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a mixed methods study

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**A FAMILY TUNE: MUSIC THERAPY WITH
PRETERM INFANTS AND THEIR PARENTS
IN THE NEONATAL INTENSIVE CARE UNIT**

A MIXED METHODS STUDY

**BY
DANA YAKOBSON**

DISSERTATION SUBMITTED 2021



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AALBORG UNIVERSITY
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CV

Dana Yakobson was born in Tel-Aviv, Israel in 1986, and lives in Tel Aviv with her husband and their daughter. Coming from an artsy family of music and dance teachers she studied piano and ballet from an early age and became a teacher for voice development and singing. Being a curious social creature, she earned her BA in social work in 2010 and practiced in an adult mental health rehabilitation service. In parallel, she led music and movement classes for children and adults in special education. The love for music has guided her wish to work with this media in a defined therapeutic setting. From there, the path to studying music therapy (MT) was established. She graduated from the University of Haifa, Israel with a master's degree in MT in 2013 with the highest honors certificate. Following the MA studies, she was accepted for a year of research fellowship at the "Louis Armstrong center for music and medicine" in NYC, USA, where she practiced as a music therapist with oncologic and palliative patients and completed her training as a grandparent of the "First Sounds: Rhythm, Breath and lullaby" model (RBL) for neonatal MT services. Since then, she returned to Israel and initiated a collaboration with a neonatal intensive care unit (NICU), introducing and implementing MT services in an Israeli NICU for the first time. This initiative was accepted as her PhD project at Aalborg University in August 2016.

She has trained several students in the RBL model, currently leads the MT program at the NICU of "Meir" medical center in Kfar Saba, Israel, and aims to assist in the dissemination of MT in other Israeli NICUs. In her clinical and research activities, she has mainly focused on preterm infants and their parents, and children diagnosed with autistic spectrum disorder.

Her other interests in life include teaching and practicing Yoga, traveling, and spending time with dear friends and family.

ENGLISH SUMMARY

This PhD project set out to examine the effects and experiences of music therapy (MT) with preterm infants and their parents during their admission period to the neonatal intensive care unit (NICU). Current research has demonstrated varied beneficial effects of MT on improved physiological parameters and feeding abilities in preterm infants and their mothers' anxiety reduction. In the last decade, there has been a blossoming of MT studies that promotes the family-centered care approach and highlights the importance of supporting parents as leaders of the intervention, using live and attuned music interventions. However, the need to present rigorous randomized controlled trials of neonatal MT studies, including fathers, longer-term examinations, and applying sensitive physiological outcomes is still called for. In parallel, qualitative explorations of parents' experiences of MT with their infants are relatively new and scarce.

The current quantitative driven mixed methods study aimed to answer the need to present an objectivist study measuring the effects of MT for preterm infants and their parents to further support the dissemination of MT as part of the standard developmental care of preterm infants and their parents. Another aim was to provide first-hand knowledge of parents' experiences and to describe the mechanisms of the specific MT intervention.

The quantitative examination included a cluster-randomized control trial (c-RCT) with 68 infants and their parents. The families participated in two sessions in the NICU and a three-month follow-up session at home. The primary outcome focused on preterm infants' autonomic nervous system (ANS) stability during combined family-centered MT and skin-to-skin care (SSC), compared to SSC alone. The ANS activity in preterm infants was indicated by spectral analysis of their heart rate variability (HRV) power, and specifically focused on the change in the high frequency (HF) power of the HRV. HRV analysis is a useful non-invasive procedure that provides information on the activity of the parasympathetic and sympathetic branches of the ANS, thus indicating stress and rest states. Secondary outcomes

included other HRV indices of low frequency (LF) and the LF/HF ratio during sessions, physiological vital signs, and behavioral state evaluation. Parental outcomes included state-anxiety and attachment-to-infant evaluations. The qualitative inquiry focused on parents' experiences of the MT intervention, and their perceptions of the c-RCT methodology.

Results from the statistical analysis of infants' measurements during sessions demonstrated a significant beneficial effect of MT as compared to SSC alone in the improvement of preterm infants' ANS stability. Parental outcomes did not yield significant group differences.

The qualitative study contained a thematic analysis of nine interviews with parents. The findings suggested that parents experienced MT as an activity that provided a special connection between parents and infants during the NICU period. MT sessions promoted relaxation in both parents and their infant facilitated states of intimacy and focus in the here-and-now, which further assisted them to connect with their babies. A flexible approach to the MT intervention allowed for transition between active and receptive participation and assisted in supporting parents' musical engagement and continuous participation in the intervention and the study.

Overall, this PhD may contribute to the evidence-based literature and clinical practice of MT in neonatal care by the provision of a detailed c-RCT protocol which yielded significant statistical results, in combination with a qualitative study that provided a deep understanding of parents' experiences of MT with their preterm infant.

DANSK RESUME

Dette PhD-projekt blev iværksat for at undersøge effekter og oplevelser af musikterapi (MT) med for tidligt fødte spædbørn og deres forældre i løbet af deres indlæggelsesperiode på en neonatal intensivafdeling (NICU). Aktuell forskning har vist forskellige gavnlige virkninger af MT i forhold til forbedring af fysiologiske parametre og optagelse af føde hos præmature spædbørn samt i forhold til angstreduktion hos deres mødre. I det sidste årti har der været en opblomstring af MT-undersøgelser, der fremmer den familiecentrerede tilgang, og disse fremhæver vigtigheden af at støtte forældrene som ledere af musikterapien gennem brug af levende musik og attunement i forhold til forældrenes og spædbarnets behov. Behovet for at præsentere kvalificerede randomiserede kontrollerede neonatale MT-undersøgelser, som inkluderer fædre, længerevarende undersøgelser og anvendelse af mere sensitive fysiologiske resultater, er imidlertid stadig aktuelt. Parallelt hermed er kvalitative undersøgelser af forældres oplevelser af MT med deres spædbørn relativt få og nye.

Denne kvantitativt drevne mixed methods undersøgelse havde til formål at præsentere en objektivistisk undersøgelse, der måler effekter af MT hos for tidligt fødte spædbørn og deres forældre for yderligere at understøtte implementeringen af MT som en del af den standardiserede behandling til præmature spædbørn og deres forældre. Et andet formål var at skabe førstehåndsviden om forældrenes oplevelser af musikterapi, og at beskrive mekanismerne i den specifikke MT-intervention.

Den kvantitative undersøgelse omfattede et cluster-randomiseret kontrolleret forsøg (c-RCT) med 68 spædbørn og deres forældre. Familieme deltog i to sessioner i NICU'en og en opfølgningssession i hjemmet efter tre måneder. Undersøgelsen fokuserede på at stabilisere for tidligt fødte spædbørns autonome nervesystem (ANS) under en kombination af familie-centreret MT og skin-to-skin care (SSC) sammenlignet med SSC alene. Der blev målt på spædbørnenes heart rate variability (HRV) under alle sessioner, og forskellen på High Frequency power (HF) i begyndelsen og slutningen af anden session var det primære outcome mål. Sekundære mål var LF og HF/LF ratio, samt observationer af vitale tegn hos børnene ifølge NIDCAP protokollen. Hos forældrene blev der målt på angst (Spielbergers State

anxiety) før og efter hver session, og på tilknytning til spædbarnet (Condon og Corkindales Maternal Postnatal Attachment Scale) før og efter interventionen. Den kvalitative undersøgelse fokuserede på forældrenes oplevelser af MT-interventionen og deres opfattelse af c-RCT-metodikken.

Resultater fra den statistiske analyse af målinger på spædbørns HRV under sessionerne viste en signifikant gavnlige effekt af MT sammenlignet med SSC alene i forhold til forbedringen af HF i løbet af anden session. Målinger på forældrenes angst og tilknytning viste ikke signifikante gruppeforskelle. Den kvalitative undersøgelse indeholdt en tematisk analyse af ni interviews med forældre.

Resultaterne antydede, at forældre oplevede MT som en aktivitet, der skabte en særlig forbindelse mellem forældre og spædbørn i NICU-perioden. MT-sessionerne fremmede afslapning hos både forældre og deres spædbørn, skabte intime mødeøjeblikke og fokus på nuet, hvilket hjalp forældrene med at etablere en dybere kontakt med deres babyer. En fleksibel tilgang til MT-interventionen gav mulighed for overgang mellem aktiv og receptiv deltagelse og hjalp med at støtte forældrenes musikalske engagement og kontinuerlige deltagelse i interventionen og undersøgelsen.

Samlet set kan denne PhD bidrage til den evidensbaserede litteratur og kliniske praksis indenfor MT i neonatal pleje og behandling gennem at levere en detaljeret c-RCT-protokol, der udmøntede sig i signifikante statistiske resultater, i kombination med en kvalitativ undersøgelse, der gav en dyb forståelse af forældrenes oplevelser af MT med deres præmature spædbarn.

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An ancient African proverb says that "It takes a village to raise a child". Well, I feel that this idea may reflect the intense journey of this PhD study. I have been fortunate to have met and be supported by many people along the way and would like to express my gratitude for their contribution.

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dietitian, Liat Avraham the physiotherapist, all the amazing nurses and doctors, you all have welcomed me in so warmly, made me feel a part of the staff long before my role was officially granted. Thank you.

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LIST OF PHD PUBLICATIONS

Article 1:

Yakobson, D., Arnon, S., Gold, C., Elefant, C., Litmanovitz, I., & Beck, B.D. (2020). Music Therapy for Preterm Infants and Their Parents: A Cluster-Randomized Controlled Trial Protocol. *Journal of Music Therapy*, 57 (2), pp. 219–242.

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Article 2:

Yakobson, D., Gold, C., Beck, B.D, Elefant, C., Bauer Rossak, S. & Arnon, S. (2021). Music therapy improves autonomic stability in preterm infants: A randomized controlled trial. Manuscript ready for submission.

Article 3:

Yakobson, D., Elefant, C., Lindeman, L. & Beck, B.D. (2021). Together in the music - Parents' reflections on participating in a family-centered music therapy intervention with their preterm infant in the NICU. Manuscript ready for submission.

CHAPTER ONE: INTRODUCTION

Great advances in perinatal care and the medical care of preterm infants in the last decades have significantly improved preterm infants' survival rates in high-income countries (Murphy et al., 2017). Yet, preterm birth rates continue to arise worldwide and constitute the leading cause of death in children under five years of age. This growing global concern was estimated in 2014 with 15 million babies that are born prematurely each year (i.e., one out of each ten newborns) (Chawanpaiboon et al., 2019). These infants are at high risk of short- and long-term morbidities and disabilities related to neurodevelopment, learning, hearing and visual disorders, and psycho-emotional development (Harrison & Goldenberg, 2016; WHO, 2016). In parallel, parents of preterm infants are prone to experience high levels of emotional distress, anxiety, depression, and sleep problems, which may result in acute stress disorder or post-traumatic stress disorder (Gooding & Trainor, 2018). Due to the critical medical care, preterm infants are physically separated from their parents from the moment of birth and are treated in the Neonatal Intensive Care Unit (NICU), a high-tech medical environment that often challenges their un-developed nervous system with various external stimuli and repeated painful medical procedures (Pineda et al., 2017). Accordingly, parents have limited opportunities to touch and actively perform the caregiving tasks, while witnessing their infant's medical course along the NICU hospitalization. This complicated state further stresses their ability to construct intimacy and focus on the parent-infant bond, thus posing another risk for their attachment process (Ettenberger et al., 2021; Ghetti et al., 2021).

The challenges inherited in the medical care of preterm infants have brought to the emergence of various developmental care and family integrated care modalities that aim to address infants' needs of sensory regulation, parents' inclusion in their ongoing medical care, and the warranted emotional support for the premature family. Leading models in the field such as the "Newborn Individualized Developmental Care and Assessment Program" (NIDCAP) (Als, 1979; Als, 2009; Als & McAnulty, 2011; McAnulty et al., 2009;

McAnulty et al., 2010) and the family integrated care model (Franck et al., 2020; Gómez-Cantarino et al., 2020; O'Brien et al., 2015, 2018) have inspired neonatal care worldwide. Accordingly, the importance of applying medical pediatric care through the family-centered approach was supported by the American Academy of Pediatrics (“Patient- and Family-Centered Care and the Pediatrician's Role,” 2012), and other healthcare institutions (Craig et al., 2015). These models and other developmental and sensory-based interventions for preterm infants and/or their parents in the NICU will be further elaborated on in chapter two.

Among the auditory interventions designed for preterm infants and later also their parents, music therapy (MT) has gradually evolved in the last decades into an evidence-based treatment modality in neonatal care (Bieleninik et al., 2016; Foroushani et al., 2020; Haslbeck, 2012; Standley, 2002; 2012). MT services in the NICU are characterized by the professional adaptation of musical activities including singing, playing, and listening to live or recorded music. Such interventions aim to address the complex needs of preterm infants' sensory regulation, parents' emotional wellbeing, and support of the developing parent-infant relationship (Yakobson et al., 2020). The theoretical paradigm shift within neonatal care emphasizing the importance of treating preterm infants and their parents within a family-centered care approach (Hutchfield, 1999) were reflected in the practical and theoretical development within MT as well (Ettenberger et al., 2017; Ghetti et al., 2019; Haslbeck et al., 2020; Loewy et al., 2013; Shoemark, 2017; Standley & Gutierrez, 2020).

Varied meta-analyses and systematic reviews on MT and music intervention studies for preterm infants demonstrated beneficial effects across a variety of infants' physiological and developmental outcomes (Anderson & Patel, 2018; Bieleninik et al., 2016; Foroushani et al., 2020; Standley, 2002; 2012; Yue et al., 2020). However, the studies included in those reviews presented a wide heterogeneity of outcomes, participants, methodological approaches, types of music interventions, and a range of multi-disciplinary professionals who implemented the interventions and study designs. Accordingly, the varied reviews repeated similar conclusions that called for parents' (and specifically fathers) inclusion in studies, clarity of intervention

procedures, protocol design, and appliance by a certified NICU music therapist, report of long-term outcomes, and rigorous randomized controlled trial (RCT) design.

1.1. THE CONTEXT FOR THE PhD PROJECT INITIATIVE

The motivation to perform the current research project was derived from personal, national, and global considerations. In late 2015, I returned home to Israel after a year of research fellowship in the "Louis Armstrong center for music and medicine" in "Mount Sinai Beth Israel" medical center in New York, USA. During that year I completed the training in the "First sounds: rhythm, breath, and lullaby" model (Loewy et al., 2013), a veteran model for the appliance of MT with preterm infants and their parents in the NICU. In my experience, this unique method offered infants and their parents a simple way to be together, to co-regulate, relax, ventilate, and find joyful and encouraging experiences to better their emotional states and connectedness at such a harsh entry point to life and to becoming a family. I felt blessed to have had such a special experience as a music therapist and was eager to continue this work.

However, the state of medical MT in Israel was far behind. Among the different fields and populations in MT care, the medical field is less developed. Music therapist's positions in public hospitals are scarce and can be found mainly within pediatric care. Such positions are administered through the Israeli ministry of education (i.e., as part of the educational program for children admitted to pediatric units), and so do not include neonatal care, nor are they acknowledged by the Ministry of Health. In specialized medical institutes (such as rehabilitation facilities, psychiatric hospitals, dementia care, etc.) MT is much more common and, in some places, already a part of the standard para-medical care (Simchon, 2008). Still, there is a long way to go for the inclusion and implementation of MT in neonatal care in Israel.

This PhD was set out in the meeting point between the international state of MT in neonatal care – a growing evidence-based field requiring new rigorous RCTs, highlighting live, active interventions

within a family-centered approach (Bieleninik et al., 2016; Haslbeck, 2012); and the local state of neonatal MT in Israel – that was missing. Fortunately, there was one specific NICU that did investigate the use of music interventions and had already provided a few validated reports in the field (Arnon et al., 2006; 2014; Schlez et al., 2011). The senior neonatologist who led these investigations, Professor Shmuel Arnon, was also more than eager to introduce an informed MT program into the unit, and we estimated that research would be the best entry point to offer MT in the hospital. Furthermore, the NICU at "Meir" medical center in Israel, is one of the six training centers worldwide for the NIDCAP model. Accordingly, together with Professor Arnon, I aimed to conduct a well-designed RCT that would address the current gaps in research, and would also provide an MT intervention that might be incorporated as part of the developmental care in the unit, in line with the NIDCAP principles (Yakobson et al., 2020).

I hope this thesis will contribute to the evidence-based literature on MT for and with preterm infants and their parents by presenting a rigorous design with innovative outcome measures. Also, I hope to encourage and provide knowledge for young MT researchers on the various challenges and advances inherited in multi-disciplinary collaboration, and of research as a fundamental means for the implementation and development of MT programs in medical fields.

1.2. THE OVERALL STRUCTURE OF THE PhD THESIS

This PhD thesis presents a quantitative driven mixed-methods study, and is article-based, as per the updated requirements and structure of PhD studies in the Doctoral Program of Music Therapy at Aalborg University. It is composed of three articles concerning the core issues of the mixed methods study: 1. The quantitative study protocol, 2. The quantitative results paper, and 3. The qualitative inquiry of parents' reflections on their experience of music therapy.

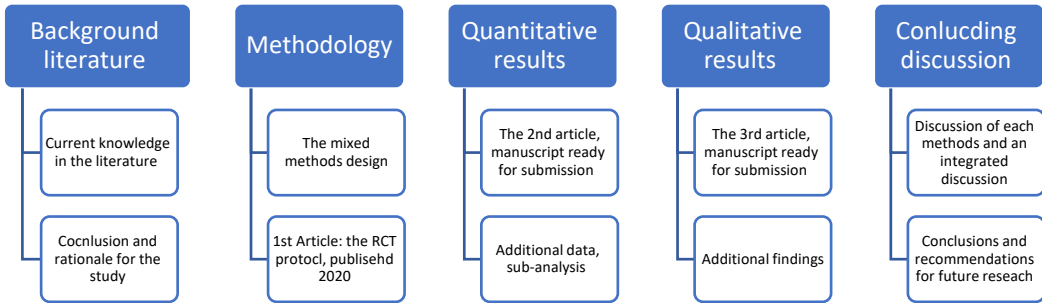
The linking text that binds the PhD together provides essential information that did not fit with the scope of the single articles yet is

fundamental for the generation of this thesis into one comprehensive whole.

The following chapters include Chapter two: Theoretical background literature for the study on the clinical and academic development of MT in the NICU, from which the current study aims, rationale, and questions were derived. Chapter three: The study's methods. Chapter four: The results of the RCT study, and additional sub-analysis of results that were not included in the article. These include preterm infants' physiological parameters and behavioral states during sessions. Chapter five: The results of the qualitative inquiry concerning parents' experiences of the MT intervention, and additional findings that discuss their reactions to the RCT methodology. And, Chapter six: A concluding discussion where the two parts of the mixed methods study are seen together. The discussion will be devoted to a reflexive inquiry and commentary of various issues of the study's conduct and results: Implementational considerations connected to research in "the real world", reflections on the study design and intervention, reflections on the dual role of researcher and clinician and an integrative summary.

The first article of this PhD project presents the protocol of the randomized controlled trial (RCT) and provides a detailed description of the rationale and aims of the music therapy (MT) intervention; the study design, procedures, and measurements. The second article is devoted to the results of the RCT, and the third article presents the qualitative investigation of parents' experiences from participating in the MT intervention. Figure 1 provides a graphic visualization of the papers and the linking materials. I recommend reading the linking text and the articles according to their order from left to right.

Figure 1: The linking text and the PhD articles relation



CHAPTER TWO: BACKGROUND LITERATURE

2.1. PREMATUREITY AND THE NEONATAL INTENSIVE CARE UNIT

Infants born before the completion of 37 weeks of pregnancy are defined as premature. Additional sub-classification is based on gestational age and includes extremely preterm (less than 28 weeks of gestation), very preterm (28 to 32 weeks), and moderate to late preterm (32 to 37 weeks) (World Health Organization, 2018). Preterm birth may occur spontaneously or as the result of early labor or cesarean birth induction. Spontaneous preterm labor is considered a syndrome derived from multiple causes such as infection or inflammation, vascular disease, hemorrhage, uterine overdistension, stress, and additional immunologically mediated processes. Induction of preterm birth may also occur due to varied maternal or fetal indications, including eclampsia and pre-eclampsia, intrauterine growth restriction, chronic diseases such as diabetes and high blood pressure, and multiple pregnancies. Nevertheless, often a specific mechanism or cause cannot be identified (Goldenberg et al., 2008; WHO, 2018).

Preterm infants are at high risk of mortality, and several severe conditions related to the preterm birth or the prematurity of body systems and organs that harness their development can be present. Dependent on their gestational age, preterm infants may face major to minor morbidities including neurological impairments, lung and heart disorders, intestinal diseases, visual and hearing deficits, and sepsis (Manuck et al., 2016; Patel, 2016). A lower gestational age is associated with an increase in major neonatal morbidities, and higher gestational age with less frequent, minor morbidities and length of hospitalization (Manuck et al., 2016). Their medical intensive care is critical and often followed by repeated invasive and painful procedures (Montirosso et al., 2017). In the Neonatal Intensive Care Unit (NICU), infants undergo approximately fourteen painful procedures each day for various causes (Williams & Lascelles, 2020). Common procedures compile diagnostical ones such as repetitive heel stick and eye exams, supportive treatments of mechanical ventilation or central line insertion, nursery routine of diaper and clothes change,

surgical acts such as anomaly repairs or minimally invasive ones, and many more (Williams & Lascelles, 2020).

