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[Research]

Music Therapy With Premature Infants and Their Caregivers in Colombia – A Mixed Methods Pilot Study Including a Randomized Trial

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Abstract

This article reports the results of a three-arm mixed methods pilot study of music therapy with premature infants and their caregivers in a Neonatal Intensive Care Unit (NICU) in Bogotá, Colombia. The study included 19 medically stable babies born between the 30th and 37th week of gestation and their caregivers. Two intervention groups were compared with a control group. The objectives were to find out whether music therapy could help the neonates stabilize their physiological states and help mothers to reduce anxiety and strengthen the relationship with their baby. The data collection included the babies´ weight gain, heart rate, oxygen saturation, size, cephalic perimeter and length of hospitalization. Mothers filled out the State-Trait Anxiety Inventory (STAI-C) and the Mother-to-Infant Bonding Scale (MIBS) before the first and after the last intervention. Thematic analysis was used to analyze the qualitative data obtained through questionnaires. A trend towards an increased weight gain for both intervention groups and a shorter length of hospitalization for one of the intervention groups was noticed. Anxiety and bonding in mothers appears not to follow linear trends, as new challenges arise for parents at different stages during hospitalization. Mothers stated that music therapy was helpful for them, their baby, and their relationship with the baby. Mothers across the groups think that music therapy should offered regularly in the NICU and that music therapy helps to humanize the NICU environment.

Keywords: Music therapy, Neonatal Intensive Care Unit (NICU), randomized trial, preterm infants, Colombia, South America

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Introduction

This article reports the results of a pilot study that investigated music therapy with premature infants and their caregivers in a Neonatal Intensive Care Unit (NICU) in Bogotá, Colombia, as part of a PhD study collaboration with Anglia Ruskin University, Cambridge, UK.

Preterm birth has become a global challenge for families, institutions, and national health systems. While the advances in medical technology lead to constantly higher survival rates of preterm infants (Hille, et al., 2001; Larson, Desai, & McNett, 2010; Wolke, Schulz, & Meyer, 2001), there is also an increasing concern about potential negative effects of preterm birth (Heinonen et al., 2010; Marlow, 2004; Verrips et al., 2008;). Research shows that the successes in survival do not parallel the improvements in long-term developmental outcomes of prematurely born infants (Stephens & Vohr, 2009; Wilson-Costello, Friedman, Minich, Fanaroff, & Hack, 2005).

Preterm birth can also be a traumatic experience for parents and is often connected with high levels of stress, grief, emotional imbalance, feelings of guilt, and difficulties in establishing a relationship with the neonate (Aagard & Hall, 2008; Gutbrod & Wolke, 2007; Nöcker-Ribaupierre, 2007). Limited physical contact, worries about the health conditions of the baby, and shattered expectations about having a “normal” birth may put the mother-infant relationship at risk. This can produce anxiety, worries, and feelings of helplessness in both mothers and fathers of preterm infants (Bialoskurski, Cox, & Hayes, 1999; Hollywood & Hollywood, 2011; Korja et al., 2009; Lindberg, Axelsson, & Öhrling, 2007; Nagata, Nagai, Sobajima, Ando, & Honjo, 2004).

Research in music therapy (offered by a trained music therapist) or music and auditory stimulation with preterm infants is a young but internationally growing area of research (Haslbeck, 2012; Hodges & Wilson, 2010b; Hartling et al., 2009; Krueger, 2010;

Nöcker-Ribaupierre, 2013; Standley, 2002; Standley, 2012) since the first studies were carried out in the 1970s (Chapman, 1978; Field, Dempsey, Hatch, Ting, & Clifton, 1979; Katz, 1971; Malloy, 1979).

Music therapy interventions in the NICU aim at attenuating potential developmental impairments of preterm infants and at improving the quality of hospitalization for both neonates and caregivers. Preterm birth is a radical interruption of the foetus´ normal development since the intrauterine environment—in which cell growth, neuronal maturation, and organization usually take place—is not available anymore. At the time when most preterm infants are born (3rd trimester), their hearing capacities are still developing (Graven & Browne, 2008; McMahon, Wintermark, & Lahav, 2012; Moore & Linthicum Jr., 2007). This is also the time when the wiring of neuronal circuits is especially active (Fischer & Als, 2007; Sizun, Westrup, & ESF Network Coordination Committee, 2004), which is not only regulated by endogenous factors, but also by sensory input and experience (Fischer & Als, 2007; Music, 2011; Sizun et al., 2004). This suggests that the developing auditory abilities of the foetus are strongly linked to its neurological development.

However, the regular and patterned intrauterine sound environment differs heavily from the chaotic and disorganized sounds of a NICU (Hanson Abromeit, 2007; Philibin, 2000). Therefore, the neuro-developmental response to this new environment may change drastically and the sound environment of NICU's have been criticised for being potentially noxious for the development of preterm infants (AAP Committee on Environmental Health, 1997; Bremmer, Byers, & Kiehl, 2003; Konkani & Oakley, 2012; White-Traut et al., 2009).

Today, there is a growing body of literature available indicating that music can support the neonates in their physiological and behavioural self-regulation and the parents in coping with their infant's hospitalization. This can be achieved by using live music and singing, the use of recorded music, the mother's voice, intrauterine sounds, or a combination of music with tactile, vestibular or vibro-tactile stimulation (for an overview of related outcomes and references see Table 1 below). Music might also help to improve the quality of the sound environment in the NICU by integrating the disorganised and unpredictable background noise into an organized and appropriate musical structure (Stewart & Schneider, 2007). Most studies show favourable effects of music therapy and music or auditory stimulation on the physiological and behavioural response of preterm infants, but some studies report also inconclusive findings (Alipour, Eskandari, Tehran, Hossaini, & Sangi, 2013; Blumenfeld & Eisenfeld, 2006; Cassidy, 2009; Calabro, Shoemark, & Wolfe, 2003; Chapman, 1984; Eskandari, Alipour, Tehran, Hossaini & Sangi, 2013; Hodges & Wilson, 2010a; Johnston et al., 2009; Johnston, Filion, & Nuyt, 2007; Keller, Krueger, Miller, & Sizemore, 2008).

The following table (Table 1) gives an overview of some of the outcomes related to MT or music and auditory stimulation in the NICU. The table was adapted and modified from an existing literature review on the topic (Haslbeck, 2012, p.7) and updated up to 2014. It includes some new categories such as "fewer critical events", "increased breastfeeding rates", or "parental relaxation" for example.

Preterm Infants	
Improved behavioural states	Loewy et al., 2013; Bozette, 2008; Arnon et al., 2006; Whipple, 2000; Nöcker-Ribaupierre, 1999; Coleman et al., 1997; Burke et al., 1995; Caine, 1991; Collins & Kuck, 1991;
Improved behavioural states after painful medical interventions	Filippa et al., 2013; Tramo et al., 2011; Whipple, 2008; Butt & Kisilevsky, 2000; Bo & Callaghan, 2000; Burke et al., 1995;
Reduction of crying episodes	Keith et al., 2009; Lai et al., 2006;
Positive effects on oxygen saturation	Loewy et al., 2013; Filippa et al., 2013; Teckenberg-Jansson et al., 2011; Yildiz & Arikan, 2011; Farhat et al., 2011; Arnon et al., 2006; Chou et al., 2003; Bo & Callaghan, 2000; Nöcker-Ribaupierre, 1999; Coleman et al., 1997; Cassidy & Standley, 1995; Burke et al., 1995; Collins & Kuck, 1991;
Positive effects on heart rate	Garunkstiene et al., 2014; Loewy et al., 2013; Teckenberg-Jansson et al., 2011; Yildiz & Arikan, 2011; Keith et al., 2009; Arnon et al., 2006; Bo & Callaghan, 2000; Butt & Kisilevsky, 2000; Coleman et al., 1997; Cassidy & Standley, 1995; Burke et al., 1995;
Positive effects on respiratory rate	Farhat et al., 2011; Keith et al., 2009; Arnon et al., 2006; Cassidy & Standley, 1995; Ingersoll & Thoman, 1994;
Less days in hospital	Yildiz & Arikan, 2011; Standley et al., 2010; Cevasco, 2008; Whipple, 2000; Standley, 1998; Coleman et al., 1997; Caine, 1991;
Improved weight	Kemper & Hamilton, 2008; Cevasco & Grant, 2005; Whipple, 2000; Standley, 1998; Coleman et

