Berklee College of Music
Office of Graduate Studies
Music Therapy Department

We hereby approve the culminating project of

The Effects of Music Therapy on Neonates Undergoing Retinopathy of Prematurity Screening

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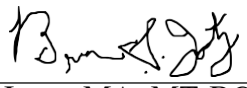

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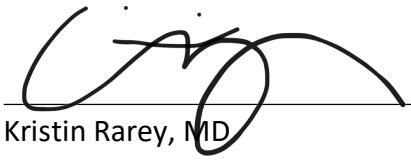

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The Effects of Music Therapy on Pain Scores in Neonates Undergoing Retinopathy of Prematurity Screening

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Abstract

Premature infants who are less than 30 weeks gestational age or 1500 grams at birth require screening for a dangerous retinal disease, retinopathy of prematurity (ROP). During and after ROP screening exams, newborns typically experience adverse effects such as pain, increase in apnea/bradycardia/desaturation spells, feeding intolerance, and risk of infection. This study examined the effects of music therapy on pain scores during retinopathy of prematurity screenings using the Neonatal Pain, Agitation, and Sedation Scale (NPASS). The music therapy protocol was provided during the screening exam, in one eye. The infants acted as their own control by not receiving the music therapy protocol during the exam for the other eye. These data are meant to inform the medical community and promote the use of music therapy to mitigate pain and stress responses during ROP exams.

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The Effects of Music Therapy on Neonates Undergoing Retinopathy of Prematurity Screening

In the United States alone, several hundred thousand screening exams are performed each year to assess high risk infants for a retinal disease called retinopathy of prematurity (ROP) (Dunbar et al., 2009). While these exams have been adopted as the primary way to assess infants for the risk of this disease, research shows that there is still a need to minimize pain and adverse effects associated with these screenings. With infants becoming viable at younger ages, such as 23 weeks, the need for ROP exams has and will continue to increase.

After providing music therapy for two years with infants in the Neonatal Intensive Care Unit (NICU), I have directly seen the benefit of music therapy in this setting. Infants in the NICU are extremely sensitive and additional training for this population must be completed by any music therapist providing these services. Personally, I have received additional training for board certified music therapists from First Sounds: Rhythm, Breathe, Lullaby at Mount Sinai, Beth Israel in New York and from Florida State University's National Institute for Infant and Child Medical Music Therapy. This additional training is essential to understand how to use live music in the moment to benefit these infants.

Due to the immense fragility of this population, music therapy interventions can cause harm if not provided correctly. It is vital for music therapists to not only learn the specific interventions used in this setting, but also to learn regulate these interventions to match infants and promote the desired response. My additional training has helped me to understand what an infant needs in each moment and how to provide services safely to this fragile population. I have personally seen the benefit music therapy interventions can have in helping infants to tolerate painful procedures. After reading the literature concerning retinopathy of prematurity and witnessing these exams first hand, I realized that these NICU infants are in great need of a non-

invasive intervention to help them cope with the adverse effects associated with these exams. I hypothesized that music therapy could be used to decrease infant's pain during ROP screenings.

Literature Review

An increasing amount of research has shown that music therapy in the Neonatal Intensive Care Unit (NICU) can be beneficial in addressing many issues for preterm infants. Music therapy is defined by the American Music Therapy Association (AMTA) as "the clinical and evidence-based use of music interventions to accomplish individual goals within a therapeutic relationship by a credentialed professional who has completed an approved music therapy program" (AMTA, 2018, para. 1). Published research has supported the use of music therapy in the NICU for feeding support, pain management, procedural support, stabilization of vitals, neurodevelopment enhancement, decreasing parental stress and anxiety, and enhancing bonding/attachment.

Infants in the Neonatal Intensive Care Unit (NICU)

The incidence of prematurity is consistently rising in the United States and advances in technology and medicine have led to an increase in survival rate in premature infants (March of Dimes, 2019, para. 2). The World Health Organization (WHO; 2018) estimates that 15 million babies are born prematurely around the world every year, with prematurity being the leading cause of death across the world in children under the age of five. Prematurity is defined as infants who are born less than 37 weeks completed gestation. Preterm infants are often considered viable outside of the womb at 23-24 weeks gestation (WHO, 2018).

An increasing number of infants born prematurely survive, yet there are risks, complications, and stressors that may affect the child throughout his/her lifetime. Complications of prematurity may include feeding difficulties, respiratory distress, difficulty with regulating vital signs and nervous system function, as well as prolonged length of stay in the NICU (Kenner & McGrath, 2010). Children who are born extremely premature show an increase in cognitive

and neuromotor impairments as well as impairments in intellectual functioning and behavioral disturbances (Kenner & McGrath, 2010).

Music Therapy in the NICU

The benefits of music therapy in the NICU are diverse and are not simply for the infants, but for the caregivers and providers as well. Music therapy has been shown to be valuable in helping infants through feeding support, enhancing bonding and attachment with caregivers and can stabilize physiologic parameters as well as mitigate pain responses.

