The Lullaby Project: A Musical Intervention for Pregnant Women

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Introduction

During pregnancy, symptoms of stress, anxiety, and depressed mood are common (Alder, 2007; Monk, 2008) and often associated with risk factors including low socio-economic status, financial concerns, lack of social support, and younger and older maternal age (Britton, 2008; Cunningham & Zayas, 2002; Lancaster et al., 2010). Stress in pregnancy bears clinical and public health relevance due to the association between high maternal stress and poor maternalinfant outcomes (Cook, Ayers, & Horsch, 2018) including higher rates of preterm birth and analgesia use in labor (Alder, Fink, Bitzer, Hösli, & Holzgreve, 2007). Maternal stress is also associated with poorer maternal infant attachment (Monk, Leight, & Fang, 2008) and a subsequent diagnosis of antenatal and/or postnatal depression (Britton, 2008; Heron et al., 2004).

Interventions focused on reducing maternal stress, anxiety, and depression in pregnancy and thus improving maternal-fetal outcomes are warranted. In particular, non-pharmacological based interventions are desirable due to concerns about the impact of medication use on the developing fetus. The use of music and maternal singing during pregnancy represents one such non-pharmacological intervention that may be of benefit. Previous research has demonstrated preliminary evidence for some beneficial effects of exposure to music during pregnancy for both mother and the developing baby (Alder et al., 2007; Arya, Chansoria, Konanki, & Tiwari, 2012; Chang, Chen, & Huang, 2008; Partanen, Kujala, Tervaniemi, & Huotilainen, 2013) including: pain management during labor and birth (Sidorenko, 2000), reduced stress, anxiety, and depression (Chang et al., 2008), improved maternal infant attachment (Blumenfeld & Eisenfeld, 2006; Cevasco, 2008), and improved adjustment among teenage mothers (McDonald et al., 2009).

Over the last seven years, Carnegie Hall's Weill Music Institute (WMI) Lullaby Project pairs pregnant women and new mothers with professional musicians to write and sing personal lullabies for their babies, supporting maternal health, aiding child development, and strengthening the bond between parent and child. Since 2011, approximately 900 lullabies have been created nationally in hospitals, correctional facilities, shelters, high schools, programs for teen parents, and other settings. The purpose of this music based intervention is to encourage and support the bonding process, to support parents' aspirations to create the family they want for their children, and to harness their creativity as a tool for imagining and building future opportunities for healthy beginnings for their family. Preliminary insights from a two year qualitative analysis of the Lullaby Project by WolfBrown Associates (Wolf, Dennie Palmer, 2017) suggest that lullabies may have the capacity to strengthen bonds between parents and children, and also provide an opportunity for parents to experience positive emotions including feelings of competency, that may help promote resilience during difficult circumstances.

The transition to parenthood is a unique developmental phase that constitutes a period of stressful and sometimes maladaptive change for a significant proportion of new parents. Caring for an infant or young child can be taxing among the healthiest of parents, particularly in times of high stress. Adults who have experienced overwhelming and frightening events in their childhood, such as abuse and neglect, and/or adverse experiences in adulthood such as poverty or homelessness, are at higher risk for experiencing parenting challenges on a day-to-day basis. These adults are also at higher risk for reporting greater levels of parenting stress, which has been associated with problematic parenting and poor developmental outcomes in children. Historically, intervention efforts aimed at improving developmental outcomes in children and families have been primarily focused on high-risk mothers and children, such as women with

depression, substance abuse, trauma, and children exposed to severe sexual, physical abuse, or domestic violence. Intervention efforts have been less focused on treating vulnerable children and mothers identified as at-risk, but not high-risk, such as women with poor social support or economic hardship.

The purpose of the present pilot study was to investigate the potential impact of exposure to a brief musical intervention on maternal-fetal attachment, self-reported psychiatric symptoms, and perceived stress in a multicenter, randomized control trial of pregnant women. Specifically, the study seeks to answer the following questions:

- 1. Does participation in the Lullaby Project intervention impact maternal-fetal attachment?
- 2. Are there differences in mental health outcomes based on participation in the Lullaby Project intervention?
- 3. Does participation in the Lullaby Project intervention reduce perceived maternal stress?

Methods

Participants

Research participants consisted of 44 pregnant women recruited from the Virginia Commonwealth University Health System (VCUHS) in Richmond, VA and Jacobi Medical Center in Bronx, NY. Eligibility criteria included being at least 18 years of age, pregnant in the second or third trimester, English speaking, and ability to provide informed consent. Exclusion criteria included being less than 18 years of age and/or presenting with language barriers that limited one's ability to provide informed consent. This study was approved by the Institutional Review Board at both sites.

Measures

The Maternal Fetal Attachment Scale (MFAS) (Cranley, 1981) is a 24-item Likert scale designed to measure the construct of maternal-fetal attachment during pregnancy. The instrument has five subscales that propose to measure aspects of the relationship between mother and fetus, which include the extent to which women engage in behaviors that represent affiliation and interaction with their unborn baby.

The Symptom Checklist (SCL-27-plus) (Hardt & Gerbershagen, 2001) is a short, multidimensional screening instrument for mental health problems. It contains five scales on current symptoms: depressive, vegetative, agoraphobic, and sociophobic symptoms and pain; a global severity index (GSI-27); a lifetime assessment for depressive symptoms; and a screening question for suicidality.

