MUSIC IN EMERGENT SETTINGS

(Working Paper)

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PART ONE: ABSTRACT

Every year, more than 130 million patients access emergency care in America. Emergency departments are high stress environments and are one of the most significant drivers of healthcare costs in the US. The most prevalent complaint of patients who seek care in an emergency department (ED) involve the perception of pain. The failure to recognize and treat pain in an appropriate and timely manner has become a marker for quality of care in emergency medicine. In addition, the rise of the opioid crisis in the US and worldwide has brought further attention to the need for multimodal and alternative approaches to successful pain management in acute settings. In this study, we aim to investigate the impact of live preferential music in an emergency and trauma care setting on patient outcomes.

The specific aims of the study were to determine whether live preferential music can impact acute musculoskeletal pain reduction, and to determine the effect of live preferential music on the environment of care, patient satisfaction and the overall cost of care (both pharmaceutical and non-pharmaceutical) to patients presenting to the ED. This study was conducted prospectively with a randomized, controlled, double-blinded intervention designed with patient deception. Patients were block randomized to receive or not receive a music intervention by days of the week, however, they were unaware that their participation involved a music intervention because they were informed that they were participating in a pain assessment study to ensure blinding. A total of 2262 patients were screened for the study. 272 (94 interventions, 128 controls, and 50 declined-music controls) patients were recruited from two UF Health Shands free-standing EDs.

The primary outcome of interest was the assessment of pain reduction using a validated pain assessment tool. There was no difference noted in pain reduction between

groups controlled for baseline pain intensity. There was no difference in the amount of pain medication administered between groups as measured in morphine equivalents. While there is substantial qualitative evidence of the benefit of live preferential music in acute care settings and while this study has demonstrated that live preferential music interventions can be rigorously studied in an emergency department environment, this study was unable to show a benefit. Limitations were identified that may have contributed to lack of discriminatory effect of the music intervention including the inability to control for the diversity in pain and location characteristics within the broad category of musculoskeletal complaints, variation in provider care strategies, and the institution of new state and federal guidelines for pain management.

PART TWO: EXECUTIVE SUMMARY

Introduction. The University of Florida (UF) Center for Arts in Medicine and UF Department of Emergency Medicine have partnered on a three-phase research plan to assess the impacts of Live Preferential Music (LPM) on quality of care and operations in the emergency and trauma care setting. Following an initial observational pilot study involving 1,200 patients, the second phase of the study randomized 855 subjects to an intervention utilizing a group of highly talented musicians to provide live preferential music in the Emergency Department of an academic tertiary receiving trauma center. The third phase of the study, a prospective experimental trial conducted with a convergent mixed methods design, was conducted with 272 patients in two free-standing emergency departments. To our knowledge, this project represents the first systematic investigation of its kind investigating the impact of live preferential music in an emergency and trauma care setting on patient outcomes, quality and cost of care.

Goals and Methods. In this study, we aimed to determine whether live preferential music could impact pain reduction for patients presenting to the Emergency Department with musculoskeletal pain. We also sought to determine the impact of live preferential music on the environment of care, patient satisfaction and the overall cost of care (pharmaceutical and non-pharmaceutical costs). This phase-three trial included a prospective randomized, controlled, double-blinded trial to assess the utility of a new Live Preferential Music (LPM) Protocol.

The primary outcome of interest was pain reduction using a validated pain assessment tool, PAIN*Report*It®, which is a validated computerized extension of Melzack's (© 1970) McGill Pain Questionnaire (Melzack, 1975) and measures the pain intensity on a 0-10 scale. A block randomization was used to determine the days of music intervention over the duration of the study. Enrolled subjects were informed that they were participating in a pain assessment

study, without any discussion of music in the study. The research team employed the deception strategy of incomplete disclosure regarding the music intervention to allow for true blinding and to limit potential bias. This was believed to be ethical because the intervention would be unlikely to cause harm to the patient, and after study completion, patients would receive letters disclosing the deception. The primary inclusion criteria included English-speaking patients age 18 and older with a chief complaint of musculoskeletal pain.

The music intervention was offered to patients who passed the screening criteria, completed the informed consent process and completed initial pain measures with a trained research assistant (RA). A musician in residence used the Live Preferential Music (LPM) Protocol to assess the patient's interest in the music intervention. If the patient was interested, the musician discussed music preference with the patient using the LPM protocol and offered to perform appropriate preference-based music. The post-measures were completed by the RA 30-minutes after the pre-measurement was collected. Variables collected from the medical record included patient age, gender, mailing address, Glasgow coma score, presence of altered mentation, triage acuity, height, weight, medical early warning sign score, area of ED care, and pain scales at presentation and post intervention using PAIN*Report*It®. Medication utilization, primary and secondary clinical diagnosis, admission status, and admission location were collected. In addition, vital signs including blood pressure, heart rate, oxygen saturation, and respiratory rate, prior to, during, and after the music intervention were collected.

Pain data were exported from the PAIN*Report*It® structured query language (SQL) database into Microsoft Excel and imported into SPSS for statistical analysis. All clinical data were extracted from REDCap to SPSS. Descriptive statistics (means, frequencies, and percentages) and inferential tests (the independent t test, Chi-square test, and Fisher exact test)

were used to examine the relationships between the outcome variable and the covariates. All p-values were from two-sided tests, and results were deemed statistically significant at $P<0.05$.