Such disruptive yet necessary procedures happen in a critical period of neurodevelopment when the infants' nervous system is highly vulnerable due to immaturity and neuroplasticity and by so, possess multiple negative potential long-term effects (Gui et al., 2019). A recent meta-analysis and systematic review (Allotey et al., 2018), included more than 60,000 children born premature demonstrated poor results across various outcomes, compared to term-newborns. Children born preterm had lower cognitive scores for full-scale IQ tests (standardized mean difference: = 0.70; 95% CI: -0.73 to -0.66), lower scores in motor skills, behavior, reading, spelling, and mathematics. These observed scores at primary school persisted to secondary school age (except for mathematics). An ADHD diagnosis was doubled in preterm infants, with a differential effect observed according to the severity of prematurity. Gestational age at birth accounted for 38–48% of the observed IQ variance. Another meta-analysis (Arpi et al., 2019), demonstrated similar results in children born preterm and compared to full-term at ages three and five years. Children born preterm demonstrated worse IQ mean score ($d = -0.77$ [95% CI -0.88 to -0.66]), attention, memory, visuomotor integration skill and executive functions.

Early pain experiences is another important factor that may influence the somatosensory scaffolding of later perceptual, cognitive, and social development, pharmacological needs, chronic pain responses, and health states (Maitre et al., 2017; Williams & Lascelles, 2020). For example, a study that examined 50 children born prematurely reported that repetition of painful invasive procedure in the NICU was associated with a lower index of white matter maturation in the brain at seven years of age ($p=.01$), which also correlated with low IQ (Vinall et al., 2014).

Nevertheless, preterm infants' critical health conditions and intense care requirements are not the only significant stressors harshly influencing their overall developmental course along their NICU admission. Their development in the familiar, usually protective, utero environment is highly conflicted in their transition to the outside NICU. Due to the intensive care nature and requirements this medical

physical space exposes them to external stimuli such as strong bright lights, repeated machine noise, an excessive surrounding sound level, and sleep disruption (Montirosso et al., 2017). Consequently, preterm infants are at a constant struggle of overstimulation, that further challenges their undeveloped nervous system and their already fragile ability to recover and develop (Heidelise Als et al., 2004). The constant strive for homeostasis involving the "fight or flight" reactions may trigger a chronic stress state also described as allostatic load (Moore et al., 2014). Furthermore, reactions that lead to the overactivation of the sympathetic branch of the autonomic nervous system are often associated with developmental trauma, and may as well disrupt brain architecture and increase other potential stress-related diseases (McNeil, 2018; Smith et al., 2011). At last, and maybe above all, preterm infants must endure these numerous harsh conditions while being separated from their parents from the moment of birth.

2.2. STRESS AND TRAUMA IN PREMATURE PARENTS

Parents of preterm infants are often affected by the complex consequences of the stressful birth, their newborn's critical health state, and the stressful NICU environment. They must bear the existential risk for their baby's life and health, while having limited opportunities to help them in the process, as the intense care inevitably relies on the medical staff and procedures (Flacking et al., 2012, 2016). Preterm infants' appearance may be overwhelming, and their behavior (i.e., movement, facial expressions) may be hard to interpret or relate to. Dependent on their gestational age, and especially at first, they may be perceived more as a fetus than a baby (Green et al., 2015). They may be connected to several monitor cables and/or life-support machines. These elements further increase parents' sense of separation, helplessness, worries, fear, and lack of confidence in the ability to safely touch and care, thus challenging the parental role (Flacking et al., 2012, 2016; Grosik et al., 2013; Lefkowitz et al., 2010). The NICU's physical space, often shared with other babies and parents, the external noxious stimuli around the clock, complex medical language, and interactions with changing medical staff may

also contribute to feelings of exhaustion and disorientation (Athanasopoulou & Fox, 2014; Treherne et al., 2017). And so, parents often experience significant stress levels, severe emotional reactions, and difficulties in interacting with their baby, partner, or medical staff (Ionio et al., 2016; Jiang et al., 2014).

The prevalence of these complex consequences was vastly emphasized in the literature. A systematic review of qualitative studies on parents' experiences during their infant's NICU stay (Al Maghaireh et al., 2016), thematically analyzed nine studies of parents' interviews and questionnaires. Parents reported on varied emotional reactions including sadness, grief, isolation, anticipation, loss of control, or loss of their baby to the NICU. The overarching themes of this review included the stress of hospitalization, alterations to the parenting role, and the impact of their infant's NICU admission on their psychological and emotional health, and disruptions in their parent-infant attachment process. Other qualitative reports revealed similar themes. The NICU period was described in parents' interviews as an 'emotional roller coaster' (Stacey et al., 2015), as their infants' wellbeing was an important predictor of their own wellbeing and coping process. The physical space and presence of other people or involvement of many others in the infant's care also challenged parental coping. In other interviews (Lundqvist et al., 2019). Mothers described physiological responses as a scaffold for feelings of existential loneliness and guilt, and the difficulty to be both mothers and intimate partners. Fathers also dealt with conflicts in managing their role in the family dynamics together with the attempt to maintain their job, which negatively influenced their transition into fatherhood. Both parents shared an ambivalent stance towards their relationship with medical staff.

Several quantitative studies reported on immediate, short, and long-term noxious effects in parents of preterm infants concerning posttraumatic stress, anxiety, depression, and quality of life (Amorim et al., 2018; Cook et al., 2018; Lefkowitz et al., 2010). Yaman & Altay (2015) examined post-traumatic stress experiences in 132 parents, using the Impact of Events Scale-Revised (IES-R), a tool aimed to assess stress reactions at the time of completion after a series of traumatic events (Sundin & Horowitz, 2002). Mothers had significantly higher stress levels than fathers ($p < 0.05$), yet the

majority in both genders (81.8% and 66.7%, respectively) experienced posttraumatic stress (PTS) ($p=0.001$). Another study demonstrated similar results in 323 mothers and 237 fathers during the NICU phase (Winter et al., 2018). Almost 50% of the mothers and 16.9% of fathers showed a moderate or high probability of depression, moderate to severe PTS symptoms (38.1% of mothers and 23.7% of fathers), and high relationship distress (above 20%) in both genders, measured by the relationship quality index (RQI)(Norton, 1983). Depression was further associated with having older children, financial stress, a recent referral to mental health services, and severe PTS symptoms. A higher degree of relationship distress increased the likelihood of depression or PTS symptoms.

Recently, a group of researchers have presented the first, long-term examination on the effects of prematurity on parental wellbeing, and provided several meaningful reports (Barthel et al., 2020). A controlled multicenter cohort study followed 230 families (230 mothers and 173 fathers) of Very Low Birth Weight (VLBW) preterm infants and term infants, from the postpartum period until school age, and tested them at six-time points (Helle et al., 2018). Compared to term-mothers, mothers of preterm infants had significantly higher levels of Postpartum Posttraumatic Stress Symptoms (PTSS) in all dimensions (intrusions, avoidance, and hyperarousal), and had higher total scores of the Impact of Events scale (IES-R, $p<0.001$). The fathers of preterm infants also demonstrated significantly higher levels of postpartum PTSS in the avoidance and hyperarousal dimensions and the total IES-R score ($p=0.003$). Additional results of this study (Helle et al., 2015, 2016), reported that parents of the preterm group had significantly higher levels of state and trait anxiety and stress during birth. In the weeks after birth, mothers, and fathers of VLBW infants had a 29.1- and 20.6-times higher risk for a current adjustment disorder, and 7.1- and 2.9-times higher risk for minor and major anxiety symptoms, compared to parents of term infants. These mothers also had a 3.0-times higher risk for varied lifetime anxiety disorders (Helle et al., 2016). Furthermore, the risk for postnatal depression was 4 to 18 times higher in mothers and 3 to 9 times higher in fathers, compared to the term group (Helle et al., 2015). To conclude, parents of preterm infants may suffer from a wide range of

negative effects on their emotional and psychological wellbeing and may need preventive care, attention, and support.

2.2.1 PRETERM INFANT-PARENT RELATIONSHIP IN THE NICU

The process of parent-infant bonding, and attachment often begins before the baby is born, is gradually emphasized in the third trimester, and further develops after birth (Hall et al., 2015; Wigert et al., 2006). The natural course of a nine-month pregnancy, birth, and bonding at home is harshly interrupted in the preterm birth (Trumello et al., 2018). Communications and physical interactions between preterm infants and their parents are further challenged during the NICU period (Grosik et al., 2013). Likewise, special characteristics related to prematurity may influence the bonding and attachment process. Infants' social behavior and responsiveness may be stressed by physical and neurobehavioral sensitivity, and their parents' physical or emotional susceptibility may influence their resources to appropriately react or respond to their child (Fernández Medina et al., 2018). For example, early interactions will often require parents to take a more adaptive approach to compensate for their child's reduced responsivity. Parents may also fear or focus on their child's vulnerabilities or developmental delays (Ruiz et al., 2018).

Studies investigating the impact of prematurity on attachment and bonding have presented mixed results. A systematic review on early mother-infant relationships in the context of prematurity included 29 studies concerning maternal attachment, mother-preterm interaction, and infant attachment (Korja et al., 2012). Mothers of preterm infants, compared to full-term showed some differences in maternal interaction mostly in the first six months postpartum. These related to a more intrusive and controlling interaction during dyadic play. Similarly, the preterm infants were more passive and less alert during interactions in the first six months than full-term infants. Yet, an additional meta-analysis that focused on preterm infants' attachment concluded differently. Seven out of eight studies demonstrated equal or higher quality of preterm mother-infant interactions (64% pooled

proportion of secure attachment classification, comparable with 62% found in full-term infants).

Similar positive trends for parents of preterm infants were showed in a study that focused on parent-infant bonding (Hall et al., 2015). Mothers and fathers of 72 full-term infants, 69 moderate preterm infants, and 70 very preterm infants were compared. Emotional bonding was assessed by the Postpartum Bonding Questionnaire (PBQ) (Brockington et al., 2001) at one month and six months postpartum. Mothers in both preterm groups reported significantly higher feelings of bonding than mothers of full-term babies at the two-time points (PBQ1: $p=.01$, PBQ2: $p=.04$), with no differences between the preterm group's age classification. However, fathers of all groups did not show significant differences in PBQ scores, regardless of gestational age and time point.

In contrast, other studies reported on significant negative influences of prematurity on attachment and its link to an infant's development. Wolke et al. (2013), compared longitudinal data of 71 VLBW preterm infants and 105 full-term infants and their mothers. Infants' measures included twin status, distressing cry and cry duration at three months, and developmental delays at 18 months corrected age using the Bayley Scales of Infant Development (BSID II) (Bayley, 1993). Maternal sensitivity, meaning the ability to deduce the infant's signals and respond appropriately (Pederson et al., 1990), was assessed at term by neonatal nurses using the Boston City Hospital Assessment of Parental Sensitivity (BCHAPS) (Zahr & Cole, 1991). Mother-infant interaction was assessed at three months by trained researchers, and included a rating of maternal behaviors (including positive emotional expression, sensitivity, and stimulation level), through a scale adapted from the Emotional Availability Scales (Biringen, 1990); and the quality of interaction was rated using the Infant and Caregiver Engagement Phases (Weinberg & Tronick, 1996). Attachment security or disorganization was assessed at 18 months, using the Strange Situation Assessment (Ainsworth et al., 2015). Both groups demonstrated secure attachment (61% in preterm and 72% in full-term). However, higher rates of disorganized attachment were found in the preterm group (32%) than the full-term (17%). Preterm infants' distressing cries and developmental delay were associated with this

classification. Nonetheless, maternal sensitivity was predictive of disorganized attachment only in the full-term group.

Similarly, Ruiz et al. (2018) compared 290 preterm and full-term infants and their parents. Outcome measures included the quality of attachment using the Attachment Q-Sort (AQS) instrument (Waters, 1995), and child development by the BSID III (Albers & Grieve, 2007). Secure attachment was significantly higher ($p < .001$) in parents of full-term infants than in the preterm group. Correlations between low attachment scores and child development were significant only for fathers of preterm infants. In this sub-group, the link between less parental education, infant's male gender, and low development score was strongly associated with lower attachment scores ($p < .001$). Another recent study investigated the link between prematurity indexes and reactive attachment disorder (Upadhyaya et al., 2020). The study included 614 cases of children diagnosed with reactive attachment disorder and 2423 controls. A test validation of the diagnosis was performed for 40 children. Results reported on associations between low gestational age (< 32 weeks) ($p = .003$), low birthweight (< 2500 grams) ($p = .01$), and NICU hospitalization ($p = .01$) as significant risk factors for reactive attachment disorder diagnosis.

These inconclusive findings may correspond to the complexity of prematurity, reflected in both infants' and their parents' varied difficulties and needs. Infants' relationship with their parents forms the foundation for their social and emotional development (Ballantyne et al., 2017). Accordingly, encouraging and supporting parent-infant interactions are essential for their developing relationship (Jiang et al., 2014). Parents' support or unaddressed needs are crucial influencers in this process. Hence, without a supportive and nurturing environment preterm infants' physical, cognitive and socio-emotional development may be harmed (Als, 2009; Browne, 2021).

2.3. DEVELOPMENTAL CARE FOR PRETERM INFANTS AND THEIR PARENTS

The last decades have brought about the emergence of varied developmental and family-centered interventions and methodological approaches aimed to address the complex needs of preterm infants and their parents during the NICU period. A growing body of literature emphasizes how attending to infants' sensorial and developmental needs and inclusion of parents in the routine care of their infant are essential for infants' mental health, physical and cognitive development, as well as for parents' mental health and their bonding processes (Heidelise Als et al., 2004; Ballantyne et al., 2017; Browne, 2021; Ding et al., 2019; Gómez-Cantarino et al., 2020; Soleimani et al., 2020; Steinhardt et al., 2015). Parental reports on the matter revealed corresponding stances. In an interview study with 18 families (Wigert et al., 2014), parents of preterm infants emphasized that the inclusion in their infants' care and the communications with medical staff were primary impactors for their self-management during the NICU hospitalization. Similarly, in a survey including 141 parents (Ottosson & Lantz, 2017) parents' perceptions of participation were characterized by their interactions with the medical team and ability to nurse their baby. A qualitative thematic inquiry formed five essential themes that enhanced the "pathways for emotional closeness" (Flacking et al., 2016, p. 3) for parents and their preterm infants. These include parents' support (training and developmental education), inclusion in their infants' everyday care, physical bonding and time spent together as family, reassurance, and education on infant health.

The "Newborn Individualized Developmental Care and Assessment Program" (NIDCAP) is considered a leading methodological approach in the field. It was initiated three decades ago by Professor Heidelise Als, based on her "Synactive theory of development" (Als, 2009a; Als et al., 1986, 2003; Als & Duffy, 1983). The theory describes how preterm infants initially communicate through their behavior. Their development is an interactive process involving the main body systems - autonomic, motor, and state system (indicating the infant's neurobehavioral development and ability to respond to the

environment), with emphasis on the emanating attention system; and the regulatory (or 'self-regulation') system (Maltese et al., 2017). Each system provides specific behavioral communication signals such as breathing patterns or color fluctuations derived from the autonomic system; muscle tones and posture in the motor system; and a range of states such as sleep, wakefulness, or aroused-upset that reflect levels of arousal and awareness in the state system. The regulatory system is reflected in infants' efforts and success in re-regulation of the other sub-systems. Observation of the fine signals, infants 'behavioral language', offers a method to view infants' competencies, and provide appropriate support according to their developmental status and needs (Als, 2009b). Furthermore, the integration of the main autonomic, motor and state systems enables infants' alertness to single sensory inputs. Later on, in their development, it will be reflected in the ability to react and use social cues and prolonged attention, and to gradually use vocalization, social seeking, and participation. These actions form the fundamentals of social-emotional development (Als, 1979). Accordingly, infants' neurobehavioral development is considered to be enhanced by nurturing and social learning, experiences, and environment (Browne, 2021).

The NIDCAP model derives from a relationship-based, family-centered approach, with a highly regarded set of guidelines for a developmental medical treatment of preterm infants and their parents. It aims to reduce and regulate environmental stress, to contribute to infants' maturation and neural-behavioral development, to support parents in understanding their infant's behavior, and to promote their initial bonding (Als, 2009; Als & Gilkerson, 1997; Als et al., 1994; Als & McAnulty, 2011). The model is a set of practices where specially trained infant developmental specialists and NICU staff repeatedly assess the preterm infant's developmental status and ability to withstand stress in the NICU before, during, and after caregiving procedures using specific validated observational scales. Based on this assessment, an individualized plan of care is proposed, typically limiting untimely stimuli, protecting sleep, and fostering developmentally appropriate, family-centered interactions with carefully supported parents (Als, 2009). NIDCAP is an evidence-based system applicable to all infants and is especially powerful with very low- and extremely low-birthweight preterm infants (Lawhon et

al., 2013). NIDCAP's beneficial effects on short and long term outcomes of infants' cognitive, motor, and emotional development were described through numerous studies (Als et al., 2003, 2004; McAnulty et al., 2009; Ohlsson et al., 2013; Peters et al., 2009; Westrup, 2007). Hundreds of NICU professionals around the globe were educated in the NIDCAP model, and it now evolved into an international federation with 21 certified training centers worldwide.

Another example of a leading modality in the field was presented by the family integrated care model, initiated through a collaboration of neonatologists, nurses, veteran parents of preterm infants, and other NICU health professionals, developed at "Mount Sinai" hospital in Toronto, Canada in the last two decades. This model, based on the family-centered care approach, aims to facilitate deep partnerships with parents and the medical team during the NICU admission of their infants. This is done by information sharing, education, and involving parents in all possible aspects of their infant's care, collaborative decision-making, and including parents in medical rounds (Lee & O'Brien, 2014; O'Brien et al., 2015). The family integrated care model was tested in several large-scale trials and demonstrated beneficial effects for infants' improved weight gain, reduction of parental stress, and anxiety, and increased high-frequency exclusive breastmilk feeding at discharge (Cheng et al., 2019; Ding et al., 2019; He et al., 2018; Jiang et al., 2014; O'Brien et al., 2018).

A variety of other non-pharmacological strategies to promote developmental care were further implemented in NICUs worldwide. In 2005 the European Research Network on Early Developmental Care (European Science Foundation), proposed eight universal principles of infants' and family-centered care in the NICU. These principles were recently reviewed by a European expert group (Roué et al., 2017), and include: Allowing 24 hours of parental access; psychological support for parents; infants' pain management plan; controlling for a supportive NICU environment; postural support for infants; supporting skin to skin care, lactation and breastfeeding; and infants' sleep protection.

Specific parental support programs may include developmental care education, parent-to-parent interactions, and support groups, psychological support, communities of support by veterans parents of

preterm infants, journaling, and scrapbooking (Huenink & Porterfield, 2017; Jiang et al., 2014).

An integrative review of sensory-based interventions for very preterm infants in the NICU included 88 studies from the last 20 years (Pineda et al., 2017). The review presented a variety of tactile interventions such as gentle human touch, massage, and skin-to-skin care; visual interventions of cycled lights in the NICU space; physical therapy; olfactory and gustatory interventions, and vestibular stimulation; multimodal (sensorial) interventions; and several auditory interventions of live and recorded music therapy and music based-interventions, maternal voice and recorded maternal biological sounds. Results of this review reported on several beneficial effects related to infants' developmental outcomes and maternal stress reduction for skin-to-skin care, music and language exposure, and multimodal interventions involving combined sensorial interventions such as tactile and auditory together.

2.3.1. SKIN TO SKIN CARE

Skin to Skin Care (SSC), also known as Kangaroo mother care, is a fundamental intervention in developmental care worldwide. It has an essential role in the NIDCAP's comprehensive approach (Heidelise Als & McAnulty, 2011). SSC is a holding position, where the parent holds the infant up right, with chest-to-chest in skin-to-skin contact. In SSC, parents serve as a live incubator as their body temperature assists their infant to maintain and regulate their body temperature (Bergman et al., 2010). This nursing modality was developed in Bogota, Colombia in 1978 due to overcrowding and lack of sufficient medical resources in NICUs, which affected high mortality and morbidity rates in low-birthweight infants (Charpak et al., 2005). A compelling body of literature including the World Health Organization (WHO, 1997; 2003) supports the practice of SSC in stable infants over the age of 28 weeks, irrespective of financial setting or geographical location (Altimier & Phillips, 2018; Boundy et al., 2016; Campbell-Yeo et al., 2015; Hubbard & Gattman, 2017; Jefferies & Canadian Paediatric Society, 2012; Nyqvist et al., 2010).

