Interactive Music Therapy as a Treatment for Preoperative Anxiety in Children: A Randomized Controlled Trial

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In this study, we examined whether interactive music therapy is an effective treatment for preinduction anxiety. Children undergoing outpatient surgery were randomized to 3 groups: interactive music therapy ($n = 51$), oral midazolam ($n = 34$), or control ($n = 38$). The primary outcome of the study was children's perioperative anxiety. We found that children who received midazolam were significantly less anxious during the induction of anesthesia than children in the music therapy and control groups ($P = 0.015$ and $P = 0.005$, respectively). We found no difference in anxiety during the induction of anesthesia between children in the music therapy group and children in the control group. An analysis controlling for therapist revealed a significant therapist effect; i.e., children treated by one of the therapists were significantly less anxious than children in the other therapist group and the control group on separation to the operating room (OR) ($P < 0.05$) and on entrance to the OR ($P < 0.05$), but not on the introduction of the anesthesia mask (P = not significant). Children in the midazolam group were the least anxious even after controlling for therapist effect ($P < 0.05$). We conclude that music therapy may be helpful on separation and entrance to the OR, depending on the therapist. However, music therapy does not appear to relieve anxiety during the induction of anesthesia.

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Many children and adults who undergo surgery experience significant anxiety in the preoperative holding area and during the induction of anesthesia (1,2). Both behavioral and pharmacological modalities are currently used to treat this perioperative anxiety. Recently, music has gained popularity as a part of complementary medical therapies directed at patients undergoing medical and surgical procedures (3,4). In fact, the American Music Therapy Association indicates that perioperative music can result in a reduction of anxiety and a positive change in mood (5). In general, the adult medical literature substantiates the relationship between music and the reduction of surgery-related anxiety (3,6–8), despite numerous methodological flaws (3,9). Music therapy has been described as an interactive relationship between the therapist and patient that is based on communication through music (10). Most reported studies of music therapy in the medical literature, however, describe interventions that consist of patients passively listening to music. It is interesting to note that results from a meta-analytic review appear to indicate that studies that use interactive music therapy, although significantly fewer in number, show higher overall effect sizes when compared with studies of taped-listening music therapy (8). This apparent superiority may result from the advantages of interactive music therapy as described by Barrera et al. (9): more personalized effect, greater relevance, and better potential for engagement of the patient.

A recent issue of the *Journal of the American Medical Association* underscored the importance of introducing evidence-based medicine into the domain of music therapy (11), reiterating a 1996 call to demonstrate that music therapy is effective and efficient (10). Previously we have used rigorous methodology, including a randomized controlled design, validated outcome measures, and high statistical power, to address the issue of decreased sensory stimuli in the operating room (OR) plus background classical music for children undergoing the induction of anesthesia (12). We demonstrated that such an intervention is indeed effective in

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reducing anxiety during the induction of anesthesia. This study is a randomized controlled trial that examines whether interactive music therapy is effective in reducing preoperative anxiety in children undergoing outpatient elective surgery.

Methods

This randomized, controlled study was conducted with children undergoing general anesthesia and elective outpatient surgery. Consecutive patients aged 3–7 yr old, ASA physical status I–II, scheduled to undergo general anesthesia and elective outpatient surgery were considered for enrollment. Children were excluded from participation if they had any history of chronic illness, prematurity, or developmental delay or significant hearing or visual impairments. All anesthesia inductions were performed by a group of six pediatric anesthesiologists. The IRB approved the study protocol, and informed consent was obtained from the parents of each subject.

The primary end-point of this study was the anxiety manifested by children undergoing the induction of anesthesia. Children's compliance during the induction of anesthesia was a secondary end-point. Patients were assigned to one of three groups by using computer-generated random assignment:

1. Control group: children in this group were not offered midazolam or music therapy.
2. Music therapy group: children in this group received interactive music therapy as detailed below and in Appendix 1.
3. Midazolam group: children in this group received oral midazolam 0.5 mg/kg 30 min before surgery up to a maximum of 20 mg.

Two music therapists participated in this study. Music Therapist 1 trained Music Therapist 2 to perform the intervention and checked adherence for five sessions before data collection began. The music therapy intervention was semistructured; it began in the holding area and extended for approximately 20–30 min (mean ± SD, 32 ± 15 min). All variation in session length was due to OR timing constraints. A music therapist then accompanied each child who participated in the intervention into the OR. Music therapy ended on completion of the induction of anesthesia. Children's parents were present in the preoperative holding area during the music intervention but were separated from their child before the child entered the OR with the music therapist. Please see Appendix 1 for a detailed description of the music intervention.