Key Findings. The study examined the change in pain intensity scores between groups after the music intervention, controlling for the baseline pain score, using the model: post intervention pain score = Constant + (a * baseline pain score) + (b * group). A total of 2,262 patients were screened, and 272 patients were consented to participate. Of those consented, 94 received the music intervention and 128 were in the control group. In addition 50 patients were consented on intervention days and declined the music intervention. The mean age of the sample was 48 years (95% CI: 45.92, 50.68); age ranged from 18 to 95 years. Adjusting for the baseline pain scores (6.84 (2.48) control and 6.28 (2.57) music), the post-intervention pain scores showed that the intervention group had a non-significant lower pain score (4.97 (2.69), p=0.292) than the control group (5.63 (2.59). Also adjusting for patient's gender, age groups (< 50 vs >50), race, and payer status, also showed no significant predictor except baseline pain score.

While there were absolute reductions in pain perception for patients who were either randomized to control or intervention cohorts, the differences in the perception of pain reduction were not statistically significantly different between groups. Absolute reductions in pain scores were more clinically significant in patients with moderate initial pain intensity scores as opposed to higher or lower pain intensity scores. There was no difference in pain medication administration between groups as determined by morphine equivalent administration.

Discsussion. While the study was adequately powered to detect a clinically significant difference in the perception of pain, it should be noted that selection bias with regard to patients who were approached for intervention but declined may have affected results. Qualitative analysis of data from the group randomized to the live music intervention (no-music intervention) but who

declined the intervention showed that the most common reason patients provided for declining music was that they were in too much pain for music. This finding corresponded with the no-music intervention and control subjects having slightly higer levels of pain at baseline (6.79 and 6.84, respectively) than intervention subjects (6.28). Because the no-music intervention subjects declined music, these findings suggest there may be a specific range of pain in which music may be most appropriate and acceptable to patients in the emergency department setting. One can hypothesize that a subset of patients with moderate intensity pain perception may be more likely to show quantifiable benefit from such an intervention. Previous phases of the study demonstrated clear evidence of a qualitative impact on patient's perception of pain.

The Live Preferential Music protocol was a useful means for obtaining a patient's musical preference, and represented a significant improvement from our phase two study approach. Additional testing and qualitative data collection at other sites could enhance the specificity and reliability of the instrument.

Live preferential music interventions in the emergency department have significant potential to alter the environment of care and impact patients in terms of their perception of pain and satisfaction with care. Demonstration of the quantifiable difference in outcomes we sought was limited by an unexpedted change in study site, study design and power and the diversity and variability in patient diagnosis, care team strategies and provider variation in care. The strategies that we have developed to provide this alternative intervention in the emergency department is imminently scalable and easily disseminated. A larger, more narrowly focused multisite study with like organizations may be required to demonstrate quantitative outcomes in reducing costs and supporting benefit in patient care in the acute setting. During our study, we did not experience negative impacts on the presence of live preferential music in these settings.

PART THREE: RESEARCH ARTICLE

Background and Rationale

Every year, more than 130 million patients access emergency care in America. Emergency departments are high stress environments and are one of the significant drivers of high costs in healthcare. The most prevalent chief complaints of patients who seek care in an emergency department (ED) involve the perception of pain. The failure to treat pain appropriately and in a timely manner in the acute setting has become a marker for quality of care in emergency medicine with healthcare quality organizations recognizing a gap between the accepted standards and the practices that are most prevalent. In addition, the rise of the opioid crisis in the US and worldwide has brought further attention to the need for multimodal and alternative approaches to successful pain management in acute settings. Live preferential music in medicine has been more thoroughly studied outside of the acute care setting.

To our knowledge, this project represents the first systematic investigation of its kind investigating the impact of live preferential music in an emergency and trauma care setting on patient outcomes. The ED and its patient population represent a traditionally challenging clinical environment for research, creating both a novel environment but a greater level of difficulty in successfully executing this study protocol. The University of Florida Center for the Arts in Medicine was established in 1996 and provides a framework for interdisciplinary collaborations among University of Florida faculty and students, health care providers, clinical artists, and local and regional communities. The Center was established to develop interdisciplinary research studies and education curricula on all levels and to serve as a national model for arts in health research, education and training.

The Center employs talented artists who have developed the professional skills to interact seamlessly in patient environments, providing live preferential music to patients in a variety of settings. Live professional music in the acute care setting, however, has remained largely unexplored. The Emergency Department setting, especially, because of the relative chaos in comparison to other clinical settings, along with a wide diversity of clinical challenges and circumstances, has been a traditionally difficult setting to develop live professional music strategies.

The rationale for this study was supported by prior protocol phases at the University of Florida and UF Health, the first of which was the development of strategies for introducing live preferential music in emergency department settings. The successful development of the protocol and the experience developed by our current group of musicians led to the undertaking of this first systematic investigation on the impact of live preferential music in acute care settings.

Hypothesis

For the primary outcome of this study of patients presenting to the Emergency Department with musculoskeletal pain, we hypothesized that controlling for baseline pain intensity, the live preferential music group would have significantly greater reduction in pain intensity than the usual care group. We also expected secondary effects of live preferential music on the environment of care, patient's satisfaction, physiologic effects (including vital signs, blood pressure, heart rate, oxygen saturation, and respiratory rate), and the overall cost of care (both pharmaceutical and non-pharmaceutical costs) for patients presenting to the Emergency Department with musculoskeletal pain.