gain	al., 1997; Caine, 1991;
Improved feeding rates	Loewy et al., 2013; Standley, 2003;
Proceeding faster to oral feeding	Yildiz & Arikan, 2011;
Less days to full enteral feeds	Krueger et al., 2010;
Fewer episodes of feeding intolerance	Krueger et al., 2010;
Shortened gavage feeding length	Standley et al., 2010;
Positive effects on caloric intake	Coleman et al., 1997; Caine, 1991;
Increased NNS – Non-nutritive sucking	Standley, 2003; Standley, 2000;
Improved sucking behaviour	Loewy et al., 2013;
Improved sleep states	Garunkstiene et al., 2014; Loewy et al., 2013; Lai et al., 2006; Arnon et al., 2006; Ingersoll & Thoman 1994; Thoman & Graham, 1986; Schmidt et al., 1980;
More mature sleep wake cycles	Olischar et al., 2011;
Reduction of REE – Resting Energy Expenditure	Lubetzky et al., 2010;
Lowered activity levels	Barnard & Bee, 1983; Bozette, 2008;
Improved long-term development	Nöcker-Ribaupierre, 1999; Barnard & Bee, 1983;
Seeking contact	Thoman & Graham, 1986; Thoman & Ingersoll, 1993;
Fewer critical events (hypoxemia, bradycardia and apnoea episodes)	Filippa et al., 2013; Doheny et al., 2012;
Caregivers	
Less anxiety in mothers	Schlez et al., 2011; Lai et al., 2006;
Improved parent-infant interaction	Walworth, 2009; Whipple, 2000;
Increased breastfeeding rates	Vianna et al., 2011; Nöcker-Ribaupierre, 1999;
Coping with hospitalization	Cevasco, 2008;
Less parental stress	Loewy et al., 2013;
Parental relaxation	Teckenberg-Jansson et al., 2011;
Environment	
Improving NICU	Stewart & Schneider, 2007;

sound environment	

(Table adapted and modified from: Haslbeck, 2012, p.7, in: Haslbeck, F. (2012). Music therapy for premature infants and their parents: an integrative review. *Nordic Journal of Music Therapy, 21*(3), 1-38, doi:10.1080/08098131.2011.648653)

Table 1: Music therapy and music/auditory stimulation in the NICU – examples of results and references

Most of the studies so far focused on the use of recorded music and are based on quantitative research designs. However, this is gradually shifting and recently more live music approaches are investigated (Arnon et al., 2006; Filippa et al., 2013; Garunkstiene et al., 2014; Haslbeck, 2013a; Haslbeck, 2013b; Kemper & Hamilton, 2008; Loewy et al., 2013; Schlez et al., 2011; Teckenberg-Jansson et al., 2011; Vianna et al., 2011). Friederike Haslbeck (2013a, 2013b) conducted a qualitative study and Joanne Loewy et al. (2013) and Pia Teckenberg-Jansson et al. (2011) reported both quantitative and qualitative data collection. Also, the experiences of caregivers have been included, and an increasing number of studies report various benefits of music therapy for the parents of preterm infants such as less anxiety or stress in mothers or an improved relaxation of parents (Cevasco, 2008; Lai et al., 2006; Loewy et al., 2013; Schlez et al., 2011; Teckenberg-Jansson et al., 2011). Other studies report an improvement of mother-infant interaction through music therapy (Walworth, 2009; Whipple, 2000) or increased breastfeeding rates of mothers who participated in music therapy (Vianna et al., 2011).

This rich diversity in investigations indicates that music therapy in the NICU is not a homogeneous field and despite the fact that some authors have proposed guidelines (e.g. Neal & Lindeke, 2008; Standley, 2002), there is no agreed standard protocol for music therapy or music interventions in the NICU (Hanson Abromeit, 2003).

Method

The aim of this pilot study was to extend the existing knowledge about music therapy in the NICU and to provide new insights by using live music, carried out by a qualified music therapist, and engaging the parents actively in the therapy sessions. A mixed-methods research design (“embedded design”, Andrew & Halcomb, 2009) was used to collect and analyze both quantitative and qualitative data. The research questions and sub-questions were,

1. Does music therapy help to stabilize the physiological states of premature infants?
2. Does music therapy help to improve the wellbeing of their caregivers and the relationship between the caregivers and their infants?

Sub-questions included,

- Does music therapy help to reduce anxiety in mothers of preterm infants?
- Does music therapy help to improve bonding in mothers of preterm infants?
- If music therapy helps to improve the relationship between mothers and babies, how does this happen?
- If music therapy helps stabilize preterm infants´ physiological and behavioural states, what are the important features found in this process?

The research process included several stages:

- Preparation of the environment for clinical work and research
- Research design
- Participants
- Data collection and outcome measurements
- Procedure and music therapy interventions

Preparation of the Environment for Clinical Work and Research

This study took place at the “Centro Policlínico del Olaya” (CPO)[1], a hospital located in one of the poorer neighbourhoods of Bogotá, the capital of Colombia. The NICU of the CPO offers 28 beds distributed on two floors for both intensive and acute care and intermediate care for the more stable infants. Each unit consists of a 9x6 single room and is equipped with about 12-14 incubators or open cribs.

Kangaroo care[2] is a standard intervention in the NICU and an occupational therapist and a speech and language therapist work regularly with the babies. Psychological service is available for the caregivers upon request or recommendation by the medical staff.

Music therapy is a very new treatment in Colombia and not commonly found in clinical settings. Therefore, the music therapy service at the CPO had to be implemented first before the study start and the experiences obtained during the implementation period shaped also the design for this pilot study. Additionally, an observation period was implemented in order to get to know the clinical environment in greater detail. The observation period consisted of several semi-structured observations and included also a series of Sound Level Measurements (SLM) at the unit. During the observations, a field diary was used to take notes about the number of staff and caregivers present, medical or care interventions taking place, aspects of the sound environment and personal reflections about the atmosphere at the unit. During peak times, more than 25 people (including staff and parents) were present simultaneously at the NICU. In Colombia, physical spaces are constantly shared; thus constructs such as privacy or individuality might have different meanings here than in other cultures such as Europe or the United States.

Simultaneously to the semi-structured observations, a variety of SLM were taken free field and inside the incubators on various days and at different points in the NICU. The sound level meter used was a NTi Audio Acoustilyzer AL1[3] in combination with a MiniSPL microphone. All measurements were recorded in dB(A)[4]. The aims of the SLM were to complement the reflections made during the observation period and to address practical issues such as detecting quiet periods or spots within the unit in order to optimize the music therapy interventions. Random SLM during the study period later on ensured that the music therapy interventions would not unnecessarily increase the overall sound level in the NICU. A relatively stable mean sound level (AVG LEQ[dB]) between 63-65 dB(A) was recorded on both units on each of the observation days. The measurements inside the incubator indicated an approximated 10 dB(A) reduction with the incubator doors closed and an approximated 5 dB(A) reduction with the doors open.

These findings indicate an environmental sound level above the recommended standards (AAP Committee on Environmental Health, 1997; Bremmer et al., 2003; Konkani & Oakley, 2012; Sixth Census Conference on Newborn ICU Design, 2006). However, notions such as loudness or noise are also biographically and culturally shaped and might differ from culture to culture. While talking quietly or whispering in the NICU might be considered as normal in Europe for example, inter-personal communication (verbal and other) in Colombia is often paired with high levels of emotional expressivity. This evidently has an influence on the noise level at the unit, but also shapes the perception and acceptance of what is considered as loud or not in this specific context.

The clinical environment in which research takes place is not frequently reported in neonatal research studies, although it clearly has an impact and influence upon the process and outcomes of research. The knowledge obtained through the observation period mentioned above had a strong impact on the method of this pilot study and demonstrates that also wider cultural realities are reflected in a clinical research environment. These realities need to be considered when comparing research from different cultural backgrounds.

Research Design

The mixed-methods research design for this pilot study included a randomized trial with three arms:

- Intervention Group 1 (IG1): standard care + music therapy with the caregivers during kangaroo care
- Intervention Group 2 (IG2): standard care + music therapy with the babies alone
- Control Group (CG): standard care alone

While the quantitative data was collected and analyzed within the frame of an experimental research design, the qualitative data was analyzed based on the principles of thematic analysis (Braun & Clarke, 2006). A mixed-methods research design was chosen because caregivers were encouraged to participate actively in the therapy process (Intervention Group 1) and the meaning that music therapy might have for the parents was considered to be equally important as the quantitative outcome measurements.

Participants

The target population of this study were male and female preterm infants and their parents or caregivers. The inclusion criteria included, a signed informed consent by the parents, medically stable infants born between the 30th and 37th week of gestation (without the requirement of inotropic support or mechanic ventilation and absence of frequent episodes of apnoea), and having initiated kangaroo care. The exclusion criteria included, parents who declined to participate in the study, medically instable infants, infants who suffered from congenital malformations, and if a surgery was scheduled for the week after the initial music therapy session. In case of eligible preterm infants who were the result of multiple births (twins, triplets, etc.), all neonates were allocated to the same intervention group. To avoid potential secondary effects and reduce the possibilities of over-stimulation through the music therapy interventions, the following procedure was established: If a preterm infant showed signs of hypersensitivity towards the intervention (unusual agitated behaviour, excessive alteration of the vital signals), the music therapy intervention would be stopped. During a second intervention, a member of the medical staff would accompany the music therapist. If the same signs mentioned above occur again and if the member of the medical staff interprets these signs as a

potential hypersensitivity towards the intervention, the preterm infant would be excluded from the study.

