

Longitudinal Study of Music Therapy's Effectiveness for Premature Infants and Their Caregivers (LongSTEP): Feasibility Study With a Norwegian Cohort

Claire M. Ghetti, PhD, MT-BC

The Grieg Academy—Department of Music, University of Bergen, Bergen, Norway

GAMUT, NORCE Norwegian Research Centre, Bergen, Norway

Bente Johanne Vederhus, PhD, RN

Department of Children and Youth Clinic, Haukeland University Hospital, Bergen, Norway

Tora Söderström Gaden, MA

GAMUT, NORCE Norwegian Research Centre, Bergen, Norway

Annette K. Brenner, PhD

GAMUT, NORCE Norwegian Research Centre, Bergen, Norway

We thank Mari Hysing, Hanne Cecilie Braarud, and Trude Os for valuable comments on the protocol that informed this pilot study; Line Remme Solberg and Astrid Linnea Andreassen Østerholt for preparing data for this study; and the families who participated.

C. M. Ghetti contributed to the study design and drafted the manuscript. B. J. Vederhus, T. S. Gaden, A. K. Brenner, E. Bieleninik, I. Kvestad, J. Assmus, and C. Gold contributed to study design and provided critical revision of the manuscript. T. S. Gaden contributed to qualitative data analysis and A. K. Brenner to quantitative data analysis. All authors contributed to the refinement of the manuscript and approved the final version.

Funding for this study was provided by the Faculty of Fine Art, Music and Design at the University of Bergen, the Research Council of Norway (RCN, project number 273534), and POLYFON Knowledge Cluster for Music Therapy. The funders of the study had no role in the design or conduct of the study.

T. S. Gaden, C. M. Ghetti, and C. Gold are trained music therapists. The remaining authors declared no conflicts of interest.

Address correspondence concerning this article to Claire M. Ghetti, PhD, GAMUT—The Grieg Academy Music Therapy Research Centre, The Grieg Academy—Department of Music, University of Bergen, Postbox 7805, 5020 Bergen, Norway. E-mail: claire.ghetti@uib.no. Phone: +47-465-08-095.

Łucja Bieleninik, PhD

Institute of Psychology, University of Gdańsk, Gdańsk, Poland
GAMUT, NORCE Norwegian Research Centre, Bergen, Norway

Ingrid Kvestad, PhD, PsyD

Regional Center for Child and Youth Mental Health and Child Welfare, NORCE Norwegian Research Centre, Bergen, Norway

Jörg Assmus, PhD

GAMUT, NORCE Norwegian Research Centre, Bergen, Norway

Christian Gold, PhD

GAMUT, NORCE Norwegian Research Centre, Bergen, Norway

Premature infants and their parents experience significant stress during the perinatal period. Music therapy (MT) may support maternal–infant bonding during this critical period, but studies measuring impact across the infant’s first year are lacking. This nonrandomized feasibility study used quantitative and qualitative methods within a critical realist perspective to evaluate the feasibility, acceptability, and suitability of the treatment arm of the Longitudinal Study of music Therapy’s Effectiveness for Premature infants and their caregivers (LongSTEP) (NCT03564184) trial with a Norwegian cohort (N = 3). Families were offered MT emphasizing parent-led infant-directed singing during neonatal intensive care unit (NICU) hospitalization and across 3 months post-discharge. We used inductive thematic analysis of semi-structured interviews with parents at discharge from NICU and at 3 months and analyzed quantitative variables descriptively. Findings indicate that: (1) parents of premature infants are willing to participate in MT research where parental voice is a main means of musical interaction; (2) parents are generally willing to engage in MT in NICU and post-discharge phases, finding it particularly interesting to note infant responsiveness and interaction over time; (3) parents seek information about the aims and specific processes involved in MT; (4) the selected self-reports are reasonable to complete; and (5) the Postpartum Bonding Questionnaire appears to be a suitable measure of impaired maternal–infant bonding. Parents reported that they were able to transfer resources honed during MT to parent–infant interactions outside MT and recognized parental voice as a central means of building relation with their infants. Results inform the

implementation of a subsequent multinational trial that will address an important gap in knowledge.

Keywords: *feasibility study; external pilot; NICU; parent involvement; voice; music therapy*

Background

As medical advances have contributed to improved survival rates for infants born preterm, there is a corresponding shift to concern for the long-lasting sequelae of prematurity. Infants born preterm are at greater risk for poorer mental health, cognitive development, and quality of life than infants born full term (Båtsvik et al., 2015; Blencowe et al., 2013; Fevang et al., 2016; Twilhaar et al., 2018), and parents of preterm infants are at greater risk for postpartum depression, posttraumatic stress disorder, and elevated levels of stress (Bieleninik, 2012; Bieleninik & Gold, 2014; Winter et al., 2018). Physical separation and prolonged neonatal intensive care unit (NICU) hospitalization can pose a challenge to the formation of healthy parent–infant bond (Bidzan et al., 2009; Bieleninik et al., 2009), which may have implications for subsequent development of attachment.

The terms *maternal–infant bonding* (or *mother–infant bonding*, *mother–infant relationship*, *maternal attachment*) and *attachment* are often used interchangeably in the literature (Perrelli et al., 2014), though they represent two distinct concepts (Brockington et al., 2006). Attachment describes the lasting relationship that forms between an infant and primary caregiver that serves an adaptive purpose for the infant, enabling the infant to establish a secure base from which to explore the world (Bowlby, 1969). Attachment theory was originally formulated by John Bowlby (Bowlby, 1958, 1969) and further refined and expanded in collaboration with Mary Ainsworth (Ainsworth, 1964, 1969; Ainsworth & Bowlby, 1991; Bowlby, 1979). The quality of a child's attachment is demonstrated in situations when the child becomes stressed by a stranger in the absence of the primary caregiver, most famously demonstrated in experiments of the *Strange Situation* (Ainsworth & Bell, 1970; Ainsworth & Wittig, 1969). Four attachment styles are generally recognized: secure,

insecure avoidant, insecure ambivalent/resistant, and insecure disorganized (Ainsworth et al., 1978; Main & Solomon, 1990). In comparison to secure attachment styles, insecure attachment styles are correlated with an increased risk of psychosocial and mental health problems as the child develops into adolescence and adulthood (Bornstein, 2014; Groh et al., 2017; Mikulincer & Shaver, 2012; Spruit et al., 2020).

While a child typically develops attachment to an attachment figure around one year of age, maternal–infant bonding represents the process of a mother’s emotional tie to her infant, generally occurring within the first year of the infant’s life (Kinsey & Hupcey, 2013). The concept of maternal–infant bonding was first posited by Klaus and Kennell (1976), who argued that the presence or absence of mother–infant skin-to-skin contact during a critical postpartum *sensitive period* could strongly impact subsequent infant development. The evidence that served as grounds for their argument on the importance of this sensitive period was later contested, and Klaus and Kennell retreated somewhat from their original conceptualizations. In contemporary academic literature, the concept is most often used to depict the affective experience of a mother’s feelings toward her infant, and it may correlate with resulting behaviors, though there is no clear consensus on what those behaviors are (Kinsey & Hupcey, 2013).

The establishment of healthy maternal–infant bonding lays a foundation for the eventual formation of an infant’s secure attachment to a primary caregiver. Moreover, parent–infant relationships can have a lasting impact on an infant’s development, for example, as a foundation of the child’s social-emotional development and eventual formation of intimate relationships (Ainsworth et al., 1978; Bowlby, 1969). It is, therefore, important to safeguard the development of healthy parent–infant bonding during the critical postnatal period. Factors such as maternal psychological well-being (Korja et al., 2008) and the presence of postpartum depression (Muller-Nix et al., 2004) strongly impact the parent–infant relationship in the postnatal period. Furthermore, infants who are born very preterm or with very low birthweight later demonstrate an increased risk for disorganized attachment compared with full-term infants (Wolke et al., 2014).