Methods

This prospective experimental trial, conducted with a convergent mixed methods design, represents phase three of a three-phase study. This phase-three trial included a randomized, controlled, double-blinded trial with one experimental and one control arm , along with two qualitative arms. One arm collected qualitative data to triangulation with the study's quantitative data, and the other to assess the usefulness of a new Live Preferential Music (LPM) Protocol.

A block randomization was used to determine the days of music intervention over the duration of the study. Within blocks of four, six, and eight days, randomly ordered, the days were assigned to music intervention or no music intervention. Patients were enrolled using deception and were not informed to the study's relation to music, or their potential exposure to music, however, they were told initially that they would be part of a pain assessment study. After study completion, plans were for patients to receive letters disclosing the deception. The primary outcome of the interest was the assessment of pain reduction using a validated pain assessment tool, PAINR*eport*It®, which is a validated computerized extension of Melzack's (© 1970) McGill Pain Questionnaire (MPQ) (Melzack, 1975) and measures the pain intensity on a 0-10 scale. Pain intensity was measured with the Pain Intensity Number Scale (PINS) (Wilkie et al., 1990), which allows the patient to indicate the level of the current and least and worst pain intensity during the past 24 hours (baseline) or since the last measure (post intervention). The PINS provides ratio level data as a measure of pain intensity (Murphy et al., 1987). The patient designates the pain as a number between 0 and 10, where 0 is "no pain" and 10 is "pain as bad as it could be." Concurrent (r=.80 to .89) (Wilkie et al., 1990) and construct validity have been reported (Downie et al., 1978; Jensen, Karoly & Braver, 1986). PINS scores separated by two weeks were correlated at a moderate level ($r(45)=.41$, $p<.005$) (Boyd-Seal et al, 2010). The PINS

with its standardized instructions can be completed by patients with cancer in less than 1 minute (Wilkie et al., 1990).

Inclusion criteria included English-speaking patients age 18 and older with a chief complaint of musculoskeletal pain, grade two reading level or greater, and those who were physically and cognitively able to participate. Exclusions included those who could not consent and prisoners.

The sample size was calculated based on the MUES phase II pain data. To detect a 25% reduction in pain (from MUES II) with 80% power required a total of 242 subjects (121 per group). The choice of 25% reduction and 80% power was based on study duration and clinical feasibility. Data collection is ongoing to achieve the desired sample size.

The study took place with trained musicians and research associates (RAs) in the free-standing Shands Emergency Departments in 5-hour shifts from 12:00-5:00pm on randomized week days. Only the study statistician and the UF Health Shands Arts in Medicine assistant director, who was responsible for supervision of the musicians, knew the days assigned to each condition. The ED staff members were blind to day assignment until the musicians presented in the ED. Patients were screened for participation and enrolled in the study via informed consent by an emergency medicine RA. The RA then administered the PAINR*eport*It pre-questionnaire and then notified the musician of the patients who consented. The musician subsequently consulted with the charge nurse and/or attending physician(s) to identify patients for whom music would be appropriate. If the provider agreed, the musician entered the patient room and offered music to the patient within a 15-minute window of completion of the pre-measure. If the patient was interested, the musician discussed music preference with the patient using the Live Preferential Music (LPM) Protocol and offered to perform appropriate preference-based music.

The music interactions lasted an average of 8-9 minutes, including conversation and performance. Musicians were guitarist-vocalists with broad musical repertoires that allowed them to respond to a range of requests across musical genres. The patient's door remained closed during the interaction to limit the drift of sound to other areas. Per the normal practice of artists in the UF Health Arts in Medicine program, patients were provided the option to decline or discontinue the interaction at any time. Each of the musicians participating in the study was a guitarist/vocalist with a very broad repertoire of musical styles. The RA then returned to the patient room to complete the post-measure 30-minutes after the pre-measurement was collected.

In order to assess the qualitative and LPM arms of the study, the musicians documented their interactions with patients by completing a questionnaire following interaction with each patient. The questionnaire documented the location, time and length of the interaction, the number and roles of the people in the room, the patients' gender, the music played (genres, artists, songs), and how preference was (or was not) established in relation to the LPM Protocol. The musicians also entered a narrative description of the interaction.

Based on the study's phase two findings, a Live Preferential Music Protocol (LPMP) was developed and used by the Musicians in Residence to determine patients' musical preference. This protocol was developed by the musician and investigator team, based on established professional practices. Per the protocol, each conversation between the musician and patient, following introductions, started with the question "What would you like to hear?" and subsequently went from broader levels of preference (genre) to specific (song), based on whether the patient had an initial music preference or not. The protocol contains six distinct pathways to preference. Musicians utilized the protocol as a framework, rather than a script, and always deferred to the patient's comfort with answering questions. Following each interaction, the

Musicians in Residence documented the pathways used to achieve preference within the LPMP. The questionnaire documented at what level and by what pathway preference was (or was not) achieved and the music performed (genres, artists, songs).

Variables were collected from several data sources and cross-referenced using the subject's medical record number and the date of visit. Bedside collection of the patient medical record number, music selection, and date/time of the intervention were recorded at the time of the musician visit. Variables collected from the medical record included patient age, gender, mailing address, Glasgow coma score, presence of altered mentation, triage acuity, height, weight, medical early warning sign score, area of ED care, and pain scales at presentation and post intervention using PAINR*eport*It®. Medication utilization, primary and secondary clinical diagnosis, admission status, and admission location were collected. In addition, vital signs including blood pressure, heart rate, oxygen saturation, and respiratory rate, prior to, during, and after the music intervention were collected.

