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as Procedural Support under Peripheral Intravenous Access involving Young Children

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The Effects of Music Therapy as Procedural Support on Distress, Anxiety, and Pain in Young Children under Peripheral Intravenous Access: an RCT

Ilan Sanfi

The Effects of Music Therapy as Procedural Support on Distress, Anxiety, and Pain in Young Children under Peripheral Intravenous Access: a Randomised Controlled Trial

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Thesis Submitted for the Degree of Doctor of Philosophy

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Declaration

I hereby confirm that this thesis has not previously been submitted (as a whole or in part) for assessment with a view to acquiring an academic degree or a prize at an institution of higher education in Denmark or abroad.

Date Ilan Sanfi

Abstract

Background

Peripheral intravenous access (PIVA) is an umbrella term for all types of invasive procedures that require insertion of needles into a vein (e.g. intravenous catheters, blood drawing). PIVA constitutes the most frequently performed medical procedure in the paediatric setting. In spite of administration of local anaesthesia, PIVA may cause pain in addition to elevated levels of anxiety and distress. Moreover, physical restraint during the procedure is often necessary, especially in young children. Consequently, as documented in the research literature, painful and distressing medical procedures may cause detrimental long-term effects. Three studies have examined the effect of music therapy procedural support (MTPS) under needle procedures. Consequently, this study aims at examining the effects of MTPS in an RCT. Moreover, the study addresses clinical aspects of the applied MT intervention and provides research-based clinical tools.

Methods

41 children (1 to 10 years) were enrolled and underwent a single PIVA procedure. The children were randomly assigned to either an MT or a comparable control group receiving PIVA. In addition, the music therapy (MT) group received individualised MTPS (i.e. music alternate engagement) before, during, and after PIVA. The intervention was performed by a trained music therapist and comprised preferred songs, improvised songs/music, and instrument playing. The study was carried out in accordance with the rules in force regarding research ethics and clinical MT practice.

The study examined the effect of MT in relation to 16 outcome measures comprising these outcome domains: Distress, Anxiety, Pain intensity, Overall satisfaction with PIVA, Compliance, Number of needle pricks, Duration of the PIVA procedure, and Satisfaction with the applied MTPS intervention. In short, self-report, observational data, and count data were used.

Results

From an overall perspective, the results of the study were in favour of the MT group, except for parent-rated *Child Pain*, which was slightly higher in the MT group. In addition, similar mean scores were found in the two groups for *Parent Compliance*. The results showed that a single MTPS session was highly significantly effective in reducing the *Duration* of the PIVA procedure (33%). The MT intervention was also significantly effective in reducing *Child Anxiety*. Trends towards significance were also found for child *Anxiety, Pain*, and *Compliance*. Results suggested that MTPS may be effective in reducing the *Number of needle pricks*. No significant result was found for *Overall satisfaction with PIVA*. Furthermore, the majority of the participants found the MT intervention beneficial. Finally, after removal of an outlier, the overall picture became more distinct and two additional significant results were found.

Conclusion

The study shows that a single MTPS session was statistically significantly effective in reducing the anxiety of the children and the *Duration* of the PIVA procedure. These findings combined with the overall picture of the results merit further research.

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Aalborg University

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The Participants

I wish to express special thanks to all the children and parents who voluntarily participated in the study and provided me with deeper insight into the phenomenon of children´s various responses to painful medical procedures and the use of music therapy as procedural support in this clinical context.

Aarhus University Hospital

Now, I would like to thank the paediatric department at Aarhus University Hospital for supporting me and making this PhD research possible. Thanks to head nurse Inge Pia Christensen for supporting me, for your interest in my profession, and for housing and promoting this research study. Also thanks to the former as well as the present ward nurse Lene Spanggård and Elin Høymark, respectively, for supporting and nurturing a good co-operation. I warmly thank Søren Rittig, the head physician of the unit and my supervisor, for all the professional inputs and discussions regarding practical and statistical aspects of the research. I would also like to thank Anne Aagaard Laursen for your help in administrating the recruitment of the research subjects. Likewise, I would like to express my appreciation to the medical personnel at paediatric nephro-urological unit and day unit for our good co-operation. Similarly, I would like to thank the many engaged and competent specialists at the AUH´s Department of Communication, including John Christensen and Tonny Foghmar for the many evocative and expressive photos and the illustrative DVD, Louise Langberg for the tasty and inviting information brochure and poster. Also thanks to Anne-Mette Siem, my personal “spin doctor”, for competent inspiration and support in promoting the study in the media.

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Foundations

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Forsknings- og Innovationsstyrelsen
Ministeriet for Videnskab Teknologi og Udvikling

Aarhus University Hospital

DOF

Det Obelske Familiefond

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CHAPTER 1
Introduction

IN THIS CHAPTER, I WILL DESCRIBE THE BACKGROUND AND SCOPE OF THE PHD STUDY PLUS MY PERSONAL MOTIVATION. SUBSEQUENTLY, I WILL PROVIDE AN OVERVIEW OF THE THESIS.