The varied benefits followed by SSC include the enhancement of autonomic nervous system development, maintenance of infants' physiological stability, and increase of immunity (Butruille et al., 2017; Feldman & Eidelman, 2003). Further benefits are optimization of breastfeeding (Ruxer et al., 2015), facilitation of the parent-infant bonding (Tessier et al., 1998), and mitigation of infants' traumatic experiences in the NICU associated with stress and pain responses (Eliades, 2018; Feldman et al., 2014). A Cochrane review of SSC and neonatal outcomes included 21 randomized controlled trials (RCTs) (n=3042 infants) and presented consistent beneficial effects across a variety of outcomes (Conde-Agudelo & Díaz-Rossello, 2016). Compared to conventional neonatal care, SSC was found to reduce mortality in low-birth-weight infants at discharge or 40 to 41 weeks postmenstrual age and to reduce common morbidities derived from premature birth. Furthermore, SSC significantly contributed to increased weight, length, and head circumference gain, and breastfeeding at discharge as well as at 40 to 41 weeks postmenstrual age and one to three months follow-up. Additionally, an increase in mothers' satisfaction with infants' care and measures of mother-infant attachment were reported. Another Cochrane review (C. Johnston et al., 2017) included 25 RCTs (n=2011 infants). It emphasized a significant contribution of SSC to pain reduction in neonates during varied medical procedures. This review and another recent study (Shukla et al., 2021) also tested for differences between mothers' and fathers' provision of SSC. No significant differences were found, and SSC with fathers was found effective for neonatal pain control as well as with mothers.

2.4. MUSIC THERAPY SERVICES IN THE NICU

2.4.1. MUSIC THERAPY FOR THE PRETERM INFANT

The fundamental understanding that infants long to hear their mothers' voice and are capable to learn and react to music in a form that enhances their neurological and socioemotional development may be considered as a cornerstone for the use of MT with preterm infants

(Gaden et al., 2021; Loewy & Jaschke, 2020). The auditory system in human fetuses and infants develops early, and in sequence to the development of the other sensorial system (i.e., kinesthetic, proprioceptive olfactory, gustatory, etc.). The anatomical or structural parts of the ear are functional by 20 weeks of gestation, as the entire auditory system gets functional around 25 weeks of gestation. At this stage, a loud noise in the womb or outside NICU may lead to disruptions in the autonomic system's functionality, affecting the heart and respiratory rates, oxygen saturation, and gastrointestinal movements (Graven & Browne, 2008). Fetuses are capable of in-uterus learning of the maternal voice, simple music, or common environmental sounds. A developing neonate can hear their mother's heartbeat as early as 16 weeks (Hepper & Shahidullah, 1994), and develops higher-order auditory perception before birth (Kisilevsky et al., 2004). Infants can recognize, often prefer, and may be soothed by the familiar maternal voice from the moment of birth (DeCasper & Fifer, 1980). Trehub (2010), further explains that infants are born "*music listeners*", and display adult-like abilities that are related to musical perception. They are sensitive to melodic contours, simple frequency ratio, and some harmony elements. Professor Colwyn Trevarthen and Professor Stephen Malloch (2002) add that even the tiniest babies in the NICU are capable of learning and enjoying comforting music that is adapted to their state of arousal, especially when it is provided through intimate physical contact with their caregivers. In parallel, their parents can enjoy comforting them through and with music. According to Trevarthen & Malloch (2002) music thus can serve as an initial, basic pathway for communication and interaction for most human beings, regardless of age and language, and in a form that does not require high developmental skills. As postulated in their theory of 'communicative musicality', from the very beginning, infant-parent dyads communicate in a non-verbal musical form. Their early dialogs compile essential musical components of reciprocal coordination of melodic, timbral, and rhythmic elements, defined as 'communicative musicality' (Malloch & Trevarthen, 2009).

Jane Standley (2012), a pioneer NICU music therapist and researcher, therefore, argued that music is an intentional, preferred auditory stimulus, possessing great potential for soothing, learning, and

neurologic development that is perceived early in fetal development (Standley, 2012). Since various cognitive elements of music are processed simultaneously or in sequence by both cerebral hemispheres, music may enable neurologic development stimulation (Graven & Browne, 2008).

2.4.2. THEORETICAL AND CLINICAL PRACTICE DEVELOPEMNT

Music therapy (MT) and music interventions in the NICU have been recorded in professional literature worldwide since the 1970s and varied methodological approaches have been presented. In general, MT services in the NICU aim to assist both infants and their parents by promoting sensory regulation, stress reduction, and facilitation of meaningful parent-infant interactions. MT interventions in the NICU may involve receptive listening to live or recorded music, or active musical engagements with the preterm infant and/or their parents. Essential elements include improvised, entrained, and attuned musical activities that aim to correspond to the infant's current needs and communicational signals (Bieleninik et al., 2016; Haslbeck, 2012; Haslbeck & Hugoson, 2017; Loewy et al., 2013; Shoemark et al., 2015; Standley & Gutierrez, 2020). Entrainment is broadly defined as A "phenomenon in which two or more independent rhythmic processes synchronize with each other" (Clayton et al., 2004, p.3). Referring to its physical and rhythmical sense, Thaut et al. (2015) explained that in the process of entrainment, two (human) bodies that move independently in periodic or rhythmical cycles with different frequencies, come to share a common period through their interaction. Dimaio (2010) adds that during MT sessions, the therapist can synchronize the music to the patient's physical rhythms (such as breathing pulse), and gradually slow down the music to help the patient stabilize their own rhythm.

In music therapy, attunement refers to both musical and emotional aspects and is intended to "allow for moments of synchronization, to work on sensory integration and affect regulation, and to create moments of affective attunement, emotional sharing, and hence an emerging shared narrative" (Mössler et al., 2020, pp.3922). The

processes of entrainment and attunement in MT with preterm infants and their parents may be viewed in multiple forms. The music therapist aims to adapt and adjust the music-making to the infants' communicational signals (breathing patterns, heart rate, movements, and vocalizations), as well as to the parents' movements and vocalizations, or the parent-infant dyad as a whole. In continuance, the therapist aims also to assist the parent to synchronize with the baby's communicational signals and bodily rhythms (Yakobson et al., 2020).

In the past two decades three major models of MT specifically designed for preterm infants and/or their parents have been developed, and highly contributed to the development of research and practice of neonatal MT services. The NICU-MT model initiated by Jayne Standley from Florida, USA (Standley, 1998; 2001). Standley presented a behavioral approach and mainly focused on the use of music to promote infants' medical and physiological outcomes such as feeding behaviors, weight gain, sleep protection and length of hospital admission. She presented an innovative intervention to improve infants' feeding competencies, using the "Pacifier Activated Lullaby" (PAL) (Standley, 2000). The PAL plays lullabies in response to the infants' sucking activity. It has demonstrated beneficial results for infants' non-nutritive sucking activity and weight gain in several studies (Cevasco & Grant, 2005; Chorna et al., 2014; Standley, 2003; Standley et al., 2010).

Friederike Haslbeck from Switzerland presented the "Creative Music Therapy" (CMT) model (Haslbeck, 2014), following the original approach developed by Nordoff & Robbins (1977) for coma patients. The CMT model includes the family unit as a whole and perceives the infant as an active participant in the interaction. CMT's main technique uses improvisational, infant-directed singing, which can be accompanied by a special vibroacoustic monochord (Haslbeck et al., 2020). The MTs sing or hum in attunement to the infant's breathing patterns and guides the parent to do the same. The improvisation is adapted to the infants' changing behavioral signals with caution to prevent over-stimulation (Haslbeck, 2014). Haslbeck (2013) presented video footage of 122 MT sessions with 18 premature infants with a broad range of social and diagnostic diversity and their parents, as well as data derived from parents' interviews. The study demonstrated

that CMT was able to assist infants to actively respond and react through communicative musicality (Malloch & Trevarthen, 2009), which assisted the enhancement of self-regulation and relationship building. Recently, the CMT model has established the first longitudinal RCT trial to examine long-term effects of MT on preterm infants' brain development and neurobehavioral outcomes up to 5 years of age (Haslbeck et al., 2017). Results from a pilot trial (derived from the planned longitudinal study) showed that CMT was successful in improving the short-term effects of functional brain networks and integration in 24 preterm infants, compared to 16 control infants who received standard SSC (Haslbeck et al., 2020).

The third model of MT for preterm infants and their parent is the "First Sounds: Rhythm, Breath, and Lullaby (RBL)", initiated by title Joanne Lowey and her team at "Mount Sinai Beth Israel" medical center, New York City, USA (Lowey et al., 2013). The RBL model aims to improve infants' physiological and behavioral outcomes, promote sensory regulation and stress reduction in infants, their parents, and their surrounding environment. Within a family-centered and culturally sensitive approach, the RBL focuses on the use of parents' voices and musical preferences to create the family's special 'song of kin' (Loewy, 2015). The song of kin may be any song that is meaningful for the parents, adapted to a soft, repeated, and predictable lullaby style (usually in 3/4 or 6/8 tempo). The RBL also emphasizes the use of specific instruments that resembles the intra-uterine sound environment. These include an 'Ocean disk' (drum) that is associated with the amniotic fluid sounds and used to reorganize breathing patterns and promote relaxation, and a 'Gato box', resembling the maternal heart beats, to provide infants' with an intermittent rhythmic pattern synchronized with sucking rhythm to support feeding skills (Loewy et al., 2013b; Loewy & Jaschke, 2020). The RBL interventions were tested in 282 infants and showed beneficial effects for their physiological vital signs (i.e., improvement of heart and respiratory rates), improved feeding, and sleep (Loewy et al., 2013). The fundamental RBL principles of the use of parental voices and musical preferences were further investigated in other family-centered MT trials (Ettenberger et al., 2014, 2017; Palazzi et al., 2017; 2019), as well as in the current study.

In the last decades, these three models have been developed into manualized, evidence-based modalities. Each model provides a special training program, and today hundreds of therapists around the globe are certified and educated in the unique principles of MT for and with preterm infants and their parents in the NICU (Standley, 2014).

2.4.3. MUSIC THERAPY, MUSIC STIMULATION, AND MUSIC MEDICINE IN THE NICU

The potential benefits of MT and music interventions for preterm infants have been of high interest in scientific literature. So far, three meta-analyses (Bieleninik et al., 2016; Standley, 2002; 2012), six systematic reviews (Anderson & Patel, 2018; Ding et al., 2019; Foroushani et al., 2020; Hartling et al., 2009; van der Heijden et al., 2016; Yue et al., 2020), two integrative reviews (Haslbeck, 2012; Hodges & Wilson, 2010) and a narrative literature review (Palazzi et al., 2018) on the use of MT or music interventions in the neonatal care were published. Furthermore, a protocol for a Cochrane systematic review on the efficacy of auditory stimulations for preterm infants was recently published (Haslbeck et al., 2019). Except for the meta-analysis by Bieleninik et al. (2016), that included studies implemented or planned by a music therapist, the varied reviews presented studies that investigated interventions that were planned and applied by other professions such as neonatology and nursing.

Varied terms such as "music stimulation" "music-based interventions" and "music medicine" were used and often confusedly defined as MT interventions (Anderson & Patel, 2018; Palazzi et al., 2018). The discourse on the importance of differentiating MT from other musical interventions was apparent in other populations besides prematurity, such as oncology, dementia, and adults mental health (Gold et al., 2011; Wheeler et al., 2019), wherein addition to MT studies, several studies have implemented music interventions and referred to it as MT. Accordingly, before continuing the current literature background which involves both MT and other music interventions experimental studies, a clear definition of the varied terms will be provided. In a revised third version of his original text, Kenneth Bruscia (Bruscia, 2013) provides a working definition for MT, where he connects the

therapeutic relationship and the musical experiences in a process aimed to address the client's health:

Music therapy is a reflexive process wherein the therapist helps the client to optimize the client's health, using various facets of music experience and the relationships formed through them as the impetus for change. As defined here, music therapy is the professional practice component of the discipline, which informs and is informed by theory and research (Bruscia, 2013, p. 36).

Accordingly, the presence of a music therapist is a basic component when defining an intervention as MT. Wheeler et al. (2019) uses the definitions provided by Dileo (2013) and explain that in contrast, music medicine refers to the use of music stimuli that is applied by a medical person and within a medical setting, as a complement to medical treatment, with the aims of reducing anxiety, pain or autonomic reactivity and improving the wellbeing of medical patients. Usually, such interventions include the use of recorded music listening (Dileo, 2013). Music-based or music-stimulation are other common terms used, and similarly refers to the use of music to assist patients' wellbeing and are applied by other health professionals or the patient's caregivers and not by a certified music therapist (Palazzi et al., 2018). Accordingly, the following background literature will use the broad term "music interventions" for studies and interventions that were applied by other disciplines than MT.

2.4.4. RESULTS OF META-ANALYSES AND SYSTEMATIC REVIEWS ON MT AND MUSIC INTERVENTIONS IN THE NICU

The first meta-analysis (Standley, 2002) presented beneficial effects of neonatal MT or music interventions within ten RCT studies, with a large effect size (Cohen's $d = 0.83$, 95% CI 0.68 to 0.97, $p < 0.001$) across various dependent variables including heart rate, oxygen saturation, weight gain, behavior state, nonnutritive sucking and length of hospitalization. Multiple benefits from short periods of music listening in the incubator or crib included improvement of infants' calm states, earlier discharge, weight gain, stabilization of

physiological measures, and a long-term effect on calmness and irritability. An updated meta-analysis by Standley (2012), included the addition of twenty-five studies and resulted in a similar large effect size ($d=0.82$, 95% CI reported only >0). Most of the early trials (1970's-2000) in these two meta-analyses (Standley, 2002;2012) used recorded music, played solely to infants. The later meta-analysis compared live versus recorded MT and music-based interventions and demonstrated favorable effects for live MT interventions over recorded music (Cohen's $d=1.4$, $p=.00$, CI not reported) (Standley, 2012).

A later meta-analysis (Bieleninik et al., 2016), restricted to RCTs and a music therapist's involvement in the protocol, compared MT combined with standard NICU care to standard care alone in 16 studies. The analysis included in total 1071 medically stable infants aged between 24 to 37 weeks and 286 parents.

The most common MT approaches used lullabies, including four studies of parents' provision of live infant-directed singing (Arnon et al., 2006, 2014; Cevasco, 2008; Loewy et al., 2013). One study also included instruments resembling the intra-uterine sound environment (Lowey et al., 2013). Three studies used recorded music of lullabies (Keith et al., 2009; Shoemark et al., 2003), and recorded maternal voice (Johnston et al., 2007). Other studies included the PAL instrument (Standley, 2003; Standley et al., 2010; Whipple, 2008); the PAL combined with recorded maternal voice (Chorna et al., 2014); interactive MT for mothers (Vianna et al., 2011); and a developmental multimodal stimulation accompanied with live lullaby singing (Walworth et al., 2012). The meta-analysis compared MT combined with standard NICU care to standard care alone ($n= 13$ studies) and demonstrated a significant effect favoring MT for infants' respiratory rate ($p=.048$, mean difference $-3.91/\text{min}$, 95% CI, -7.8 to -0.03), and for maternal anxiety reduction ($p<.001$, mean difference -1.82 , 95% CI -2.42 to $-.122$).

This meta-analysis described the methodological shift towards the use of more active, live MT approaches that included parents, yet this was still only used in very few studies. Only six out of 14 studies included parents, and none gave specific attention to fathers. The authors

criticized the lack of parents' involvement (and specifically the absence of fathers) and recommended more clarity of intervention procedures, report of long-term outcomes, and rigorous randomized controlled trial (RCT) designs (Bieleninik et al., 2016).

The systematic reviews included similar conclusions. A systematic review of nine RCTs (Hartling et al., 2009), demonstrated beneficial effects of music listening in the NICU and presented various comparisons of types of music used: recorded intrauterine sounds for pain and stress modulation (Bo & Callaghan, 2000; Marchette et al., 1991); recorded vocal and instrumental versions of Brahma's and Sandman's lullabies (Butt & Kisilevsky, 2000; Shoemark et al., 2003); and two studies examined the impact of the activated pacifier lullaby (PAL) on infants' sucking activity (Standley, 2003; Whipple, 2008) (Standley, 2003; Wipple, 2000). Only one study compared the effect of live singing to a recorded version of the same music or no music at all (Arnon et al., 2006), and found beneficial effects for live music compared to recorded music. The music used in this study was of lullaby style with Eastern and Western musical elements, wordless female vocals, and instrumental accompaniment. Similarly, another systematic review of RCTs on music-based interventions (van der Heijden et al., 2016), updated the review presented by Hartling et al. (2009) and repeated the same conclusions on the poor quality of methodology plans and reports

An integrative review (Haslbeck, 2012) aimed to present a more comprehensive understanding of MT processes beyond the basic effect of music on infants' physiological or behavioral outcomes. It aimed to explore parents' perceptions, and the MT interventions' methods and impact. Out of 43 examined studies, only six also investigated the effects of MT on the wellbeing of mothers. These studies presented various interventions such as recorded heartbeat combined with kinesthetic stimuli, and recorded mother's voice and mother's live singing for their babies (Blumenfeld & Eisenfeld, 2006; Cevasco, 2008). Conclusive findings of these trials showed a positive influence on the mothers and in one case the mothers' and fathers' wellbeing, their coping behavior, and on mother-infant interaction patterns. In addition, a positive effect on mothers' motivation to sing

for their infant both in the NICU and later at home was identified (Haslbeck, 2012).

To conclude, the varied reviews discussed the wide heterogeneity of outcomes, participants, attention to sound levels, methodological approaches in the use of recorded or live music, multi-disciplinary professionals who implemented the interventions, and lack of rigorous RCT designs and reports (Standley 2002; 2012, Hartling et al., 2009; Haslebeck, 2012).

2.4.5. UPDATED LITERATURE SEARCH SINCE THE CURRENT STUDY INITIATION IN 2016

Since 2016 there has been a rise of RCTs trying to answer the gaps in research that has been mentioned in the literature. Recent MT studies described varied interventions within a family-centered approach. As part of the study protocol, parents are encouraged to lead the musical interaction (singing, humming, or speaking), and are educated in reading their infants' communication signals and behavioral language. Music therapists support parents to provide attuned and entrained responses that correspond to their infant's developmental status, concerning their cultural context and favorable music (Ettenberger et al., 2017; Ghetti et al., 2019; Haslbeck & Hugoson, 2017; Loewy, 2015; Palazzi et al., 2019; Shoemark & Ettenberger, 2020). A few studies described the use of MT to support painful medical procedures (Corrigan et al., 2020; Ullsten et al., 2018). Also, mothers and fathers' subjective experiences have been given more attention through qualitative examinations (McLean et al., 2018; McLean, 2016; Mondanaro et al., 2016).

Two large-scale RCTs protocols have been published in which the long-term effects of MT on preterm infants' developmental outcomes, parental mental health, and parent-infant bonding and attachment are examined. Haslbeck and colleagues (Haslbeck et al., 2017), presented a prospective, randomized, controlled single-center pilot trial protocol including 60 preterm infants (<32 weeks of gestational age), in preparation for a multi-center trial. The study will compare preterm

infants and their parents that were provided with at least ten 'creative music therapy' (CMT) sessions across their NICU admission to preterm families that received only standard NICU care. The planned longitudinal study will investigate preterm infants' neurobehavioral development. Infants will be followed-up at two and five years of age through neurological and developmental outcomes measures including the Bayley Scales of Infants and Toddler Development III (BSID-III) (Albers & Grieve, 2007); cognitive, neurological, visual, and hearing exams; and gross motor, adaptive behavior and executive functioning assessments (Haslbeck et al., 2017). Results from the related feasibility pilot trial were recently published (Haslbeck et al., 2020). Out of 82 recruited infants, a final sample of 40 infants completed all assessments (n= 24 in the CMT group, n=16 in control). Infants in the CMT group received an average of 15 CMT sessions, either individually with the therapist while they laid in their crib, or during SSC with their parents. Outcome measures compared short- and medium-term effects on brain connectivity and functionality at term age through MRI acquisitions. The trials' findings demonstrated novel evidence of CMT's effects on preterm infants' brain networks and functional brain integration. Compared to the control group, infants in the CMT group had significantly lower thalamocortical lag ($p<.05$), and higher improvements in prefrontal, supplementary motor, and temporal brain regions ($p<.05$). These functions are associated with later higher-order cognitive, socio-emotional, and motor functions.

A second protocol for a longitudinal trial of MT with preterm infants and their parents was also recently published (Ghetti et al., 2019). This is an international multicenter, 2×2 factorial, pragmatic RCT project, aimed to recruit 250 preterm infants and their parents. Families will participate in an MT intervention that is focused on parental singing, corresponding to the infant's response and developmental needs and abilities (thus incorporating the fundamental principles of the CMT and RBL models). The MT sessions will be provided across the NICU admission, and/or at home, during the first six months post-NICU discharge. The study's primary outcome will focus on mother-infant bonding at six months corrected age using the parental bonding questionnaire (PBQ) (Brockington et al., 2001). Secondary outcomes will include child development at two years corrected age using the BSID III (Albers & Grieve, 2007); mother-infant bonding at discharge

and 12 months corrected age; parental depression, anxiety, and stress; and infants' rehospitalization rates across the study period. This trial has also provided preliminary results from a feasibility pilot trial (Ghetti et al., 2021). This mixed-methods study with three families demonstrated that parents were willing to participate in the specified MT intervention both in the NICU and at home, and the selected self-report questionnaires were reasonable to complete. Furthermore, parents reported that they could apply the techniques learned in the MT sessions into their everyday routine.

