroschisis defects?

2. Does music therapy promote parental/caregiver reduction of stress and provide the perspective that music is an effective tool to calm and soothe their infant at risk for chronic gastrointestinal discomfort?

CHAPTER TWO: LITERATURE REVIEW

An infant born with gastroschisis has a very long and complicated road to recovery. This birth defect causes significant morbidity and has increased in frequency over the last twenty years both in the United States and abroad (Chircor, 2009; see also Lao, 2010b; Payne, 2009). While the cause of this abnormality is yet unknown, there is a commonality among studies that possible factors may include young maternal age of <20 and /or possible exposure to environmental chemicals (Bradnock, 2011; see also Chircor, 2009; Lao, 2010a, 2010b; Payne, 2009). At the beginning of the fourth week of development, the umbilical cord first appears as the primitive umbilical ring, containing the connecting stalk and yolk sac stalk, or vitelline duct, which later combine to form the primitive umbilical cord (Khati, 1998). The abdominal cavity becomes too small to contain the elongating primary intestinal loops by the sixth week of development and the loops are pushed into the umbilical cord, forming a physiologic hernia, which normally does not persist past the twelfth week where the herniated loops are contained in the abdominal cavity (Khati, 1998). If the umbilical ring does not close completely, the abnormalities of omphalocele and gastroschisis may result.

The study by Khati (1998) defined gastroschisis as a paraumbilical opening through which the abdominal contents protrude and the edematous loops of intestine floating freely in the amniotic cavity lack a covering membrane. In addition to needing surgery to place the intestines back into the abdomen, exposure to amniotic fluid can cause peritonitis, interfering with normal intestinal development (Tibboel, 1986b). A clinical investigation by Tibboel (1986a) found that intestinal ischemic changes of the bowel wall may also lead to postoperative hypoperistalsis and malabsorption which may continue past the first year of life. The intestines often do not function properly resulting in delayed rhythmic contractions that move food through the intestinal tract

and potential blocked or kinked areas that require additional surgical repair (MN Neonatal Physicians PA, 2010). Infants may spend days on the ventilator, require weeks of intravenous feedings, and experience slow and delayed growth and developmental rates up through adolescence. Only 60% of children born with the abdominal wall congenital malformations omphalocele and gastroschisis survive through their first year of life (Chircor, 2009).

Figure 1. Gastroschisis with intestine in a matted mass. The infant's head is to the right. Photo courtesy of David Rustad, MD. (MN Neonatal Physicians PA, 2006.) Used with permission.

In addition to the cause of gastroschisis being yet unknown, data on any therapeutic treatments to aid in reducing the perception of pain, promoting positive physiological states for optimal recovery and development and helping to reduce the amount of time spent in the hospital was not found in review of literature. Through several studies the average gestational age at birth was between 36-37 weeks and the median for length of hospital stay was 39 days with the exception of hospitals in the United Kingdom and Ireland (Bradnock, 2011; see also Lao, 2010a,

2010b; Payne, 2009). The research found on gastroschisis is focused on the type of surgical procedure used to correct the abnormality and the length of stay associated with each procedure. In the study by Bradnock (2011), gastroschisis was defined as simple gastroschisis, containing an intact continuous bowel that is not compromised; or as complex gastroschisis, as the presence of one or more intestinal atresia, perforation or necrosis at delivery is present. Surgical procedure is always necessary in order to close the abdominal wall and requires a longer length of stay in the hospital which is usually due to gastrointestinal complications (Payne et al., 2009).

Figure 2. Photograph of "silo" enclosing the intestine. The "silo" is gently squeezed to push the intestine back into the abdomen over several days. Photo courtesty of David Rustad, MD. (MN Neonatal Physicians PA, 2006.) Used with permission.

Figures 3 a-c. These three figures starting in upper left and moving clockwise show the same patient before reduction of the intestines into the abdomen, after reduction, and after closure of the hole in the abdominal wall. Photo courtesy of Pediatric Surgical Associates, P.A. (MN Neonatal Physicians PA, 2006.) Used with permission.

The review of literature also discusses the high risk of complications from surgical procedures and parenteral nutrition including central line sepsis, hepatic dysfunction associated with parenteral nutrition and liver transplant with an overall fatality median at 4% - 6% (Bradnock, 2011; see also Lao, 2010a, 2010b; Payne, 2009). Many of these infants return for treatment for up to three years of life (MN Neonatal Physicians PA, 2010). In the study by Bradnock (2011), nearly one third of infants developed some form of infectious sepsis and it was suggested that neonates with gastroschisis are likely transferred postnatally to hospitals with a children's designation where studying allows for a better understanding of outcomes specific to children's institutions.

After surgical repair of gastroschisis, most neonates exhibit severe intestinal dysmotility (Auber, 2013). There is a great deal of visceral pain from the extent of abdominal trauma and

invasive surgical repair that an infant with gastroschisis must undergo. A study by Wolf (2012) stated that a stress response included alterations in metabolic, hormonal, inflammatory and immune systems. Not all components of the stress response, which included pain responses and cardiovascular responses, were suppressed together when treated with different analgesic modalities. Continuous infusion of pharmacological pain management should be monitored and used with caution in infants as higher concentrations can lead to a further decrease in gastrointestinal motility (Saarenmaa, 2000).

There are currently no studies on the effect of music therapy or alternative healing practices with this population. A review of literature found many studies examining the effect of music on: premature infants for growth, weight gain and length of hospital stay; short term procedural pain from heel sticks/blood draw; and the ability for newborn infants to neurologically process music. A review of nonpharmacological pain management in infants and children included non-nutritive sucking, kangaroo care, swaddling and rocking/holding but did not include music (Pillai, 2011). The purpose of this study is to update the knowledge of the effect of music therapy on this population.

Music Processing

The brain of a newborn infant is already able to process changes in music as neural correlates of music processing can be identified through a functional MRI (Perani et al., 2010). The authors found hemispheric specialization in processing Western tonal music and altered versions of music as early as the first postnatal hours. The tonal music showed greater activations in the right hemisphere in primary and higher order auditory cortex while alterations in the music evoked activations in the prefrontal cortical areas, primarily the left inferior frontal

cortex and limbic structures. These activations identify that newborns are also already able to produce a neural emotional response to musical stimuli. The authors concluded that at birth, the neuronal architecture which processes music is already present and that the neural responses of newborns can be modulated by alterations within the musical stimuli. Infants born with gastroschisis often reach full term and would have the neural connections that process music fully developed; therefore changes in musical stimuli would invoke an emotional and physiological response by activating the auditory cortex and prefrontal cortical areas.

