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Family-centred music therapy with preterm infants and their parents in the Neonatal Intensive Care Unit (NICU) in Colombia – A mixed-methods study

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ABSTRACT

This article reports a mixed-methods study of Music Therapy (MT) with preterm infants and their parents in a neonatal intensive care unit (NICU) in Colombia. The aim was to find out whether live MT during kangaroo care had an effect on the physiological outcomes of the neonates and would help parents to decrease their anxiety levels and improve parent–infant bonding. The participants were 36 medically stable neonates born between the 28th and 34th week of gestation and their parents. The quantitative data collection included heart rate, oxygen saturation, weight gain, length of hospitalization and re-hospitalization rate. The assessment measures for anxiety and bonding were the State-Trait Anxiety Inventory (STAI) and the Mother-to-Infant-Bonding Scale (MIBS). Thematic analysis was used to analyse the qualitative data collected with semi-structured interviews and questionnaires. The quantitative results showed statistically significant improvements in maternal state-anxiety ($p = .007$) and in the babies weight gain per day during the intervention period ($p = .036$). Positive trends were found regarding the babies' length of hospitalization and re-hospitalization rate. Both parents improved their scores with the MIBS, but this was not statistically significant. The qualitative analysis showed that MT was important for parental well-being, for bonding and for fostering the development of the neonates. Interacting musically with their babies helped parents to experience feelings of connectedness and to distract themselves from their difficulties and from the noisy hospital environment.

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KEYWORDS Music therapy; Neonatal Intensive Care Unit (NICU); preterm infants; bonding; anxiety; mixed methods

Introduction

Having a preterm baby in the Neonatal Intensive Care Unit (NICU) can be a distressing life event for many parents. Mothers of preterm infants frequently experience symptoms of depression, psychological distress or fear about their baby's health and survival (Johnson et al., 2009; Parker, 2011). Also, an alteration of their parenting

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 Supplemental data for this article can be accessed [here](#).

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role and feelings of guilt, helplessness and anxiety are common among mothers in the NICU (Fabiyyi, Rankin, Norr, Shapiro, & White-Traut, 2012; Nagorski Johnson, 2008). Some mothers show behaviours related to a grief response, such as numbness, anger, search for meaning and resignation (Whitfield, 2003).

Although traditionally attention was paid primarily to the experience of mothers in the NICU, more recently also the experiences of fathers are being considered. Similarly to mothers, also fathers of preterm babies have to cope with increased stress levels, emotional exhaustion and difficulties in transitioning into fatherhood (Garten, Nazary, Metze, & Bühner, 2013; Sloan, Rowe, & Jones, 2008). Fathers also go through particular challenges in the NICU. Especially during the mother's hospitalization, fathers are often torn between caring simultaneously for the mother and the preterm baby (Ahn & Kim, 2007). Furthermore, they might face difficulties in transitioning to fatherhood based on the culture-dependent expectations about gender roles in society (Hugill, Letherby, Reid, & Lavender, 2013) and struggle for being acknowledged as competent partners in the care for their baby (Hollywood & Hollywood, 2011; Lindberg, Axelsson, & Öhring, 2007).

The stress caused by the baby's hospitalization could also be enduring for parents. Families with a preterm infant show more risk towards increased stress, depression and anxiety after birth compared to families with full-term infants (Van Riper, 2001). Whitfield (2003) reports that the symptoms of Post-traumatic Stress Disorders in parents of preterm infants can be found until several months after hospitalization. Davis, Edwards, Mohay, and Wollin (2003) found in 40% of mothers of preterm infants symptoms of depression one month after their babies' birth. Also, Shah, Clements, and Poehlmann (2011) detected that at 9 months post-term, around 30% of mothers still showed unresolved grief with respect to their baby's preterm birth.

Combined, these challenges might pose a threat to the development of a secure and stable relationship between parents and their babies. Mothers, who experience psychological distress, anxiety or depressive symptoms, tend to be less sensitive to their infant's communicational cues (Zelkowitz, Na, Wang, Bardin, & Papageorgiou, 2011). Lower responsiveness, increased stress or depressive symptoms are again associated with insecure attachment patterns (Evans, Whittingham, & Boyd, 2012). This is crucial, because from attachment theory we know that a secure relationship is essential for an infant to thrive (Bowlby, 1988; Kraemer, 1992).

Thus, helping parents in establishing a nurturing relationship with their preterm baby is an important feature of family-centred care in the NICU and might play a crucial role in the infant's development later on in life. Live music therapy (MT) that integrates both mothers and fathers to the therapy process could provide an opportunity for parents to engage in reciprocal communicational experiences with their baby in a relaxed and pleasurable manner. In this way, they might be able to get to know their baby better and increase their sensitivity towards the baby's inner states. Experiencing positive moments during a period of increased stress could also counterbalance some of the emotional disturbances that parents normally go through in the NICU, and thus act as a reinforcing factor for coping and trauma prevention.

Literature review of MT with preterm infants and caregivers in the NICU

MT (provided by a trained music therapist) or music and auditory stimulation (provided by other professionals than music therapists) in the NICU is an

internationally expanding area of research and practice (Ettenberger et al., 2014; Haslbeck, 2012; Loewy, 2015; Nöcker-Ribaupierre, 2013; Standley, 2014).

Today, there is much evidence that MT and music or auditory stimulation is beneficial for preterm infants. Traditionally, most studies focused on the potential benefits of music, voices or sounds on the preterm infants alone, without taking the parents or caregivers into account. However, since the turn of the millennium, an increasing number of studies report the integration of parents to the study protocols (Supplemental data Appendix 1). Yet, just a handful of those studies report also some sort of data collection by the participating parents (Table 1).

The studies in Table 1 show that the data collection from parents is a quite recent strategy in studies about MT or music and auditory stimulation in the NICU. Notably, just two studies (Ettenberger et al., 2014; Haslbeck, 2013b) analysed qualitative data from the participating parents. That also fathers are an important part in the care of preterm babies and have specific needs, which can be addressed by MT, has only lately been acknowledged (Mondanaro, Ettenberger, & Park, *in press*). While different approaches of MT in the NICU exist around the globe, recent research suggests that current best practices are inclusive of live MT entrained to infants' states and of including parents to the therapy process (Ettenberger et al., 2014; Haslbeck, 2013b; Teckenberg-Jansson et al., 2011; Loewy, Stewart, Dassler, Telsey, & Homel, 2013). The worldwide diversification of MT in the NICU and the importance of taking cultural aspects into account was recently summarized by Shoemark (2015).

This article presents a mixed-methods study of family-centred live MT in a NICU in Colombia, South America. MT is still a new treatment in Colombia, and not commonly found in clinical settings.¹ This study builds upon the experiences and results of a pilot study that was conducted in the same research institution in 2013 (Ettenberger et al., 2014). Parents were actively integrated to the MT sessions and both quantitative and qualitative data were collected from the mothers, fathers and babies. It is hoped that this study helps to fill some of the gaps in current research about MT in the NICU and provides insights to how and why the active incorporation of parents to the therapy process could be beneficial for them and/or their babies in the NICU.

Method

Study design

This was a mixed-methods study using concurrent triangulation² (Kroll & Neri, 2009) and a within-subject repeated measures design. The research questions were:

- (1) Does MT help to improve the physiological short-term outcomes of preterm babies?
- (2) Does MT help to improve the relationship between parents and their babies?
If yes, how does this happen?

¹A more detailed description of the cultural background of the study, including the research institution and the MT landscape in Colombia can be found in the work by Ettenberger (2016) and Ettenberger et al. (2014).

