

Short-term Music Therapy for Families With Preterm Infants: A Randomized Trial

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abstract

OBJECTIVES: To evaluate short-term effects of music therapy (MT) for premature infants and their caregivers on mother-infant bonding, parental anxiety, and maternal depression.

METHODS: Parallel, pragmatic, randomized controlled-trial conducted in 7 level III NICUs and 1 level IV NICU in 5 countries enrolling premature infants (<35 weeks gestational age at birth) and their parents. MT included 3 sessions per week with parent-led, infant-directed singing supported by a music therapist. Primary outcome was mother-infant bonding as measured by the Postpartum Bonding Questionnaire (PBQ) at discharge from NICU. Secondary outcomes were parents' symptoms of anxiety measured by General Anxiety Disorder-7 (GAD-7) and maternal depression measured by Edinburgh Postpartum Depression Scale (EPDS). Group differences at the assessment timepoint of discharge from hospital were tested by linear mixed effect models (ANCOVA).

RESULTS: From August 2018 to April 2020, 213 families were enrolled in the study, of whom 108 were randomly assigned to standard care and 105 to MT. Of the participants, 208 of 213 (98%) completed treatment and assessments. Participants in the MT group received a mean (SD) of 10 sessions (5.95), and 87 of 105 participants (83%) received the minimum of 6 sessions. The estimated group effect (95% confidence interval) for PBQ was -0.61 (-1.82 to 0.59). No significant differences between groups were found ($P = .32$). No significant effects for secondary outcomes or subgroups were found.

CONCLUSIONS: Parent-led, infant-directed singing supported by a music therapist resulted in no significant differences between groups in mother-infant bonding, parental anxiety, or maternal depression at discharge.



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WHAT'S KNOWN ON THIS SUBJECT Significant positive effects of music therapy (MT) have been confirmed on premature infants' respiratory rate and maternal anxiety. Small-scale studies have suggested positive effects of MT in NICU on parent-infant bonding, but large-scale studies investigating parent-infant mutual outcomes are lacking.

WHAT THIS STUDY ADDS This randomized controlled trial investigating bonding and parental mental health demonstrated high retention of parents in music therapist-supported, parent-led, infant-directed singing with their preterm infants during NICU, despite no significant effect on parent-infant bonding. Research using salutogenic outcomes is indicated.

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Preterm birth is considered a global health challenge, as prematurity is associated with higher mortality and poorer mental health, cognitive development, and quality of life for the child.¹ Premature birth (before 37 weeks' gestation)¹ affects both infants and their families. Parents of premature infants are at greater risk for developing symptoms of anxiety, depression, and posttraumatic stress disorder than parents of full-term babies.^{2–6} Moreover, delays and disturbances of parent-infant bonding have been described as a consequence of the distress of experiencing preterm birth and uncertainty about the health and development of the child.^{2,3,7,8} Bonding refers to parental perception of the emergent parent-infant relationship, including feelings, thoughts, and behaviors of the parent toward the baby.^{9,10} Bonding is influenced by physical proximity between parent and infant after birth¹⁰ and may be supported by breastfeeding, co-rooming and other proximity activities such as skin-to-skin holding.¹¹ Bonding is also influenced by maternal emotional state¹² and infant ability to communicate needs to the parent.¹³ This initial parent-infant bonding contributes to the quality of the early parent-infant relationship, which may have long-term implications for infant health.^{14–16}

Music therapy (MT) refers to the informed use of music, facilitated by a music therapist within a therapeutic relationship, whereby engagement in musical processes serves as a resource to promote health. MT in neonatal care is consistent with principles of family-centered care and aims to support infant development and parent-infant relationship by empowering parents in their parental roles and understanding of their infant.^{17,18} A meta-analysis of MT in neonatal care demonstrates short-term impacts on

infant respiratory rate and maternal anxiety, but evidence of long-term effects on infant and parental outcomes and effects on parent-infant mutual outcomes is lacking.¹⁹ Pilot studies and small-scale randomized controlled trials (RCTs) suggest improvements in parent-premature infant bonding after MT.^{20–25}

Parental voice emerges as a key resource when aiming to strengthen parent-infant bonding. During pregnancy, fetal auditory capacity is fully developed around 25 gestational weeks, and fetal response to auditory stimuli has been recorded as early as 19 weeks.^{26,27} Thus, parental voice, and particularly maternal voice, can serve as a familiar and comforting link between the protected environment in utero and the often-overwhelming NICU sensory environment.^{26,28} Evidence from systematic review suggests that live and recorded maternal voice interventions are associated with physiologic and behavioral stabilization of preterm infants, with fewer cardiorespiratory events.²⁹ In mothers of full-term infants, singing is associated with increased positive affect, reduced maternal cortisol levels, improved perceived mother-infant closeness,³⁰ and faster improvement of symptoms of moderate-severe postpartum depression.³¹ Soothing singing is associated with decreased arousal levels in both mothers and infants.³² Parents of premature infants report that MT focusing on voice and singing reduces anxiety²⁵ and provides tools to enhance early communication and intimacy.³³

