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Music therapy as procedural support for young children undergoing immunizations: A randomized controlled study

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Abstract

Background: Children undergoing routine immunizations frequently experience severe distress, which may be improved through music therapy as procedural support.

Objective: The purpose of this study was to examine effects of live, cognitive-behavioral music therapy during immunizations on (a) the behaviors of children, their parents, and their nurses; and (b) parental perceptions.

Methods: Participants were children between the ages of 4 and 6 years ($N = 58$) who underwent immunizations, their parents ($N = 62$), and the nurses who administered the procedure ($N = 19$). Parent/child dyads were randomly assigned to receive music therapy ($n = 29$) or standard care ($n = 29$) during their immunization. Afterward, each parent rated their child's level of pain and the distress their child experienced compared to previous medical experiences. All procedures were videotaped and later viewed by trained observers, who classified child, parent, and nurse behaviors using the categories of the Child-Adult Medical Procedure Interaction Scale-Revised (CAMPIS-R).

Results: Significant differences between the music therapy and control groups were found in rates of child coping and distress behaviors and parent distress-promoting behaviors. Parents of children who received music therapy reported that their child's level of distress was less than during previous medical experiences, whereas parents of children in the control group reported that their child's level of distress was greater. No significant differences between groups were found in parents' ratings of children's pain or in rates of nurse behavior.

Conclusions: Live, cognitive-behavioral music therapy has potential benefits for young children and their parents during immunizations.

Keywords: child, immunization, music therapy, parents, pain

Music therapy as procedural support for young children undergoing immunizations:

A randomized controlled study

Children who undergo immunizations frequently experience distress behaviors (Taddio et al., 2009), clinically significant pain (Cassidy et al., 2002), and require restraint (Blount et al., 1992). Unmanaged pain during pediatric immunizations can have negative long-term effects on children, including anticipatory fear regarding future medical procedures (Cohen et al., 2001), increased pain sensitivity, decreased effectiveness of topical analgesics, and difficulty completing future procedures (Taddio et al., 2009). Distressing immunization experiences may also lead to fear and avoidance of medical procedures during adulthood (Pate, Blount, Cohen, & Smith, 1996) and needle phobias (Taddio et al., 2009).

Parents, who are often present during their child's immunization, may experience increases in anxiety, heart rate (Smith, Shah, Goldman, & Taddio, 2007), and salivary cortisol (Mörelius, Theodorsson, & Nelson, 2009) upon seeing their child in distress during a medical procedure. Pediatric vaccinations can also be difficult for the providers (most often, nurses) who administer them. A survey of Canadian nurses conducted by Ives and Melrose (2010) revealed that immunizing children who are fearful and resistant of needle injections is frequently stressful for nurses and presents an ethical dilemma when children are strongly resistant or parents are overly forceful with their children. Nurses also reported that parent responses occasionally make it difficult and unsafe for nurses to vaccinate children, and that insufficient resources are available to help nurses cope with these difficult situations (Ives & Melrose, 2010). Given the challenges inherent in the administration of vaccines and the importance of administering all pediatric immunizations to prevent the spread of disease, finding and implementing effective techniques for managing pain and distress during pediatric vaccinations is an important consideration.

Recent investigations into psychological interventions have identified several effective treatments for pediatric immunization pain and distress. Distraction and hypnosis were found to be the most effective psychological treatments for needle-related pain in a recent systematic review by Uman et al.

(2013). A review by Chambers, Taddio, Uman, and McMurtry (2009) also found breathing exercises and combined cognitive-behavioral interventions to be effective treatments for decreasing pain and distress during child immunizations. In addition, Chambers and colleagues (2009) found that nurse-led and child-led distraction tend to be more effective than parent-led distraction during medical procedures, which may be a result of behaviors displayed by many well-meaning parents that unintentionally promote child distress during medical procedures (Blount et al., 1989; Blount, Landolf-Fritsche, Powers, & Sturges, 1991; Blount, Sturges, & Powers, 1990; Cohen, Manimala, & Blount, 2000; Frank, Blount, Smith, Manimala, & Martin, 1995; Smith et al., 2007). See Blount et al. (1990) for descriptions of adult distress-promoting behaviors, which include reassuring comments such as "you're okay," apologies, and criticism.

Music-based interventions have also been used for procedural support during pediatric immunizations, although the majority of studies in this area have involved the use of recorded music administered by healthcare professionals (also known as music medicine). Within the studies on music medicine as distraction during pediatric immunization, reductions in child-reported pain (Fowler-Kerry & Lander, 1987; Kristjánsdóttir & Kristjánsdóttir, 2011) and behavioral distress (Megel, Houser, & Gleaves, 1998) have been noted. A study by Noguchi in which recorded music was implemented by a music therapist within an interactive children's story during immunizations showed improvements in reported pain and observed distress that were not statistically significant (Noguchi, 2006).

The use of live, interactive music therapy conducted by a board-certified music therapist has been shown to be of great benefit to patients in medical settings (Standley, 2000), although few researchers have investigated music therapy as procedural support during pediatric immunizations (Yinger & Gooding, 2015). Music therapy as procedural support is defined as "the use of music and aspects of the therapeutic relationship to promote healthy coping and decrease distress in individuals undergoing medical procedures" (Ghetti, 2012, p. 6). Music therapy as procedural support has been shown to alleviate pediatric pain, anxiety, distress, and fear during pediatric medical procedures such as hemodialysis (Callaham, 2004) and burn dressing changes (Whitehead-Pleaux, Baryza, & Sheridan,

2006), and may decrease the need for certain medications and shorten procedure times during echocardiograms and CT scans, resulting in greater cost-effectiveness (Walworth, 2005).

