

## Full-Length Article

## The Effects of Music Intervention on Women's Anxiety Before and After Cesarean Delivery: A Randomized Controlled Trial

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### Abstract

**Objective:** To assess the potential effects of perioperative music intervention on maternal anxiety levels, physiologic metrics, and medication use for anxiety, nausea and pain during and after scheduled cesarean section.

**Methods:** Women assigned to the music intervention group were compared with controls. Physiologic metrics, medication requirements, and STAI scores were assessed for all participants.

**Results:** 50 women were enrolled, assigned to either music intervention (n=25) or control (n=25) and analyzed. Physiologic metrics were similar between groups. Antiemetic, anxiolytic, and analgesic medication use intraoperatively and postoperatively were not significantly different. State and Trait scores by the STAI did not vary significantly by intervention (p=0.09). STAI scores before and after procedure demonstrated the least change for the intervention group (r=0.6) when compared to controls (r=0.2; p<0.05).

**Conclusion:** Patient-selected music employed as a perioperative intervention resulted in maternal mood stabilization as demonstrated in the least amount of change in STAI scores. Further studies are warranted to determine if extending patient-selected music intervention time length will likewise have a desirable impact on pain and anxiety levels.

**Keywords:** stress, perioperative, caesarean, music intervention, STAI scores, anxiety, maternal mood

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### Background

A wealth of information currently exists on the use of music as an intervention to regulate mood and performance in everyday life, and particularly as it relates to the military, athletics, and education. Music is in its infancy in regard to implementation in medicine and has largely been used in psychotherapy and has scientifically substantiated neurochemical changes [1].

Over the past several years, medical and surgical specialists have investigated and used music with success. Specifically, music has been suggested and evaluated as a therapeutic intervention to reduce preoperative anxiety for surgical patients. Some investigators report reduced anxiety following an introduction of music therapy [2-5]. The bulk of

obstetric and obstetric anesthesiology literature has previously hinged upon pharmacological approaches to providing adequate analgesia and anesthesia to reduce anxiety around the time of operative delivery; notably this approach was in response to pain having a profound impact on anxiety levels, both subjectively and as it was measured in physiological response [6,7]. Hence, clinical implementation of music interventions for reduction of anxiety during obstetrical care remains largely in an early phase of development. Our knowledge remains insufficient to generate guidelines or consensus statements, either in support or against widespread implementation.

Using a variety of physiologic markers and patient self-reported stress levels, prior studies indicate that music may be helpful in the setting of cesarean section [8,9]. However, little is known about potential effects of utilizing patient-selected music as an intervention in the absence of formal music therapy. Our group sought to assess the utility of patient-selected music intervention consistent, reliable, well-validated tool for measuring effect. Accordingly, one broad-spectrum and validated tool for assessing anxiety is the State Trait Anxiety Inventory (STAI). The STAI was developed in 1970 by Spielberger et al and represents a 40-item self-report measure of state and trait anxiety. State anxiety refers to the immediate sense of how an individual is feeling, or the

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transitory emotional state, while trait anxiety is thought to be more stable and general. Spielberger specifically defined trait anxiety as “the relatively stable differences in anxiety proneness, that is, the differences between people in the tendency to respond to situations perceived as threatening in state intensity.” [10]

The STAI has been useful for measuring both state and trait anxiety levels in medical research. STAI has been previously validated, and many view it as the gold-standard for medical measures of anxiety. The STAI has also been favored over other anxiety scales because it consists of two sets of statements that each measure a different dimension of anxiety [10-13]. To our knowledge, STAI has not been used to assess the effect of music on anxiety in context of cesarean delivery.

Our group had observed subtleties of patient anxiety preceding and during cesarean deliveries in spite of adequate analgesia and anesthesia. We had concerns as to whether previous study data was applicable to our patient population. Because of conflicting data in the literature and our concerns for limitations of the data generated by other studies, our group selected STAI to validate our intervention of music. Specifically, we sought to determine whether the intervention of patient-selected music before and after obstetrically-warranted Cesarean delivery would effectively decrease patient anxiety levels in our patient population in central North Carolina.