All data were entered into the University of Florida's secure REDCap database for the duration of the study. IPad / MS Surface devices owned by the Department of Emergency Medicine team were used to collect the information when approaching and implementing the internet-based PAIN*Report*It® survey for enrolled subjects.

Analysis and Results

Pain data were exported from the PAIN*Report*It® structured query language (SQL) database into Microsoft Excel and imported into SPSS for statistical analysis. All clinical data were extracted from the REDCap to SPSS. Descriptive statistics (means, frequencies, and percentages) and inferential tests (the independent t test, Chi-square test, and Fisher exact test) were used to

examine the relationships between the outcome variable and the covariates. All p-values were from two-sided tests, and results were deemed statistically significant at $P<0.05$.

The primary study outcomes was the change in pain intensity scores between groups after the music intervention, controlling for the baseline pain score. The model for this is: post intervention pain score = Constant + (a * baseline pain score) + (b * group). Where a and b are regression coefficients and group is a binary dummy variable with control coded as 0 and treatment coded as 1. The main coefficient of interest is b, which is the estimated difference between the treatment and control group. An analysis of covariance (ANCOVA) adjusts each subject's follow up score for their own baseline score, but is unaffected by baseline differences and regression to the mean.

A total of 2262 patients were screened for the study, and 272 patients were consented to participate at two UF Health Shands free-standing emergency departments by RAs. Of those consented, 94 received the music intervention and 128 received usual care in the control group. An additional 50 patients were consented on intervention days, completed measures, but declined the music intervention and are excluded from the main analysis.

Table 1. Patient Characteristics

Characteristics	Intervention (N=94)	Control (N=128)	Total (N=222)
Age in years, mean (95% CI)	48.54 (44.63, 52.44)	48.12 (45.10, 51.15)	48.30 (45.92, 50.68)
Body Mass Index, mean (95% CI)	32.14 (30.20, 34.08)	30.64 (29.15, 32.13)	31.28 (30.10, 32.47)
Length of stay in hours, mean (95% CI)	4.46 (3.25, 5.67)	4.18 (3.35, 5.02)	4.4 (3.78, 5.03)
Morphine equivalence, mean (95% CI)	29.49 (15.45, 43.44)	24.64 (16.55, 32.73)	26.69 (19.22,34.16)
Gender			

Male	35 (37.23)	45 (35.16)	80 (36.04)
Female	59 (62.77)	83 (64.84)	142 (63.96)
Race			
White	61 (68.54)	90(72.00)	151 70.56)
Black	28 (31.46)	35 (28.00)	63 (29.44)
Payer status			
Private/Commercial	29 (32.22)	51 (41.13)	80 (37.38)
Medicare	23 (25.56)	21 (16.94)	44 (20.56)
Medicaid	24 (26.67)	32 (25.81)	56 (26.17)
Self-pay	14 (15.56)	20 (16.13)	34 (15.89)
Triage Acuity			
Urgent	53 (56.38)	63 (49.22)	116 (52.25)
Less urgent	39 (41.49)	58 (45.31)	97 (43.69)
Immediate	0	1 (0.78)	1 (0.45)
Emergent	2 (2.13)	6 (4.69)	8 (3.60)

Note: Other race (n=9) are not shown here.

All characteristics were non-significant at 0.05 level.

Table 1 outlines patients characteristics and as well as differences in characteristics between the control and intervention group.

The mean age of the sample was 48 (95% CI: 46, 51); age ranged from 18 to 95 years. The majority of the patients was female (63.96%), white (71%), and 37% were privately insured.

The triage acuity distribution was 52% urgent, 44% less urgent, and 4% were emergent patients. The mean body mass index was 31.28% and mean length of stay was 4.4 hours.

Table 2. Comparison of pain measurements

	Control (N=128), mean (SD)	Intervention (N=94), mean (SD)	Difference between means, (95% CI)	p-value
Pain Now				
Baseline	6.84 (2.48)	6.28 (2.57)	-0.56 (-0.11, 1.24)	0.101
Follow-up	5.63 (2.59)	4.97 (2.69)	-0.65 (-0.05, 1.36)	0.068
Change Pain Intensity scores	-1.21	-1.34	-0.14 (-0.48, 0.76)	0.667
Pain Worst				
Baseline	8.56 (1.74)	8.35 (1.91)	-0.21 (-0.27, 0.70)	0.401
Follow-up	7.55 (2.37)	7.18 (2.54)	-0.37 (-0.28, 1.03)	0.266
Change Pain Intensity scores	-1.01	-1.17	-0.16 (-0.71, 0.38)	0.562
Pain Least				
Baseline	4.90(3.14)	4.64 (3.02)	-0.26 (-0.57, 1.09)	0.537
Follow-up	4.54 (2.83)	4.35 (2.85)	-0.19 (-0.57, 0.95)	0.617
Change Pain Intensity scores	-0.36	-0.29	0.07 (-0.63, 0.73)	0.848

Table 2 shows the mean pain intensity score of all three pain measurements by groups and changes in pain intensity scores within group. The *pain now* had the highest reduction of

pain intensity for the control (-1.21) and the intervention (-1.34) among all the three pain measurements.

