Psycho-Oncology
Psycho-Oncology **17**: 699–708 (2008)
Published online 21 November 2007 in Wiley InterScience (www.interscience.wiley.com). **DOI**: 10.1002/pon.1301

Randomized controlled trial of the active music engagement (AME) intervention on children with cancer

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Abstract

***Background*: Coping theorists argue that environmental factors affect how children perceive and respond to stressful events such as cancer. However, few studies have investigated how particular interventions can change coping behaviors. The active music engagement (AME) intervention was designed to counter stressful qualities of the in-patient hospital environment by introducing three forms of environmental support.**

***Method*: The purpose of this multi-site randomized controlled trial was to determine the efficacy of the AME intervention on three coping-related behaviors (i.e. positive facial affect, active engagement, and initiation). Eighty-three participants, ages 4–7, were randomly assigned to one of three conditions: AME ($n = 27$), music listening (ML; $n = 28$), or audio storybooks (ASB; $n = 28$). Conditions were videotaped to facilitate behavioral data collection using time-sampling procedures.**

***Results*: After adjusting for baseline differences, repeated measure analyses indicated that AME participants had a significantly higher frequency of coping-related behaviors compared with ML or ASB. Positive facial affect and active engagement were significantly higher during AME compared with ML and ASB ($p < 0.0001$). Initiation was significantly higher during AME than ASB ($p < 0.05$).**

***Conclusion*: This study supports the use of the AME intervention to encourage coping-related behaviors in hospitalized children aged 4–7 receiving cancer treatment.**

Received: 9 April 2007
Revised: 4 October 2007
Accepted: 5 October 2007

Keywords: cancer; oncology; music therapy; hospitalized children; coping behavior

Introduction

Although the hospital environment can be a significant source of stress for young children diagnosed with cancer, there are few empirically tested interventions designed to counter the hospital environment in a way that will increase active coping in this population. The purpose of this study was to test the immediate effect of an active music engagement (AME) intervention that was developed to increase coping-related behaviors in hospitalized pediatric oncology patients aged 4–7 years.

Literature review

Young children represent a significant portion of the pediatric cancer population. According to the National Cancer Institute, approximately 12 400 children and adolescents under the age of 20 are diagnosed with cancer each year. Forty-nine percent of reported cases occur in children nine years of age or younger. In addition, the annual number of deaths from pediatric cancer is 2300, making cancer the most common cause of death by disease for children in the United States [1].

Young children can experience significant stress during hospitalization for diagnosis and treatment of cancer [2–5]. Three qualities of the hospital environment can contribute to this stress—chaos, coercion, and neglect [6–8]. Despite dramatic improvements in the hospital environment, many aspects of hospitalization remain unpredictable (chaos), threaten independence (coercion), and affect emotional availability of parents or care providers during treatment (neglect) [6,7,9–12]. In contrast, supportive environments are defined in terms of structure, autonomy support, and relatedness [8,13]. When children encounter supportive environments they are able to anticipate what will happen in that environment (structure), they are encouraged to make choices and exercise their independence (autonomy support), and they have parents and care providers who are physically and emotionally available during treatment (relatedness).

According to coping theorists, the child's perception of an environment as stressful or benign will directly influence his/her behavior [8,13–15]. For example, when children perceive the environment as stressful, a common reaction is to withdraw from the situation, a behavior described as disengagement [8]. Long-term disengagement from a stressful environment or situation is not desirable because it inhibits the young child's ability to learn and enact adaptive patterns of coping during cancer treatment [8,16–19]. In contrast, children generally respond to supportive environments with a high level of behavioral engagement—an essential prerequisite for learning [6–8]. Qualities of behavioral engagement are consistent with three coping-related behaviors—positive facial affect, active engagement, and initiation [7,8,11,20–25].

Without supportive interventions that encourage engagement, young children undergoing active treatment for cancer may experience high levels of stress that prevent them from learning and using effective coping strategies [8,16–19]. Given that coping responses are hypothesized to be responsive to changes in the immediate environment, there is a need for intervention studies that investigate how particular interventions within the hospital environment might affect coping-related behaviors [3,14].