²A concurrent triangulation design involves a simultaneous collection of qualitative and quantitative data sets and its main objective is "to validate the findings generated by each method through evidence produced by the other" (Kroll & Neri, 2009, p. 43).

Table 1. Studies that include parents to their study protocols and report a data collection from parents, 1970–2014.

Type of intervention	Author(s)	Description of music, voice or sound	Results preterm infants	Results parents
Recorded maternal voice	Cevasco (2008)	Singing lullabies, children's songs and popular tunes with guitar accompaniment provided by the MT	Shorter hospitalization; No differences in weight gain	Better coping with baby's hospitalization; More value of music in experimental mothers*; More time singing for babies in experimental mothers; No differences in the amount of music used at home; Inconclusive findings regarding bonding Increased breastfeeding rates;
Live maternal voice	Nöcker-Ribaupierre (1999)	Mothers reading a children's story	Advanced motor and verbal development*; Improvement in verbal activities	Less burdened and physically more stable mothers; Mothers perceived intervention as supportive; Decrease in state anxiety (STAI Y-scale)*
	Arnon et al. (2014)	Mothers singing	Effects on LF and HF and LF/HF ratio of the HRV*; No differences in HR, OS, RR, BS	
	Blumenfeld and Eisenfeld (2006)	Singing songs chosen from a list of familiar songs	No differences in HR, RR, feeding duration, volume intake	No differences in mothers perception of quality of feedings
Recorded music during KC	Lai et al. (2006)	Mothers chose from three types of lullabies: eastern vocal, instrumental lullaby and aboriginal Taiwanese lullaby	More quiet sleep states*; Less crying*; No differences in HR, OS, RR	Decrease in state anxiety (STAI Y-scale)*
Live music during KC	Schlez et al. (2011)	Harp music	No differences in HR, OS, RR (neonatal and maternal), BS (neonatal)	Decrease in state anxiety (STAI Y-scale)*
Parent training in Multimodal Stimulation	Whipple (2000)	One hour of parent training in Music and Multimodal Stimulation	Fewer infant stress behaviours*; Shorter hospitalization; Improved weight gain	More appropriate parent actions and responses*; More time spent in the NICU*
Live singing by the therapist	Haslbeck (2013a; 2013b)	Infant-directed humming	Qualitative analysis: promotion of communicative musicality, self-regulation and development	Qualitative analysis: improved well-being, self-confidence and quality of interactions

(Continued)

Table 1. (Continued).

Type of intervention	Author(s)	Description of music, voice or sound	Results preterm infants	Results parents
Mixed approaches of live music, singing and sounds by the therapists and/or the parents	Teckenberg-Jansson et al. (2011)	A ten-stringed lyre with humming and singing during KC	Improved HR*, OS*, RR*, BP*	Calming and relaxing effect for parents and babies
	Vianna, Barbosa, Carvalhaes, and Cunha (2011)	MT with various instruments including verbal expression, musical expression and relaxation	No data collection reported	Increased breastfeeding rates*
	Loewy et al. (2013)	Entrained womb, heart and breathing sounds and entrained song of kin adapted to 3/4 or 6/8 metre	Lower HR*, more caloric intake*, improved sucking behaviour*, more positive sleep patterns*, improved RR	Reduction of parental stress perception*
	Ettenberger et al. (2014)	Parent-preferred lullaby singing during KC, humming and entrained sounds to infant states; Improvised instrumental music during receptive MT	Improved weight gain, shorter hospitalization; No differences in size and cephalic perimeter	Qualitative analysis: MT is relaxing for mothers and babies, and helps mothers to develop competences, increase sensitivity towards their babies' inner states and get to know their babies better; Quantitative analysis: no differences in anxiety (STAI-C) or bonding (MIBS)

HR = Heart Rate; OS = Oxygen saturation; RR = Respiration Rate; BP = Blood Pressure; BS = Behavioural State; HRV = Heart Rate Variability; LF = Low Frequency; HF = High Frequency; KC = Kangaroo Care; MT = Music Therapy;
 * = $p < .05$ or $p < .001$.

The sub-questions were:

- Does MT help to reduce anxiety levels in mothers and fathers of preterm babies?
- Does MT help to improve bonding in mothers and fathers of preterm babies?
- If MT helps to improve the short-term outcomes of preterm babies, what are the important features found in this process?

Participants and setting

The study took place from October 2013 to June 2014 in the Level III NICU of the “Centro Policlínico del Olaya” (CPO),³ a large hospital in one of the very poor areas of Bogotá, Colombia (for a detailed description of the setting, see Ettenberger et al., 2014). Ethical approval for the study was given by the institutional review board of the CPO and by the Anglia Ruskin University UK Ethics Board.

The inclusion criteria were: medically stable male and female infants born between the 28th and 34th week of gestation; signed informed consent by the parents or legal representatives; birth weight <2000 grams and having initiated kangaroo care. A completion of at least two therapy sessions was necessary for the babies in order to be included in the final data analysis. The exclusion criteria were: preterm infants who were medically unstable (requirement of inotropic support, mechanic ventilation or frequent episodes of apnoea); who suffered from congenital malformations; or if a surgery was programmed for the week after the start of MT.

Group allocation

In this study all participants were allocated to one intervention group and then compared to a control group:

- Music Therapy (MT) = Standard care + MT with the parents and the baby during kangaroo care.
- Control Group (CG) = Standard care alone.⁴

The data for the CG was extracted from the hospital’s database⁵ and included preterm babies who were admitted to the NICU during periods when no MT was taking place at the hospital (i.e. during travels and holidays, in which the researcher and music therapist was not present at the hospital). During these periods, no major changes in the structural environment or in terms of staff changes took place. The following data for the control group were extracted with the help of the secretary of the NICU at the CPO, who was blind to the purposes of the study: age of mother, number of children, type of birth, sex of the baby, Apgar scores at 1, 5 and 10 minutes, birth diagnoses, birth weight, gestational age at birth, weight at start of kangaroo care, gestational age at start of kangaroo care, weight at hospital discharge,

³The CPO provided the permission to name it as the research institution in this publication. <http://www.cpo.com.co/site/>; Address: Cra. 21 # 22 – 68 Sur, Bogotá D.C., Phone: +57(1)3612888.

⁴Kangaroo care is a standard intervention for all preterm infants in the NICU of the CPO.

⁵Permission for this procedure was granted by the Institutional Review Board of the CPO.

gestational age at hospital discharge, length of hospitalization and number of re-hospitalizations four months after hospital discharge.

A total of 33 mothers, 17 fathers and 36 infants (three pairs of twins) were invited to participate in this study. All parents were informed about the procedures and aims of the study and written consent was obtained. No parent declined to participate. For the control group, the same total numbers of participants were identified that fulfilled the same inclusion and exclusion criteria as the MT group.

In order to avoid possible secondary effects of the MT interventions and reduce the possibilities of over-stimulation, the same safety protocol as reported in our pilot study was used (Ettenberger et al., 2014). Additionally, infants did not receive MT before having reached 30 weeks of gestation and having started kangaroo care.

The process of the participant allocation was as follows: in a first step, the medical staff identified possible participants according to the inclusion and exclusion criteria. In a second step, the researcher and music therapist invited the parents to an initial information talk, in which the key aspects of the study were explained and the informed consent form was handed out. Then, parents filled out the socio-demographic data form and the first set of questionnaires. Additionally, the researcher asked the participating parents about their musical background, eventual musical training, music they listened to during pregnancy and songs they liked or songs they could imagine to sing for their babies. After these steps, the parents and babies were allocated to the intervention group.

Figure 1 shows the flow diagram of this study.