Feeding support. Preterm infants often have feeding intolerance and are in need of feeding facilitation and support. The development of suck, swallow, breathe is vital for infants to learn how to feed, but does not typically develop until 34-37 weeks corrected gestational age (Kenner & McGrath, 2010). In order for infants to feed successfully, they must have neuromaturation, maintainability of energy, and rhythm for suck-swallow-breathe coordination (Kenner & McGrath, 2010). Until infants have developed neurologically they are fed through a nasogastric tube. Music therapy can be beneficial in helping the infant to pace and organize their suck, as well as engage the rhythmic patterns needed for suck, swallow, breathe coordination. This can increase their overall oral intake (Loewy, 2016).

Contingent music has also shown to have benefits in feeding support with the use of Pacifier Activated Lullaby, or PAL. Infants who were given the PAL had an increase in non-nutritive sucking, endurance, and had decreased need for feeds given through nasogastric tube. This led to a shorter length of stay in the NICU (Standley, 2000). The PAL has also been used with a recording of the mother's voice. This use of the PAL with mother's voice was shown to have statistical significance with an increase in feeding rate and oral intake (Chorna, Slaughter, Wang, Stark, & Maitre, 2014).

Parents in the NICU. Music therapy has been found to be advantageous to parents in the NICU. Engaging in music therapy can decrease parental anxiety and stress while enhancing bonding/attachment with their infant. In some cases when the infant is very premature, parents may not be able to touch or hold their infant for several days after birth. There are many music therapy techniques that may help the parents bond with their infant. One specific example is called "Song of Kin," developed by Loewy (2016). This technique involves a special song that parents can create for their child with the help of a music therapist. Facilitation of Song of Kin has shown to be beneficial in giving parents a sense of control in the NICU, as well as a unique way to bond with their baby (Loewy, 2016). Coaching parents to sing to their infants can enhance bonding and attachment, especially when singing their own special songs.

Parents of babies in the NICU have also shown benefit from receiving music therapy in a self-care group. With the implementation of family centered care in most NICUs, parent's needs are emphasized and are often treated in addition to their infant's critical care. In Bogota, Columbia, a music therapy self-care group was employed with the use of interventions such as guided relaxations, breathing techniques and music therapy used for self-expression. This study showed that these music therapy support groups were beneficial in reducing parental stress and anxiety levels and improved parent's mood (Roa & Ettenberger, 2018).

Physiological responses and pain. Many premature infants have difficulty regulating their nervous systems which can present as incidences of bradycardia, apnea, or oxygen desaturations. Music can have a positive impact on physiological processes such as heart rate, respiratory rate, and oxygen saturation. Researchers found that live and recorded music can have a positive effect on physiologic parameters, behavioral states, and pain in preterm infants (Hartling et al., 2009).

Loewy, Stewart, Dassler, Telsey, and Homel (2013) examined the use of three different receptive music therapy interventions, including the therapist playing an ocean disc, singing lullabies (often parent preferred) and a gato box, a small, two-toned drum that imitates the heartbeat. Results showed that ocean disc, a sealed drum that creates wave-like sounds, had a favorable outcome in decreasing heart rate and increasing sleep patterns (Loewy et al., 2013). This outcome is most likely due to the therapist's entrainment to the infant's breath and respiratory rate and the therapist's use of the instrument itself. Ocean disc was found to be beneficial in recreating the sounds of the womb in utero. This creates a familiar sound for the infant and can emphasize homeostasis.

In utero, the infant's environment is dark, quiet, and calm. Comparatively, many NICUs are known to be loud, bright, and have many noxious stimuli which can adversely affect the premature infant's brain development. The premature infant is underdeveloped and therefore less equipped to deal with the stressors of the NICU (Donia & Tolba, 2016). Some researchers contend that the repeated stress on these infants can also have adverse effects on their immune systems (Grunau, Holsti, & Peters, 2006). If music therapy can be beneficial in decreasing stress in these infants, then it could have a positive impact on their immune systems as well.

While in the NICU, premature infants are subjected to many painful procedures which are necessary and often life-saving measures. Infants receiving frequent painful procedures may also develop a low pain threshold, making them hypersensitive to negative stimuli and pain (Grunau, Holsti, & Peters, 2006). Many infants have to undergo procedures such as heel stick, IV starts, lumbar punctures, peripherally inserted central catheter (PICC) line insertion, umbilical line starts, arterial sticks, and intubation. These are among the more painful procedures that infants can experience in the NICU, but other procedures such as insertion of a nasogastric tube or blood pressure checks can be perceived as painful for the infant. Due to the central nervous system's

immaturity and fragility, procedures that would not often be designated as painful, can indeed be experienced this way (Donia & Tolba, 2016).