The Perceived Stress Scale (PSS) (Yokokura et al., 2017) is the most widely used psychological instrument for measuring the perception of stress. It is the measure to the degree of situations in one's life are appraised as stressful. Items include 10 questions that were designed to tap how unpredictable, uncontrollable, and overloaded respondents find their lives. The scale also includes a number of direct queries about current levels of experienced stress.

Demographics assessing participant age, sex, racial background, educational level, relationship status, number of prior pregnancies, number of living children, household income, and employment status.

Procedure

A description of the study concept and procedure was provided via a secure online survey platform. Interested potential participants completed initial screening questions online to determine eligibility. Eligible participants were then asked to provide their name and phone number so study staff could contact them to review the consent form, answer any questions they may have, and inquire about their consent to participate in this study.

Sampling and Randomization: Women who consented to participate were randomly assigned in a 1:1 ratio to participate in an intervention or control group. The comparison group was necessary to account for possible biases arising from intervention effect and other related factors that may artificially impact the outcome variables being assessed. All participants, regardless of which group they were assigned to, were provided with referral information for mental health support. To ensure balance between treatment and control groups, and to avoid possible risk for selection bias, blocked randomization (unknown or blinded to the investigators and research assistants) was used. To ensure adequate balance between the groups, randomization was stratified by race and parity (primipara and multipara).

Baseline Assessments at Enrollment: Upon completion of consent, each participant was asked to complete a self-report battery of questionnaires (described above) via the online secure platform pertaining to their pregnancy, mental health, and perceived stress. Participants could opt not to answer any questions they chose, and could elect to end the survey at any time.

Intervention: Women randomized to the intervention participated in three group sessions described below with approximately 8-10 other pregnant women at Virginia Commonwealth University (VCU) and Jacobi Medical Center. The three group sessions were scheduled within a three week window in April-May of 2017.

- i. Session 1: (5 hours) Participants collaborated with 1-2 project musicians to compose an original lullaby.
- ii. Session 2: (5 hours) Participants collaborated with project musicians to refine and record

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their lullaby.

iii. Session 3: (2 hours) In a group format, all participants listened to each recorded lullaby and were invited to reflect on their experience.

Control Group: This study assessed outcomes for women who met the study eligibility criteria, but were not randomized to the intervention group. Participation for the control group took approximately one hour, and consisted of completing the online questionnaires on two occasions: upon enrollment and one follow up online session around the same time as the conclusion of session 3 of the intervention group in May of 2017. Funds were unavailable to offer the intervention to the control group.

Post-Intervention Assessments: To determine the potential impact of the intervention, women participating in the intervention group completed the same online questionnaires administered at baseline (with the exception of demographics) at the conclusion of Session 3.

Participants who completed the study were compensated for their time. For VCU, intervention group participants were compensated with a \$20.00 Amazon gift card and control group participants were compensated with a \$10.00 Amazon gift card. For the Jacobi site, intervention participants were compensated with \$20.00 cash. Control group participants were compensated with \$10.00 cash. Metro transit cards were provided to assist with travel.

Data analysis

Analyses were done for each of the sites separately, as well as combined. Due to the nonnormality of the data, non-parametric tests were conducted, and the appropriate statistics were reported. Each scale and its corresponding subscale was summarized using medians and ranges. The Wilcoxon signed-rank test was used to assess whether the median scores calculated for each instrument and subscale after session 1 (baseline) were significantly different from the median scores calculated after session 3 (post-intervention) for women in the intervention group, and also for women in the control group. Additionally, for each scale and subscale the Wilcoxon rank-sum test was used to evaluate whether the median scores for the intervention group were significantly different to those in the control group. All statistical analyses were completed in SAS v9.4 using a significance level of $\alpha = 0.05$.

Results

Virginia Commonwealth University Health System

The majority recruited from VCUHS were white or Hispanic (54.6%), married (59.1%), with a college degree or higher (54.6%), and had been employed for at least one year (65.0%) (Table 1 supplemental materials). Additionally, most women had singleton births (95.5%), and did not use reproductive technology to become pregnant (90.9%). The median age of the participants was 29 years. There was no statistically significant difference in demographic characteristics between the intervention and control group except for parity.

There was no statistically significant difference in the median scores of the MFAS, SCL-27 and PSS between the intervention and control groups at baseline (Table 2). However, the MFAS subscale 'attributing characteristics to the fetus', the median score at baseline was significantly different between the intervention and control group (*p-value* = 0.0320).