Investigating which interventions support bonding for families in NICU is a strategic research priority.^{34,35} Adequately powered and controlled studies are needed to investigate the impact of MT on parent-infant bonding.¹⁹ Building from the evidence base, we propose parent-

led, infant-directed singing as a resource-oriented form of MT to target early parent-infant relationship.^{36,37} Resource-oriented MT focuses on nurturing strengths, resources, and potentials of individuals, and views the therapeutic encounter as a collaboration between client(s) and therapist.³⁸

The primary aim of this study was to evaluate the effect of MT on mother-infant bonding, with secondary aims of evaluating effects on parental anxiety and maternal depression in parents of premature infants. Our hypothesis was that MT plus standard care would lead to better mother-infant bonding and improved parent mental health, compared with standard care alone.³⁶

METHODS

Design

This study is part of the Longitudinal Study of music Therapy's Effectiveness for Premature infants and their caregivers (LongSTEP) (clinicaltrials.gov NCT03564184).³¹ This part of the LongSTEP trial is designed as a 2-arm parallel, multinational, pragmatic, randomized controlled trial evaluating short-term effects of MT on parents of preterm infants at the point of discharge from NICU.³⁶

Participants and Settings

Participants were recruited from 8 NICUs in Argentina, Colombia, Israel, Norway, and Poland. Participating NICUs were equipped to provide care for complex and critically ill newborns (7 level III and 1 level IV).³⁹ The NICUs were located in countries where public support and welfare initiatives ensure high parental presence during hospitalization. Eligible sites had staff with necessary scientific and clinical expertise to conduct the

trial, including a trained music therapist. Eligible premature infants were: (1) born <35 weeks gestational age (GA), (2) likely to be hospitalized a minimum of 2 weeks from inclusion, and (3) declared by NICU staff as medically stable to start MT (typically after 26 weeks postmenstrual age [PMA]). Parent inclusion criteria were: (1) written, site-specific informed consent, (2) willingness to engage in at least 2 of 3 MT weekly sessions, (3) sufficient understanding of the respective national language(s) to answer the questionnaires and participate in MT, and (4) capacity to complete the intervention and questionnaires.³⁶ Ethics approval was granted by The Regional Committees for Medical and Health Research Ethics (2018/994/REK Nord, July 03, 2018).

Trial Procedures and Intervention

A user advisory group with parents of premature infants provided consultation before and during implementation. Intervention and outcome measures were tested in feasibility studies.^{40,41} Intervention providers were 11 music therapists with training or clinical experience with MT in NICU. Five of the 8 NICUs offered MT services before the study, while 3 implemented MT for the first time. Providers were trained in the intervention before commencing the study and received supervision from the study core team during early implementation to enhance protocol adherence. Treatment and evaluation fidelity strategies included standardized training, individual evaluation of intervention adherence, and video and audio recordings of sessions for treatment fidelity analysis that will be published as a separate article.

After providing site-specific informed consent and undergoing baseline assessments, participants were randomized to receive either MT plus standard care or standard

care alone during hospitalization. The MT consisted of parent-led, infant-directed singing supported by the music therapist. Families in the MT group were offered 3 individual MT sessions per week throughout their hospitalization, with a maximum of 27 sessions. Sessions were realized at bedside or in the family's room during skin-to-skin-time, feeding, or with the infant lying in the incubator or cot. Sessions lasted approximately 30 minutes, with time spent actively making music dependent on infant tolerance. Nonmusic session time was devoted to therapist-parent dialogue on the family's needs. For infants aged PMA ~26 to 32 weeks, MT contained cautious use of parental singing and toned voice (eg, single notes, simple melodies or short musical phrases adapted from children's songs or parent-preferred music) matched to infant state and engagement cues, such that the infant "directed" the parent's use of voice. From week 32 and onwards, this was expanded on by adding increased musical complexity and interplay.^{36,42} Accompanying instruments were used sparingly to underline the importance of parental voice. Further details about the MT intervention can be found elsewhere.^{36,37}

Standard care varied across sites but included a range of medical, nursing, developmental, and supportive care, with the exclusion of other MT approaches. All except 1 NICU included skin-to-skin time as part of standard care.

An independent data safety monitoring committee monitored safety throughout the trial.