## Methods

Wake Forest University and Forsyth Medical Center IRB approvals were obtained. Study design for RCT followed CONSORT guidelines. This study was registered with the National Institutes of Health and is listed on <https://clinicaltrials.gov>. Initial approval was obtained September of 2008 and the study was completed December 2014 and last updated on the website December 2017. Study participants were recruited and enrolled either in the pre-anesthesia visiting area at Forsyth Medical Center or from resident and faculty prenatal clinics at Wake Forest University School of Medicine, Department of Obstetrics and Gynecology.

Women were deemed eligible to participate if they met the following criteria: 1. age 18 and older; 2. a history of one prior Cesarean delivery and scheduled for an elective repeat Cesarean delivery under neuraxial anesthesia; or 3. undergoing a primary cesarean delivery under neuraxial anesthesia. Women were excluded for cardiovascular disease, chronic hypertension, insulin dependent diabetes mellitus, multiple gestation pregnancies, psychiatric disorders, and/or diagnosis of fetal anomaly.

Study personnel performed informed consent as approved by IRB. Patients were then randomized to receive music intervention through a portable mp3 player provided by the research nursing staff. The individuals in the

experimental group were asked to choose a preferred music playlist from the following genres: Classical, Country, Pop/Top 40, R&B, Gospel, and Soft Rock. The rationale behind encouraging patients to select a genre was to enable them to choose listening to music that they personally found comforting around the time of childbirth. Songs from each genre were those felt commonly associated with the music category/style by the investigative team. Individuals in the control group did not receive an mp3 player. Each patient was assigned a study identification number to ensure confidentiality; this number was the referent patient identifier for all communication and subsequent data analysis. Study personnel contemporaneously maintained study data in a password-protected database.

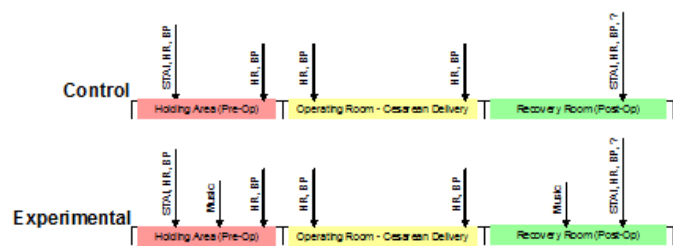
While in the holding room, all study participants completed the State and Trait Anxiety Inventory (STAI). To measure state anxiety, individuals reported the intensity of their feelings to 20 state anxiety items using a 4-point scale, where 1 is “not at all” and 4 is “very much so.” For the 20 trait anxiety items, participants indicated how they generally felt by reporting how often they experience anxiety-related thoughts and feelings on a 4-point scale, with 1 being “almost never” and 4 being “almost always.” The total scores for state and trait sections separately range from 20 to 80 as per convention with higher scores indicating greater state and trait anxiety [2,10-13].

The experimental group listened to their selected music for a minimum of 30 minutes. After completing the STAI, patient care staff recorded an initial blood pressure and pulse rate on all patients. Individuals randomized to the experimental group were then given the portable mp3 player to listen to their selected music playlist during their time in the preoperative holding area. Experimental patients received instructions to not stop the music or put the device on mute unless they experienced significant discomfort. However, to prevent possible hearing loss, participants were advised to avoid increasing the volume of the music above 80 decibels. Participants experiencing any discomfort from the headphones were permitted to remove them at will. Additionally, participants were allowed to control the volume level of the music in order to interact with operating staff. The portable mp3 player was retrieved when the patient was moved to the operating room. A final reading of blood pressure and pulse was recorded immediately before leaving the holding room. Again, heart rate and blood pressure were recorded upon operating room entry and exit. Information regarding the type and amount of anesthesia and length of surgery were likewise recorded for each participant.

Once participants arrived in the recovery room and vital signs were deemed stable, they were given the same portable mp3 player to continue listening to their selected music playlist for a minimum of 30 minutes following guidelines as above. Individuals in the experimental and control groups were asked to complete the state portion of the STAI again after 30 minutes. A final reading of heart rate and blood

pressure were recorded for all participants. Additionally, all study participants in the music intervention group were asked to complete a subjective evaluation of the delivery to provide more qualitative results. This evaluation was specifically designed by the investigators to contain open-ended questions aimed at measuring discomfort, stress, and other mental and/or emotional states that may have been experienced by the participants during the study. Post-partum analgesic use was recorded (Figure 1). A questionnaire was designed to collect a qualitative patient assessment (Figure 2).