	Intervention Group	Control Group		
	Median [Range]	Median [Range]	Median Difference	p-value ¹
Maternal-Fetal Attachment	96.0 [84.0-114.0]	90.0 [77.0-101.0]	6.0	0.1445
score				
Subscales:				
Differentiation of self	17.0 [12.0-20.0]	15.0 [14.0-20.0]	2.0	0.3798
Interaction with the fetus	18.5 [13.0-23.0]	18.0 [11.0-20.0]	0.5	0.3079
Attributing characteristics to the fetus	22.5 [18.0-30.0]	20.5 [14.0-23.0]	2.0	0.0320*
Giving of self	21.0 [15.0-25.0]	21.0 [18.0-24.0]	0.0	0.6355
Role taking	20.0 [15.0-20.0]	17.0 [15.0-20.0]	3.0	0.0635
PSS	28.0 [10.0-38.0]	29.0 [23.0-34.0]	-1.0	0.5906
SCL27	37.0 [27.0-84.0]	37.0 [28.0-62.0]	0.0	0.7337
Subscales:				
Depressive symptoms	4.0 [4.0-14.0]	5.0 [4.0-8.0]	-1.0	0.4216
Dysthymic symptoms	7.0 [4.0-17.0]	9.0 [5.0-17.0]	-2.0	0.4244
Vegetative symptoms	8.0 [6.0-18.0]	8.0 [6.0-18.0]	0.0	0.8849
Agoraphobic symptoms	5.5 [5.0-13.0]	5.0 [5.0-13.0]	0.5	0.9296
Social phobia symptoms	5.0 [4.0-12.0]	5.5 4.0-10.0	-0.5	0.9576
Symptoms of mistrust	4.5 [4.0-10.0]	5.0 [4.0-10.0]	-0.5	0.5845
* Indicates signif	icance at $\alpha = 0.05$ level			

Table 2 VCU Comparison of Scales at Baseline

* Indicates significance at α = 0.05 level

¹Wilcoxon Rank Sum Test (between group differences)

Table 3 shows that there was no statistically significant difference in the median MFAS, SCL-27 and PSS scores between baseline and post-intervention in both intervention and control groups. Additionally, no statistically significant difference was observed in the median MFAS, SCL-27 and PSS scores between intervention and control groups post-intervention.

		Inte	Intervention Group			Control Group					
		Baseline		Post Intervention			Baseline		Post Intervention		
	n	Median [Range]	n	Median [Range]	p-value ¹	n	Median [Range]	n	Median [Range]	p-value ¹	p-value ²
			11		•		- 01			•	-
Maternal-Fetal Attachment score	12	96.0 [84.0-114.0]	7	106.0 [93.0-109.0]	0.1719	10	90.0 [77.0-101.0]	8	96.5 [82.0-107.0]	0.1250	0.5964
Subscales:											
Differentiation of self	12	17.0 [12.0-20.0]	7	17.0 [16.0-20.0]	>0.99	10	15.0 [14.0-20.0]	8	15.0 [13.0-18.0]	0.7813	0.5697
Interaction with the fetus	12	18.5 [13.0-23.0]	7	20.0 [13.0-22.0]	0.5938	10	18.0 [11.0-20.0]	8	18.5 [13.0-22.0]	0.1563	0.5120
Attributing characteristics to the fetus	12	22.5 [18.0-30.0]	7	26.0 [22.0-28.0]	0.2500	10	20.5 [14.0-23.0]	8	21.0 [18.0-26.0]	0.1563	0.7644
Giving of self	12	21.0 [15.0-25.0]	7	21.0 [20.0-25.0]	0.5000	10	21.0 [18.0-24.0]	8	23.0 [17.0-25.0]	>0.99	0.5521
Role taking	12	20.0 [15.0-20.0]	7	20.0 [15.0-20.0]	>0.99	10	17.0 [15.0-20.0]	8	18.5 [14.0-20.0]	0.4453	0.1601
PSS	12	28.0 [10.0-38.0]	8	29.5 [25.0-35.0]	0.9531	10	29.0 [23.0-34.0]	10	29.0 [27.0-36.0]	0.9063	0.6253
SCL27	12	37.0 [27.0-84.0]	8	46.5 [28.0-58.0]	0.5781	10	37.0 [28.0-62.0]	10	38.0 [27.0-66.0]	0.6094	0.2912
Subscales:											
Depressive symptoms	12	4.0 [4.0-14.0]	8	6.0 [4.0-9.0]	0.7188	10	5.0 [4.0-8.0]	8	5.0 [4.0-10.0]	0.2500	0.9475
Dysthymic symptoms	12	7.0 [4.0-17.0]	8	9.5 [4.0-17.0]	0.9141	10	9.0 [5.0-17.0]	8	7.0 [4.0-16.0]	0.1641	0.4536
Vegetative symptoms	12	8.0 [6.0-18.0]	8	7.5 [6.0-15.0]	>0.99	10	8.0 [6.0-18.0]	8	9.0 [6.0-18.0]	0.3438	0.6946
Agoraphobic symptoms	12	5.5 [5.0-13.0]	8	5.5 [5.0-11.0]	0.7500	10	5.0 [5.0-13.0]	8	5.5 [5.0-9.0]	0.9375	0.7896
Social phobia symptoms	12	5.0 [4.0-12.0]	8	7.0 [4.0-8.0]	0.6563	10	5.5 [4.0-10.0]	8	6.5 [4.0-8.0]	0.9375	0.6780
Symptoms of mistrust	12	4.5 [4.0-10.0]	8	6.5 [4.0-11.0]	0.4219	10	5.0 [4.0-10.0]	8	5.0 [4.0-7.0]	0.1250	0.0690

Table 3. Data analysis

¹Wilcoxon Signed-Rank Test (within group differences)

² Wilcoxon Rank Sum Test (between group differences)

Jacobi Medical Center

Participants recruited from the Jacobi Medical Center were black (47.6%), unmarried (72.7%), with some college education (40.0%), had singleton births (95.5%) and did not use reproductive technology to become pregnant (95.5%) (Table 4 supplemental materials). The median age of the participants was 28.0 years. There was no statistically significant difference in demographic characteristics between the intervention and control group except for parity.