Outcome measures

Mother-infant bonding was measured by the Postpartum Bonding Questionnaire (PBQ).^{43,44} The PBQ is a 25-item screening instrument with 4 factors (factor 1,

general impaired bonding [12 items]; factor 2, rejection and pathologic anger [7 items]; factor 3, anxiety about the infant [4 items]; and factor 4, incipient abuse [2 items]). The questionnaire consists of statements concerning the mother's feelings, experiences and attitudes toward their infant, rated on a 6-point Likert scale with responses from "always" to "never." Total score ranges from 0 to 125, with higher scores implying impaired bonding. Each factor has its own suggested cutoff point.^{43,44} This study's main outcome was PBQ total score (≥ 26 points indicate impaired bonding, ≥ 40 points indicate severe bonding disorder) with factor 1 (general impaired bonding) included as an outcome in the exploratory analysis (≥ 12 points indicate impaired bonding).⁴³ Anxiety was measured for both mothers and fathers by the Generalized Anxiety Disorder self-report tool (GAD-7) (total score ranges from 0 to 21, cutoff scores of 5, 10, and 15 indicating mild, moderate, and severe anxiety, respectively).^{45,46} Maternal depression was measured by the Edinburgh Postnatal Depression Scale (EPDS) (total score ranges from 0 to 30, >10 points indicate depression).⁴⁷ Assessments also included parent demographics and infant medical factors, including measures of common health issues for preterm infants.^{39,48–52} Discharge assessments were completed 1 to 2 days before discharge. However, assessments completed up to 2 weeks after discharge were considered valid.

Randomization and Blinding

All participants were randomized to either the control or music therapy group using a 1:1 randomization stratified by site with random block sizes of 2 or 4. Randomization occurred after informed consent and baseline assessments, using the

online randomization system www.sealedenvelope.com. The system was administered by a core team member with no involvement in clinical work. In case of multiple pregnancies, only the first-born infant was included and randomized, whereas remaining siblings received the same interventions for ethical and practical reasons. Because of the nature of the intervention, participants, providers, and data collectors were not blinded. Data analysts were kept blinded to participant allocation until data analysis was completed.

Sample Size

With an intended sample size of 250 participants (with each NICU encouraged to recruit ~50 families), the study was planned to have 80% power to detect a difference of 4 points on the PBQ (SD = 8) as the minimal clinically important difference for this study. This was based on a two-sided 5% significance level, clustered by country (ICC 0.01) and 20% attrition.³⁶

Statistical Analysis

Descriptive methods were used to characterize the sample. An intention-to-treat approach was applied by using all available data from all 213

participants as randomly assigned, regardless of the intervention actually received. Special approaches for handling missing data were deemed unnecessary because the rate of missingness was low (<10%) (Table 1). We examined effects of the intervention by testing group differences in PBQ total score at discharge by linear mixed-effects models (ANCOVA) adjusted for site because of stratified randomization (PBQ [discharge]~ group + PBQ[(baseline) + 1|site]). The same analyses were carried out with secondary outcomes. The quality of the models was evaluated by residual plots. Exploratory analyses of PBQ total score were conducted for prespecified subgroups (sex; GA at birth [<28 weeks, 28 to <32 weeks, and 32 to <35 weeks]; hearing status measured at discharge [normal versus abnormal]; PBQ factor 1 [impaired bonding score ≥ 12 vs <12]; parental socioeconomic status [education level]; average parental skin-to-skin care during NICU [4 or more days per week vs <4 days per week]; treatment per protocol [≥ 6 MT sessions]³⁶). Analyses were done with the statistics software R (Version 4.1.0) by using two-sided 5% significance level.

RESULTS

From August 2018 to April 2020, 213 participants were enrolled and randomly assigned to the study. Of those assigned, 208 (98%) completed assessment at discharge (Fig 1). Infant and parent demographic and medical data are similar in the two groups (Tables 1–3). Baseline scores of bonding and maternal anxiety were similar in both groups, indicating low levels of impaired bonding and mild anxiety. Paternal anxiety was slightly higher in the MT group at baseline, indicating mild anxiety. For maternal depression, both groups scored below the cutoff.

Participants assigned to MT received a mean (SD) [range] of 9.98 (5.95) [0–27] sessions. Eighty-seven of 105 (83%) received per-protocol MT (≥ 6 sessions). Mothers were present in 8.39 sessions (SD 6.01), fathers in 2.15 (SD 3.39), both parents in 2.73 (SD 3.69). Mean (SD) [range] session length was 30.8 (11.22) [0–50] minutes.

From baseline to discharge, PBQ mean total score (SD) decreased from 7.66 (9.05) to 5.51 (6.65) in the MT group, and from 7.08 (6.55) to 5.92 (6.38) in