1.1 Background and Scope of the PhD Study

This PhD thesis concerns the effects of music therapy as procedural support (hereafter MTPS) in relation to peripheral intravenous access involving young children having nephro-urological diseases. Peripheral intravenous access (hereafter, PIVA[1]) is an umbrella term for a variety of needle procedures that require insertion of a needle into a vein. PIVA is used for several medical and diagnostic purposes, including blood drawings and infusion of fluids (e.g nutrition, medicine such as antibiotics), which makes it the most frequently performed medical procedure in paediatrics (Ellis, Sharp, Newhook, & Cohen, 2004, pp. 144-145). However, the research literature shows that many children regard needles as one of the most distressing aspects of being hospitalised (Cummings, Reid, Finley, McGrath, and Ritchie, 1996; Ellis et al. 2004). In continuation of this, the literature also shows that lack of adequate pain management including application of non-pharmacological interventions can cause detrimental long-term effects such as medical fears and distorted memories of medical procedures (Young, 2005; Blount et al., 2009). In that connection, it is emphasised that special attention should be given to premature infants, babies, and young children in that they are more vulnerable to painful medical procedures compared to school-aged children (Blount et al., 2009; Cohen 2008; Young, 2005). As to the paediatric music therapy literature, most of the clinical texts about music therapy as procedural support (hereafter, MTPS) relate to *other* types of distressing and/or painful medical procedures and surgery than *needle procedures* such as debridement (burns), X-rays, CT scanning, pre-operative anxiety (Edwards, 1995; Edwards, 1999; Jarred, 2003; Loveszy, 1991; Nguyen et al. 2005; Robb, 2003; Walworth, 2005).

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1 *Please note, throughout the thesis, I use the terms Peripheral Intravenous Access, PIVA, IV-access, IV-procedure, and needle insertion procedure synonymously.*

In continuation of this, at present, the research literature counts three outcome studies on music interventions performed by music therapists or musicians in relation to needle procedures involving paediatric patients (Caprilli et al., 2007; Malone, 1996; Pfaff et al., 1989). Thus, rooted in the this gap in the research literature and the clinical needs related to PIVA, this PhD study aims at investigating whether MTPS is effective for children having various nephro-urological diseases under PIVA procedures in reducing:Child Distress

- Child Anxiety
- Pain Intensity
- Number of Needle Pricks
- Duration of PIVA Procedure

and in enhancing:

- Child Compliance
- Parent Compliance
- Overall Satisfaction with Medical Procedure
- Positive Child Behaviour

In addition, the study also aims at examining to what extent the families, randomised to the music therapy group, are satisfied with the applied MTPS intervention. In short, the overall objective of the study is to add new knowledge to the existent but limited MT research literature in relation to a widely common clinical phenomenon, namely PIVA. Moreover, unlike previous MTPS studies, this PhD study generates a broader picture of the effects of MTPS by including an array of recommended inter-related core outcome domains e.g. pain intensity, emotional response, global judge of satisfaction treatment, duration of needle procedure, number of needle pricks (McGrath et al., 2008). Finally, although using a fixed RCT design with two comparable conditions (Robson, 2011), the study strongly emphasises the clinical dimension and aims at linking the results of the study to clinical relevance and clinical applicability. In that connection, I made efforts to describe and illustrate the applied music therapy (hereafter, MT) intervention comprehensively, apart from serving the purpose of replication. Moreover, the thesis provides clinical guidelines and practical tools that are intended to be directly applicable for paediatric music therapists as

well as researchers within the realm of MTPS. Finally, as clarified above, the study examines the use of MTPS under a specific medical procedure, which reflects the fact that the medical procedure precedes the children´s medical conditions (i.e. various nephro-urological diseases). Hence, the research study might have involved children with other diseases, but I was so fortunate as to have an established contact with the paediatric nephro-urological unit at Aarhus University Hospital, Denmark (AUH), which was both willing to and capable of co-operating prior to the start of the PhD project.

Ontologically, I place myself within a bio-psycho-social-spiritual paradigm and my approach to MT is humanistic and person-centered (Wigram, Pedersen, & Bonde, 2002, p. 66). In a therapeutic/clinical context, this view entails that I perceive and address the children´s needs according to these levels. In the context of the PhD study, this fundamental approach to therapy is reflected in the MT intervention. Based on the *music alternate engagement* (MAE) approach to MTPS, the MT intervention is designed to meet a variety of individual bodily, psychological, emotional, and social needs. The overall therapeutic objectives of the MT intervention are to:

- Establish resources before the needle procedure and subsequently draw on them to support healthy coping
- Promote the child´s level of active engagement and sense of control
- Provide distraction, support, and comfort
- Reduce distress, anxety, and pain
- Counteract traumatisation

In short, while the applied RCT study protocol is fixed, the clinical protocol is complex and person-centered, which I will account for in the method chapter (section 5.10). Finally, due to the nature of the PIVA procedure, the clinical context in which the MT intervention was applied was to a great degree an inter-disciplinary and dynamic enterprise. In the study, the PIVA procedures were performed by a physician and an assisting nurse. The MT intervention was developed to fit their working routines as well as the often rapidly shifting inter-personal dynamics, which were furthermore influenced by the presence of several persons, including the child, parent(s), research-assistant, music therapist, and sometimes one or two medical students.