A primary challenge is identifying an intervention powerful enough to override emotional and behavioral reactions to stress so that engagement can be initiated and maintained. Music-based interventions hold promise for meeting this challenge for several reasons. First, there is an extensive body of research establishing music as an effective medium for altering mood states and diminishing state anxiety [26–31]. Second, music-based interventions have been effective in directing and sustaining children's attention during stressful medical procedures [32–35]. Finally, the social qualities of music have been used in clinical situations to foster family communication and interaction [36–39].

In 2000, Robb proposed a contextual support model of music therapy that specified how music can be used to systematically counter stressful environmental attributes of hospitalization [11]. This conceptual model is based on Skinner and Wellborn's proposition that supportive environments can influence children's coping-related behaviors by (1) affecting whether a child remains engaged with the environment and (2) buffering the effects of stress by reducing psychological distress [8]. Our study was concerned with examination of Skinner and Wellborn's first proposition that supportive environments can influence the manner in which children cope. Coping-related behaviors examined in this study included positive facial affect, active engagement, and initiation.

The AME intervention was designed based on the contextual support model of music therapy [6,7,11]. Essential elements of the intervention are as follows: (1) The intervention uses age-appropriate, music-based activities to create a predictable environment that supports the actions of children (structure). (2) Children are given numerous opportunities to choose materials and the inherent flexibility of live music is used to support initiated actions of children (autonomy support). (3) Interventions are guided by a board-certified music therapist (MT-BC) who keeps the child's decisions and actions central to the activity at hand (relatedness).

The purpose of the AME intervention is to create an environment that supports children's efforts to self-regulate during stressful experiences—in this case in-patient hospitalization for cancer treatment. Outcomes from a preliminary pilot study that tested the AME were positive and indicated that the intervention may be effective in eliciting positive changes in two coping-related behaviors—facial affect and active engagement [11]. A second pilot study by Barrerra and colleagues provided additional evidence that active music-based interventions may benefit young hospitalized children [36]. These pilot studies informed the current investigation, which examined whether modification of the immediate hospital environment—specifically through the introduction of structure, autonomy support, and relatedness—would result in greater coping-related behavior. Our study hypotheses were as follows:

1. When compared with music listening (ML) or audio storybooks (ASB), the AME intervention will result in greater positive facial affect.
2. When compared with ML or ASB, the AME intervention will result in greater active engagement.

3. When compared with ML or ASB, the AME intervention will result in greater initiation.

Method

Study design

A randomized clinical trial design was used with one experimental condition (AME) and two control conditions (ML and ASB). ML was used to control for effects that may come from listening to music. The ASB condition was used to control for listening to a non-musical, auditory stimulus. Both control conditions included contact with a trained interventionist to control for possible effects that may have resulted from attention.

Conditions

Experimental condition: AME

The AME offered patients numerous opportunities to experience mastery, make choices, and interact with other people through a variety of developmentally appropriate music activities. Materials for the AME intervention included age-appropriate music, an acoustic six-string guitar, a variety of hand-held rhythm instruments, and several visual aids including illustrated song books, puppets, and plastic animals. AME activities were subdivided into five categories: (a) greeting song (adapted version of the song *Willoughby Wallaby Woo* [40], which incorporated the child's name and encouraged manipulation of a stuffed vinyl monkey), (b) instrument playing (choice of hand-held rhythm instruments played to live music including adapted versions of the songs *I am a Great Musician* and *Momma Don't Allow* [41]), (c) action songs (finger puppets, props, and sound effect instruments used with the songs, *Five Little Speckled Frogs* [42] and *Five Little Monkeys* [43]), (d) illustrated songs in story-book form (*Wheels on the Bus* [44] and *Down by the Bay* [45]), and (e) closing song (an original song *Time to Say Good-Bye*, which included choice of sound effects).

Following the greeting song, participants selected activities from a 'musical menu' that had pictorial representations of activities from categories (b)–(d) listed above. Each activity included a wide range of materials from which children could choose. Physical activity requirements were varied across activities to allow for differences in patient fatigue. For example, illustrated song book activities required less physical energy than instrument playing. Sessions always concluded with the closing song.