Four reviews were published since 2018 including a systematic review on music listening in the NICU (Anderson & Patel, 2018), a systematic review on music interventions and physiological outcomes in preterm infants (Foroushani et al., 2020), a systematic review, and a meta-analysis on the effects MT on preterm infants (Yue et al., 2020) and a narrative literature review on MT and music interventions in the NICU (Palazzi et al., 2018). However, one of these (Yue et al., 2020), despite being entitled to evaluate only MT studies has included several music interventions studies such as Alipour et al. (2013) and Schlez et al. (2011), that were applied by neonatologists. The results of the different reviews aligned with the former meta-analyses and literature reviews mentioned above. Though new studies (from 2015-2020) were included in the new reviews, they all repeated the conclusions of the potential beneficial effects of MT and music intervention on the improvement of infants' physiological parameters. And they similarly critiqued the wide heterogeneity in infants' outcomes, small sample sizes, unclear methodology reports, and low numbers of family-centered interventions. Additionally, two reviews emphasized the prevalence of studies that mistakenly considered music interventions as MT, thus, highlighted the importance of applying such interventions by a trained NICU music therapist (Foroushani et al., 2020; Palazzi et al., 2018). Furthermore, one systematic review suggested that future MT studies should use sensitive physiological markers such as heart rate variability (HRV) examination (Foroushani et al., 2020). Accordingly, the main conclusions of the last reviews still called for the need to provide more rigorous RCTs of MT within a family-centered approach.

2.5. MUSIC THERAPY AND MUSIC INTERVENTIONS IN COMBINATION WITH SSC

Recent evidence suggests that a good method to provide MT within a family-centered approach, while also considering the sensory-regulation precautions for preterm infants would be to combine MT during SSC position. Haslbeck & Stegemann (2018) explained:

Since kangaroo care is now a standard routine in many neonatal intensive care units, this may be the most natural way to deliver music to the preterm infant in a multi-sensory and family-centered manner. It facilitates bonding by containing the infant's need for closeness and safety, and the parents' need for taking care and connecting emotionally with their child. Of course, not all parents feel comfortable singing in the high-tech environment of a neonatal intensive care unit. The support and encouragement by a specially trained music therapist can enable them to use their voice in an infant-directed, responsive way with the required sensitivity. (Haslbeck & Stegemann, 2018, p. 217)

This statement was supported in another recent integrative review on sensorial interventions in the NICU (Pineda et al., 2017). The main findings of this review highlighted the beneficial potential impact of SSC, music, and language exposure, and suggested that multimodal interventions such as SSC coupled with music may have a beneficial additive effect. However, only a few trials have investigated combined music or MT interventions and SSC. Accordingly, the next section will elaborate on the existing literature of combined SSC and MT or music interventions.

The first trial that reported on the combination of music and SSC in the NICU (Lai et al., 2006) included 30 dyads of preterm infants (age ≤ 37 weeks) and their mothers. The infants in the experimental group ($n=15$ dyads) listened to recorded lullabies chosen by the mothers during SSC, for 60 minutes per day along three consecutive days. The control group received standard incubator care. The study results showed a positive effect of music listening during SSC on maternal anxiety reduction ($p<.01$), and on infants' behavioral states including

more quiet sleep and less crying, compared to the control group ($p < .05$). No differences were found in infants' physiological vital signs between groups. Another RCT included 90 women post-cesarean section, and their full-term infants (Norouzi et al., 2013). They were randomly assigned to three groups: SSC and recorded music listening, SSC alone, and no treatment at all. The treatment groups were placed in the SSC position right after the C-section. The SSC and music group listened to 30 minutes of recorded music by Johann Sebastian Bach through an mp3 player. Six hours post-treatment, the severity of maternal state anxiety was reduced in both treatment groups compared to no treatment at all, with no differences between SSC alone and SSC combined with recorded music listening ($p = .02$).

Schlez et al. (2011) conducted a prospective randomized, crossover repeated-measures study, with fifty-two (preterm) mother-infant dyads that acted as their own controls for two consecutive days. The dyads listened to live harp playing during SSC and were tested again during SSC alone (with a random sequence allocation). The study results showed a significant effect of music listening during SSC compared to SSC alone on maternal anxiety reduction ($p < .01$), but no change in infants' physiological markers was found. A later study carried out in the same NICU used the same cross-over design (Arnon et al., 2014). It tested the combination of maternal singing during SSC compared to SSC alone in 86 stable preterm infants (age ≥ 32 weeks) and their mothers. The mothers were instructed to sing with a repetitive, soothing sound in a simple, slow tempo. They were asked to include lullabies, preferably ones that were sung during pregnancy and in their preferred language. A sound analyzer was placed near the infant's ear, as the mothers were instructed to sing at a sound level between 60 to 70 dB. Compared to SSC alone, maternal singing during SSC significantly reduced maternal anxiety levels ($p = .03$), and improved infants' autonomic stability, measured by their heart rate variability indexes ($p < .05$).

Very few studies have investigated combined MT and SSC. The first study that reported on the combined modalities was a mixed-methods study (Teckenberg-Jansson et al., 2011). The study included 61

preterm infant-parent dyads in MT+SSC sessions and compared their results with medical data of 52 other dyads which did not receive MT. The study conditions presented a wide range of MT+SSC sessions (range 1 to 14, median=6), and of infants' physiological measurements (range 10 minutes to 2 hours before and after, and twice during the sessions). The intervention group dyads acted as their own control and received MT+SSC and only SSC in alternating order, three days per week along their hospitalization period. The MT intervention protocol described the use of the music therapist's voice (humming or singing) accompanied by a pentatonic wooden lyre. These musical elements were chosen to create an ambient sound that would contrast the NICU's sound environment. The study's main findings revealed significant effects on infants' vital signs during MT+SSC sessions, compared to SSC alone. These included stabilizations of infants' heart rate across the six first sessions ($p<.05$); decreased respiratory rates ($p<.001$); and improved oxygen saturation levels ($p<.05$). Additionally, after the intervention parents completed a survey regarding their perceptions of the effects of the dual treatment on themselves and their infant. Parents reported that the combined intervention promoted calmness and relaxation for both them and their infants. The researchers noted that combined MT and SSC showed better results with time, implying that each of the modalities (combined and independently) is a learning experience. Hence, with every engagement in treatment, the dyad can utilize and maximize its benefits for their needs. Changes in the separate control group included only weight gain measurement at the end of hospitalization (which did not yield any significant differences).

Another mixed-methods pilot study (Ettenberger et al., 2014) investigated the implementation of an MT program in a NICU in Bogota, Colombia. Nineteen mother-infant dyads were randomized to three groups: Individual MT sessions for infants ($n=5$), MT combined with SSC ($n=8$), and a control group with no MT ($n=6$). The MT+SSC group participated in two to four sessions during two weeks of their hospitalization. The MT interventions were based on the MT's training in the RBL model (Loewy et al., 2013b). Technical limitations of available, intact monitors prevented the creation of sufficient data for an in-depth statistical analysis of infants' primary vital signs.

However, a favorable effect for MT on infants' increased weight gain per day during the intervention period was found for both intervention groups ($p=.05$). Mothers' measurement of the mother-to-Infant Bonding Scale (MIBS) (Taylor et al., 2005), demonstrated no statistically significant differences between groups. The Colombian version of the State-trait-Anxiety-Inventory for Children (STAI-C) (Castrillon Moreno & Borrero Copete, 2005) did show significant effects favoring MT in two dominant factors of the questionnaire (factor 2 before first intervention, indicator of state anxiety, $p=.01$; and factor 6 after the last intervention, indicator of trait anxiety, $p=.0418$). The main findings of the interviews reported that the mothers sensed that the MT sessions were helpful for both them and their baby and their developing relationship. Furthermore, that MT assisted in humanizing the NICU environment (Ettenberger et al., 2014).

Based on this pilot study experience, the researchers conducted another trial that focused solely on combined MT and SSC (Ettenberger et al., 2017). In a mixed-methods design, they aimed to investigate MT's effect on infants' physiological markers, their parents' anxiety levels, and parent-infant bonding. Participants included 36 medically stable preterm infants (28-34 weeks of gestational age), 33 mothers, and 17 fathers. Their data was compared to a demographically matching control group, that was admitted during periods when MT was not offered in the NICU (such as holidays). Their data were extracted from medical charts. The experimental group participated in two weekly MT+SSC sessions until their home discharge. The MT intervention was again informed by the RBL model and allowed for parental active singing, or receptive listening to live music provided by the music therapist. Infants' heart rate and oxygen saturation level were measured in a 10-minute interval from 10 minutes before to 10 minutes after each session. Also, infants' weight gain per day during the intervention period, hospitalization's length, and re-hospitalization rates at five months follow-up conversation with parents were measured. Parents' measurements included the MBIS bonding scale, and the state-trait anxiety inventory (STAI)(Spielberger et al., 1983), handed out before the first treatment and after the last treatment. Qualitative measurements included 53 semi-structured interviews with parents after the MT sessions, 41

questionnaires after the last session, and 12 semi-structured telephone interviews three to five months post-discharge. Compared to the control group, preterm infants in the MT+SSC group had higher weight gain per day during the intervention period ($p=.036$), and shorter (but not statistically or clinically significant) length of hospitalization by 1.885 days. Also, a 50% less rehospitalization rate in the MT group was found. An in-depth analysis of infants' heart rate and oxygen saturation was not completed due to a high number of unreliable measurements (derived from infants' movement artifacts during the sessions). Parents' results showed improvement in both the bonding scores and anxiety reduction from the beginning to the end of the intervention period. A statistical significance was demonstrated only for the mothers' anxiety reduction from pre- to post-intervention ($p=.007$). The qualitative findings reported that parents stated the participation in MT helped improve their wellbeing, their infant's development, and their relationship building, also as a meaningful distractor of inner and external hazards related to the chaotic NICU surroundings (Ettenberger et al., 2017).

A recently published trial on combined MT and SSC (Kostilainen et al., 2020), presented results from one cohort, as part of a larger international longitudinal cluster-RCT in Sweden and Finland, that is still ongoing (ClinicalTrials.gov: NCT03795454). This trial named "Singing Kangaroo", aims to investigate the long-term effects of parental singing during SSC on preterm infants' sound discrimination and parental anxiety at term corrected age (40 weeks of gestation age); and on preterm infants' cognitive development at two years of age. For now, results of the Finnish cohort related to mothers' outcomes are presented (Kostilainen et al., 2020). In this convergent mixed-methods design, 24 mothers in the singing group and 12 in the control group completed all measures to be included in the final analysis. Mothers' measurements included the change of anxiety levels measured by the STAI (Spielberger et al., 1983), from baseline point of infants' 35 weeks of gestational age to end point (40 weeks of gestation); Parental diary reports on their daily participation and self-report questionnaires focused on their experiences of singing during SSC in the NICU or afterward at home. In the singing intervention, parents were guided and supported by the music therapist on how to sing to their infant in an attuned, protective manner, and received booklets of song

suggestions associated with age-appropriate musical dynamics (such as soft soothing nursery songs and the early stages or playful songs with changing melodies or intensity that can enhance infants' responses at a later stage). They were asked to sing at each SSC session, for a duration of their choice. The control group performed daily SSC as part of the standard family centered care at the participating NICUs and did not receive any instructions or recommendations to sing. Parental diary reports described that on average, in the singing group mothers sung for 41 minutes per day, along 36 days. In the control group, SSC was performed daily across 47 days, and no singing was reported. In both groups SSC's mean duration per day was 130 minutes. The singing mothers showed a statistically significant reduction of anxiety levels at the intervention's end point ($p=.016$). Qualitative findings derived from the self-report questionnaires suggesting that singing during SSC promoted relaxation for both the mothers and their infants, and enhanced emotional closeness by the creation of meaningful moments of interaction.

Finally, another recent study combined MT and SSC and specifically focused on preterm infants with severe brain injury (Epstein et al., 2020). In a cross-over repeated measures RCT design, forty preterm infant-mother dyads participated in three MT sessions that focused on maternal singing and acted as their own control in additional SSC-only sessions. The study findings demonstrated controversial results (to the above-mentioned studies). The researchers found that during the MT sessions combined with SSC compared to SSC alone, infants demonstrated higher instability in physiological and behavioral measures. These included poorer heart rate variability (HRV) indices of higher LF/HF ratio ($p=.01$), higher heart rate ($p=.04$), and higher score in the behavioral state (Brazelton & Nugent, 2011) which indicated higher arousal. Additionally, mothers in the MT group demonstrated higher anxiety levels compared to SSC alone ($p=.04$).

2.6. SUMMARY AND CONCLUDING RECOMMENDATIONS FOR THE CURRENT STUDY

To the best of my knowledge, only five studies have investigated the effects of combined MT and SSC, and a few more have investigated maternal singing or recorded music listening during SSC. These studies have managed to show varied beneficial effects of music and MT interventions for infants and their parents during SSC. However, the MT studies were all small-scale studies, and none of them provided a justifying power calculation. Furthermore, only one study (Teckenberg-Jansson et al., 2011) produced a meaningful statistical analysis of preterm infants' physiological vital signs outcomes, yet with an unclear study design and conditions. Of the above-mentioned studies, two studies did present rigorous RCT methodology (i.e., transparent design and power calculation, consistency of measurements, etc.) and focused on maternal singing without therapeutic support (Arnon et al., 2014), or maternal singing during MT (Epstein et al., 2020). Both trials applied heart rate variability (HRV) analysis and were able to find significant group differences.

2.6.1. INVESTIGATING EFFECTS OF MT ON HRV IN PRETERM INFANTS

Heart rate variability (HRV) refers to the time variations between each successive heartbeat. These differences originate from the autonomic nervous system (ANS) influence on the heart and provide information on the parasympathetic and sympathetic branches of the ANS (Pacing, 1996). Through a spectral power analysis of its high and low frequencies (i.e., HF and LF) domains, the HF band appears at 0.15-0.40 Hertz and is considered to reflect vagal efficiency in the parasympathetic system. The LF band appears at 0.04-0.15 Hertz and may indicate sympathetic activity, or parasympathetic withdrawal (Pacing, 1996). The LF/HF ratio may therefore reflect the sympathovagal balance, a relationship between relaxation and stress (Pagani et al., 1986). Accordingly, the HRV analysis indicates activity in the ANS thus informing on stress and arousal reactions (Cowan, 1995). In general, the sympathetic system activates motor activities such as the fight-or-flight reactions, and the parasympathetic system activates vegetative functions and rest states such as the rest-and-

digest response (Bentzen & Hart, 2015). HRV analysis is therefore considered a useful and non-invasive method to evaluate preterm infants' responses to pain and medical procedures, as well as an important predictor of impending neonatal morbidities (Gardner et al., 2018). Increased HRV and specifically HF-HRV power indicate preterm infants' ANS stability and ability to modulate stress, where decreased HRV can be correlated with pathological conditions (Gardner et al., 2018). Several neonatal studies included the analysis of preterm infants' HRV indices as a predictive biomarker of risk of morbidities such as necrotizing enterocolitis (Doheny et al., 2014) and sepsis (Sullivan et al., 2014); also to evaluate the beneficial effects of SSC in the improvement of preterm infants ANS stability (Butruille et al., 2017; Feldman & Eidelman, 2003; McCain et al., 2005); and even to examine the autonomic regulation in adolescents who were born premature (Haraldsdottir et al., 2018).

Within other fields of MT studies, HRV analysis was applied to examine the effects of MT in stress reduction in varied populations such as hospitalized pregnant women (Teckenberg-Jansson et al., 2019), elders with cerebral vascular deficits, and dementia (Kurita et al., 2006), or pre-competition sports performance (Kachanathu et al., 2013). Kachanathu et al. (2013) argued on the importance of HRV analysis in examining the effects of MT, as it is a meaningful outcome that enables the understanding of the physiological mechanism of change:

As evidence-based Music Therapy (MT) turns its attention to physiological responses; it will need outcome measures that are grounded in an understanding of mechanisms which drive physiological activity. Despite strong indications for the involvement of the Autonomic Nervous System (ANS) in health and disease, very few studies have systematically explored the therapeutic or interventional effects of music on ANS function. (Kachanathu et al., 2013, p.418)

2.6.2. STUDY RATIONAL

As described earlier in this review, SSC is the first main form of physical bonding between preterm infants and their parents in the NICU, thus considered a key intervention in the developmental family-centered care for preterm infants and their parents (Heidelise Als & McAnulty, 2011). Music therapy might enhance the effects of SSC both by the physical vibration of the voice through the chest (Arnon et al., 2014), and by supporting the provision of parental voice through the rhythmic entrainment and synchronization with the infants' behavioral sings. Music therapy might provide preterm infants and their parents with appropriate support during SSC, that creates a holding relaxing environment in which meaningful interactions may be enhanced, and by so may be of high value for infants and parents emotional wellbeing and their developing relationship (Arnon et al., 2014; Ettenberger et al., 2017; Yakobson et al., 2020).

The current study will try to address the current gaps in the literature regarding the need of rigorous family-centered RCTs of MT with preterm infants and their parents (Bieleninik et al., 2016; Foroushani et al., 2020; Palazzi et al., 2018;). This will be carried out by reinforcing on essential effects of combined MT and SSC, through defined procedures and data collection including the sensitive physiological outcome of HRV.

CHAPTER THREE: METHODOLOGY

3.1. EPISTEMOLOGICAL AND ONTOLOGICAL CONSIDERATIONS

This research project was derived from two aims. The first was to demonstrate the effectiveness of MT in the NICU through the conduct of a rigorous randomized trial and thereby fill in the current gaps in the music therapy research in the NICU (i.e., well-powered RCTs of family-centered MT, meaningful physiological outcomes, and long-term examination). A second derivative aim was to use the study to serve as a platform to introduce and justify the inclusion of MT as part of the standard developmental care in the specific unit.

The project was initiated in a multi-disciplinary collaboration between MT and neonatology, in a NICU set out according to the NIDCAP fundamental principles. Accordingly, it involved a mix of basic epistemology positions that needed to be collaborated in some form to reach the mutual study goals. The music therapy profession has developed through an empirical practice, which informed and generated theory and practice from within itself and in conjunction with knowledge from other disciplines as well (Wigram, 1999). In the last decades, neonatal music therapy had evolved into an evidence-based modality, pertaining to objective physiological and behavioral outcomes (Bieleninik et al., 2016), as well as interpretive subjective processes of bonding and the interactional potentials of music-making (Ettenberger et al., 2017; Haslbeck, 2014). The high-tech medical world of prematurity care seeks to find objectivist truth, with defined outcomes and their appropriate interventions and measures; where the field of developmental care of preterm infants represents a combination of values – emphasizing the need to understand and attend to the subjective individual needs, through an environmental organization, systematic observation, and intervention (Heidelise Als, 2009a). Accordingly, the last two disciplines may be regarded as post positivists, based on the objectivist research paradigm seeking to confirm or deny a specific hypothesis; where music therapy studies may embrace both the objectivists and interpretivists paradigms, aimed at exploring the phenomenon that is revealed during the study

(Wheeler & Brucia, 2016). Nevertheless, experiences of participating in music therapy (or therapy in general) may have common themes or similar effects between people, though each participation is inevitably subjective. The unifying theoretical perspective between the three disciplines that met in the specific unit were sensory-protective, family-centered care for preterm infants and their parents, and the evidence-based methodology.

3.1.1. REAL-WORLD RESEARCH

Real-world research "endeavors to understand the lived-in reality of people in society and its consequences...Much real-world research focuses on problems and issues of direct relevance to people's lives, to help find ways of dealing with the problems or of better understanding the issues" (Robson & McCartan, 2016; pp. 3-4). It might as well be viewed as moving from the laboratory and basic research, into the field, the real setting where the investigated phenomenon takes place. Accordingly, in this study, the decisions on design and outcome variables were based on the neonatologists' perception of meaningful outcomes and the appropriate research methods in this medical field, namely, the randomized controlled trial. Other methodological considerations also accounted for what would be valuable for policy makers, such as the hospital management; as well as the patients, basing on developmental care and MT knowledge on preterm infants and their parents' needs; and finally, what would be feasible to do in the specific NICU.

Robson & McCartan (2016) argues that such impact on the values of the organization in which the study will take place may seem risky, due to the potential of "capitulation to the values of an enterprise culture"(p. 10). The advantage in such a case, where the focus of the research is determined also by external values than the researcher's, is that it increases the likelihood that the "findings are both usable and likely to be used" (p.10). Furthermore, the acknowledgment of the important values on which organizational, practice, and policy decisions are made, makes the root to form evidence-based policy and practice.

3.1.2. PRAGMATISM

Much of the real-world research is rooted in the pragmatic philosophical tradition. The pragmatists, such as Dewey (1938), Peirce (2014), and James (1907) emphasize a value-oriented approach in research conduction. They believe that knowledge is both constructed and based on the reality of the natural, physical world we live in, as well as on the inner world of human experience. Thus, pragmatists strongly advocate for practical empiricism to conclude "what works", and support the development of a practical theory that would guide effective practices (Legg & Hookway, 2021). The theoretical application of pragmatism in research will therefore be to use all necessary philosophical or methodological approaches to understand the specific research problem (Moon & Blackman, 2014).

The study goals as described above, the existing conditions (such as open-space NICU) and resources (such as funding, one music therapist available for a limited time), as well as the mixed theoretical perspectives, had shaped the study design and methods including the chosen outcomes, intervention, and the overall analysis. In that sense, it may reflect several elements in the description of "real-world" research (Robson & McCartan, 2016), that was applied pragmatically.

3.1.3. A PRAGMATIC REAL-WORLD RESEARCH

Robson & McCartan (2016), argue that the relationship between the research paradigms and methods may be reconsidered and adjusted according to the need of the research:

"There is a more complex two-way relationship between research methods and paradigms, where paradigms are evaluated in terms of how well they square with the demands of research practice" (Robson & McCartan, 2016, p.175).