TABLE 1 Infant Baseline Characteristics

Baseline characteristic	Standard Care		Music Therapy		All Participants	
	N	Value	N	Value	N	Value
Sex (female) ^a	108	59 (55)	105	50 (48)	213	109 (51)
Singleton pregnancy ^a	108	81 (75)	105	70 (67)	213	151 (71)
Cesarean delivery route ^a	108	89 (82)	105	83 (79)	213	172 (81)
Birth wt (g) ^b	107	1475 (445) [480, 2440]	105	1360 (421) [620, 2335]	212	1414 (422) [480, 2440]
GA at birth (wk) ^b	108	30.57 (2.77) [22.86, 34.71]	105	30.26 (2.57) [25.29, 34.29]	213	30.42 (2.67) [22.86, 34.71]
<28 wk ^a	—	17 (16)	—	21 (20)	—	38 (18)
28–32 wk ^a	—	44 (41)	—	47 (45)	—	91 (43)
32–35 wk ^a	—	47 (43)	—	37 (35)	—	84 (39)
PMA enrollment (wk) ^b	107	33.06 (1.68) [27.43, 37.29]	105	33.07 (2.21) [27.43, 44.00]	212	33.07 (1.96) [27.43, 44.00]
Apgar at 5min ^b	107	8.6 (1.27) [5, 10]	101	8.6 (1.43) [1, 10]	208	8.6 (1.35) [1, 10]
Weight at enrollment (g) ^b	104	1604 (378) [705, 2730]	105	1630 (451) [820, 3680]	209	1618 (415) [705, 3680]
Estimated severity of IVH ^{a,c}	108	—	105	—	213	—
Cranial ultrasound not indicated	—	45 (41)	—	44 (42)	—	89 (42)
None	—	52 (49)	—	50 (47)	—	102 (48)
Grade 1–2	—	10 (9)	—	9 (9)	—	19 (9)
Grade 3–4	—	1 (1)	—	2 (2)	—	3 (1)

IVH, intraventricular hemorrhage; PMA, postmenstrual age; —, not applicable.

^a N (%).

^b Mean (SD) [min, max].

^c IVH was diagnosed by cranial ultrasound and graded according to Papile et al.⁵⁰

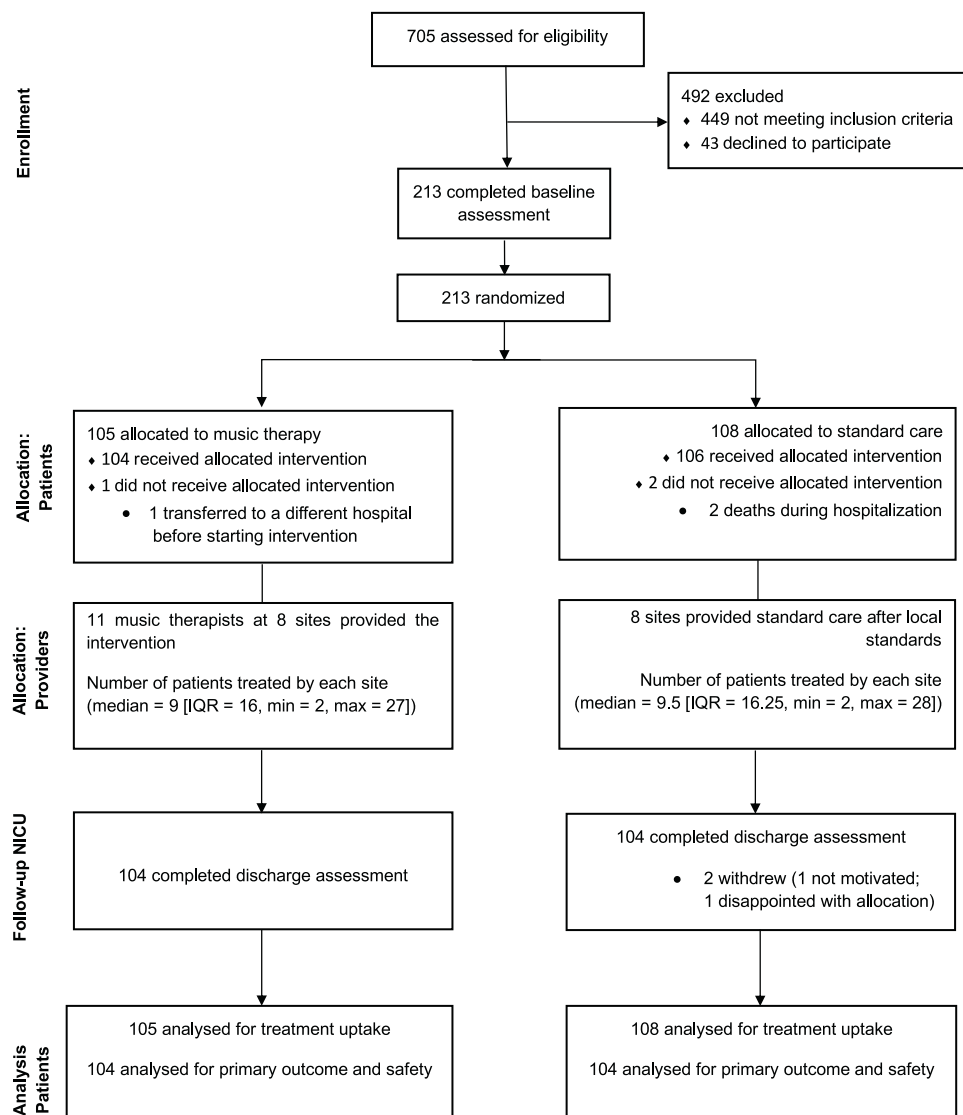


FIGURE 1
Participant flow.