27 parents (31 infants – two pairs of twins) were asked to participate in the study, which took place between February and June 2013. One pair of parents declined to participate (*n* = 1). During the course of the study, several infants had to be excluded from the final analysis due to the following reasons: medical complications (*n* = 5), short hospitalization (*n* = 5), or formal study requirements (*n* = 1). 19 infants and 18 mothers (one pair of twins) were included in the final analysis, 8 infants and 8 mothers in IG1, 5 infants and 5 mothers in IG2 and 6 infants and 5 mothers in CG.

The flow diagram for this pilot study can be observed in Figure 1:

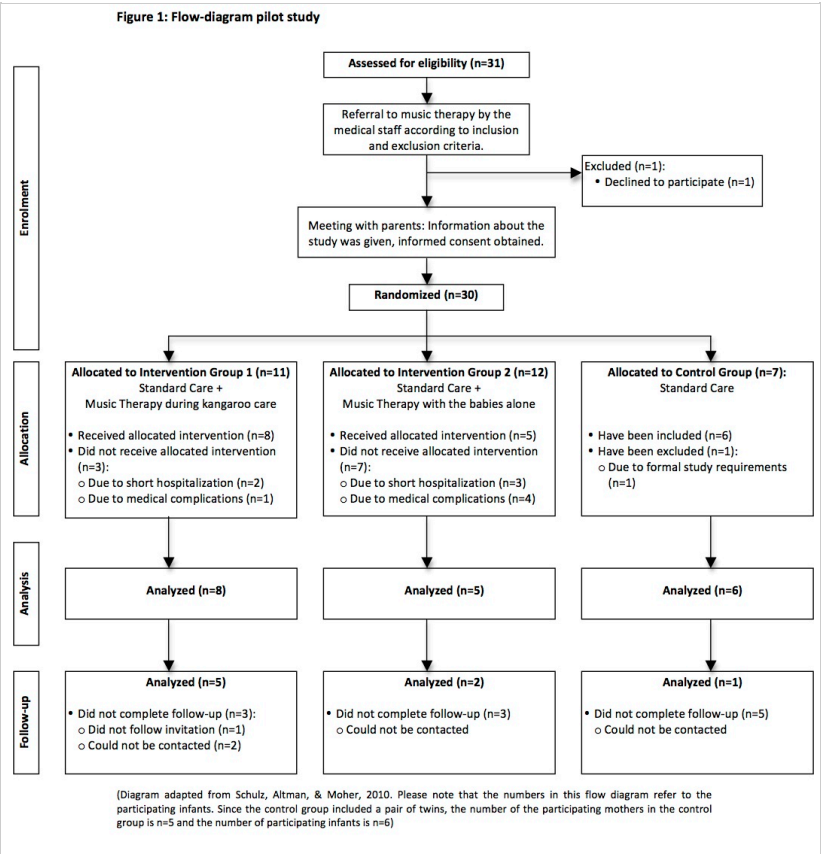

Figure 1. Flow diagram pilot study.

Ethical approval for this study was given by the Institutional Review Board of the "Centro Policlínico del Olaya" and by the Ethics Committee of Anglia Ruskin University. Randomization took place in form of assigning the participants according to a set of randomized numbers generated by computer software (Excel 2008, Microsoft Cooperation). A member of the administrative staff was the only person with this set of numbers and at the time of giving written consent to participate in the study, neither the music therapist nor the participants did know to which group the participants will be assigned.

Data Collection and Outcome Measurements

Both quantitative and qualitative data were collected with the aim to obtain information from an immediate, short and medium-term perspective. An immediate perspective was defined as data collected shortly before, during, or shortly after the therapy sessions. A short-term perspective was defined as data collected from the infants' birth until the end of hospitalization. A medium-term perspective was defined as data collected during the follow-up when the infant has reached 40 weeks of corrected gestational age. However, since nearly all participants live in poor to very poor neighbourhoods of Bogotá, structural limitations (difficulties in establishing contact with the mothers after hospitalization, long travel distances to the hospital, etc.) resulted in a low response rate to the follow-up meeting. Therefore, data from just 8 out of 19 follow-up participants could be included in the final analysis (see flow diagram Figure 1). Table 2 summarizes the outcome measurements and methods of data collection for the quantitative data of this study.

Outcome measurement	Method of data collection
Heart rate - preterm infants (Relates to research question 1 – immediate perspective)	Heart rate was averaged and stored via the hospital monitors on a one minute basis for approx. 10 min. before the intervention, during the intervention.
Oxygen saturation - preterm infants (Relates to research question 1 – immediate perspective)	Heart rate was averaged and stored via the hospital monitors on a one minute basis for approx. 10 min. before the intervention, during the intervention.
Weight gain - preterm infants (Relates to research question 1 – short-term perspective)	Taken from the nursery sheets twice a week.
Size - preterm infants (Relates to research question 1 – short-term perspective)	Taken from the nursery sheets twice a week.
Cephalic perimeter - preterm infants (Relates to research question 1 – short-term perspective)	Taken from the nursery sheets twice a week.
Length of hospitalization - preterm infants (Relates to research question 1 – short-term perspective)	Calculated after the infants left the hospital: date of hospital discharge – birth date = days in hospital.
Colombian adaption of the State-Trait-Anxiety-Inventory for Children (STAI-C)[5] - mothers (Relates to research question 2 – short- and medium term perspective)	Handed out before the first intervention, after the last intervention and during the follow-up. The STAI-C adapted by Catstrillón Moreno & Borrero Copete (2005) consists of a single form with 18 statements rated on a 3-point Likert scale, which is divided into 6 factors. Two factors measure state anxiety and four factors measure trait anxiety.
Mother-to-Infant Bonding Scale (MIBS) - mothers (Relates to research question 2 – short- and medium term perspective)	Handed out before the first intervention, after the last intervention and during the follow-up. The MIBS, developed by Taylor, Atkins, Kumar, Adams, & Glover (2005), consists of 8 adjectives regarding how mothers feel towards their baby at the moment rated on a 4-point Likert scale (loving, resentful, neutral or felt nothing, joyful, dislike, protective, disappointed, aggressive). The MIBS was translated into Spanish by the music therapist who is fluent in both Spanish and English and was controlled by a native Spanish speaking colleague who is fluent in English.

Table 2: Outcome measurements and method of data collection

The main instruments for collecting the qualitative data in this pilot study were two questionnaires that were handed out to the participating mothers after the last therapy session and during the follow-up. Additionally, all therapy sessions were recorded on video and documented afterwards. Several short and informal interviews have been taken place between the music therapist and the caregivers, and keywords and personal reflections have been written down in a field diary in order to complement the qualitative data collection.

Tables 3 and 4 summarize the questions asked to the participating mothers after the last therapy session and during the follow-

up meeting.

Questions IG1 – after the last intervention	Questions IG2 – after the last intervention	Questions CG – after the last intervention
1. Could you please describe your experiences during the music therapy sessions in your own words?	1. Although you have not been directly involved in the music therapy sessions, do you think that the music therapy sessions have been helpful for your baby? (Options: Yes, No, I am not sure) Why?	1. Although you have not been directly involved in the music therapy sessions, do you think that music therapy should be a regular service in the NICU? (Options: Yes, No, I am not sure)
2. Do you think that the music therapy sessions have been helpful for your baby? (Options: Yes, No, I am not sure) Why?	2. Although you have not been directly involved in the music therapy sessions, do you think that music therapy should be a regular service in the NICU?	2. Although you have not been directly involved in the music therapy sessions, do you think that music therapy helps that the environment of the NICU becomes more "human"? (Options: Yes, No, I am not sure)
3. Do you think that the music therapy sessions have been helpful for yourself? (Options: Yes, No, I am not sure) Why?	3. Although you have not been directly involved in the music therapy sessions, do you think that music therapy helps that the environment of the NICU becomes more "human"?	
4. Have there been differences for you between being in kangaroo care with or without music therapy? (Options: Yes, No, I am not sure) If yes, what are the differences?		
5. Do you think that music therapy should be a regular service in the NICU? (Options: Yes, No, I am not sure)		
6. Do you think that music therapy helps that the environment of the NICU becomes more "human"? (Options: Yes, No, I am not sure)		