Among the benefits of music therapy is procedural support. This is defined by Beer and Lee (2017) as the interactive use of music by a board-certified music therapist during an invasive or painful medical procedure; the music is designed to specifically address a patient's needs including reducing anxiety and pain perception, and to encourage healthy coping behaviors. In the NICU, the music therapist is bedside and uses interventions such as vocal holding, contingent singing, ocean disc, entrainment, and Iso principle to bring the infant to desired behavioral states or stabilize physiologic functions. The use of entrainment during these painful procedures is utilized to meet the patient in the moment of their pain, and work to decrease their perceived pain to bring them to the desired behavior state (Beer & Lee, 2017). Another technique used during painful procedures with premature infants is lullaby singing. The use of live singing of these predictable songs has been shown to be effective in improving homeostatic processes (Ullsten, Eriksson, Klassbo, & Volgsten, 2017).

As more music therapists have been providing procedural support, the model for this intervention during invasive and non-invasive medical procedures has continued to develop. Ghetti (2012) explains the use of music therapy in the moment while the music therapist continually provides flash assessments to gauge the patient's response and positively affect the outcome of less perceived pain.

Studies have shown music therapy to benefit infants' physiological parameters and behavioral states during these painful procedures. Tramo et al. (2011) examined the incidence of inconsolable crying and found that the infants who were exposed to recorded music decreased this behavior. Using recorded lullabies as a positive stimulus during heel stick, these researchers also found that the infants heart rate decreased when compared to those in the control group

Other studies of live and recorded music show that music can increase transcutaneous oxygen saturations in preterm infants (Chou, Wang, Chen, & Pei, 2003). Infants listening to recorded music during endotracheal suctioning were found to have higher oxygen saturations and elevated saturation levels above baseline for as long as 45 minutes after the lullaby was played (Chou et al., 2003; Jabraeili, Sabet, Gharebaghi, & Hamidi, 2016). The improvement that was noted, well after the time of the music intervention, is a unique benefit to support the use of music. Music therapy can have a positive effect and ongoing benefits even after the session has been completed.

Retinopathy of Prematurity (ROP)

A complication that premature infants may experience is retinopathy of prematurity (ROP), an ocular disorder that primarily affects preterm infants who are born before 30 weeks of gestation or at an extremely low birth weight, less than 1500 grams (Fierson, 2013). An estimated 14,000-16,000 low birth weight and premature infants are diagnosed with ROP, and of these approximately 1,500 require treatment for the disease (Lyon & Warren, 2006). If untreated, ROP can cause irreversible vision loss in affected babies. A thorough retinal exam by a pediatric ophthalmologist is required to assess ROP.

It is well documented that there are negative side effects and stressors on the infant resulting from these retinal exams (Mitchell, Green, Jeffs, & Roberson, 2011). Infants are at risk for pain, stress, apnea, bradycardia, tachycardia, and gastrointestinal disorders. These side effects can occur up to 72 hours after the exam has been performed (Jiang et al., 2016). The American Academy of Pediatrics suggests using combinations of different behavioral and pharmacologic interventions during painful procedures (Samra & McGrath, 2009). Some methods, such as swaddling and administration of sucrose, are commonly used to ease infant stress. While these methods are used to decrease immediate pain in these infants, recent research has questioned

whether sucrose used during pain procedures can be detrimental to infant brain development and behavioral outcomes. A recent study determined that repeated use of sucrose can have detrimental outcomes on memory function and can negatively impact brain volumes (Ranger et al., 2019).

Retinopathy of prematurity and music therapy. Music therapy can be used to affect physiological responses during painful procedures for infants in the NICU (Shabani, Nayeri, Karimi, Zarei, & Chehrazi, 2016). The gate control theory suggests that music can serve as incoming sensory information and can inhibit the amount of pain that is transmitted to the brain (Melzack & Wall, 1965). This theory suggests that music therapy provided as procedural support for these infants during their ROP exams would serve as an inhibitor to the pain receptors. Thus, infants are likely to perceive less pain.

Interventions such as vocal holding, humming, and ocean disc have been used to create a soothing and familiar environment for these infants (Loewy et al., 2013). These interventions will be utilized to decrease pain response and stabilize vital signs during these important, and yet painful, retinal exams.

Method

Participants/Setting

This study took place in a Level III Neonatal Intensive Care Unit in Vancouver, Washington. The participants of this study were infants who qualified for retinal screening for retinopathy of prematurity. Guidelines by pediatric ophthalmologists and neonatologists are set to ensure that all babies who qualify receive screening for this disease. These guidelines require that infants who were born at less than 30 weeks gestation, and/or under 1500 grams, undergo screenings for ROP (Fierson, 2013). Depending on the severity of the disease, the exams are repeated every one to three weeks until the risk from this disease has passed. Once the eye has

completed full vascularization, or the disease is resolved with surgery, the exams are discontinued (Lyon & Warren, 2006). A convenience sample of sixteen infants who qualified for ROP screening were referred to the music therapist by the pediatric ophthalmologist. All parents of infants taking part in this study gave written and verbal consent prior to the infant's participation (see Appendix A).