Data collection and outcome measurements

In this study, both quantitative and qualitative data were collected and analysed from an immediate perspective (i.e. observable changes during a MT intervention), a short-term perspective (i.e. observable changes during hospitalization) and a medium-term perspective (i.e. observable changes after hospitalization).

Quantitative data collection of preterm infants

- Immediate perspective: Heart rate (HR) and oxygen saturation (OS) was averaged and stored by a portable Mindray PM-60 Pulse Oximeter on a 10 second interval basis for 6–10 minutes before the intervention, during the intervention and for 6–10 minutes after the intervention.
- Short-term perspective: Weight gain was taken from the nursery sheets on each day of the MT interventions.
- Short-term perspective: Length of hospitalization was calculated after the infants left the hospital: date of hospital discharge – birth date = days in hospital.
- Medium-term perspective: Number of re-hospitalizations was assessed at four months after hospital discharge via the hospital's electronic database.

Quantitative data collection of parents

- Short-term perspective: State-Trait Anxiety Inventory (STAI) (Spielberger, Gorsuch, & Lushene, 1994): Handed out to the participating parents before the first intervention and after the last intervention. The STAI is an internationally

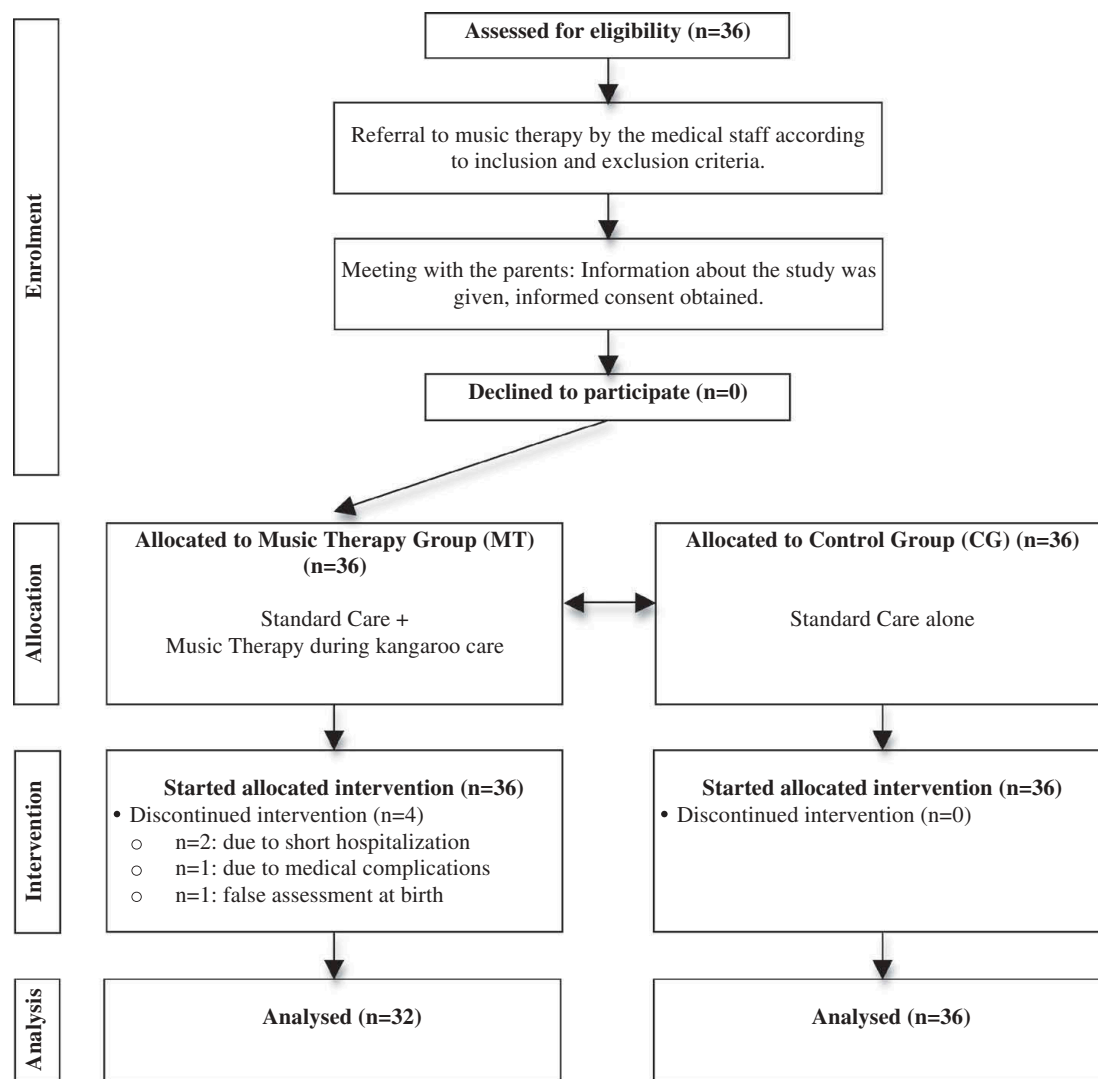


Figure 1. Flow-diagram. (Diagram adapted from Schulz, Altman, & Moher, 2010. Please note that the numbers in this flow diagram refer to the participating infants. Since both the intervention group and the control group included 3 pair of twins, the number of parents in the both groups is $n=33$. The time elapsed between the allocation and the start of the intervention was on average 2.7 days. The data for the CG was extracted from the hospital's database and included preterm babies who were admitted to the NICU during periods when no MT was taking place at the hospital. The quantitative data of the CG that was compared to the MT group included the preterm infants' weight gain, length of hospitalization and number of re-hospitalizations.)

renowned questionnaire consisting of 40 items rated on a 4-point Likert scale measuring trait anxiety and state anxiety on two forms (Form X and Form Y).⁶

- Short-term perspective: Mother-to-Infant Bonding Scale (MIBS) (Taylor, Atkins, Kumar, Adams, & Glover, 2005): Handed out to the participating parents before the first intervention and after the last intervention. The MIBS consists of 8 adjectives regarding how mothers and fathers feel towards their baby (*loving, resentful, neutral or felt nothing, joyful, dislike, protective, disappointed, aggressive*) rated on a 4-point Likert scale. The MIBS was translated into Spanish by the

⁶Before the first therapy session, both forms of the STAI (Form X and Form Y) were handed out to the parents in order to detect any baseline abnormality in trait anxiety. However, since it was not expected to see any changes in trait anxiety over the relatively short course of the therapy process, after the last therapy session just Form Y (state anxiety) was handed out.

researcher and music therapist who is fluent in both Spanish and English and was proofread by a native Spanish-speaking colleague who is fluent in English.

The quantitative data collection for the CG included the preterm infants' weight gain, length of hospitalization and number of re-hospitalizations. HR, OS and the psychometric questionnaires (STAI, MIBS) were not compared to the MT group.

Qualitative data collection

The qualitative data collection included:

- Immediate perspective: 53 semi-structured interviews with the participating mothers and fathers directly after the therapy sessions (held with 32 mothers alone, 3 fathers alone and 18 mothers and fathers together).
- Short-term perspective: 41 questionnaires handed out to the participating mothers and fathers after the last therapy session (31 mothers and 10 fathers).
- Medium-term perspective: 12 In-depth semi-structured telephone interviews three to five months after hospitalization (10 mothers, 2 fathers).

The questions were related to the parents' perception of MT and their potential effects on themselves, their babies and the relationship between parents and babies (a full list of the questions can be consulted in Supplemental data Appendix 2).