The need to provide a rigorous examination, and to try and demonstrate an objective effect of MT was clear. However, as a clinician, acknowledging the subjectivity of participants' experiences,

and the potentially limited description of the MT experience and intervention using only quantitative measures and robust outcomes; without looking into the complex layers of dynamic processes was apparent as well. Together with that, parental first-hand presentations in neonatal MT studies are scarce (McLean, 2016). Furthermore, the client's experience, preferences, and values constitute valuable data for the construction of evidence-based practice (Wheeler & Brucia, 2016). Thus, including parents' knowledge and experiences of the intervention was perceived as another important issue to investigate.

With different aims requiring different, and to some maybe even contradictory approaches including objectivist examination of the effects of MT; and subjective evaluation of parents' experiences, a pragmatic combination of the objective and interpretive paradigms called for the use of mixed methods approach, to include both quantitative and qualitative data collection and analysis.

3.1.4. MIXED METHODS

In the last two decades, the mixed methods approach also referred to as multi-strategy or multiple methods, has gained increasing awareness and popularity within vast disciplines. Advocators of the new approach argued against the incompatibility thesis which claimed that quantitative and qualitative research cannot be combined as they derive from different paradigms which are incompatible (Onwuegbuzie & Leech, 2005). Robson & McCartan (2016) cited several scholars who instead suggested that despite the obvious differences of qualitative and quantitative methods, they also share many similarities such as multiple data collection methods for the inquiry of a single question (Huberman, 1987). The different methods may support or even complete each other. An objective statistical analysis is valid based on its' credible scientific background arguments and assumptions, which may as well be based on preceding qualitative ruling (Campbell, 1975). Using both methods may provide researchers with multiple means to answer the research question(s) and by so enhance a more deep and comprehensive understanding. However, using the mixed methodologies may be challenging as it will demand

more resources (and work), and may limit the potential of reaching a deep investigation within each methodology (Robson & McCartan, 2016).

Mixed methods studies have been applied by MT researchers in varied fields such as the PhD projects on Guided Imagery and Music (GIM) by Beck (2012), with adults on sick leave suffering from work-related stress, or Hertrampf's exploration of GIM in psycho-oncology (Hertrampf, 2017). Other examples can be found in studies such as Bradt et al. (2016), a mixed-methods study on vocal music therapy for pain management in adults; and Gottfried's (2016) project on music-oriented parent-counseling for parents of children with an autism spectrum disorder. Specifically, in neonatal MT studies, the use of mixed methods approach has recently increased as well, as a small number of researchers/clinicians have used this methodology to examine quantitative effects of MT, together with qualitative explorations of parents' experiences from participation (Ettenberger et al., 2014, 2017; Ghetti et al., 2021; Teckenberg-Jansson et al., 2011).

3.1.5. THE STUDY GOALS

The current study aimed to enable an inquiry that would provide a rich evaluation of MT in the NICU in a form that may explain to the medical world the potential effects. Another aim was to explore parents' experiences from participation and their perception of the mechanisms of MT.

Further objectives were to include fathers, as well mothers of preterm infants, and perform a follow-up examination after the NICU discharge. A macro-objective of the study was to introduce and implement MT services in the participating NICU through the study.

3.2. RESEARCH QUESTIONS

The research questions of the current study were based upon the findings and gaps found in the related scientific literature presented in Chapter 2.

3.2.1. Overarching research question

How do combined family-centered MT and SSC affect premature infants and their parents?

3.2.2. Quantitative research questions

1) What is the effect of combined family-centered MT and SSC compared to SSC alone on the autonomic nervous system activity of preterm infants, as indicated by the difference in the high frequency (HF) of their heart rate variability?

The secondary research questions are:

2) What are the effects of combined family-centered MT and SSC compared to SSC alone on:

2.1. Preterm infants' other HRV indices including low frequency (LF) power and LF/HF power ratio?

2.2. Preterm infants' physiological vital signs (heart rate, respiratory rate, and oxygen saturation level) and behavioral states?

2.3. Parental state anxiety levels?

2.4. Parent-to-infant attachment level?

3.2.3. Qualitative research questions

1) How did parents experience MT with their preterm infant during the NICU admission?

1.1. How did parents describe what happened to them or their baby during MT?

1.2. Which elements in the intervention are described to be meaningful for the parents?

1.3. What roles or meaning did the MT experience have for the parents?

2) How did parents experience the study conditions and measurements?

2.1. How did aspects of the study methods (such as setting and measurements) contribute or were meaningful to the parents' experience of MT?

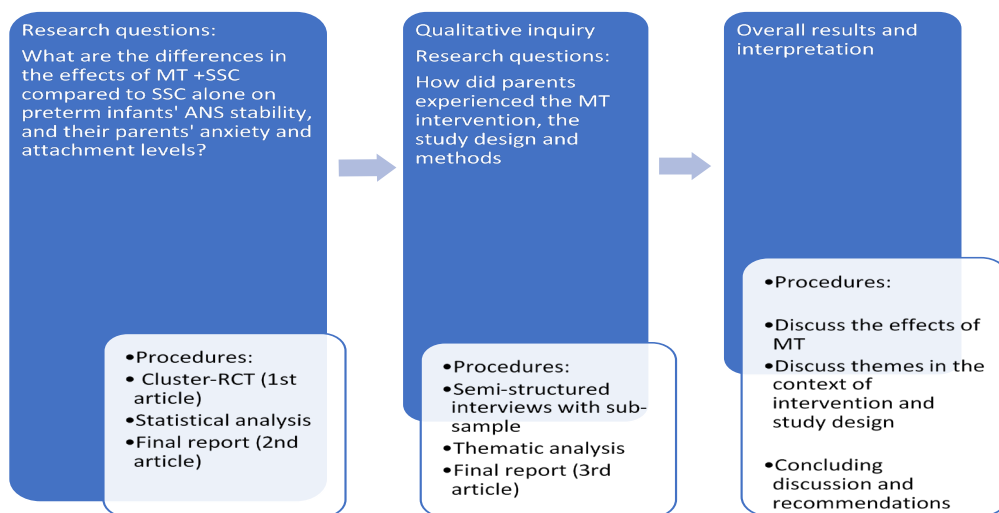
2.2. What kind of conditions were needed to support parents' general participation in the study, specifically in the MT intervention?

3.3. STUDY DESIGN AND METHODOLOGY

A quantitative-driven embedded mixed-methods design was applied (Creswell, 2013). In the embedded mixed methods design, one data set constitutes the main design, as the second data is set out to supports the overall design. The collection of secondary data may occur before, during, or after the procedures related to the main design. The rationale for the use of the embedded design is that different research questions may not be sufficiently answered by the analysis of a single data set. The embedded design is therefore specifically useful for experimental studies when a qualitative element needs to be embedded within a main quantitative design. The supportive inquiry may aim to evaluate and develop the intervention, deepen the understanding of the intervention's dynamics or its' mechanisms that relate to certain measured outcomes (Creswell & Clark, 2010).

The current study was mainly focused on the quantitative data collection and analysis (hence the design is defined as quantitative-driven) and first, a cluster-randomized controlled trial (cRCT) was carefully planned and administered. Following the quantitative data collection completion, some parents were invited to participate in an additional qualitative inquiry, to explore and provide their perspectives and experiences from participating in the cRCT (Figure 2). Accordingly, the objectivist and interpretivist positions were applied separately. The study was first aiming to produce objectivist outcomes of the MT intervention. Afterward, an exploration of the subjective experiences and the mechanisms of the MT intervention as perceived by participating parents took place.

Figure 2: The quantitative driven embedded mixed methods study design:



3.3.1. QUANTITATIVE DATA COLLECTION

The chosen quantitative design was a cluster-randomized controlled trial. Ten time clusters of two months each were randomized using constrained randomization of paired-wise matching clusters. Each cluster was allocated to either the experimental condition of combined MT and SSC or the control condition of SSC alone. In each time-cluster, each parent-infant dyad (mother-infant or father-infant, separately) participated in two weekly sessions of the assigned intervention, and in a three-month follow-up session at home (Yakobson et al., 2020). The cluster design was constructed as a solution for potential difficulties that a classic 1:1 randomization sequence would cause, as was previously experienced by the collaborating neonatologist in the NICU (Shmuel Arnon). These are mainly related to the contamination bias due to the setting of the open space NICU.

A detailed description of the trial's methodology including infants and parents inclusion criteria, sample size justification, study design, setting, data collection procedures, interventions, outcome measures,

randomization, and allocation concealment, data analysis plan, blinding, monitoring, and ethical considerations are provided through the first article: "Music Therapy for Preterm Infants and Their Parents: A Cluster-Randomized Controlled Trial Protocol" (Yakobson et al., 2020).

3.3.2. QUALITATIVE DATA COLLECTION

The qualitative inquiry was conducted after the quantitative part. Parents who had completed their MT sessions were invited to semi-structured interviews to share their perceptions and experiences from the study participation. The interviews were conducted in the second year of data collection, most by another music therapist (Liron Lindeman). She had joined the unit as part of her MT internship, and assisted the researcher as well (observed sessions, obtained measurements, and led few MT sessions which I observed). The interviews were recorded and then transcribed word-by-word.

3.3.3. THE FAMILY-CENTERED INTERVENTION: MT COMBINED WITH SSC

The MT intervention was based on the "First sounds: Rhythm, Breath and Lullaby" model (Loewy et al., 2013b). It aimed at providing immediate physical and emotional support and reducing stress levels for both the infant and their parent. Furthermore, it aimed to support the enhancement of meaningful interactional moments, and provide parents with a method that could be easily continued independently afterward.

The fundamental aspects of the RBL model include specific attention to the infant, parent, and the environment, and their reciprocal interaction; entrainment (in its rhythmic sense of music rhythm to the infant, parent, or the environment, and parent's rhythm to infants' rhythm); use of parents' voice and musical heritage; and incapsulating the sounds of the intrauterine environment (RBL compendium, 2015). The intervention's protocol (Yakobson et al., 2020), emphasized a family-centered approach by focusing on the parent-infant dyad and

parental leading of the intervention. It intended to correspond to both infants' and parents' alternating needs, by basing on parents' preferences and in attunement to an informed observation of the infants' communicational signals. Supporting parental use of voice and singing was perceived as an essential method, nevertheless, the wider goal was to support interactional moments during the NICU period. Therefore, additional means for musical engagement were offered, including guided breathing and relaxation accompanied by the ocean disk, and receptive listening to their songs of kin (Loewy, 2015).

The choice to combine MT and SSC was derived from several aspects: The collaborating neonatologist and the NIDCAP professionals at the unit recommended the dual treatments, suggesting it may adhere to the principles of providing protective sensorial care within a family-centered approach. Interestingly, similar supportive arguments for the combined modalities had become increasingly apparent in the literature published after the implementation of the study (Ettenberger et al., 2017; Haslbeck & Hugoson, 2017; Pineda et al., 2017a). Accounting for methodological considerations, SSC is a standard care treatment in the NICU's routine; thus, could be a clear control condition, though still reflective of a real clinical state/practice. Finally, considering the feasibility aspects of the new MT service that was offered through the study, initiating MT during SSC seemed to be easily engaged, understood, or accepted by the medical staff and routine.

3.3.4. QUANTITATIVE OUTCOMES MEASURES

The primary outcome was improvement in the autonomic nervous system (ANS) stability in preterm infants, as indicated by the parameters of their heart rate variability (HRV) specifically focusing on the HF power of the HRV during the second session. Secondary outcomes included the high frequency (HF) power, low frequency (LF) power, and LF/HF ratio in all sessions. Physiological stability was measured by the immediate vital signs of heart rate, respiratory rate, and oxygen saturation level. Furthermore, behavioral state in preterm infants was measured by the NIDCAP's manual for behavioral

state evaluation (Brazelton & Nugent, 2011). Infants' measures were recorded during each session, from ten minutes before until ten minutes after the intervention, in a five-minute interval.

Parental outcomes included state-anxiety, measured by the state dimension of the State-Trait Anxiety Inventory (STAI) (Spielberger et al., 1983), and parent-to-infant attachment level, measured by the Maternal Postnatal Attachment Scale (MPAS) (Condon & Corkindale, 1998).

Focusing on stress reduction in preterm infants was congruent with the current research in the field emphasizing the noxious effects of neonatal stress for preterm infants' neurological and socioemotional development (Browne, 2021). The concept of stress in the current investigation refers to both physiological and psychological indicators. The choice to measure HRV was based on its' consideration as a meaningful, objective indicator of the ANS activity (Feldman & Eidelman, 2003). Stress reduction and ANS stability are considered crucial for preterm infants' neurological, and psycho-social development (Graven & Browne, 2008). The theoretical understanding underlying the choice to focus on stress is that preterm infants are born with an immature ANS, and the neonatal stress exposure harms its' already fragile development. Reduced stress improves autonomic stability (Nist et al., 2019), and improved autonomic stability increases the infant's ability to handle the external stressors of their environment thus improving developmental outcomes (Mulkey & du Plessis, 2019).

Parental state in this process is another meaningful influential factor. Parents' mental wellbeing may as well be harmed by the stressful premature birth and the NICU experience, and by so negatively affect their bonding and attachment processes with their infants (Browne, 2021). For parental outcomes, the stress effects on their wellbeing was measured through psychological assessments of state-anxiety levels. Epel et al. (2018), explain that stress measurement is inevitably complex as it is defined so broadly, it is highly subjective and experienced on multiple levels (social, psychological, and physiological). Accordingly, stress measurement may include varied antecedent, stimuli, or response. The authors therefore try to provide specified definitions and measurement operations. They suggest that

perceived stress concerns a "response to specific conditions" and "typically includes several psychological components of the stress response – feelings of overwhelm, or anxiety, as well as cognitions that demands outweigh resources, or not having control" (Epel et al., 2018; p.147). McEwen et al. (2012) also argue that stress may lead to imbalance in the artificial neural network, and negatively affect cognition, decision making, anxiety and mood. Accordingly, the current study focused on expressions of perceived stress as may be indicated by state-anxiety. Parental measures of state-anxiety included the highly validated and commonly used questionnaires of STAI. Additionally, the attachment-to-infant MPAS assessment, assuming these scales could provide clear, valid information on parental processes.

3.3.5. DATA ANALYSIS

The process of data analysis was conducted in several stages:

1. Quantitative data analysis: The process included pre-processing of the HRV data by an external neonatologist; statistical analysis of all outcomes based on the intention-to-treat principles, using descriptive methods and linear mixed-effects (LME) models to examine changes over time or during each session; interpretation and writing. The results are provided in Chapter 4.
2. Qualitative data analysis: The process included thematic analysis of the interviews' scripts. The findings are provided in chapter 5.

3.4. ETHICAL CONSIDERTIONS

The study received the approval of the institutional review board of the hospital (approval no.0283-15), and was registered in ClinicalTrials.gov, NCT03023267. Families were invited to participate in the study after screening and meeting inclusion criteria by the senior neonatologist and the NIDCAP trainer in the unit. They received a detailed explanation of the study procedures by the music therapist. All parents have completed an informed consent form for their own participation, and for their infant's participation (appendix

1). Informed consent explanation and signing was conducted by the senior neonatologist and the NIDCAP trainer (Yakobson et al., 2020).

CHAPTER FOUR: QUANTITATIVE RESULTS

4.1. RECRUITMENT

Between May 2017 and November 2018, ten clusters were randomized: five in each arm, including 68 eligible preterm infants (MT, N=37, SSC, N=31), and 79 parents across both arms (MT, N=42, SSC, N=37). The clusters' distribution is presented in the following table:

Table no. 1: Clusters distribution

Cluster No.	1	2	3	4	5	6	7	8	9	10
Allocation	MT+ SSC	SSC	SSC	MT+ SSC	SSC	MT+ SSC	SSC	MT+ SSC	MT+ SSC	SSC
N of infants	8	5	5	7	5	6	6	8	8	8

4.1.1. UPTAKE OF INTERVENTION

Of the maximum 6 sessions each infant could receive, 60% had completed three sessions, 24 % had less than three, and 16 % had more (Table 2). A mean number of 3.33 sessions was found in MT+SSC (SD=1.26, median 4, range 1 to 6) and similarly in SSC (M=3.44, SD=1.22, median 4, range 1 to 6). In both groups most infants (79%) had participated with one parent therefore could not have received more than three sessions. Sessions with mothers had a mean of 2.29 (SD=0.96), compared to 1.09 (SD=0.71) with fathers.

Table 2: Uptake of intervention

variable	MT+SSC		SSC		P value
No. of completed sessions per infant	N	n (%)	N	n (%)	P value
	37		31		.96
1	3	8%	2	6%	
2	5	13%	6	19%	
3	22	60%	19	61%	
4	4	11%	2	6%	
5	2	5%	1	3%	
6	1	3%	1	3%	

4.2. Answers to the quantitative research questions

The analysis and results of the cluster-randomized controlled trial are presented in the second article of the PhD project: "Music therapy improves autonomic stability in preterm infants: A randomized controlled trial" (Yakobson et al., 2021; manuscript ready for submission). The following sections will therefore provide a summary of the results.

4.2.1. THE MAIN QUESTION OF THE CLUSTER-RCT was:

What is the effect of combined family-centered MT and SSC compared to SSC alone on the autonomic nervous system activity of preterm infants, as indicated by the difference in the high frequency (HF) of their heart rate variability (HRV)?

The analysis focused on the change in preterm infants' HF-HRV during the second session. The results indicated that both modalities contributed to an increased HF power in infants' HRV during the session. However, MT was demonstrated as more beneficial in improving infants' HF power compared to SSC alone. During the

entire session, HF power was significantly higher in the MT group, and the increase of HF from the first part to the last part of the session was significantly higher in the MT group compared to SSC alone.

4.2.2. THE SECONDARY RESEARCH QUESTIONS were:

What are the effects of combined family-centered MT and SSC compared to SSC alone on:

- 1). Preterm infants' other HRV indices including low frequency (LF) power and LF/HF power ratio?
- 2). Preterm infants' physiological vital signs (heart rate, respiratory rate, and oxygen saturation level) and behavioral states?
- 3). Parental state anxiety levels?
- 4). Parent-to-infant attachment level?

The answers to questions number 1, 3, and 4 are provided in detail in the second PhD article as well. The secondary parameters of infants' HRV included the change in LF power and LF/HF ratio during the second session, and the mean of HF, LF, and the LF/HF ratio in the first session and the third follow-up session at home. During the second session, similarly to the HF pattern, an improvement in LF and LF/HF ratio was indicated in both groups. The values of these indices were significantly lower in the MT group (indicating improvement). Yet, the differences between groups in these outcomes were not clear, as the reduction in values from the first to last part of the session was significantly larger in the SSC alone group. In the first session, no significant differences were demonstrated between groups. The third session demonstrated a nonsignificant beneficial effect of MT for improved HF, and significant effects of MT compared to SSC alone for LF and LF/HF ratio reduction.

Parental outcomes did not yield significant results neither in each group alone nor compared. The anxiety evaluation showed a nonsignificant trend favoring the effect of MT on parental anxiety reduction. However, in all of the time points parents demonstrated

normal anxiety levels, below the clinical cut-off. Similarly, the attachment-to-infant evaluations at all measurements ranged between medium to high attachment-to-infant levels in both groups.

4.3. SECONDARY QUESTION NUMBER 2.2: PRETRM INFANTS' PHYSIOLOGICAL VITAL SIGNS AND BEHAVIORAL STATES DURING SESSIONS

A first/preliminary analysis of these outcomes measures was conducted using SPSS for Windows version 25 (SPSS Inc., Chicago, IL, USA). Infants' heart rate (HR), respiratory rate (RR), oxygen saturation (O2S), body temperature, Newborn Infant Parasympathetic Evaluation (NIPE) monitor scores, and behavioral states were recorded every five minutes during all sessions (Yakobson et al., 2020). For each session, a mean of each outcome variable was calculated and compared between groups using independent simple *t*-tests. For all outcome variables, a significance level of 0.01 was set to account for multiplicity.

4.3.1. RESULTS OF ADDITIONAL ANALYSIS

In the analysis of mother-infant sessions (N=47/68 infants , 72%), most outcome variables were similar between groups. A significant difference indicating the beneficial effect of MT was observed for infants' lower behavioral scores during the first and second session, regarding a deeper sleep state (Table 3). The mean of each outcome variable in all sessions combined demonstrated a beneficial effect of MT on infants' lower respiratory rate (Table 4).

Table 3: Infants' physiological parameters and behavioral states in each session (sessions with mothers).

1 st session mothers	MT+SSC (N=37 infants)	SSC (N=31 infants)	P- value
HR	151.9±10.3	154.5±8.6	P=0.31
RR	40.8±11.1	43.8±10.9	P=0.29
OS2	96.9±1.9	96.1±2.5	P=0.14
Body Temp.	36.6±0.04	36.5±0.08	P=0.31
NIPE	60.7±8.33	62.8±8.37	P=0.32
Als score	1.82±0.41	2.21±0.47	P=0.00
2 nd session, mothers			
HR	154.0±9.4	155.4±7.7	P=0.55
RR	41.1±10.3	43.2±11.4	P=0.49
OS2	97.3±1.4	96.9±1.7	P=0.34
Body Temp.	36.5±0.26	36.5±0.05	P=0.70
NIPE	58.6±6.37	59.6±11.04	P=0.69
Als score	1.69±0.43	2.14±0.50	P=0.001
3 rd session, mothers			
HR	138.4±19.9	138.6±9.6	P=0.95
RR	39.6±4.9	41.4±4.4	P=0.20
OS2	96.5±2.9	98.1±2.4	P=0.07
Body Temp.	36.6±0.015	36.6±0.035	P=0.38
NIPE	62.7±5.58	62.02±2.96	P=0.60
Als score	2.73±0.88	2.39±0.59	P=0.14

Abbreviations: MT= music therapy, SCC=skin to skin care, HR=heart rate, RR=respiratory rate, OS2= oxygen saturation level, NIPE= newborn infant parasympathetic evaluation (NIPE) monitor, Als= behavior state score, according to the criteria by Als et al. (1986).