Perceptions of Pain and Stress Response

In 2001, the American Academy of Pediatrics and the International Evidence-Based Group for Neonatal Pain made statements recognizing that health care providers may not be adequately trained in newborn pain assessment techniques, and may lack knowledge about a newborn's ability to feel pain; therefore newborns may not be receiving appropriate pain relief for invasive procedures (Aucott, 2002). Studies concur that an infant at 25 weeks gestation can feel pain, has full awareness of pain and that nociceptive pathways develop early in fetal life, as young as 23 weeks gestation, increasing cortisol and endorphin production (Aucott, 2002 & Standley, 2011). The study by Aucott (2002) stated that while afferent fibers are present and functioning in preterm infants at birth, the descending neurotransmitters that modulate pain develop later in postnatal life therefore; preterm infants have an increased sensitivity as compared to adults. Nociceptive processes undergo important postnatal structural and functional changes in transmitter levels, receptor distribution and function can alter responses to noxious stimuli and influence the response to analgesia and injury (Walker, 2008).

In a review of Complementary and Alternative Medicine (CAM) by Tsao (2008), music was thought to exert a primary analgesic effect indirectly by distraction of attention from the pain of the medical procedure; the assumption is that when attention is occupied with another strong stimulus such as music, the individual undergoing the painful procedure will be less able to process painful stimuli. Premature critical care infants are subjected to repeated procedural interventions which are necessary to monitor intensive care management and for infants with gastroschisis; major surgery is required to correct the congenital abnormality. While these studies indicate music to be beneficial to reduce stress and provide distraction from quick and more procedural pain, no indication of the effect on chronic pain was indicated.

In the Neonatal Intensive Care Unit (NICU), music therapy is nonpharmacological treatment and its interventions can be used to promote development, manage stress and alleviate pain. It is commonly prescribed for preterm infants due to the amount of research studies that report physiological, behavioral and developmental benefits for the premature infant with the absence of negative side effects (Standley & Walworth, 2010) and those with multiple, serious medical conditions (Standley, 2011). Infants born with gastroschisis are usually born at full-term or near term and are admitted to the NICU shortly after birth. The length of hospital stay may be correlated with the amount of stress to which an infant is exposed. Individual preterm infants thrive when receiving music therapy as evidenced by weight gain, increased oxygen saturation levels, and development of independent feeding skills, as well as studies reporting a shortened length of stay due to music therapy procedures (Standley, 2011).

The study of music therapy for premature infants by Caine (1991) focused a great deal on promoting weight gain by decreasing physiological and behavioral stress response. Stress was measured as increased heart rate, respiration, crying and disruptive sleep. The study found that

music therapy can significantly reduce the stress behaviors of infants in the NICU environment and may reduce their length of stay (Caine, 1991). Through lowering the stress level of infants, Caine (1991) found that while an increase in weight gain was not at significant levels, the amount of initial weight loss was lowered and music improved feeding. The use of music may promote more stable and acceptable physiological and behavioral responses in premature infants and impact overall growth and development. Through Caine's study, music therapy performed to stable preterm infants was shown to promote a deeper sleep up to 30 minutes after music therapy had ended. Adequate rest is a key component to healing from major surgery and vital for infants with gastroschisis.

A study by Cassidy and Standley (1995) examined the physiological responses of heart rate, oxygen saturation and respiration in premature infants listening to recorded lullaby music. Low birth weight infants usually have sensory stimulation restrictions, yet results indicated that listening to the music elicited positive physiological effects and thus music was not contraindicated during the infants first week of life. The initial exposure to music showed immediate and positive effects to oxygen saturation, heart rate and respiratory rate. On the second and third days of the study more minimal effects on these physiological responses were noted, with a view that the infants may have acclimated to the musical stimuli. While premature infants often have difficulty in processing different levels of stimulation, there were no short term detrimental effects in using music at appropriate decibel levels. Furthermore, those in the music experiment group had more stable and medically acceptable responses than infants in the control group. More stable heart rates, respiratory rates, and higher oxygenation levels were found in infants under peaceful sleeping conditions as well as when in relaxed and comforted states.

In a related study by Arnon et al. (2006), live music played in the neonatal intensive care unit to stable preterm infants resulted in an improvement of physiological and behavioral short term stress parameters. A significant decrease in heart rate and a calmer deeper sleep was measured 30 minutes after the therapy had ended. An infant with gastroschisis would benefit from decreased levels of stress during the recovery phase of hospital care.

Physiological data as well as changes to head circumference on premature infants were recorded in a study on the decibel level of musical stimuli (Cassidy, 2009). The researcher used recorded lullaby/vocal music and classical music at various decibel levels compared to a control group of no music. While the mean heart rate decreased across time, data on the respiration rate was inconsistent and changes in head circumference were concluded to be unrelated to the music condition; the researcher stated that informal observations of infants in the music listening conditions indicated that infants acknowledged the presence of music, often open opened their eyes or pausing from arm/leg movements when the music started, and nearly all infants fell asleep by the end of the treatment. Cassidy (2009) further concluded that data from the study supported the contention that lullaby or orchestral music played at responsible decibel levels does not create unwarranted stress in infants' auditory environment and is not an inhibitor to relaxation and sleep. There is no indication that lullaby music played for an infant with gastroschisis would create a negative effect on the infant's stress level or prevent relaxation and sleep.

A study on the effects of music therapy following cardiac surgery had the hypothesis that music acts on autonomic function, stimulating the pituitary, resulting in the liberation of endorphin, reducing pain and leading patients who receive music therapy to potentially reduce analgesic requirements (Hatem, 2006). In this study, pediatric heart patients ages 1 day to 16

years, were randomized systematically to either receive 30 minutes of recorded classical music through a head set after surgery or to receive 30 minutes of a "blank CD" playing no music. Physiological parameters were assessed which included heart rate, respiration, saturation, temperature, blood pressure plus a facial pain scale prior to the start of the music therapy and again 30 minutes after the intervention. This study found a significant difference in the facial pain scale between the two groups after the intervention and also a significant difference in lower heart rate and respiration rate among children given the music therapy. Due to the invasive nature of cardiac surgery, this study may provide the closest evidence that music therapy can be beneficial in children's recovery from complex medical procedures such as gastroschisis repair.