Thematic analysis was used to analyse the qualitative data. Thematic analysis is a method for identifying, analysing and reporting themes or patterns within a data set (Braun & Clarke, 2006; Clarke & Braun, 2013). In step one, the data was transcribed and then organized. In a second step, the data was translated from Spanish to English by the first author, who is fluent in both languages, and then proofread by a native Spanish-speaking colleague who is fluent in English. In a third step, a list was created about the overall content of the data, and interesting features of the initial data set were highlighted in colours. In the next step, coding segments were extracted from the data sets. Codes are "the most basic segment, or element, of the raw data or information that can be assessed in a meaningful way regarding the phenomenon" (Boyatzis, 1998, p. 63 cited in Braun & Clarke, 2006, p. 88). Then, the coding segments were allocated and merged into potential sub-themes and themes and afterwards refined. Clarke and Braun (2013) emphasize that this process is an "active" one, in which the researcher constructs themes that are built upon the different codes: "If codes are the bricks and tiles in a brick-and-tile house, then themes are the walls and roof panels" (Clarke & Braun, 2013, p. 121). The thematic analysis was done separately for mothers and fathers. In a last step, a combined thematic map for both parents was created.

Procedure and MT interventions

MT took place twice a week from the entry of the study until hospital discharge. A disinfection protocol was established for the musical instrument (guitar) in order to avoid contamination with external or internal microorganisms and guarantee patient security. About 6–10 minutes before the intervention, a member of the nursery staff wrapped the sensor for measuring HR and OS around the baby's foot or hand. During MT, the parents sat on chairs besides the incubator, holding their baby upright on the chest providing skin-to-skin contact. The baby was covered with a

blanket. The music therapist sat in front of the parent or, in case both parents participated, three chairs were arranged in form of a triangle. After MT, the parents continued being in kangaroo care without MT for at least another 6–10 minutes.

A total of 116 MT sessions were held in this study, with an average length of 19 minutes (range 10–40) per session. The length of the sessions was determined by the infants' and parents' states as well as by the structural aspects of the research institution (i.e. visiting hours, shift changes, medical exams, etc.). Fathers participated actively in 42 sessions (36.2%). The interventions were based on the music therapists' training in *First Sounds: RBL (Rhythm, Breath, Lullaby)*, a model developed by Joanne Lowey and her team at the Louis Armstrong Center for Music & Medicine in New York. In the majority of the cases (103 sessions or 88.8%), the MT sessions consisted of singing together with the parents songs that had a positive meaning for them and that were familiar, important or representative for the family's culture (i.e. *song of kin*, Loewy, 2015; Loewy et al., 2013). Parents most frequently chose to sing traditional lullabies or nursery rhymes (59%), followed by pop music (19%), spiritual or religious music (13%), rock music (4%) or other music styles popular in Colombia, such as "Vallenato" or "Ranchera" (3%). In a few occasions welcome songs were composed together with the parents. In case a parent did not mention any specific song, the therapist proposed lullabies or nursery rhymes that are known to most of the population in Colombia. In 13 cases (12%), parents opted for a receptive session, in which the music therapist played improvised music on a nylon-string guitar with the aim to create a comfortable and holding musical atmosphere.

In order to make all the musical styles adequate for the preterm babies' developmental stage, the songs were often adapted. The music was slowed down in tempo or changed into a "lullaby style" (3/4 times, 60–80 bpm, accompanied by simple chord progressions). Most traditional lullabies or nursery rhymes in Colombia have similar musical structures as in Europe or the United States and are based upon harmonic progressions using I-IV-V structures. They include simple melodies that ascend or descend in a step-by-step fashion or minor/major thirds. With a few exceptions, nearly all lullabies or nursery rhymes were in major tonalities. While the pop songs, rock songs or spiritual songs that the parents proposed included somewhat more complex harmonic progressions (e.g. I-V-VI-IV, I-VI-IV-II-V), they were kept simple in terms of harmonic accompaniment. For example, in case the original music used chords that included harmonic tensions such as a $b5$ or $b13$, these were removed and just the triad was played. Many parents intuitively modulated their singing together with the music therapist depending on their infants' states and communicational cues. In case parents needed help with this, the music therapist guided the parents either implicitly (e.g. through slowing down the tempo of the music) or explicitly through discussing with them the musical elements they could use to better match their babies' states in the moment. Ettenberger (2016) includes further detailed descriptions of the sessions and also case vignettes.

Results

Quantitative results

Statistical analysis

Statistical analyses were performed for HR, OS, weight gain, length of hospitalization, rate of re-hospitalization, the STAI and the MIBS, using the computer program R (R Development Core Team, 2013). Bias-corrected and accelerated confidence limits

were obtained using function `boot.ci` from R package `boot` (Canty & Ripley, 2011; Davison & Hinkley, 1997). The permutation test was done with function `permTS` from R package `perm` (Fay & Shaw, 2010). As shown in Figure 1, retrospectively four babies in the MT group did not fulfil some of the inclusion criteria: two babies completed just one MT session due to short hospitalization; for one baby the MT process was stopped due to medical complications and the fourth baby was falsely assessed with a birth weight of less than 2000 grams. This was an omission during the admission procedures, and was recognized after the second MT session, which was then stopped. Since the statistical analysis did not follow an intention-to-treat-analysis (ITT), these four babies were excluded from the final analysis. However, following the TREND statement for non-randomized designs (Des Jarlais, Lyles, & Crepaz, 2004), it is intended to provide the greatest possible transparency in reporting and discussing the results. Therefore, a sensitivity analysis including all babies can be found at the end of this section.

Group comparison

The socio demographic and baseline data of the MT and the CG group were matched for age of the mothers, number of children, gestational age, birth weight, Apgar scores (10 minutes) sex, number of twins and type of birth. No statistically significant differences were found between the groups (Table 2).

Heart rate and oxygen saturation

No in-depth statistical analysis was possible for the data regarding HR and OS of the preterm infants. This was due to the large amount of unreliable measurements, which were the result of movement artefacts that happened when the preterm babies moved or when parents adjusted their position during kangaroo care.

Weight gain and length of hospitalization

Weight gain was analysed for weight gain per day during the intervention period. A statistically significant increased weight gain per day during the intervention period was found for the MT group versus the CG (24.20 gr./day vs. 18.54 gr./day; $p = .036$). Also, a shorter hospitalization of 1.885 days of the MT group compared to the CG was noted, but this result did not reach statistical significance ($p = .489$) (Table 3).

Table 2. Comparison of socio-demographic and baseline data – categorical and quantitative variables by intervention.

	MT	CG	<i>p</i> -Value
Total number of participants, number of males	Total 36, 19 males	Total 36, 19 males	1.000
Total number of set of twins	3	3	1.000
Type of birth, number of Caesarean	30	31	1.000
Age of mother (years)	25.9, <i>SD</i> 6.9 range 13–41	22.9, <i>SD</i> 6.2 range 14–37	.053
Number of children	2.06, <i>SD</i> 1.12 range 1.0–5.0	1.97, <i>SD</i> 0.91 range 1.0–5.0	.821
Gestational age at birth (weeks)	32.1, <i>SD</i> 1.9 range 28.0–35.0	32.0, <i>SD</i> 1.7 range 28.0–35.0	.956
Weight at birth (g)	1573.2, <i>SD</i> 246.3 range 995–2120	1544.7, <i>SD</i> 302.8 range 810–1960	.660
Apgar score (10 minutes)	9.33, <i>SD</i> 0.63 range 8.0–10.0	9.36, <i>SD</i> 0.76 range 8.0–10.0	1.000

Table 3. Weight gain during the intervention period and length of hospitalization. Main analysis ($n = 32$ in MT).