Assessors were trained by using videotapes of children undergoing the induction of anesthesia to reliably measure children's anxiety with the Yale Preoperative Anxiety Scale (mYPAS). Interrater and intrarater reliability of the assessors was assessed with weighted κ statistics for overall chance-corrected agreement (K_w). Agreement in the various domains of the mYPAS between and within the assessors ranged from 0.91 to 0.96. Assessors were kept blinded to the purpose of the study and the groups involved. All children in the study were videotaped in the holding area until the induction of anesthesia. These blinded assessors then used the videotapes to rate children's anxiety for this study. The same assessor ranked the child's anxiety at the various time points.

The mYPAS (13,14), an observational instrument, quantifies children's anxiety in the preoperative area and during the induction of anesthesia. The instrument contains 27 items in 5 categories that indicate preoperative anxiety in children: activity, emotional expressivity, state of arousal, vocalization, and use of parents. The mYPAS has good to excellent reliability and validity (13,14).

The Induction Compliance Checklist (ICC), an observational instrument, was previously developed by our laboratory to describe the compliance of a child undergoing the induction of anesthesia. This instrument has very high interclass r values both within (0.998) and between (0.978) observers (15).

The EASI (emotionality, activity, sociability, and impulsivity) Scale of child temperament, a parental report instrument, assesses four temperament categories—emotionality, activity, sociability, and impulsivity—in children and is widely used in the medical and psychological literature (16).

The State-Trait Anxiety Inventory (STAI), a self-report anxiety inventory, contains 2 separate 20-item subscales that measure trait (baseline) and state (situational) anxiety. It has been used in more than 1000 studies published in peer-reviewed literature (17).

After recruitment and informed consent, demographic data, temperament (EASI) of the child, and trait anxiety (STAI) of the parent were obtained. Also, parents rated the quality of their child's previous medical encounters (visual analog scale of 0–100; higher scores indicate higher anxiety at previous medical encounters) and noted whether their child had attended the voluntary preoperative preparation program.

All children in the study were videotaped while in the holding area until the induction of anesthesia. The music group received the music therapy intervention, and the premedication group received midazolam. The control group received standard medical care and did not receive a sedative.

For all groups, parents accompanied their child to the OR doors before separation. The music therapist accompanied children in the music therapy group into the OR and continued the music intervention throughout. Parental anxiety was assessed after the separation

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process (STAI). If a child exhibited extreme anxiety (as determined solely by the attending anesthesiologist), parental presence during the induction of anesthesia was offered as rescue therapy. The music intervention continued throughout this stage.

Anesthesia was induced with oxygen/N_2O and sevoflurane administered via a scented mask. The music intervention continued until the anesthesiologist indicated to the therapist that the child was "asleep." It is important to note that the volume of the music intervention was adjusted during induction so as not to compromise the medical management of the child. Videotaping of all children continued throughout the induction of anesthesia to facilitate anxiety (mYPAS) and compliance (ICC) ratings while maintaining the blinding of the assessors.

Trained assessors (see above) who were blinded to the purpose of the study, the design of the study, and to group assignment as much as was possible rated the videotapes. Although the music therapist was occasionally visible in the videotapes, we believe that the potential effect on the assessors, who were blinded to the purpose of the study, was negligible.

This sample size was based on investigations involving music and children (18,19). These investigations reported a change of 25%–30% in the anxiety level of the children. Because we previously reported a mean anxiety score of 50 ± 12 (mYPAS score; mean ± SD) during the introduction of an anesthesia mask in children undergoing the induction of anesthesia, we expected mYPAS scores of 40 ± 9.4 in the intervention group. Thus, a sample size of 32 subjects in each group was calculated to be sufficient to detect a 25% difference in anxiety level with a power of 0.95 and an α of 0.05. However, to ensure an adequate number of cases in each of the 2 music therapists' groups, we randomized more patients to the music therapy group than to the control group or midazolam group via permuted block randomization in a 1:1:1.5 ratio with a projected n of 32 per cell for the control and midazolam groups and 48 for the music therapy group. Differences among groups were analyzed with one-way analysis of variance (ANOVA) or Student's t-test for continuous variables and with χ^2 tests for categorical variables. Changes in anxiety over time were analyzed with two-way repeated-measures ANOVA. Data are reported as mean ± SD. Significance was accepted at $P = 0.05$. Data were analyzed with SPSS 11.0 (SPSS Inc., Chicago, IL).