Reducing early separation in the NICU by actively involving parents in an infant’s care can reduce parental stress, positively impact the bonding process, and enable parents to form a parental identity, which in turn may contribute to more beneficial long-term

outcomes for infants and parents (Fegran et al., 2008; Korja et al., 2012; McLean et al., 2019; Olsson et al., 2017). The importance of integrally involving parents as part of family-centered care for hospitalized and premature infants was acknowledged in the field of music therapy (MT) in the early 2000s (Hanson Abromeit, 2003; Shoemark & Dearn, 2008). Further development of family-centered approaches to MT for premature infants and their families has blossomed in the past decade, where parents are recognized as essential partners in the music therapeutic process with their infants (Ettenberger, 2017; Haslbeck & Bassler, 2020; McLean et al., 2019; Shoemark, 2011; Standley & Gutierrez, 2020; Ullsten et al., 2020). The unique contributions of fathers have been acknowledged (Mondanaro et al., 2016), as well as the inherent challenges when empowering parents to actively engage musically with their infants in NICU settings (McLean et al., 2019; Shoemark, 2011, 2017). MT, as practiced from a family-centered (Shoemark & Dearn, 2008) and resource-oriented perspective (Rolvsjord, 2010), may offer a structure in which parents can be supported to naturally embody their caregiving roles with their infants, in a way that promotes mutual regulation and contributes to better outcomes for infant and parents alike.

Researchers have long recognized the benefits of maternal sung and spoken voice for premature neonates, as evidenced in a review by Filippa et al. (2017). Similarly, mothers of full-term infants report experiencing emotional closeness through the process of singing to their infants (Fancourt & Perkins, 2018), demonstrate more maternal responsiveness and warmth, and a greater number of interaction behaviors with their infants when contingently singing a lullaby to reduce crying behavior (Robertson & Detmer, 2019). Research demonstrates that MT promotes sensory regulation in the preterm neonate (Haslbeck, 2012; Standley, 2012), and that involving parents in the provision of MT during NICU hospitalization decreases parent and infant distress (Whipple, 2000), and contributes to the formation of parental identity (McLean et al., 2019).

Evidence from randomized controlled trials (RCTs) of premature infants demonstrates beneficial short-term effects of MT, including favorable changes in physiological state, behavior state, feeding ability and weight gain, length of stay, and maternal anxiety (Bieleninik et al., 2016; Hartling et al., 2009; Haslbeck, 2012; Loewy et al., 2013; Standley, 2012). Though a few quasi-experimental

and retrospective studies have explored the long-term impacts of MT on premature infants (Hamm et al., 2017; Walworth, 2009), evaluating such impacts for infants and parents remains a significant gap in knowledge (Bieleninik et al., 2016). In particular, a recent systematic review and meta-analysis of MT for premature infants and their parents identified a lack of sufficiently powered definitive RCTs that evaluate the use of MT extending past the point of discharge from NICU, as well as a lack of such studies that evaluate the long-term impact of MT for preterm infants and their parents (Bieleninik et al., 2016). One recent exception is a prospective, single-center randomized controlled pilot trial (ClinicalTrials.gov, NCT02434224) of MT with standard care versus standard care alone to evaluate effects on brain growth and development and long-term neurobehavioral outcomes up to 5 years of age for infants born preterm (Haslbeck et al., 2017, 2020). The Haslbeck et al. (2017, 2020) pilot trial used an interactive, infant-directed improvisational approach known as *Creative Music Therapy* that incorporated parents when possible (Haslbeck, 2004, 2014) and aimed to assess the feasibility of the study protocol ahead of a multisite definitive trial. Results of creative MT on brain imaging in this pilot trial suggest beneficial short-term effects on functional brain activity and connectivity (Haslbeck et al., 2020).

Pilot and Feasibility Studies

Pilot and feasibility studies provide a crucial preliminary step in the research process (Robb, 2013). Such studies explore the *degree to which* a set of procedures is feasible to implement, *if* one should proceed to a definitive study following the feasibility testing phase and *how* one should proceed (Eldridge, Lancaster, et al., 2016). The terms *pilot study* and *feasibility study* are not used consistently in the literature (Eldridge, Lancaster, et al., 2016; LaGasse, 2013; Thabane et al., 2010). Eldridge, Lancaster, et al. (2016) developed and validated a conceptual framework for defining pilot and feasibility studies that occur in preparation for subsequent RCTs. The conceptual framework views *feasibility* as an overarching concept for such studies (Eldridge, Lancaster, et al., 2016). Pilot studies then emerge as a subcategory of feasibility study, in which parts or wholes of a future RCT are tested on a smaller scale to see if they are feasible, and they may be randomized or nonrandomized. When the end goal is to implement a definitive RCT to evaluate a

complex intervention like MT, the conduct of a feasibility study is explicitly recommended as a first step to inform the subsequent trial (Craig et al., 2008).

Purpose

A modest number of music medicine studies have explored the role of music listening on maternal–infant bonding with premature neonates or maternal–fetal bonding, with mixed results (Chang et al., 2015; Vahdati et al., 2017). Very few RCTs have evaluated the impact of MT on maternal–infant bonding with premature neonates (Cevasco, 2008; Ettenberger et al., 2014); we could identify no RCT that examined this outcome up to one year of infant corrected age. Furthermore, we could identify no previous RCT that evaluated the impact of MT continuing past the point of discharge from NICU using longer-term outcomes. We, therefore, aim to address these gaps by conducting a definitive RCT to examine the longer-term impact of longer-term MT intervention on maternal–infant bonding, infant development, and parental well-being. The definitive trial Longitudinal Study of music Therapy’s Effectiveness for Premature infants and their caregivers (LongSTEP) evaluates the longitudinal effect of MT in the NICU and/or after discharge on preterm infants and their primary caregivers across a 2-year time period (Ghetti et al., 2019). In order to sufficiently power such a study, it is necessary to take a multisite approach, which means that the RCT will be implemented at multiple sites across countries with similar social support societies.

Prior to implementing the international multisite RCT, we aimed to determine the feasibility of various aspects of the main trial’s study protocol and the acceptability of implementing it in various cultural contexts consistent with those to be included in the main study. For these reasons, we implemented two nonrandomized feasibility studies: one completed in Norway and described in this manuscript, and the other completed in Poland and described separately (Bieleninik et al., 2020). Both feasibility studies were designed as external pilots, such that data collected were not used in the main trial’s statistical analyses (Arain et al., 2010). The primary aim of the current nonrandomized feasibility study was to evaluate the feasibility, acceptability, and suitability of the treatment arm of the LongSTEP trial (Ghetti et al., 2019) with a Norwegian cohort. Specific objectives of this feasibility study were:

- (1) To evaluate feasibility in terms of recruitment and retention,
- (2) To evaluate acceptability and suitability of the LongSTEP MT intervention and study procedures during hospitalization and post-discharge phases (including from parental perspectives),
- (3) To assess the acceptability and suitability of outcome measures and data collection procedures and refine these ahead of the definitive trial, and
- (4) To evaluate the required resources and ability to manage and implement the protocol.