	Intervention type	Mean	Standard deviation	Percentiles					Number of values	p-Value
				Smallest 0%	25%	Median 50%	75%	Largest 100%		
Baby weight gain per day during the intervention (g)	MT	24.20	8.91	3.5	18.6	24.25	27.5	43.8	32	.036
	CG	18.54	12.68	-28.3	15.5	21.55	26.1	35.6	36	
Length of hospitalization from birth (days)	MT	22.78	7.07	11.0	18.4	21.50	28.2	38.0	32	.489
	CG	24.67	12.76	9.0	14.4	21.50	31.3	58.0	36	

Table 4. Re-hospitalization by intervention.

	Intervention				Difference between percentages	95% confidence limits		<i>p</i> -Value
	MT, <i>n</i> = 32		CG, <i>n</i> = 36			Lower	Upper	
Re-hospitalization	Count	%	Count	%				
Yes	5	15.6	11	30.6	−14.9	−33.4	5.5	.17

Table 5. Summaries of before and after scores MIBS and STAI – mothers and fathers. Main analysis (*n* = 32 in MT).

Variable		Before	After	Difference After-Before	<i>p</i> -Value
Mothers	Mother to Infant Bonding Scale (MIBS)	1.06, <i>SD</i> 1.64 range 0–7, <i>n</i> = 32	1.03, <i>SD</i> 1.59 range 0–7, <i>n</i> = 30	0.13, <i>SD</i> 2.03 range -4–7	.806
	State-Trait Anxiety Inventory-State Anxiety (STAI S-A)	15.03, <i>SD</i> 10.27 range 1–38, <i>n</i> = 31	11.27, <i>SD</i> 9.40 range 0–40, <i>n</i> = 30	-3.80, <i>SD</i> 7.41 range -28–11	.007
Fathers	Mother to Infant Bonding Scale (MIBS)	1.46, <i>SD</i> 1.20 range 0–3, <i>n</i> = 13	0.25, <i>SD</i> 0.71 range 0–2, <i>n</i> = 8	-1.12, <i>SD</i> 1.25 range -3–0	.128
	State-Trait Anxiety Inventory-State Anxiety (STAI S-A)	12.31, <i>SD</i> 7.17 range 0–23, <i>n</i> = 13	11.12, <i>SD</i> 8.43 range 1–24, <i>n</i> = 8	-1.38, <i>SD</i> 6.84 range -13–9	.630

Re-hospitalization rate

After four months of hospital discharge, 50% less re-hospitalizations were observed in the MT group compared to the CG (MT: 5 vs. CG: 11), although this was not statistically significant ($p = .17$) (Table 4).

Mother-to-infant bonding scale (MIBS) and state-trait anxiety inventory (STAI)

Both the scores of the MIBS and the STAI were analysed separately for mothers and fathers in the MT group. The results showed an improvement in the MIBS scores for both parents (mothers: before 1.06 vs. after 1.03, fathers: before 1.46 vs. after 0.25), but this was not statistically significant (mothers: $p = .806$, fathers: $p = .128$).

With respect to the STAI, the results showed an improvement for state anxiety for both mothers and fathers (mothers: before 15.03 vs. after 11.27; fathers: before 12.31 vs. after 11.12), with the results for the mothers being statistically significant (mothers: $p = .007$, fathers: $p = .630$) (Table 5).

Additional sensitivity analysis

In order to maintain greatest transparency, an additional sensitivity analysis was performed for the data regarding weight gain, length of hospitalization, MIBS and STAI including all infants of the MT group ($n = 36$) (Tables 6 and 7).

Qualitative analysis

In general, MT was highly appreciated by both mothers and fathers. All parents thought that MT was helpful for their babies, for themselves and for the relationship with their babies. Apart from one blank answer, all parents thought that MT helped in the humanization of the clinical environment. The vast majority of parents felt a

Table 6. Weight gain during the intervention period and length of hospitalization. Sensitivity analysis ($n = 36$ in MT).

	Intervention type	Mean	Standard deviation	Percentiles					Number of values	p – Value
				Smallest 0%	25%	Median 50%	75%	Largest 100%		
Baby weight gain per day during the intervention (g)	MT	22.03	10.586	0.0	15.4	23.80	27.2	43.8	36	.212
	CG	18.54	12.678	–28.3	15.5	21.55	26.1	35.6	36	
Length of hospitalization from birth (days)	MT	22.14	7.950	9.0	16.4	21.00	28.2	38.0	36	.326
	CG	24.67	12.764	9.0	14.4	21.50	31.3	58.0	36	

Table 7. Summaries of before and after scores MIBS and STAI – mothers and fathers. Sensitivity analysis ($n = 36$ in MT).

Variable		Before	After	Difference After–Before	<i>p</i> -Value
Mothers	Mother to Infant Bonding Scale (MIBS)	1.06, <i>SD</i> 1.60 range 0–7, $n = 36$	0.94, <i>SD</i> 1.54 range 0–7, $n = 33$	0.03, <i>SD</i> 2.01 range –4–7	1.000
	State-Trait Anxiety Inventory-State Anxiety (STAI S-A)	14.43, <i>SD</i> 9.83 range 1–38, $n = 35$	10.70, <i>SD</i> 9.24 range 0–40, $n = 33$	–3.82, <i>SD</i> 7.35 range –28–11	.004
Fathers	Mother to Infant Bonding Scale (MIBS)	1.53, <i>SD</i> 1.36 range 0–4, $n = 15$	0.30, <i>SD</i> 0.67 range 0–2, $n = 10$	–1.20, <i>SD</i> 1.32 range –3–0	.066
	State-Trait Anxiety Inventory-State Anxiety (STAI S-A)	11.53, <i>SD</i> 7.01 range 0–23, $n = 15$	10.50, <i>SD</i> 7.91 range 1–24, $n = 10$	–0.80, <i>SD</i> 6.27 range –13–9	.742

positive difference between being in kangaroo care with MT compared to kangaroo care without MT and thought that MT should be a regular offer in the NICU. The thematic analysis resulted in three main themes: *Parental well-being*, *Bonding* and *Fostering development*. Figure 2 shows the final thematic map for the participating parents:

Parental well-being

Parental well-being is a theme composed by the three sub-themes: *Parents can relax*, *Enjoying MT* and *Distraction*. It refers to statements made by parents that underline how or why MT was helpful for them.

Parents frequently mentioned “Relaxation” during MT. Most often, they described MT as “relaxing”, “calming” or as experiencing “tranquillity”. The sub-theme Distraction is about being able to forget or blend out the NICU environment or other worries during MT. Often, parents referred to this as “forgetting being in a hospital”. However, there were also some gender differences: mothers stated more often being distracted from their worries, while fathers mentioned more often being distracted from the NICU environment. Enjoying MT summarizes parents’ comments about liking or enjoying MT. Parents frequently described the MT sessions as “beautiful”, that they “felt good” or that they “liked music therapy”.

Bonding

The theme Bonding consists of the sub-themes *Interaction/Communication*, *Feeling connected* and *Complacent feelings*. It embraces the statements that parents made with respect to the relationship that evolved between them and their babies.

While a successful interaction and communication is crucial for bonding, it is always mediated by feelings, sensations and emotions. Thus, the interactional or reciprocal dimension of bonding is reflected by the sub-theme Interaction/Communication, which includes the observations of parents regarding their babies’ smiles, gestures or movements. More emotional dimensions are portrayed by the other two sub-themes: Complacent feelings includes statements that referred to either a primary complacent feeling towards their baby during MT (e.g. “love”,

“tenderness”), or a secondary feeling that is likely to support the experience of a primary feeling (e.g. “peace”, “harmony”). Feeling connected refers to a more explicit dimension of the relationship between parents and babies. Recurrently, parents noted a “better” or “more” connection with their baby during MT or stated that they “got to know better” their baby.