Table 3. ANCOVA model predicting follow-up pain score

	t value	p-value	Beta coefficient
Baseline pain score	10.899	<0.001	0.62
Group (Intervention vs control)	-1.056	0.292	-0.306

Table 3 shows the results of the ANCOVA model. In the ANCOVA model, we adjusted for the baseline pain score effect on the post-intervention pain score. Results show that the intervention group had a non-significant lower pain score (p=0.292) than the control group. The ANOVA model equation with the predictors was Post-intervention pain score = Intercept (1.394) + (0.62) * baseline pain score + (−0.306) * intervention group. The regression equation showed the non-significant group effect on decreasing the pain score at follow-up when controlling the baseline pain score. We conducted a similar analysis-adjusting patient's gender, age groups (less than 50 years vs 50 or above), race, and payer status; found no significant predictor except baseline pain score.

Table 4. Comparison of vital signs

	Control, mean (SD)	Intervention, mean (SD)
Vital signs	N=128	N=94
Systolic Blood Pressure		
Baseline	129.8 (20.13)	133.71 (24.39)

Follow-up	128.98 (19.5)	133.71 (22.05)
Diastolic Blood Pressure		
Baseline	75.0157 (80.13)	77.86 (13.08)
Follow-up	74.0694 (78.98)	79.46 (11.8)
Heart Rate		
Baseline	74.21 (13.05)	73.36 (12.07)
Follow-up	75.94 (13.09)	75.16 (12.4)
Oxygen Saturation		
Baseline	97.98 (1.91)	97.76 (1.9)
Follow-up	96.16 (10.7)	97.77 (2.13)
Respiratory Rate		
Baseline	16.01 (4.5)	15.5 (1.94)
Follow-up	17.31 (10.59)	15.48 (1.83)

Qualitative data garnered from narrative reports provided by musicians following each music interaction and decline were analyzed thematically by a team of investigators and research assistants. The resulting themes were used to explain and triangulate with the quantitative findings. Eight themes were derived from the data:

- Patients had positive responses to the music interaction
- Patients expressed gratitude for the interaction
- Patients reported reduction in pain
- Patients participated actively in the interaction (i.e., singing along, dancing)
- Initial hesitation followed by positive response to the interaction

- The interaction provided meaningful social engagement for the patient
- Patients shared the experience with others

It was notable in the qualitative analysis that all of the themes were positive in nature, genrally and overtly reflecting appreciation and satisfaction with the music intervention. A common theme was patient-reported reduction in the perception of pain, suggesting that a more highly powered study may detect more significant effects on pain.

Live Preferential Music (LPM) Protocol data were analyzed using SAS. Among the 94 data entries for the music intervention group, six were missing data and nine noted "other" as a means of achieving preference. These 15 entries were removed from analysis, leaving 79 live preferential music data points. Initial preference was documented for 62% (n=49) of patients, while 38% (n=30) did not express an initial preference. When patients had an initial music preference, P3 (genre–artist–song) was the most common pathway to preference (77.5%). When patients did not have an initial music preference, NP3 (tempo–genre–artist–song) was the most common pathway (70%).

Discussion

Musculo-skeletal (MSK) pain is a common reason patients seek emergency care. Improving quality of care for MSK pain is an important priority for patients, clinicians, and policy makers. MSK pain conditions (e.g., low back pain, osteoarthritis, cervical and thoracic spine pain) share similarities in mechanisms, prognosis, and clinical trajectory, which has led to overarching clinical practice guidelines for assessment and management (Lin, Wiles, & Waller, 2019). Recommendations include patient centered care with effective communication, shared decision-making, screening for serious pathology, physical examination, and assessment of psychosocial status. Especially given the current opioid public health crisis, non-pharmacologic therapies,

including those that promote relaxation, such as live music, are becoming important in reducing the dependency on narcotic prescription therapy and could be an important adjuvant to other pain reduction strategies. Reduction of pain by 1 to 2 points on a 0 to 10 pain intensity scale or a 30% reduction is typically considered clinically important (Farrar et al., 2001) and patients greatly appreciated the relief, especially if severe pain (7 to 10/10) is reduced to moderate (4 to 6/10) or mild (1 to 3/10) pain (Olsen, Bjerre, & Hansen, 2017).

Over the past two decades, partnerships between musicians, music therapists and clinical researchers have yielded unprecedented development of clinical interventions supported by rigorous scientific studies (Thaut & McIntosh, 2010). Hundreds of studies have confirmed the effect of music on reducing pain, anxiety, and other clinical measures such as vital signs. There is clearly documented evidence of the physiologic impact of music including effects on parasympathetic activity, stress hormone levels and immunity, suggesting its efficacy in decreasing stress-induced autonomic and neuroendocrine arousal and the facilitation of the relaxation response. There is also evidence in the medical environment that music can be a safe and low-cost, non-pharmacologic intervention to reduce anxiety and enhance relaxation in intensive care patients as well as to reduce pain perception, anxiety and stress levels in the emergency department (ED) setting (Mangoulia & Ouzounidou, 2013; Holm & Fitzmaurice, 2008).

Music has been widely shown in various patient populations and procedures to positively affect pain control, pain tolerance, and pain perception (Henry, 1995; Whipple and Glynn, 1992; Nilsson, Rawal, & Unosson, 2003; Good, 1995; Good et al., 2001; Mitchell and MacDonald, 2006; Pancekauskaitė and Jankauskaitė, 2018), as well as the need for anesthesia and sedation (Newman et. al, 2010; Lee et al., 2002). Mangoulia's 2013 meta-analysis of music therapy and

music medicine (music administered in healthcare by a musician who is not a music therapist) in intensive care concluded that music is a safe and low-cost non-pharmacologic intervention to reduce anxiety and enhance relaxation in intensive care patients. The study recognized live music as having more importance than recorded music as an intervention for this population. Another important meta-analysis, conducted by Nilsson in 2008, looked at 42 studies that measured the effects of music on pain and anxiety. Nilsson's analysis found that approximately half of the studies reported significant positive effects. A 2016 meta-analysis of 97 studies by Lee found that music interventions had statistically significant effects in decreasing pain, emotional distress from pain, opioid intake, non-opioid intake, systolic blood pressure, diastolic blood pressure, and respiration rate.