In a 1996 study of children under the age of 7 years who received various types of needle insertions, Malone found that children who received live music therapy and breathing exercises as distraction showed significantly less behavioral distress than patients who received standard care (Malone, 1996). The results of a recent systematic review of music-based interventions for procedural support indicate that there is a need for more high-quality research on the use of active music therapy during pediatric medical procedures, with particular emphasis on the interventions and techniques used by the music therapist (Yinger & Gooding, 2015).

The effects of live music therapy treatment combined with cognitive-behavioral interventions on coping and distress behaviors in children undergoing routine immunizations have not yet been examined in the research literature. Given the potential benefits of live music therapy and cognitive-behavioral interventions during other pediatric needle-related procedures (Malone, 1996), further research on the effects of live music therapy during pediatric immunizations is warranted. In addition, no previous research could be found on the effects of music therapy as procedural support on parent or nurse behaviors. The purpose of this study was to examine the effects of live, cognitive-behavioral music therapy on behaviors of young children who underwent routine immunizations, parent and nurse behavior, parents' ratings of their children's pain and distress, and parents' perceptions of music therapy. Specific research questions included:

1. Are there differences between young children undergoing immunizations who receive music therapy compared to standard care in the rates of (a) coping behaviors and (b) distress behaviors observed?
2. Are there differences between the parents of young children undergoing immunizations who receive music therapy compared to standard care in the: (a) rates of coping-promoting behaviors displayed, (b) rates of distress-promoting behaviors displayed, (c) ratings of child's distress during immunizations relative to previous medical experiences, or (d) ratings of child's pain?

3. Do parents of children who receive music therapy during immunizations perceive (a) benefits for to their child, (b) benefits to themselves, or (c) improved perceptions of the healthcare facility?
4. Are there differences between the nurses who administer immunizations to young children who receive music therapy compared to standard care in the: (a) rates of coping-promoting behaviors displayed, and (b) rates of distress-promoting behaviors displayed?

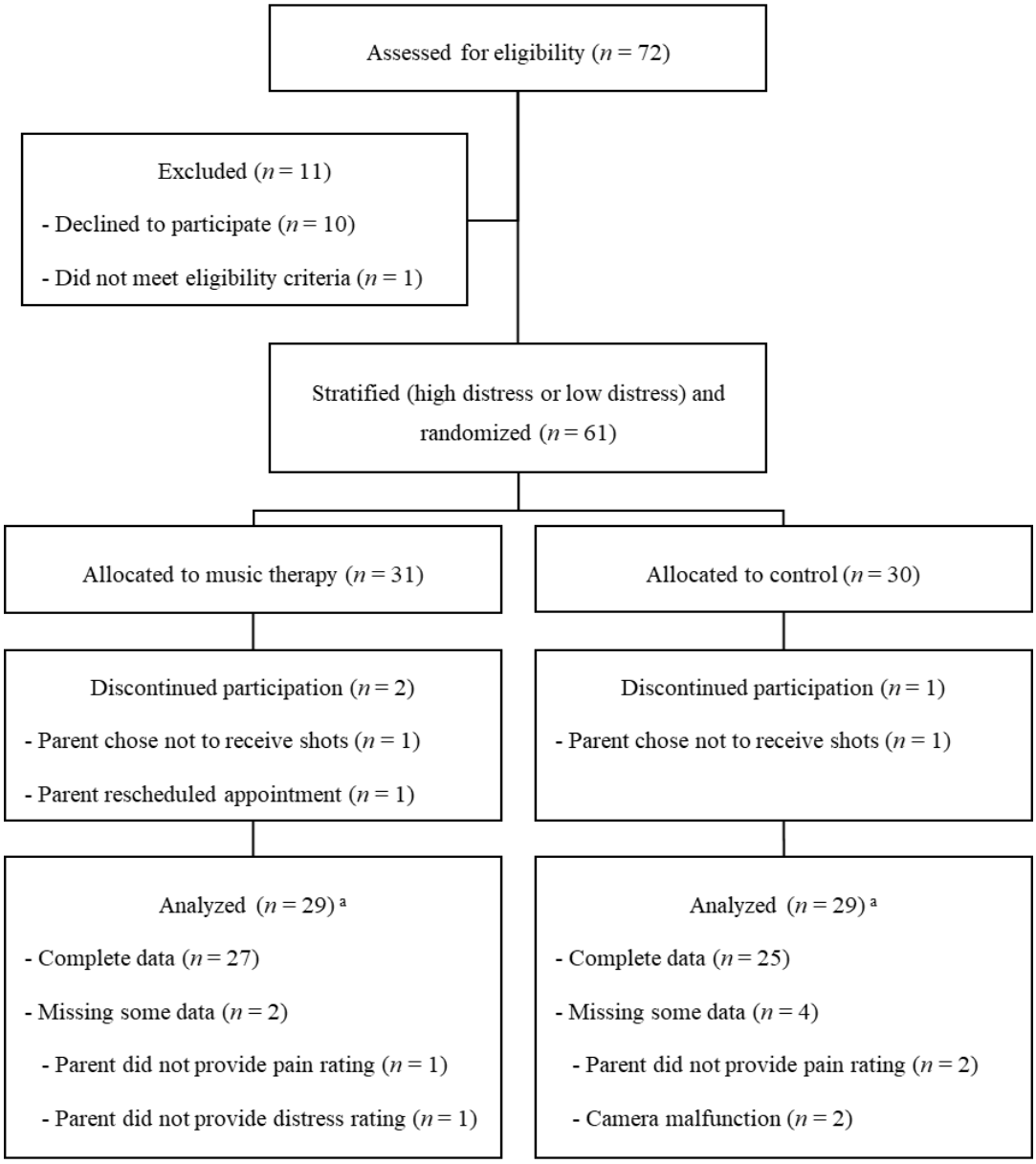
Method

Approval to conduct the present study was obtained from the Institutional Review Boards at both the university and the hospital with which the author was affiliated. This study used a posttest-only control group design with random assignment and a stratified sample. Figure 1 shows the number of child/parent dyads involved with each step of the study.