Fostering development

Fostering development is composed by the sub-themes *Babies can relax*, *Music works*, *Empowerment of parents* and *Using music at home*. The first and second sub-theme relate directly to the effects of MT in helping the babies in their self-regulation capacities and in their development. Empowerment of parents is indirectly related to the babies’ development, since it refers to the learning experiences of parents on how to use music for their babies. Using music at home is closely related to the latter, but the data for this sub-theme came exclusively from the telephone interviews after hospitalization. This is indicated by the dotted line that connects the sub-theme with the main theme in Figure 2.

Babies can relax includes all references of parents about how music helped their babies to relax. Many times, they referred to MT as being “relaxing” or “calming” for their babies. Music works embrace the comments made regarding the effectiveness or

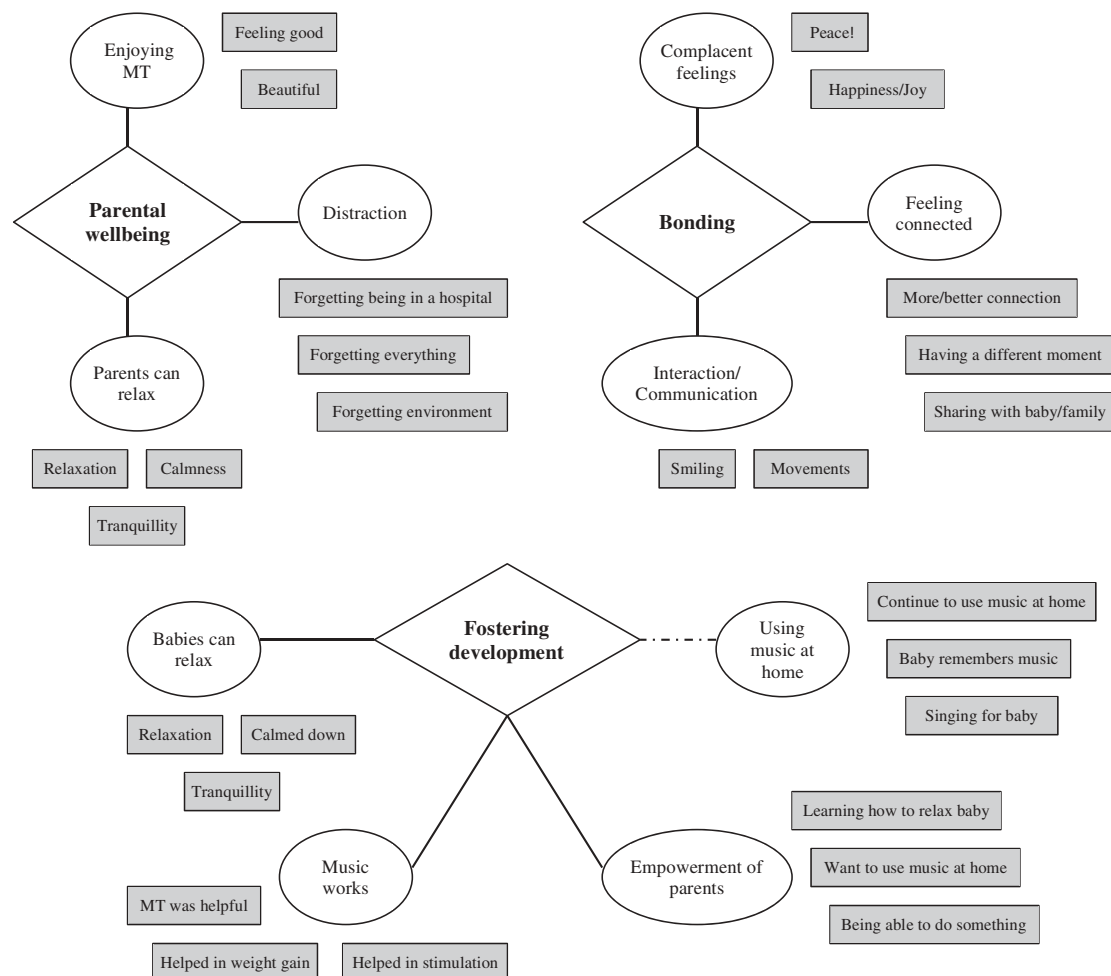


Figure 2. Final thematic map parents.

potential benefits of MT for the babies' development. Parents regularly stated that MT was "helpful for the development" of the baby or "important for its stimulation". But often, they were also quite specific and noted that MT "helped in the weight gain" of the baby, that it "improved the sucking" or that it was "good for its auditory development". Empowerment of parents relates to MT as a learning experience and to music as a tool that can be used by the parents during and after hospitalization. Parents most often stated that MT helped them in "knowing how to relax the baby" or "being able to do something". Using music at home refers to the statements that parents made after hospitalization about how they continued to use music at home. They often mentioned using music "for relaxation", "to stimulate the baby" or "to help the baby sleep".

Discussion

The hypothesis of this study was that live MT during kangaroo care had a positive effect on the physiological outcomes of the neonates and would help parents to reduce their anxiety levels and improve parent–infant bonding. In light of the findings presented so far, this hypothesis can be supported.

Quantitative outcome measures

Heart rate and oxygen saturation

Similarly to the experiences in our pilot study (Ettenberger et al., 2014), also in this study, an in-depth analysis of the HR and OS data was not feasible. The high proportion of movement artefacts (pauses or alterations in the readings due to the infants' movements) made a reliable analysis impossible. Whereas a complete statistical analysis was not possible, a tendency for mixed results regarding the HR (i.e. lower or higher HR during the sessions) and a stable or improved OS was noticed.

Reasons for this might be: first, the MT interventions took place during kangaroo care, in which the babies showed diverse behavioural states (e.g. asleep, awake, fuzzy) or they 'transitioned' between two or more states. Since both HR and OS are also dependent upon the infant's actual state, this has to be taken into account. Second, MT in this study was offered as an individualized treatment and thus had changing goals according the parents' and babies' needs (e.g. stimulation, relaxation, stabilization). Therefore, changes in vital signs may have occurred in coherence with the therapeutic goals. Third, when parents sing for their baby, they intuitively use different musical elements (tempo, pitch, etc.) in order to promote attention regulation and to communicate affective information (Conrad, Walsh, Allen, & Tsang, 2011; Nakata & Trehub, 2004; Trainor, 1996). While this 'intuitive' practice might be interrupted by the traumatizing event of preterm birth and the hospitalization in the NICU, MT might have helped parents to reconnect with such practices and thus influenced the babies' vital signs. Some of the sub-themes of the thematic analysis hint at possible mechanisms for that (e.g. *distraction* or *parents can relax*). Some authors point also to differential effects of male and female voices on the HR of preterm infants (Lee & White-Traut, 2014). Since both mothers and/or fathers sang during the sessions, this could have had an additional effect on HR or OS.

Weight gain

Weight gain is a frequent outcome measure in related studies (Barnard, 1973; Caine, 1991; Cevasco & Grant, 2005; Coleman, Pratt, Stoddard, Gerstmann, & Abel, 1997; Ettenberger et al., 2014; Kemper & Hamilton, 2008; Standley, 1998; Whipple, 2000). To gain weight is crucial for preterm babies and an important clinical factor when considering hospital discharge. In this study, two potential pathways were identified that might have led to an increased weight gain. On the one hand, many parents noted that the babies relaxed more during MT. This could have resulted in a lower Resting Energy Expenditure (REE) and thus in less calorie expenditure. Rosenfeld Keidar, Mandel, Mimouni, and Lubetzky (2014) and Lubetzky et al. (2010) showed that music can positively influence REE. On the other hand, MT could have helped parents and babies to achieve better feeding outcomes. Parents reported frequently that they got to know their babies better during MT and that they identified what the babies liked and what not. Also, parents participated regularly in using music for helping their babies transitioning smoothly from a sleep to a more alert state (that is needed during feeding) and vice versa. This might have helped parents in a more effective feeding also when no MT sessions took place. Also, the study by Loewy et al. (2013) showed a higher caloric intake of the babies with “song of kin”.