Throughout the AME, music therapists (MT-BCs) followed specific procedures for offering choices and incorporating patient comments and actions into music-based activities. Therapists began with an open-ended statement, 'Which activity would you like to do?' If the participant was unable to respond with a choice, the therapist began to narrow the number of options available. Comments and actions initiated by the participant were incorporated into songs and activities offered using improvisational techniques. For example, if a participant began to dance, the MT-BC would immediately sing about the participant dancing. Additionally, the MT-BC would change the tempo and stylistic qualities of the music to match the actions and activity level of the participant.

Control condition: ML

During the ML condition, participants were asked to listen to a compact disc (CD) of children's music. The CD was a professional sound recording made specifically for this study. Musical selections, instrumentation, and voicing on the sound recording were identical to that used in the AME condition. The recording was played from a CD player without headphones; with the participant confirming that the volume was at an adequate level. Participants were free to sit quietly and listen to the music or engage in other activities while the music played. MT-BCs followed guidelines for interaction with participants and delivery of the condition. The MT-BC was instructed to listen quietly with the participant and respond to participant-initiated interactions. The MT-BC would engage in any participant-directed interactions or requests, but MT-BCs were instructed not to guide or direct participants' activities during the ML condition. For example, if the participant asked the MT-BC a question, she would answer. However, the MT-BC would not initiate or stimulate conversation.

Control condition: ASB

The MT-BC presented two illustrated storybooks and asked the participant to choose one. Materials for the ASB condition consisted of two commercially produced children's picture books with audio-taped narration [27,28]. Each audio storybook was 10–15 min long. Participants were given the illustrated storybook that corresponded with the audio narration. Stories were played from an audiocassette recorder without headphones. After the participant selected a book, the MT-BC started the tape and asked the participant if the volume needed adjustment. The participant was then instructed to follow the storybook while listening to the audio narration with the MT-BC. The MT-BC helped the participant if he/she missed the cue for page turns and responded to interactions initiated by the participant. The MT-BC did not use any additional strategies to keep participants engaged with the book; however, the therapist was instructed not to interfere with parent-initiated

DOI: 10.1002/pon

strategies aimed at encouraging their child's involvement with the book.

Participants

Eighty-three pediatric oncology patients were recruited from six hospitals within the United States. Inclusion criteria were: (a) age 4–7 years inclusively, (b) inpatient admission as a pediatric oncology patient, and (c) English as the primary language. Exclusion criteria were: (a) a mental age less than a 4-year equivalent as based on physician judgment or (b) admission to an intensive care setting. One participating hospital excluded first-time admissions for cancer treatment/diagnosis from study participation because of concerns about family stress levels associated with presentation of multiple studies, along with diagnostic/treatment information during the first admission. These participants were recruited for study participation upon their second admission.

Procedures

Patients who met study participation criteria and their parent(s) or legal guardian were approached by study personnel to share information and ascertain interest in study participation. Following introductory information, study procedures were explained and informed consent and assent were obtained for participation in a single 30-min study session. Following informed consent, participants were sequentially assigned to one of three study conditions. Assignment was done in the same manner at each hospital to maintain an equal number of participants in each condition across all sites. Sequential assignment tables were maintained at each site to track and monitor randomization.

Ten MT-BCs employed by the six participating hospitals received 8 h of training for human subjects' protections, hospital-specified procedures for infection control, and study protocols specific to each condition. The MT-BC delivered both experimental and low-dose conditions and remained present in participants' rooms for the duration of all conditions. This was done to control for possible effects that may have resulted from the presence or absence of personal attention from, and interaction with, a person other than a parent or guardian. Parents were also asked to remain in the room for the duration of their child's participation in the assigned study condition.

Sessions were videotaped to facilitate collection of behavioral data. Five minutes of pre-condition baseline data were videotaped before each study condition. Upon arrival at the participant's room, the MT-BC set a video camera on a tripod, activated it, and informed the participant and family that the camera was in recording mode. The MT-BC then left the room after informing the family that she would return in 5 min. Participants and their families were encouraged to maintain the activities they were engaged in at the time of the MT-BC's arrival for the 5-min recording period which served two functions. First, it gave the participant time to become desensitized to the camera. Second, it provided a collection of behavioral baseline data which could be used in the analyses to determine whether behavioral engagement was similar across study groups before experiencing a study condition. Following the 5-min video baseline, the MT-BC re-entered the room and delivered the assigned study condition.