Table 3: Questionnaire for mothers after the last therapy session

Questions IG1 – during follow-up	Questions IG2 – during follow-up	Questions CG – during follow-up
1. Do you use music for your baby? (Options: Yes, No)	1. Do you use music for your baby? (Options: Yes, No)	1. Do you use music for your baby? (Options: Yes, No)
2. In what situations do you use music for your baby? (Options: For stimulation, For sleeping, Other [please specify])	2. In what situations do you use music for your baby? (Options: For stimulation, For sleeping, Other [please specify])	2. In what situations do you use music for your baby? (Options: For stimulation, For sleeping, Other [please specify])

3. What type of music do you use for your baby? (Options: I sing for him/her, I use recorded music, Other [please specify])	3. What type of music do you use for your baby? (Options: I sing for him/her, I use recorded music, Other ([please specify])	3. What type of music do you use for your baby? (Options: I sing for him/her, I use recorded music, Other [please specify])
4. Do you think that the music therapy sessions have been helpful for the wellbeing of your baby until now? (Options: Yes, No, I am not sure) Why?	4. Although you have not been directly involved in the music therapy sessions, do you think that the music therapy sessions have been helpful for the wellbeing of your baby until now? (Options: Yes, No, I am not sure) Why?	4. Other comments
5. Do you think that the music therapy sessions helped you to improve your relationship with your baby during the hospitalization? (Options: Yes, No, I am not sure) Why?	5. Other comments	
6. If yes, do you think that this experience is still helpful for you and/or your baby? (Options: Yes, No, I am not sure) Why?		
7. Other comments		

Table 4: Questionnaire for mothers during the follow-up

The answers of the questionnaires were analyzed based on the principles of thematic analysis as described by Braun & Clarke (2006) who describe it as a flexible method that is not bound to a specific epistemological or theoretical framework. These reasons seemed to fit well the secondary aims of this pilot study, which was to test the study design and the measurement tools, as well as to lay the groundwork for a larger study in the future.

Braun & Clarke (2006, p. 87) propose a six-step procedure for thematic analysis:

1. Familiarizing yourself with your data
2. Generating initial codes
3. Searching for themes
4. Reviewing themes
5. Defining and naming themes
6. Producing the report

First, the questionnaires were thoroughly reviewed several times. Interesting aspects or phrases of the answers were highlighted to be able to come back to these data parts later on. In a second step, the highlighted phrases were transformed into data items, trying to grasp the essence of what the phrases were about. In a third step, similar data items were clustered into sub-themes that represent various or single data items on a broader basis. Out of the sub-themes main themes were created. The answers obtained from the questionnaires handed out after the last therapy intervention and during the follow-up were analyzed together.

Procedure and Music Therapy Interventions

Based on the initial experiences of music therapy at the NICU, it was estimated that stable preterm infants that met the inclusion criteria would stay for approximately 2-3 weeks at the NICU. To establish a process-oriented therapy service that stressed the importance of the therapeutic relationship and bonding between premature infants and their caregivers, up to four music therapy sessions over a course of two weeks were offered. The therapy sessions took place twice a week on two different days of the week directly at the unit, either with the caregivers during kangaroo care (IG1) or with the babies alone (IG2). To be included in the final data analysis, participation of at least two out of the four therapy sessions was required.

During music therapy with IG1 (music therapy during kangaroo care), both mothers and fathers were invited to participate. Normally, the parent(s) sat on a chair beside the incubator with their baby in kangaroo care. The baby was wrapped in a blanket. Before the therapy started (baseline), the heart rate and oxygen saturation sensors were strapped on a foot of the preterm infant by the nursery staff. During the music therapy session, the therapist sat in front of the parent(s). When both parents were

present, three chairs were arranged in a triangle. Fathers participated actively in 6 out of 23 music therapy sessions for IG1.

In most cases, the music therapy sessions consisted of singing lullabies or children's songs together with the parents, or other songs that had a positive meaning for the caregivers (Song of kin, Loewy et al., 2013). If possible, the songs were chosen by the caregivers rather than proposed by the therapist. Other musical styles proposed by the parents were pop songs, sung prayers, Christian songs, or songs that caregivers invented for their babies. These were slowed down in tempo or adapted to a "lullaby style" (3/4 times, 60-80 bpm, accompanied by simple chord progressions. Normally, the music therapist accompanied the singing with guitar playing (classical guitar with nylon strings). In case a caregiver did not mention any specific music, the music therapist proposed lullabies or children's songs that are familiar to most of the population in Colombia or offered a receptive session. In the receptive sessions, the music therapist used a guitar or a harp for improvising music with the aim to create a comfortable and holding musical environment. In one case, a mother opted to listen to improvised music while she read a children's story for her baby. A summary of the data regarding the music therapy sessions with IG1 can be observed in Table 5.

Number of participating pairs of infants and parents	8
Total number of music therapy interventions	23
Number of sessions in which fathers participated actively	6
Length of interventions (minutes)	13.7 (range 8-25)
Number of sessions with singing songs with the parents	17
- Number of sessions in which lullabies were used	3
- Number of sessions in which children's songs were used	8
- Number of sessions in which other songs were used	6
Reading a story accompanied by improvised music	1
Number of sessions with receptive music therapy	5

Table 5: Intervention Group 1 - Data regarding the music therapy sessions

The therapy sessions with IG2 (music therapy with the neonates alone) normally took place when the mothers had to leave the unit for providing breast milk. This point of time was chosen in order not to take "time away" from parents to be with their babies, and because a reduced number of people at the unit resulted in less background noise. The music therapy sessions with the babies alone took place while the neonates were both lying in the incubators or open cribs. At baseline, the sensor for the heart rate and oxygen saturation was strapped on the foot of the preterm infant by the nursery staff. In 88% of the interventions, the infants were in supine position and 22% of the infants were in prone position.

For the music therapy interventions, the accompanying instrument was either a classical guitar with nylon strings or instruments that aim at imitating the intrauterine sound environment, namely the ocean drum and the gato-box. The ocean drum is a round frame drum with a skin on both sides of the frame. Inside the frame are normally small iron pellets. When inclining it from one side to another, the sound generated is similar to periodic sound of waves arriving at a beach. The gato-box is a small tongue drum with a few tongues cut into the wooden top. When tapping the tongues with the fingers it is possible to imitate the sound of a beating heart (Loewy et al., 2013). In most sessions, the therapist used wordless gentle humming or toning together with the instruments. Entrainment (e.g. to the infant's or heart rate or breathing patterns) was essential in all therapy sessions. A summary of the data regarding the music therapy sessions with IG2 can be observed in Table 6.

Number of participating infants	5
Total number of music therapy interventions	17
Length of interventions (minutes)	7.2 (range 5-10)
Number of interventions with babies in an incubator	8
Number of interventions with babies in an open crib	9
Number of interventions with the use of voice and guitar	6
Number of interventions with the use of voice and ocean drum	5
Number of interventions with the use of voice and gato-box	1
Number of interventions with the use of ocean drum alone	1
Number of interventions with the use of mixed instruments	3

Table 6: Intervention Group 2 - Data regarding the music therapy sessions

The control group did not participate in any music therapy activity, but the music therapist offered all participating parents (including the control group) an individual informal talk about how music could be used at home shortly before hospital discharge.

Results

Quantitative Results

Statistical analysis was completed for the preterm infants' size and cephalic perimeter, weight gain, heart rate and oxygen saturation and length of hospitalization. For the participating mothers, the statistical analyses included the socio-demographic data, the data obtained with the State-Trait-Anxiety-Inventory for Children (Colombian adaption by Castrillón Moreno & Borrero Copete, 2005), and the Mother-to-Infant Bonding Scale (Taylor et al., 2005). All analyses were performed using the computer program R (R Development Core Team, 2013). Bootstrapping has been performed using function two.boot from R package simpleboot (Peng, 2008). 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 for one-way analysis of variance was done using function aovp from R package lmPerm (Wheeler, 2010).

Group Comparison

Tables 7 and 8 provide a summary of the relevant group and baseline data for this study. The data has been categorised in terms of the intervention groups. The three groups did not differ significantly in terms of socio-demographic or baseline data. Just one statistically significant association was found between the groups in terms of Social Security Status (paying or beneficiary) (p = 0.01).