Figure 1: Timeline for Patient Assessment per Study Protocol



LEGEND:

STAI – State-Trait Anxiety Inventory

HR – Heart rate

BP – Blood pressure

? – Qualitative evaluation

Figure 2: Qualitative Questionnaire

1. How satisfied were you with this Cesarean delivery? Why or why not?
2. How does this delivery compare with your previous Cesarean delivery? Why?
3. Did this Cesarean delivery meet your expectations? Why or why not?
4. How comfortable were you during this delivery?
5. Do you feel that you were given enough medication for pain?
6. Did you feel respected during the delivery?
7. Did you feel that you were aware of the events of the delivery?
8. Did you feel that you were well-informed of the progress of the delivery?
9. If there was anything that you could change to make this delivery a better experience, what would it be?

For the experimental group:

10. Do you feel that the music had any effect on your delivery? If yes, in what way?
11. If given the option, would you want music with your next delivery?

Randomization occurred with a random numbers table where operative staff and investigators had no knowledge of the patients’ group assignments. Individuals were excluded from the final analysis when they required emergent Cesarean delivery, had an intra-operative complication, or were deemed

unstable in the postoperative period. Quite naturally, music intervention was discontinued for these patients.

STATISTICS:

A sample size of 50 individuals was deemed sufficient to detect a 10% difference in anxiety levels measured by STAI between the two groups at the 0.05 level of significance for two-way analysis of variance (ANOVA) with repeated measures. This was based on a calculation utilizing a power of 0.90.

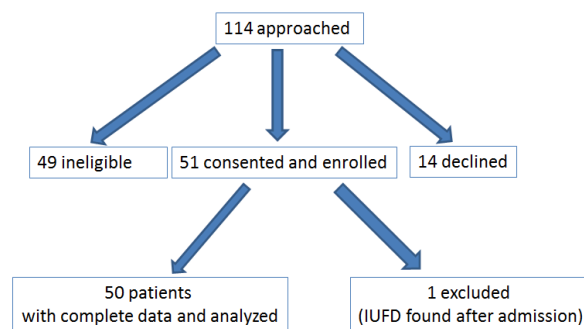
Review of the labor and delivery data at Forsyth Medical Center revealed that approximately 6,500 patients deliver annually at our facility. Of these patients, 694 have elective repeat Cesarean deliveries. In our study, we were particularly interested in women choosing repeat Cesarean deliveries with a history of only one previous Cesarean delivery. We anticipated that the projected enrollment would be met in 3-6 months.

Univariate analyses (2-tailed t-test for means, 2-tailed t-test for proportion, Kruskal-Wallis and Wilcoxon Rank Sum Test) were used where appropriate to compare differences in demographic and categorical data between the experimental and control groups. Two-sample t-tests were used to compare the mean differences in the STAIs between the experimental and control groups. Repeated measures ANOVA were conducted to determine the effects of music on women’s anxiety and physiological measures. The accepted level of significance for all analyses was set at  $p < 0.05$ . Univariate analysis was utilized to evaluate the open-ended questions.

Results

Our study recruited 50 women with routine pregnancies undergoing planned cesarean delivery at the Maya Angelou Center for Women's Health & Wellness at Forsyth Medical Center in Winston-Salem, NC. Twenty-five women were assigned to the control group while the remaining 25 were assigned to receive music intervention following randomization (see screening and patient enrollment according to CONSORT guidelines for reporting RCT; Figure 3).

Figure 3: Flow of Patients in the Study



Patient demographics were similar with regard to age, number of prior cesarean deliveries, number of previous vaginal deliveries, and presence of a support person during delivery. None of the women in either group had any chronic medical illnesses, psychiatric disorders, or either known or found fetal anomalies preceding or after delivery. All patients had both a support person present for surgery and received either a spinal anesthetic or a combined spinal-epidural anesthetic. See **Table 1**. Music choices for participants in the intervention group are listed in **Table 2**.