Note: All tests were conducted using students' independent simple t-tests, with equal variances not assumed.

Table 4: Infants physiological parameters and behavioral states in all three sessions (mothers and fathers)

All sessions, mothers + fathers	MT+KC; N=37	KC; N=31	P- value
HR	148.84±7.65	151.12±7.62	P=0.22
RR	39.65±5.89	43.91±6.54	P=0.006
OS2	97.03±1.26	96.69±1.50	P=0.32
Body Temp.	36.57±0.06	36.56±0.04	P=0.34
NIPE	60.42±5.13	62.43±6.46	P=0.16
Als score	2.06±0.41	2.21±0.31	P=0.097

Abbreviations: MT= music therapy, SCC=skin to skin care, HR=heart rate, RR=respiratory rate, OS2= oxygen saturation level, NIPE= newborn infant parasymphathetic evaluation (NIPE) monitor, Als= behavior state score, according to the criteria by Als et al. (1986). *Note:* All tests were conducted using students' independent simple t-tests, with equal variances not assumed.

4.3.2. SUMMARY

The main findings of this sub-analysis demonstrated the beneficial effect of MT on the improvement of infants' respiratory rates during sessions, as compared to SSC alone. These results will be further discussed in the final discussion chapter (section 6.1). It is important to note that this sub-analysis is relatively limited as it was based only on the mean of each variable. Accordingly, another analysis of the change in each variable during the sessions (i.e., observation of the full five-minute interval) still needs to be carried out using the LME models.

CHAPTER FIVE: QUALITATIVE RESULTS

5.1. THE THIRD ARTICLE

The findings derived out of parents' experiences of participation in the MT intervention are presented via the third article of the PhD project: "Together in the music - Parents' reflections on participating in a family-centered music therapy intervention with their preterm infant in the NICU". Nine parents' have shared their experience of participation through semi-structured interviews. Their data was analyzed using the methods of thematic analysis (Clarke & Braun, 2016), and the thematic networks analysis model (Attride-Stirling, 2001). The main themes derived from parents' interviews revealed a circular process that occurred during MT sessions, in which moments and meanings of connection (to self or baby), relaxation (within self or baby), and reaching a state of the here-and-now occurred. A global theme of "being together in the music " concluded this process (Figure 3, right side). Parents explained that MT sessions were perceived as unique moments solely dedicated to connecting with their baby, which was different from the medical routine. Singing was experienced as a mean to provide something from deep within themselves to their baby, and motivated coping processes by overcoming personal difficulties of singing in the NICU. MT promoted relaxation for both parents and their baby, and feelings of intimacy and being in the moment with their baby emerged. Participating in the study had informed and motivated their use of music throughout the hospitalization period and was generated to their everyday lives.

5.2. ADDITIONAL FINDINGS

Most of the interview studies in the field have naturally focused on parents' perceptions and experiences of the intervention itself, related to the NICU experience or space. However, considering the context in

which the MT was offered and provided – a randomized controlled trial - some elements related to the study design or intervention protocol, general willingness to participate, or other aspects that an RCT may add have yet to be raised. The only known study to date that described these elements was the feasibility trial by Ghetti et al. (2021). Special characteristics of the NICU may further influence parents' experiences in MT through an RCT. Some conditions such as timing (limited number of sessions, forced pauses, or early termination), filling out questionnaires before or after the intervention, committing to a study while having a hospitalized infant and other methodological considerations may also shape the overall experience of participation, and maybe even influence the parents' measurements.

This chapter presents additional findings derived from the thematic analysis of parents' interviews, concerning their reflections on the study design and procedures. These findings were not included in the third article, due to an intended focus on the exploration of their experiences of the MT intervention, and due to a choice not to mix this investigation with the reflection on the c-RCT methodology.

During the interviews, parents were asked to reflect upon a few aspects of the study methodology. These questions included:

How did you experience the study conditions and measurements?

- In what ways, if at all did the research setting relate to the MT experience?
- What aspects, if at all, of the study methods were meaningful for your participation?
- Which conditions were needed to support the general participation in the study, and specifically in the MT intervention?

5.3. RESULTS: REACTIONS TO THE STUDY DESIGN AND PROCEDURES

Some parents referred to specific methodological aspects that were embedded in their overall experience. These findings were grouped

into three categories including conditions that were viewed as a) supporting, b) limiting, and c) both supporting and limiting by different parents, in terms of participating in the intervention and the study in general.

5.3.1. SUPPORTIVE ELEMENTS

Flexibility in scheduling sessions

Scheduling sessions according to parents' preferences and alternating needs was a way in which the MT was experienced as different from the NICU routine. When parents' requests to reschedule were accepted with understanding, they felt that their needs were valid.

Anxiety questionnaires informed about the mental state

Anxiety questionnaires helped some parents to track changes in their mental state and reflect on it.

"It deals with a lot of questions of how you are feeling, mood. It was interesting to ask myself how anxious I am. It was something that provoked thinking in me..." (T).

I really did not remember what I had written exactly. I tried to be as authentic with my answers, also the confused ones. And I saw a very, very big difference in the form (before and after intervention). So probably something happened here and it's unlikely that I'm fooling myself. So, I think this is it. Simply that moment when you finish it and then you say, wow! Really, I am not feeling the same as when I entered. (J)

Filling out the questionnaires at the follow-up session at home, helped two mothers to reflect and see their process of mental health stabilization.

It gave me a little comfort because I understood that when I saw the questions I was breathing. I was breathing because I saw that I am in a different place. There (in the NICU) I felt all the anger and frustration... There were even items that I did not agree to fill out there. And here I answered everything. I felt I

could cut some slack to myself. And it's empowering and strengthening and fun. Very much. (TA)

NICU sessions versus the home follow-up session

The session at home was described as much more fun and intimate than in the NICU. It served as a positive reminder and a kind of closure of the NICU experience. Some mothers explained that they realized they were much more relaxed, as they saw how their baby had grown and developed, and their connection had progressed a lot by then. However, the monitors and skin-to-skin were disturbing for some parents.

It brings up something because you see a character from the NICU, but it was a happy meeting. There you cannot describe what you go through there. At home was happy.... But I was less available because he (her baby) was already bigger and much (more) active. He wanted to touch her guitar, the ocean disk... We don't do kangaroo anymore cause he's not into it. So, the home experience was much more fun, but it was different. It wasn't like the quietness, the peacefulness (experienced in the NICU). (T).

"It was really fun; you can't compare it. At home you already know that they are fine, they are with you..." (M).

5.3.2. LIMITING ELEMENTS

Timing conditions

Two mothers found the fixed condition of the timing of the session (i.e., in SSC position and after feeding) challenging on certain days. One mother explained that finding that moment to sit in SSC after her baby was fed while navigating through the milk pumping and other NICU routines was hard at the second week of intervention. Another mother added that during a specific tough day she felt that she could not practice SSC or participate in the MT session since she was emotionally unavailable.

You need to maneuver to find for yourself even this tiny bit of time... but finding this timing between all the NICU's rules and procedures is very hard! So, at first, you turn everything around for that, and then with time, you are so tired that you say: I don't feel like it anymore. And then you're finding that you are escaping that as well. (TA)

5.3.3. SUPPORTIVE AND LIMITING

Inclusion criteria: the period between enrollment and the start of the sessions is fragile

Two mothers started their MT sessions around a month after their very preterm infants were born (at 25 and 27 weeks of gestation). For one mother, approaching when the infant was in a medically stable state was important for her sense of safety.

It is possible that if it (offering MT) was at the beginning of hospitalization I would have said “thank you very much, I don't want to, I'm not available right now”. But maybe because I was at a different place, I've gone through things a month or two, maybe more. So maybe the timing was actually good. I was used to the environment. (T).

However, for the other mother, this conditioned timeline had led her too long to start the sessions.

".. From the beginning, I wanted it (MT) and when they were in Kangaroo I would always put on music. I am really connected to music. I understood that according to the study conditions, they had to be unventilated." (M).

The small number of sessions: Different attitudes regarding the need for extra sessions

Most parents wanted more MT sessions. Some described that they had meaningful empowering experiences from the MT sessions. They had looked forward to the sessions, but the overall experience was for

some a relatively small aspect throughout their entire NICU experience. Accordingly, sessions were perceived as immediately relaxing. More time was needed to reach a deeper processing experience.

You are looking forward to that... although how many sessions were there two, three, but it was still something meaningful. But actually, parents such as in my situation, parents for very small preterm infants that have many dramas. it is something that is important to do with a higher frequency.... Music therapy was related to relaxing and less for processing. If it was at a higher frequency maybe I would have got to the phase of processing it (the NICU experience). (TI)

Others had also suggested that frequent MT sessions would be of high value, though it may have been just enough to what they could handle at that moment.

"I wish there were more (sessions)... It (the intervention) was little, but I also did not feel that I could do more times..." (TA).

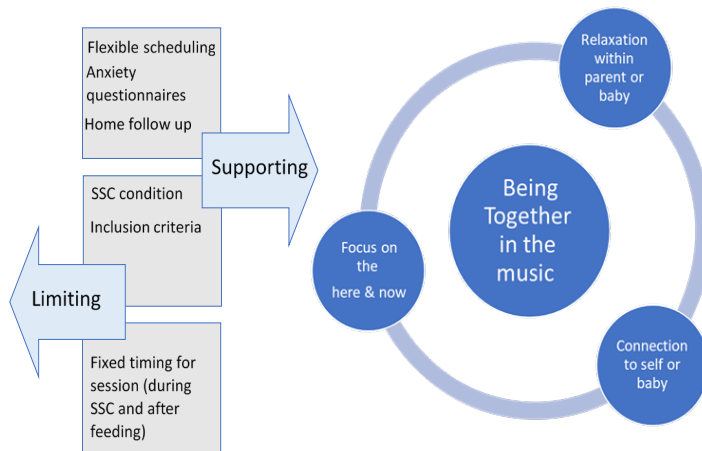
SSC condition

Most parents thought that the combination of MT and SSC was appropriate and "natural" and further enhanced the SSC experience, as it promoted feelings of safety by being looked after while being in SSC. In contrast, two mothers said they would have preferred to not combine. One explained that she was still not calm in general during SSC, and the other that her infant was less comfortable in full SSC, so she had to transition him to a slightly different position (on his side).

I would prefer to just hug him and listen to the music. Cause then I would have been in my comfort zone. All the time they (NICU staff) said he is feeling the mother, he's feeling the way you are, and that you need to be relaxed. Well, I was not relaxed then in general, you see? (TA)

Figure 3 presents an overview of the supporting and limiting conditions in relation to the parents' experiences of the MT intervention and participation on the study.

Figure 3: Concluding themes of qualitative analyses:



5.4. SUMMARY

The current findings have raised some important ethical dilemmas that are related to the unique characteristics and needs of parents to premature infants. The parents have highlighted a few methodological considerations including the inclusion criteria, number of sessions, the SSC condition, and the anxiety questionnaires that have shaped their overall experience. These findings may therefore offer some new insights to acknowledge when planning to implement a new study or an MT program in a NICU. These will be further reflected upon and discussed in the following chapter (in sections 6.2.2; 6.3; 6.5).

CHAPTER SIX: DISCUSSION

The current mixed-methods investigation aimed to explore how combined family-centered MT and SSC in the NICU affect premature infants and their parents. The following sections will first discuss the quantitative and qualitative results and methods separately, then will be brought together to a concluding mixed-methods discussion.

6.1. QUANTITATIVE RESULTS

The quantitative examination highlighted the need to address the stress experiences of both preterm infants and their parents. Accordingly, this study has focused on the preterm infants' autonomic nervous system activity during MT, compared to control sessions (Yakobson et al., 2020). The use of heart rate variability (HRV) measures was congruent with current literature in the field that emphasizes the ability of HRV and specifically the high frequency (HF) HRV examination to provide information on infants' stress responses and ability to modulate stress, through a method that is robust, objective and non-invasive (Butruille et al., 2015; Gardner et al., 2018). Several studies have demonstrated the beneficial effect of SSC on the improvement of HRV measures (Butruille et al., 2017; Cong et al., 2009; Feldman & Eidelman, 2003; Kommers et al., 2017; McCain et al., 2005). This effect was affirmed in the current investigation. The preceding beneficial effect of SSC on HRV improvement was considered as a potential variable that may diminish or reduce the effect of MT, yet the current results indicate otherwise.

The current cluster-RCT study was able to demonstrate a novel finding of the contribution of MT to improved autonomic regulation in preterm infants, compared to SSC alone, as indicated by improved HF-HRV power. So far, only one MT study (Epstein et al., 2020) had used HRV analysis and demonstrated negative results regarding the influence of MT on preterm infants and their mothers. It is important to note that this study focused on preterm infants with severe brain damage. In that case, MT that focused on maternal singing during

SSC was found to reduce autonomic stability and increase maternal anxiety. The authors thus concluded on the critical need to design specific interventions for this sub-population.

Parental outcomes included anxiety reduction and attachment-to-infant and were examined using validated psychological self-report questionnaires (Yakobson et al., 2020). These outcomes did not demonstrate significant effects of either MT or SSC alone on parental anxiety reduction or improvement of attachment-to-infant level. The anxiety evaluation presented a tendency for a larger reduction from pre- to post-measurement, and an overall lower anxiety level in the MT group. Yet these differences did not reach statistical significance. In contrast, earlier studies that investigated combined MT and SSC did find significant effects of MT on maternal anxiety reduction (Ettenberger et al., 2014, 2017; Kostilainen et al., 2020). These studies examined the change in anxiety level along the entire intervention period and not before and after each session. In one of these studies (Ettenberger et al., 2014) the results were significant for only two items of the entire questionnaire. Furthermore, in the current study, in both groups, the parental anxiety levels across all assessments were below the recommended clinical cut-off level for the STAI evaluation (Julian, 2011) indicating normal anxiety levels. The evaluation of attachment-to-infant level in both groups maintained a medium score (range of 72- 82 points) across all three assessments, with no significant group differences. To the best of my knowledge, the attachment-to-infant scale was not used in former NICU MT studies. Of the studies that focused on combined MT and SSC, Ettenberger et al. (2014, 2017) have examined the effects of MT on the parent-infant relationship through the mother-to-infant bonding scale (Taylor et al., 2005). In similarity to the current nonsignificant results for attachment-to-infant, in both mentioned studies no significant effect of MT for parent-to-infant bonding was demonstrated. In the current study, the small number of sessions may have influenced the study's ability to detect meaningful effects on anxiety or attachment-to-infant. The repetition of questionnaires' completion within a short period may have contributed to a worn-out in parents' attention or authenticity in reply, introspective ability or social desirability (Althubaiti, 2016).

Physiological measures of preterm infants (presented in chapter three) showed an overall significant effect of MT compared to SSC alone on reduction of infants' respiratory rate. This finding aligned with the results of a former meta-analysis (Bieleninik et al., 2016), that demonstrated a significant contribution of MT on the reduction of preterm infants' respiratory rates, as compared to standard care alone. The Newborn Infant Parasympathetic Evaluation (NIPE) monitor scores found similar values (above 60), indicating improved HF power, as was found in a former study that used this monitor's evaluation system (Butruille et al., 2017). In similarity to HRV power, the preceding beneficial effects of SSC alone on improved HR, O2S, and behavioral states were previously demonstrated as well (Carbasse et al., 2013; Conde-Agudelo & Díaz-Rossello, 2016; Pados, 2019) and may have impeded the study ability to detect meaningful group differences in preterm infants' physiological parameters.

6.1.1 METHODS AND PROCEDURES OF THE CLUSTER-RCT

The great investment in the construction of the cluster-RCT design may be reflected through the first article of this PhD project, the study protocol (Yakobson et al., 2020). The wish to conduct a rigorous study considering all limitations of the real-world setting of the specific open-space NICU and feasibility aspects (mainly concerning my limited availability as the only, non-funded music therapist) was challenging. The time-clusters design was a relatively innovative suggestion, made by my secondary supervisor (prof. Christian Gold), as an attempt to answer the request of the NICU staff to avoid the individual randomization sequence. However, as described in previous studies it required time to conduct (Torgerson, 2001), namely, almost two years of data collection. Nevertheless, it was highly adaptable and easy to use, for both the research team to comprehend and follow-through, and for the parents. Parents in the control condition were not blinded, but they did not see what they were "missing" by not receiving MT. The broad inclusion criteria together with the block randomization of clusters were also helpful to reduce selection bias, as I could not control any aspect related to recruitment of families to either of the allocated conditions (Tripepi et al., 2010). Rather, I could

only invite all the eligible families at the time of enrollment for each cluster (i.e., the first month of the cluster). The time-clusters design has worked as planned, and except for one case of a family from the MT arm, all families were released home before the end of their cluster period. Accordingly, the contamination bias between groups was reduced (Robinson et al., 2020). Furthermore, the cluster design randomization was deemed successful since baseline balance between groups in infants' characteristics was achieved, and a low dropout rate was evident.

The small number of sessions was one major limitation of the cluster-RCT design and was highly influenced by feasibility aspects of funding and my availability as the music therapist and researcher. It might be possible that the small number of sessions together with repetition of the same questionnaire have reduced the effect of MT in parents' quantitative outcomes. Accordingly, previous scholars in the field of neonatal MT had recommended a minimum of eight sessions to test for therapeutic effects (Hanson-Abromeit et al., 2008). Nevertheless, the home-follow up sessions provided a novel procedure and finding, as the evidence of rigor long-term examinations of MT with preterm infants and their parents are missing (Bieleninik et al., 2016; Haslbeck & Bassler, 2018).

6.2. QUALITATIVE RESULTS

6.2.1. FINDINGS OF ARTICLE 3: PARENTS' REFLECTIONS ON PARTICIPATING IN MT IN THE NICU

The main themes that emerged from the thematic analysis of parents' interviews suggested that parents have experienced the MT sessions as special moments throughout their NICU admission. The sessions were perceived as an activity that is dedicated to the parent-infant connection. Parents explained that MT had promoted relaxation in both them and their babies, and so assisted them in co-regulation. By reaching a mutual relaxation, and with the help of the music to mask the surrounding NICU environment, parents reached a state of focus in the here-and-now, their musical engagement with their baby

increased, and feelings of intimacy and deeper connectedness emerged. Accordingly, the main unique finding of this study suggested that a flexible transition between active and receptive participation (i.e., singing, and receptive listening) was meaningful to promote parents' comfortability and musical engagement. Receptive listening to the family's special songs of kin (Loewy, 2015) was found similarly meaningful to parents, and some even preferred this over singing. The fundamental role of singing and its contribution to infants, parents, and their relationship building has been thoroughly investigated (Ghetti et al., 2021; Haslbeck, 2014; Kostilainen et al., 2020; Bargiel, 2004; McLean, 2016; O'Gorman, 2007; Shoemark & Arnup, 2014). The current study findings, therefore, provide new insight into the ability of parents to connect through music without singing, and the importance of providing parents with additional means to engage musically in NICU sessions. Several findings have echoed former studies that interviewed parents after participating in a family-centered MT intervention with their preterm infant in the NICU. These concern themes such as the ability of MT to promote relaxation within parent or baby (Ettenberger et al., 2014, 2017; Teckenberg-Jansson et al., 2011); and the challenging though rewarding process of singing to the infant in the NICU (Ghetti et al., 2021; Kostilainen et al., 2020; Elizabeth McLean, 2016). Considering the relatively small numbers of studies in the field, the similarity between findings may symbolize the similarity of intervention techniques or suggest that the studies had a common focus on general needs of preterm infants' and their parents related to relaxation and regulation, and support of the infant-parent relationship through facilitation of musical interactions.

6.2.2. ADDITIONAL FINDINGS: PARENTS' REFLECTIONS ON THE RCT METHODOLOGY

The qualitative investigation also explored several methodological considerations of the RCT, and the roles it had for the parents' overall experiences (presented in Chapter five). Study conditions including the short-term design, inclusion criteria, fixed timing for intervention during SSC position, and measurements (the anxiety scales) were perceived as supportive and limiting parents' participation. The main

findings of this sub-analysis highlighted the theme of flexibility and timing and raised some ethical dilemmas related to keeping the protocol with such a sensitive population.

Being flexible and attending to parents' need to reschedule sessions due to feeling too tired for example on a certain day or finding it hard to seat in SSC and maneuver through the time-consuming breast milk pumping had made them feel understood and not being judged for not 'making it', thus promoted the therapeutic alliance and further emphasized the uniqueness of MT compared to the routine medical care they had to adapt to. Ghetti et al. (2021) also investigated parents' perceptions of study logistic and similarly found that finding the right moment (in their case when the infant was alert and after feeding) required a level of flexibility and availability from the MT' to attend when notified that such moments appeared and was important to maintain parents' participation.