Participants

Participants were pediatric patients ($N = 58$) between the ages of 4 and 6 years (48.1 and 70.8 months, $M = 56.6$, $SD = 6.7$) who were scheduled to undergo routine immunizations over a seven-month period at one of three healthcare sites in the southeastern United States, and their parents/legal guardians ($N = 62$, since four children had two parents/guardians present). In order to meet inclusion criteria, children had to be between 48 and 72 months of age, accompanied by at least one English-speaking parent or legal guardian, and scheduled to receive at least one immunization via injection during their doctor visit. Although 72 potential child/parent dyads were assessed for eligibility, ten parents declined to participate because they did not want their child to be video recorded. One child initially thought to be eligible was later deemed ineligible when the clinician-researcher learned that the shot the child was to receive (an allergy shot) was not on the Center for Disease Control and Prevention (CDC) immunization schedule and that the shot was to be administered in such a way (in the gluteal region) that it was considered a different procedure. Three additional child/parent dyads discontinued participation in the study after consenting to participate because they elected not to receive shots ($n = 2$) or they had to reschedule their appointment ($n = 1$). In addition, eighteen nurses and one nurse practitioner were eligible

to participate and all of them consented to take part in this study, although for simplicity they will be referred to collectively as nurses ($N = 19$) throughout the remainder of this paper.



[a] There were 4 child/parent dyads in which an additional parent or guardian was present. These child/parent triads were equally distributed between the music therapy group ($n = 2$) and the control group ($n = 2$).

Figure 1. Study enrollment flowchart: Child/parent dyads

Setting

Site One was a family medicine practice in an urban area that did not accept Medicaid patients. Site Two was a family medicine clinic housed within a regional medical center in an urban area that served many patients from nearby rural areas; approximately 90% of all patients treated at Site Two received Medicaid. Site Three was a pediatric practice affiliated with a hospital in a rural area; approximately 75% of all patients treated at Site Three received Medicaid or another government subsidized health insurance program for low income families who did not qualify for Medicaid.

Participants met with the clinician-researcher initially and completed consent forms in the waiting room at their respective healthcare site or, if the waiting room was crowded and a treatment room was available, in a treatment room. Immunizations and the music therapy intervention (for participants in the experimental group) took place in treatment rooms, which were similar with regard to arrangement of furnishings at the three healthcare sites. Each treatment room had an exam table, a lamp, a chair, a rolling stool, and a sink with a counter. Two of the treatment rooms at Site Three had a window, while treatment rooms at Sites One and Two were windowless. One of the treatment rooms at Site One had a small table with several children's toys on it. None of the rooms were sound-proof, and some ambient noise from the hallway or other treatment rooms was occasionally heard at all three healthcare sites.

Independent Variable: Type of Intervention

The independent variable in this study was the type of intervention children received during immunizations: either standard care or a single-session music therapy intervention, which included live music and cognitive-behavioral techniques as procedural support.

Intervention theory. The music therapy intervention was developed based on cognitive-behavioral theory, which is governed by the assumptions that: "(a) Cognitive activity affects behavior, (b) cognitive activity may be monitored and altered, and (c) desired behavior change may be effected through cognitive change" (Dobson & Dozois, 2010, p. 4). Furthermore, cognitive-behavioral theory purports that overt behavior and covert behavior (cognitions) not only interact with each other, they also influence and are influenced by one's environment (Dobson & Dozois, 2010). When applying cognitive-behavioral

theory to pediatric medical procedures, cognitive-behavioral interventions are defined as those that combine at least one cognitive intervention and at least one behavioral intervention. Cognitive interventions involve identifying and modifying negative thinking relative to the medical procedure, and include cognitive distraction (including non-procedural talk) and preparation/provision of information. Behavioral interventions target specific behaviors and include behavioral distraction (including engagement in games), breathing exercises, and staff coaching (Uman, Chambers, McGrath, & Kisely, 2008). Cognitive-behavioral music therapy incorporates traditional cognitive-behavioral techniques with music therapy interventions to address non-musical goals.

Interventionists. Data collection and the music therapy intervention were implemented by the researcher and a research assistant, both of whom are board-certified music therapists who have undergone advanced clinical training in the use of music therapy in pediatric medical settings. For the purposes of this article, the author and the research assistant will be referred to collectively as "clinician-researchers." Only one clinician-researcher was present for each immunization. The clinician-researchers practiced the songs utilized in the study together and reviewed the music therapy treatment protocol to ensure consistency.

The author served as the music therapist for 48 of the participants (23 experimental and 25 control), whereas the board-certified music therapist who served as a research assistant served as a music therapist for 10 of the participants (six experimental and four control). The participation of two clinician-researchers was done in part because of time constraints on the part of the author, and in part to help control for experimenter effects. Due to scheduling constraints, it was not possible for the clinician-researchers to see an equal number of participants.

Music selection, content, delivery, materials, and strategies. Music was selected by the clinician-researchers based on assessment of the patient's needs and musical preferences. The songs used consisted of age-appropriate children's songs, some widely known by young children and some that were likely to be unfamiliar. Live music was delivered by the clinician-researchers, although patients and parents were encouraged to make music as well by singing and playing instruments when possible.