Methods

Study Design

This nonrandomized feasibility study used quantitative and qualitative methods within a critical realist perspective to evaluate the feasibility and acceptability of an abbreviated version of the MT treatment arm of the LongSTEP trial (Ghetti et al., 2019). [Supplementary Figure 1](#) provides a detailed illustration of the study design. Adopting a realist ontology and constructivist epistemology as part of our critical realist perspective enabled us to coherently combine quantitative and qualitative elements while viewing each as equally valid (Maxwell & Mittapalli, 2010). All participants enrolled in the feasibility study received the MT intervention. In comparison to the main trial, the post-discharge phase of the MT intervention was shortened from 6 months to 3 months for purposes of feasibility testing, and we took final outcome measurements at 3 months infant corrected age (CA, i.e., chronological age reduced by number of weeks born preterm; [American Academy of Pediatrics, 2004](#)) instead of at 12 months CA. We increased post-discharge MT sessions to twice per month during the 3-month post-discharge intervention period, instead of approximately once per month. Additionally, we reduced MT sessions in the NICU from 3 to 2 per week with the music therapist, while parents were encouraged to independently use what they learned in MT at least once per week with their infant. We followed the CONSORT 2010 statement extension for randomized pilot and feasibility trials (Eldridge, Chan, et al., 2016) when reporting this feasibility trial.

The main LongSTEP trial is designed as a 2×2 factorial, multi-national pragmatic RCT with two randomization points: after completion of baseline outcome assessments and after completion of outcome assessments at discharge from the NICU (Ghetti et al., 2019). The factorial design allows for the testing of independent effects of each combination of conditions: NICU-MT, post-discharge MT, both, or neither, along with interactions among them. User representatives, namely parents of premature infants, contributed feedback during the generation of the protocol to assure user relevance. A detailed description of the study protocol for the main trial is described elsewhere (Ghetti et al., 2019). This feasibility study received ethics approval from the Regional Committees for Medical and Health Research Ethics (2017/2249/REK Nord, date of approval: December 05, 2017). Participants provided written consent prior to commencing engagement in the feasibility study and were informed of its relation to the main study.

Participants and Setting

We used pragmatic sampling and recruited families from the NICU of a university hospital in a large city within Norway between February 2018 and April 2018, according to the following inclusion and exclusion criteria (Ghetti et al., 2019):

- (1) Infants: Born below 35 weeks of gestational age (GA), of both genders, any ethnicity, from single or multiple pregnancies, who had achieved sufficient medical stability (as determined by medical staff) to start MT, and were likely to be hospitalized for longer than 2 weeks from time of recruitment.
- (2) Primary caregivers: Primary caregivers agreeing to engage in two MT sessions per week during NICU, and in five of the six MT post-discharge sessions. Primary caregivers living within reasonable commuting distance from the treating NICU and having sufficient understanding of the respective national language(s) to answer study questionnaires and participate in the intervention. Parents with a documented mental illness or cognitive impairment that prevented them from being able to complete the MT intervention or the outcome assessments were excluded.

There were no changes to eligibility criteria during the course of the feasibility study. Potential participants were screened and identified by a nurse educator with research responsibility, who was also a collaborator on this feasibility study. The nurse educator was not assigned direct daily care for the potential participants but had a dual role as an educator for parents on the unit regarding developmentally appropriate care of their infants. The nurse educator screened potential participants for eligibility in consultation with the unit medical staff, was the first to approach potential participants to describe the study, and completed the informed consent conversations with them.

Intervention

Intervention in the feasibility study included individualized MT with a high level of parental involvement, provided during the course of NICU hospitalization, and at home during the first three months following discharge. The approach to MT was resource oriented (Rolvjord, 2010) in that it drew upon parental musical and nurturing resources to facilitate developmentally appropriate musical interactions with their infants and attempted to transfer the *expert* role from the therapist to the parents. Consistent with family-centered care, the parent–infant relationship was viewed as primary, with the music therapist taking a role of supporting the parent–infant dyad/triad (Shoemark, 2011). Thus, the therapeutic aim was directed toward the parent–infant dyad/triad, to support maternal–infant bonding, enable mutual regulation (Beeghly & Tronick, 2011), and promote beneficial gains for infants and parents alike. Parental voice and song, along with physical positioning and physical presence, served as a foundation for attuned interactions between parents and infants. A board-certified music therapist supported parents in their parental and musical roles and helped them learn how to read and musically respond to their infants' subtle signals. Parents learned how to vary their sung/spoken voice and facial expressions in relation to their infant's breathing patterns, engagement or disengagement cues, facial expressions, and gesticulations, so that the singing remained infant-directed (Haslbeck & Bassler, 2020). The nature of the parent–infant musical interaction developed progressively in pace with the infant's development over time. MT in the pilot study was conducted

following the procedures specified in detail within the protocol for the main trial (Ghetti et al., 2019).

MT was offered to study participants twice per week during the length of NICU hospitalization for approximately 40–50 minutes per session. Time spent actively making music with infants varied depending upon their tolerance (typically 15–40 minutes), and the remaining time consisted of the music therapist providing psychotherapeutic support to parents and coaching them in how to musically relate with their infants. Once participants were discharged home, they were offered MT sessions twice per month in the home or at the hospital for a period of three months. Parents chose the setting that best suited them and their schedules. Post-discharge MT sessions lasted approximately 50–60 minutes and consisted of a verbal checking-in with parents regarding progress and concerns, trying out of various parent–infant musical exchanges based on infant needs, modeling by music therapist when needed, and discussion of potential adaptations and variations that could facilitate infant self-regulation or parent–infant musical interaction, depending upon the needs identified by the parent.

The board-certified music therapist who provided the intervention holds graduate degrees in MT, has completed specialized training in NICU MT,¹ and previously received training by a NICU-specialized physical therapist on neurodevelopmental positioning for premature neonates. The music therapist has worked with parents and children within intensive medical settings for over 10 years, six of which were with families and infants in the NICU setting. The music therapist providing the intervention was also the music therapist who led its development (first author) and thus was able to test out the procedures first hand and use those experiences to further refine the intervention procedures in advance of the main study.

In order to promote intervention delivery in alignment with the procedures outlined in the study protocol, the music therapist frequently reviewed the key elements of the intervention, guidelines for intervention in NICU, and steps of the post-discharge sessions as described in the study protocol (Ghetti et al., 2019). The music

¹In particular, certified as NICU music therapist by National Institute for Infant & Child Medical Music Therapy (USA) along with the completion of First Sounds: Rhythm, Breath and Lullaby—Tier I training.

therapist used an MT session tracking form after each session to summarize the content and note any deviations that came close to exceeding the flexible frames of the intervention guidelines along with reasons for such (e.g. session length that was longer than anticipated, sessions in which parental voice was not the predominant voice). This feasibility study did not aim to evaluate treatment fidelity (e.g. adherence to intervention protocol), which will be evaluated in the main trial, but instead enabled the team to test the feasibility of the intervention and fine tune it prior to the main trial.

All participants in the pilot study also received standard care services during NICU and post-discharge phases. Standard care included necessary and routine medical and nursing care, inclusive of individualized developmental care, skin-to-skin care, breast-feeding support, and family-oriented care.

Feasibility Analysis

Recruitment and retention rates. We kept a log of eligible families who were invited to participate in the study, those who consented, and those who completed all phases of the pilot study.