The participants in the study are children at the ages of one to ten having various nephro-urological diseases who attended a planned PIVA procedure at the nephro-urological outpatient unit at AUH. The PIVA procedure was performed preparatory to a subsequent planned kidney-scanning elsewhere at the hospital. For general information, AUH is the second largest hospital in Denmark. However, at present, the hospital undergoes substantial expansion and is expected in few years to be one of the largest hospitals in Northern Europe. The paediatric department is a 91-bed university teaching hospital and comprises eight units. The department serves highly specialised functions within most of the main paediatric medical specialties, including neonatalogy, oncology, heart diseases, arthritis, intensive care, nephrology, and urology. In addition, the paediatric department performs an array of educational and research obligations being a part of Aarhus University Hospital. The paediatric department performs diagnosing, treatment, and care of sick children plus research on an international level (http://www.auh.dk). The paediatric department primarily serves patients from Central Denmark Region. Besides that, the department also serves patients with complex or rare diseases from other regions in Denmark. On a yearly basis, the paediatric department provide medical treatment and care for approximately 10.000 inpatients, whereas the ambulatory serves another 20.000 children. In addition to the traditional medical personnel, an array of professionals is affiliated to the paediatric department, including teachers, pedagogues, six psychologists, and two trained hospital clowns. However, at present, the music therapy profession is not included in the overall inter-disciplinary treatment. Unfortunately, this reflects a broader Danish fact within the context of paediatrics as well as the general hospitals. Here, music therapy is only in its very infancy (as opposed to the Danish hospice setting and psychiatric hospitals).

1.2

Personal Motivation

My motivation for carrying out this doctoral thesis arose from circumstances of both personal and professional natures. The personal perspective relates to my early childhood during which I underwent surgery. I cannot recall much from the admission except that I just wanted to go home and that I got very angry with the medical personnel each time I felt my integrity was invaded (e.g when the nurses touched me in order to inspect the scar). Furthermore, eight years ago, my niece was born. But eight weeks after birth, she was suddenly admitted to AUH, where the physicians discovered a congenital heart defect. The next day, she underwent a major successful heart operation. Two years after, she underwent another major heart surgery. The course of her treatment has been quite hard for the whole family. Fortunately, she is fine today. Now, I will address the professional perspective. In 1999 I attended a lecture on the application of MT and music medicine for premature infants held by the American researcher and music therapist Jayne Standley, who visited the Doctoral Programme in Music Therapy at Aalborg University (hereafter AAU). At that time, I was a bachelor student on the music therapy programme at AAU. Standley´s lecture purely and simply sowed the seeds of my professional interest in the paediatric area.

Some years later, as a postgraduate student in music therapy, I began to pursue my professional wish of gaining professional knowledge and clinical experience within this area. During these years I established a nascent cooperation with the paediatric department at AUH. Even though my clinical experience as a music therapist was limited at that time, it played a vital role for the PhD study. As a postgraduate student, I did a four-month practicum at the paediatric oncology and nephro-urological units. Subsequently, I collected data for my master´s thesis in the former. In order to prepare my clinical work for the practicum, I used the preceding 8th semester project to assess the wishes and clinical needs of the children, their families, and the medical personnel. In the practicum, my clinical work was primarily *ecological* (Bruscia 1998). I conducted different music activities with open groups

in common areas of the units as well as individual sessions at the bedside. However, I also assisted some of the children with cancer under different invasive medical procedures. I witnessed the manifold needs of these children and experienced how some of these could be met by MTPS (e.g. reduction of anxiety and distress, promotion of pleasant emotions, opportunities to exercise control).

- In summation, this PhD study arose from the combination of:
- My personal experiences with hospitalisation
- My previous clinical experience as a music therapist
- The research literature on common clinical needs and risk of negative long-term effects related to PIVA procedures
- Clinical inspiration in the MT literature
- My prior co-operation with the paediatric department at AUH
- The paediatric department´s wish to improve pain management measures related to needle procedures
- A strong professional wish to gain more clinical experience and knowledge of MTPS

Finally, as a trained music therapist, I also wished to pay back some of my debt to AAU, to move the MT profession forward, and not least to make a contribution to the limited MT research literature.

1.3

Overview of the PhD Thesis

In this first chapter, I have provided an introduction to the PhD study. In Chapters 2 to 4, I will present the theoretical framework of the PhD study. Chapter 2 contains theoretical aspects related to invasive medical procedures and MT as procedural support. Specifically, I will clarify the current practice regarding IV-access procedures at AUH plus theoretical aspects of pain, trauma, coping, and MT as procedural support. In Chapter 3, I will address myself to more clinically related aspects and provide a summation of research-based clinical recommendations and guidelines regarding non-pharmacological interventions and MTPS under medical procedures involving paediatric patients. Finally, in Chapter 4, I will present a literature review of 11 outcome studies on MT as procedural support under *needle procedures* and *other* medical procedures involving children. Next, in Chapter 5, I will present the research questions and hypotheses and account for the methodological considerations and choices in connection to the study protocol and the MT protocol, including the applied evaluation design and measuring tools, a description of the MT intervention and ethical aspect among other things. In Chapter 6, I will present the main results of the study plus some additional findings. In Chapter 7, the results will be discussed in the context of the (research) hypotheses and the existent research literature reviewed in Chapter 4. Moreover, the discussion will also address the clinical method, the clinical applicability, and the limitations of the study. The discussion chapter culminates in a short summative conclusion followed by directions for future research. At the end of the thesis, the following can be found: the list of references and appendices. Finally you can find an enclosed DVD containing a video excerpt illustrating the applied MTPS intervention (track 1) and an illustration of PIVA (track 2). Finally, in figure 1.1, I have provided an overview of the PhD thesis.