Variables	Intervention Group 1 n = 8		Intervention Group 2 n = 5		Control Group n = 6	
	nCat3	% nCat3	nCat2	% nCat2	nRef	% nRef
Number of children (n | % 2)	2	25.0	4	80.0	1	16.7
Sex (n | % Male)	4	50.0	4	80.0	3	50.0
Twin (n | % Yes)	0	0.0	2	40.0	2	33.3
Type of birth (n | % Natural)	4	50.0	1	20.0	3	50.0
Pregnancy type (n | % Unplanned)	3	37.5	3	60.0	3	50.0
Number of interventions completed (n | % 3)	1	12.5	1	20.0	4	66.7
Education (n | % University)	3	37.5	2	40.0	1	16.7
Social Security status (n | % Paying)	6	75.0	2	40.0	0	0.0
Relationship status (n | % Single)	0	0.0	2	40.0	0	0.0
Living with father (n | % Yes)	7	87.5	3	60.0	5	83.3
Father gives support (n | % Yes)	8	100.0	4	80.0	5	83.3
Average monthly income (n | % 1-2 x minimum wage)	6	75.0	3	60.0	1	16.7
Occupation (n | % Student/working)	5	62.5	4	80.0	2	33.3
nRef = number of positive cases for the variable for the reference category (Control Group) of the classification variable nCat# = number of positive cases for the variable for other category (Intervention Group 1 and Intervention Group 2) of the classification variable						

Table 7: Comparison of variable percentages for categories of classification – Socio-demographic data mothers

Variables	Intervention type					
	Intervention Group 1 *n* = 8		Intervention Group 2 *n* = 5		Control Group *n* = 6	
	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation
Age of mother (years)	23.12	6.73	26.00	7.18	22.50	5.17
Gestational age at birth (weeks)	32.12	1.55	31.60	2.07	33.50	0.84
Weight at birth (g)	1598.38	388.30	1642.00	284.99	1890.83	257.34
Cephalic perimeter at birth (cm)	29.19	1.69	30.30	1.35	30.17	1.17
Size at birth (cm)	42.00	2.45	42.00	3.08	42.17	2.32
Standard deviations are based on within-group data (not on pooled estimates).						

Table 8: Summary of continuous variables by intervention group - Baseline data

Size and Cephalic Perimeter

No statistically significant differences for the groups were found in terms of size and cephalic perimeter at the first intervention, at the last intervention, and at hospital discharge (see Table 9).

Variables (cm)	Intervention groups						*p*-value
	Intervention Group 1 *n* = 8		Intervention Group 2 *n* = 5		Control Group *n* = 6		
	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation	
Size first intervention	42.25	3.37	42.80	1.48	42.50	1.87	0.93
Size last intervention	42.88	2.42	44.00	1.22	43.50	2.17	0.63
Size at hospital discharge	43.38	1.85	44.50	2.06	43.83	1.94	0.60
Cephalic perimeter first intervention	29.69	1.31	30.30	1.30	29.92	0.66	0.65
Cephalic perimeter last intervention	30.75	0.88	31.50	1.12	29.69	1.73	0.08
Cephalic perimeter at hospital discharge	30.25	1.75	32.00	1.22	31.17	0.98	0.13
Standard deviations are based on within-group data (not on pooled estimates). *p*-values have been obtained using 1000000 permutation samples. A *p*-value is not calculated for a variable if one of its groups has fewer than 3 unique values.							

Table 9: Size and cephalic perimeter for intervention groups at first intervention, last intervention and hospital discharge

Weight Gain

A favourable effect towards an increased weight gain was observed for both intervention groups compared to the control group. No statistically significant differences were found for any of the parameters related to weight gain, but the weight gain per day during the intervention period for IG1 was noted to be clinically significant (mean 26.39 gr./day for IG1 vs. 3.98 gr./day for CG).

Table 10 summarizes preterm infants´ weight for the intervention groups at the first intervention, at the last intervention, at hospital discharge, the total weight gain during the intervention period, and the weight gain per day during the intervention period.

Variables (grams)	**Intervention Groups**						***p*-value**
	Intervention Group 1 *n* = 8		**Intervention Group 2 *n* = 5**		**Control Group *n* = 6**		
	Mean	**Standard Deviation**	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	
Weight at first intervention	1802.50	334.74	1738.00	211.15	1847.50	181.21	0.82
Weight at last intervention	1963.12	321.35	1920.00	87.68	1897.50	79.36	0.96
Weight at hospital discharge	2013.75	286.96	2091.00	211.97	1968.33	140.84	0.72
Total weight gain during the intervention period	160.62	121.02	182.00	153.20	50.00	136.93	0.23
Weight gain per day during the intervention period	26.39	15.83	9.44	20.55	3.98	13.83	0.05

Standard deviations are based on within-group data (not on pooled estimates).
p-values have been obtained using 1000000 permutation samples.
A *p*-value is not calculated for a variable if one of its groups has fewer than 3 unique values.

Table 10: Preterm infants´ weight for intervention groups at first intervention, last intervention, hospital discharge, total weight gain and weight gain per day the during intervention period

Figure 2 shows the development of the preterm infants´ weight gain from birth to hospital discharge including the first and the last intervention.

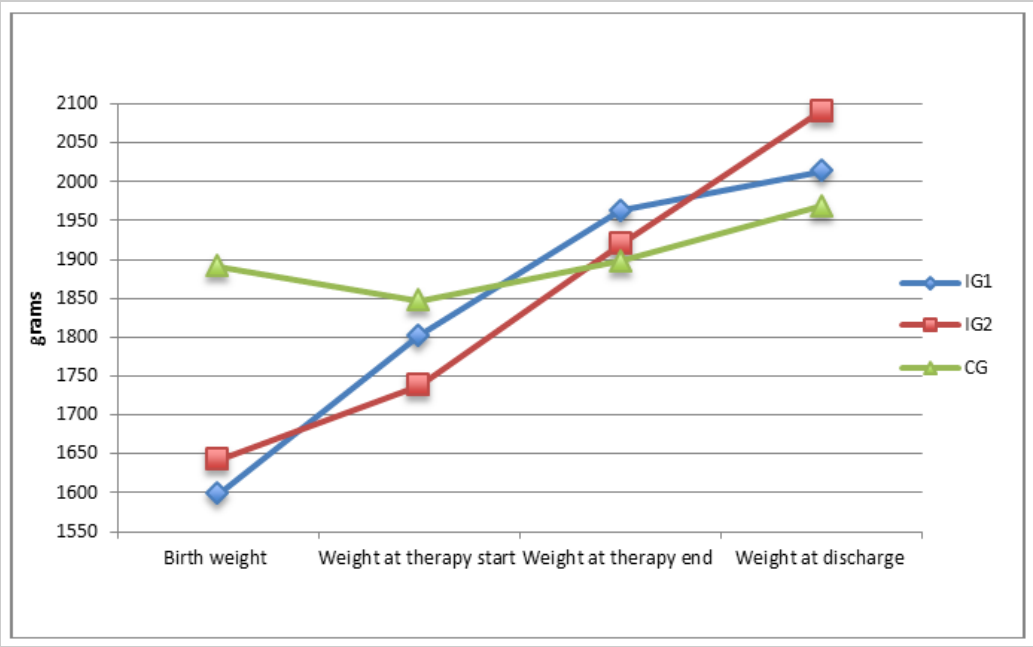

Figure 2. Mean weight gain from birth to hospital discharge for the intervention groups.

Heart Rate and Oxygen Saturation

Heart rate (HR) and oxygen saturation (OS) were recorded before, during, and after the intervention. However, limitations of the clinical environment made it difficult to obtain reliable data for each intervention. Monitors were not always been available and sometimes the sensors did not work properly. From a total of 23 interventions in IG1, reliable heart rate and oxygen saturation data was collected for 14 sessions (60,9%). From a total of 17 interventions in IG2, reliable heart rate and oxygen saturation data was collected for 16 sessions (94%). From a total of 20 interventions in CG, reliable heart rate and oxygen saturation data was collected in 16 occasions (80%). For the control group, heart rate and oxygen saturation was recorded in 7 cases during kangaroo care (for comparison with IG1) and in 9 cases while the babies were alone in the incubator or open crib (for comparison with IG2). The lack of data did not allow an in-depth statistical analysis, but for the data available no statistically significant differences were found.

Length of Hospitalization

No statistically significant differences between the groups were found in terms of total length of hospitalization, days in hospital from the first intervention to hospital discharge, and days from the last intervention to hospital discharge. Table 11 summarizes the variables regarding length of hospitalization, intervention period, gestational age, and post-birth days at the first intervention, the last intervention, and at hospital discharge.

Variables	Intervention Groups						*p*-value
	Intervention Group 1 *n* = 8		Intervention Group 2 *n* = 5		Control Group *n* = 6		
	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation	
Length of hospitalization (days)	28.12	24.80	27.80	15.42	14.67	7.00	0.39
Intervention period (days)	7.00	4.57	11.40	4.77	9.17	2.04	0.18
Post-birth days at first intervention (days)	20.25	23.37	12.00	11.22	4.50	3.33	0.21

Post-birth days at last intervention (days)	26.25	24.71	22.40	14.55	12.67	3.88	0.42
Gestational age at first intervention (weeks)	35.02	2.59	33.31	1.61	34.14	0.71	0.33
Gestational age at last intervention (weeks)	35.87	2.66	34.80	1.30	35.31	0.46	0.72
Gestational age at hospital discharge (weeks)	36.14	2.71	35.57	0.79	35.60	0.21	0.92
Days in hospital from the first intervention to hospital discharge (days)	8.00	4.81	15.80	8.35	10.17	5.85	0.11
Days in hospital from the last intervention to hospital discharge (days)	1.88	1.64	5.40	5.86	2.00	3.95	0.24

Table 11: Summary of variables regarding length of hospitalization, intervention period, gestational age and post-birth days at the first intervention, at the last intervention and at hospital discharge

Analysis of variance was performed by adjusting the gestational age of the three groups (Table 12) since the infants in both intervention groups were younger in comparison to the infants in the control group. A 3.83 days shorter hospitalization was observed for IG2 when length of hospitalization was adjusted for gestational age, although this difference was not statistically significant.