Inclusion criteria:

- Infants born before 30 weeks gestation
- Infants born weighing less than 1500 grams
- Infants with clear risk factors for ROP, including long-term use of oxygen for life sustaining treatment, or unstable course of oxygen treatment

Exclusion criteria:

- Infants who are not qualified to undergo retinal screening based on the guidelines set by AAP guidelines
- Infants with congenital deformity of outer or inner ear that would interfere with hearing capabilities
- Infants who are too medically unstable to undergo retinopathy screenings

Design

A single-subject design using repeated measures was employed with sixteen participants. Each infant received retinal screenings every one to three weeks, depending on severity of the disease. Infants served as their own controls to discover the feasibility and effectiveness of this music therapy protocol during procedural support for ROP exams. The music therapy protocol was provided during the screening exam in one eye. The administration of the music therapy protocol during either the first or second eye being examined was randomly selected according to a computer program. The infant did not receive the music therapy protocol during the exam for

the other eye, making it the control. Each infant had a ten-minute period of rest after the first eye had received the ROP exam to allow for regulation and stabilization of vitals before the exam began on the second eye. Other standard practices such as swaddling, use of pacifier and sucrose were used to mitigate pain and provide comfort to the infant during the exam.

Procedures

Literature has shown the effectiveness in using ocean disc and humming to stabilize physiologic parameters and support infants through painful procedures. These interventions were used to create a music therapy protocol to be provided as procedural support during ROP exams(Ullsten, Eriksson, Klassbo, & Volgsten, 2017; Loewy et al., 2013). This music therapy protocol consisted of vocal holding/humming and playing of an ocean disc, a sealed drum with metal balls to create an ebb and flow sound. The music therapist used the ocean disc to entrain to the infant's respiratory rate which provided auditory containment for the infant. The ocean disc was played for two minutes prior to the start of the procedure and continued throughout the exam. At the start of the exam, the music therapist hummed an unspecified melodic tune and matched the pitch of the infant's cry with her own voice using vocal holding. This holding of a specified note then resolved to the dominant of the unspecified tune once the infant had entrained to the music therapist. Using the Iso principle, the therapist matched the music to the mood/behaviors of the infant and gradually altered the music to bring the infant to the desired behavioral state of decreased pain. After the exam had been completed, the music therapist ceased humming and played ocean disc for an additional two minutes.

The music therapy intervention started two minutes before the exam and continued until two minutes post-exam period. In the unlikely situation that the infant showed signs of over stimulation from the procedure or music therapy protocol, music therapy was discontinued immediately and the data for this session was not used. Signs of overstimulation include, but are

not limited to, instances of sustained bradycardia/apnea/desaturations, frequent sneezing/yawning, halt hand, splayed fingers, tongue protrusion, or arched back. The researcher, a board-certified music therapist pursuing her master's degree in music therapy, was the principal investigator. An independent/unbiased observer assessed this specific music therapy protocol and the potential decrease of infant pain.

All infants had mydriatic, dilation drops placed in each eye twenty minutes prior to the exam. Immediately before examination, tetracaine was used as an ophthalmic anesthetic. All of the infants were offered sucrose two minutes prior to the exam and a pacifier if the infant showed interest in sucking; additionally each infant was swaddled tightly. These measures are part of the standard of care.

Assessments

An independent observer who was specifically trained using this pain assessment evaluated infant pain using the NPASS: Neonatal Pain, Agitation, Sedation Scale (Hummel, 2017). This researcher had been given permission by the creator to use this tool for this research study (see Appendix B). The infant's vitals and behavioral state were assessed for two minutes before the music therapist entered the room to create a baseline prior to the exam. The observer continued to evaluate the infant's state and vitals throughout the exam and music therapy protocol to inform their NPASS score. Pain assessments were performed immediately prior to exam, upon insertion of eye retractor, at 30 seconds, and one minute after the start of the exam. A post-exam, pain assessment was performed at five minutes after the exam has ceased (see Appendix C).

Data Analysis

The NPASS scores were collected by an unbiased independent observer who was specifically trained in using this assessment to measure procedural pain. The infant was assessed based upon five categories: crying and irritability, behavioral state, facial expression, tone and

extremities, and physiologic data. The higher the infant was scored based upon these criteria, the more pain the infant exhibited. These scores were compared to the pain scores collected during exams in which the infant did not receive procedural support through the music therapy protocol. All data was kept and stored in a secure, locked location and all infants received a subject number to ensure anonymity. These data are intended to inform the medical community on alternative therapies and the potential benefits for pain management in procedural support for premature infants.

Results

These data collected during this study was analyzed by a statistician. Sixteen participants and thirty-two separate eye exams were analyzed. For the primary objective to discover if music therapy can decrease pain scores during ROP screening exams, an independent samples t-test showed that infant pain scores during the eye exam were significantly lower when infants received the music therapy protocol (with protocol: $M = 14.44$, $SD = 6.66$; without protocol: $M = 21.75$, $SD = 7.34$; $t_{30} = 2.95$, $p < .01$). Table 1 and Figure 1 depict this data.