Figure 1.1. Overview of the PhD Thesis.

CHAPTER 1
INTRODUCTION

CHAPTER 2
THEORETICAL FRAMEWORK I/III

CHAPTER 3
THEORETICAL FRAMEWORK II/III

CHAPTER 4
THEORETICAL FRAMEWORK III/III

CHAPTER 5
METHOD

CHAPTER 6
RESULTS

CHAPTER 7
DISCUSSION AND CONCLUSION

1.4

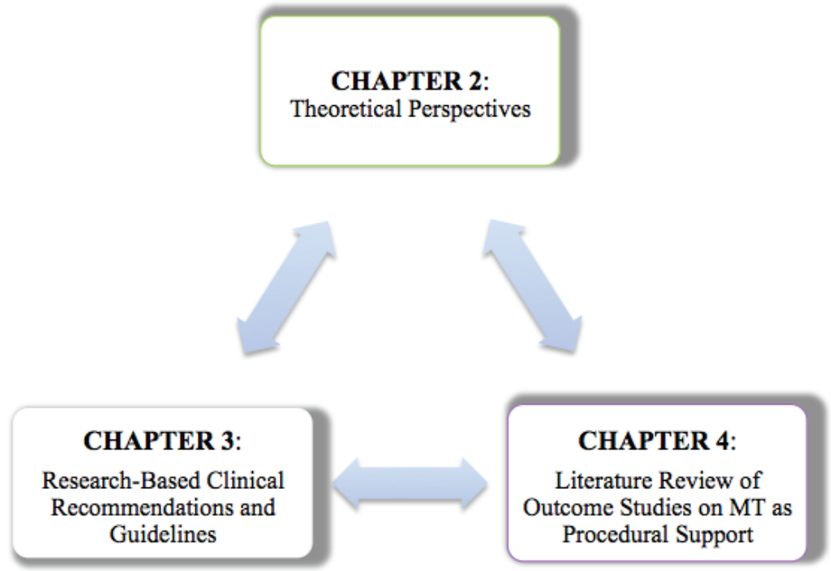
Formatting

As to the applied house style and linguistic aspects, the thesis is written in British English and follows the requirements of the Doctoral Programme in Music Therapy at Aalborg University. The formatting of the reference list and citations follow the standards described in the sixth edition of the Publication Manual of the American Psychological Association, (APA, 2010). Finally, the PhD thesis of the Danish music therapist & researcher Karin Schou (2008) and the Consolidated Standards of Reporting Trials (CONSORT), (Moher et al. 2010) inspired me and informed the writing of the present PhD thesis.

CHAPTER 2
Theoretical FrameWORK:

The theoretical framework of the PhD study is divided into three separate chapters that illuminate theoretical, clinically related, and research-based perspectives, respectively, related to MT as procedural support under needle procedures in paediatric patients. These aspects of the theoretical framework will be presented in Chapters 2 to 4. As indicated in figure 2.1, these three overall aspects formed a mutually inter-related unity in the PhD study.

Figure 2.1. Graphical illusration of the theoretical framework of the PhD study.



The overall objectives of the three chapters are to identify, define, narrow down, and establish a multi-faceted theoretical framework for the PhD study. The main aim of Chapter 2 is to identify an appropriate theoretical understanding of the manifold aspects related to MT as procedural support under PIVA procedures. This will be supplemented by Chapter 3, in which I will present research-based practical and useful clinical recommendations and guidelines related to non-pharmacological interventions. Finally, Chapter 4 holds a literature review of existent studies on MT as procedural support under various medical procedures. Here the main focus is studies on needle procedures. However, studies on *other* medical procedures are also included. Besides these objectives, the literature review (i.e. Chapter 4) also identifies methodological weaknesses, gaps, and challenges within this field of MT research. Please note, since the main focus in the thesis is the application of MT as procedural support, related literature on music medicine (hereafter, MM) will only by accounted for to a minor extent, although MM interventions are found beneficial and are widely reported in the research literature. Likewise, the application of MT and MM within the neonatal medical specialty will not be described.

Figure 2.2 sums up the contents of the Chapters 2 to 4. Specifically, in this chapter, I will provide a short description of the medical characteristics of the nephro-urological paediatric population. I will also describe the current practice at AUH regarding the carrying out of PIVA. Next, I will address myself to theoretical aspects on pain, trauma, and coping. After that, I will summarise definitions of medical MT and provide an overview of the use of MT in paediatrics. Finally, I will describe various theoretical aspects of MT as procedural support.

At this point, I will make do with the above-mentioned introductory summation of the contents of this chapter. However, introductory to Chapters 3 and 4, I will provide a similar outline of the structure of these chapters. Furthermore, in order to provide and maintain a clear overview of the structure and contents of the three chapters that constitute the theoretical framework of the PhD study, I will provide summative figures along the way like figure 2.2.