Acceptability and suitability of the intervention. We determined the acceptability and suitability of the intervention primarily through semi-structured interviews with parents who participated in the pilot study. The music therapist who conducted MT interviewed parents 1 or 2 days prior to discharge from the hospital and again when the infant reached 3 months CA. Interviews lasted approximately 20–30 minutes at discharge and approximately 30–45 minutes at 3 months CA and were audio-recorded for subsequent data analysis. The first interview took place on the NICU in a location of the parents' choice, while the second occurred in the participants' homes at the conclusion of the last post-discharge MT session. Interviews were semi-structured with the music therapist using an interview guide as a point of departure (see [Supplementary Appendix A](#)). Open-ended questions were designed to elicit parents' thoughts related to the acceptability and suitability of the intervention and study procedures. Questions were developed by the first author and modified by a senior researcher and psychologist who contributed to protocol development. The music therapist interviewed the parents, due to her familiarity with feasibility

study aims and intervention, and experience with conducting semi-structured interviews. To reduce the influence this dual role might have on participants' responses, we asked parents about potential negative or least helpful experiences related to participating in MT, and what they would change about the MT experience. We also included an open-ended question to encourage parents to mention any other important aspects that were not covered in the interviewer's questions. Interviews were conducted and transcribed in Norwegian. The music therapist conducting MT sessions also kept notes on how the intervention procedures were accepted by unit staff, along with any modifications in the intervention that were required during the pilot study or that might be warranted in advance of the main study.

Acceptability and suitability of outcome measures and data collection procedures. A central aim of the feasibility study was to assess whether it was feasible and desirable to evaluate maternal–infant bonding as a primary outcome, and if so, which assessment tool was most suitable for use in the main study. We also evaluated the acceptability and suitability of other outcome measures intended to be used in the main study to evaluate maternal depression, parental anxiety, parental stress, and infant development. We used validated Norwegian versions of these questionnaires. Self-report data were collected from parents via electronic tablets. Parents were assigned usernames and passwords to gain access to the Qualtrics online survey platform, Version 2018 (Qualtrics, Provo, UT). We assessed outcomes at several time points as illustrated in [Supplementary Figure 1](#), namely: (1) at baseline, (2) one or two days before discharge home, and (3) at 3 months CA.

Primary outcome. Maternal–infant bond was evaluated at all time points using the Postpartum Bonding Questionnaire (PBQ). PBQ is a self-rating screening instrument for disorders of the early mother–infant relationship consisting of 25 statements on a 6-point Likert scale (sum score ranging from 0 to 125 and higher scores indicate problematic maternal–infant bonding). The questionnaire assesses problems in the mother–infant relationship based on weakened bonding, rejection and anger, anxiety about care, and risk of abuse ([Brockington et al., 2001](#)). The scale is validated and widely used in clinical practice and research ([Perrelli et al., 2014](#)) and has good internal consistency ([Wittkowski et al., 2010](#)) and test–retest reliability ([Brockington et al., 2001](#)).

To evaluate alternative instruments to the PBQ, we also used the Mother and Baby Interaction Scale (MABISC) to assess the interaction between mother and infant (Hackney et al., 1996), which correlates with maternal–infant bonding. We also trialed the Mother-to-Infant Bonding Scale (MIBS) (Taylor et al., 2005) as a simple, 8-item self-report measure of maternal–infant bonding to assess its performance relative to the PBQ and MABISC.

Since maternal–infant bonding is most often measured by self-report, we also evaluated whether it was feasible and preferable to adopt an observational measure instead of a self-report questionnaire. We identified an observational tool that assesses the quality of maternal–infant interaction, the Emotional Availability Scales (4th ed.) (Biringen, 2008), and evaluated whether it was a viable alternative that offered methodological superiority through more objective measures.

Secondary outcomes. We assessed the acceptability and suitability of several tools for measuring secondary outcomes:

Parental depression. The Edinburgh Postnatal Depression Scale (EPDS) is a 10-item self-report instrument that assesses maternal postpartum depressive symptoms (Cox et al., 1987). High scores indicate more depressive symptoms, and scores range from 0 to 30.

Parental anxiety. The Generalized Anxiety Disorder Assessment (GAD-7) is a self-report 7-item questionnaire that serves as both a screening tool and a severity measure for generalized anxiety disorder (Spitzer et al., 2006). High scores indicate higher anxiety, and scores range from 0 to 21.

Parental stress. The Parental Stress Scale (PSS) is a self-report 18-item questionnaire that assesses stress levels associated with parenting (Berry & Jones, 1995). High scores indicate higher stress levels, and scores range from 18 to 90.

Infant socio-emotional development. The Ages and Stages Questionnaire Social-Emotional, second edition (ASQ:SE-2) is a parent-reported questionnaire that targets infant social-emotional competence and problem behaviors, with 19 or 22 Likert-scaled items depending on child age (Squires et al., 2001, 2015; Yovanoff & Squires, 2006). Lower scores indicate better socioemotional development.

We also trialed questions related to parent demographics (e.g., age, education level, and hours worked per week), infant medical factors (e.g., birth weight, presence of various medical complications, oxygen requirements), as well as infant feeding and sleeping factors. These data were collected from parent reports or from records in the infant's medical chart.

Required resources for trial implementation. Music therapist time resources were evaluated by calculating time used for face-to-face and non-face-to-face portions of MT sessions, along with travel time for post-discharge MT sessions.

Data Analysis

We assessed the feasibility and acceptability of the aforementioned elements in accordance with the types of data obtained. We used descriptive statistics and visual inspection to describe and evaluate data from recruitment rates, outcome assessments, and therapist resources. We used inductive thematic analysis to analyze qualitative data from parent interviews.

Qualitative analysis. Our approach to inductive thematic analysis of qualitative data from parent interviews was consistent with the steps outlined by [Braun and Clarke \(2006, p. 87\)](#). One author (C. M. Ghetti) analyzed the transcripts using the inductive generation of codes and themes. A second author (T. S. Gaden) then reviewed the transcripts and the first set of codes and themes, suggested variations, and these two authors came to a consensus on a final set of codes and themes. The analysis was conducted in Norwegian; themes, subthemes, and parent quotations were translated to English for the report. In keeping with inductive thematic analysis, we sought to identify themes that were prevalent across the data set, as well as those that conveyed key elements in relation to participants' perceptions of acceptability and suitability of the intervention and study procedures ([Braun & Clarke, 2006](#)). In generating themes, our aim was to create a rich description that represented the entire data set, including predominant and important themes ([Braun & Clarke, 2006](#)). We adopted a critical realist ontology and epistemology in relation to analyzing and interpreting the qualitative data ([Danermark et al., 2001](#); [Fletcher, 2017](#)). Critical realism, with its realist ontology and constructionist epistemology, has been adopted by researchers within and beyond the discipline of MT as

a philosophical stance that has particular relevance within mixed methods research (Bradt et al., 2013; Creswell & Plano Clark, 2011; Maxwell & Mittapalli, 2010). We took a realist position in relation to both the status of the data and of the analysis itself, not only taking parents' descriptions at face value but also trying to understand the underlying structures that generated their experiences (Willig, 2012). In so doing, we sought to identify and articulate an accurate and valid account of parents' experiences as they experienced them (Willig, 2012). Nevertheless, our interpretations remain a constructive process and thus reflect one possible actuality.

Results

Participants and Participant Flow

Six families were screened for eligibility during the recruitment period; of those, one family did not meet inclusion criteria and two declined to participate. Three eligible families consented to participate in the feasibility study and completed all study procedures during the NICU phase. One of these families declined to continue participating in MT post-discharge, citing that they were overwhelmed with commitments related to their other children. This family also reported that some of their feelings of being overwhelmed were linked to the high likelihood that their premature infant would have significant developmental challenges. The family stated willingness to be contacted for the 3 months CA assessment but did not reply when contact was attempted at that timepoint. [Figure 1](#) illustrates the flow of participants through all phases of the study.