**Table 1:** Demographic Characteristics

	Control Group	Music Intervention	p-value
Age (yrs)	31.2 +/- 1.2	29.9 +/- 1.3	0.70
Weight (lbs)	182.7	211.7	0.03*
Number of Prior Cesarean Deliveries (avg)	1.04	1.16	0.68
Number of Prior Vaginal Deliveries (avg)	0.28	0.16	0.69
Operative Time (mins)	63	72	0.04
Support person present (%)	100	100	1.0
Average Trait score	32.96	33.76	0.09

**Table 2:** Music choices for intervention group

Gospel	8.0%
Pop/Top40	16.0%
Classical	8.0%
Soft Rock	12.0%
R&B	36.0%
Country	20.0%

Physiologic data for patients in each group were similar. Pre- and post-operative mean vital signs between the music intervention group and control group are displayed in **Table 3**. Aside from mean pulse when leaving the pre-operative holding area, preoperative vital signs entering and leaving the holding area were similar between groups. Mean vital signs upon entering the OR were not significantly different between the music intervention group and control. Mean vital signs upon leaving the OR did not differ by group. Lastly, mean vital signs did not differ when measured in the post-operative recovery room.

**Table 3:** Peri-operative vital signs by group

Vital Signs	Music	Control	2-tailed T-test (p-value)
Pre-operative Pulse (mean bpm)-entering holding area	92.4	87.5	0.18
Pre-operative SBP (mean mm Hg)-entering holding area	123.8	118.7	0.22
Pre-operative DBP (mean mm Hg)-entering holding area	58.7	59.7	0.76
Pre-operative Pulse (mean bpm)-leaving holding area	96.6	87.9	0.02
Pre-operative SBP (mean mm Hg)-leaving holding area	130.8	130.7	0.99
Pre-operative DBP (mean mm Hg)-leaving holding area	76.88	75.0	0.7
Pre-operative Pulse (mean bpm)-entering OR	81.1	81.9	0.78
Pre-operative SBP (mean mm Hg)-entering OR	123.8	118.7	0.22
Pre-operative DBP (mean mm Hg)-entering OR	58.7	59.7	0.76
Post-operative pulse (mean bpm)-leaving OR	83.1	82.3	0.83
Post-operative SBP (mean mm Hg)-leaving OR	115.8	117.7	0.68
Post-operative DBP (mean mm Hg)-leaving OR	63.3	68.5	0.07
Post-operative pulse (mean bpm)-entering holding area	79.5	880	0.90
Post-operative SBP (mean mm Hg)-entering holding area	121.8	119.6	0.62
Post-operative DBP (mean mm Hg)-entering holding area	71.3	70.8	0.85

Perioperative medication requirements were similar for both groups. The proportion of patients requiring intraoperative doses of intravenous antiemetics (intervention 44% vs. control 52%; 2-tailed t-test p=0.57) as well as the proportion of patients requiring intravenous opioids in the immediate postoperative period did not differ significantly by intervention (24% music group vs. 28% control group; p=0.75). The mean number of postoperative ibuprofen doses were similar between groups. (1. Post-op day 1: intervention 4.0 doses vs. control 3.6 doses; 2-tailed t-test p=0.07). Likewise, the mean number of post-operative doses of opioids did not differ by music intervention (1. Post-op day 1: intervention 1.8 doses vs. control 1.7 doses; 2-tailed t-test p=0.93; 2. Post-op day 2: intervention 1.7 doses vs. control 1.3 doses; 2-tailed t-test p=0.48; and, 3. Post-op day 3: intervention 0.6 doses vs. control 0.6 doses; 2-tailed t-test p=1.0).

The mean Trait scores were not significantly different between the music intervention group and control group (intervention 32.96 vs. control 33.76; 2-tailed t-test p=0.72). Likewise, the mean initial State scores were not significantly different between the music intervention group and control group (intervention 38.8 vs. control 35.4; 2-tailed t-test

p=0.26). The average post-operative STAI State scores were also similar being 32 for the intervention group and 29.64 for the non-intervention group. The State Scores levels demonstrated a non-significant reduction from the intervention of music. Specifically, there was a 4.64-point reduction for the intervention group and a reduction by 4.56 points for the non-intervention group (2-tailed t-test p=0.97); see Table 4.