the standard care (SC) group (Tables 1 and 4, Fig 2), but no significant differences between groups were found ($P = .32$). The estimated group effect (95% confidence interval [CI]) for PBQ was -0.61 (-1.82 to 0.59). Estimated group effects (95% CI) for GAD-7 was 0.14 (-0.85 to 1.12) for mothers, -0.90 (-2.03 to 0.22) for fathers, and -0.60 (-1.72 to 0.52) for EPDS. No significant between-group differences were found for secondary outcomes (Table 4, Fig 2) or predefined subgroups (Table 5). An interaction test carried out before

subgroup analysis showed no evidence of interaction.

Two serious adverse events (infant deaths) occurred during hospitalization. Both were in the standard care arm and not related to study procedures.

DISCUSSION

We investigated the effect of a MT approach using parent-led, infant-directed singing during NICU hospitalization on mother-infant

bonding and parent mental health in parents of premature infants. Our trial showed no significant effect on mother-infant bonding, parental anxiety, or maternal depression measured at discharge from NICU.

To our knowledge this is the first RCT sufficiently powered to investigate the effect of a parent-led, infant-directed singing music therapist-supported intervention on the mother-infant bond and parental mental health. Although small-scale studies have shown promising

TABLE 2 Parent Baseline Characteristics

Baseline Characteristic	Standard Care		Music Therapy		All Participants	
	N	Value	N	Value	N	Value
Maternal characteristics						
Age (y) ^a	106	32.77 (5.55) [17, 44]	104	33.11 (5.42) [21, 46]	210	32.94 (5.47) [17, 46]
Education (y) ^a	103	15.77 (2.64) [6, 21]	103	15.85 (3.35) [4, 22]	206	15.81 (3.01) [4, 22]
Usual work situation ^b	108	—	105	—	213	—
Full-time or self-employed	—	83 (77)	—	70 (67)	—	153 (72)
Other ^c	—	22 (23)	—	35 (33)	—	60 (28)
Civil status ^d	108	—	104	—	212	—
Married or living together with partner	—	96 (89)	—	98 (94)	—	194 (92)
PBQ bonding score ^a	105	—	104	—	209	—
Total score	—	7.08 (6.55) [0, 31]	—	7.66 (9.05) [0, 62]	—	7.37 (7.88) [0, 62]
Total score above cutoff (≥ 12) for impaired bonding	—	3 (0.3) [0, 15]	—	5 (0.5) [27, 62]	—	8 (0.4) [27, 62]
GAD-7 anxiety score ^a	105	6.10 (5.34) [0, 21]	104	6.39 (4.78) [0, 19]	209	6.24 (5.06) [0, 21]
EPDS postpartum depression score ^a	107	7.95 (5.07) [0, 20]	103	8.47 (5.17) [0, 24]	210	8.20 (5.12) [0, 24]
Paternal characteristics^d						
Age (y) ^a	101	35.37 (6.45) [22, 56]	99	36.02 (6.29) [21, 57]	200	35.69 (6.37) [21, 57]
Education (y) ^a	97	15.12 (3.21) [6, 22]	96	15.02 (3.77) [3, 25]	193	15.07 (3.49) [3, 25]
Usual work situation ^b	101	—	99	—	200	—
Full-time or self-employed	—	96 (95)	—	90 (91)	—	186 (93)
Other ^c	—	12 (12)	—	15 (15)	—	27 (14)
GAD-7 anxiety score ^a	98	4.71 (4.35) [0, 21]	98	6.30 (5.73) [0, 21]	196	5.51 (5.13) [0, 21]

GAD-7, General Anxiety Disorder-7; EPDS, Edinburgh Postpartum Depression Scale; PBQ, Postpartum Bonding Questionnaire; —, not applicable.

^a Mean (SD) [min, max].

^b N (%).

^c Other includes part-time, homemaker/stay-at-home parent, student, unemployed because of ill health or a disability.

^d Same-sex parents were invited to participate in the study but none were enrolled.

results on the impact of MT on bonding^{20–24} our study does not confirm these findings. Our failure to detect a definitive effect on bonding or parental well-being may be related to an insufficient number of sessions. Haslbeck et al noted a dose-dependent effect of creative MT on brain development in preterm infants, with no plateauing of the effect.⁵³ Their median sessions (14.87) was nearly double ours (8), which may suggest that a longer intervention period could have a positive impact on outcomes.

We used the PBQ, a screening questionnaire designed to identify disorders in mother-infant bonding.^{43,44} In spite of receiving the strongest psychometric evaluation rating in a recent systematic review,⁵⁴ the PBQ may lack sensitivity to detect changes in mothers reporting a relatively healthy bond with their premature infant. In our study, very few

mothers demonstrated impaired bonding at baseline, and although bonding scores were slightly improved at discharge from hospital, no between-groups differences were found. The strong focus on pathology within the items of the PBQ could have created a flooring effect, making it challenging to detect differences between mothers in the subtler and health-oriented aspects of bonding.