Intervention Groups	Number of values	Mean	Standard error	95% confidence limits	
				Lower	Upper
Intervention Group 1	8	25.48	4.14	20.07	38.87
Intervention Group 2	5	20.47	5.33	13.19	36.28
Control Group	6	24.30	4.91	17.20	38.59

Table 12: Means of the number of days in hospital adjusted for the number of weeks of gestation by Intervention group with bootstrap standard error and 95% confidence limits

Mother-to-Infant Bonding Scale (Taylor et al., 2005)

The analysis of the MIBS (Table 13) did not show any statistically significant differences between the groups at baseline (Q1 - before the first intervention) compared to the data obtained after the last intervention (Q2 – after the last intervention).

Variables (points)	Intervention Groups						*p*-value
	Intervention Group 1 *n* = 8		Intervention Group 2 *n* = 5		Control Group *n* = 6		
	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation	
Q1 MIBS	2.50	2.45	2.00	0.71	1.83	1.47	0.80

Q2 MIBS	2.00	2.00	1.00	0.71	1.17	1.33	0.49

Table 13: Mother-to-Infant Bonding Scale (MIBS) before the first intervention (Q1) and after the last intervention (Q2)

State-Trait-Anxiety-Inventory for Children (STAI-C, Colombian adaption from Castrillón Moreno & Borrero Copete, 2005)

The STAI-C is a shorter version of the STAI and combines 18 items divided into six factors (Factor 1-6). Factors 1 and 2 refer to state anxiety and Factors 4 to 6 refer to trait anxiety. The raw points obtained are converted into percentiles and percentiles between 1-15 and 85-100 are reported to be clinically significant (Castrillón Moreno & Borrero Copete, 2005).

A statistically significant difference was found for Factor 2 before the first intervention (Q1 – F2) and for Factor 6 after the last intervention (Q2 – F6). Table 14 (above) summarizes the analysis of the Factors and percentiles of the STAI-C.

Variables (percentiles)	Intervention Groups						*p*-value
	Intervention Group 1 *n* = 8		Intervention Group 2 *n* = 5		Control Group *n* = 6		
	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation	
Q1 STAIC % F1	43.12	18.31	57.20	23.96	42.50	20.68	0.44
Q1 STAIC % F2	55.62	27.31	9.60	4.93	27.83	24.04	**0.01**
Q1 STAIC % F3	36.88	31.54	55.00	25.25	50.00	31.94	0.54
Q1 STAIC % F4	20.12	31.05	38.00	21.39	11.67	5.16	0.19
Q1 STAIC % F5	54.62	30.65	72.40	28.17	60.83	21.78	0.54
Q1 STAIC % F6	53.75	19.23	77.00	16.43	52.50	24.03	0.11
Q2 STAIC % F1	43.57	21.55	59.00	17.10	46.67	25.63	0.47
Q2 STAIC % F2	36.17	34.35	20.60	23.46	43.50	29.69	0.46
Q2 STAIC % F3	19.00	15.61	57.40	42.29	48.17	26.50	0.08
Q2 STAIC % F4	27.14	28.85	45.00	38.57	23.33	30.61	0.51
Q2 STAIC % F5	44.83	30.86	60.40	23.15	42.50	16.66	0.44
Q2 STAIC % F6	41.43	14.64	62.00	16.43	35.00	16.43	**0.0418**

Table 14: Percentiles obtained with the STAI-C for the intervention groups before the first intervention (Q1) and after the last intervention (Q2)

Follow-up

For the follow-up meetings, it was planned to apply most of the measurements used during the infants´ hospitalization (weight, size, cephalic perimeter, MIBS, STAI-C and questionnaires). Additionally, the occupational therapist of the NICU, who is also an experienced clinician working with the Bayley Scales of Infant Development, applied an adaption of the Bayley II scales to detect potential neuro-developmental risks for the participating infants. However, due to the small response rate of the follow-up, no statistical analysis was performed for the quantitative outcome measurements. No neuro-developmental risks were detected for

the participating infants examined with the Bayley II.

Qualitative Analysis

In general, the responses from the participating mothers were very positive in terms of the value of music therapy for them and their babies. All mothers in IG1 and IG2 responded that music therapy was helpful for their babies. All mothers from IG1 reported that music therapy was helpful for them and for the relationship with their babies. Across the groups, all mothers conferred that music therapy was helpful in humanizing the environment of the NICU. All but one mother (CG participant) reported that music therapy should be a regular service in the NICU.

Since the level of involvement in the music therapy sessions was different for each group (IG1: direct involvement, IG2: indirect involvement, CG: no involvement), the most relevant data about the mothers´ experiences in music therapy came from IG1. A more systematic analysis of the qualitative follow-up data was just possible for IG1 and, to a certain extent, for IG2. During the follow-up, mothers from IG1 (*n* = 5) and IG2 (*n* = 2) still thought that music therapy had been helpful for them, their babies, and the relationship with their babies. Mothers in all groups reported that they continue to use music at home, either for stimulation or relaxation.

Thematic Analysis IG1

The following figure (Figure 3) shows the thematic map obtained from the answers of IG1. Three main themes were found: “music therapy is helpful for mothers,” “music therapy is helpful for babies,” and “music Therapy is helpful for the relationship between mothers and babies.” The main themes are surrounded by several sub-themes. The stronger sub-themes (sub-themes that are built upon data items that come up more frequently) are highlighted in grey.

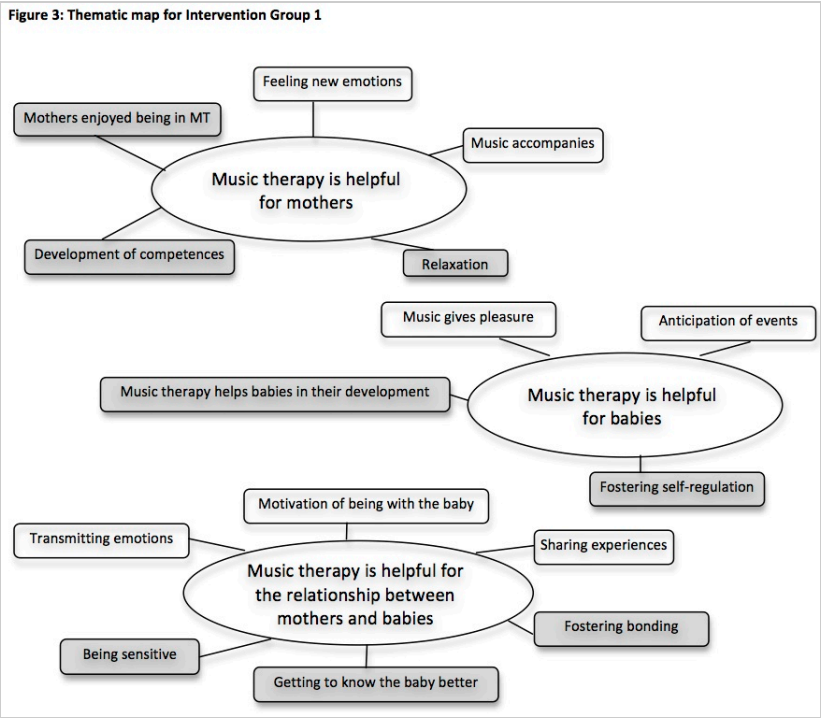

Figure 3. Thematic map for invention group 1.

Theme 1 in Figure 3: Music therapy is helpful for mothers

This theme includes sub-themes and subsequent data items that relate to why the participating mothers think that music therapy was helpful for them. Examples of these sub-themes include, the mothers enjoyed being in music therapy; the therapy sessions helped the mothers develop competences; music therapy was relaxing for them; they became aware of their own feelings through the music therapy sessions. Mothers described their experiences in music therapy as “pleasant,” “relaxing,” or “beautiful.” They frequently stated that music therapy helped them and their babies to relax, and that they became sensitive to how they felt towards their babies. Converse to kangaroo care without music therapy, mothers stated that with music therapy they felt motivated to be with their babies.