There was no statistically significant difference in the SCL-27 and PSS median scores between the intervention and control groups at baseline (Table 5). However, there was a statistically significant difference in the MFAS (p-value = 0.0412), particularly in the 'giving of self' subscale (p-value = 0.0211).

	Intervention	Control Group		
	Group			
			Median	
	Median [Range]	Median [Range]	Difference	p-value ¹
Maternal-Fetal Attachment	102.0 [81.0-	92.0 [80.0-	10.0	0.0412*
score	107.0]	104.0]		
Subscales:				
Differentiation of self	17.0 [13.0-20.0]	16.0 [12.0-20.0]	1.0	0.3935
Interaction with the fetus	18.0 [15.0-21.0]	15.0 [10.0-21.0]	3.0	0.0867
Attributing characteristics	24.0 [19.0-28.0]	23.0 [19.0-27.0]	1.0	0.5586
to the fetus				
Giving of self	23.0 [17.0-25.0]	20.0 [14.0-24.0]	3.0	0.0211*
Role taking	19.0 [14.0-20.0]	19.0 [15.0-20.0]	0.0	0.4474
PSS	20.0 [15.0-30.0]	26.0 [8.0-35.0]	-6.0	0.3047
SCL27	44.0 [27.0-67.0]	40.0 [27.0-87.0]	4.0	0.8093
Subscales:				
Depressive symptoms	5.0 [4.0-11.0]	6.0 [4.0-8.0]	-1.0	0.7124
Dysthymic symptoms	7.0 4.0-15.0	6.0 [4.0-19.0]	1.0	0.6626
Vegetative symptoms	12.0 [6.0-18.0]	9.0 [6.0-21.0]	3.0	0.3042
Agoraphobic symptoms	7.0 5.0-13.0	7.0 5.0-16.0	0.0	0.9927
Social phobia symptoms	4.0 4.0-10.0	6.0 4.0-12.0	-2.0	0.5842
Symptoms of mistrust	4.0 [4.0-16.0]	6.0 [4.0-13.0]	-2.0	0.7951

Table 5. Jacobi Comparison of scales at baseline

* Indicates significance at α = 0.05 level

¹Wilcoxon Rank Sum Test (between group differences)

Table 6 shows that there was no statistically significant difference in the median MFAS, SCL-27 and PSS scores between baseline and post-intervention in both intervention and control groups. Additionally, no statistically significant difference was observed in the median MFAS, SCL-27 and PSS scores between intervention and control groups post-intervention. However, there was statistically significant difference in the SCL-27 subscale assessing agoraphobic symptoms (p-value = 0.0079).

Table 6. Data analysis							
	Inte	rvention Group		С			
	Baseline	Post Intervention		Baseline	Post Intervention		
	Median [Range]	Median [Range]	p-value ¹	Median [Range]	Median [Range]	p-value ¹	p-value ²
Maternal-Fetal Attachment score	102.0 [81.0-107.0]	110.0 [91.0-112.0]	0.0625	92.0 [80.0-104.0]	98.0 [84.0-113.0]	0.4375	0.5714
Subscales:							
Differentiation of self	17.0 [13.0-20.0]	18.0 [13.0-20.0]	>0.99	16.0 [12.0-20.0]	17.0 [15.0-18.0]	0.5000	0.5159
Interaction with the fetus	18.0 [15.0-21.0]	19.0 [16.0-22.0]	0.6250	15.0 [10.0-21.0]	14.0 [9.0-24.0]	0.7500	>0.99
Attributing characteristics to the fetus	24.0 [19.0-28.0]	27.0 [23.0-30.0]	0.1250	23.0 [19.0-27.0]	24.0 [17.0-30.0]	0.6250	0.5397
Giving of self	23.0 [17.0-25.0]	24.0 [22.0-25.0]	0.5000	20.0 [14.0-24.0]	24.0 [20.0-25.0]	0.1250	0.1032
Role taking	19.0 [14.0-20.0]	20.0 [17.0-20.0]	>0.99	19.0 [15.0-20.0]	20.0 [19.0-20.0]	0.2500	0.4048
PSS	20.0 [15.0-30.0]	18.0[10.0-27.0]	0.6250	26.0 [8.0-35.0]	15.0 [7.0-23.0]	0.0625	0.1508
SCL27	44.0 [27.0-67.0]	45.0 [30.0-68.0]	0.8125	40.0 [27.0-87.0]	31.0 [27.0-38.0]	0.0625	0.0952
Subscales:							
Depressive symptoms	5.0 [4.0-11.0]	5.0 [4.0-8.0]	0.7500	6.0 [4.0-8.0]	5.0 [4.0-5.0]	0.2500	0.3095
Dysthymic symptoms	7.0 [4.0-15.0]	6.0 [5.0-10.0]	0.8750	6.0 [4.0-19.0]	4.0 [4.0-5.0]	0.5000	0.1746
Vegetative symptoms	12.0 [6.0-18.0]	12.0 [6.0-23.0]	0.7500	9.0 [6.0-21.0]	7.0 [6.0-9.0]	0.5000	0.5556
Agoraphobic symptoms	7.0 [5.0-13.0]	7.0 [5.0-13.0]	0.5000	7.0 [5.0-16.0]	5.0 [5.0-8.0]	0.0625	0.0079*
Social phobia symptoms	4.0 [4.0-10.0]	7.0 [4.0-8.0]	0.7500	6.0 [4.0-12.0]	4.0 [4.0-6.0]	0.2500	0.2381
Symptoms of mistrust	4.0 [4.0-16.0]	6.0 [4.0-6.0]	>0.99	6.0 [4.0-13.0]	4.0 [4.0-8.0]	0.5000	0.3968