Results

Children's and parents' baseline demographic and personality characteristics are presented in Table 1. The 3 groups were similar with regard to variables such as age, sex, temperament, parental state and trait anxiety, previous surgery experience, anxiety during previous medical encounters, and participation in the voluntary preparation program. There were no differences in the observed anxiety level (mYPAS) among the 3 groups when children entered the preoperative holding area ($P = 0.61$) (Table 1).

Using two-way repeated-measures ANOVA, we analyzed changes in the observed anxiety level by group along four time points: holding area (T_1), separation to the OR (T_2), entrance to the OR until introduction of the anesthesia mask (T_3), and introduction of the anesthesia mask until anesthesia was induced (T_4). We found that the anxiety within subjects increased over the four time points ($F_{3,111} = 16.17$; $P = 0.001$). We also found a group × time effect, indicating that changes in observed anxiety differed significantly among the 3 groups ($F_{6,339} = 2.20$; $P = 0.042$) (Fig. 1). *Post hoc* analysis (Bonferroni) demonstrated that the midazolam group was significantly less anxious overall than the music therapy and control groups ($P = 0.019$) and that anxiety levels of children in the music therapy and control groups did not differ significantly ($P = 0.83$) (Fig. 1).

We next compared the baseline characteristics of the Therapist 1 group with those of the Therapist 2 group. The two groups were similar with regard to baseline variables such as age, temperament, previous surgery, and parental and child anxiety in the holding area (P = not significant). We examined the anxiety levels on separation and during the induction of anesthesia of children in the two therapist groups as well as children in the midazolam and control groups (Fig. 2). A one-way ANOVA showed significant differences among the various study groups (Fig. 2) (T_2: $F = 4.2$, $P = 0.008$; T_3: $F = 4.4$, $P = 0.006$; T_4: $F = 5.5$, $P = 0.002$). To localize the differences (while adjusting for multiple comparisons), we performed a Scheffé *post hoc* test. We found that on both separation to the OR and entrance to the OR, the anxiety of children in the midazolam group was significantly less compared with the anxiety of children in the control group (separation $P = 0.005$ and entrance $P = 0.003$) and the anxiety of children in the Therapist 1 group (separation $P = 0.007$ and entrance $P = 0.005$), but not compared with the anxiety of children in the Therapist 2 group (separation $P = 0.7$ and entrance $P = 0.06$). In contrast, on introduction of the anesthesia mask, the anxiety of children in the midazolam group was significantly less compared with the control group and the Therapist 1 and Therapist 2 groups ($P = 0.005$, $P = 0.003$, and $P = 0.01$). Direct comparison between the Therapist 1 and Therapist 2 groups revealed that children's anxiety scores were significantly lower in the Therapist 2 group during separation to the OR ($P = 0.034$) and on entrance to the OR ($P = 0.01$) (Fig. 2). Also, children who received the intervention from Therapist 2 were less anxious than the control group on separation ($P = 0.025$) and on

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Table 1. Demographic Characteristics of the Study Participants and Their Parents

Variable	Intervention group (n = 51)	Midazolam group (n = 34)	Control group (n = 38)	P value[a]
Child's age (yr)	5.6 ± 1.2	5.1 ± 0.9	5.5 ± 1.4	0.14
Child's temperament (EASI)				
Emotionality	11.0 ± 3.3	11.5 ± 4.0	10.3 ± 3.3	0.39
Activity	14.6 ± 4.7	15.6 ± 4.5	14.0 ± 3.8	0.35
Sociability	16.9 ± 3.8	16.7 ± 4.3	15.2 ± 4.4	0.14
Impulsivity	11.1 ± 3.6	11.5 ± 3.9	11.6 ± 3.7	0.76
Parent's trait anxiety (STAI-T)	35.7 ± 5.9	35.9 ± 7.1	36.0 ± 6.5	0.97
Parent's state anxiety (holding area; STAI-S)	42.3 ± 10.1	42.7 ± 10.3	42.6 ± 10.8	0.98
Previous medical encounters (VAS)	85.2 ± 18.6	87.7 ± 14.5	85.6 ± 15.6	0.76
Child's sex (M/F) (%)	64.8/35.2	64.7/35.3	64.1/35.9	0.99
Previous surgery (no/yes) (%)	65.4/34.6	61.8/38.2	69.2/30.8	0.8
Preparation program (no/yes) (%)	68.5/31.5	66.7/33.3	69.2/30.8	0.97
Child's anxiety (holding area; mYPAS)	33.8 ± 12.2	31.2 ± 10.5	33.2 ± 13.1	0.61