At the conclusion of the 20-min conditions, the MT-BC removed all study materials except the camera that was left in recording mode to collect 5 min of post-session data. Patients and families were informed by the MT-BC that the camera was still running to engage in any activity of their choosing, and that she would return in 5 min. These data were used to compare participants' post-session behavior across all conditions. After 5 min of post-session video recording, the MT-BC re-entered the room, deactivated the camera, and thanked the participant and parent for their participation.

The videotape of each participant's single research session was sent, along with a copy of the signed, informed consent document, to the principal investigator within one week. All videos were locked and secured with the principal investigator. Parents or guardians who requested that their child's videotape be returned received their child's tape at the conclusion of the study.

Measurements

Behavioral coding

A behavioral coding form, used in a previous pilot study, allowed for objective measurement of behaviors [11]. Behaviors included in the coding form were drawn from Skinner and Wellborn's Motivational Theory of Coping and indicate the presence or absence of three coping-related behaviors—facial affect, active engagement, and initiation [8]. Independent observers viewed videotaped sessions and coded the presence or absence of each behavior using 10-s time intervals of observation, followed by 5-s time intervals to record observed responses.

Independent observers completed training in behavioral coding and time-sampling procedures using sample videotapes. Training of behavioral observations and scoring continued until intraobserver and interobserver reliability reached a minimum criterion of 0.85. Reliability was computed using an index of concordance (sum of agreements/sum of agreements + disagreements). To ensure consistency among observers, interob-

DOI: 10.1002/pon

server reliability checks were conducted periodically for the duration of the project and remained at a minimum criterion of 0.85.

Behavioral coding was done using 2-min time intervals. One time interval was coded for pre- and post-condition baseline periods. Material for baseline coding intervals was taken at the mid-point of each 5-min baseline period (see Figure 1). Six time intervals were coded for experimental and control conditions, resulting in 12 min of coded material for each participant. Material for experimental and control conditions was coded at equal time points across the 20-min experience to account for any behavioral changes that occurred over time (see Figure 1). This resulted in behavioral scores during eight discrete time intervals for each participant: one during baseline, six during the condition, and one during the post-condition period.

Computation of mean scores

The investigators first calculated mean frequency scores for each discrete time interval. This was done for each condition to examine any time-related changes in behavior. In addition, combined mean frequency scores for each condition were calculated for time intervals 1–6. These scores enabled the investigators to compare outcomes for each condition.

Mean frequency scores were computed for three coping-related behaviors—*positive facial affect*, *active engagement*, and *initiation*. Mean frequency scores were computed as follows:

1. *Positive facial affect*. Scores were computed based on the frequency of facial affect scores coded as 'positive.' The definition for positive facial affect is provided in Table 1.
2. *Active Engagement*. Scores were computed by averaging the frequencies of 'active' responses under 'physical activity,' 'focused' responses under 'focus of attention,' 'yes' responses under 'follows directions,' and 'yes' responses under 'makes a choice.' Definitions for each active engagement behavior are provided in Table 1.
3. *Initiation*. Scores were computed by averaging the frequency of 'verbal' and 'gestural' responses under 'initiation.' Definitions for verbal and gestural initiation are provided in Table 1.