¹ Wilcoxon Signed-Rank Test (within group differences)

² Wilcoxon Rank Sum Test (between group differences)

Combined: Virginia Commonwealth University Health System and Jacobi Medical Center A total of 44 women were available for analysis; 23 women were randomized to the intervention group and 21 to the control group. The proportion of women who were white or Hispanic was equal to the proportion of women who identified as black (41.9%). Most women were unmarried (56.8%), had completed college (42.9%), and had been employed for 1 year or more (66.7%) (Table 7 supplemental materials).

The baseline median MFAS score for the intervention group was significantly different to the median score for the control group (p-value = 0.0181); however, there were no statistically significant differences in the SCL-27 and PSS median scores (Table 8). The results from the Wilcoxon signed-rank test for the intervention group showed that there was a significant difference between baseline and post-intervention median MFAS score (p-value = 0.0166). Specifically, there was a statistically significant difference between baseline and post-intervention median MFAS score (p-value = 0.0166). Specifically, there was a statistically significant difference between baseline and post-intervention median score for the 'attributing characteristics to the fetus' subscale (p-value = 0.0215). For the control group there was a statistically significant difference in the MFAS baseline and post-intervention medians (p-value = 0.0396), and the 'dysthymic symptoms' and 'symptoms of mistrust' subscales of the SCL-27-plus scales (p-value = 0.0430 and p-value = 0.0313 respectively). The results from the Wilcoxon rank-sum test showed no statistically significant differences between the intervention and control group with the exception of the 'symptoms of mistrust' subscale of the SCL-27-plus scales (p-value = 0.0315) (Table 9).

	Intervention Group	Control Group		
			Median	
	Median [Range]	Median [Range]	Difference	p-value ¹
Maternal-Fetal Attachment	99.0 [81.0-114.0]	91.0 [77.0-104.0]	8.0	0.0181*
score				
Subscales:				
Differentiation of self	17.0 [12.0-20.0]	16.0 [12.0-20.0]	1.0	0.1945
Interaction with the fetus	18.0 [13.0-23.0]	16.0 [10.0-21.0]	2.0	0.0555
Attributing characteristics to the	23.0 [18.0-30.0]	22.0 [14.0-27.0]	1.0	0.0703
fetus				
Giving of self	22.0 [15.0-25.0]	20.0 [14.0-24.0]	2.0	0.2167
Role taking	20.0 [14.0-20.0]	18.0 [15.0-20.0]	2.0	0.0674
PSS	20.0 [9.0-34.0]	23.0 [7.0-35.0]	-3.0	0.2901
SCL27	38.0 [27.0-84.0]	37.0 [27.0-87.0]	1.0	0.8884
Subscales:				
Depressive symptoms	5.0 [4.0-14.0]	5.0 [4.0-8.0]	0.0	0.3901
Dysthymic symptoms	7.0 [4.0-17.0]	8.0 [4.0-19.0]	-1.0	0.7869
Vegetative symptoms	10.0 [6.0-18.0]	8.0 [6.0-21.0]	2.0	0.5720
Agoraphobic symptoms	6.0 [5.0-13.0]	6.0 [5.0-16.0]	0.0	0.8640
Social phobia symptoms	5.0 [4.0-12.0]	6.0 [4.0-12.0]	-1.0	0.6390
Symptoms of mistrust	4.0[4.0-16.0]	5.0 [4.0-13.0]	-1.0	0.4475

Table 8. Comparison of scales at baseline for VCU and Jacobi

* Indicates significance at α = 0.05 level

¹Wilcoxon Rank Sum Test (between group differences)