Materials used in the intervention included a full-sized classical guitar, plastic maracas, lollipop drums, tambourines, castanets, a rainstick, an ocean drum, and children's books.

The music therapy intervention included different songs and cognitive-behavioral techniques within each phase of the medical procedure, consistent with the recommendations of Blount et al. (2009). During the preparatory phase, the clinician-researcher presented an introductory song, a song to teach deep breathing, information provision, and additional songs. Deep breathing and actively engaging in music are considered forms of behavioral distraction, whereas providing information to help prepare the child for the procedure is a cognitive technique. During the procedure phase, the clinician-researcher provided coaching and active engagement in music as behavioral distraction, in addition to engaging children in non-procedural talk about the music as a form of cognitive distraction. During the recovery phase, the clinician-researcher presented a new instrument and additional songs to provide distraction. After the child had recovered and no longer displayed distress behaviors, the clinician-researcher presented a goodbye song to aid with completion of the procedure. Additional details of the music therapy intervention strategies and content are described in Figure 2.

Outcome Measures

Child coping/distress and parent/nurse coping-/distress-promoting behaviors. The Child-Adult Medical Procedure Interaction Scale-Revised (CAMPIS-R) (Blount et al., 1989) was used to measure child distress and coping behaviors and adult distress- and coping-promoting behaviors. Definitions of behaviors assessed by the CAMPIS-R were generated by the research of Blount and colleagues, in which they performed time lag analyses on videos of children undergoing medical procedures to determine which adult behaviors tended to precede child distress and coping behaviors. Child distress behaviors include crying, screaming, verbal resistance, and verbal expressions of fear or pain. Adult distress-promoting behaviors include making reassuring comments, apologizing, making empathic statements, giving control to the child, and criticizing. Child coping behaviors include audible deep breathing, non-procedural talk by the child, and the use of humor by the child. Adult coping-

promoting behaviors include non-procedural talk or humor to the child and commands to use coping strategies. See Blount et al. (1990) for complete descriptions of behaviors measured by the CAMPIS-R.

Treatment Phase	Music Therapy Interventions and Songs	Purpose
Preparation	• Singing, instrument play. **Songs:** Upbeat, child-selected songs (e.g. *Old MacDonald*; *Twinkle, Twinkle, Little Star*) with child-selected instruments (e.g. maraca, tambourine). • Singing a song that contains cues for deep breathing. **Song:** *Yodeling Song* (based on the song *Oh, An Austrian Went Yodeling*) • Treatment-based education through music. **Song:** *Sparky, the Dragon* (by April Malone) • Additional singing, instrument play. **Songs:** Upbeat, familiar, participatory child-selected songs (e.g. *Shake my Sillies Out*, *If All the Raindrops*) with child-selected instruments (e.g. lollipop drum, maracas, castanets).	• Building rapport, normalizing the environment, providing opportunities for autonomy. • Teaching coping techniques (deep breathing), engaging in imaginative play. • Providing basic information about the procedure, practicing coping techniques (deep breathing, distraction). • Behavioral distraction, normalizing the environment, providing opportunities for autonomy.
Procedure	• Singing a song that contains cues for deep breathing; engaging in non-procedural talk related to the song. **Song:** *Yodeling Song*	• Providing distraction and coaching in the use of coping techniques.
Recovery	• Singing, instrument play, iso-principle. **Songs:** Novel song performed with tempo rubato and pauses (*The Beads go 'Round and 'Round*, based on *Jarabe Tapatío*, the "Mexican hat dance") paired with a novel, colorful instrument (rainstick or ocean drum), to engage the child's attention, followed by progressively slower familiar songs (e.g. *Rain, Rain, Go Away; You Are My Sunshine*). • Singing a goodbye song that focuses on the fun aspects of the music therapy experience. **Song:** *Goodbye (Bop Shoo Woo!)* (by Jen Reece)	• Focusing the child's attention on a novel, engaging activity to decrease distress and promote recovery (distraction). • Providing closure, helping the child resume normal activities.

Figure 2. Details of the music therapy intervention.

In reviews of assessments of pediatric coping, stress, and pain, the CAMPIS-R has been classified as a well-established assessment that guides treatment (Blount et al., 2008; Cohen et al., 2008). The CAMPIS-R has been reported to have high levels of convergent and predictive validity, as well as sensitivity to change (Blount et al., 1997; Blount et al., 2008). Inter-rater reliability for the CAMPIS-R (calculated using Cohen's kappa) was reported by Blount et al. (1997) to be between .72 and .91 for child behaviors, between .65 and .82 for parent behaviors, and between .88 and .92 for staff behaviors. The lowest reliability was reported for child neutral (.72), parent neutral (.65), and parent coping promoting (.78) behaviors; reliability for all other behaviors exceeded .80.