Table 1

T test for Total NPASS scores

		Levene's Test for Equality of Variances		t-test for Equality of Means		
		F	Sig.	t	df	Sig. (2-tailed)
TOTAL NPASS	Equal variances assumed	.034	.854	2.950	30	**.006**
	Equal variances not assumed			2.950	29.720	**.006**

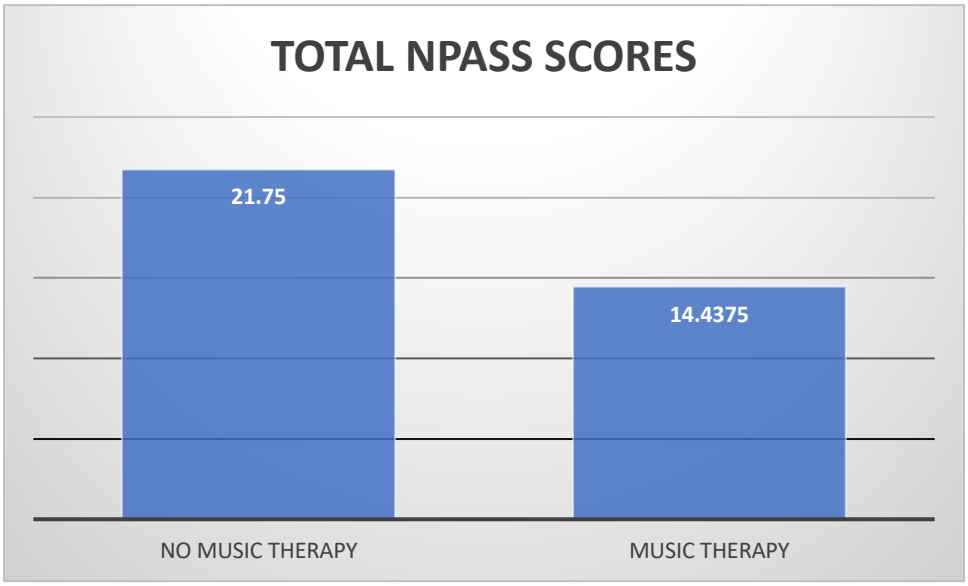

Figure 1. Mean Total NPASS scores without the music therapy protcol and with the music therapy protocol.

Following this, a one-way ANOVA was conducted to investigate differences in pain scores observed with and without the music therapy protocol at successive time-points across the eye exam. There were no significant differences in pain scores before or after the eye exam which depict the infant's baseline prior to the exam, and a return to this baseline after the exam (see Table 2). However, pain scores were consistently and significantly lower when infants received the music therapy protocol at onset of the procedure (with protocol: $M = 3.00$, $SD = 2.72$; without protocol: $M = 5.31$, $SD = 3.34$; $F_{1,30} = 4.63$, $p < .05$), thirty seconds into the procedure (with protocol: $M = 4.56$, $SD = 2.71$; without protocol: $M = 6.88$, $SD = 2.50$; $F_{1,30} = 6.30$, $p < .05$), and one minute into the procedure (with protocol: $M = 5.13$, $SD = 1.50$; without protocol: $M = 8.06$, $SD = 2.18$; $F_{1,30} = 19.78$, $p < .01$). These data are shown in Table 2 and Figure 2.

Table 2

ANOVA Pain Scores Across Time

		Sum of Squares	Df	Mean Square	F	Sig.
PreNPASS	Between Groups	.125	1	.125	.380	**.542**
	Within Groups	9.875	30	.329		
	Total	10.000	31			
OnsetNPASS	Between Groups	42.781	1	42.781	4.626	**.040**
	Within Groups	277.438	30	9.248		
	Total	320.219	31			
30secNPASS	Between Groups	42.781	1	42.781	6.301	**.018**
	Within Groups	203.688	30	6.790		
	Total	246.469	31			
1minNPASS	Between Groups	69.031	1	69.031	19.782	**.000**
	Within Groups	104.688	30	3.490		
	Total	173.719	31			
PostNPASS	Between Groups	.031	1	.031	.016	**.900**
	s	58.437	30	1.948		
	Total	58.469	31			