Studies of music in emergency care have presented positive outcomes related to anxiety and stress (Holm & Fitzmaurice, 2008; Short & Ahern, and Bonde, 2009), pain management (Bauman & McManus, 2005; Negrete, 2011), and reduction of noise stress (Short et al., 2010). Most interventions use recorded music, and some engaged technology such as iPods (Young et al., 2010). In a clinical trial with 200 patients in an emergency department in Turkey, Kilic, et al. (2015) found significant decreases in pain and anxiety among patients who were provided with recorded music. In a randomized clinical control trial with 291 emergency department patients, moderately anxious ED patients, Weiland et al. (2011) found that state anxiety was reduced most significantly by music exposure, as compared to other or no sound.

Studies have shown that music can reduce the need for pain medication in emergency and other care. Menegazzi et al (1991) demonstrated a significant decrease in pain among patients listening to recorded music during laceration repair in an emergency department. Music has been shown to significantly reduce pain and anxiety during burn dressing changes (Tan et al., 2010;

Son & Kim, 2006). Smolen and colleagues (2002) demonstrated decreased administration of Versed® and meperidine during colonoscopy when self-selected recorded music was utilized. Similarly, Schiemann (2002) reported lower use of analgesics, higher procedure completion rate and accelerated procedure time when music was used during colonoscopy. Lee et al. (2002) also demonstrated a reduced need for sedation with music.

Stress and anxiety also significantly affect the perception of pain, and music has been widely demonstrated to reduce both in medical settings (Holm & Fitzmaurice, 2008; Richards et al., 2007; Dritsas, 2013). Music has also been shown to reduce anxiety among patients waiting for test results (Haun, Mainous & Looney, 2001), which is common in an Emergency Department. Agwu & Okoye (2007) investigated the use of live preferential music during hysterosalpingography procedures. Patients who listened to music during the procedure had lower State Anxiety scores than a control group.

Studies have shown music to be a risk-free alternative to pharmacological interventions, and to significantly reduce the costs of medical procedures such as CT scans (Loewy, et al., 2005; Walworth, 2005). Walworth (2005) documented use of music during pediatric CT scans that almost entirely eliminated the need for sedation and anesthesia, eliminated overnight stays, yielded a 98% procedure success rate, put three hours of nursing time back on the floor per procedure, and documented cost savings of $567 per procedure. With over four million CT scans performed annually on children, the potential cost savings of using musicians for this procedure alone exceeds $2.25 billion nationally. Far more such procedures are performed on adults in emergency and critical care centers than on children.

Wider utilization in recent years of music in medical settings and partnerships between musicians/music therapists and clinical researchers are yielding advances in clinical interventions

supported by scientific evidence (Thaut and McIntosh, 2010; Sonke, 2011). As brain-imaging technologies have advanced in sophistication over the past twenty years, neurological research has been able to identify some of the structures that may underlie the outcomes noted above. Studies have shown that the neural networks that process music also process other functions, such as attention (Bengtsson et. al, 2009). As music occupies attention as a pleasurable stimulus, it has the potential to reduce anxiety and the perception of pain (Lin et al., 2011; Voss et al., 2004).

While most studies focus on use of recorded music, limited investigation has been conducted on the use of live music specifically, as an intervention for pain and anxiety. Ferrer (2007) documented positive effects of live music on fear, fatigue, diastolic blood pressure, and relaxation levels among patients receiving chemotherapy. A study by Holmes et al. (2006) suggests that live music has advantages over recorded music, a conclusion cited as well in Aldridge's (1994) review of music therapy literature. Live music has been shown to be beneficial for neonatal, pediatric, burn, post-operative, and palliative care populations (Teckenberg-Jansson et al., 2011; Hartlin et al., 2009; Tan et al., 2010; Galleghar, 2011; Engwall & Duppils, 2009). A recent study by Bro, et al. (2019) found that live patient-preferred music resulted in greater anxiety reduction than recorded music. More such research is needed in emergency and acute care environments.

Preferential music is also becoming the standard in music interventions as studies show that choice, preference, and familiarity with music can enhance its effectiveness as an intervention and can contribute to reductions in pain and anxiety (Dileo, 1999; Schmid and Aldridge, 2004; Thaut & Davis, 1993; Cepeda et al., 2006; Reimnitz, & Silverman, 2018; Silverman, Letwin & Nuehring, 2016). Several terms are used for such interventions, including

patient preferred music, customized music, and patient directed music (Perkins et al., 2018; Chlann, et al., 2013, Chlan & Heiderscheit, 2009).

Some more recent studies have begun to look specifically at live preferential music as an intervention, using terms such as patient preferred live music, live preferred music, and live preferential music. These studies have found significant improvements in the reduced perception of pain and anxiety, in particular (Reimnitz & Silverman, 2018; Verstegen & Silverman, 2018). In a review of the literature on patient preferred live music, Ramaswami & Silverman (2018) offered a neuroscience-based rationale for patient-preferred live music as a receptive music therapy intervention for adult medical patients. They suggest that there is ample neuroscientific evidence regarding the brain's neurologic response to music, mostly pertaining to the reward system and the process of dopamine release. They also offer evidence to suggest that both exposure to familiar stimuli and the act of making a choice may be neurologically reinforcing. In a recent systematic review of patient preferred live music with adult medical patients, Silverman, Letwin & Nuehring (2016) found these interventions to be applicable for affective states, pain, nausea, and physiological measures for adult cancer and transplant patients.