Figure 2.2. Graphical illustration of the three chapters that constitute the theoretical framework of the PhD study.

2.1

Epidemiology: Common Nephro-Urological Diseases in Children

The participants in this PhD study were children having various nephro-urological diseases. They attended the nephro-urological day unit at AUH with an aim to undergo a PIVA procedure preparatory to a kidney scanning requiring injection of a nuclear tracer (e.g. MAG3 renography, DMSA scintigraphy, or a Cr-EDTA) the same day elsewhere in the hospital. However, as clarified in section 1.1, the focus of the study is more the children´s responses to the IV-access procedure rather than their *diagnoses*. But to set the record straight, I will provide a short description of the medical characteristics of the participants.

Nephrology originates from Greek and is the medical term for the study of the function and diseases of the kidney. *Urology* also originates from Greek and is the medical term for the study of the female and male urinary systems plus the male genitals as well as congenital diseases in these. As to *nephrology*, the main function of the kidneys is to filter and excrete waste products from the blood in the form of urine (Rittig, 2008). Phylogenetically the creation of the kidney and the urinary system starts to mature in the 5th week of gestation. And at the 35th week of gestation, all nephrones are created. Nephrones are specialised active cells that constitute the functional urine producing unit of the kidneys, which facilitate urinal secretion of the body´s waste products (Rittig, 2008, p. 279). According to Rittig, (2008, p. 279), normal kidney function is fully matured at the end of the second year of a child´s life. In the first two

years, the kidneys´ ability to filter the waste products (i.e. glomerular filtration rate) increases substantially. By the second year of life, the kidneys reach an adult capacity of glomerular filtration rate. In the first two years of life, the kidneys are particularly vulnerable to damaging factors (e.g. such as infections and obstructions). On the contrary, if the kidneys increase concurrently with the growth of the body, normally developed kidneys are supposed to be oversized in terms of their capability to filter and excrete waste products, according to Rittig. However, children who have decreased kidney function excrete too much protein, that is why it is important to monitor their kidney function closely, at least until adulthood. In the following, I will address myself shortly to the most commonly occurring *nephrological* and *urological* diagnoses among the participants in the PhD study. In summation, two thirds of the children had nephrological diseases, whereas the remaining part of the children had urological diseases. The nephrological diseases comprised:

- Urinary tract infections Acute infection in the upper urinary system (Acute Pyelonephritis)
- Other diseases that were erroneously recorded

According to Rittig (2008, pp. 291-293), acute infection in the upper urinary tract frequently occurs in childhood, especially in boys and during the first year of life. If not treated, this condition may cause scar tissue, which consequently may result in long-term complications such as loss of kidney function. Finally, the infection is associated with a substantial risk of relapse. In addition, other types of nephrological diseases in children include return flow of urine to the kidneys (vesicoureteral reflux).

As to the *urological* diagnoses, the most frequently exhibited ones comprised:

- Congenital and functionally related deformities in the form of congenital hydronephrosis (dilatation of the urinary tract)t
- Duplex kidney
- Sever congentinal dilatation of the ureter

According to Rittig (2008), congenital hydronephrosis is the medical term for a constriction of the urinary tract, which prevents the urine from flowing normally through the urinary system and results in dilatation of the renal

pelvis. When this exceeds 12mm, it is called hydronephrosis. This condition may cause urinary tract infection and consequently may result in loss of kidney function. Children diagnosed with *ren accessorius* are born with an extra kidney, which in some cases. This condition also is associated with increased risk of infection. Megaureter congenitus means that he ureter is enlarged which can be caused by a stenosis at the ureterovesical junction or by vesicoureteral refkux (flow of urine from the bladder to the ureter). In addition, other types of urological diseases in children include deformities of the outlet of the urethra in the penis (hypospadi), non-descended testicles (cryptorchidism, ryptocism, incontinence including involuntary nightly urination (Enuresis).

2.2

Current Practice regarding Peripheral Intravenous Access Procedures at AUH

In this section, I will account for the current practice at Aarhus University Hospital (AUH) regarding the carrying out of PIVA. After this, I will shortly outline commonly prevailing needs in children during various needle procedures as described in the research literature. Finally, I will account for the current practice at AUH in relation to management of pain and anxiety under IV-access procedures.

2.2.1 Course of Admission for Participating Outpatients

In the study, the children underwent an IV-access procedure with an eye to infusing a nuclear tracer into their blood in relation to a subsequent scanning of their kidney function. Hence, the participants´ total course of admission included an initial IV-access procedure at the paediatric nephro-urological unit and a subsequent kidney scanning elsewhere in the hospital. Although the PhD study only concerns the first part, I will shortly describe the course of the participants´ outpatient admission. Upon arrival at the outpatient section of the paediatric nephro-urological unit, the families announced their arrival to the outpatient staff. The families were then either referred to the waiting room or sometimes directly to an empty treatment room. After a possible, rather short waiting period, topical local anaesthesia in the form of EMLA plasters was administered on the back of the child´s hands or elbow

joints. As to a minority of the children, this was administered at home before arrival at the hospital. In order to take effect, the EMLA plaster was administered 60 to 90 minutes before the IV-access procedure. In the meantime, a nurse measured the child´s weight and height. In addition, hereafter some of the children went for ultrasound scanning elsewhere in the hospital. Only after these initial procedures, were the actual data collection and the IV-access procedure initiated. After completion of the medical procedure, the families waited in the treatment room for a hospital porter to escort them to the nuclear scanning department, which is located elsewhere in the hospital. On the same day after completion of the scanning, the participants went home again.