While infants born with gastroschisis do not have all of the same challenges as a low birth weight - premature infant, this literature demonstrates that it is reasonable to hypothesize that music will also promote positive behavioral and physiological responses while these infants are in the NICU. The findings of the effect of music with preterm infant populations have been positive and should continue to be studied. Studies with other infant populations, such as gastroschisis, should be considered.

An area that has also been overlooked in this literature is the parent or caregiver's perception of the effectiveness of music. The stress level of a parent or caregiver of an infant with a medical condition is extremely high and normal activities of daily living are compromised. Family members must follow medical protocols for holding, feeding and caring for their infant. The family must also endure a long hospital stay and the knowledge that their infant is often experiencing pain and discomfort.

This study will update the knowledge of the effect of music therapy on infants born with gastroschisis by addressing these two questions.

1. Does music therapy have beneficial effects on physiologic parameters, behavioral states, and pain scale evaluations in infants with gastroschisis defects?

2. Does music therapy promote parental/caregiver reduction of stress and provide the perspective that music is an effective tool to calm and soothe their infant at risk for chronic gastrointestinal discomfort?

CHAPTER THREE: METHODS

A mixed methods study was used to determine if music therapy has beneficial effects on physiological parameters, behavioral states, and pain scale evaluations in infants with gastroschisis defects and if music therapy promotes parental/caregiver relaxation and demonstrates to the parent/caregiver that music is an effective tool to calm and soothe their infant at risk for chronic gastrointestinal discomfort. The protocol was approved by Children's Hospitals and Clinics of Minnesota IRB #1110-096 on October 21, 2011.

Participants

Infants born with gastroschisis were enrolled over a one year period. All infants were newborns admitted to the Minneapolis Neonatal Unit at Children's Hospitals & Clinics in Minneapolis, Minnesota. The infants enrolled were both male and female, however were not diverse in race and ethnicity as all infants born with gastroschisis were Caucasian. Infants were enrolled during the perinatal period, and the therapy began after surgical repair of the gastroschisis defect and when the attending neonatologist determined the patient was stable enough for music therapy intervention. Enrolled subjects received up to three music therapy sessions per week and sessions were continued until discharge. There was no follow up after discharge.

If diagnosis of gastroschisis was known prenatally, the Neonatologist informed parents of the study opportunity during the pre-birth consultation. Parents of infants diagnosed after birth were approached for study participation after stabilization of their child. After the infant was born, study personnel confirmed that the infant met the inclusion criteria and parents were approached again about consenting to the study (see Appendix A and B). Once a study candidate

was identified, and informed consent was obtained, research personnel notified the Children's Child Life Specialist of the study participant. The Child Life Specialist notified the MacPhail Neurologic Music Therapist of the study participant and a schedule for the music therapy sessions was determined. Scheduled sessions were charted in the nurses' care notes during times when the infant was most likely to be available and in between medical care procedures.

Design

The protocol for each one-hour study session consisted of 5 minutes of base-line data collection, 20-30 minutes of live music followed by 30 minutes of quiet time. A present family/caregiver was informed of the study session progression and reminded of the appropriate behavioral protocol to maintain a therapeutic environment during the session. For example: cell phone was turned off, minimal or no talking, and minimal or no touching. A "Do Not Disturb" sign was posted on the study participant's door and the infant's pre-study behavior state was assessed and recorded using CRIES scale (see Appendix C and E). The CRIES scale is an assessment tool for infant pain as determined by: Crying, Requiring oxygen for oxygenation saturation levels less than 95%, Increased vital signs, Expression, and Sleepiness (Krechel, S.W., & Bildner, J., 1995). Children's Hospitals and Clinics of Minnesota uses this pain assessment tool for patients in the NICU and ICC units. Five minutes of baseline vital signs were recorded; heart rate, respiration rate, and oxygenation saturation level if available. Oxygenation saturation is not always continuously measured during later stages of recovery.

The music therapy intervention was started at the six minute mark. Using a guitar and / or Reverie Lap Harp, the Neurologic Music Therapist performed live lullaby type music, with and without vocals, from the approved song list (see Appendix D). Lullaby songs were determined

by percentage of family requests from Child Life Specialists and nursing staff and were found to be simple and non-alerting, contain minimal chordal changes, constant in rhythm, soothing and relatively unchanging (Standley. & Walworth, 2010). Music was started as a humming of the melody line, then accompanying instrument was added and lastly lyrics to the lullaby were added if no observable signs of overstimulation were observed from the infant. Decibel levels were checked near the infant's ear and was maintained at 65-70dB. The music intervention lasted 20-30 minutes and was halted if the infant showed any signs of distress or overstimulation – excessive crying, signs of agitation, splayed fingers or hand in front of infant's face or any negative change in vital signs from baseline. Music would resume back to the intervention level prior to the sign of distress and continue unless another indication of overstimulation or distress was observed.

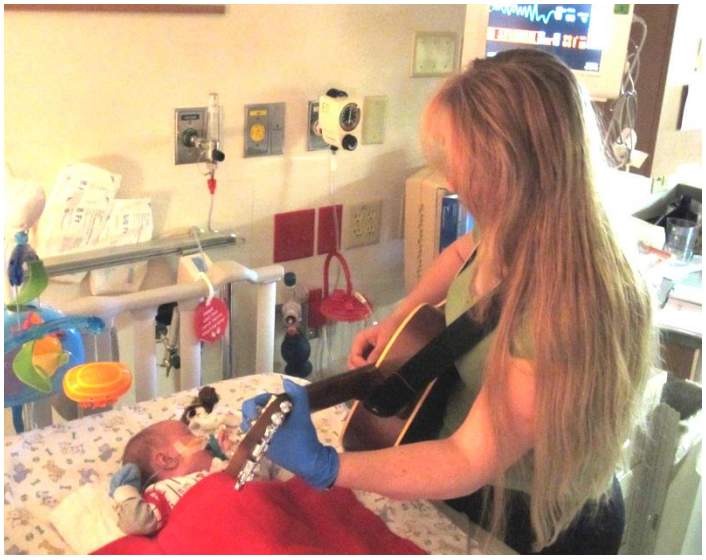


Figure 4. Music therapy session with an infant with gastroschisis. (Children's Hospitals and Clinics of Minnesota, 2012.) Used with permission.