	Inte	ervention Group		Control Group			
	Baseline	Post Intervention		Baseline	Post Intervention		
	Median [Range]	Median [Range]	p-value ¹	Median [Range]	Median [Range]	p-value ¹	p-value ²
Maternal-Fetal Attachment score	99.0 [81.0-114.0]	107.0 [91.0-112.0]	0.0166*	91.0 [77.0-104.0]	99.0 [82.0-113.0]	0.0396*	>0.99
Subscales:							
Differentiation of self	17.0 [12.0-20.0]	17.0 [13.0-20.0]	0.9375	16.0 [12.0-20.0]	15.0 [13.0-18.0]	0.8066	0.9527
Interaction with the fetus	18.0 [13.0-23.0]	19.0 [13.0-22.0]	0.4600	16.0 [10.0-21.0]	18.0 [9.0-24.0]	0.1074	0.5101
Attributing characteristics to the fetus	23.0 [18.0-30.0]	26.0 [22.0-30.0]	0.0215*	22.0 [14.0-27.0]	22.0 [17.0-30.0]	0.1582	0.5177
Giving of self	22.0 [15.0-25.0]	22.0 [20.0-25.0]	0.2813	20.0 [14.0-24.0]	23.0 [17.0-25.0]	0.1748	0.8491
Role taking	20.0 [14.0-20.0]	20.0 [15.0-20.0]	0.7500	18.0 [15.0-20.0]	20.0 [14.0-20.0]	0.1367	0.0919
PSS	20.0 [9.0-34.0]	18.0 [10.0-29.0]	>0.99	23.0 [7.0-35.0]	15.0 [7.0-28.0]	0.4053	0.5430
SCL27	38.0 [27.0-84.0]	45.0 [28.0-68.0]	0.4465	37.0 [27.0-87.0]	32.0 [27.0-66.0]	0.0762	0.1131
Subscales:							
Depressive symptoms	5.0 [4.0-14.0]	6.0 [4.0-9.0]	0.3867	5.0 [4.0-8.0]	5.0 [4.0-10.0]	0.8633	0.6413
Dysthymic symptoms	7.0 [4.0-17.0]	8.0 [4.0-17.0]	0.7446	8.0 [4.0-19.0]	5.0 [4.0-16.0]	0.0430*	0.1414
Vegetative symptoms	10.0 [6.0-18.0]	8.0 [6.0-23.0]	0.7227	8.0 [6.0-21.0]	8.0 [6.0-18.0]	0.9141	0.8772
Agoraphobic symptoms	6.0 [5.0-13.0]	6.0 [5.0-13.0]	0.3125	6.0 [5.0-16.0]	5.0 [5.0-9.0]	0.1777	0.0772
Social phobia symptoms	5.0 [4.0-12.0]	7.0 [4.0-8.0]	0.6328	6.0 [4.0-12.0]	5.0 [4.0-8.0]	0.1250	0.2598
Symptoms of mistrust	4.0[4.0-16.0]	6.0 [4.0-11.0]	0.5547	5.0 [4.0-13.0]	4.0 [4.0-8.0]	0.0313*	0.0315*

Table 9. Data analysis

* Indicates significance at α = 0.05 level

¹ Wilcoxon Signed-Rank Test (within group differences)

² Wilcoxon Rank Sum Test (between group differences)

Discussion/Conclusions

Music has the power to build a sense of community and belonging. The purpose of this music based intervention is to encourage and support the bonding process, to support parents' aspirations to create the family they want for their children, and to harness their creativity as a tool for imagining and building future opportunities for healthy beginnings for their family. This pilot study builds on the foundational qualitative data obtained previously and represents the first multi-site randomized control trial examining the potential impact of this brief musical intervention on measured outcome variables. Together, these features allow the current study to address methodological limitations obtained from a purely qualitative approach. Overall, our findings indicated that exposure to a lullaby intervention was not associated with statistical differences with regard to maternal-fetal attachment, maternal mental health, and perceived stress. This was the case across both sites and also in terms of combined data.

The significantly different associations with regard to parity across sites represents a methodological limitation with regard to potential study bias attributable to a randomization error that occurred within the online platform. It is possible that the higher baseline median MFAS scores in the intervention group is an artifact more closely related to the variable of first pregnancy. It is interesting, however, that baseline SCL-27 scores were comparable, which suggests that the groups may not be altogether different. Nonetheless, if this limitation was corrected, the question remains whether or not we would have seen a difference with regard to maternal-fetal attachment. Some significantly different associations with regard to the MFAS subscales did occur that might be compelling to conduct a number of follow up analyses. Caution, however, should be exercised interpreting the subscales due to the small sample. Future studies should consider exploring differences within the subscale with a larger sample.

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The small sample size and potential study bias could have contributed to the lack of statistical differences with regard to the outcome variables in this study. Moreover, it is possible that different outcome variables might have produced findings of statistical difference. Future studies with larger samples and different outcomes are suggested.

Although there is interest in the relationship between music and social bonding, there is no current consensus about the mechanisms by which this might occur. It has been argued that group-music making leads to social bonding due to the release of neurohormones, specifically oxytocin (Freeman, W.J. III, n.d.; Grape, Sandgren, Hansson, Ericson, & Theorell, 2003; Huron, 2001), although such explanations are tenuous. Other studies have investigated activation of the endogenous opioid system (EOS) through music. Additional research related to potential mechanistic theories is needed.

Regarding maternal-fetal attachment during pregnancy, our findings were consistent with the literature about mother-newborn bonding, suggesting a progressive increase in the level of bonding from birth onwards. Indeed, a recent quasi-randomized study examining maternal singing during pregnancy and three months after birth found no significant differences with regard to prenatal attachment (Persico et al., 2017). In contrast, postnatal bonding was significantly greater in the singing group three months after birth. These results add to existing evidence demonstrating a beneficial impact of maternal singing after birth. Future research efforts may benefit from employing longitudinal methodology across pregnancy and during the postpartum period.

Mothers in the lullaby intervention reported experiencing positive emotions while singing. This has been supported elsewhere, including maternal report that the act of singing enriches the relationship new mothers have with their babies (Persico et al., 2017). It is possible that

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subjective ratings of maternal emotions while singing lullabies and the feelings mothers selfreport in relation to their babies when they engage in singing may, in fact, differ from more objective and face-valid assessment measures of these constructs. More attention to these issues in future research is needed.