While our earlier phase efforts demonstrated clear evidence of a qualitative impact on patient's perception of pain, for this randomized controlled study, even though there were absolute reductions in pain perception for patients who were either randomized to control or intervention cohorts, the differences in the perception of pain reduction were not statistically significantly different between groups. Absolute reductions in pain scores were more clinically significant in patients with moderate initial pain intensity scores as opposed to higher or lower pain intensity scores. These outcomes were adjusted for baseline pain score, age and gender. There was no

difference in pain medication administration between groups as determined by morphine equivalence administration.

While the study was adequately powered to detect a clinically significant difference in the perception of pain, it should be noted that selection bias may be a factor with regard to patients who enrolled but declined intervention. Qualitative analysis of data from the group randomized to the live music intervention (no-music intervention) but who declined the intervention showed that the most common reason patients provided for declining music was that they were in too much pain for music. These patients did not receive the intervention and were excluded from the group analysis. This finding corresponded with the no-music intervention and control subjects having slightly higer levels of pain at baseline (6.79 and 6.84, respectively) than intervention subjects (6.28). Because the no-music intervention subjects declined music, these findings suggest there may be a specific range of pain in which music may be most appropriate and acceptable to patients in the emergency department setting. . One can also hypothesize that a subset of patients with moderate intensity pain perception may be more likely to show quantifiable benefit from such an intervention.

The Live Preferential Music Protocol was a useful means for obtaining a patient's musical preference, and represented a significant improvement from our phase two study approach. Additional testing and qualitative data collection at other sites could enhance the specificity and reliability of the instrument. In addition, the term "preference" and the level of preference (i.e. genre, artist, song) needed to qualify as true preference need further definition in relation to hospital bedside music. While this study marks significant advancement in defining the term "Live Preferential Music", further work is needed.

Limitations

The study enrollment began at a period of extraordinarily high census during the flu season. Due to unexpectedly high patient volumes, the study was suspended for several reasons. Patients initially meeting enrollment criteria were triaged to locations that did not meet the required criteria for isolating the music to the individual patient. In addition, all personnel, including the musicians, were required to wear masks, making the intervention even more challenging and significantly chaning the nature of the interaction. As a result, the music protocol was relocated to two satellite Emergency Departments where further challenges to enrollment occurred, specifically because fewer patients met the inclusion criteria for musculoskeletal pain. In addition, the greater efficiency, shorter length of stay and lower acuity of the satellite facilities resulted in fewer opportunites for enrollment. Further, patient length of stay may have also impacted the the length of time and exposure of patients to the specific intervention, which, in turn, could be an important factor impacting outcomes. Among patients who enrolled in the intervention group, the majority were only exposed to one song (53%) or two songs (36%). In contrast, our previous phases of this study, where substantial qualitative reductions in the perception of pain were demonstrated, the majority of patients had substantially greater exposure to music intervention (two to four songs).

Regarding other aims of the study, patient satisfaction data were only available in monthly aggregates from the free-standing emergency departments. Given the complexity of the emergency department environment and the number of variables present, no quantitative conclusions could be made regarding the effect of the music intervention on patient satisfaction. Overall costs of care were also not accounted for in this study but our prior unpublished results from earlier phase work suggested a low likely hold of detecting any significant differences in

the cost of care. The purpose in part of restricting patient enrollment to patients who had only a narrow subset of chief complaints -musculoskeletal pain- was an attempt to narrow the variability of costs of intervention and thus increase the possibility of detecting a difference between groups. However, the variability in practice patterns of physicians and care teams may have a far more significant impact on cost variables than may have been originally realized. A sufficiently powered study would require greater numbers of a narrower subgroup of patients to adequately detect a statistical difference in costs of care.

In addition, there were substantial challenges in recruiting patients who were interested in the study and who met inclusion criteria for musculoskeletal pain, and who had a sufficient length of stay in the Emergency Department to complete the study. And, among those who enrolled in the intervention group, the majority were only exposed to one song (53%) or two songs (36%). In our previous studies in a primary hospital-based memergency department, the majority of patients were exposed to two to four songs. The reduced exposure was likely due to the short time-to-discharge at the free-standing emergency departments.

Live preferential music interventions in the emergency department have significant potential to alter the environment of care and impact patients in terms of their perception of pain and satisfaction of care. There is ample qualitative evidence of beneficial impact. The challenge of demonstrating a quantifiable difference in the outcomes we sought were limited by study design, inadequate power, and the diversity and variability in patient diagnosis, care team strategies and provider variation in care. The strategies that we have developed to provide these alternative and unorthodox interventions in the emergency department is imminently scalable and easily disseminated. A larger more narrowly focused multisite study with like organizations with a similar infrastructure and sophistication of Arts in Medicine programs may be required to

demonstrate quantitative outcomes in reducing costs and supporting benefit in patient care in the acute setting. During our study, we did not experience negative impacts on the presence of live preferential music in these settings.