Another time-related aspect concerned the inclusion criteria that required infants' medical stability. In this case, flexibility was not allowed, and infants were recruited only after reaching medical stability. This issue was specifically meaningful for two mothers of very preterm infants. These families participated in MT sessions after around a month of hospitalization, and the mothers had presented controversial perceptions regarding this condition. For one, engaging in MT sessions when her infant was already medically stable was helpful, as before that she was not mentally available. However, for the other mother, this condition was limiting, as she longed to have MT sessions since her twins were born at 27 weeks of gestation. Accordingly, she felt that the entire MT experience did not fulfill its potential to accompany her through the NICU admission. Retrospectively, her participation should have been considered again. Maybe for her, it had been better to not participate in the study, and just receive MT sessions whenever possible.

In continuance, the small number of sessions was highlighted in the varied interviews. Most parents stated that they wanted more sessions in the NICU, than the two study sessions during SSC time. Sessions at a higher frequency were needed to support them through the medical

treatment period. Two mothers explained that they did not have enough time to get into deep processing of their NICU experiences. As one father had explained, it was a rather small part of their entire NICU experience: "Small and excellent. I would go through it exactly the same, just if you added more sessions" (A). Accordingly, most parents argued for the necessity to provide music therapy in the NICU frequently. Indeed, in the clinical reality in the field, there are cases of only a few sessions, but often families participate in more than two sessions (depending on their infant's length of hospitalization; usually they receive one to two weekly sessions). This theme was not apparent in former interview studies, maybe simply because most have provided more than two sessions in the NICU. Hence, the findings regarding parents' experiences in the sessions discussed the here-and-now, and the meaningful immediate contribution of MT to relaxation and intimacy construction, though did not present themes related to deeper personal processes that occurred over time, such as the formation of parental identity (McLean et al., 2018; McLean, 2016), or the development of the therapeutic relationship and the processing of fathers' NICU experiences through varied music-making activities such as the song of kin creation and recording (Mondanaro et al., 2016).

Finally, some understandings regarding the potential roles of the anxiety questionnaire were revealed. Some parents explained that filling out the anxiety questionnaire helped them track changes in their mental state. During the NICU sessions, it provoked awareness of their mental state or motivated them to continue participating in the MT sessions (since they saw and felt the immediate relief). At home, it served as a reassuring reflection of their stabilization and recovery from the NICU period. Ghetti et al (2021) have also asked parents about their perception of several questionnaires from a feasibility stance. Parents had pointed out whether the content was appropriated, or if the burden of filling it out was acceptable. Their findings similarly revealed that parents perceived that completion of several questionnaires was tolerable and appropriate.

6.2.3. METHODS OF QUALITATIVE ANALYSIS

The method of thematic analysis was chosen due to its high flexibility and accessible approach. The thematic analysis specifically details a number of steps that assist in organizing a large data set and examining different participants' perspectives, yet, keeping the complex layers of the content (Braun & Clarke, 2006). Nowell et al., (2017), argues that since this broad approach does not require specific theoretical knowledge, it may also disadvantage the analysis by leading to a lack of consistency and clarity while developing themes. The authors cite other scholars (Holloway & Todres, 2003), that suggest that reaching a coherent report may be enhanced by taking a clear epistemological position that can adhere to the research aims. Indeed, after the first analysis of the interviews' transcripts, I found myself navigating back and forth in the long list of the different themes, trying to make a sense of it altogether. I chose to use a hermeneutic approach, which guided this procedure of checking and rechecking the appropriateness of the analysis while admitting the inevitable interpretive component of the analysis and the researcher's inherent role in this process (George, 2020). To reach a comprehensive understanding of the varied themes and subthemes, at a certain point I needed another means to organize and conceptualize the data as a whole and thought that a visual figure may assist. Accordingly, I used Attride-Stirling's thematic networks analysis model (Attride-Stirling, 2001), which provides detailed guidance in organizing the varied subthemes and themes that were generated in the first thematic analysis. This process led to a refined identification of the main subthemes, and to conceptualize the encompassing idea – the processes and events that parents described to occur in the sessions. These concepts were brought together to the final overarching theme (of the MT experience) "being together in the music". By so doing, the figure established the closure of the hermeneutic circle of the analysis. After additional readings of the interviews and checking that indeed the entire (or at least the majority) of the data set is represented, I sensed that it reached a comprehensive understanding of the whole and its parts (Grondin, 2015).

The qualitative findings were divided between the third article and chapter five of the current text. The article focused on parents' experiences and perceptions of the intervention, and Chapter five addressed the RCT methodology and how it shaped their overall participation. Listening to parents' reflections on the RCT methodology has touched on a few ethical dilemmas which I perceived as important to highlight for clinicians and future studies in the field. Accordingly, enough space to keep listening to parents, and give the parents a voice in the study, was made.

6.3. MIXED METHODS RESULTS

The findings of this mixed-methods study suggest that family-centered music therapy during SSC assisted preterm infants and their parents in physiological and psychological domains. Compared to SSC alone, MT has promoted relaxation and stress reduction in preterm infants as was indicated by their improved autonomic nervous system stability and respiratory rates. Parents' quantitative measures of anxiety showed a tendency of a larger reduction of anxiety from before to after MT sessions. The qualitative findings provided deeper insights into the mechanisms of the MT intervention. Parents explained that MT promoted relaxation in both them and their infants and assisted the construction of intimacy and focus in the here-and-now experience with their infant. During this process, parents' feelings of connectedness with their baby and their musical engagement have deepened. These findings highlighted the importance of keeping a flexible approach in the MT intervention, and supporting parents' musical engagement through varied means, including singing, guided breathing, and receptive listening to their song of kin (Loewy, 2015). Accordingly, it could further deepen the understanding of the beneficial quantitative results of the infants. Infants in the MT group showed increased autonomic stability and improved respiratory rates in MT sessions, during a very protocolized yet flexible intervention that did not focus solely on singing. This study, therefore, suggests that attending to parents' alternating needs and preferences in the participation approach had promoted relaxation and deeper musical engagement with their infant, which led to an improved state in the infants' autonomic nervous system.

A discrepancy between the quantitative and qualitative findings concerned the anxiety evaluations. In the quantitative analysis, a nonsignificant trend favoring the effect of MT was demonstrated, yet overall, in the entire sample, the anxiety levels were kept below the clinical cut-off representing normal anxiety levels. However, parents elaborated at length on the questionnaire's completion, and the positive contribution it had for their ability to self-track changes in their mental state in the NICU, and along the home session.

A common limitation that seemed to be meaningful in the different analyses related to the short-term design. The small number of sessions may have impeded the RCT's ability to detect meaningful effects on parents' anxiety or attachment-to-infant levels. And in the qualitative analysis, the need for more sessions was a consensus between parents' interviews. Teckenberg-Jansson et al., (2011) noticed that preterm infants' vital signs (HR and RR) were improved in correlation with an increase in the number of sessions they experienced. The authors, therefore, concluded that the combined modalities of MT and SSC may be a learning process for infants as well as for parents. Infants may learn and process the experience only after the multimodal session and so the beneficial physiological effects may be visible only after 2-3 sessions. Similarly, parents' acquaintance and comfortability in MT sessions may be gradually improved in the first sessions, and their initial tension may have impacted the infants' ability to benefit from MT in the first session. In this study the quantitative analysis focused on the second intervention session and considered the first session as preparatory, assuming that by the second session parents would be more familiar with the process (Yakobson et al., 2020). Nevertheless, the current results presented beneficial effects for infants starting from the second session.

6.3.1 MIXED METHODS ADVANTAGES AND LIMITATIONS

The use of both quantitative and qualitative methods was based on the acknowledgment that it was very important to provide a rigorous quantitative examination of MT in the NICU using meaningful physiological outcomes (Foroushani et al., 2020). Nonetheless, the complex layers, influences, mechanisms, and subjective experiences

of MT called for a thorough qualitative exploration (McLean, 2016). Accordingly, the mixed methods embedded design enabled a more comprehensive evaluation and understanding to answer the research questions (Creswell, 2013). The pragmatic application of and navigation between objective and interpretive positions, aims, and research questions were optionable by using the embedded mixed-methods design (Robson & McCartan, 2016). The study was able to provide meaningful findings that would adhere to the objectivist paradigm, which is central in the medical world of the NICU and emphasize the importance of including MT within standard neonatal care. In parallel, the interpretive qualitative inquiry was helpful to further expand the evidence-based knowledge regarding parents' experiences of the MT intervention, and by so to generate deeper insights in the parents' experience and on the mechanisms of the intervention; how the shared musical experience had assisted infants and their parents to reach co-regulation and mutual relaxation.

The risk of discrepancies between quantitative and qualitative findings (Robson & McCartan, 2016) did occur when parents' perceptions on the meaningfulness of the questionnaires' completion were not reflected with significant statistical differences. Nevertheless, the qualitative inquiry did not aim to quantify the qualitative findings and answer the same quantitative question. Rather it aimed to explore and elaborate on parents' mental processes during sessions. Another limitation concerning the use of the embedded mixed methods design related to the need for more resources to produce a thorough investigation in each method. The assistance of L.L (my MT intern) in performing the qualitative interviews and recording infants' and parents' measurements in several sessions during the second year of data collection was helpful. Despite the known risk of mixed-methods investigation to limit the depth of each investigation (Creswell & Clark, 2010), I believe the final reports provide thorough inquires in both methods.

6.4 THE MT INTERVENTION

The intervention protocol (Yakobson et al., 2020) emphasized a family-centered approach focused on the parent-infant dyad and

parental leading of the intervention. Acknowledging the varied inner and external challenges that may follow singing in the public space, I wished to offer parents additional means for musical engagement including guided breathing and relaxation accompanied by the ocean disk, and receptive listening to their songs of kin (Loewy, 2015). The intervention design was based on my clinical experiences from meeting families at the NICU, using the knowledge I learned from the RBL training. At many occasions, I realized that parents did not sing at all sessions; or that within the session, there were different parts. Even the most enthusiastic music-lovers, or professional musicians at certain times asked for other musical elements such as the ocean disk, humming, receptive listening; and often also verbal communication - for ventilation, and emotional processing of the preterm birth or the NICU admission experiences. From the initial work on the research proposal, I realized I had a strong feeling/intuition and practical need to explain to my mentors that it is important to not define the intervention as singing. Accordingly, the intervention protocol emphasized the flexibility of intervention, supporting both active and receptive participation, where the main aim was to assist parents and their infants to create a 'bubble', a safe intimate environment in which they could be together (Yakobson et al., 2020).

Specific elements of the "first sounds: rhythm breath and lullaby (RBL) model" (Loewy et al., 2013) were highlighted by parents as meaningful to their processes of relaxation and musical engagement. These included the creation and use of families' song of kin (Loewy, 2015), the attention to the infant, parent and the environmental needs. The reciprocal interaction (i.e., how the music affects the regulation of the sound environment, and how both the session and the environment contributed to it). The use of the ocean disk to promote breathing and relaxation also appeared as important element (Loewy et al., 2013). The current study therefore highlights the shared communicative musicality experience between all three parts in a session: infant, parent, and music therapist, that promoted interaction, connection and relaxation.

The methodological decision to apply the MT intervention during SSC time was suggested by Prof. Arnon, the senior neonatologist at the unit. It was based on his former successful study of combined

maternal singing and SSC (Arnon et al., 2014); and was further reinforced while we aimed to provide an intervention that is in line with the NIDCAP principles. Ettenberger et al. (2014; 2017) had also applied a family-centered MT intervention during SSC that was based on the RBL principles and similarly offered parents of preterm infants to alternate between active and receptive participation. He explained that SSC may be the most intimate moment parents and infants may have in the NICU, and by so it has a crucial role for their developing relationship. At the early SSC phase, parents are often still very anxious, do not feel comfortable or confident when holding their baby as they are just getting to know them and their behavioral cues. The babies are also very sensitive and feel their parents' tension. Accordingly, supporting the dyad to calm down and try to be together, physically, and emotionally in these precious fundamental moments is essential (Ettenberger et al., 2017)

6.4.1 TREATMENT FIDELITY

There were no systematic efforts to provide treatment fidelity. However, a few described procedures were simultaneously taken to adhere to the intervention protocol. First, I completed written personal reports after each MT session and had clinical supervision to process and discuss upon the clinical work. During the sessions, I used the infants' tracking sheets and wrote each event (such as singing, speaking, humming, etc.) in its respective time of occurrence. Finally, I was also a clinical supervisor of L.L., an MT intern who joined the research and assisted in recording infants' measures during sessions and interviewed parents. She observed many sessions and posed questions, so I had to reflect on and explain what were happening during the sessions. The fact that I was observed and needed to explain the intervention further assisted me in maintaining awareness and keeping the intervention in line with the protocol. The risk of bias due to the double role of researcher and therapist that also recorded measurements during sessions (for the control group as well) were reduced by the repeated observation. After a thorough training by the NIDCAP trainer in the NICU (Dr. Dalia Silberstein), L.L also recorded infants' measures. I have described these conditions in the study protocol (Yakobson et al., 2020).

6.5. VALIDITY AND QUALITY ASSESSMENT

The study protocol was critically peer-reviewed several times to account for multiple aspects that would enhance the validity of the methods and findings. These relate to the chosen design, outcomes, measurements, and analysis procedures (Yakobson et al., 2020). The concept of stress reduction in preterm infants was measured by the analysis of infants' HRV during sessions. This outcome was chosen due to a theoretical agreement within varied scholars in the fields of neonatology and child development on the useful application of HRV analysis as an indicator of the autonomic nervous system activity (Butruille et al., 2015; Feldman & Eidelman, 2003; Gardner et al., 2018; Mulkey & du Plessis, 2019; Porges & Furman, 2011).

The HRV analysis in the current study was conducted by an external neonatologist, and so further strengthened the robust, objective analysis and findings. However, along the analysis process a discourse regarding the appropriate level of data procession occurred. First, the external neonatologist had conducted the HRV analysis on a group level; gathering all infants' ECG recordings together to analyze through the HRV software. He explained that it was his common year-long practice; similar to a CT scan analysis which many image slices of body tissues are collapsed together (NIBIB, 2018), and that the method of analyzing each individual separately would provoke a higher standard deviation. My supervisor and the study statistician did not agree, arguing that individual data was critical to perform a valid analysis, that would have sufficient data to examine changes during or across sessions. The neonatologist kindly agreed to conduct another HRV analysis on an individual level. Indeed, the standard deviation of the individual participant data was higher, and the results of the group means in the HRV indices were slightly different than the first analysis. Retrospectively, I am grateful for this discourse, that was not so comfortable to handle at the time. Having individual data for each infant was fundamental to conduct the statistical analysis using the linear mixed-effects (LME) models. The LME model is considered as state-of-the-art in its ability to include complex cases of repeated measures, and its flexible ability to deal with missing data, and model

and estimate the variance and covariance structures of both random and fixed effects (Chen et al., 2013; Yakobson et al., 2020).

Parental outcome measures of state anxiety (Spielberger et al., 1983) and attachment-to-infant (Condon & Corkindale, 1998) were similarly chosen due to their high validity and common use in related literature. However, the power analysis for the required sample size was targeted at infants and not parents' outcomes, which may have contributed to a lack of power to detect meaningful effects or group differences. The short-term design as discussed earlier might have influenced these results as well. The attachment-to-infant assessment seemed appropriate in its content, though was probably not amenable to examine in such a short therapeutic process. Additionally, the anxiety assessment might have been eroded due to the high degree of repetition of the questionnaire before and after each test.

The use of self-report questionnaires may have some advantages such as high feasibility (i.e., may be easy to obtain), and can be applied anonymously, and by so promote trust-worthy responses (Warner et al., 2011). Indeed, the examination of self-report state-anxiety levels in a wide range of music and MT studies is common, though it may as well be supported by physiological measurements (de Witte et al., 2020). Accordingly, it can be argued that additional physiological measures for parental stress such as salivary cortisol levels examination, would have provided important information and may have resulted in different results compared to the state-anxiety evaluations.

In the qualitative thematic analysis, several steps were taken to establish the trustworthiness of the findings, including credibility and confirmability (Nowell et al., 2017). The analysis was enhanced by the length of engagement with the text, the visual mapping using thematic networks, and several members checking to verify the level of compatibility between the parents' views and the representation of those in the analysis. This process occurred between me, B.B my supervisor, and L.L, which conducted most of the interviews and transcribed them. The final generated themes were also congruent with current literature in the field, and by so suggested that parents had described their authentic experiences and that the analysis did not

misinterpret or presented vague descriptions. The process of analysis was transparent and discussed in detail in the third PhD article.

6.5.1. TRIANGULATION

Triangulation is a method to enhance the validity and credibility of the research findings (Noble & Heale, 2019). It is considered as one of the main advantages when conducting a mixed-methods study, as the use of several different methods allows the researcher to investigate different but related questions. By so it may assist to evaluate the "plausibility of threats to validity of the primary research technique used" (Robson & McCartan, 2016; p. 384). The current study included methodological triangulation in the overall mixed methods design, and data triangulation of physical and psychological quantitative measurements (Denzin, 2012). In the qualitative examination, a sort of researcher triangulation had occurred, as both L.L and myself analyzed the interview transcripts separately, and B.B reviewed and discussed the analysis and themes several times.

6.5.2. DOUBLE ROLE: MUSIC THERAPIST/ RESEARCHER POSITION

In my perception, being in the dual role of a researcher and therapist had varied benefits and limitations. While I was aiming to present a well-designed and conducted randomized controlled trial (RCT), I was occupied with its' limitations that were also mentioned by some parents - regarding the short number of sessions, and the limitation it brought for their possibility to "dive into" an emotional investigation. As the MT, I felt that despite these limitations, in most cases the sessions did contribute to help these families in various ways. Reading parents' interviews helped me to get out of the quantitative focus and reminded me of the "magic" that happened during sessions, and why I originally chose to devote myself to conduct this study. I sensed that the most meaningful "effects" were reflected on in a deep way. The role as a quantitative researcher that I have maintained throughout this project as the primary investigator of the RCT has fairly influenced my thinking (with a focus on efficacy, numbers, what did we manage to prove, etc.). And so, it was challenging to move to another mindset

and begin a qualitative exploration. Nevertheless, it was also liberating to know I can explore and reflect upon the study from a different angle. Being in the dual role of a researcher and therapist in the quantitative study had its' own benefits and limitations, yet in some way, the deviation between both roles was clearer. The objectivist measurements made me feel safe, that my position as the music therapist would not affect the results. The qualitative inquiry was a different case. Being the music therapist who conducted the sessions I had so many reactions to parents' reflections. I was sometimes surprised by the shared experiences, and the precise memories parents had. I felt even more inspired and appreciative of the parents' efforts in the NICU. At sessions end, I would usually thank parents for allowing me to join their intimate moment of SSC. After I have completed the data collection, I became a mother (of a full-term). As I sang to my baby during SSC in the privacy of my own home, I was even more struck and amazed by the fact that parents collaborated. And realized even more how much their participation was not that obvious.

The project was also the first step of providing MT at that specific NICU. I had a lot to reflect on as a therapist, who was forced to work under certain conditions, including the study design and methods and being the researcher as well. During sessions, I also monitored and documented infants' measures and collected questionnaires from parents. Not a classic therapeutic relationship. I have focused on a specific intervention, MT during SSC, for a long period with many families. It has deeply affected my practice, witnessing how intimacy, connection, relaxation, and release are further enhanced through MT during the essential time of SSC. To my perception, it is essential to start MT processes in the NICU during SSC. I was happy and reassured to read that others had argued the same (Ettenberger et al., 2017; Haslbeck & Hugoson, 2017; Teckenberg-Jansson et al., 2011). Having that understanding as I came to analyze the data, may have influenced the way I presented it, also emphasizing my personal stance on the uniqueness of combined MT and SSC. It is interesting to note that the theme of flexibility was also reflected in the RCT, with insisting on offering a flexible intervention or accommodating timing according to parents' and infants' alternating needs. Maybe again it also reflects on my dual role as a researcher and music therapist,

trying to provide a rigorous trial but to address the needs of people as I experienced them in the NICU.

6.6. STUDY LIMITATIONS AND ADVANTAGES

The pitfalls of each methodology were elaborated on in the preceding sections. This section will therefore relate to the macro level of the study. The choice of the embedded mixed methods was deemed appropriate, as the secondary qualitative investigation addressed a different research question (Creswell, 2013). By so it could complement a deeper understanding of the effects and mechanisms of the MT intervention. The use of mixed-method may therefore be much appropriate to the health care setting, where both methods are used to improve the evidence-based practice (Kajamaa et al., 2020). The triangulation of the different methods did result in some discrepancies in the findings (Robson & McCartan, 2016). The concept of stress was examined through physiological and psychological measures and was deeply elaborated upon in parents' interviews. Infants' outcomes did show improvement in stress reduction, though parental anxiety measures did not. Nevertheless, the qualitative inquiry did not ask parents the same question (i.e., what was their mood as in the anxiety questionnaire). Rather what has happened and how did they experience the intervention. Accordingly, the findings are reported separately and are not directly integrated (Creswell, 2013). The different methods did not interfere with each other as possibly could if another design was used (for example, parents' reflections did not inform or guided the intervention during the study or the measurements). In that sense, it was relatively a straightforward reflection on the RCT, which also reflected the dominance of the quantitative data set.