Parent ratings of child pain. The University of California at Los Angeles (2004) Universal Pain Assessment Tool was used to measure parents' ratings of their child's pain. Chan (2007) reported high content validity (1.00) and test-retest reliability (.89) for this measure, which is widely used in clinical settings. The Universal Pain Assessment Tool combines the Wong-Baker Facial Grimace Scale (Wong & Baker, 1988), a verbal descriptor scale, an activity tolerance scale, and a 10-point Likert-type scale. Although many studies on interventions have utilized self-report measures of pain for young children, researchers often report that preschool children have difficulty understanding how to use these measures and/or require extensive training to use them appropriately (Chen, Zeltzer, Craske, & Katz, 1999). Parents' ratings of their child's pain have been used as alternatives to children's reports of pain in research on pediatric medical procedures (Schechter, Bernstein, Beck, Hart, & Scherzer, 1991), and high correlations have been reported between children's and parents' ratings of the pain children experience (Schneider & LoBiondo-Wood, 1992). Uman and colleagues (2013) cautioned that "…self-reports of pain from preschoolers should be interpreted with caution and complementary observational assessments (for example, by parents) are also recommended" (p. 6). In addition, the author of the present study hypothesized that asking the child to rate their pain after the procedure would cause them to focus on the pain rather than distracting them from the pain during the recovery phase of the procedure. Due to the age of children in this study, the lack of time to train children to use self-report measures of pain, and the

researcher's desire not to add to participants' perception of pain and distress, the parents' rating of their child's pain was selected as a dependent measure rather than the child's self-report pain rating.

Parent ratings of child distress. Upon completion of the procedure, all parents were asked to complete a researcher-created questionnaire modeled after that used by Manimala, Blount, and Cohen (2000), comparing their child's present level of distress to previous medical experiences using a 7-point Likert-type format (-3 = much worse, -2 = worse, -1 = slightly worse, 0 = the same, 1 = slightly better, 2 = better, and 3 = much better).

Parent perception survey. After their child's procedure, parents of children who received music therapy were asked to complete a survey that included four questions: (1) "Did your child benefit from music therapy?" (2) "Did you benefit from music therapy?" (3) "Did music therapy improve your perception of this facility?" and (4) "Would you like to receive music therapy services again if you return to this facility?" A similar survey was used by Barton (2008) and Chorna (2010) to assess the satisfaction of hospital patients and their parents upon receiving music therapy during a medical procedure.

Procedure

Healthcare staff at the three sites notified the clinician-researcher assigned to that facility on a particular day when a child who met study inclusion criteria had an appointment scheduled for an immunization. When patients who met the criteria for inclusion in the study came to their doctor's office for their appointment, a clinician-researcher met with each child's parent or legal guardian prior to the procedure to explain the nature of the study, obtain informed consent, and obtain demographic information. Children also gave verbal assent to participate and be videotaped and, if assigned to the music group, were asked if they would like to participate in music. The nature of the study was also explained to the nurses who would be performing immunizations for children at each facility, and their consent was obtained and documented prior to participation in the study.

Each parent was asked to fill out a demographic inventory, indicating the child's date of birth, gender, and number of previous doctor visits (using one of three categories: (a) fewer than 10, (b) 11 to 20, or (c) 21 or more). Since differences in children's coping abilities have been shown to impact

responsiveness to coping interventions (Blount et al., 1991), parents were also asked to rate their child's reaction to previous doctor visits using a 7-point Likert-type format (-3 = very negative, -2 = negative, -1 = slightly negative, 0 = no reaction, 1 = slightly positive, 2 = positive, 3 = very positive), which was adapted from an assessment of pediatric medical history used by Bijttebier and Vertommen (1998). Children whose parents rated their reaction to previous doctor visits at 0 or higher were considered "low distress," whereas children whose parents rated their distress at less than 0 were considered "high distress." A clinician-researcher then randomly assigned each participant to a music therapy intervention group or a standard care control group, using a separate randomly generated enrollment list for high distress and low distress children to assure that a comparable number of high distress and low distress children would be assigned to each group. Randomization was achieved using the web-based randomization program www.random.org. Full allocation concealment was not possible in the present study due to time constraints and the stratified randomization technique. Although clinician-researchers may have been aware of upcoming group assignments, participants and healthcare staff were not aware of group assignments until after the parents/guardians had signed consent forms.

A clinician-researcher met with children and parents/guardians in the music therapy intervention group prior to the immunization to develop rapport and assess music preferences. The clinician-researcher set up a video camera on a tripod in the treatment room where the procedure was to take place, which recorded the child, as well as the parent(s), the clinician-researcher, and the nurse(s) during the procedure. The clinician-researcher taught children in the music therapy group cognitive-behavioral coping skills and engaged in music activities immediately before, during, and after the immunization.

For participants in the standard care control group, the clinician-researcher remained in the room to hold and monitor the video camera, but did not interact with the child, child's parents, or nurse(s). Upon completion of the procedure, all parents were asked to rate their child's pain during the immunization and level of distress compared to previous medical experiences, and were given the opportunity to write comments about their child's experience. Parents of children in the music therapy

group were also asked to complete a brief survey, indicating their perceptions of the music therapy treatment.

Data Analysis

Videos of procedures were transcribed by three research assistants (graduate or senior undergraduate music therapy majors) who underwent a three-month training period, during which they met once a week to receive instruction and practice in transcribing videos and coding them using the CAMPIS-R. Training continued until observers achieved at least 80% agreement in coding practice videos. Each transcript was reviewed for accuracy by two research assistants and the author. Research assistants then independently reviewed each transcript while watching the corresponding video and classified each statement on the transcript using the CAMPIS-R.

For video analysis purposes, treatment was divided into three phases. The first phase (preparation) began when the nurse entered the treatment room to administer the immunization(s) and ended when the child was appropriately positioned for the procedure. The second phase (procedure) began immediately after the child was positioned for the procedure and ended when the final needle injection had occurred. The third phase (recovery) began at this point and ended either when the child demonstrated their final distress behavior or when the child left the treatment room, whichever occurred first.

A power analysis was conducted to determine the necessary sample size for this study. It was determined that in order to detect an effect size of 0.7 with a power level of 0.8 and an alpha level of .05 (one-tailed), 52 participants were needed. However, since several participants who completed the present study had some missing data (see Figure 1), a total of 58 participants were recruited for the study to ensure at least 52 complete data sets. Participants with missing data were included in the portions of the analysis for which data were available.