Table 4: Pre- and Post-operative STAI State Scores

Group	Pre-op STAI State Score	Post-Op STAI State Score	Delta State	p-value
Music Intervention	38.8	32	-6.8	0.09
Control	35.6	29.6	-5.72	0.09

Nonetheless, patients receiving music intervention were more likely to have an anxiety level closer to their baseline (r= 0.6 with intervention vs. r=0.2 without intervention; p <0.05). This suggests that music has the effect of avoiding emotional fluctuation perioperatively. See Figure 4 and Figure 5. Surprisingly, post-operative State scores were lower as compared to Trait scores in the group receiving usual care as compared to the intervention group; see Figure 6.

Figure 4: STAI Trait Score for Usual Care Without Music Intervention

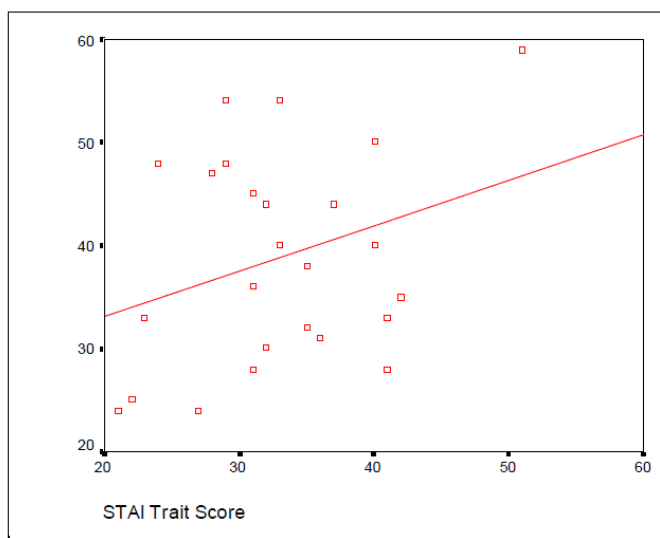


Figure 5: STAI Trait Score in Perioperative Music Intervention Group

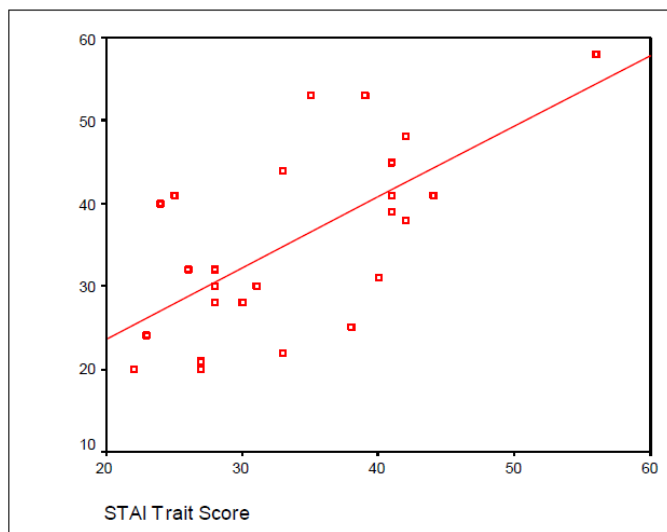
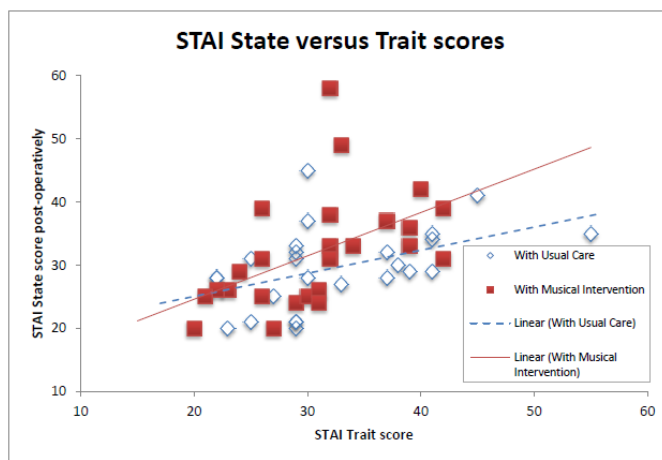