Vital signs from the infant's monitor computer were recorded through the electronic medical record (EMR) every minute. Spacelab technology was used to later transfer recorded data from the monitor to a permanent coded file. Using CRIES scale, the end of music intervention behavior state was assessed, the music therapy data sheet was and recorded and any present family/caregiver was given a Likert-style scale study questionnaire to complete about their perception of the live music intervention (see Appendix F and G). Directions were given to seal the questionnaire in the provided envelope and place in the designated box in the patient's room when completed for pick up later by the research coordinator. The 30 minutes of quiet time began and vital signs from the infant's monitor computer were recorded through the EMR every minute. After the 30 minutes of quiet time was complete, the end of session vital signs and behavioral state were recorded using CRIES scale. Finally the "Do Not Disturb" sign was removed.

Data Collection

All data from the session that was collected from the infant monitor computer and EMR was transferred to a permanent file through Spacelab entered into a database. All data sheets, behavioral assessments and other paper documents were coded. The coded forms were stored in a locked file cabinet, in a locked office with limited access. The coded data were entered into an electronic database on Children's Hospitals & Clinics of MN system computer, server supported drive. The server supported drive was private, secure and backed-up. All documents, both electronic and paper will be stored for a minimum of two years after completion of recruitment and all study data has been recorded, analyzed and published.

CHAPTER FOUR: RESULTS

In the year of the study, only eight infants were born with gastroschisis at Children's Hospital, and only seven infants were officially enrolled in the study. Infants were Caucasian, of a gestational age between 36 and 37 weeks and included two males and five females. The number of sessions that each infant received was not consistent, as the length of hospital stay varied by each subject. A total of 29 music therapy sessions were conducted on the NICU and ICC units. Infants had their first two sessions on the NICU and sessions continued when upgraded to care in the ICC. As an infant's recovery improves, the oxygenation saturation monitor is turned off; therefore, only 18 sessions contained saturation data.

Physiological parameters were recorded every minute of the session from the baseline assessment through the end of the quiet time period. The mean score for each physiological parameter for each session was determined. As heart rate and respiration rate are categorized as quantitative and discrete, the mean score was rounded to the next whole integer. Statistical calculations were conducted on a TI-84 Plus. Examples of the physiological data collected from the infant's monitor and transferred by Spacelab during one music therapy session are found in Table 1. At times the data from Spacelab would indicate a "???" instead of a number for a physiological parameter. That data may indicate a poor sensor connection on the infant at the point where the sensors have been placed during the second that the monitor recorded the data. In instances where a "???" was noted, the therapist would review the EMR monitor printout and find the point in question and manually insert accurate data number.

Table 1. *Physiological Parameters of One Music Therapy Session*

	Pre				MT				Post			
DATE	TIME	HR	SAT	RR	TIME	HR	SAT	RR	TIME	HR	SAT	RR
3/14/2012	16:57	140	98	46	17:02	147	98	45	17:28	142	98	50
	16:58	145	100	47	17:03	136	99	41	17:29	157	97	46
	16:59	139	97	47	17:04	142	98	53	17:30	133	98	63
	17:00	144	98	48	17:05	145	97	60	17:31	135	99	52
	17:01	134	98	49	17:06	148	98	46	17:32	145	99	69
					17:07	145	99	56	17:33	156	98	35
					17:08	143	98	50	17:34	134	99	69
					17:09	147	97	46	17:35	148	98	62
					17:10	146	96	46	17:36	133	99	75
					17:11	145	97	51	17:37	157	98	92
					17:12	142	97	49	17:38	166	99	35
					17:13	151	96	95	17:39	132	100	62
					17:14	154	96	52	17:40	151	98	66
					17:15	166	96	36	17:41	130	100	48
					17:16	163	98	62	17:42	146	100	58
					17:17	???	97	30	17:43	165	99	67
					17:18	144	100	55	17:44	140	99	57
					17:19	138	98	54	17:45	132	98	52
					17:20	165	98	81	17:46	158	99	44
					17:21	136	98	59	17:47	140	99	47
					17:22	144	99	37	17:48	10	98	38
					17:23	132	97	54	17:49	133	100	53
					17:24	139	98	55	17:50	130	99	55
					17:25	141	98	53	17:51	135	100	71
					17:26	139	97	74	17:52	155	99	43
					17:27	146	99	77	17:53	137	100	80
									17:54	136	100	62
									17:55	133	99	50
									17:56	134	100	65
									17:57	137	100	62
									17:58	131	99	55

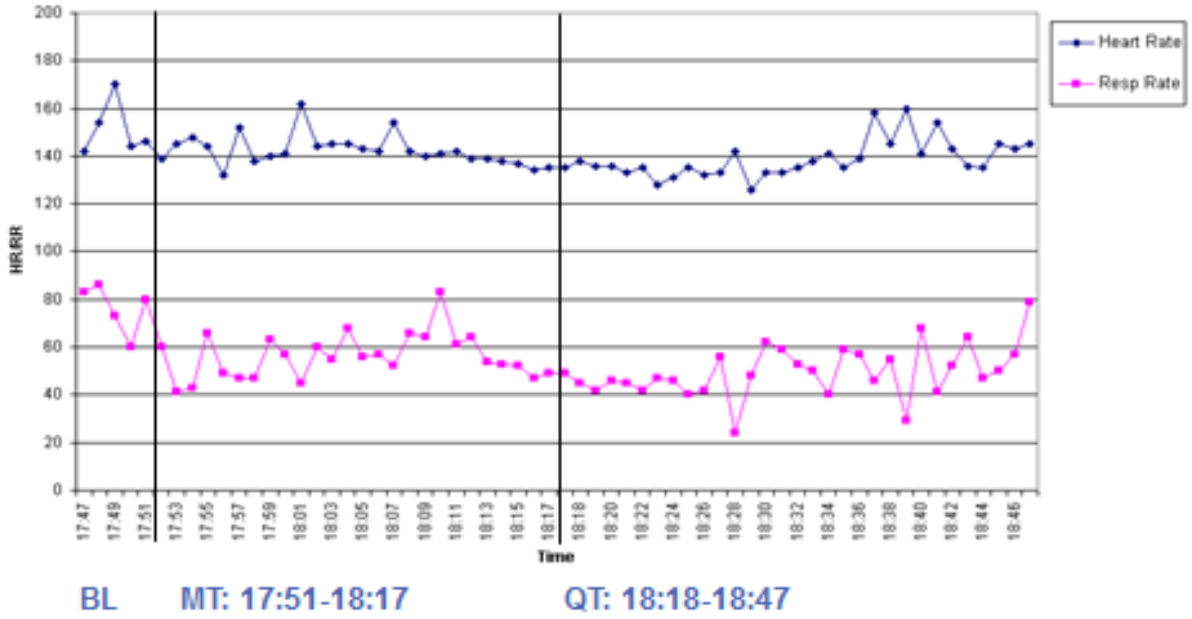
Heart Rate, Oxygenation Saturation and Respiratory Rate

The behavioral assessment was conducted through the CRIES scale. Maximum score on the CRIES is 10 and a lower score indicates an infant that is under less distress and/or pain. See Table 1.2 for the CRIES scale of one music therapy session. The EMR monitor records the physiological parameters of the infant every minute in a telemetry readout (see Table 1.3 for the readout of one music therapy session) which is later processed by Spacelab into numerical integers for data analysis.