Statistical analyses

Univariate analyses were conducted to obtain descriptive statistics for all variables and their underlying distributions. After adjusting for gender and the baseline measures, a repeated measures analysis was performed separately for each outcome. Using mixed linear models, the effects of group (condition), time (observation interval), and group × time interaction were tested. Mixed linear models accounted for correlated within-patient

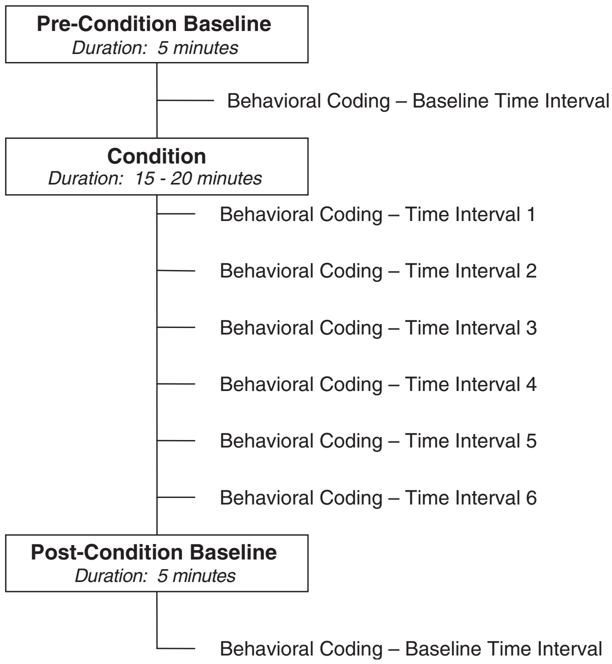

Figure 1. Behavioral coding schedule. The duration of each behavioral coding time interval was 2 min

data. A random statement with random intercept in the mixed linear models was specified using a correlation matrix with the fewest assumptions (i.e. unstructured). Interactions between group (condition) and other confounding variables were tested. Only the group × time interaction was significant in all models. To describe this interaction, the means of the outcomes for each time interval and group level were computed and graphed. ANCOVA was performed to (a) compute adjusted means for each group (AME, ML, and ASB) and (b) provide *post hoc* comparisons across groups while controlling for overall alpha using the Tukey–Kramer method. Although the three conditions did not differ on gender distribution, because gender is potentially a theoretically important cofounder of behavioral engagement, gender was included as a covariate in all models.

Results

Hypothesis 1. When compared with ML or ASB, the AME intervention will result in greater positive facial affect.

Group assignment (i.e. condition) had a significant ($p < 0.0001$) effect on positive facial affect, measured by the mean frequency for time intervals 1–6. Table 2 reports effect sizes and summarizes the overall mean frequency scores and SDs for each condition after adjusting for gender and baseline scores. AME resulted in the highest mean frequency score for positive facial affect, followed by

Table 1. Coding definitions for coping-related behaviors

Coping-related behavior	Definition
Positive facial affect	'Positive' was coded when the participant smiled or laughed during the time interval. Neutral or flat facial expressions were not coded as positive
Active engagement	
1. Physical activity	'Active' responses were defined as the participant engaging in a play activity during the coding interval (e.g. painting, puzzles, blocks, dolls, playing an instrument, singing, turning pages of a book). The participant's engagement in an activity had to involve active manipulation of materials or active use of self (e.g. moving body to music, turning book pages) to be considered an active response
2. Focus of attention	'Focused' responses were defined as the participant's eyes (attention) being fixated on the activity that he/she was engaged in or that was presented by another adult
3. Choice making	'Yes' for choice making was coded when the participant either physically (i.e. pointing or reaching) or verbally indicated a choice
4. Follows directions	'Yes' for follows directions was coded when the participant verbally or physically responded to a verbal direction
Initiation	
	'Verbal' was coded when the participant initiated a comment, question, or request to another person. These comments, questions, or requests could not be in response to a question or statement by another person
	'Gestural' was coded when the participant initiated communication by pointing or gesturing to another person or object. Gestures could not be in response to questions posed by another person

Table 2. Efficacy of condition on behavioral outcome

	Mean scores and SDs			Effect size (ES) with 95% confidence interval						
	AME	Music listening	Audio storybooks	AME versus music listening		AME versus audio storybooks		Music listening versus audio storybooks		P values
Positive affect	18.63 (13.0)[1]	7.7 (7.5)[2]	2.0 (2.3)[3]	1.03	(0.58 1.60)	1.80	(1.22 2.39)	0.93	(−0.04 1.90)	<0.0001
Active engagement	26.03 (4.1)[1]	15.65 (6.2)[2]	15.17 (4.9)[2]	1.97	(1.13 2.32)	2.41	(1.39 2.80)	0.09	(−0.48 0.61)	<0.0001
Initiation	14.19 (8.3)[1]	15.89 (11.2)[1]	7.43 (6.6)[2]	−0.17	(−0.80 0.32)	0.90	(0.02 1.51)	0.92	(0.29 1.48)	0.002

Different superscripts within rows denote significant group differences per *post hoc* Tukey tests.