Participating families consisted of three couples, along with their premature infants. Mothers and fathers (both ranging in age between 20 and 40) participated along with their infants, who were all enrolled between 33 and 34 weeks post-menstrual age (PMA). Two infants were male and one female; all were from single births and were born between 27 and 32 weeks of GA, with birth weight ranging from 950 to 1,180 g. Parents reported their educational level as ranging from the completion of high school diploma to at least 4 years of higher education and described their household economy as average to very good. Two mothers worked full time prior to maternity leave, while one worked part time. All

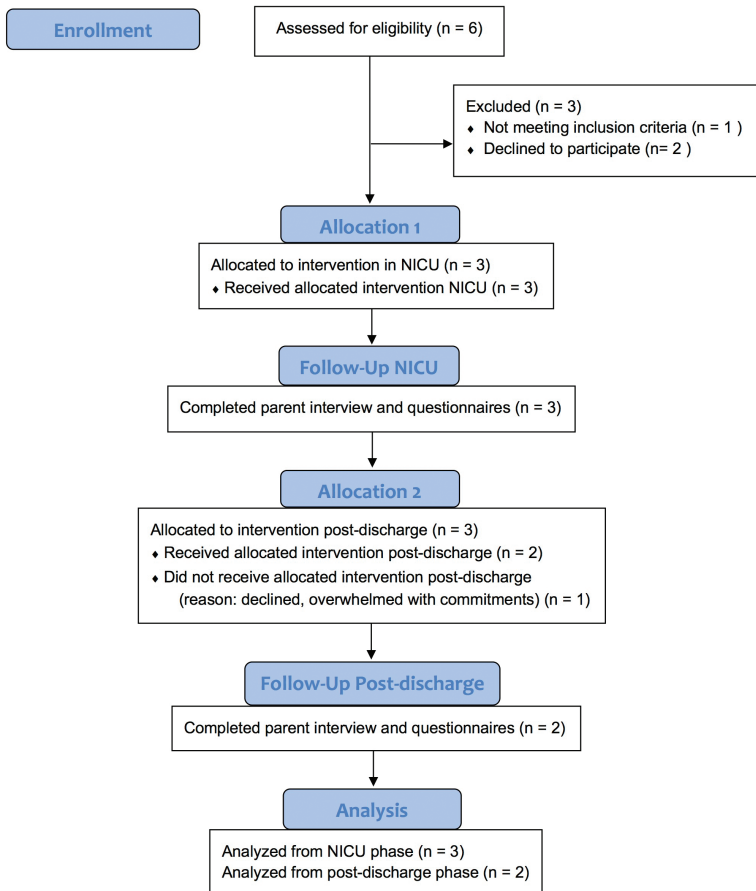


FIGURE 1.
Flow diagram.

three couples were either married or were living together but not married.

Recruitment and Retention Rates

Of the five eligible families who were invited to participate in the study, three consented to participate. Of these, all three completed assessments at baseline and discharge, whereas two completed assessments at 3 months CA. All three families took part in MT in

NICU, with a range of four to seven sessions each. Two families engaged in MT sessions post-discharge and received four and six sessions across the 3-month period, respectively. Thus, one family dropped out of the intervention at discharge and effectively out of the study at 3 months CA.

Acceptability and Suitability of the Intervention

Results from parent interviews. Through inductive thematic analysis of transcripts of the parent interviews, we identified themes within the general domains of: (1) experience of MT, (2) logistics of the study, (3) suggestions for changes in the study, and (4) experience of completing study questionnaires.

Experience of MT. A list of themes and subthemes related to parental experiences of MT is available as [Supplementary Table 1](#). These themes are described herein using the content from the respective codes to substantiate each theme. Parental quotations are integrated for further illustration.

Experienced as exciting, interesting, cool, cozy, fun, and a break. Parents described MT sessions as exciting, interesting, cool, cozy, fun, and a break from hospital routines. Parents found it exciting and interesting that infant responses to MT were clearly evident via their behavioral cues (which parents labeled as “signals”) or physiological parameter monitoring. Such responses were particularly evident when infants were in an alert state or were slightly more neurologically mature, such as during the post-discharge period. Mother 1 explained, “You see signals that the infant is sending... and we become better acquainted with him, too.” In the beginning, it was hard for some parents to see infant reactions to MT, if indeed there were any, or to discriminate if behaviors they saw were typical of all infants or were specifically related to the music. Parents found it “very fun” when they could clearly see their infant reacting to music, such as when the infant searched after their voices. Parents expressed how MT offered a break in the typical hospital routine, which was particularly appreciated during long hospitalizations.

Serves as Something “Different”. Parents perceived MT as being something “different.” They reported that MT was a new experience and something unique from other approaches they learned from nurses in the NICU, such as principles of developmental

care consistent with Newborn Individualized Developmental Care and Assessment Program (NIDCAP) (Als, 1986). In contrast to these other approaches, parents reported that MT offered a chance to immediately observe reactions. Mother 1 explained, "...with music, you get to see how he responds directly to sound and to your voice. And you form that relationship then." One mother experienced some level of frustration during breastfeeding attempts, as her infant had difficulty feeding. MT during breastfeeding attempts offered this mother a "different" experience and a break from feelings of frustration, "For me it has been good to have a little different time [in MT] than the typical breastfeeding times" (Mother 2). This mother reported that MT changed her perception of the breastfeeding experience, even when she did not observe a difference in how the infant reacted. Parents stated that MT also provided a means for a "different" kind of focus on the infant, namely a more "normal focus":

...it became a little less hospital-like during those times... there was a little different focus than needlesticks and delivering medicine. It became a little more of a normal focus. (Mother 2)

In being perceived as "different," MT provided various opportunities for parents to experience a more normalized interaction with their infants, despite being hospitalized.

Affords an opportunity for parent(s) and infant(s) to become known to each other. Parents expressed that MT afforded an opportunity for them and their infants to become known to each other. Father 3 describes it thus:

Prematurity was new for both of us. [MT] was a way to get to know her, to become acquainted. In the same way that [the nurses] interpret how she is doing in a different way than with a typical baby.

Parents perceived parental voice as the primary means through which this knowing was possible. Through a focus on parental voice, Mother 1 described that her infant "...came to know my voice, and therefore a sense of security...I see that he calms down when I sing." Parents articulated that MT provided a frame for communication and interaction where the infant's personhood

emerged clearly. Mother 1 described this connection, “That direct communication, while holding him close, looking into his eyes and such, yes, we can see then that he reacts.”

Affords new or different opportunities to music together as a family. Parents reported that MT also afforded new or different opportunities to music together as a family. In the NICU, MT offered opportunities for family singing and musicking together in a way that was not typical of their home life (Mother 2). Though sibling visits to the NICU were restricted due to infection control at the time of this study, mothers and fathers sang together during MT sessions. Such occasions were perceived as being “very nice,” especially when it was clear that the infant was responding positively. When her infant was a little more mature during the post-discharge phase at home, one mother noted that he reacts very positively when his older siblings sing for him, “then he sings loudly back” (Mother 2).

Abilities developed in MT transfer to other settings. Parents reported that abilities they or their infants developed in MT transferred to other settings. A main goal of the LongSTEP MT approach is that parents will carry forward aspects they learn in MT to their ongoing interactions with their infants. Parents in this pilot study expressed that they continued singing and using principles they had learned in MT once they returned home. This held true even for parents who perceived they had limited singing ability (Father 1). At home, parents continued to adapt and intentionally use certain songs during specific times such as feeding, sleeping, or during diaper changes. They sang at home to calm the infant down, to gain the infant’s attention, or to help the infant self-regulate. As Father 1 noted, when the infant is upset, “... if you then begin to sing to him, or mostly hum for my part, I am not so good at singing, but then you notice that he becomes secure and calms down again.” Parents who had previously sung to their older children said that their use of singing is now different and more deliberate, based on what they have learned in MT:

[We have] been a little more deliberate in communicating with him with our voices, instead of just sitting and holding him, for example. (Mother 2)

At home, parents used more active songs when their infants were awake, such as songs with movements. Some families tried to pair

certain songs with transitioning to sleep and perceived that their infants recognized and responded accordingly.