EASI = Emotionality, Activity, Sociability and Impulsivity; STAI = State-Trait Anxiety Inventory; VAS = visual analogue scale; mYPAS = modified Yale Preoperative Anxiety Scale.
[a] One-way analysis of variance.

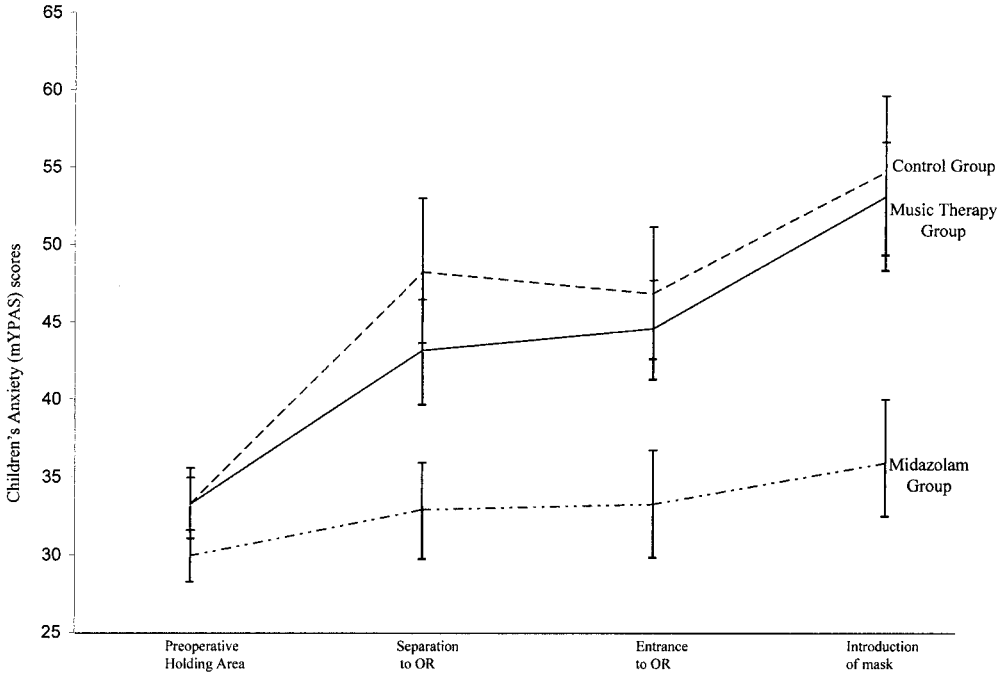

Figure 1. Changes in children's perioperative anxiety (modified Yale Preoperative Anxiety Scale; mYPAS) for the music therapy group, the control group, and the midazolam group. Data are reported as mean ± SE. Within subjects: $F_{3,111} = 16.17$; $P = 0.001$. Group × time: $F_{6,339} = 2.20$; $P = 0.042$. OR = operating room.

entrance to the OR ($P = 0.047$), but not on introduction of the anesthesia mask (P = not significant) (Fig. 2).

We next investigated any potential effect of the length of the music therapy session on anxiety scores. Results showed that there was no relationship between the length of music therapy sessions and children's anxiety scores on separation (T_2; $r = -0.03$), entrance to the OR (T_3; $r = 0.52$), or introduction of the anesthesia mask (T_4; $r = 0.098$).

Children who were rated a 0 or 1 on the ICC were categorized into a "compliant" group; children who scored higher on the ICC were categorized into a "noncompliant" group. A χ^2 test showed significant differences in compliance during the induction of anesthesia among the three groups. *Post hoc* analysis revealed that the midazolam group was much more likely to be compliant during the induction of anesthesia ($P = 0.004$) and that there was no difference in compliance between the control group and the music therapy group ($P = 0.28$). In addition, there was no difference in compliance between children who received music therapy from Therapist 1 or from Therapist 2 ($P = 0.53$).