Figure 6: Depiction of STAI State versus Trait Scores



Lastly, both groups completed a qualitative assessment. Briefly, the majority of patients in either group recorded a positive experience. The group exposed to music were more likely to compare this delivery in a positive manner with their prior experience than unexposed controls (question 2: p=0.046; OR 20.2 CI 1.1-385.9). Otherwise, the groups answered in a manner that was similar for questions 1 and 3-9. As one would expect, only the music group completed questions regarding music exposure’s affect on delivery experience and whether it would be desired with the next delivery. A large percentage (88%) stated music had a positive effect on delivery and all but one (96%) stated that patient selected music would be desired with the next delivery; see Table 5.

**Table 5: Qualitative Evaluation**

**Questions**

1. How satisfied were you with this Cesarean delivery? Why or why not?
2. How does this delivery compare with your previous Cesarean delivery? Why?
3. Did this Cesarean delivery meet your expectations? Why or why not?
4. How comfortable were you during this delivery?
5. Do you feel that you were given enough medication for pain?
6. Did you feel respected during the delivery?

7. Did you feel that you were aware of the events of the delivery?
  8. Did you feel that you were well-informed of the progress of the delivery?
  9. If there was anything that you could change to make this delivery a better experience, what would it be?
- For the experimental group (music only):
10. Do you feel that the music had any effect on your delivery? If yes, in what way?
  11. If given the option, would you want music with your next delivery?

	Positive [n for control, music]	Neutral [n for music]	control,	Negative [n for control, music]	N/A, no response [n for control, music]	p-value (OR 95% CI)
(1)Satisfied with delivery	25, 25	0,0		0,0	0,0	1.0 (NS)
(2)Comparison of this delivery with prior cesarean	14, 22	0,0		6, 0	5,3	0.046 (20.2 CI 1.1-385.9)
(3)Meet expectations	25, 25	0,0		0,0	0,0	1.0 (NS)
(4)Comfortable during delivery	24,24	1,1		0	0,0	1.0 (NS)
(5)Pain medication adequate	19,19	0,2		6, 4	0,0	0.57 (NS)
(6)Feel respected during delivery	24,24	1,1		0,0	0,0	1.0 (NS)
(7)Feel that you were aware of events of the delivery	25,25	0,0		0,0	0,0	1.0 (NS)
(8)Feel well-informed of progress of delivery	25,25	0,0		0,0	0,0	1.0 (NS)
(9)Any desired changes of delivery process	14,16	1,1		10,8	0,0	0.55 (NS)
(10)Feeling about music effect on delivery n(%)*	22(88%)	0 (0%)		3(12%)	0 (0%)	N/A
(11)If given the option would you want music with your next delivery n(%)*	24 (96%)	0 (0%)		1(4%)	0 (0%)	N/A

\*music intervention group only (ie, control group survey did not query regarding music satisfaction)

**Discussion**

There are many proposed benefits of lessening preoperative maternal state anxiety levels. One reported benefit is the requirement for fewer analgesic drug amounts both in the operating room and in the recovery room.<sup>7</sup> Our group found few studies addressing the impact of music surrounding cesarean delivery and none utilizing patient-selected music as an intervention. One study performed in Taiwan focused specifically on women having scheduled Cesarean deliveries. This study of 64 women measured anxiety (using the visual

analog scale for anxiety, or VASA), satisfaction (using a satisfaction of Cesarean delivery scale, or SCDS), oxygen saturation, temperature, respiration, pulse, and blood pressure. Published results showed significantly lower anxiety and higher satisfaction of the experimental group that listened to patient-selected music for at least thirty minutes from the start of anesthesia until the end of surgery. Like previous studies, there were again no significant differences in any of the physiological markers [8].

Another recent study by Li et al utilized classical Chinese music in the perioperative period to determine effect on

anxiety levels using the Zung Self-Rating Anxiety Scale (SAS). While results indicated effective reduction in anxiety, SAS scales, by being a “self-rating” assessment, introduce inherent subjectivity. Additionally, classical music is a unique genre of music that may not be appreciated by all patient populations and consequently not applicable to every obstetrician’s practice.<sup>9</sup> Our patient population demonstrated an eclectic blend of selected genres.