We based our hypothesis on research suggesting a higher risk of impaired bonding in mothers of premature infants.^{2,3,55,56} In our study, a very small number of mothers from a range of countries and socioeconomic statuses reported impaired bonding, which challenges this assumption. Our findings are consistent with research suggesting that mothers of premature infants may demonstrate equal, or better, quality of mother-infant interaction and attachment as

compared with mothers of full-term infants.⁸ Borghini et al argue that parental emotional arousal during hospital stay may facilitate parental involvement, which in turn might strengthen the parent-infant bond.⁵⁷ The NICUs in our study are located in countries where parents are expected to be continuously present and partake in the care of their child. Ninety-nine of 103 (96%) SC parents, and 97 of 105 (92%) MT parents, reported being present almost daily. Hence, it is possible that the parents in our study had a lower risk of impaired bonding compared with parents in other settings who experience unwanted separation.

The majority of the infants in our study were classified as very low birth weight and were hospitalized on average 7 weeks. During NICU hospitalization, instability in the baby's medical needs might be more of a concern to parents than

TABLE 3 Infant Clinical Characteristics at Discharge

Discharge characteristic	Standard Care		Music Therapy		All Participants	
	N	Value (%)	N	Value (%)	N	Value (%)
Weight at discharge, g, mean (SD) [range]	101	2464 (471) [1646, 4140]	—	2443 (464) [1640, 4320]	205	2485 (479) [1640, 4320]
Nutrition during admission, n (%)	103	—	105	—	208	—
>50% mother's breast milk	—	58 (56)	—	66 (63)	—	124 (60)
<50 mother's breast milk	—	29 (28)	—	24 (23)	—	53 (25)
Donor breast milk +/- infant formula	—	3 (3)	—	2 (2)	—	5 (2)
>90% infant formula	—	13 (13)	—	13 (12)	—	26 (13)
BPD, n (%)	104	—	105	—	209	—
None	—	58 (56)	—	55 (52)	—	113 (54)
Mild	—	30 (29)	—	27 (26)	—	57 (27)
Moderate	—	11 (11)	—	11 (10)	—	22 (10)
Severe	—	5 (5)	—	12 (11)	—	17 (8)
Discharged with O ₂ supply, n (%)	104	—	105	—	209	—
Yes	—	32 (31)	—	31 (30)	—	63 (30)
No	—	72 (69)	—	74 (70)	—	146 (70)
Systemic infection during hospitalization, n (%)	104	—	105	—	209	—
Yes	—	19 (18)	—	28 (27)	—	47 (22)
No	—	85 (82)	—	77 (73)	—	162 (78)
NEC, n (%)	103	—	105	—	208	—
No	—	99 (96)	—	104 (99)	—	203 (98)
Suspected	—	2 (2)	—	0 (0)	—	2 (1)
Confirmed	—	2 (2)	—	1 (1)	—	3 (1)
ROP, n (%)	96	—	100	—	196	—
None	—	84 (88)	—	78 (78)	—	162 (83)
Grade 1–2	—	9 (9)	—	16 (16)	—	25 (13)
Grade 3	—	3 (3)	—	6 (6)	—	9 (4)
Estimated severity of IVH, n (%)	108	—	105	—	213	—
Cranial ultrasound not indicated	—	38 (35)	—	34 (32)	—	72 (34)
None	—	59 (55)	—	55 (52)	—	114 (53)
Grade 1-2	—	10 (9)	—	14 (13)	—	24 (11)
Grade 3-4	—	1 (1)	—	2 (2)	—	3 (1)
Hydrocephalus posthemorrhage, n (%)	103	—	105	—	208	—
Yes	—	0 (0)	—	1 (1)	—	1 (1)
No	—	103 (100)	—	104 (99)	—	207 (99)
PVL, n (%)	102	—	101	—	203	—
None	—	99 (97)	—	95 (94)	—	194 (96)
Grade 1-2	—	3 (3)	—	3 (3)	—	6 (3)
Grade 3-4	—	0 (0)	—	3 (3)	—	3 (1)
Hearing test status, n (%)	71	—	77	—	148	—
Passed	—	70 (99)	—	69 (90)	—	139 (94)
Not passed	—	1 (1)	—	8 (10)	—	9 (6)