"It has been a very pleasant experience, it has been nice and relaxing for my baby and I got to know many emotions that I did not feel before." (Participant MT2)

"[…] I learned and know now how to calm my baby and help him to sleep." (Participant MT2)

“They helped me to be able to connect myself much more to him and to relax a little bit, even more being in an environment in which one is very worried about the health of the baby. These moments of calmness helped me to transmit this also to my baby." (Participant MT9)

Theme 2 in Figure 3: Music therapy is helpful for babies

This theme includes sub-themes and subsequent data items that relate to why the participating mothers think that music therapy was helpful for their babies. Examples of such sub-themes include, mothers think that music therapy was developmentally helpful for their babies (development in general and with regard to specific developmental goals such as neurological or auditory development); music therapy fostered self-regulation capacities for their babies because it helped them to relax and to be more attentive.

"Because I felt him more clam and that he had more contact with me." (Participant MT10)

"Because with the progress of the sessions I felt him more reactive to the music." (Participant MT9)

"It stimulates the neurological parts and it helps him to relax." (Participant MT5)

Theme 3 in Figure 3: Music therapy is helpful for the relationship between mothers and babies

This theme includes sub-themes and subsequent data items that relate to why the participating mothers think that music therapy was helpful for the relationship with their babies. More latent analysis was needed for this theme to understand the meaning of their answers. Results include, mothers felt more motivated to be with the baby because of the music therapy sessions; mothers felt that they could give more love during music therapy; music therapy sessions helped the mothers to get to know their baby better. Since all mothers still continued to use music at home after the infants´ hospitalization, in the follow-up meeting the sub-theme of sensitivity towards the inner states of the babies was extended to statements that relate to the anticipation of events created by and with music.

"Thanks to the sessions I learned how to get to know my baby better." (Participant MT7)

"Because I feel that I can give more love and that she will do better at my side. Her development will be better." (Participant MT 10)

"Because they helped me to get to know the expressions of my daughter." (Participant MT14)

"Because now the music is very familiar to him and when I play certain songs, these songs help him to anticipate what is coming, for example he knows when he will have a bath, when it is time to sleep or he knows what music I use to play with him." (Participant MT9)

Thematic Analysis IG2

Although the involvement of parents in IG2 was indirect, it was nevertheless interesting to find out whether mothers thought if and why music therapy was helpful for their babies. Figure 4 shows the thematic map for IG2.

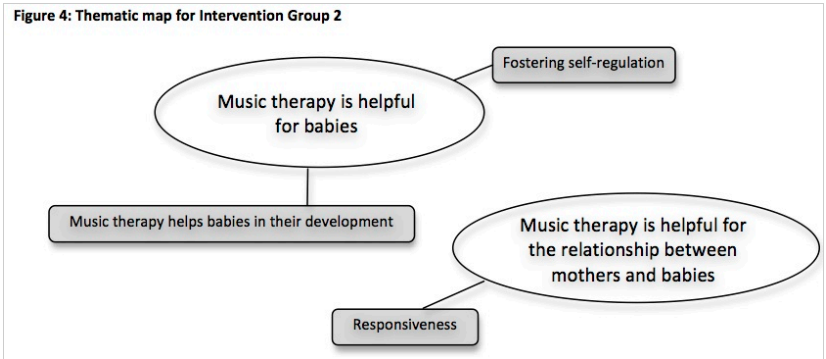

Figure 4. Thematic map for intervention group 2.

Theme 1 in Figure 4: Music therapy is helpful for babies

This theme includes sub-themes and subsequent data items that relate to why the participating mothers think that music therapy was helpful for their babies. These sub-themes included statements regarding the enhanced self-regulation that mothers observed in their babies (stimulation and/or relaxation) or that mothers thought that music therapy helped them in their development.

> "Because every day I felt that my babies progressed in their development." (Participant MT12)
>
> "It helped him a lot to recognise sounds and to stimulate this hearing." (Participant MT15)
>
> "Because it helped to recognize more the voice of the parents an to be a little bit more attentive." (Participant MT27)
>
> "It stimulated very much his senses and he as been more attentive to what happened around him." (Participant MT15)

Theme 2: Music therapy is helpful for the relationship between mothers and babies

This theme is about why the participating mothers think that music therapy was helpful for their relationship with their babies. The main sub-theme includes statements that relate to the enhanced responsiveness of the babies towards their environment or their parents´ voices.

Discussion and Conclusions

Quantitative Results

Some conclusions can be drawn comparing the results of our study with the existing literature. Size and cephalic perimeter did not show any statistically significant differences between the groups. This is in line with findings from other studies (Cassidy, 2009; Chapman, 1984). In our study, we also observed that some numbers regarding size and cephalic perimeter taken from the nursery sheets fluctuated from day to day. Since both size and cephalic perimeter were taken by hand measurements, small differences for size and cephalic perimeter might have occurred depending on the nurse that took the measurements. This might have influenced the outcomes and could be avoided if the same nurse carried out all the measurements.

Both intervention groups showed increased weight gain compared to the control group. In the case of weight gain per day, this difference was rated to be clinically significant by the medical staff. Such favourable effects of music therapy on the weight gain of premature babies replicates the findings of other studies (see Table 1).

An increased oxygen saturation and a decrease in heart rate of preterm infants is most commonly reported in research studies related to music therapy and music or auditory stimulation. The experiences from our pilot study show differential results. Although the missing data did not allow an in-depth statistical analysis, the difference was in the direction of an increase in heart rate and an increase in oxygen saturation for IG1, a decrease in heart rate and a stable oxygen saturation for IG2, as well as a stable heart rate and a slightly decreased oxygen saturation for the control group.

A possible explanation of the increase of heart rate in IG1 might be that in most of the music therapy sessions the mothers were singing to their babies causing the to be more attentive or awake. Filippa et al. (2013) and Courtnage (2001) made similar conclusions. Lee & White-Traut (2013) report a decrease in heart rate or preterm infants for recorded male voices, but not for female voices. Maiello (2007) suggests that the more middle and high frequency range of a mother’s voices might result in an increase of the infant’s heart rate as opposed to low frequency sounds. However, also the music, and the way mothers and the music therapist sang to the babies, influenced the results. In addition, the goals for each music therapy session differed depending on the needs and possibilities of the participating infants and mothers and a decrease in heart rate was not always a therapy goal.

On the other hand, the differential findings regarding heart rate and oxygen saturation might also be the result of how these parameters are traditionally reported (as means for the overall length of intervention). Within the context of this pilot study, a stabilizing effect of music therapy on the heart rate and oxygen saturation was observed, rather than an increase or decrease of these parameters (Figure 5).

Figure 5 shows the heart rate (HR in bpm - red line) and the oxygen saturation (OS in % - blue line) of a preterm infant, born at 33 weeks and with a post-gestational age of 11 days during kangaroo care with the father of the baby before the start of music therapy (first vertical black line at minute 11:22), during kangaroo care with the father of the baby during music therapy (between minute 11:22 and 12:31), and during kangaroo care with the father of the baby after music therapy (after the second vertical black line at minute 11:31). Although a stabilization of heart rate and oxygen saturation can be observed during music therapy, the means (depicted as the dotted green and orange lines) indicates a higher heart rate during music therapy in reference to the

baseline (before music therapy).

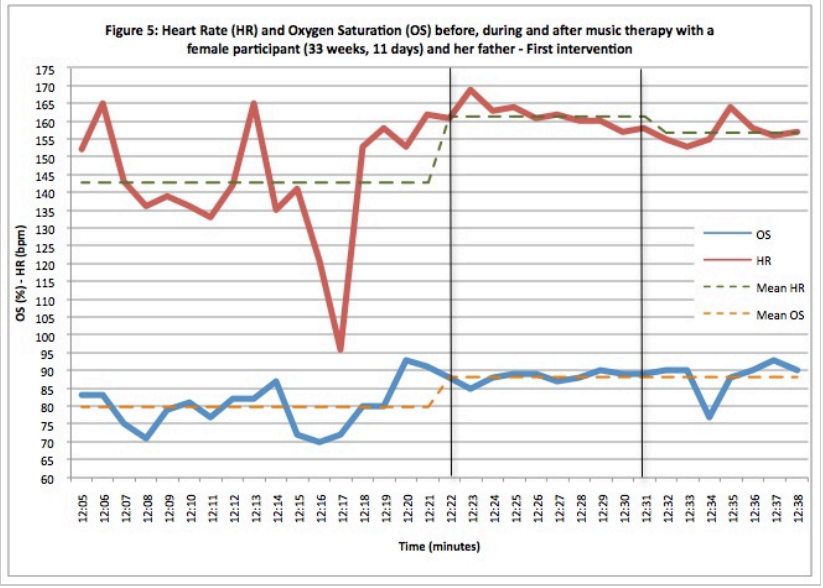

Figure 5. Hearth rate (HR) and Oxygen satiration (OS) before, during and after music therapy with a female participant (33 weeks, 11 days) and her father - first intervention.