2.2.2 Current Practice regarding Peripheral Intravenous Access Procedures at AUH

Peripheral intravenous access (PIVA) is an umbrella term for all types of invasive procedures implying insertion of a needle into a vein (e.g. venflon, IV-starts, veinipunctures, blood drawing). IV-access is used for many purposes, among other things blood drawings and injection of fluids (e.g. nutrition, water, and electrolytes, chemical or radioactive tracer for investigational purposes, and injection of medicine such as antibiotics). This makes it the most performed medical procedures in the paediatric population. Since it involves break of skin, it can therefore be defined as an invasive medical procedure (see further definition in section 2.7.1). IV-access procedures can be performed in all accessible veins. But if the access is intended for prolonged use or in young children, it is often performed on the back of the hand or in the elbow joint. At the paediatric department at AUH, PIVA is performed as described in the following. In addition to the present description, I have provided a supplementary visual illustration of PIVA in the form of a video excerpt on the enclosed DVD (track 2). Initially, the child is placed in a secure position. After an applicable vein is identified, the skin spot is disinfected with surgical spirit. If the procedure is carried out on an extremity e.g. the hand, a tourniquet is wrapped around the arm in order to make the veins more visible. Next, an intravenous catheter is inserted into the vein. The catheter consists of a needle and a thin plastic tube. After successful insertion into the vein, the needle is removed so only the plastic tube remains in the vein. The plastic tube is then fastened to the skin. If the IV-access is intended for prolonged use, a bandage is placed around the outer part of the intravenous catheter as well as the plaster in order to stabilise and prevent accidentally removal of the intravenous catheter. The remaining part of the intravenous catheter (i.e. the plastic tube) subsequently provides direct intravenous access to the blood stream. The duration of the IV-access procedure depends to a great extent on

how quick a suitable vein can be accessed in practice. However, obtaining PIVA in children may be time consuming and difficult due to several, including smaller and less visible veins, lack of compliance, and subcutaneous adipose (Reigart et a., 2012, p. 1). Moreover, the following factors may also influence the course and time needed to perform the procedure: the child´s cognitive-developmental level plus level of stress and anxiety, possible medical fears, and need of physical restraint (personal communication, medical personnel at AUH).

In continuation of this, the standard clinical practice guidelines for IV-access procedures at AUH are as follows. The IV-access procedures are performed by a physician and an assisting nurse. If the physician does not succeed in completing the IV-procedure with a maximum of two or three needle pricks, an additional and more experienced physician is called for. The second physician then is allowed to make only one attempt to perform the procedure. In the PhD study, the children underwent IV-access procedure and were scheduled to a subsequent kidney scanning. In that connection, the clinical guideline was as follows. If both physicians fail to perform the IV-procedure, the kidney scanning is to be postponed to another day when the child will be sedated. In that connection, for general information, AUH keeps no record of insertion success rates required to complete the procedure. Instead, due to lack of these data, I will refer to the literature, which unfortunately is sparse on this topic (Linniger, 2003; Reigart et al., 2012). On the basis of a non-randomised sample comprising 249 IV placements in paediatric patients at the ages 20 days and 20 years, Linniger found the following cumulative success rates: 53% on the first attempt, 67% on the second attempt, and 91% within four attempts. The average number of attempts was 2.35 needle pricks. On the basis of 592 IV-access procedures involving paediatric patients at the ages of 0 to 18, Reigart et al. found the following cumulative success rates: 48% at the first attempt and 24% at the second attempt. Besides one outlier, the remaining 182 children completed the IV placements receiving one to nine additional needle pricks in before IV placement was obtaining.

Similarly, AUH keeps no record of the mean duration as to the duration of the IV-access procedure. Due to the absence of such a record, I will refer to the two studies that appropriately illuminate this topic in relation to paediatric patients (Ellis et al., 2004; Reigart et al., 2012). Of these, Reigart et al. relates exclusively to the conduction of PIVA and is most comparable to the context of the PhD study, whereas Ellis et al. relate to various types of needle procedures. On the basis of 592 IV-access procedures, Reigart et al. found a *median duration* of 9 minutes. Specifically, the time to succeed PIVA (termed IV-access) varied among the four pre-defined age groups:

- Infants aged 0 to 2 (n = 283): 11 minutes
- Young children aged 3 to 5 (n = 73): 8 minutes
- School-aged children aged 6 to 11 (n = 91): 8 minutes
- Adolescents: aged 12 to 18 (n = 120): 7 minutes

As appears, the authors found that it take a longer time to accomplish the procedure in the infant group, which was statistically significant. In continuation of this, the Canadian study Ellis et al. (2004) partly touches on the topic of duration of placing intravenous catheters. However, contrary to Reigart et al. (2012), Ellis et al. made their calculation on the basis of different types of needle procedures. In that connection, only 13% of these were intravenous cannulisation. The data collection took place at a 150-bed paediatric teaching hospital. Here the authors recorded the duration of 374 needle procedures during a 23-day data collection period. The median age of the participants was 6 years (range 10 days to 20 years). Of the 387 procedures, the majority (63%) were venipunctures for blood work followed by intravenous cannulisation (13%). When the various types of needle procedures were analysed *together*, the mean duration of a procedure was 9.3 minutes (median 10 and range 2 to 90 minutes). Of the 387 procedures, 315 (81%) were performed *without* EMLA and had a mean duration and standard diviation of 9.5 (7.3) minutes. As to the remaining 72 (19%) of the procedures *with* EMLA, the mean duration was 8.6 (4.2) minutes.