Distributions for rates of distress, coping, distress-promoting, and coping-promoting behaviors were examined. Data for rates of behavior were positively skewed due to a high number of zero values. Because the data were not normally distributed, non-parametric tests were used to analyze data. A series

of Mann-Whitney *U* tests was used to determine whether the music therapy and the control group differed with regard to rates of coping, distress, coping-promoting, and distress-promoting behaviors, as well as parent ratings of distress and pain. Effect sizes (*r)* were calculated based on the *z*-scores associated with the Mann-Whitney *U* values, using the formula described by Field (2009).

Results

Demographic information was examined to determine whether the music therapy group and the control group were different with regard to healthcare site, gender, music therapist, age, number of shots, number of previous doctor visits, and reactions to previous doctor visits. No significant differences were found between the experimental and control groups for any demographic factors ($p > .05$). The length of each phase of the treatment procedure was recorded (in seconds) for each participant. No significant differences were found between the music therapy group and the control group with regard to the length of the preparation phases, procedure phase, or recovery phase, $p > .05$. The groups did not differ significantly in the total lengths of procedures. Demographic information and lengths of treatment phases can be seen in Table 1.

Inter-Observer Reliability

Inter-observer reliability was calculated by having a second research assistant independently code 20% of the videos, using the formula: agreements divided by the sum of agreements plus disagreements (Madsen & Madsen, 1998). Reliability coefficients ranged from .80 to .91 with a mean of .85, which was deemed an acceptable level of reliability and is comparable to the levels of inter-rater reliability reported by Blount et al. (1997) for the CAMPIS-R.

Children's Behaviors

Children in the music therapy group showed significantly higher rates of coping behaviors during the preparation phase, $z = 3.18$, $p = .001$, $r = .42$, and the procedure phase, $z = 3.16$, $p = .001$, $r = .42$, and significantly lower rates of distress behaviors during the procedure phase, $z = -2.76$, $p = .003$, $r = -0.37$, and the recovery phase, $z = -2.99$, $p = .001$, $r = -0.40$, compared to children in the control group.

Table 1

Demographic Information and Lengths of Treatment Phases

Demographic	Music Therapy (n = 29)	Control (n = 29)	Total (N = 58)
Healthcare Site			
Site One	6	3	9
Site Two	14	16	30
Site Three	9	10	19
Number of Shots Administered			
One	9	8	17
Two	1	3	4
Three	3	5	8
Four	11	12	23
Five	5	1	6
Guardian Present			
Mother	22	24	46
Father	6	6	12
Other (grandmother, aunt)	3	1	4
Number of Previous Doctor Visits			
Fewer than 10	6	8	14
11 to 20	19	17	36
21 or more	4	4	8
High Distress			
Male	3	7	10
Female	7	3	10
Low Distress			
Male	7	10	17
Female	12	9	21
Treatment Phase	Music Therapy (n = 29) [a]	Control (n = 27) [a]	
Preparation	75.79 (53.06)	71.56 (33.15)	
Procedure	126.83 (123.61)	99.52 (78.28)	
Recovery	65.17 (70.17)	63.33 (52.09)	
Total	267.45 (204.21)	234.41 (110.63)	

[a] Means (standard deviations) of treatment phase lengths are reported in seconds. High variability in treatment phase length is likely due to the number of shots administered, which ranged from one to five.

No significant differences were found between groups in rates of child coping behaviors during the recovery phase or rates of child distress behaviors during the preparation phase, $p > .05$.

Parents' Behaviors and Ratings of Pain and Distress

Parents of children in the music therapy group showed significantly lower rates of distress-promoting behaviors during the preparation phase, $z = -2.61$, $p = .005$, $r = -0.35$, the procedure phase, $z = -2.80$, $p = .003$, $r = -0.37$, and the recovery phase, $z = -2.99$, $p = .001$, $r = -0.40$. Differences in the rates of parent coping-promoting behavior did not reach statistical significance during the preparation, procedure, or recovery phases, $p > .05$. Parents of children in the music therapy group rated their children's level of distress as significantly better than during previous procedures, $z = 3.57$, $p < .001$, $r = 0.48$, compared to parents of children in the control group. Parents of children in the music therapy group rated their children's distress relative to previous medical experiences at 1.18 ($SD = 1.54$), which falls between 1 (slightly better), and 2 (better) on the 7-point Likert-type item ranging from -3 to 3. In contrast, parents in the control group rated their children's distress relative to previous medical experiences at -0.41 ($SD = 1.60$), which falls between 0 (the same) and -1 (slightly worse) using the same 7-point Likert-type format.

There was no significant difference between groups in parents' ratings of their children's pain. On average, parents of children in the music therapy group rated their children's pain at 3.18 ($SD = 1.88$) on a scale of 0 to 10, with 10 being the worst pain. Parents of children in the control group rated their children's pain at 4.46 on average ($SD = 3.10$). Scores between 3 and 6 are considered "moderate pain" (University of California at Los Angeles, 2004). Means, standard deviations, and Mann-Whitney U test results for child/parent behavior and parent ratings of distress and pain are shown in Table 2.