BPD was diagnosed according to the criteria of Bancalari et al.⁴⁸ Systemic infection was considered if positive blood cultures coincided with clinical signs suggesting blood infection. NEC was determined by clinical and radiologic criteria of Bell et al.⁴⁹ Only definite NEC (Bell stages II to III) was included. ROP was graded according to the international classification by the Committee for the Classification of Retinopathy of Prematurity, and was recorded as the most severe stage in either eye.⁶³ IVH was diagnosed by cranial ultrasound and graded according to Papile et al.⁵⁰ Hydrocephalus was diagnosed in accordance with Volpe.⁵¹ PVL was diagnosed by ultrasound after 28 d of life, with grading from 1 to 4 in accordance with De Vries and Rennie.⁵² BPD, bronchopulmonary dysplasia; IVH, intraventricular hemorrhage; NEC, necrotizing enterocolitis; PVL, periventricular leukomalacia; ROP, Retinopathy of prematurity; —, not applicable.

immediate and longer-term relationship and bonding. Interventions aiming to support parent-infant bonding might be more effective after discharge from hospital when infants are typically more stable and families have returned home.^{58,59} A qualitative study of a LongSTEP cohort supports this possibility, where parents experienced that

postdischarge MT led to positive change in their parent-infant relationships (Epstein et al, unpublished data, December 2021).

We found no significant effects of our intervention on maternal depression or parental anxiety. Our findings related to anxiety contrast with a meta-analysis reporting a reduction in maternal anxiety after

MT.¹⁹ The timepoint of assessment could explain this discrepancy. We assessed anxiety shortly before discharge, a time when anxiety and stress might peak as parents prepare for transitioning from hospital to home and taking full responsibility for their child's care.^{58,59} Kehl et al found that MT significantly reduced parental anxiety 2 weeks after birth and

TABLE 4 Observed Values at Discharge, Changes From Baseline, and LME Results

	Observed Values				Change From Baseline			Group Effect (LME) ^b		
	SC		MT		SC	MT	Difference ^a			
	N	M (SD)	N	M (SD)	M	M	M (95% CI)	Coefficient (95% CI)	df	P
PBQ total score	101	5.92 (6.38)	105	5.51 (6.65)	−1.29	−2.15	−0.85 (−2.32 to 0.61)	−0.61 (−1.82 to 0.59)	192	.318
GAD-7 mother	99	4.60 (4.67)	105	4.74 (3.78)	−1.69	−1.66	0.03 (−1.23 to 1.29)	0.14 (−0.85 to 1.12)	191	.787
GAD-7 father	92	4.54 (4.58)	95	4.24 (4.18)	−0.24	−2.03	−1.80 (−3.31 to 0.29)	−0.90 (−2.03 to 0.22)	173	.115
EPDS	101	6.2 (5.21)	104	6.02 (4.45)	−1.59	−2.47	−0.88 (−2.18 to 0.42)	−0.60 (−1.72 to 0.52)	194	.290

df, degrees of freedom; M, mean.

^a From *t* test, assuming equal variance.^b Based on a linear mixed-effects model including variables mother-infant bonding, parent anxiety, and maternal depression with site as random effect.

halfway through NICU stay, but not at 2 weeks after discharge.²³ Although an RCT including mothers with moderate–severe postpartum depression found singing to give faster improvement in symptoms,³¹ no large-scale RCTs have investigated the effect of MT on depression in mothers of premature infants. Our findings of no effects on maternal depression are, however, in line with pilot studies.^{23,24} The complex caretaking role parents take

might compromise parents' capacity to manage their own crisis of experiencing preterm birth.⁶⁰ Although the study protocol includes elements of psychotherapeutic support for parents in alignment with trauma-preventive models,³⁶ the training and intervention protocol³⁷ might not have addressed this sufficiently enough for therapists to implement it in a uniform way, or therapists may have struggled to adequately meet parental needs

within the sessions. Additionally, the emphasis on parent-led singing might have placed too much responsibility on parents in a critical phase. However, qualitative results from feasibility testing of LongSTEP contrast such a notion.⁴⁰ Parents in the feasibility study reported that MT helped them get to know their infants, and that resources they developed during MT were transferrable to parent-infant interactions outside of MT.¹⁹ Further