ML and ASB. There was a statistically significant difference in positive facial affect between AME and both ML and ASB groups ($p<0.0001$ for both). There was also a significant difference between ML and ASB groups ($p = 0.0413$).

A significant time effect indicated that the frequency of positive facial affect changed significantly with each time interval over all groups combined ($p = 0.04$). A significant interaction between time interval and group assignment ($p = 0.03$) indicated that the magnitudes of the differences in scores were not the same at each time point (see Figure 2). AME had the highest frequency of positive facial affect at each time interval. The graph in Figure 2 illustrates variations in scores over time, with markings to indicate the occurrence of significant differences among the conditions.

Hypothesis 2. When compared with ML and ASB, the AME intervention will result in greater active engagement.

Group assignment (i.e. condition) had a significant ($p<0.0001$) effect on active engagement, measured by the mean frequency scores for time intervals 1–6. Table 2 reports effect sizes and summarizes the overall mean frequency scores and SDs for each condition after adjusting for gender and baseline scores. AME resulted in the highest mean frequency score for active engagement, followed by ML and ASB. There was a statistically significant difference in active engagement between AME and both ML and ASB groups ($p<0.0001$ for both). There was no statistically significant difference between ML and ASB groups ($p = 0.9527$).

The frequency of active engagement changed significantly by time interval over all groups combined ($p<0.0001$). A statistically significant interaction between time interval and group assignment ($p = 0.012$) indicated that the magnitudes of the differences in active engagement scores were not the same at each time point (see Figure 3). The graph in Figure 3 illustrates variations in scores over time, with markings to indicate the occurrence of statistically significant differences among the conditions. The AME condition had the highest frequency of active engagement at each time interval; these differences were statistically significant.

Hypothesis 3. When compared with ML or ASB, the AME intervention will result in greater initiation.

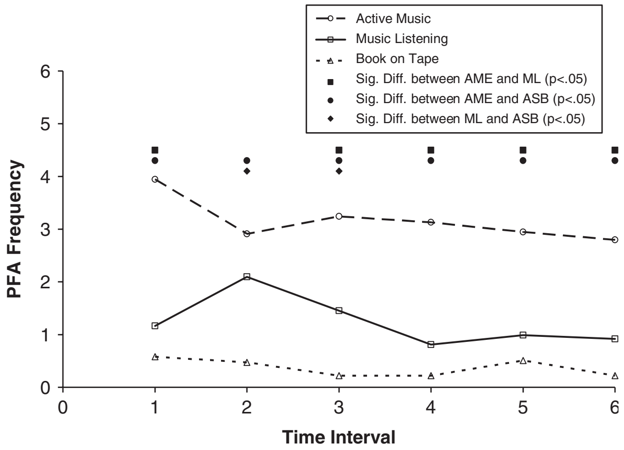

Figure 2. Mean scores for positive facial affect (PFA) by time interval/group assignment

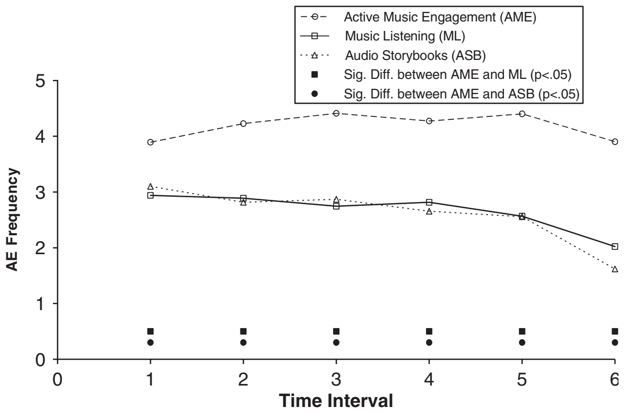

Figure 3. Mean scores for active engagement (AE) by time interval/group assignment