Parent Perceptions of Music Therapy

Parents of children in the music therapy group responded to four questions related to their perceptions of music therapy treatment. The majority of parents whose children received music therapy reported that their child benefited from music therapy ($n = 24$, 83%), that they (the parent) benefited from music therapy ($n = 24$, 83%), that music therapy improved their perception of the facility ($n = 21$, 72%),

Table 2

Means, Standard Deviations, and Mann-Whitney Test Results for Child and Parent Behaviors and Parent Ratings of Pain and Distress

	Music Therapy		Control						
Outcome Measure	*M*	*SD*	*M*	*SD*	*N*	*z*	*p*		*r*
Child Coping Behaviors									
Preparation	4.78	3.09	2.21	2.84	(29, 27)	3.18	<.01	**	0.42
Procedure	3.39	2.43	1.68	2.43	(29, 27)	3.16	<.01	**	0.42
Recovery	1.02	1.53	1.29	1.46	(29, 27)	-0.66	.25		
Child Distress Behaviors									
Preparation	0.84	1.81	3.89	6.16	(29, 27)	-1.56	.06		
Procedure	5.97	4.52	11.43	7.50	(29, 27)	-2.76	<.01	**	-0.37
Recovery	5.91	3.88	13.60	14.06	(29, 27)	-2.99	<.01	**	-0.40
Parent Coping-Promoting Behaviors									
Preparation	0.81	1.38	0.72	1.08	(29, 27)	0.02	.49		
Procedure	1.48	1.97	2.05	1.96	(29, 27)	-1.31	.10		
Recovery	1.75	2.46	2.05	3.30	(29, 27)	0.20	.42		
Parent Distress-Promoting Behaviors									
Preparation	0.00	0.00	1.09	2.46	(29, 27)	-2.61	<.01	**	-0.35
Procedure	0.70	1.51	3.46	4.65	(29, 27)	-2.80	<.01	**	-0.37
Recovery	1.52	4.35	4.48	5.62	(29, 27)	-2.99	<.01	**	-0.40
Parents' Ratings									
Child Distress	1.18	1.54	-0.41	1.60	(28, 29)	3.57	<.01	**	0.48
Child Pain	3.18	1.88	4.46	3.10	(28, 27)	-1.55	.06		

** $p < .01$.

and that they would like to receive music therapy services again upon return to the same facility (n = 23, 79%). Results from parent perception surveys are shown in Table 3. Comments written after the procedure by parents of children in both groups are shown in Figure 3.

Table 3

Responses to Parent Perception Survey Questions (n = 29)

Question	Yes, Very Much	Yes	No Opinion	Not Really	Not at All
Did your child benefit from music therapy?	13 (45%)	11 (38%)	2 (7%)	3 (10%)	0
Did you benefit from music therapy?	15 (52%)	9 (31%)	3 (10%)	2 (7%)	0
Did music therapy improve your perception of this facility?	12 (41%)	9 (31%)	4 (14%)	4 (14%)	0
	Yes		Maybe	No	
Would you like to receive music therapy services again if you return to this facility?	23 (79%)		6 (21%)	0	

Comments from Parents of Children in the Music Therapy Group
I loved it, should definitely be a part of all immunizations.
Kids had fun.
Thank you.
Thank you- she loved it!
Will talk to son to see what he thought. A little concerned it might draw out the vac [sic] process rather than just keep it short and sweet. Nursing staff would have better idea of whether it helps.
Great job!
[Music therapist] is great! In the past, pain was a 12.
I really love it and so did [child]. Thank you so much!
I think it would have been different if their father were here. I'm a stay-at-home mom and they react differently to him.
Didn't help during the immunization, but helped ease her anxiety leading up to the shots and shortened recovery time.
Comments from Parents of Children in the Control Group
Seeing the needles.
He gets hysterical when a doctor does any work on him.
[Child] is just frightened of any doctor visit, they are all equally stressful for her.
He never has a bad reaction. He isn't scared of needles, apparently.
Hates shots. Had bad experience with previous visits so not sure how he acts because I'm never really in the room. But he cried pretty hard this time.

Figure 3. Comments written by parents.

Nurses' Behaviors

No significant differences were found between groups in the rates of nurse coping-promoting or distress-promoting behaviors in any of the three treatment phases, $p > .05$. Table 4 shows means, standard deviations, and Mann Whitney *U* test results for nurse behavior.

Table 4

Means, Standard Deviations, and Mann-Whitney U Test Results for Nurse Behaviors

		Music Therapy		Control				
Behavior	Phase	*M*	*SD*	*M*	*SD*	*N*	*z*	*p*
Nurse Coping-Promoting Behaviors	Preparation	3.32	6.01	3.73	7.58	(29, 27)	-0.02	.49
	Procedure	4.14	4.81	4.28	5.87	(29, 27)	0.16	.44
	Recovery	2.45	4.61	3.95	5.17	(29, 27)	-1.51	.07
Nurse Distress-Promoting Behaviors	Preparation	0.04	0.21	0.48	1.45	(29, 27)	-0.95	.17
	Procedure	1.62	2.16	2.59	3.04	(29, 27)	-1.28	.10
	Recovery	3.25	6.41	4.22	5.83	(29, 27)	-1.54	.06

Discussion

Children in the music therapy group showed significantly greater rates of coping behaviors during the preparation phase and the procedure phase compared to children in the control group, but not during the recovery phase. The clinician-researchers observed that there was greater variability in events that occurred during the recovery phase compared to the preparation and procedure phases. The lack of difference in children's coping behaviors during the recovery phase may be attributable to the way the recovery phase was defined. Since the recovery phase was determined to be over once the child appeared calm, it is possible that additional coping behaviors were exhibited after data collection ended.

Children in the control group showed significantly higher rates of distress behaviors during the procedure phase and the recovery phase compared to children in the music therapy group. Rates of distress behaviors increased from the preparation phase to the procedure phase for both groups and from the procedure phase to the recovery phase for the control group but not for the music therapy group. This indicates that children in the music therapy group did not show the same increase in distress behaviors over the course of the session that children in the control group demonstrated.