Conclusion

Live preferential music interventions in the emergency department have significant potential to alter the environment of care and impact patients in terms of their perception of pain and satisfaction of care. There is ample qualitative evidence of beneficial impact. The challenge of demonstrating a quantifiable difference in the outcomes we sought were limited by study design, inadequate power, and the diversity and variability in patient diagnosis, care team strategies and provider variation in care. The strategies that we have developed to provide these alternative and unorthodox interventions in the emergency department is imminently scalable and easily disseminated, and our experiences so far have not revealed any negative impacts on the presence of live preferential music in these settings. A larger more narrowly focused multisite study with like organizations with a similar infrastructure and sophistication of Arts in Medicine programs may be required to demonstrate quantitative outcomes in reducing costs and supporting benefit in patient care in the acute setting.

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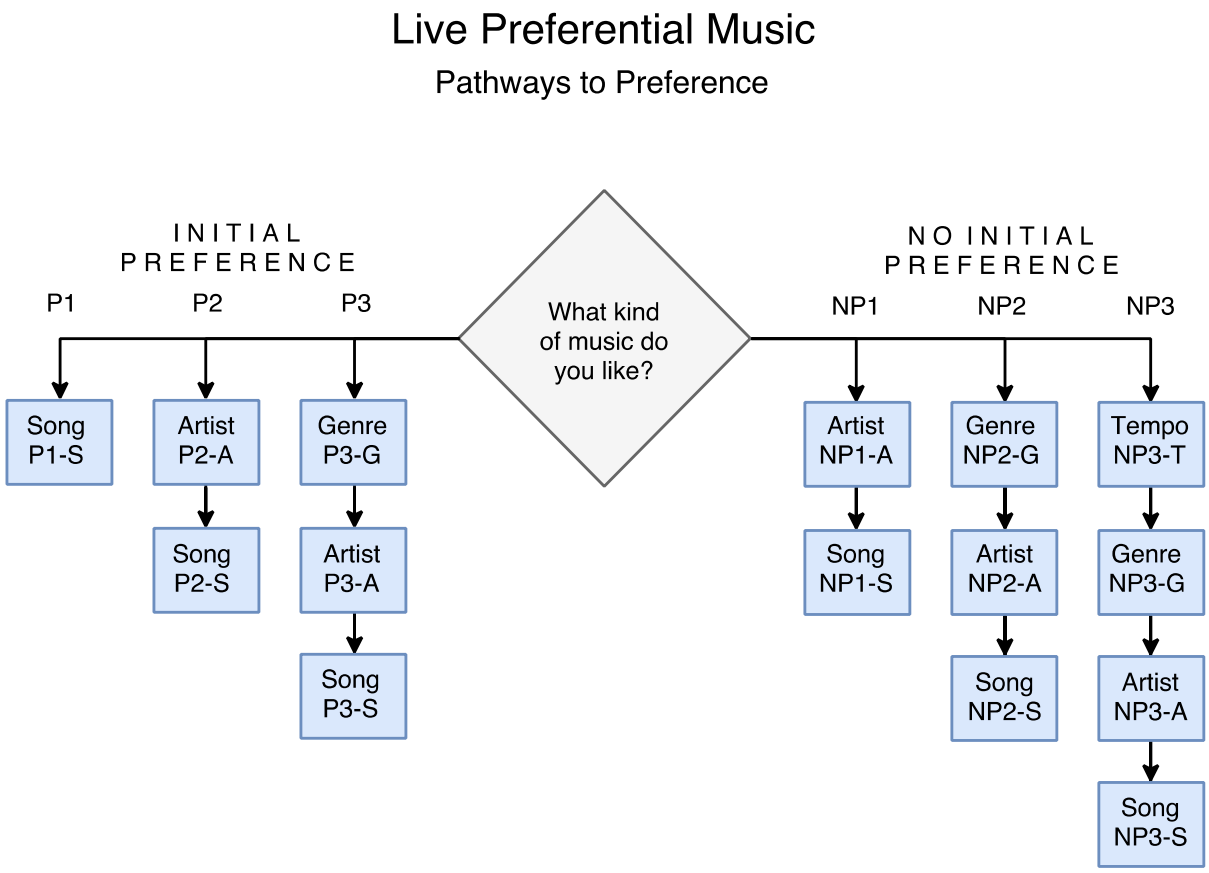
Live Preferential Music Protocol



Live Preferential Music Protocol User Guide

Upon entering a patient room, a musician will typically engage in a conversation to explore musical preference. The following guide is not intended to serve as a script, but rather, as a framework to guide this conversation and assist with documentation of preference and the general pathway taken to achieve preference.

1) To broach this conversation, start with a question like, *"What would you like to hear?"* or *"What kind of music do you like?"*

2) If the patient has an initial preference:
   a) Note and play the requested song(s)
   b) If the patient requests an artist or genre, try to get to a song-level preference **or** play something similar to the requested genre/artist, with the patient's permission. Be sure to use the word "like", rather than "*how about…"* or "*is it OK if I play…"*
   c) Indicate on the survey the level of preference obtained from the patient (P1-S, P2-A, P2-S, P3-G, P3-A, or P3-S)

3) If the patient has no initial preference:
   a) Ask if they have a preferred genre or artist
   b) If patient doesn't offer a preference, ask about tempo: *"would you prefer something relaxing or upbeat?"*
   c) Indicate on the survey the level of preference you obtained from the patient (NP1-A, NP1-S, NP2-G, NP2-A, NP2-S, NP3-T, NP3-G, NP3-A, or NP3-S)

4) Indicate "other" for any other pathway taken, or if you are unsure of the pathway. Please provide an explanation.

5) Indicate "No preference obtained" if you weren't able to achieve preference from the patient