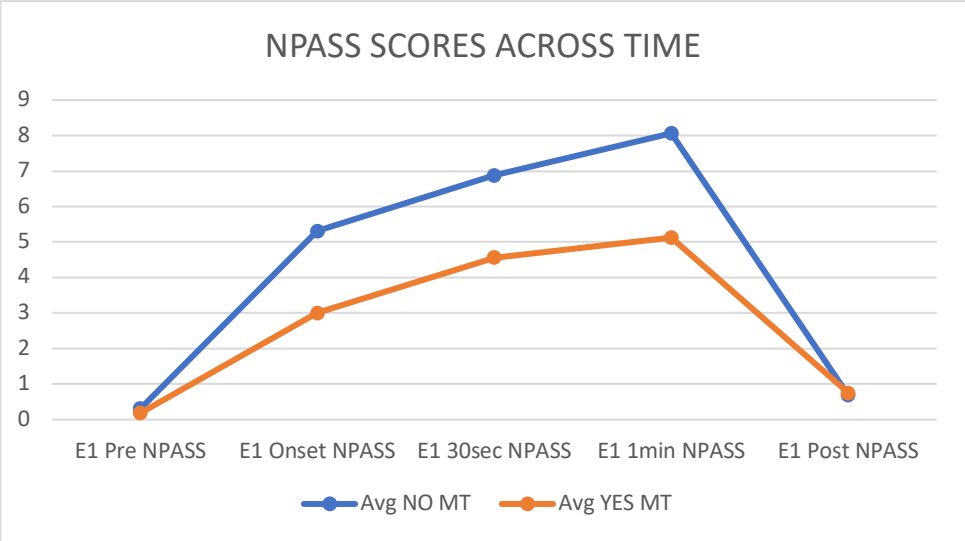

Figure 2. Average NPASS scores at each interval throughout the exam without the music therapy protocol and with the music therapy protocol

A secondary outcome was analyzed to assess if music therapy had lasting effects when music therapy was received during the exam on the first eye, but not the second. The principle investigator hypothesized that the effects of the music therapy protocol would continue even after the music therapy had been discontinued. ANOVA analysis of these NPASS scores between groups showed a trend such that infants who received the protocol on their first eye were observed to have lower pain scores during the second eye exam without receiving the music therapy protocol ($M = 18.38$, $SD = 6.35$) as compared to the observed pain scores of the first, non-music therapy trial for the infants who did not receive the protocol until their second eye exam ($M = 25.13$, $SD = 7.02$; $t_{30} = 2.95$, $p < .01$). The following results were yielded in Table 3.

Table 3

ANOVA NPASS scores spillover effect of music therapy

		Sum of Squares	df	Mean Square	F	Sig.
PreNPASS	Between Groups	.563	**1**	.563	**2.032**	**.176**
	Within Groups	3.875	**14**	.277		
	Total	4.438	15			
OnsetNPASS	Between Groups	16.000	**1**	16.000	**2.383**	**.145**
	Within Groups	94.000	**14**	6.714		
	Total	110.000	15			
30secNPASS	Between Groups	3.063	**1**	3.063	**.401**	**.537**
	Within Groups	106.875	**14**	7.634		
	Total	109.938	15			
1minNPASS	Between Groups	12.250	**1**	12.250	**7.977**	**.014**
	Within Groups	21.500	**14**	1.536		
	Total	33.750	15			
PostNPASS	Between Groups	.000	**1**	.000	**.000**	**1.000**
	Within Groups	45.000	**14**	3.214		
	Total	45.000	15			

Discussion

This is the first prospective study to explore whether music therapy used as procedural support can have an effect on pain scores in neonates undergoing retinopathy of prematurity screening. Results showed that music therapy used as procedural support was statistically significant in decreasing overall pain scores, and pain scores throughout the exam. This study also found a trend toward the decrease in pain scores in which infants received the music therapy

protocol during the examination of the first eye but not the second eye. This suggests that the effects of the music therapy protocol can continue to last even after music therapy has been discontinued. This could hold implications for further research to discover how long the effects of music therapy can last after being discontinued when used as procedural support.

The strengths of this study included the involvement of a single music therapist providing the music therapy protocol and a single pediatric ophthalmologist performing exams. All exams were performed using binocular indirect ophthalmoscopy (BIO). The same independent observer was employed for 12 of the exams while a single but different observer was used for the other four exams. Both of these observers were specifically trained in using NPASS and were unbiased in their assessments.

The limitations of this study were most notably the reduced sample size of 16 eye exams and 32 separate eyes total; music therapy and non-music therapy. While the sample size for this study was small, the data analysis showed statistical significance, which point toward evidentiary support for this music therapy protocol. The observers collecting pain scores were unbiased but the music therapist and pediatric ophthalmologist were not blind during this study as they administered the eye exam and music therapy protocol.

Many variables were accounted for at the beginning of this study, and many variables surfaced that were unforeseen. For three of the screening exams, the time of the exam fell directly before a feeding which could contribute to an increased pain score due to the infants being more irritable and showing hunger cues. The data for one exam was discarded from the study as the nurse fed the baby a bottle in the transition period between the examination of each eye. The infant was showing vigorous hunger cues and the nurse was unaware of the effects that feeding the infant could have on study data. Other variables of note included whether the infant was on continuous positive airway pressure (CPAP) at the time of the examination. CPAP

prongs are inserted into the nose can be more irritating to an infant than the CPAP mask which covers the nose. Infants on CPAP prongs could have showed higher pain scores due to the fact that they were more irritable from the beginning of the exam.