Table 2. *C.R.I.E.S. Scale of One Music Therapy Session*

DATE	3/19/2012	**Pre Music**	**Post Music**	**Post 30 min Quiet**
TIME		9:40	10:09	10:40
Crying		0	0	0
Requires O2 for SaO2 <95%		0	0	0
Increased Vital Signs (BP and/or HR)		0	0	0
Expression		1	0	0
Sleepless		2	2	1

Table 3. *EMR Monitor of Physiological Parameters of One Music Therapy Session*



The mean physiological parameters and CRIES of each music therapy session were determined for each infant pre, during and post music intervention. The infant study number along with the session number for each infant was numerically coded. Table 2. reports all mean scores for each session of study participants 1 through 5 and Table 2.1 reports all mean scores of each session of study participants 6 through 7.

Table 4. *Mean Physiological Parameters and CRIES of the Music Therapy Session Infants 1-4*

Infant #01 Mean Scores

	PRE				MT				POST			
Session	**HR**	**SAT**	**RR**	**CRIES**	**HR**	**SAT**	**RR**	**CRIES**	**HR**	**SAT**	**RR**	**CRIES**
1	148	98.2	32	0	145	96.8	45	0	138	94.3	44	1
2	138	95.8	45	6	142	95.5	52	1	149	95.2	56	0
3	141	98.2	48	3	146	97.6	55	2	138	99	58	1
4	192	98.4	51	2	180	97.6	73	1	175	98.1	68	1
5	184	NA	54	2	176	NA	71	1	174	NA	61	1
6	142	NA	59	0	144	NA	60	0	153	NA	53	0

Infant #02 Mean Scores

	PRE				MT				POST			
Session	**HR**	**SAT**	**RR**	**CRIES**	**HR**	**SAT**	**RR**	**CRIES**	**HR**	**SAT**	**RR**	**CRIES**
1	173	NA	58	2	173	NA	65	1	173	NA	62	1
2	160	NA	69	1	160	NA	70	1	158	NA	61	1

Infant #03 Mean Scores

	PRE				MT				POST			
Session	**HR**	**SAT**	**RR**	**CRIES**	**HR**	**SAT**	**RR**	**CRIES**	**HR**	**SAT**	**RR**	**CRIES**
1	130	100	73	1	137	99.9	69	1	139	100	65	1
2	143	99	64	1	146	99.3	55	1	146	99.3	49	1
3	163	99.6	50	2	157	98.4	56	1	164	99.1	60	1
4	133	100	60	2	130	99.9	62	1	130	99.3	61	0
5	133	98.8	61	0	135	98.6	56	1	129	99.2	44	0
6	152	NA	77	6	142	NA	56	1	133	NA	49	0
7	148	NA	85	3	144	NA	74	1	147	NA	78	1
8	150	NA	63	2	148	NA	75	2	141	NA	72	2
9	150	NA	42	4	141	NA	43	1	140	NA	38	0
10	159	NA	64	2	157	NA	73	2	160	NA	65	1
11	147	NA	43	2	146	NA	41	1	148	NA	41	1

Infant #04 Mean Scores

	PRE				MT				POST			
Session	**HR**	**SAT**	**RR**	**CRIES**	**HR**	**SAT**	**RR**	**CRIES**	**HR**	**SAT**	**RR**	**CRIES**
1	173	96.8	63	2	154	94.8	77	1	147	93.1	74	0

Table 5 *Mean Physiological Parameters and CRIES of the Music Therapy Session Infants 5-7*

Infant #05 Mean Scores

	PRE				MT				POST			
Session	**HR**	**SAT**	**RR**	**CRIES**	**HR**	**SAT**	**RR**	**CRIES**	**HR**	**SAT**	**RR**	**CRIES**
1	169	88	115	2	170	91.2	97	0	175	93.1	73	2
2	181	99.2	72	7	193	98.1	48	2	179	98	62	3
3	181	99.8	72	2	171	99.7	72	2	178	99.6	61	2
4	169	100	71	2	170	99.3	60	0	174	96.8	57	0

Infant #06 Mean Scores

	PRE				MT				POST			
Session	**HR**	**SAT**	**RR**	**CRIES**	**HR**	**SAT**	**RR**	**CRIES**	**HR**	**SAT**	**RR**	**CRIES**
1	159	98	59	1	139	98	47	0	142	99.6	48	0
2	160	95.6	59	1	153	97.4	53	1	144	98	52	0

Infant #07 Mean Scores

	PRE				MT				POST			
Session	**HR**	**SAT**	**RR**	**CRIES**	**HR**	**SAT**	**RR**	**CRIES**	**HR**	**SAT**	**RR**	**CRIES**
1	136	100	42	0	138	99.5	47	0	136	99.3	41	0
2	149	97.8	50	3	146	96.8	42	1	152	99.5	50	0
3	144	NA	67	2	153	NA	58	2	149	NA	53	0

Sample size is small so the values of *t* distribution were used as it is reasonable to regard these samples as representative of the parameters under study. The average heart rate, respiratory rate and the CRIES score between pre and post music therapy was compared using the paired t-test. A two-sided p-value < 0.05 was used as the significance level. Statistical significance was found for respiration rate during the post intervention quiet time $p=0.0047$. The effect of music therapy on physiological parameters of saturation and heart rate, as well as CRIES during and post intervention, was found to not be statistically significant on infants born with gastroschisis (Table 3).