Some parents also noted that their infants appear to have developed the ability to tolerate music and more complex levels of auditory stimuli because of MT. On a basic level, the infants became used to singing voices (mother, father, music therapist, etc.), and this can generalize to better tolerance of other sung and spoken voices. Parents believed that participation in MT could contribute to an infant being more ready to handle group music situations like parent/infant music groups. Mother 1 elaborated that if her son had not had MT prior to Baby Song group, "...then I think it would have been too much [for him]." One mother noted that her infant was more "talkative" than the other infants of his same developmental age, but she did not know if this was by chance or not (Mother 2): "He loves to use his voice. There is no doubt about that."

Provides a means of demonstrating development over time. Parents described how MT provided a means of illustrating infant development over time. It was "fun" for parents to see this development, which occurred most markedly during the post-discharge phase, and to notice more eye contact, babbling, and interaction (Mothers 1 and 2). Their infants began to communicate more clearly, smiling more, and moving more. Parents expressed that they were able to read infant cues even better during this period. Over time, infants began to anticipate and react to specific movements in known songs (Family 1), and one infant whose father played guitar also grew to enjoy hearing the guitar (Family 2).

Enables an experience of relation to the infant. Parents perceived that they were able to experience relationships with their infants through MT. In particular, song was a central means of connecting. One mother noted:

It was a way for us to tell him that we were there, that he could hear us, you know? ... There are limits to how much you are able to talk to them. You don't have much to tell [laughter]. So then it's easier to come with a song. (Mother 2)

For this mother, the voice was a way to assure the infant of her presence, and she found it easier to use song to do so than to rely only on speaking. Parents were also aware that it was important

that the sound environment was adapted for the infant's particular needs. For example, one infant calmed with voice but was often over-stimulated by guitar. His mother explains, "...he comes a little closer, or is a little more relaxed when there is only us, or in very safe frames, than maybe for example with guitar" (Mother 1).

Parents recognize the voice as central. Parents reported that through the process of MT, they became aware that their voices offered a primary means of connecting with their infants. Parents described how their infants' responses were connected to known voices and to the way those voices were used. Parents recognized that voice was very important and had a lot of influence. Furthermore, they recognized that when infants were so premature, they do not require so much stimulation, and thus voice offered a good match to their needs.

Some challenges are experienced along the way. The experience of MT was not without challenges. A predominant aspect of this theme is related to how parents perceived the act of singing within a hospital context. Parents articulated that singing in front of others could be perceived as something new, a little embarrassing, and it could make parents feel exposed. Despite these challenging perceptions, parents in this study said singing in the hospital was not necessarily negative or strange. Instead, they recommended that sessions take place in individual rooms, where parents could be more at ease and there would also be fewer disruptions. One mother expressed a desire to not disturb others or the quietness in a shared room when she sang. Another important aspect of this theme relates to the challenge of when an infant is ready for MT and how much stimulation to include. Mother 1 acknowledged that her infant did not always respond positively to MT, and it really depended upon timing:

Or if he is very tired, or has just eaten or has a tummy ache or such things, then it is not a given that he will think music is so fun...there is a lot that influences whether he will enjoy it.

Parents recognized that voice alone was sufficient at the start and infants were often not ready for more complex auditory environments. One family noted that their infant was unaccustomed to the sound of guitar, and thus he had difficulty tolerating it during the

portions of post-discharge sessions when it was used. Thus, parents became aware that their infant's response to music and MT was dependent upon the infant's current state and general progression of development.

Parents' relation to music influences how and how much they use music actively with their infant(s). Parents' relation to music influenced how and how much they used music actively with their infants. Parents who felt like less capable singers often preferred to hum instead and were more concerned that other people in the shared hospital room would find the singing to be unpleasant. Parents in the study tended to choose songs they had grown up with, or enjoyed singing, and learned how to adjust these to match the infant's needs and responses. It took a little time for some parents to become comfortable singing in a shared hospital room.

Logistics of the study. Parents acknowledged that finding the best time for MT sessions was challenging and was difficult to plan in advance. During NICU hospitalization, the windows in which infants were awake and alert were short and infrequent, most commonly occurring just prior to feeding time. Although the intervention was intended to address the needs of both parents and infants, parents were most focused on the challenge of finding timing that was best for the infant. Parents recommended to avoid days when more taxing procedures occurred, such as ophthalmology tests. Two families thought it would be helpful to be able to page, message, or call the music therapist when the infant was alert and available for a session. One family found the planning of home visits to be slightly more challenging than the NICU phase, while another family had no such challenge. Some parents preferred post-discharge sessions at home, while others were open to either having them at home or at the hospital. As previously mentioned, one family chose to discontinue MT after discharge, due to feeling overwhelmed with their situation.

When questioned about who it is most important to focus on during the main study, the mother or father, participants expressed that mothers have a unique connection to the infant and most likely have particular needs that are important to follow closely. Father 3 explains, "I think absolutely that she has another...level of worry, you know, than me. Maybe a different attachment." Fathers might have different experiences than mothers during this time, but fathers have many strong feelings, too (Father 3). Thus, parents

thought it made the most sense to closely follow the mother in relation to bonding with the infant, but that both mothers and fathers should have their own sets of questionnaires. Parents also agreed that it was important for both parents to actively engage in MT itself. One parent who was familiar with research said that it was likely that parents would still be interested in participating even if the study were a randomized trial with the potential to receive standard care instead of MT.

Suggestions for changes in the study. Two families expressed that they would have preferred to receive additional information about the aims and precise mechanisms of MT prior to beginning sessions with their infants. The informed consent form included information about the aims of the study and scope of parental participation. In addition, the music therapist provided a short summary of this information again once parents were enrolled in the study and described techniques related to infant-directed parental singing as sessions progressed. However, two families said it would be helpful to have an expanded discussion of infant signals and techniques for voicework and an overview of how the use of song and music would progress over time in accordance with infant development. They felt that such information could be conveyed via an expanded discussion, perhaps including the use of videos, prior to beginning to sing with their infants.

Parents felt that the frequency of three sessions per week would be reasonable for the main study. One family suggested that it might be helpful to start with even more frequent use of MT and then as parents become more comfortable to continue on their own, sessions could decrease. Such intensity would allow parents to “practice” their musical interactions with their infants and enable them to “come into a shared understanding” with their infants (Mother 1). Though parents agreed that MT taking place in a shared NICU room is not necessarily unpleasant, they all concurred that parents will likely be more at ease and more likely to sing frequently if sessions are in individual rooms. Two families mentioned that they could imagine that some parents might be reluctant to sing in front of strangers.

Experience of completing study questionnaires. Parents reported that some questions were not applicable to their infant at baseline and discharge. They referred to some feeding and sleeping questions as well as an occasional item that assumed an infant

who was not hospitalized. Regarding the questionnaires related to bonding, parents had few comments about the MABISC or MIBS, but mentioned that there were items on the PBQ that they were surprised by. The PBQ items that address more extreme aspects of impaired parental bonding, such as parental harm to infant, were perceived as either not relevant and thus not provocative or as surprising and disconcerting. One mother doubted if other parents would answer such items honestly and wondered what such items had to do with MT. Overall, parents reported that the burden of completing the questionnaires was not excessive and that it took approximately 10–15 minutes to answer questionnaires at baseline and discharge. Parents reported that it was easy to use electronic tablets, and in one instance a cell phone, to gain access to the questionnaires via a secure online survey platform.