With regard to the length of hospitalization, this study showed a small reduction in hospital stay for IG2 (3.83 days) after adjusting the gestational age of the groups. However, in the clinical and cultural environment in which our study took place, the length of hospitalization does not only depend on the readiness of the baby to leave the hospital. Some babies spent a day or longer in the hospital because the parents were not able to respond immediately to the administrative requirements for the hospital discharge, for example if oxygen was needed to take home.

Few studies report the inclusion of parents in the therapy process and only two studies report the measurement of anxiety in mothers (Lai et al., 2006; Schlez et al., 2011). Both these studies report favourable effects of anxiety and Lai et al. (2006) suggest a linear trend of anxiety reduction with music therapy. Our pilot study shows no statistically significant changes. However, our study design is quite different. Lai et al. (2006) offered recorded music on three consecutive days and Schlez et al. (2011) offered live harp music during kangaroo care alternating with kangaroo care alone. The findings from our pilot study suggest that state anxiety does not follow linear trends, at least not over longer periods of time during the infants´ hospitalization. A reason for this might be the fact that new challenges for caregivers arise at different stages during hospitalization. For example, the STAI-C used in this study was applied before the first therapy session (baseline) and after the last therapy session. In most of the cases, the last therapy session coincided with an immediate or very soon hospital discharge of the baby. This can be a moment of joy and relief, but also a period of additional stress and uncertainty since from hospital discharge onwards, the parents need to take care of their still fragile baby. This might influence the state-anxiety levels of parents.

Also, the difference in the STAI used for our study make comparisons difficult. While both Schlez et al. (2011) and Lai et al. (2006) used the state-anxiety form from the STAI (Spielberger et al., 1983), in this study a Colombian adaptation of the STAI-C was used. Also, in both studies by Schlez et al. (2011) and Lai et al. (2006), just the state-anxiety form was used without any information about trait-anxiety, although trait-anxiety clearly influences state-anxiety.

With respect to the Mother-to Infant Bonding Scale (MIBS) (Taylor et al., 2005), no other study regarding music therapy or music and auditory stimulation in the NICU was found that uses a bonding scale[6]. A general improved bonding score was observed in all three groups, it should be noted that in IG1 three mothers obtained slightly inferior scores during the second measurement. Again, the close hospital discharge could have had an effect on this result. On the other hand, a recurrent theme from the qualitative data obtained from IG1 was also a greater awareness of the mothers´ own feelings and towards how mothers felt in terms of the relationship with their babies. Therefore, it could be hypothesized that music therapy might have played a role in not only identifying and working with the resources and positive aspects of the early mother-infant relation, but also in making conscious more difficult feelings or thoughts that mothers might have towards their baby. This might have influenced the slightly higher scores for IG1 during the measurement after the last therapy session.

Qualitative Analysis

Having a preterm baby in the NICU is very challenging and for both the baby and the parents, this experience may well be described in terms of a trauma (Stewart, 2009a; Stewart, 2009b). Inviting the caregivers to participate actively in the music therapy sessions provided not only the possibility to integrate the parents' voices to the therapy process, but also gave them a chance to engage actively in the care of their babies. Aagard & Hall (2008) describe five metaphors derived from a meta-synthesis of mothers´ experiences of having a preterm infant in the NICU:

- Mother–baby relationship: From their baby to my baby
- Maternal development: Striving to be a real normal mother
- A turbulent neonatal environment: From foreground to background
- Maternal caregiving and role reclaiming strategies: From silent vigilance to advocacy
- Mother–nurse relationship: From continuously answering questions through chatting to sharing of knowledge (Aagard & Hall, 2008, pp.31)

Much of what the participating mothers in our pilot study stated about their experiences with music therapy is connected to these metaphors. Becoming sensitive towards their babies´ inner states, becoming aware of their own feelings towards their babies, the development of competences, the active participation in the care of their babies, the fostering of self-regulation, the possibility to relax themselves and their babies, sharing a joyful experience with their baby (and their partners!), or to get to know their baby better are all sub-themes connected with most of the metaphors presented by Aagard & Hall (2008). The incorporation of fathers to the therapy session in this pilot study was a highly motivating experience and showed that fathers are equally competent in soothing and establishing a relationship with their babies through singing as mothers and are in need of being recognized as such competent partners in the care of their baby. The music therapy sessions that included both caregivers provided a possibility for the parents to share positive moments with their baby already as a family, something that might help in the transition from the clinical to the home environment.

Limitations

There are several limitations of this study.

1. Since this is a pilot study, the sample size is small and generalizations of the results need to be drawn cautiously.
2. A broad variety of outcome measures were used for this study to set the path for reliable outcome measures that will be used in a larger study that is planned to start soon. However, more outcome measures add also complexity to the data recollection and analysis process.
3. In comparison to similar studies that report music therapy or music and auditory stimulation on a few consecutive days, in this study a process-orientated research design with 2-4 interventions over the course of two weeks was used. The aim of our design was to stress the importance of staying close to the clinical practice and to follow infants and parents over a longer period of time. Since parents are going through a difficult time in the NICU with different emotional challenges at different points during hospitalization, a therapeutic relationship needs to be established between the parents and the music therapist. Nevertheless, this design is also more complicated in practical terms. In the specific clinical environment of this pilot study, stable babies with enough weight are normally sent home between the 34th and 35th week of gestation, some even before reaching 34 weeks. This means that the time frame to work with stable babies is relatively short.
4. It was intended to integrate both parents to the therapy process. This means that in IG1 in some sessions the music therapist worked just with the mother, other sessions began with the father and the mother joined the session later on, or the session began with the mother and father simultaneously. This could have been a confounding factor in the data analysis.
5. To have a simultaneous intervention group and control group seems to not be the best option for the structure of this specific NICU. Since the units consist of just one room, it was not possible to assure that babies and/or parents of the control group were not affected by the music therapy sessions that took place at the unit.
6. In-depth interviews would have certainly been the preferred instrument for collecting the qualitative data, but were in this case not possible due to the limited time resources of the parents.
7. There are inherent challenges of the clinical and cultural environment in which the study took place. The music therapist researcher was trained in Austria and the USA and living in Colombia, therefore there were many cultural differences to adjust to. These included issues such as time perception, the hospital infrastructure, the environment, different musical styles, and language for example. Also, music therapy is still not fully recognized in Colombia and impedes the growth of the services outside this research project. However, there are also advantages that may be attributed to the specific cultural setting: people in Colombia are generally very open for engaging in all kinds of relationships and the caregivers seemed to be very grateful for any kind of intervention that potentially could benefit their babies. Since most of the participating parents come from poor to very poor neighbourhoods of Bogotá, services like music therapy are normally out of reach for this population and the participants may have been especially grateful in this sense.

This study suggests that the use of music therapy in a NICU is beneficial for both the parents and their babies. Music therapy can help babies and caregivers to relax, strengthen their relationship and offers a soothing environment, which may help babies to optimize their self-regulation capacities. It is the first study in this field carried out in Colombia, Latin America, and responds to

the need for more cross-cultural investigations in this area. Further qualitative or mixed-methods research needs to be done in this field to better understand how and why music therapy can be favourable in the NICU. The complexity and challenges of introducing music therapy as a new therapy in the NICU needs to be emphasized and a culture-sensitive approach (e.g. Gilad & Arnon, 2010) is of utmost importance. The specific cultural setting clearly influences how research and clinical practice are performed and these factors need to be taken into account to make an impact on treatments in this field.

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Notes

[1]Approval for naming the research institution was given by the hospital's ethical review board.

[2] Kangaroo Care is a technique in which the baby is put upright on the chest of the caregiver providing skin-to-skin contact.

[3] With gratitude to Nti Audio AG, Im alten Riet 102, 9494 Schaan, Liechtenstein.

[4] dB(A): a specific decibel scale that suppresses low frequencies and simulates human auditory functioning (Chen et al., 2009).

[5] This Colombian adaption of the STAI-C was validated for school children between 8-15 years (Castrillón Moreno & Borrero Copete, 2005). It was assumed that this version could be appropriate for this study population because of the shorter length compared to the original (18 instead of 40 items) and due to the fact that many of the participating parents were still adolescents going to school.

[6] The MIBS was initially derived from a group of mentally impaired postpartum women (Van Bussel et al., 2010), but was recently applied to mothers of preterm infants in the NICU (Bienfait et al., 2011). The attempt of using the MIBS in the current study was to detect how mothers´ feelings towards their baby might change with or without music therapy rather than measuring attachment alone, which is a far more complex process. However, since early separation of the child from his or her attachment figure is an important aspect of attachment formation (Bowlby, 1988), and implicit in the hospitalization of preterm infants, attachment theory is considered to be relevant for the work in this field. In this sense, the results obtained with the MIBS in this study are in line with the findings from Korja et al. (2009), who suggest no substantial differences in attachment patterns of mothers with a preterm or term infant.

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