The study was designed to suit the specific conditions and guiding theoretical principles of the participating NICU, and so the need to adapt to the available resources were not necessarily the ideal test conditions. Nevertheless, it was based on real values and needs of the clinical field and so it may offer some valuable findings and methodological considerations (Robson & McCartan, 2016). The cluster design had major limitations concerning the length of time

required for data collection and the small number of sessions, though I hope it can also offer researchers another method to deal with the difficulties of individual randomization. Along the way, Prof. Arnon and I critiqued ourselves as working in "the Israeli method" - doing all on ourselves, trying to conduct a rigorous trial despite a few feasibility and methodological limitations; and while introducing the new MT service to the NICU. Accordingly, we had to "fix" and rethink things along the way such as the design or the HRV analysis. Deciding to propose this study as my PhD application was inevitably helpful in the improvement of all methodological aspects. Finally, another great outcome of overcoming the varied methodological limitations and conducting a rigorous examination was the implementation of MT in the unit, with a recent fixed position for MT that was granted by the NICU management.

6.7. IMPLICATIONS AND RECOMMENDATIONS FOR FUTURE RESEARCH

Despite several methodological limitations, the study was able to reach the aims of providing a rigorous quantitative examination of the effects of MT on preterm infants' ANS stability, together with a detailed description of parents' experiences in MT and the mechanisms of the intervention. Furthermore, the study included fathers and a follow-up session after the NICU discharge, elements that are new and called for in the field of neonatal MT studies (Bieleninik et al., 2016). Finally, it has assisted in reaching another general goal, the implementation of MT as part of the standard developmental care at the participating NICU. To maintain the study informed by the pragmatic perspective, the following sections will focus on the experiences and actions that occurred during the study and will aim to provide *actionable knowledge* (Kelly & Cordeiro, 2020). The qualitative inquiry provided important knowledge regarding the ethical dilemmas and flexibility needed when trying to adhere to the RCT protocol with such a sensitive population. Accordingly, the study may offer both clinicians and researchers some insights into how to continue listening to parents.

6.7.1. KEEPING A FLEXIBLE APPROACH

Following the NIDCAP approach at the NICU, there was enough space to keep humanizing the intervention and methods. Allowing flexibility in scheduling sessions according to parents' alternating needs was valuable to support parents' continuous participation. The theme of flexibility was found meaningful also regarding the MT intervention. The choice and transition between receptive and active techniques of the MT intervention were deeply discussed in the third paper and suggested that allowing parents additional means (besides singing) to engage musically with their infants was valuable and supported their participation.

The inclusion of fathers in the study was another new aspect compared to other studies in the field. In the quantitative study fathers have constituted 15 % of the parents, and in the qualitative inquiry two out of nine parents were fathers. Interestingly, most fathers participated when their wife has participated as well (only three fathers participated without their wife participating too). Additionally, fathers of twins were more present in the NICU. During the intervention period, allowing fathers to participate in sessions whenever they were available eased to maintain their participation. For example, even if the mother has already done with her first session, and suddenly the father was present and free than he participated before the mother has completed her second NICU session. I tried to keep as close as possible to the protocol timeline (maintaining a week difference between NICU sessions) but allowed for two to three days flexibility. Accordingly, each parent-infant dyad was accounted for separately in the statistical analysis.

The current study findings also suggest that questionnaires' completion may be a meaningful tool for parents' self-evaluation during the NICU admission. Clinicians may consider adding some self-report measurements for parents to evaluate music therapy services as part of the routine care, and not just for study purposes. Parents have explained that answering even more than one questionnaire may be amenable and benefit them by raising awareness and enabling visualization of mental state self-evaluation.

6.7.2. IMPLICATIONS FOR FUTURE RESEARCH

To the best of my knowledge, the current cluster-RCT is the first MT study that used HRV analysis with medically stable preterm infants. HRV analysis is considered a meaningful and noninvasive method to examine preterm infants' ANS stability and stress regulation (Gardner et al., 2018; Mulkey & du Plessis, 2019; Porges & Furman, 2011). Reduction of stress levels in preterm infants is fundamental to their physiological, neurological, and socioemotional development (Browne, 2021; Graven & Browne, 2008). The use of HF-HRV analysis is accessible through spectral analysis of the routine monitor recordings, or the NIPE monitor. Accordingly, it is recommended to use HRV analysis when aiming to demonstrate a meaningful effect of stress reduction. Additionally, the time-clusters design offers a new method to deal with the contamination risks of conducting a comparison test in an open bay setting.

As described in the preceding literature background (chapter 2), there are currently two large-scale longitudinal trials that are being conducted, examining long-term effects of MT on preterm infants development, their parents' wellbeing, and infant-parent bonding (Ghetti et al., 2019; Haslbeck et al., 2017). These studies have already provided promising results from their pilot studies, regarding the beneficial effects for preterm infants' brain structure and connectivity (Haslbeck et al., 2020); and the feasibility of a long-term intervention, and its potential contribution to the parent-infant interaction dynamics (Ghetti et al., 2021). Hopefully, the results of these longitudinal trials will provide meaningful evidence to support the inclusion of MT as part of the standard care for preterm infants and their parents worldwide. Nevertheless, the need to provide additional rigor family-centered NICU-MT RCTs, applying meaningful physiological outcomes such as HRV is still warranted (Foroushani et al., 2020). Similarly, longer-term qualitative explorations of MT with parents and their preterm infants after the NICU discharge are scarce and needed to inform and extended the evidence-based literature in the field.

In the current study, there are still some measures that require further analysis and dissemination, including the additional physiological measures of infants (vital signs and behavioral states), and possibly a

correlational analysis such as behavioral states and HRV (Gardner et al., 2018). Also, the parental measures concerning the use of music in everyday lives.

6.8. CONCLUSIONS

The family-centered music therapy combined with skin-to-skin care was demonstrated as a multimodal intervention with several beneficial contributions to preterm infants and their parents, including stress modulation and ANS stability, and enhancement of meaningful connecting interactional experiences. Facilitating conditions that enable co-regulation and intimacy between parents and infants during the NICU admission period is vital for their developing relationship and overall physical and socioemotional development. The current study suggests that supporting both active and receptive MT approaches is meaningful and useful to promote parental participation and musical engagement.

Personal note

Thank you, dear reader, for making this far. I would like to end this thesis with a quote from one of the fathers who participated in the qualitative inquiry. He interviewed together with his wife, and at the end of the meeting they discussed whether the intervention should be defined as singing. The mother explained that when she was first invited to participate, the neonatologist explained that she will sing, and it stressed her. The father had then answered how he felt about it, and I was simply happy to read how he explained his overall experience, just as I wished it would be:

" I had no stress about nothing. You want to sing, sing. You want to hum, hum. And then, suddenly you realize that you want to sing!" (J).

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Appendices

Appendix 1: Informed consent form

שם הנוהל: נוהל ליסויים רפואיים בבני-אדם		תאריך: מאי 2014
טופס 2 ה		מספר: 0
0283-15-MMC		טופס הסכמה מדעת להשתתפות בניסוי רפואי

אני החתום¹ מטה:

שם פרטי:	שם משפחה:
מס' תעודת זהות:	מיקוד:
כתובת:	

- (1) מצהיר בזה כי אני מסכים להשתתף בניסוי רפואי, כמפורט במסמך זה.
- (2) מצהיר בזה כי אני משתתף בזמן חתימת מסמך זה, בניסוי רפואי אחר הכרוך בשימוש במוצר מחקר כלשהו, וכי אני מתחייב לא להשתתף בכל ניסוי רפואי אחר הכרוך בשימוש במוצר מחקר במשך כל תקופת ניסוי זה.

(3) מצהיר בזה כי הוסבר לי על-ידי:

שם החוקר המסביר:

3.1 כי החוקר הראשי (שם הרופא): ד"ר שמואל ארנון קיבל ממנהל המוסד הרפואי, אישור לביצוע הניסוי, כמשמעותו בתקנות בריאות העם (ניסויים רפואיים בבני-אדם תשמ"א-1980), להלן הניסוי הרפואי.

3.2 כי לחוקר הראשי ולחוקרי המשנה יש זיקה² ליזם הניסוי³. אם יש, פרט:

חוקר הראשי הוא גם יוזם המחקר

- 3.3 כי הניסוי הרפואי נערך בנושא: השפעת הטיפול המשפחתי במוסיקה בעת תנוחת עור לעור) תנוחת קנגרו(להורדת חרדה בפגים והוריהם, ובחינת ההבדלים בין האם לאב.
- 3.4 כי אני חופשי לבחור שלא להשתתף בניסוי הרפואי, וכי אני חופשי להפסיק בכל עת את השתתפותי בניסוי, כל זאת מבלי לפגוע בזכותי לקבל את הטיפול המקובל.

3.5 כי במקרה של מילוי שאלון – אני רשאי שלא לענות על כל השאלות שבשאלון או על חלק מהן.

3.6 כי מובטח לי שזהותי האישית תשמר סודית על-ידי כל העוסקים והמעורבים במחקר ולא תפורסם בכל פרסום, כולל בפרסומים מדעיים.

3.7 כי המוסד הרפואי פעל להסדרת ניסוי ביטוחי הולם של החוקרים, הרופאים והצוות הרפואי העוסקים בניסוי הקליני מפני תביעות שיוגשו ע"י משתתפים בניסוי הקליני ו/או תביעות צד ג' הקשורות

¹ הטופס נכתב בלשון זכר מטעמי נוחות בלבד ומיועד לשני המינים.
² קשר של העסקה בשכר, או קשר מסחרי או עסקי, או קשר משפחתי או אישי, וכל קשר אחר, לרבות קשר של כפיפות בעבודה, שיש בו כדי לעורר חשש לקיום נגוד עניינים או תלות.
³ אם החוקר הראשי הוא גם יזם הניסוי, יש לציין זאת במפורש.

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Matarot Helsinki

21-Mar-17

עמוד 1 מתוך 5

0283-15-MMC

תופק ע"י: יגב רחל גראס

Please think about the environment before printing  אנא חשבו על הסביבה לפני הדפסת המסמך

שם המהלך: נוהל לניסויים רפואיים בבני-אדם		תאריך: מאי 2014
טופס 2 ה		
0283-15-MMC	מספר: 0	
טופס הסכמה מדעת להשתתפות בניסוי רפואי		

עם הניסוי הקליני בין בתקופת ביצוע הניסוי ובין לאחריו. אין באמור כדי לפגוע בזכויותי על פי כל דין.
 (3.8) כי מובטחת לי נכונות לענות לשאלות שיועלו על-ידי וכן האפשרות להיוועץ בגורם נוסף (לדוגמה רופא-משפחה, בני משפחה וכו'), באשר לקבלת החלטה להשתתף בניסוי הרפואי ו/או להמשיך בו.

(3.9) כי בכל בעיה הקשורה לניסוי הרפואי אוכל לפנות ל-**"ר שמואל ארנון** בטלפון/נייד: **09-7472225 057-7482772**, בכל שעות היממה. עלי לדווח מיד לרופא שפרטיו לעיל על כל בעיה רפואית, פציעה או אירוע בריאותי אחר העשוי להיות קשור למחקר. אם אפגע כתוצאה מהשתתפותי במחקר, עלי לפנות אל רופא המחקר על מנת לקבל טיפול רפואי מתאים וכן פרטים נוספים על זכויותי בהקשר זה. חתימה על טופס זה אינה גורעת מזכויותי לפי החוק.

(4) מצהיר כי נמסר לי מידע מפורט על הניסוי הרפואי, על פי הנושאים המפורטים להלן:

4.1 **רקע כללי וחשיבות הניסוי.** תינוקות שנולדו בטרם עת (פגים) והוריהם, אשר שוהים שבועות עד חודשים במחלקת הפגים (טיפול נמרץ לתינוקות שנולדו בטרם עת), נוטים לחוות רמות גבוהות של חרדה המובילה לתגובות לחץ מתמשכות. התייחסות ומתן מענה לצרכיהם הרגשיים והפיזיולוגיים של הפגים לשם יציבות ונוחות, כמו גם מתן תמיכה להוריהם לפיתוח תהליך ההתקשרות של ההורה- ילד. בנוסף, הפחתת תגובות לחץ, מקדמת זיכרון תפיסתי ולמידה בקרב פגים. לאורך השנים פותחו מספר מתודות להפחתת רמות חרדה המכוונות לתמוך בפגים ובהורים, כאשר שתי התערבויות מבוססות ומוכחות ביעילותן וביכולתן להציע מענה לצרכיהם המגוונים של פגים והוריהם במהלך אשפוז בפגים הינן תנוחת "עור לעור" וטיפול במוסיקה.

4.2 **מטרת הניסוי.** 1. בחינת השפעת הטיפול במוסיקה בעת תנוחת עור לעור על מדדים פיזיולוגיים (קצב לב, קצב נשימתי ורמת סטורציה בדם), המערכת האוטונומית, ומצבים התנהגותיים (שינה, עוררות שקטה, בכי ועוד) בקרב פגים.

2. בחינת השפעת הטיפול במוסיקה בעת תנוחת עור לעור על הורדת חרדה בקרב הורי הפגים.

3. בחינת ההבדלים ברמות החרדה שבין אבות לאימהות.

4. בחינת השפעת הטיפול במוסיקה בעת תנוחת "עור לעור" על תהליכי התקשרות הורה-ילד בקרב הורי הפגים.

5. בחינת החוויה האישית של ההורה בעת הטיפול במוסיקה.

4.3 **מספר המשתתפים בניסוי.** 50 טריאדות של תינוק+ אב+ אב, סה"כ 150 משתתפים

4.4 **התקופה הצפויה למשך ההשתתפות בניסוי.** שני מפגשים בזמן שהות בפגייה ומפגש בגיל 3 חודשים מתוקן עד ארבעה חודשים

4.5 **שיטות- תיאור מוצר המחקר, תיאור בקצרה של ההליכים השונים במשך תקופת הניסוי (טיפול ומעקב), תוך הבחנה ברורה בין ההליכים המחקריים לבין ההליכים המקובלים ברפואה.**

2	04/01/2017	הורים לפגים עברית
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עמוד 2 מתוך 5

0283-15-MMC

דופק ע"י:בב רחל גראוס

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שם המהלך: טהל ליטויים רפואיים בבני-אדם		תאריך: מאי 2014
טופס 2 ה		
מספר: 0	0283-15-MMC	
טופס הסכמה מדעת להשתתפות בניסוי רפואי		

מערך המחקר: כל דיאדה של אם או אב + תינוק ישתתפו בשני מפגשים ניסויים במשך שבועיים, במהלך אשפוז התינוק בפגייה. מפגש שלישי (מפגש מעקב) ייערך בגיל כשלושה חודשים מתוקן. במפגש זה יקבלו ההורה והתינוק את אותה ההתערבות בה השתתפו במהלך האשפוז בפגייה.

מערך כל מפגש ניסוי: 10 דקות של תנוחת "עור לעור", 30-45 דקות של התערבות של טיפול במוסיקה בעת תנוחת "עור לעור", 10 דקות של תנוחת "עור לעור".

- במהלך ההתערבות ההורה יישב על כיסא בזווית של 40 מעלות ליד האינקובטור. התינוק יונח בתנוחת "עור לעור" באופן ישר על חזה ההורה. ההורה והמטפלת במוסיקה יכלו לראות מכשיר קול שימום בסמוך לאוזן התינוק, על מנת לשלוט על עוצמת צליל בין 60-70 דציבל. צלילי הרקע יווסתו על מנת שלא לעבור רמת קול של 45 דציבל, דלתות החדר יהיו סגורות והתאורה נמוכה.

תיאור ההתערבות של טיפול במוסיקה בעת תנוחת "לעור לעור":

- הרפייה וחימום: חקירה מילולית של מצבו הפיזי והרגשי הנוכחי של ההורה וצרכים ייחודים, הרפייה מודרכת לשם ארגון וייצוב דפוסי הנשימה של ההורה.

- חימום קולי: המהום לדפוסים מלודיים פשוטים וחזרתיים, בהדגמה וליווי של המטפלת במוסיקה. בהדרגה, פיתוח ההמהום לשירת תנועות "אה" ו"או", באופן עקבי וחזרתי על גבי אותם דפוסי המהום.

- שירת שירי ערש לפי בחירת ההורה: כאשר ההורה ידווח על מוכנות לשיר, המטפלת במוסיקה תעניק להורה תמיכה אינטרומנטלית ו/או קולית, בכדי לשיר 2-3 שירים לפי בחירתו האישית. השירים יותאמו (על ידי המטפלת) למקצב של שירי ערש (3/4 או 6/8), שהינו רך ופשוט. בכל מקרה בו ההורה ירגיש שלא בנוח, או יבקש להאזין לשיריו המועדפים, המטפלת במוסיקה תוכל לנגן ו/או לשיר עבור הדיאדה.

-סיום: שיקוף וסיכום וורבלי של ההורה והמטפלת במוסיקה על אירועי המפגש הנוכחי

, חקירה של תגובותיו הרגשיות של ההורה, תובנות, בקשות ו/או הצעות למפגש הבא.

מילוי שאלונים על ידי ההורים: שלוש נקודות זמן למדידה

1.שאלון חדרה- 1. בעת הגיוס למחקר; 2. לפני ואחרי כל מפגש ניסוי , 3. לפני ואחרי מפגש המעקב.

2.שאלון התקשרות - 1. בעת הגיוס למחקר, 2. שלושה שבועות מיום הגיוס למחקר, 3. לפני פגישת המעקב.

3.שאלון שימוש במוסיקה בחיי היומיום- לפני פגישת המעקב.

4.6 (היתרונות הצפויים למשתתף או לאחרים, כתוצאה מהניסוי.

2	גרסה	Version	תאריך גרסה	04/01/2017	הורים לפגים עברית
		Version Date			

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21-Mar-17

עמוד 3 מתוך 5

0283-15-MMC

הוסף ע"י: טהל רחל גראוס

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שם המהלך: נוהל לניסויים רפואיים בבני-אדם		תאריך: מאי 2014
טופס 2 ה		
מספר: 0	0283-15-MMC	
טופס הסכמה מדעת להשתתפות בניסוי רפואי		

פגים: ייצוב ושיפור מדדים פיזיולוגיים (קצב לב, קצב נשימתי ורמת סטורציה בדם). המערכת האוטונומית, ומצבים התנהגותיים (שינה, עוררות שקטה, בכי ועוד).

הורים לפגים: הפחתת רמות חרדה.

הורים ופגים: חיזוק ופיתוח תהליכי התקשרות הורה-ילד.

4.7 הסיכונים הידועים /או אי-הנוחות שניתן לחזותם למשתתף במחקר. במידה שיש בניסוי הרפואי סיכון למשתתף - הסבר על הטיפול הרפואי שיקבל במקרה של פגיעה בבריאותו והאחריות לנתינתו.

אין סיכון

4.8 מחקר זה אינו כולל איסוף רקמות / דגימות

4.9 מידע רלוונטי אחר (כפי שנמסר על-ידי יזם הניסוי).

אין

5) מצהיר בזה כי את הסכמתי הנ"ל נתתי מרצוני החופשי וכי הבינתי את כל האמור לעיל. כמו-כן, קיבלתי עותק של טופס הסכמה מדעת זה, נושא תאריך וחתום כדין.

6) עם חתימתי על טופס הסכמה זה, אני מתיר ליזם הניסוי הרפואי, לוועדת הליסינקי המוסדית, לגוף המבקר במוסד הרפואי ולמשרד הבריאות גישה ישירה לתיקי הרפואי, לשם אימות שיטות הניסוי הרפואי והנתונים הקליניים. גישה זו למידע הרפואי שלי תבוצע תוך שמירת סודיות, בהתאם לחוקים ולנהלים של שמירת סודיות.

שם המשתתף בניסוי הרפואי	חתימת המשתתף בניסוי	תאריך

במקרה הצורך⁴

שם העד הבלתי תלוי	מספר תעודת זהות	חתימת העד	תאריך

⁴ במקרה שהמשתתף בניסוי, או נציגו החוקי, אינו מסוגל לקרוא את טופס ההסכמה מדעת, עד בלתי תלוי חייב להיות נוכח במשך ההסבר על מהות הניסוי הרפואי. לאחר שהמשתתף או נציגו החוקי, הביע את הסכמתו בעל-פה להשתתפות בניסוי, העד יחתום על טופס ההסכמה, תוך ציון תאריך החתימה.

2	04/01/2017	הורים לפגים עברית
גרסה	תאריך גרסה	Version Date

Protocol no.0283-15-MMC

Matarot Helsinki

21-Mar-17

עמוד 4 מתוך 5

0283-15-MMC

דפוס ע"י:בני רחל גראוס

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טופס 2 ה	
מספר: 0	0283-15-MMC
טופס הסכמה מדעת להשתתפות בניסוי רפואי	

הצהרת החוקר / חוקר המשנה:

ההסכמה הנ"ל נתקבלה על-ידי, וזאת לאחר שהסברתי למשתתף בניסוי הרפואי כל האמור לעיל וכן וידאתי שכל הסבריי הובנו על-ידי.

שם החוקר המסביר	חתימה, חותמת ומס' רשיון	תאריך

הורים לפגים עברית	04/01/2017	2
Version Date	תאריך גרסה	Version
גרסה	גרסה	גרסה

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הספק ע"י:גב' רחל גראוס

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