Results From Music Therapist Notes/Reflections. Session notes and reflections from the music therapist reveal that the intervention was feasible and acceptable with minor adjustments. Upon arriving at the unit, the music therapist checked in with the nurse educator collaborating on the project, or in her absence, with the unit manager. They discussed status of the families and projected discharge dates, when applicable. The music therapist then briefly spoke with each participant's treating nurse prior to approaching families for that day's session to remind the nurse of the purpose of the session and to assess whether there were any contraindications for having MT with the infant. The therapist then greeted the parents and confirmed that they were able to engage in a session. Maintaining communication on these levels helped assure consistent access to the families and enabled the music therapist to anticipate some aspects of what families might need on a given day.

The original intent was for NICU sessions to last approximately 30 minutes, but the music therapist discovered early in the process that session lengths needed to be longer to be effective. For example, the steps of checking in with parents, briefly assessing their needs and those of the infant, assuring that the infant was positioned in a way that enabled their receptivity for MT, engaging parents in singing in dialog with their infants, enabling an opportunity for psychosocial support, and providing closure to the session tended to span approximately 45–50 minutes. The time

actively engaging the infant in music remained approximately 25–40 minutes, in accordance with infant tolerance and developmental readiness. Thus, sessions in the feasibility study were extended in order to encompass a time frame that naturally fit the desired session elements.

One family preferred that the music therapist message them earlier the same day of the scheduled session in the NICU. This communication helped remind them of the session time and also allowed them to convey if they needed to reschedule due to extenuating circumstances. In most of the cases, they were able to keep the agreed-upon session, with minor or no modifications.

In regard to adherence to particular elements of the intervention procedures, the music therapist found that it sometimes took longer for parents to figure out how to modify their positioning of the infant and use of voice to attune to the infant, than if the music therapist had demonstrated herself. However, in order to follow the guiding principles of the intervention, it was important for the music therapist to take this time to support parents in finding their way. Similarly, the music therapist had to maintain an active effort to support parents in being the predominant voice within sessions.

Acceptability and Suitability of Outcome Measures and Data Collection Procedures

A central aim of the feasibility study was to determine the primary outcome for the main study. We assessed whether it was feasible and desirable to evaluate maternal–infant bond as a primary outcome and evaluated the acceptability and suitability of other outcome measures.

Primary outcome. We ruled out the use of an observational tool to assess the quality of maternal–infant interaction, primarily due to the lack of a psychometrically superior tool (Lotzin et al., 2015) and for reasons of logistic feasibility. Such tools would require video recording with frames clearly encompassing both infant and parent, which at best would be logistically challenging and at worst prohibited in some NICUs. Furthermore, coding videos consistently across multiple countries with different languages would add further complexity. Thus, we decided to retain a self-report measure of maternal–infant bonding as our primary outcome.

The results from the limited sample size of this pilot study suggest that the PBQ demonstrated changes over time, baseline values had room for improvement, and although mothers were surprised by some items, they expressed no particular objections to completing them. We observed a decrease in PBQ scores over time suggesting that the tool can detect changes in perceived maternal–infant bonding. Observations for PBQ sum scores at baseline of 5, 9, and 17 (possible range 0–125) were low values, but still had a potential for improvement. The MABSIC and MIBS were simple to complete and perceived by parents as less provocative than the PBQ, but we decided to retain the PBQ due to its level of validation and widespread use in research (Perrelli et al., 2014), including use for measuring treatment effects in clinical trials.

Secondary outcomes. Parents had no objection to the secondary outcomes except for the fact that some feeding and sleeping questions and some occasional items on the ASQ-2:SE were not applicable for their infants at discharge or 3 months CA, respectively. Parents felt that it was also important to track mental health outcomes for fathers, as they go through intense emotions when adjusting to the birth of a premature infant. In order to maximize the capture of data directly related to our research aims while also minimizing data points, we decided to remove the feeding and sleeping questions from the main study protocol and to assess fathers (or partners) separately on the GAD-7 and PSS. Since mothers experience unique physiological changes during and after pregnancy, we also decided that in the main study we would only assess mothers for the PBQ and EPDS, in order to increase homogeneity.

Required Resources for Trial Implementation

The music therapist used a mean of 43.12 minutes ($SD = 13.27$) of face-to-face contact per NICU session and a mean 54 minutes ($SD = 10.75$) of face-to-face contact per post-discharge MT session. We estimate that the therapist used approximately 15 minutes of non-face-to-face time per NICU session (i.e. coordinating with staff regarding infant availability and preparing materials for the session), 20 minutes of non-face-to-face time per post-discharge session (i.e. preparing materials for session, reviewing previous session notes), and approximately 2 hours of travel time for each home visit. The nurse educator who screened participants and

completed informed consent conversations estimated an average time use of 20 minutes per family for these processes.

Discussion

The purpose of this nonrandomized feasibility study with inductive thematic analysis was to evaluate the feasibility, acceptability, and suitability of the treatment arm and study procedures of the LongSTEP trial. We had originally hoped to complete a larger-scale, single-site randomized pilot study to test feasibility including randomization, but due to funding and time restrictions were limited to conducting two smaller-scale feasibility studies. Pilot testing with a Norwegian cohort suggests the following. In regard to the feasibility of recruitment and retention, the majority of eligible parents who were approached were willing to participate in research related to MT and to be highly engaged in MT and use their voices. Parents were retained over NICU and post-discharge phases, though the point of discharge from the hospital was vulnerable for dropout for parents who felt overwhelmed by family commitments. Parents perceived the MT intervention to be acceptable and suitable to their needs and particularly valued being able to see their infants increase in musical responsiveness and interaction over time. Parents reported that it would be more comfortable and natural to sing when in a private NICU room, though they were still willing to do so in shared rooms. At the beginning of the study, parents would have appreciated more information about the aims and specific approaches used in MT. Study procedures were also deemed as acceptable. The selected self-report assessments of maternal–infant bonding, parental well-being, and infant development were reasonable to complete using the online survey system and electronic tablets. Regarding the proposed primary outcome, parents reacted to some items on the PBQ, but not more than that these were perceived as a bit surprising and irrelevant for them. Given that the PBQ is widely used in the literature (Perrelli et al., 2014) due to the strength of its psychometric properties, we decided to retain it to assess impaired bonding. Regarding the required resources for study implementation, parents reported appreciating post-discharge sessions in the home setting, which we deem as desirable but potentially resource intensive.

The results of this feasibility study informed the design of the main study. We incorporated feedback from parents in this study, along with input from our User Advisory Group, which was established for the main trial and made up of parents of premature infants not enrolled in the study. In particular, for the main study, we: (1) assured that parents received expanded description of the aims and methods of MT, (2) retained maternal–infant bonding as a primary outcome, (3) retained MT as used in this pilot for the intervention, (4) requested music therapists be consistently and flexibly available for sessions during NICU phase, (5) encouraged music therapists to find ways to support parent comfort when singing in shared NICU rooms, and (6) assessed mental health outcomes for fathers/partners as well as for mothers. In addition, results from parent interviews in the feasibility study demonstrate that parents were most focused on MT's benefits for their infants and not so much about how they themselves could benefit. Subsequently, we decided to train music therapists in the main study to emphasize to parents how MT should support their needs as well as those of their infant(s).

In reference to the intervention, a main aim of the MT approach used in this trial was that parents would carry forward aspects they learn in MT to their ongoing interactions with their infants. Thus, we hoped that experiences in MT would strengthen parenting resources and enable parents to flexibly and mindfully engage musically with their infants over time. Parents in this feasibility study reported that they continued singing and using principles they had learned in MT once they returned home and that they could see and effectively respond to infant responses. In addition, parents were curious about how MT works and sought more information on the aims and specific mechanisms involved. Our findings are consistent with [Robertson and Detmer \(2019\)](#), who found that parents value and use music more with their infants when they are educated about its use and personally experience its benefits.