Discussion

Under the conditions of this trial, we found that children who received music therapy were as anxious as

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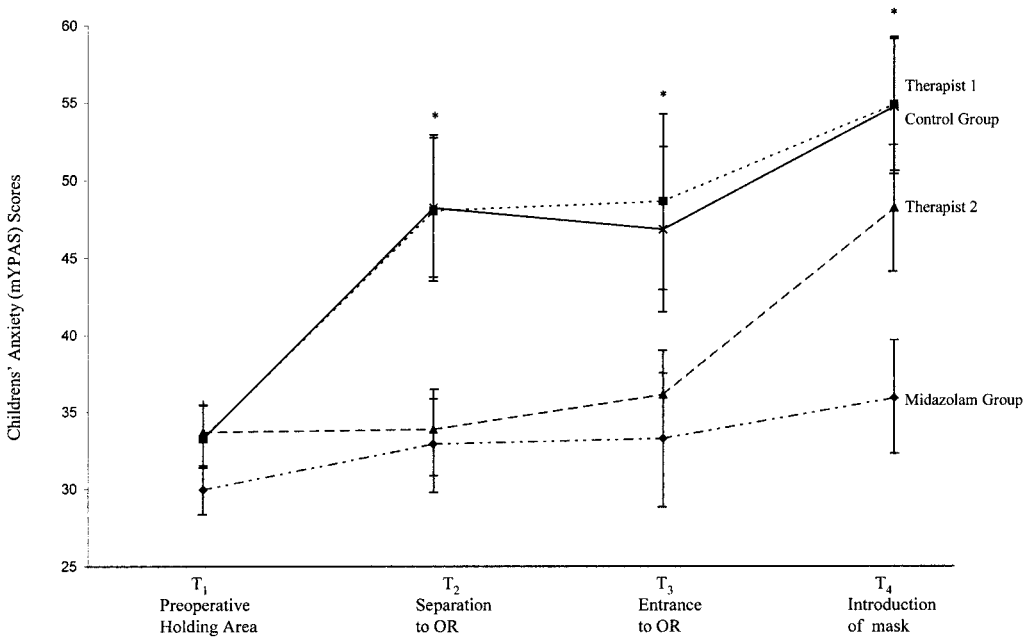

Figure 2. Changes in observed anxiety for the Therapist 1 music group, Therapist 2 music group, control group, and midazolam group. Data are reported as mean ± SE. Therapist 1 music group = children who received music therapy from Music Therapist 1 ($n = 30$); Therapist 2 music group = children who received music therapy from Music Therapist 2 ($n = 21$). *$P < 0.05$. mYPAS = modified Yale Preoperative Anxiety Scale; OR = operating room.

children in the control group. We also found, however, a significant therapist effect. That is, at separation to the OR and on entrance to the OR, children who received music therapy from Therapist 2 were significantly less anxious than children who received music therapy from Therapist 1 or who were in the control group. This therapist effect, however, did not continue on the induction of anesthesia. Finally, induction compliance scores of the midazolam group were significantly better compared with all other groups, and there was no difference in induction compliance between the control group and the music therapy group.

This study demonstrates that the effect of music therapy may be highly dependent on an individual music therapist's skill. After many years of nearly exclusive focus on the differential effects of the type or school of psychotherapy, the psychotherapy outcome literature has returned to focus on the therapist variable (20). Individual psychotherapists appear to be more variable in their effect than are the schools of thought or techniques represented (20). In other words, the same techniques or therapeutic style in the hands of one psychotherapist may have a vastly different effect in the hands of another. Similarly, in this study, both music therapists performed the same intervention, and adherence to the intervention was ensured through careful training and observation. Nonetheless, the intervention had a different effect on children's anxiety in the hands of each of these music therapists.

Few studies of music therapy in medicine have examined the provision of interactive therapy with children undergoing surgery. Robb et al. (19) used an intervention called music-assisted relaxation for children with burn injuries. The intervention consisted of music listening coupled with relaxation techniques under the direction of a music therapist. Although results showed that there was a significant reduction of preoperative anxiety in children who received music-assisted relaxation, the sample size was very small and lacked homogeneity. In addition, music therapy was mixed with relaxation techniques, resulting in a potential for confounding variables. Chetta (18) reported that, although music therapy provided the evening before surgery did not reduce anxiety, music therapy provided immediately before the induction of preoperative medication resulted in significantly reduced anxiety in children undergoing surgery. Methodological problems with this study include the lack of a reliable anxiety outcome measure. Thus, the validity of the results can be called into question.