Table 6. *Statistics and p-value for Physiological Parameters and CRIES of the Music Therapy Session*

Parameter	N=	Mean	Standard Deviation	*t*-test	*p*-value significance at <0.05	Difference of intervention to PRE; d=	*t* test statistic	*p*-value significance of <0.05
PRE Heart rate	29	158	16.79	2.05	0.05			
PRE Saturation	18	98	1.29	2.11	0.05			
PRE Respiration	29	70	17.34	2.05	0.05			
PRE CRIES	29	3.5	2.02	2.05	0.05			
MT Heart rate	29	155	15.64	2.05	0.05	-3	-0.704	0.4844
MT Saturation	18	97.7	2.08	2.11	0.05	-0.3	-0.52	0.6064
MT Respiration	29	63	13.36	2.05	0.05	-7	-1.722	0.0906
MT CRIES	29	1.4	0.5	2.05	0.05	-2.1	-1.765	0.083
POST Heart rate	29	154	15.64	2.05	0.05	-4	-0.939	0.3518
POST Saturation	18	97.9	2.21	2.11	0.05	-0.1	-0.166	0.8691
POST Respiration	29	59	10.24	2.05	0.05	-11	-2.941	**0.0047**
POST CRIES	29	1.6	0.75	2.05	0.05	-1.9	-1.502	0.1387

In twenty-nine music therapy sessions, there was a family / caregiver present for only four complete interventions. The parent / caregiver survey was completed by each of these four parents and each survey was given 30 points, the maximum possible. No comments were written on the surveys. An anecdotal comment was made to the music therapist by one family member who stated she wished she had "live music playing for her and her baby everyday – it just makes you feel better even when things are awful." No other comments were recorded as other parents only said "Thank you" at the end of the session. It is then reasonable to conclude that the family/caregiver present in the session felt a reduction of stress and had the perspective that music is an effective tool to calm and soothe their infant at risk for chronic gastrointestinal discomfort.

CHAPTER FIVE: DISCUSSION

This study had an extremely small sample size to determine significance. Children's Hospitals and Clinics of Minnesota typically would see 22 – 27 infants born with gastroschisis each year. The study will continue for at least another year, with the hope to reach n=30. However, with the severity of this disorder, the staff has indicated they are pleased in the reduction of cases. The acute effect of music therapy on infants with gastroschisis was noted by the music therapist, family member and the nursing staff. Infants would at times transition from an agitated state (grimace, crying, and extra movement) to a sleep or restful state by the end of the session (relaxed expression and no movement).

At this young of an age, any small movement will increase an infant's heart rate and respiration. While respiration rate was the only physiological parameter to see a statistical significance (p=0.0047) from baseline during the post /quiet period, it should be noted that there was a large variability in the data readings. The study by Cassidy (2009) commented that respiration rate results may vary as the probe would recognize an infant moving or stretching as extra breaths per minute. Either the monitor measures respiratory rates with much error and imprecision, or humans can change their respiratory rate so quickly from minute to minute that such a short-term measure is impossible to interpret. Respiration rates can also decrease with an increase in gestational age. Infants in this study did increase their age in the days and weeks in the hospital and the data on physiological parameters was not adjusted to reflect this slight change.

While the CRIES score has been found to be an effective measurement tool, one must disclose that the scale is highly sensitive to observer bias. In the future, the scorer should be a consistent individual who is unconnected to the study and is unaware of the area of focus and

research question. Video could also be used to record the full session and score the CRIES scale at the conclusion of the protocol to further decrease possible bias.

Scheduling sessions when an infant was available for a 60 minute period of time without interruptions was extremely difficult in this hospital setting. Music therapy sessions could only be conducted 3 days a week with a window of a 3 hour period on each day and even when sessions were scheduled in the EMR, interruptions from surgeons, cleaning staff and family members were frequent. Not all infants enrolled were able to have a consistent schedule time for music therapy sessions. This change in the session times and schedule could be a confounding variable. Future studies should consider consistent times on consecutive days to secure data with the least amount of variable change.

While the length of hospital stay was not a study parameter, out of the seven infants enrolled in the study, only one completed the anticipated number of sessions indicated in the study protocol due to an average length of stay for this abnormality. The other six infants ranged from only 1 session to 6 sessions having only stayed at the hospital for an average of 16 days, which is significantly less than the median of 39 days for infants with gastroschisis.

Infants born with gastroschisis have also been known to have a decrease in gastrointestinal motility due to the trauma of the defect to the abdominal wall, an increase in stress response and an increased need for pain modification. While also not a study parameter, it was noted by the music therapist and the nursing staff that audible bowel motility occurred during the music therapy session and the post quiet time. Nursing staff also stated that during the music therapy session, post quiet time and up to two hours after the session; infants often would have a large bowel movement. All bowel movements and voiding are measured for infants with

gastroschisis and the effect of music on smooth muscle motility could be an interesting parameter in future studies.

Studies with music therapy and premature infants have looked at physiological parameters and seen significant results. A larger sample size with more music therapy sessions might find similar findings with the gastroschisis population. Other possible variables of interest to consider for this population might include: overall length of hospital stay, amount of time needed to reach normal feeding, weight gain and/or head circumference, gastrointestinal motility and the need for pharmacological pain modification.

As the infants in this study varied in the length of hospital stay and how often music therapy services were provided; association between music therapy and all of the outcome variables will be subject to confounding bias, and strong efforts should be made to decrease bias potential. Possible confounders would include: severity of the defect (percentage of intestine and other organs displaced); number of days on silo prior to full surgical repair; medications; other complications such as sepsis or ileus; and co-morbidities or a need for other treatments such as cardiac care and continued ventilator use.

Parental stress, while a secondary outcome, is of great interest to this hospital. The trend in medical settings is to include better aesthetics throughout the hospital, promoting a more positive experience for all individuals in the hospital. Each parent that had been approached for consent of this study made positive statements about the ability of their infant to receive music therapy. However, their enthusiasm to have music therapy for their infant did not often match their ability to attend the music therapy session. It was difficult to ask parents to find the time to attend the session yet during that time they were also unable to hold their infant. A follow up survey parents are asked fill out after the conclusion of a session had the possible perception of

yet another piece of paper to complete, or unnecessary task to finish. Parents made positive verbal comments to the music therapist and the nursing staff about music therapy, but did not write the comments on the survey. A suggestion for better survey involvement would be to schedule and invite the caregiver to be involved in the session and then conduct an informal verbal interview on his/her perception of the effect of music therapy shortly before the end of the post quiet time. If physiological parameters are of interest, a blood pressure reading may provide better data as to the reduction of parental stress.

More research in the effect of music therapy on infants is needed. To the best of this researcher's knowledge, no other study on music therapy with infants born with gastroschisis is available. This data may provide a small foundation toward further study and provide the desire to produce further evidence in order to inform clinical practices with these infants. While overall statistical significance on all physiological and behavioral parameters was not found, acute effects were noted in behavioral changes of these medically compromised infants. The medical staff at Children's Hospitals and Clinics of Minnesota continues to make referrals for music therapy, stating to caregivers and other medical staff that nothing has quite soothed infants with gastroschisis and promoted better sleep like live music.