Implications for research and policy and/or practice

Historically, intervention efforts aimed at improving developmental outcomes in children and families have been primarily focused on high-risk mothers and children, such as women with depression, substance abuse, trauma, and children with severe behavioral or emotional difficulties. Intervention efforts have been less focused on treating vulnerable families identified as at-risk, but not high-risk, such as women with poor social support or economic hardship. This is an urgent political and public mental health issue because these at-risk families should receive support before they become high-risk or are identified as having developmental risk. Although there appears to be general consensus regarding the importance of intervening with young children and their parents in early childhood in particular, these families often elude early detection and intervention. There is compelling evidence for working within prevention and early intervention models of health for this population. The parenting and early childhood enterprise warrants increased scientific opportunities to conduct prevention related research aimed at better understanding developmental processes in order to better influence developmental outcomes for young children and their parents, and to establish needs for ongoing research and its application to policy.

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The Lullaby Project: A Musical Intervention for Pregnant Women

Characteristics	Total	Intervention	Control	p-value
	N = 22	N = 12	N = 10	
	n (%)	n (%)	n (%)	
Race				0.482
White (includes Hispanics)	12 (54.6)	5 (41.7)	7 (70.0)	
Black	8 (36.4)	5 (41.7)	3 (30.0)	
Other	2 (9.1)	2 (16.7)	0 (0.0)	
Marital Status				0.099
Married	13 (59.1)	5 (41.7)	8 (80.0)	
Other	9 (40.9)	7 (58.3)	2 (20.0)	
Education		()	- ()	0.392
High school or less	5 (22.7)	3 (25.0)	2 (20.0)	0.001
Some college	5 (22.7)	4 (33.3)	1 (10.0)	
College graduate or more	12 (54.6)	5 (41.7)	7 (70.0)	
Employment status	12 (34.0)	5 (41.7)	7 (70.0)	0.4108
Full-Time	9 (40.9)	6 (50.0)	3 (30.0)	0.4100
Part-Time		2 (16.7)		
	3 (13.6)		1 (10.0)	
Not presently employed	9 (40.9)	3 (25.0)	6 (60.0)	
Student	1 (4.6)	1 (8.3)	0 (0.0)	0 4 5 7
ength of current employment (n=20)	- (0.157
Less than 1 year	7 (35.0)	6 (50.0)	1 (12.5)	
1 year or more	13 (65.0)	6 (50.0)	7 (87.5)	
Estimate of yearly income				0.924
Less than \$10,000	5 (22.7)	3 (25.0)	2 (20.0)	
\$10,000 to less than \$20,000	3 (13.6)	2 (16.7)	1 (10.0)	
\$20,000 to less than \$40,000	3 (13.6)	1 (8.3)	2 (20.0)	
\$40,000 to less than \$60,000	2 (9.1)	2 (16.7	0 (0.0)	
\$60,000 to less than \$80,000	1 (4.6)	1 (8.3)	0 (0.0)	
\$80,000 to less than \$100,000	2 (9.1)	1 (8.3)	1 (10.0)	
\$100,000 to less than \$200,000	3 (13.6)	1 (8.3)	2 (20.0)	
Don't know/prefer not to answer	3 (13.6)	1 (8.3)	2 (20.0)	
First pregnancy				< 0.0001
Yes	11 (50.0)	11 (91.7)	0 (0.0)	
No	11 (50.0)	1 (8.3)	10 (100.0)	
Parity				0.454
, Singleton	21 (95.5)	12 (100.0)	9 (90.0)	
Twins	1 (4.6)	0 (0.0)	1 (10.0)	
Reproductive technology use	(-)	- ()	(/	0.480
Yes	2 (9.1)	2 (16.7)	0 (0.0)	
No	20 (90.9)	10 (83.3)	10 (100.0)	
	20 (50.5)	10 (00.0)	10 (100.0)	
	Median [Range]	Median [Range]	Median [Range]	p-value
Age (years)	29.0	28.0	31.0	0.185
אבר וארמו א	[19.0-34.0]	[19.0-34.0]	[25.0-34.0]	0.103
Gestational age (weeks) (n=21)	[19.0-34.0] 22.0	[19.0-34.0] 22.0	[23.0-34.0] 22.0	0.793

Supplemental materials

* Indicates significance at α = 0.05 level

¹ Fisher's exact test

² Wilcoxon Rank Sum Test (between group differences)