Parents articulated that MT offered a means for parents and infants to become known to each other, and that parental singing was central in the process of expressing presence and building relation with their infants, particularly during the vulnerable period of NICU hospitalization. Parents described how interesting and rewarding it was to see their infants' responses to their voices, and the complexity of these responses and interactions developed over

time. These findings are concordant with [McLean et al. \(2019\)](#), who found that parents' ability to identify their infants' responses to their voices was essential to experiencing quality of relation. Similarly, [Ettenberger et al. \(2017\)](#) found that parents experienced increased confidence and motivation and felt empowered in their musical interactions, upon seeing clear and positive responses from their infants. Thus, the premature infant's discriminating response to a parent's voice can then lead to a parent feeling recognized and validated in their parental role ([McLean et al., 2019](#)). As participants in this feasibility study experienced, parental voice served as a crucial indicator of parental role and presence, a phenomenon also articulated by [Shoemark \(2017\)](#), among others. Furthermore, parents expressed that MT offered a different experience of musicking together as a family, echoing the findings of [Ettenberger et al. \(2014\)](#).

However, our findings also indicate that parental use of voice within the NICU setting is not without challenges. [Shoemark \(2017\)](#) acknowledged that empowering parents to sing with their NICU-hospitalized infants is necessarily accompanied by challenges related to personal beliefs and experiences, contextual parameters, and temporal considerations. Similarly, we found that engaging parents in exploring the use of their voices with their infants came more or less naturally for some participants, depending upon personal and contextual circumstances. With each set of participants, the music therapist had to consider and work with these personal and contextual challenges, in order to effectively play the external supportive role to these dyads/triads that [Shoemark \(2011\)](#) described. Despite these challenges, the participants in this feasibility study still found ways to hum and sing with their infants in a manner that made the parents comfortable, while enabling them to gain a sense of relation with their infants.

Reflexivity and Limitations

Though we used quantitative and qualitative data in this feasibility study, it did not qualify as a mixed-methods study, as we did not aim to systematically integrate the findings from these two forms of data. Instead, they each helped answer different research questions and enabled us to separately consider various aspects of feasibility, acceptability, and suitability of intervention and procedures. If we

had been able to complete a larger-scale randomized feasibility study with inferential statistical analysis of the quantitative results, we might have been able to merge or connect the qualitative and quantitative results in a meaningful way in alignment with a mixed-methods design (Bradt et al., 2013; Creswell & Plano Clark, 2011).

In order to achieve our aims of evaluating feasibility, we found it pragmatic to combine an inductive thematic analysis of the qualitative data, with a descriptive statistical analysis of the quantitative data. In order to make a meaningful sense of this combination, we have taken a critical realist perspective (Maxwell & Mittapalli, 2010). To promote quality in this piece of research, we followed the CONSORT 2010 statement extension for pilot and feasibility trials (Eldridge, Chan, et al., 2016) and carefully considered Stige et al.'s (2009) evaluation agenda for qualitative research, EPICURE. Our reflections on quality follow.

We achieved a deeper level of engagement in the phenomenon of study by having the first author serve as a music therapist. The music therapist could then experience first-hand how feasible and acceptable study procedures were for the therapist, families, and the study site. In order to enable adequate processing of the qualitative data and balanced interpretation, a second author familiar with the phenomenon from clinical practice engaged in data analysis and interpretation to enable investigator triangulation. Furthermore, our interdisciplinary research team contributed to the design, analysis, and interpretation of the overall feasibility study. The first author kept session and reflective notes on the intervention and research process, as a means of tracking the intervention, examining deviations, and noting challenges with implementation. The first author held multiple roles in the research, including as the person who interviewed parents, which offered both advantages and disadvantages. These multiple roles helped assure that the researcher was deeply engaged in the topic, was grounded in the everyday reality of challenges related to intervention and study implementation, and had developed a rapport with the parents prior to the interviews. This familiarity during the interviews might have helped open up for deeper discussion, as the interviewer could draw upon their shared history at times. To safeguard against the possibility that parents would avoid reporting negative or neutral experiences, the semi-structured interview guide included questions about negative or least helpful

experiences, asked what parents would change about the MT experience, and prompted parents to mention any other significant aspects that were not covered in the interviewer's questions. We realize that despite these opportunities, it is possible that parents might not have felt comfortable expressing displeasure or dissatisfaction, or the presence of the music therapist might have led to them expressing their experiences in a more positive manner than they would have otherwise.

Though we used two researchers for data analysis and interpretation of the qualitative data, we did not make use of participant validation of the final findings. Since the main aim of our study was to examine the feasibility and acceptability of intervention and study procedures, participants' experience of MT was one portion of this goal. Trustworthiness in the findings of the thematic analysis would have been improved with the inclusion of participant validation.

The results of this feasibility study reflect the experiences of three families in one geographic context. As the main trial relies on partner sites in several countries with similar social support cultures in order to assure sufficient recruitment to adequately power the trial, it is possible that the experiences described herein will vary from parental experiences in other cultures. In particular, parent willingness to consent to participation in a randomized trial lasting two years, to sing and actively engage in MT in varying cultural contexts, and to maintain participation in the study across the study period remains to be seen. Given the reduced parameters of MT sessions in the present study, it is not possible to determine if three MT sessions per week in NICU and approximately once per month for 6 months following discharge will be well received by parents in the main study. A significant drawback of this pilot study was that we did not include a control group. Thus, we are not able to evaluate how assignment to standard care impacts parental retention in the study.

Implications for Future Research

The outcomes of this feasibility study not only are directly applicable to the main trial but also have implications for other forms of future research. The MT approach used in this study required a high level of parent participation and assumed that parents could learn how to read infant cues and respond with their voices in an attuned manner that progressed in alignment with the infant's ongoing development. Since parents who are at higher socioeconomic risk

may demonstrate lower levels of engagement in early intervention programs with their premature infants (Chin & Teti, 2013), it is important that future research evaluates the impact of socioeconomic risk. Parents in this pilot study acknowledged that it is more comfortable to sing with their infants when in a private NICU room. A critical realist perspective acknowledges that causal explanation depends upon context and thus we need to consider context when exploring the mechanisms underlying causal relationships (Maxwell & Mittapalli, 2010). Studies that explore how the physical context in which MT occurs impacts the nature of parental engagement in MT are indicated. One family suggested starting MT in the NICU with a higher frequency of sessions. Future research could evaluate the differential impact of high-intensity versus low-intensity frequency of sessions in the NICU and post-discharge phases.

Conclusions

Parents of premature infants in a small Norwegian cohort were willing to actively engage in MT with their infants during a research study where parental voice was the main means of interaction. Parents reported that such musical exchanges enabled them to know and become known to their infants and that resources they honed during MT transferred to their parent–infant interactions outside of MT. Parents found the proposed study procedures and outcome measures to be acceptable and suitable, though they desired more detail about the aims and processes of MT. Results of this nonrandomized feasibility study inform the implementation of a subsequent multinational trial that will address an important gap in knowledge related to the impact of longer-term MT on longer-term outcomes related to maternal–infant bonding, parental mental health, and infant development.

Supplementary Material

Supplementary material is available online at *Journal of Music Therapy*.

Supplementary Figure 1. Feasibility study design.

Supplementary Appendix A. Semi-structured interview guide.

Supplementary Table 1. Themes and Corresponding Sub-Themes Related to Parental Experience of Music Therapy

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