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APPENDIX A: CONSENT FORM

IRB #: 1110-096

CHILDREN'S HOSPITALS AND CLINICS of MINNESOTA
2525 Chicago Avenue South
Minneapolis, MN 55404

The Effect of Music Therapy on Infants Born With Gastroschisis

RESEARCH CONSENT FORM

INTRODUCTION
Before agreeing that you/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 being asked to participate in this study because your infant was born with Gastroschisis. Infants with gastroschisis require surgery shortly after birth. In addition to the surgical repair of this condition, many of these babies cannot eat normally for many weeks and often need to remain in the hospital for a long period of time.

Music therapy interventions are used to promote wellness, manage stress and alleviate pain. Music therapy is commonly prescribed for preterm infants because if offers many benefits with out any negative side effects. We hope that this research study will show that music therapy is beneficial for the full-term gastroschisis baby with out any negative side effects.

RESEARCH PURPOSE
We hope to learn if music therapy will have a positive effect on measurable physical signs, such as heart rate and rate of breathing, whether a baby is fussy or is able to sleep, and the pain levels displayed by babies with Gastroschisis. We would also like to find out if music therapy will also reduce stress for these babies and their families.

RESEARCH PROCEDURES
Thirty infants born with gastroschisis will be enrolled over a two-year period. Both male and female newborns, admitted to the Minneapolis Neonatal Unit, will be enrolled after birth, when the attending doctor determines the patient is stable enough for music therapy intervention.

If you decide to participate in the study, your infant may receive up to three music therapy sessions every week, Music therapy sessions will continue until your infant is discharged from the hospital. Caregivers and family are encouraged to attend these sessions.

During each music therapy session:
- The music therapist will inform everyone choosing to experience the therapy session, of how the session will progress.
- The music therapist will first assess how your baby is behaving and record your baby's heart rate, breathing rate and how much oxygen is in their blood.
- Then, using a lap harp or guitar, the music therapist will perform live lullaby-type music for 20-30 minutes.

- After the live music period the music therapist will again assess how your baby is behaving and record your baby's heart rate, breathing rate and how much oxygen is in their blood.
- Before leaving, the music therapist will leave a questionnaire to be completed by any family or caregivers that also experienced the music therapy session.
- The music therapist will then leave your infants room and allow you and your infant 30 minutes of quiet time.
- After this period of quiet time, the music therapist will return to your infant's room and assess how your baby is behaving and record your baby's heart rate, breathing rate and how much oxygen is in their blood for the last time.

RISKS
There are no risks to participation in this study.

BENEFITS
We hope that infants with gastroschisis will become more calm while listening to lullabies performed live by a music therapist and will remain in this relaxed state for a while after the 20-30 minutes of live music.

ALTERNATIVES
The alternative to this study is not to participate.

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, Dr. Ellen Bendel-Stenzel at 612-813-6288. 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 Debra McKeehen, M.S., 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 Minneapolis at 612-813-7393 or 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 Children's Hospitals & Clinics of MN and MacPhail Center for Music. Knowledge that is gained from this study may be published in scientific journals without identifying the patient.

FINANCIAL ISSUES
There is no cost for participation in this study

OTHER INFORMATION

You have been told about this research study and its 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/your child chooses not to 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 Ellen Bendel-Stenzel, MD at 612-813-6288. 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

Parent/Guardian Signature Date

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

APPENDIX B: HIPAA / DISCLOSURE FOR RESEARCH

IRB #: 1110-096

Children's Hospitals and Clinics of Minnesota
Health Insurance Portability and Accountability Protection Act (HIPAA)
Authorization to Use/Disclose Protected Health Information for Research

The privacy law, Health Insurance Portability and Accountability Act (HIPAA), protects you/your child's individually identifiable health information (protected health information). The privacy law requires you/your child to sign an authorization in order for researchers to be able to use or disclose your/your child's protected health information for research purposes in the study entitled **The Effects of Music Therapy on Infants Born With Gastroschisis.**

What protected health information may be used or disclosed?

Your/your child's individual health information that may be used or disclosed to conduct this research includes:
Name of infant and mother, date of birth, age, general contact information, gestational age, pregnancy history including length of prenatal care, date of surgery, results of medical tests effecting length of stay, vital signs (heart rate, breathing rate, amount of oxygen in the blood) before/during/after each music therapy session.

What will your/your child's protected health information be used for?

The main reason to use this information is to be able to conduct this research. The purpose of this research is to determine if music therapy has a beneficial effect on vital signs, how the baby is behaving and the level of pain for infants with gastroschisis. This research is also being done to determine if music therapy will offer relaxation to parents and caregivers who are present for music therapy sessions.

In addition, information is shared to ensure that the research meets legal, institutional and accreditation standards. Information may also be shared to report adverse events or situations that may help prevent placing other individuals at risk. Other reasons include treatment, payment or health care operations.

Who may disclose your/your child's protected health information to the researchers?

The researcher and the researcher's staff may obtain you/your child's individual health information from your infant's hospital record at Children's Hospitals and Clinics of Minnesota.

With whom would the protected health information be shared?

Your/your child's protected health information may be shared with the following:
- MacPhail Center for Music
- To your health insurer or payer, if necessary, in order to secure their payment for any covered treatment not paid for through the research
- The Children's Hospitals and Clinics of Minnesota Institutional Review Board

What is the potential for re-disclosure or your/your child's protected health information?

All reasonable efforts will be used to protect the confidentiality of your/your child's protected health information, which may be shared with others to support this research, to carry out their responsibilities, to conduct public health reporting and to comply with the law as applicable. Those who receive the protected health information may share it with others if the law requires them to, and they may share it with others who may or may not be required to follow the federal privacy rule.

For how long will you/your child's protected health information be used or shared with others?

There is no scheduled date at which this information will be destroyed or no longer used. This is because information that is collected for research purposes continues to be analyzed for many more years and it is not possible to determine when this will be complete. Because of this, this authorization does not have an expiration date.

What are your/your child's rights after signing this authorization?

You/your child have the right to withdraw from participating in this research. You have the right to revoke in writing your permission for Children's to use or share the protected health information acquired in connection with the research except to the extent that the investigator or Children's has already relied on your permission to conduct the research and related activities such as oversight. Even if you revoke your permission, Children's may preserve and use or disclose information needed for the integrity of the study. Once permission is withdrawn and you are no longer participating in the study, no further private health information will be acquired. If you want to withdraw your permission, contact the investigator and you will be asked to complete a written form.