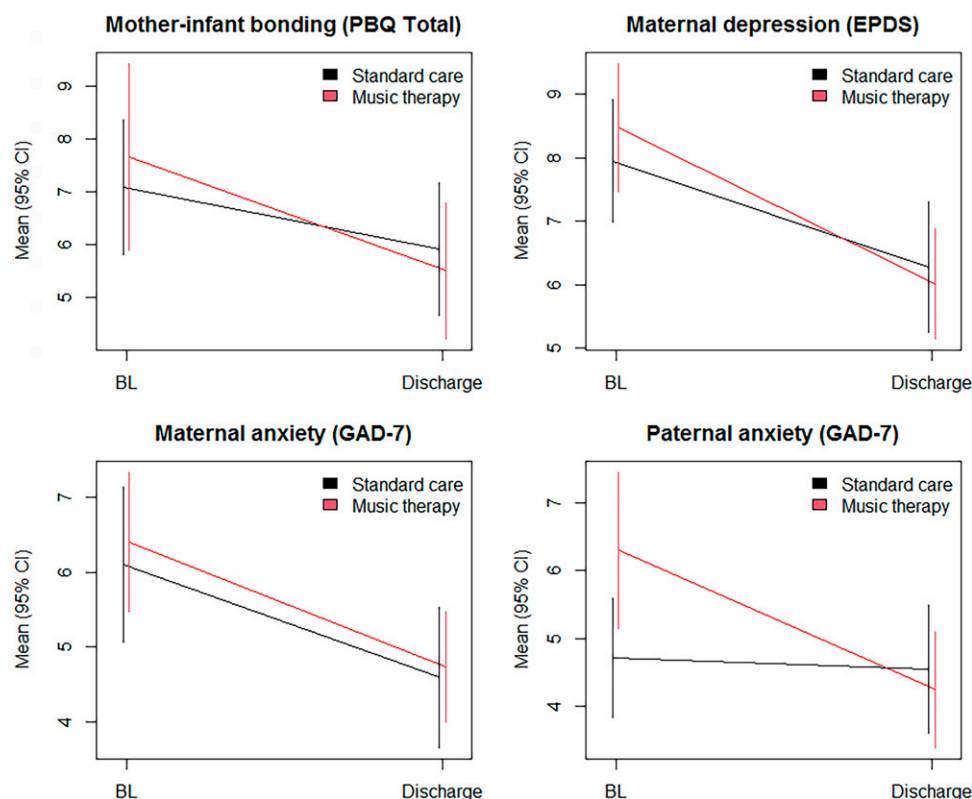
**FIGURE 2**
Results at discharge.

TABLE 5 LME Results for Subgroup Analysis

	Group Effect (LME) ^a		
	Coefficient (95% CI)	df	P
Gender	−0.60 (−1.81 to 0.60)	190	.33
GA at birth	−0.59 (−1.81 to 0.62)	190	.34
Hearing status at DC	−0.33 (−1.85 to 1.19)	132	.67
Maternal education level	−0.67 (−1.86 to 0.53)	186	.27
Paternal education level	−0.42 (−1.64 to 0.81)	173	.50
Hours of skin-to-skin care	−0.66 (−1.87 to 0.55)	189	.29
Indications of impaired bonding at baseline	−2.97 (−10.45 to 5.51)	2	.52

DC, discharge; df, degrees of freedom; GA, gestational age.

^aThis table shows the interaction of each subgroup with the intervention in a linear mixed-effects model including the variable mother-infant bonding, with site as random effect.

examination of the impact of MT on the parent-infant relationship and parental mental health is indicated. Since the LongSTEP study's MT approach is resource-oriented, future studies applying this or similar approaches might benefit from choosing outcomes that are less focused on pathology, such as quality of life, parent self-efficacy, self-confidence, and empowerment.

Strengths and Limitations

Low attrition in our study indicates a high acceptability of intervention and study procedures among participants in different cultural contexts. Whereas research often focuses exclusively on mothers, we included both parents in the intervention and study outcomes.⁶¹ Although we aimed to engage both parents actively in MT, our primary outcome was limited to mothers to promote homogeneity for reasons of analysis. Limitations include the reliance on self-report assessments, which may contribute to social desirability bias, and inclusion of outcome measures that may not have been sufficiently sensitive to circumstances of the included mothers. The chosen outcome measures may not have fit well enough with the focus of the intervention. In mothers of full-term infants, singing has been shown to positively impact arousal, affect, and stress hormones.^{30,32} Investigating

biological markers of anxiety instead of self-reported symptoms could augment our understandings of potential impacts on anxiety. Although music therapists in the study were trained on the intervention, they differed regarding previous clinical experience and expertise. Variation in intervention implementation might have affected outcomes, although we noted no specific effect for site. Variations in adherence to protocol will be further investigated in treatment fidelity analyses. Conclusions of this study are applicable to NICUs where consistent parental presence is feasible.

CONCLUSIONS

In this large-scale RCT we found no significant effects of music therapist-supported, parent-led, infant-directed singing on mother-infant bonding, parental anxiety, or maternal depression, although scores on all outcomes improved in both groups. Additional examination of the impact of MT interventions on parent-infant mutual outcomes and parental well-being would be valuable. We also suggest investigating the effect on outcomes that are more salutogenically focused, for example quality of life, parent self-efficacy, self-confidence, and empowerment.

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ABBREVIATIONS

CI: confidence interval
 DSMC: Data safety Monitoring Committee
 EPDS: Edinburgh Postpartum Depression Scale
 GA: gestational age
 GAD-7: General Anxiety Disorder-7
 IVH: intraventricular hemorrhage
 MT: music therapy
 NICU: neonatal intensive care unit
 PBQ: Postpartum Bonding Questionnaire
 PMA: post-menstrual age
 RCT: randomized controlled trial
 SC: standard care

Mangersnes and Mrs Røed coordinated data collection, and critically reviewed and revised the manuscript; and all authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

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