This study was performed to assess the effects of interactive music therapy on the anxiety and compliance of children undergoing anesthesia and surgery for routine elective outpatient surgery. The provision of music therapy is an interactive discipline that involves a trained music therapist and the individual patient or group of patients. Music therapists effect positive changes in their patients by designing music sessions or activities that will meet their assessment of the individual's overall needs (5). Music therapy occurs in a variety of ways that can include receptive music listening (live or recorded), music improvisation, lyric and song writing, imagery, using music to alter mood, or using music as a vehicle to provide pleasurable experiences. Indeed, music therapy has

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been used in a variety of medical settings for issues including pain and anxiety management, cancer treatment, psychiatric problems, and stress reduction (5). Educational and clinical training standards must be met before a music therapist can be board-certified and considered qualified to practice (5). We found that even with the more effective music therapist, the anxiolytic effect of music therapy was not maintained during the induction of anesthesia. Introduction of the anesthesia mask is the point at which most children experience their highest level of preoperative anxiety (21). Children often perceive the induction of anesthesia as a direct threat, and the anxiety that results from this stimulus is of a different quality and intensity than the previous preoperative anxiety. Whereas interactive music therapy, in the hands of some therapists, may be able to alleviate the former "soft" anxiety, in this study it appears as though interactive music therapy could not maintain its anxiolytic effect in the face of "hard" anxiety resulting from an acute and threatening medical stimulus such as the induction of anesthesia. It may be that the stress of anesthesia induction is simply too intense for this modality to be effective.

It is interesting to note that our previous study demonstrated that reduced sensory stimuli in combination with background music decreased children's anxiety during the induction of anesthesia (12). We believe that this seeming contradiction in results is related to different music intervention techniques (taped music versus interactive therapy), as well as the concomitant reduced sensory stimuli intervention included in the previous study.

In conclusion, this study found that the provision of preoperative interactive music therapy to children undergoing surgery did not significantly alleviate preoperative anxiety. We did find, however, a significant therapist effect that was evident on separation and entrance to the OR but not on introduction of the anesthesia mask. These data seem to indicate that the type of music therapy intervention examined in this study may not be cost-effective. That is, the provision of interactive music therapy may be quite expensive (US$50–US$125 per hour), and considering the results of this study, we seriously doubt whether this modality should be routinely used to reduce preoperative anxiety in children undergoing surgery. We should emphasize, however, that some preoperative patients may benefit from interactive music therapy. Future studies are needed to identify such a population. It is also important to note that music therapy may be useful and effective in numerous other medical contexts.

Appendix 1

The music therapy intervention was designed by a Certified Music Therapist with hospital and pediatric experience. This therapist (Therapist 1) and another Certified Music Therapist (Therapist 2) who also had hospital and pediatric experience performed the intervention. Therapist 1 trained Therapist 2 to perform the intervention and then observed her for five music therapy sessions to ensure adherence to the intervention protocol. The overall purpose of the intervention, as described by Therapist 1, was to relieve children's anxiety through metaphorical emotional expression and physical release. First, the child was told (both in a song and directly by the therapist) that the therapist knew the child would be having an operation, that she was there to help the child, and that they would work together to make this day easier. The child was also told that his or her role was to listen to the music while in the OR. The music therapist then introduced instruments and songs used as vehicles to encourage expression of anxiety and physical release of that anxiety. For example, the child was given the opportunity to project his or her own fears about the operation onto the feelings of children who were caught on a bus during a rainstorm as the therapist sang "The Wheels on the Bus." After such expression, the music therapist and child then explored ways to safely deal with these emotions (e.g., suggesting that the children on the bus might think about what activities they would engage in once they return home). Playing instruments or making physical movements to music were both encouraged as a means of physically releasing anxiety.

The music therapist gave each child numerous opportunities to feel in control. For example, children were able to choose which instruments to play and were able to suggest or create lyrics. The music therapist let the child set the tone of the session and followed the child's lead in terms of volume, activity level, and desire to lead. The music therapist then sang familiar songs to the child as they walked together to the OR. Once in the OR, improvised music was used to reflect and support the doctor's instructions to the child (e.g., "breathe in and out"), and comforting and soothing music was played.

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