Group assignment (i.e. condition) had a significant ($p = 0.002$) effect on Initiation, measured by the mean frequency of gestural and verbal initiation scores for time intervals 1–6. Table 2 reports effect sizes and summarizes the overall mean frequency scores and SDs for each condition after adjusting for gender and baseline scores. ML resulted in the highest mean frequency score for initiation, followed by AME and ASB. There was a significant difference in initiation between AME and ASB groups ($p = 0.0434$). There was also a significant difference in initiation between ML and ASB groups ($p = 0.0019$). There was no significant difference between AME and ML groups ($p = 0.5552$).

There was no significant time effect. There was a significant interaction between time interval and group assignment ($p = 0.01$). The graph in Figure 4 illustrates variations in initiation scores over time, with markings to indicate the occurrence of statistically significant differences among the conditions. ML had the highest frequency of initiation at every time interval except interval 5, where ML and AME scores were equal (see Figure 4). There

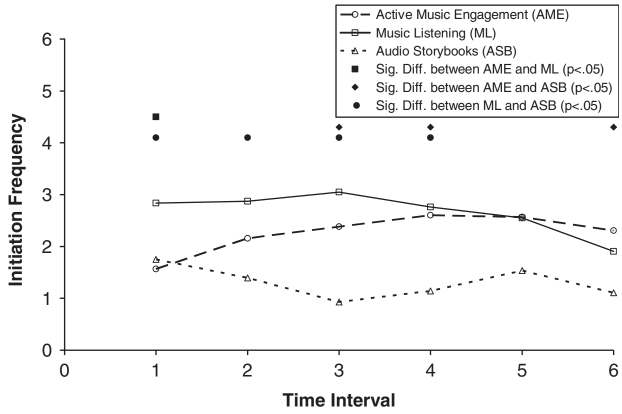

Figure 4. Mean scores for initiation by time interval/group assignment

was a significant difference between AME and ML groups at time interval 1 and between AME and ASB groups at time intervals 3, 4, and 6. Significant differences between ML and ASB groups occurred at time intervals 1–4.

Discussion

Findings indicate that AME intervention participants had a significantly higher frequency of coping-related behaviors during the intervention than participants in the two control conditions including positive facial affect, behavioral engagement, and initiation. Positive facial affect is an indicator of mood, and mood is an important variable that affects stress appraisals and self-regulation in children [48–50]. Active engagement is essential if children are to learn positive coping strategies that will help buffer the impact of stress related to hospitalization and treatment for cancer [8,20,51]. Initiation demonstrates a child's desire to explore and interact with his/her environment; an essential component for learning [7,8,13,49].

The AME intervention was the most powerful condition for all three coping-related behaviors. When compared with the ASB condition, AME participants demonstrated a significantly higher frequency of positive facial affect, active engagement, and initiation. These behavioral outcomes are consistent with Skinner and Wellborn's motivational theory of coping, in which positive mood and active engagement with the environment are considered essential in developing and using positive, adaptive coping strategies [8]. These outcomes are promising and indicate that the AME intervention can be used to help hospitalized children positively engage in their environment, an important first step in learning and using effective coping strategies.

The ML condition was not as powerful as the AME. Compared with ASB, ML participants did demonstrate a significantly higher frequency of behavior in only two areas—positive facial affect and initiation. However, when the same music was applied in an intentional manner by a trained music therapy professional (i.e. the AME condition), outcomes were significantly better for all three coping-related behaviors than when patients used music alone. These outcomes are consistent with a meta-analysis that reported (1) greater benefits from music therapist-led interventions that require active involvement with the music when compared with passive ML interventions and (2) greater benefits from interventions that used live music rather than recorded music [29].

The similar frequency of initiation for AME and ML participants was curious. When compared with ML, why would AME produce a higher frequency of positive facial affect and engagement but not initiation? In order to answer this question, future research would need to examine events that precipitate participants initiating in their environment. For example, it would be interesting to ascertain whether initiations were more often related to the music stimulus in the AME conditions compared with the ML condition.