In conclusion, due to several factors, obtaining PIVA may be stressful for the child, time consuming, and require more needle pricks.

2.2.3 Prevailing Needs in Children Undergoing Peripheral Intravenous Access Procedures

This section provides an initial and short description of some of the prevailing needs and negative effects related to needle procedures in children. For general information, further elaboration will be provided in Chapter 3. The detrimental short- and long-term effects of painful medical procedures in children are well documented in the research literature. According to this literature, it appears that invasive medical procedures, especially needle procedures, are often associated with anxiety and distress in addition to pain (Blount et al., 2009; Young, 2005). In the context of the PhD study, venipunctures for blood drawings, intravenous cannulisation, and intramuscular injections are the most commonly performed needle procedures in paediatrics (Ellis et al., 2004, p. 144-145). Based on the existent research, Ellis et al. state that many children regard these procedures as one of the most traumatic aspects of being in the hospital. Similarly, parents have also rated needle procedures as a major distressing event during their child´s admission. Due to the inherent elements of the infliction of pain, possible restraint, feelings of loss of control etc., needle procedures often cause substantial short-term pain, anxiety, and distress. However, if not treated adequately in terms of pharmacological and non-pharmacological interventions, studies show that repeated painful medical procedures result in detrimental long-term effects, including traumatisation and distorted memories of medical procedures plus high adult medical fear, pain, and avoidance of health care (Young, 2005, pp. 160-162).

In continuation of this, more factors have proved to influence the short- and long-term effects. In that connection, age plays a significant role in that it is associated with development of the cognitive capacity and maturation including coping skills. Consequently, younger children are found to be more vulnerable and score higher levels of pain, anxiety, and distress during painful medical procedures than older children. In addition, Young (2005, p. 161) states that pain responses are individual and learned. Besides the child´s medical history, a child´s pain response is also influenced by social learning. During the past 10-15 years, the research literature shows a growing awareness of the use of pharmacological and non-pharmacological interventions to amiliorating these short- and long-term effects in children, who undergo invasive medical procedures (Blount et al., 2009; Cohen, 2008; Young, 2005). An outline of this literature in the form of research-based clinical recommendations and guidelines will be provided in the next chapter related to the theoretical framework of the PhD study.

2.2.4. Pain and Anxiety Management in Relation to Peripheral Intravenous Access at AUH

The paediatric department at AUH provides topical anaesthesia for the management of pain in relation to most of the IV-access procedures. Specifically, Eutectic Mixture of Local Anaesthetic (EMLA) cream, in the form of plasters, is used. The EMLA cream consists of a combination of the two anaesthetic agents that are 2.5% lidocaine and 2.5% prilocaine. The EMLA plaster is used as follows. First, the plaster is placed on an suitable insertion spot for one hour. After removal of the EMLA plaster and further 20 minutes´ waiting, it reaches its anaesthetic peak point, which lasts for up to four to five hours (Ellis et al., 2004, p. 145). Specifically, the anaesthetic agents in the EMLA plaster penetrate and block the sensation transmission from nerve fibers of the superficial and subcutaneous skin (Fetzer, 2002). EMLA has proved efficient for a variety of medical procedures, including a number of needle procedures. Besides its efficacy, the EMLA plaster is easy to administer. In their meta-analysis, Fetzer (2002) examined the efficacy of EMLA on pain compared to placebo treatment. Based on 10 studies related to IV insertion procedures that were included in the analysis, the authors found that EMLA had a large statistically significant effect on IV insertion pain (d=1.04) with a confidence interval from 0.94 to 1.46. Furhermore, they concluded that EMLA can significantly reduce IV-insertion pain in 85% of the studied population.

As to the management of acute anxiety associated with IV-access procedures, the following measures are taken at the paediatric department at AUH. First and foremost, the paediatric department emphasises a family-based approach to paediatric treatment and medical procedures. Consequently, all IV-access procedures are performed in the presence of and in collaboration with the child´s parent(s). Secondly, the paediatric department has a number of medical play kits at its disposal that can be applied to support coping, especially in anxious children during medical procedure. Furthermore, to a minor extent (i.e. once a week), the provision of a hospital clown is offered in the nephro-urologic unit. Among other things, the clown provides assistance during medical procedures for anxious children. On the contrary, MT services are not embedded in the paediatric department´s overall inter-disciplinary treatment strategy.