Days in hospital

As mentioned above, weight gain is inherently linked to length of hospitalization. The more and faster a baby gains weight, the sooner it can be discharged. However, in this study, weight gain was not the only relevant factor for discharge: For example, when babies are sent home with oxygen supply, parents need to order the oxygen tank, which usually takes between 2–5 days. In the CPO, also the readiness of parents to care for their still fragile baby is relevant for discharge. This is determined by the parents’ abilities to handle and feed their babies correctly. Twins do not normally go home together, in order to help parents adapt gradually to their new lives with their babies at home. Psycho-social risk factors of parents (e.g. dysfunctional social or family networks) may also prolong the hospitalization of the baby. The results of this study suggest two major pathways for the shorter length of hospitalization. First, the babies reached physiological stability sooner, and the necessary discharge weight. Second, parents might have been ready more quickly to take care of their baby. This hypothesis is supported by both the qualitative analysis (e.g. through the sub-themes *Empowerment of parents* or *Feeling connected*), as well as through the lower anxiety levels and improved bonding scores of the participating parents. However, this requires certainly more research. So far, a statistically significant decrease in length of hospitalization was demonstrated by Walworth et al. (2012), Standley (1998) and Caine (1991). Both Walworth et al. (2012) and Standley (1998) used Multimodal Stimulation protocols and Caine (1991) applied a music-listening protocol. Therefore, comparisons to other studies are difficult.

Measuring length of hospitalization can also be ambiguous, since it implies an underlying economic factor. Taken together, the 32 infants of the MT group in this study went home 60.32 days sooner than the CG infants. The cost of a day in the NICU of the CPO is approximately 280 USD (700,000 COP)⁷ per day. Thus, the

⁷Exchange rate of 2500 COP per USD, 16 June 2015. Retrieved from: <http://www.oanda.com/lang/de/currency/historical-rates/>

savings for the social security company, who pays for the hospitalization, were in the case of this study 16,889 USD (42,222,500 COP). This has to be evaluated and articulated with great sensitivity, since for the social security company it may be tentative to deduce that MT helps preterm babies *per se* to go home earlier and thus discharge babies too early in order to reduce costs. As discussed earlier, the relationship of preterm babies and their length of hospitalization is much more complex.

Re-hospitalization rate

Due to their medical problems after birth, many preterm babies require continuous care also after hospital discharge. In case their conditions worsen, they may require further in-patient care. Thus, re-hospitalization rate is both an important marker of the babies' long-term development and an interesting socio-economical factor. Re-hospitalization rate was evaluated four months after the babies' hospital discharge. This was estimated to be a sensitive period after the first hospital discharge by the medical staff. While not statistically significant, more than twice as many re-hospitalizations were observed for the CG compared to the MT group (11 vs. 5). Hereby it is important to keep in mind that the babies' re-hospitalizations are often multifactorial. However, clinical experience indicates that anxious parents tend to re-hospitalize their babies more often than parents who show confidence with their babies during the NICU stay. Although highly speculative, it could be that the positive effect of MT on parental anxiety and bonding might have acted as a protective factor against re-hospitalizations in the MT group.

Mother-to-infant bonding scale (MIBS)

A general improvement was found in terms of parental bonding. Besides our pilot study (Ettenberger et al., 2014), just one other study measured bonding, not obtaining statistically significant results either (Cevasco, 2008). Cevasco (2008) assumed that less adjustment and bonding for the experimental mothers could have been the result of more post-partum medical complications of mothers or preterm infants. In our pilot study it was hypothesized that the timing of the MIBS post-intervention measurement could have influenced the outcomes. A similar conclusion can be drawn from the results of this study. While many parents experience joy due to their baby's hospital discharge, it is also a time of increased stress, because they need to take care of their baby without the expertise of the NICU staff. In general, the average MIBS baseline scores for parents (obtained before the first MT session) were relatively low with an average of 1.04. Bienfait et al. (2011) suggested a cut-off point of 2 as a risk indicator for mother-infant bonding. This may indicate that most parents in this study were not at risk for compromised bonding. However, it is worth underlining that 100% of the parents who scored more than 2 on the initial MIBS (18.2% of mothers and 26.7% of fathers) improved their scores on the post-intervention MIBS. These results hint at a need for a more differential view on bonding between parents and preterm babies in the NICU. First, parents may not *per se* be at higher risk for bonding difficulties, although the infant's hospitalization could be a trigger or an additional risk factor for such difficulties (Hoffenkamp et al., 2012). And second, MT might be especially effective for parents who find an obstacle to forming healthy bonding with their babies.

State-trait anxiety inventory (STAI)

Besides this study, a statistically significant reduction in state-anxiety of mothers was also observed by Arnon et al. (2014), Schlez et al. (2011) and Lai et al. (2006). Additionally, in this study we also measured trait anxiety for the pre-intervention phase in order to detect any baseline differences. This seemed to be relevant, since high trait anxiety levels might influence state anxiety (Meijer, 2001). Similarly to the MIBS, also the post-intervention STAI was handed out after the last therapy session, which was frequently on the day of or the day before the babies' discharge. While bonding could have been affected by the stress that some parents experience at that point of time, this did not seem to be the case for state anxiety. This could indicate a separate processing of bonding and anxiety in parents, but this hypothesis requires certainly more research.

Qualitative analysis

The qualitative analysis showed that parents in this study perceived MT as beneficial for themselves, their babies and for the relationship with their babies.

Parental well-being

Relaxation of parents may be crucial for their emotional balance during their babies' hospitalization. As discussed in the introduction, many parents face increased stress levels in the NICU. The constant beeping of alarms, the emotional turbulences that parents go through and the highly technological environment make the NICU a difficult, and sometimes traumatizing, experience (Jotzo & Poets, 2005; Miles, Funk, & Kasper, 1991). Seeing their baby connected to machines and cables regularly intensifies this impression (Turan, Başbakkal, & Özbek, 2008). Especially during the initial face of kangaroo care, many parents feel nervous and tense. They are still unsure how to hold their baby correctly and are just beginning to get to know its signs of distress or comfort. In return, preterm babies are very sensitive and often notice if the mother or father is tense. This can produce more signs of distress in them, which again could increase the tension in parents. Kangaroo care is probably the most intimate moment that parents can have with their baby in the NICU and crucial for developing relationship between them. While in this study, the participating parents frequently mentioned increased stress levels; a recent meta-analysis on the topic reveals just small differences in the stress perception of parents of preterm infants compared to parents of full-term babies (Schappin, Wijnroks, Uniken Venema, Jongmans, & Bruce, 2013). Therefore, it might be necessary to distinguish between the different sources of parental stress, such as worries about the baby, the NICU environment, having to take care of siblings at home or financial burdens related to the hospitalization.

*"I felt a moment of tranquillity and relaxation in the middle of a stressful environment."
(Father MT3)*

"Well, the moment we started, well, it took away our anxiety, knowing that they [the babies] were at the NICU, that they were a little bit fragile. You understand? [...] So, at least the music took us away from this reality, that at this moment they didn't do well and we just focused more on the music...(Mother MT12/13)

"All our attention is centred on him [the baby] and not on the environment." (Father MT9)

Being able to relax, to get distracted from the difficulties and worries, and being involved in a joyful musical activity with their baby, can be essential for helping parents to cope with their baby's hospitalization and could counterbalance some of the distress that they normally experience in the NICU. This is important, since it could help to create a more optimal disposition for bonding in parents.