The authors of this study informally observed that when AME participants initiated a comment or action, it was frequently related to the music-based activity. In contrast, ML participants were observed to initiate two types of actions—actions related to the music stimulus (e.g. using a box as a drum to play with the music or sharing memories related to the music) and random actions unrelated to the music stimulus (e.g. drawing, playing with an action figure, or playing with the bed controls). In all cases, participants may have been seeking out ways to adjust the level of stimulation in the environment—in other words, seeking more or less stimulation. Yet in the AME condition, these actions appeared to be related to the delivered music stimulus more often than what was observed in ML. Initiated actions are an indicator that children are exploring their environment, which is important to learning. Initiation without engagement in the delivered stimulus, however, would not be the desired outcome and may indicate a lack of interest. If the AME is to be used in future studies as a means for teaching music-based coping strategies it will be important that children not only feel free to explore their environment (i.e. initiation) but they also remain engaged with the intervention (i.e. active engagement).

Though one might argue that ML and ASB are passive activities that would bias engagement outcomes toward the AME condition, each condition allowed for both active and passive forms of engagement. Additional arguments against bias come through careful examination of the behaviors included in the active engagement score—which include passive (i.e. focus of attention), as well as active (i.e. physical activity) qualities of engagement. A full range of behavioral responses was observed across all conditions; however, the AME condition resulted in significantly greater active engagement than the other conditions.

In this study, males and females did not differ significantly on any of the outcomes. Even though the three conditions had a similar percentage of male and female participants, the inclusion of gender as a covariate helped to ensure robust findings of the main hypotheses regarding effect of condition. The lack of significant interactions between gender and condition shows that the effect of the AME intervention was similar for male and female patients. These outcomes are consistent with a meta-analysis of pediatric music-based intervention studies [29].

Conclusions should be interpreted in light of study limitations which included an absence of symptom severity measures, diagnostic information, and consent rate/study refusal monitoring. Although baseline data indicated that engagement levels were similar across groups, the authors did not collect symptom severity measures. As a result, it is not known whether groups experienced similar levels of anxiety, pain, nausea, or fatigue. Variations in symptom severity may have influenced effect sizes in this study. In addition, collection of diagnostic information would have strengthened the study, allowing investigators to examine whether response to condition was influenced by disease type or phase of treatment. Finally, monitoring the consent process would have enabled investigators to report on rate and reasons for study participation refusal. Refusal rate coupled with diagnostic information would have provided data necessary to evaluate acceptability of the AME intervention based on cancer type and phase of treatment.

The authors recommend that future studies examine the use of the AME intervention to help young patients and their families learn music-based strategies to manage anxiety and discomfort during hospitalization. In this study, data from the ML condition suggest that self-implementation of music without intentional application and instruction may be relatively less effective. In contrast, the AME intervention, which applied music in a systematic manner, resulted in significantly better outcomes for affect and engagement. As such, the authors recommend that music therapy programs include direct instruction for families of young children to ensure that the use of music-based strategies for self-management becomes a successful strategy for patients in the therapist's absence. Future studies that examine carry-over effects of the AME intervention will be necessary to determine whether the environment created during these sessions will enhance the learning and future enactment of music-based coping strategies during periods of heightened distress.

Acknowledgements

This study was completed while the first author was on faculty at the University of Missouri-Kansas City. The authors would like to thank the patients and families who participated in this study. In addition, the authors extend their thanks to the participating hospitals—Children's Mercy Hospitals and Clinics, Kansas City, MO; Penn State Milton S. Hershey Medical Center, Hershey, PA; Rainbow Babies and Children's Hospital, Cleveland, OH; University of Iowa Children's Hospital, Iowa City, IA; Riley Hospital for Children, Indianapolis, IN. This research study was sponsored through a National Academy of Recording Arts and Sciences (NARAS) grant awarded to the American Music Therapy Association (AMTA). This study received additional support through an institutional post-doctoral fellowship, CA 117865-O1A1. Special thanks to Dr Janet Carpenter, Indiana University School of Nursing, for her mentoring and editorial assistance on this project.

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