Our data indicate music intervention in the immediate preoperative period may be effective in avoiding significant fluctuation in anxiety levels during Cesarean delivery as the intervention group STAI scores measured post-operatively were more highly correlated with the pre-operative STAI state scores than the non-intervention group ( $r=0.6$  for the music intervention group versus  $r=0.2$  for the usual care group;  $p<0.05$ ). While our data do not support the suggestion that music intervention reduces analgesic requirements in the immediate postoperative recovery period from a cesarean section, our opinion is that the apparently stabilizing effect of patient selected music on maternal mood should not be overlooked. Additionally, the patient responses from the music intervention group were overwhelmingly positive with respect to satisfaction with cesarean, meeting expectations, adequate pain control, awareness of events during delivery, and, of course, music intervention having a positive effect on their delivery experience. From the patient perspective, music had both a positive effect on delivery (88%) and would be desired with the next delivery (96%); see Table 5.

Furthermore, a wealth of studies have demonstrated effective perioperative pain and anxiety reduction from formalized music therapy; these reports have robust data sets generating a consensus that music therapy is beneficial [2-6]. Our study had a number of strengths in formalizing the physiologic and psychologic effects of the music intervention on patient by state and trait scores. Continuing to study the obstetrical population and the effects of more goal-directed music therapy to reduce hospital associated anxiety and stress. Our study highlights the importance of utilizing a trained music therapist to facilitate aims of health care providers in using music to reduce patient stress for improved well-being, mother-baby bonding, and, in effect, also reduce hospital-related costs. Music therapists are key to facilitating patient engagement with the music intervention as well as helping select an appropriate protocol to employ music as a medium to improve anxiety and psychosomatic states of a surgical patient or, in this case, the pregnant mother in preparation for, during, and immediately after the cesarean birth of her child.

Our study has a number of limitations. First, due to the nature of the surgery, providing intra-operative music intervention may interfere with patient interaction with significant others, neonates, and operating room staff. Therefore, the instructions and actions associated with the intervention may have actually provoked additional anxiety. Alternatively, the music may have been simply a distraction in

the context of impending childbirth. On the converse, a potential benefit may be to enhance mother-baby bonding. The wide variation of music genres may have confounded the study; ie, some forms of music possibly reduced peri-operative anxiety while others may have had no effect or, alternatively, increased anxiety. Additionally, we lacked the presence of a music therapist in our study panel. Inclusion of a music therapist may have better facilitated the desired effect but more funding was needed to procure the services of a music therapist. Effectively, our data justify the need to include a music therapist to tailor the music selection, protocol, and achieve the goals and objectives of the intervention.

Our study is not adequately powered to assess the effect of the different musical genres individually. Additionally, we studied women having a Cesarean delivery, and any type of peri-operative patient isolation may increase anxiety. An inherent limitation or source of bias is that operating room staff were no longer blinded if music was provided during the delivery. A further limitation of our study is that we did not assess or control for the potential effect of ambient music being played by operating room staff in the room during the delivery. Lower maternal anxiety levels may also help initiate and prolong lactation,<sup>9</sup> which could help improve maternal and infant bonding. Our study did not assess for effect of music on initiation and prolongation of lactation.

This investigation suggests that music intervention before and after Cesarean delivery may be a beneficial intervention that should receive consideration to improve the care and satisfaction of women during surgical childbirth. That being said, the effect of simple music intervention as opposed to formal music therapy was not as pronounced as hoped. We feel that music and/or music therapy may be offered electively for future operative care of women having scheduled or emergency Cesarean deliveries. Perhaps if music and/or music therapy were offered to patients as requested rather than given for set periods of time as part of an investigation with associated questionnaires and physiologic measurements, it may be more successful at reducing anxiety. Reduced anxiety could aid in lactation initiation, improve infant bonding in new mothers, and shorten postoperative recovery time. Further studies would be needed to determine any physiologic and psychologic maternal and infant benefits of intermittent and/or elective music therapy as well as whether there are effects specific to different musical genres.

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