You have the right to choose not to sign this form. However, if you decide not to sign, you cannot participate in the research. Refusing to sign will not affect the current or future care you/your child receives at this institution and will not cause any penalty or loss of benefits to which you are otherwise entitled.

If you/your child choose to share private health information with anyone not directly related to this research, the federal law designed to protect your privacy may no longer protect this information.

What are you/your child's rights to access your/your child's protected health information?

Subject to certain legal limitations, you/your child have the right to access you/your child's protected health information that is created during this research that relates to your treatment or payment provided and is not exempted under certain laws and regulations. You may access
this information only after the study analyses are complete. To request this information, you will need to contact Children's Privacy Officer at 612-813-6911.

By signing this form, you authorize Ellen Bendel-Stenzel, MD and Melissa Wenszell and their research staff to use and disclose your/your child's protected health information for the purposes described above. You also permit you/your child's doctors and other health care providers to disclose you/your child's health information for the purposes described above.

If you have not already received a copy of the Privacy Notice, you may request one. If you have any questions or concerns about your privacy rights, you should contact the Children's Hospitals and Clinics Privacy Officer at 612-813-6911.

CERTIFICATIONS AND SIGNATURE SECTION

I am the research subject or am authorized to act on behalf of the subject. I have read this information, and I will receive a copy of this authorization form after it is signed.

_____

Signature of Research Subject/Research Subject's Authorized Representative — Date

_____

Printed name of Research Subject/Research Subject's Authorized Representative — Representative's relationship Research Subject

Please explain Authorized Representative's relationship to the Subject and include a description of the Representative's authority to act on behalf of the subject:

_____
_____
_____
_____

APPENDIX C: DO NOT DISTURB SIGN

APPENDIX D: LULLABY GENRE – SONG LIST

1. Twinkle Twinkle Little Star
2. Brahms' Lullaby
3. All the Pretty Horses
4. Hush Little Baby
5. Golden Slumbers
6. Are You Sleeping?
7. Baby Mine
8. All Through the Night
9. Beautiful Boy (Darling Boy)
10. Sleep Baby Sleep
11. Down in the Valley
12. Stay Awake
13. The Second Star to the Right
14. La La Lu
15. Irish Lullaby (Too Ra Loo Ra Loo Ral)
16. Beautiful Dreamer
17. Hush, Hush, Hushabye
18. Return to Pooh Corner

Reverie Harp

APPENDIX E: CRIES PAIN SCALE

Indications: For neonates (0-6 months)	**Pre Music**	**Post Music**	**Post 30 Min Quiet**
DATE / / Subject ID# Time			
Crying – characteristic of pain is a high-pitched cry. 0. No cry or cry that is not high pitched 1. Cry is high pitched but baby is easily consolable 2. Cry is high pitched but baby is inconsolable			
Requires O2 for SaO2 <95% - babies experiencing pain manifest decreased oxygenation. Consider other cause of hypoxemia, e.g. over sedation, atelectasis etc. 0. No oxygen required 1. < 30% oxygen required 2. > 30% oxygen required			
Increased vital signs (BP and/or HR) Take BP last as this may awaken baby, making other assessments difficult 0. HR &/or BP unchanged or less than baseline 1. HR &/or BP increased but increase is < 20% from baseline 2. HR &/or BP increased > 20% from baseline			
Expression – The facial expression most often associated with pain is a grimace. A grimace may be characterized by brow lowering, eyes squeezed shut, deepening naso-labial furrow, or open lips and mouth. 0. No grimace present 1. Grimace alone is present 2. Grimace and non-cry vocalization grunt is present			
Sleepless – Scored based upon the infant's state during the hour preceding this recorded score 0. Child has been continuously asleep 1. Child has awakened at frequent intervals 2. Child has been awake constantly			
Comments:			

*****Use baseline preoperative parameters from a non-stressed period. Multiply baseline HR by 0.2 then add to baseline HR to determine

Instructions: Each of the five categories is scored from 0-2, which results in a total score between 0 & 10. The interdisciplinary team in collaboration with the patient/family (if appropriate) can determine appropriate interventions in response to CRIES Scale Scores.

Reference: Krechel, SW & Bildner, J. (1995). CRIES: a new neonatal postoperative pain measurement score – initial testing of validity and reliability. Paediatric Anaesthesia, 5: 53-61.

APPENDIX F: MUSIC THERAPY DATA SHEET

DATE	**/ /**	**Subject ID#**		**Room #**	

	Pre Music - Behavioral Assessment - CRIES Score					
Baseline – 5 Minutes						
#	**Time**	**Heart Rate**	**Resp Rate**	**SaO2**	**Comments**	
1						
2						
3						
4						
5						

Music Session					
Start Time		**End Time**		**Total Min**	
Comments:					
	Post Music - Behavioral Assessment - CRIES Score				
Questionnaire Given to Family Member/Caregiver?					**YES / NO**
If YES Who?					

Quiet time - 30 Minutes					
Start Time		**End Time**		**Total Min**	
	End of Quiet Time - Behavioral Assessment - CRIES Score				

Comments:

APPENDIX G: FAMILY/CAREGIVER QUESTIONAIRE

FAMILY / CAREGIVER QUESTIONAIRE
MUSIC THERAPY SESSION FOR INFANT WITH GASTROSCHISIS

You have just experienced a live music therapy session with the infant in your care. Please answer these few questions in order for the research team to understand your perspective of the live music therapy session for both you and the infant in your care.
Thank you for your time and participation.

Please rate the following questions with a 1-5 scale, 5 being the highest score.
Your added comments are welcome and can be included at the bottom of this form.

	Rating Scale	**Disagree**		**Neutral**		**Agree**
1	I was able to personally enjoy the live music played during the session.	1	2	3	4	5
2	I found the live music played during the session to be relaxing for me.	1	2	3	4	5
3	I believe that the infant in my care enjoyed the live music.	1	2	3	4	5
4	I believe the live music played during the session was relaxing for the infant in my care.	1	2	3	4	5
5	I feel that live music is beneficial in the hospital setting.	1	2	3	4	5
6	I would participate again in a live music therapy session if given the opportunity.	1	2	3	4	5

Any additional comments: _____

_____

_____

Caregiver Status:_____Infant ID_____ Date_____