During the music therapy protocol and examination, infants showed signs of discomfort but not overstimulation. None of the exams needed to be discontinued due to signs of shut down or overstimulation which point toward the infants being able to tolerate the procedure due to the music therapy protocol. As this is the first prospective study to examine the effects of music therapy on pain scores in neonates undergoing retinopathy of prematurity screening exams, more research should be implemented to validate and replicate the findings of this study. Future studies should include a larger sample size and a possible randomized controlled trial could be implemented to further discover the effects of music therapy as procedural support with this population.

Conclusion

Research has indicated that preterm infants need more non-pharmacologic methods to decrease pain associated with ROP exams. Currently, music therapy is an underused modality in the NICU and could has shown promising results with little, to no side effects. Music therapy interventions, provided by a board-certified music therapist, specially trained in the use of music therapy in the NICU, could have significant implications for this fragile population. With advances in medicine and viability of infants at younger gestational ages, the number of ROP exams is increasing to ensure that infants do not develop this retinal disease. It is vital that these high risk infants receive non-invasive, non-pharmacologic interventions, like music therapy, to decrease adverse effects that are associated with these exams.

The findings of this study advocate that music therapy during retinopathy of prematurity exams is safe and may be associated with a decrease in pain scores in infants undergoing this

procedure. This is consistent with other findings in the literature showing that music therapy can have positive outcomes on pain and can improve physiologic stability in preterm infants. Due to the fact that this was a feasibility study, there were limitations to this study including the small sample size. The findings from this study need to be replicated in a larger prospective study or randomized controlled trial in order to verify these results. This study suggests that music therapy could be the non-pharmacologic, non-invasive treatment that these infants need to decrease the adverse effects associated with these exams. The results of this study show the promising nature of using music therapy as procedural support to decrease pain for these fragile infants.

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Appendix A

PeaceHealth

CONSENT TO PARTICIPATE IN RESEARCH

The Effect of Music Therapy on Pain Scores in Neonates undergoing Retinopathy of Prematurity Screening

Susan Bakouros, MT-BC from the *Neonatal Intensive Care Unit* at PeaceHealth Southwest Washington, will be conducting a research study.

You were selected as a possible participant in this study because *your infant will be receiving eye exam screenings for retinopathy of prematurity.* Your participation in this research study is voluntary.

Why is this study being done?

This study is being done to determine if music therapy can benefit babies who receive retinal screening exams for retinopathy of prematurity.

What will happen if I allow my child to take part in this research study?

If you allow your child to participate in this study, the researcher will:

- *Ask you to allow the researchers specific access to your baby's medical information, including gestational age, medical diagnosis and medications.*
- *Provide a music therapy protocol during your child's eye exam to mitigate pain responses during the exam. The music therapist will use a combination of ocean disc and vocal holding techniques to match your baby's behaviors and vital signs to help bring the infant to the desired state of decreased pain.*

How long will I be in the research study?

Participation will include any and all eye exams that your child is required to receive.

Are there any potential risks or discomforts that I can expect from this study?

- *The music therapist will be using well-defined music therapy interventions, provided by a board-certified NICU music therapist; these interventions have been well-studied in earlier research and have shown no significant risks to infants. In the unlikely event that your infant shows signs of overstimulation, the music therapy protocol will be discontinued immediately.*

Are there any potential benefits if I participate?

- *Your baby may benefit from the music therapy interventions by experiencing reduced symptoms of pain during and after their screening exam for retinopathy of prematurity.*
- *The results of the research may impact other infants undergoing screenings for retinopathy of prematurity in the future.*

What other choices do I have if I choose not to participate?

- *You do not have to allow your infant to participate in the study. Your infant may still be eligible to receive standard music therapy services outside the study parameters, if you choose to accept those services.*
- *If you choose not to allow your infant to participate in the study, he or she will still receive all appropriate NICU care, and no needed services or therapies will be withheld.*

Will information about me and my participation be kept confidential?

- *Yes. While we will use information about your child collected during the study, all of that information will be treated in a way that protects your child's anonymity. In other words, the data used in the study will not include your child's name or any identifying information. Careful safeguards will be in place to make sure that your child's (and your family's) identity remains confidential. Those safeguards include:*
    - *Limits on the number of researchers with access to your child's and family's identifying information*
    - *Computer software and physical safeguards, including passcodes and other security measures*

What are my rights if I take part in this study?

- *You can choose whether you want to be in this study, and you may withdraw your consent and discontinue participation at any time.*
- *Whatever decision you make, there will be no penalty to you, and no loss of benefits to which you were otherwise entitled.*
- *You may refuse to answer any questions that you do not want to answer and remain in the study.*

Who can I contact if I have questions about this study?