Research has shown that parent behavior during medical procedures influences child distress (Blount et al., 1989, 1990, 1991; Frank et al., 1995). In this study, parents whose children received music therapy showed significantly lower rates of distress-promoting behavior during all phases, although no

significant differences were found between groups in the rates of parent coping-promoting behavior. Perhaps parents engaged in fewer distress-promoting behaviors because they were observing their child's interactions with the music therapist. The lack of differences in coping-promoting behaviors indicates that parents may have taken a passive role when the music therapist was present. Nevertheless, parents of children in the music therapy group showed more coping-promoting behaviors than distress-promoting behaviors during all three phases, while the opposite was true for parents of children in the control group, who showed more distress-promoting behaviors than coping-promoting behaviors during preparation, procedure, and recovery.

Comments from parents whose children received music therapy included expressions of gratitude and favorable impressions of music therapy, in addition to some constructive feedback. One parent expressed concern that music therapy might make the vaccination process longer rather than keeping it "short and sweet." Although the average length of the procedure did not differ significantly between groups, it is important for music therapists providing procedural support to be mindful of parents' time constraints, particularly for those receiving care in outpatient settings. For example, music therapists providing procedural support in outpatient settings could make note of how long patients typically wait in the treatment room prior to their procedures and then carefully design music therapy interventions to fill, rather than extend, that time. Another parent commented that music therapy did not help during the immunization, but that it did help ease the child's anxiety in the preparation phase and shortened recovery time. Comments from parents of children in the control group tended to focus on their child's fear, stress, anxiety, and previous bad experiences with doctor visits, although one parent commented that the child never has a bad reaction and does not appear to be afraid of needles.

No differences were found between groups in nurses' behaviors. This lack of difference could be due to the responsibilities that nurses have in administering immunizations. Perhaps the nurses in this study were focused on successfully completing the procedure to such a degree that the presence of the music therapy intervention did not have a significant impact on their behavior.

Limitations

The lack of allocation concealment in the present study increases the potential for bias. The threat of experimenter effects was minimized, although not eliminated, by having two different music therapists administer the treatment, with each music therapist working with children under both conditions. However, since one therapist performed more of the treatments than the other, it was not possible to compare outcomes statistically to examine experimenter effects. Replications of the present study could include analysis of experimenter effects. Although one of the clinician-researchers was present during each standard-care procedure, they were not engaged in the role of providing support to the patient; therefore, it was not possible to determine whether outcomes for the treatment group were the result of the music or the presence of a therapist providing support. There is also the risk of bias due to attrition and selection bias. Ten parents chose not to participate in the study because they did not want their child to be video recorded; it is possible that the parent/child dyads who did not participate in the study would have responded differently to the presence of a music therapist.

Suggestions for Future Research

In the present study, several nurses made requests for music therapy services for children who did not meet the study's inclusion criteria due to age. When the author came to a healthcare site after not having been there the previous day, nurses frequently commented, "We needed you here yesterday" to help a child who showed distress during immunizations. Although these anecdotes suggest that nurses found the intervention helpful, surveying nurses regarding their perceptions of music therapy interventions for children undergoing immunizations is an important area for future research.

Following-up with children who previously received music therapy during an immunization would be helpful to determine whether these children show differences in behaviors during subsequent immunizations. Future research should also examine the effects of live, cognitive-behavioral music therapy procedural support interventions on children of different ages using music, language, and interactions that are appropriate for the child's developmental stage. The short-term and long-term effects

of having music therapists help train parents to coach their children in the use of procedural coping skills also warrant investigation.

Implications for Practice

In a previous study by Cohen et al. (2000), parents who had not received instruction in the use of coping-promoting techniques tended to display distress-promoting behaviors during their child's immunization, as did the parents of children in the control group in the present study. The lower rates of parent distress-promoting behaviors noted for parents of children in the present study's music therapy group, in spite of the fact that parents did not receive training prior to the procedure, is a clinically important finding. In the present study, parents used low rates of coping-promoting behaviors, indicating that additional training may be necessary to teach parents ways to help their children cope with medical procedures. Cognitive-behavioral music therapy may be a beneficial alternative or addition to parent-training programs designed to teach parents how to coach children during medical procedures.

The differences in child behavior noted during the three phases of the immunization process in the present study (preparation, procedure, and recovery) highlight the importance of paying attention to the needs of patients immediately before and after medical procedures, rather than focusing solely on the procedure phase. It is also important to note that adult behaviors that have been shown to promote distress in children during medical procedures (such as reassuring comments and empathic statements) may not necessarily be distress-promoting behaviors at other times. Because of time and scheduling constraints, the present study, which took place in an outpatient setting, only focused on the period of time immediately before, during, and after the procedure. Music therapists providing procedural support in other settings, such as inpatient facilities, may have the opportunity to interact with patients hours, days, or even weeks before their procedures, extending the preparatory phase. Empathic statements and reassuring comments made to pediatric patients well in advance of the procedure may have a different effect than they do during the procedure itself, and may not be distress-promoting. Music therapists providing procedural support should be mindful of the timing of the interventions they administer and use techniques that are appropriate for each phase of medical procedures.

This study demonstrates that the use of an evidence-based, developmentally appropriate, cognitive-behavioral intervention using live music can effectively facilitate the delivery of immunizations for young children. Learning coping behaviors during an early age has the potential to help children develop healthy attitudes about medical care. When incorporated with standard care during immunizations for young children, live music therapy has the potential to normalize and humanize a potentially threatening environment, improving the experience for children, their parents, and members of the healthcare staff.

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