"Good, very nice. Very beautiful. You can feel this vibration, this...energy." (Father MT25)

Bonding

Due to their prematurity, the communicational cues of preterm babies are very subtle, and great sensitivity is required to notice and interpret them correctly (Hannah, 2010; Maguirea, Bruilb, Wita, & Walthera, 2007). During MT, parents had many opportunities to get to know their babies' preferences and frequently noticed their gestures or changes in behaviours. Being sensitive to the neonates' behavioural cues and detecting their readiness for stimulation or their need for relaxation is very important for the baby's development. In return, the positive behavioural feedback that parents receive from their babies after an adequate stimulation can evoke feelings of love, joy or confidence that motivate parents in the often difficult path of bonding in the NICU. Being able to identify positive feelings and attribute them to the baby or to the emerging relationship is vital and provide an opportunity for "feeling connected", to experience a positive reciprocity of interaction and love.

"Yes, he moved a lot his feet, but he didn't move them in a jerky way, like when something falls down with a big noise, but with very smooth movements. [...]. And now he started to smile." (Father MT14)

"Because I can get closer to her and get to know her better." (Mother MT30)

"Well, when we sang for my baby, when I was with her [in kangaroo care], well, I felt her more mine..." (Mother MT22)

Fostering development

The stress that preterm babies face during their hospitalization can well be understood in terms of a trauma (Stewart, 2010, 2009a, 2009b). Thus, being able to relax is not only important for parents, but also for the babies' developing self-regulation capacities. Parents noticed very often instantaneously how successful music was for relaxing their babies. As outlined in the studies by Hollywood and Hollywood (2011) and Aagaard and Hall (2008), being able to play an active role in the care of their babies is extremely important for both parents, and music can be an incredible effective and intuitive tool in this sense. Many of the participating parents in this study stated that they felt more confident or empowered through MT,

"Yes, it feels like, I don't know, like she can relax, I feel that she can rest. [...]. Well, when I am breastfeeding her, she moves, is agitated, well, but when she hears that song, she calms down." (Mother MT6)

"It was not like the other therapies, for example like physiotherapy. In physiotherapy the therapist comes and does her thing and that's it, I don't feel anything. You know? [...] On the contrary, with music therapy I helped her myself, I was the one who was singing, who was making her feel comfortable, who looked at her. You understand? [...] Therefore I felt really good with her. [...] It was like, when I sang to her, I didn't feel impotent to help her..." (Mother MT6)

especially when they saw or felt that the baby reacted to their singing. This is crucial to bear in mind, since it changes the role of the therapist as an expert who does the work *for* the parents to that of a facilitator, who works *with* the parents. The empowerment of parents during the baby's hospitalization could have helped them also in continuing to use music at home. This could hint at more long-term benefits of the MT interventions.

This discussion hints at the significance that family-centred MT can have for mothers and fathers in the NICU. Since the main themes and sub-themes of the thematic analysis fitted very well the perspectives of both parents, it could be concluded that mothers and fathers perceived MT similarly. Initially, this is in line with the observations of Mundy (2010), who found no differences in the needs of parents of preterm infants. However, in this study the relative weight of each sub-theme (i.e. the frequency it was mentioned) differed between the parents. While both mothers and fathers agreed in the two most often mentioned sub-themes (*Feeling connected* and *Baby can relax*), there seemed to be important gender differences in relation to other themes. Fathers for example mentioned *Distraction*, *Enjoying MT* and *Complacent feelings* more often than mothers, while mothers mentioned more often *Music works*, *Parents can relax* and *Empowerment of parents*. This suggests a differential view of the needs of mothers and fathers in the NICU.

So far, just one other qualitative study about MT in the NICU was found (Haslbeck, 2013a, 2013b), showing interesting overlaps to this study. Haslbeck (2013b) found three main categories: *empowerment*, *communicative musicality* and *responsiveness*. Besides, there are striking similarities between what the participating parents in her study noticed and the thematic analysis presented in this study: "They focused on their infant, and adapted and became attuned to their infant's behaviour, both communicatively and musically. They reported that CMT [Creative Music Therapy] helped them to relax and intensify their attachment to their infant" (Haslbeck, 2013b, p. 13).

Limitations

There are several limitations to this study. First, and different to our pilot study (Ettenberger et al., 2014), the quantitative data from the MT group were compared to a historical control group. The formerly used randomized control group design was not considered as optimal for the specific research environment. Since the NICU of the CPO consists of just one room, it could not be guaranteed that babies and parents in the control group would not be affected by the MT interventions that went on in the same room. Owing to the relatively short hospitalization of most stable preterm babies, a waiting list design was not suitable. However, a randomized control group design certainly would have strengthened the methodological aspects of this study.

Second, as shown in Figure 1, four babies were excluded from the final statistical analysis because they did not receive the fully allocated treatment. However, for randomized trials, the CONSORT (Consolidated Standards of Reporting Trials) statement for intention-to-treat analysis recommends the analysis of all allocated participants (Gupta, 2011). Although an additional sensitivity analysis was performed including all the babies enrolled in the study in order to maintain greatest transparency, the exclusion of participants can be a confounding factor.

Third, this study used a process-oriented approach offering MT over the course of several weeks. While this allows staying close to clinical practice and stresses the importance of the therapeutic relationship with parents and babies, it is more complicated in practical terms. Due to the fluctuating health status of the infants, the risk for drop-outs increases. Also, the parents' emotional states can change rapidly depending on the current situation. This could have influenced especially the results of the STAI and MIBS.

Fourth, although both parents were invited to participate in the study, fathers were not always present. The irregularity of being in MT with the mother, the father or with both parents may have been a confounding factor in the data analysis.

Finally, the small number of participants and the specific cultural and structural environment in which this study took place make generalizations of the results difficult (Ettenberger et al., 2014). In this study, MT was very much appreciated by the parents, who in general showed great confidence in singing for their babies. Colombians are commonly proactive in engaging in social relationships and have low barriers for communicating their feelings. Thus, they were easily involved in an interactive live MT therapy approach. On the other hand, most participating parents came from very difficult socio-economic backgrounds and some were still teenagers. This might be different in other cultures and settings and can influence both the research process and outcomes.

Conclusions

This is the second study carried out in Colombia, Latin America, and responds to the need for more cross-cultural investigations in this field. Besides our pilot study (Ettenberger et al., 2014), this is the first study known to the authors that used a mixed-methods approach in this field applying both quantitative and qualitative methods of data collection and analysis. It is also the first study known to explicitly collect and analyse data of participating fathers. The results of this study indicate that family-centred MT can be beneficial for the parents, the babies and the emerging relationship between them. Therefore, parents' involvement should be an important feature of clinical training, practice and research. With regard to the latter, this study suggests important questions for future research: What is the relationship between anxiety, parental well-being and bonding? How does parental well-being influence the development of preterm babies? How does parental anxiety coincide with infants' symptoms? How do parents use music in the NICU when no MT is taking place? How do parents integrate the experiences during MT? What are the culture-specific and universal aspects when working with parents and their preterm babies in the NICU? Further qualitative or mixed-methods research needs to be done in order answer such questions and to better understand how and why MT can be beneficial for parents and babies in the NICU. Communicating transparently the cultural and structural aspects of the research environment is fundamental for a better comparability of the results among studies.

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