Characteristics	Total	Intervention	Control	p-value ¹
	N = 22 n (%)	N = 11 n (%)	N = 11 n (%)	
Race	11 (78)	11 (78)	11 (76)	>0.99
White (includes Hispanics)	6 (28.6)	3 (27.3)	3 (30.0)	20.95
Black	10 (47.6)			
Other	5 (23.8)	5 (45.5) 3 (27.3)	5 (50.0) 2 (20.0)	
Marital Status	5 (25.6)	5 (27.5)	2 (20.0)	0.6351
Married	6 (27.3)	4 (36.4)	2 (18.2)	0.0551
Other	16 (72.7)	4 (38.4) 7 (63.6)	9 (81.8)	
Education	10(72.7)	7 (03.0)	5 (01.0)	0.616
	6 (20 0)	2 (19 2)	A(AAA)	0.0100
High school or less	6 (30.0)	2 (18.2)	4 (44.4)	
Some college	8 (40.0)	5 (45.5)	3 (33.3)	
College graduate or more	6 (30.0)	4 (36.4)	2 (22.2)	
Employment status				0.4527
Full-Time	4 (18.2)	3 (27.3)	1 (9.1)	
Part-Time	3 (13.6)	2 (18.2)	1 (9.1)	
Not presently employed	15 (68.2)	6 (54.6)	9 (81.8)	
Student				
Length of current employment				>0.99
Less than 1 year	5 (31.3)	2 (25.0)	3 (37.5)	
1 year or more	11 (68.8)	6 (75.0)	5 (62.5)	
Estimate of yearly income				0.8866
Less than \$10,000	6 (27.3)	3 (27.3)	3 (27.3)	
\$10,000 to less than \$20,000	5 (22.7)	3 (27.3)	2 (18.2)	
\$20,000 to less than \$40,000	5 (22.7)	3 (27.3)	2 (18.2)	
\$40,000 to less than \$60,000	0 (0.0)	0 (0.0)	0 (0.0)	
\$60,000 to less than \$80,000	0 (0.0)	0 (0.0)	0 (0.0)	
\$80,000 to less than \$100,000	0 (0.0)	0 (0.0)	0 (0.0)	
\$100,000 to less than \$200,000	0 (0.0)	0 (0.0)	0 (0.0)	
Don't know/prefer not to answer	6 (27.3)	2 (18.2)	4 (36.4)	
First pregnancy				<0.0002
Yes	10 (45.5)	10 (0.0)	0 (0.0)	
No	12 (54.6)	1 (9.1)	11 (100.0)	
Parity				>0.99
Singleton	21 (95.5)	11 (100.0)	10 (90.9)	
Twins	1 (4.6)	0 (0.0)	1 (9.1)	
Reproductive technology use				>0.99
Yes	1 (4.6)	1 (9.1)	0 (0.0)	
No	21 (95.5)	10 (90.9)	11 (100.0)	
	Median [Range]	Median [Range]	Median [Range]	p-value
Age (years)	28.0	26.0	29.0	0.0900
	[19.0-37.0]	[19.0-36.0]	[22.0-37.0]	
Gestational age (weeks)	28.5	27.0	29.0	0.3207
	[14.0-34.0]	[14.0-33.0]	[20.0-34.0]	

Table 4. Distribution of Jacobi study sample characteristics

* Indicates significance at α = 0.05 level

¹ Fisher's exact test

² Wilcoxon Rank Sum Test (between group differences)

Characteristics	Total	Intervention	Control	p-value ¹
	N = 44	N = 23	N = 21	
	n (%)	n (%)	n (%)	
Race				0.5093
White (includes Hispanics)	18 (41.9)	8 (34.8)	10 (50.0)	
Black	18 (41.9)	10 (43.5)	8 (40.0)	
Other	7 (16.3)	5 (21.7)	2 (10.0)	
Marital Status				0.5702
Married	19 (43.2)	9 (39.1)	10 (47.6)	
Other	25 (56.8)	14 (60.9)	11 (52.4)	
Education				0.5278
High school or less	11 (26.2)	5 (21.7)	6 (31.6)	
Some college	13 (31.0)	9 (39.1)	4 (21.1)	
College graduate or more	18 (42.9)	9 (39.1)	9 (47.4)	
Employment status				0.1466
Full-Time	13 (29.6)	9 (39.1)	4 (19.1)	
Part-Time	6 (13.6)	4 (17.4)	2 (9.5)	
Not presently employed	24 (54.6)	9 (39.1)	15 (71.4)	
Student	1 (2.3)	1 (4.4)	0 (0.0)	
Length of current employment				0.4815
Less than 1 year	12 (33.3)	8 (40.0)	4 (25.0)	
1 year or more	24 (66.7)	12 (60.0)	12 (75.0)	
Estimate of yearly income				0.7845
Less than \$10,000	11 (25.0)	6 (26.1)	5 (23.8)	
\$10,000 to less than \$20,000	8 (18.2)	5 (21.7)	3 (14.3)	
\$20,000 to less than \$40,000	8 (18.2)	4 (17.4)	4 (19.1)	
\$40,000 to less than \$60,000	2 (4.6)	2 (8.7)	0 (0.0)	
\$60,000 to less than \$80,000	1 (2.3)	1 (4.4)	0 (0.0)	
\$80,000 to less than \$100,000	2 (4.6)	1 (4.4)	1 (4.8)	
\$100,000 to less than \$200,000	3 (6.8)	1 (4.4)	2 (9.5)	
Don't know/prefer not to answer	9 (20.5)	3 (13.0)	6 (28.6)	
First pregnancy				< 0.0001
Yes	21 (47.7)	21 (91.3)	0 (0.0)	
No	23 (52.3)	2 (8.7)	21 (100.0)	
Parity				0.2220
Singleton	42 (95.5)	23 (100.0)	19 (90.5)	
Twins	2 (4.6)	0 (0.0)	2 (9.52)	
Reproductive technology use		. ,	. ,	0.2342
Yes	3 (6.8)	3 (13.0)	0 (0.0)	
No	41 (93.2)	20 (87.0)	21 (100.0)	
	Mean (SD)	Mean (SD)	Mean (SD)	p-value
Age (years)	28.1 (4.6)	26.6 (4.6)	29.8 (4.1)	0.0206*
Gestational age (weeks)	24.5 (5.7)	24.0 (5.6)	25.2 (5.9)	0.4855

Table 7. Distribution of combined study sample characteristics

* Indicates significance at α = 0.05 level

+ Chi square test

¹ Fisher's exact test

² Two-sample t-test