- **The research team:**

If you have any questions, comments or concerns about the research, you can talk to the one of the researchers. Please contact:

1. *Susan Bakouros, MT-BC at (503) 956-7754; susan.bakouros@gmail.com*
2. *Heather Wagner, PhD, MT-BC at (860) 550-4884; hwagner@berklee.edu*

- **PeaceHealth System Institutional Review Board:**

If you have questions about your rights while taking part in this study, or you have concerns or suggestions and you want to talk to someone other than the researchers about the study, please call the IRB at (541) 686-6949 or email to: IRB@peacehealth.org.

You will be given a copy of this information to keep for your records.

SIGNATURE OF STUDY PARTICIPANT

_____
Name of Participant

_____ _____
Signature of Participant Date

SIGNATURE OF PERSON OBTAINING CONSENT

_____ _____
Name of Person Obtaining Consent Contact Number

_____ _____
Signature of Person Obtaining Consent Date

Appendix B

Berklee

Susan Bakouros <sbakouros@berklee.edu>

NPASS Permission

2 messages

Susan Bakouros <sbakouros@berklee.edu> Wed, Aug 22, 2018 at 10:50 AM
To: phummel@lumc.edu
Cc: Heather Wagner <hwagner@berklee.edu>

Dear Pat,
I am a graduate student at Berklee College of Music pursuing my master's degree in music therapy. I am a NICU music therapist at PeaceHealth Southwest Medical Center and would like to ask your permission to use your NPASS scoring system for my thesis project. I will be collecting data on pain scoring during retinal exams for retinopathy of prematurity to ascertain if there is a difference between pain scores when using music therapy. I will be sure to properly cite and reference the scoring system. Please let me know if you have any questions.
I appreciate your help.
Thank you,
Susan Bakouros, MT-BC

PATRICIA A. HUMMEL <PHUMMEL@lumc.edu> Fri, Aug 24, 2018 at 8:00 AM
To: Susan Bakouros <sbakouros@berklee.edu>
Cc: Heather Wagner <hwagner@berklee.edu>

That sounds like an amazing project/study!

You do have permission to use the N-PASS tool

I'm attaching the tool for you to use as you want.

Let me know if you need more than this email.

Regards,

Pat Hummel, Ph.D., NNP-BC, PPCNP-BC
Loyola University Medical Center
2160 S 1st Ave
Maywood, IL 60153
708-327-9055
fax 708-216-9434

From: Susan Bakouros <sbakouros@berklee.edu>
Sent: Wednesday, August 22, 2018 12:50:09 PM
To: PATRICIA A. HUMMEL
Cc: Heather Wagner
Subject: [External] NPASS Permission

Warning: This email originated from the Internet!

DO NOT CLICK links if the sender is unknown, and NEVER provide your password.

[Quoted text hidden]

Confidentiality Notice:
This e-mail, including any attachments is the property of Trinity Health and is intended for the sole use of the intended recipient(s). It may contain information that is privileged and confidential. Any unauthorized review, use, disclosure, or

Appendix C

ROP NPASS Scoring Criteria Data Sheet

Date of Exam:_____ Eye: FIRST/SECOND_____Music Therapy: YES/NO

Participant:_____ GA:_____ CGA_____

Pre NPASS Scoring: (5 minutes before exam)

Crying/Irritability:	Extremities/Tone	Behavior State:
-2 -1 0 +1 +2	-2 -1 0 +1 +2	-2 -1 0 +1 +2
Facial Expression:	Vital Signs:	
-2 -1 0 +1 +2	-2 -1 0 +1 +2	

Onset NPASS Scoring:

Crying/Irritability:	Extremities/Tone	Behavior State:
-2 -1 0 +1 +2	-2 -1 0 +1 +2	-2 -1 0 +1 +2
Facial Expression:	Vital Signs:	
-2 -1 0 +1 +2	-2 -1 0 +1 +2	

30 Sec. NPASS Scoring:

Crying/Irritability:	Extremities/Tone	Behavior State:
-2 -1 0 +1 +2	-2 -1 0 +1 +2	-2 -1 0 +1 +2
Facial Expression:	Vital Signs:	
-2 -1 0 +1 +2	-2 -1 0 +1 +2	

1 min. NPASS Scoring:

Crying/Irritability:	Extremities/Tone	Behavior State:
-2 -1 0 +1 +2	-2 -1 0 +1 +2	-2 -1 0 +1 +2
Facial Expression:	Vital Signs:	
-2 -1 0 +1 +2	-2 -1 0 +1 +2	

2 min. NPASS Scoring:

Crying/Irritability:	Extremities/Tone	Behavior State:
-2 -1 0 +1 +2	-2 -1 0 +1 +2	-2 -1 0 +1 +2
Facial Expression:	Vital Signs:	
-2 -1 0 +1 +2	-2 -1 0 +1 +2	

Post NPASS Scoring: (5 minutes post exam)

Crying/Irritability:	Extremities/Tone	Behavior State:
-2 -1 0 +1 +2	-2 -1 0 +1 +2	-2 -1 0 +1 +2
Facial Expression:	Vital Signs:	
-2 -1 0 +1 +2	-2 -1 0 +1 +2	