2.3

Theoretical Aspects of Pain

In the context of the PhD study, pain plays a central role for several reasons. The IV-access procedure implies infliction of pain, which moreover may potentially affect the 15 remaining outcome measures. In addition, I defined observed distress as the main outcome variable, which partly relates to overt pain behaviours (in addition to the anxiety dimension). Finally, one of the primary foci of the applied MT intervention was to reduce pain. Consequently, in the following sections, I will address myself to theoretical aspects of pain, primarily focusing on pain having a brief duration, which is referred to as *transient pain*[1] by Loeser & Melzack (1999). As a point of departure, I will refer to the pain definition suggested by the International Association of the Study of Pain (IASP). Next, I will present theoretical aspects related to components and types of pain as suggested by Loeser & Melzack (1999). To a minor extent, I will refer to Patel (2010). After this, I will present the neuromatrix theory of pain as described by Loeser & Melzack (1999), Melzack (1999), and Melzack (2001). In the study, I have chosen the neuromatrix theory as the conceptual framework of pain, since Ronald Melzack´s theoretical contributions have been very influential and widely internationally recognised.

2.3.1 Definition of Pain

The pain definition suggested by the International Association for the Study of Pain (IASP) is widely used and cited in the literature. According to the IASP pain is: “An unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damages” (www.iasp-pain.org). As appears, the IASP definition is broad in that it includes both sensory and emotional dimensions, which are furthermore related to both actual as well as potential tissue damages.

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1 *However, please note, that in the paediatric literature on procedural pain, this is often termed acute pain.*

2.3.2 Components and Types of Pain

According to Loeser & Melzack (1999) "The existence of many types of pain can be understood by the identification of four broad categories: nociception, perception of pain, suffering, and pain behaviours. Behind each of these clinical categories are anatomical, physiological, and psychological substrates" (pp. 1607-1608).

Nociception is the bodily process of encoding and transmitting noxious stimuli due to tissue damage. This process is carried out by nociceptors that are attatched to two types of nerve fibres called A delta and C fibres. According to Patel (2010) "Nociceptors are unspecialized, free, unmyelinated nerve endings that convert (transduce) a variety of stimuli into nerve impulses, which the brain interprets to produce the sensation of pain" (p.13). When tissue is damaged (e.g. due to a needle prick), a number of chemicals are produced or released (referred to as the inflammatory soup), which stimulate and modulate nociception. The nerve impulses are conducted via A delta and C fibres to the spinal cord, through the central nervous system, and further to the brain. C fibres have a small diameter, are unmyelinated, and conduct the nerve impulses slowly (i.e. two meters per second). On the contrary, A delta fibres have a large diameter, are lightly myelinated, and conduct nerve impulses ten times faster (i.e. 20 meters per second). Damage of tissue (for instance due to a needle prick) results in an initial fast and sharp sensation of pain plus a delayed dull pain sensation. The former is related to the transmission of neural impulses trough the fast-conducting A delta fibers, whereas the latter relates to the slow-conducting C fibers (Patel, 2010, pp. 13-14).

According to Loeser & Malzack (1999, p. 1608), *Perception of pain* is frequently elicited by a noxious stimulus for example an injury or disease, but also due to lessions in the peripheral or central nervous system (e.g. a stroke or spinal-cord injury). In addition, the authors put forward that pain can occur without nociception as seen in chronic pains.

Loeser & Malzack define *Suffering* as a negative response caused by pain, but also by anxiety, fear, stress, and related phychological states. The authors emphasise that suffering relates to threats of an individual´s physical and psychological integrity.

Finally, Loeser & Malzack (1999, p. 1608) classify *Pain behaviours* as overt quantifiable behaviours (such as crying, grimacing, lying down etc.) one does or does not do in response to the occurence of tissue damage. Moreover, they state "All these behaviours are real and are also probably influenced by actual or expected environmental consequences. From pain behaviours and the history and physical examination, we infer the existence of nociception, pain, and suffering" (Loeser & Melzack, 1999, p. 1608).

Besides that, Loeser & Melzack (1999) classify pain into three types, which are *transient pain*, *acute pain*, and *chronic pains*. In that connection they state that:

- Transient pain "is elicited by the activation of nociceptive transducers in skin or other tissues of the body in the absence of any tissue damage" (Loeser & Melzack, 1999, p. 1608). They point out that this type of pain is omnipresent in everyday life. Moreover, in a medical clinical context, transient pain only occurs in relation to procedural pain.
- Acute pain "is elicited by substantial injury of body tissue and activation of nociceptive transducers at the site of local tissue damage. The local injury alters the response characteristics of the nociceptors, their central connections, and the autonomic nervous system in the region. The local injury does not overwhelm the body's reparative mechanisms: "healing" can occur without medical intervention" (Loeser & Melzack, 1999, pp. 1608-1609).
- Chronic pains "are commonly triggered by an injury or disease, but may be perpetuated by factors other than the cause of the pain. The injury may exceed the body's capability for healing, because of the loss of the body part, the extensiveness of the trauma and subsequent scarring, or the involvement of the nervous system in the injury itself. The nervous system may be damaged by the original injury in such a way as to be unable to restore itself to a normal state" (Loeser & Melzack, 1999, p. 1609).

In summation, Loeser & Malzack suggest a conceptual framework of pain, which comprises four different components or dimensions. In addition, they classify three types of pain, which have distinguished features. In short, *transient pain* is not caused by tissue damage as opposed to *acute* or and *chronic pains*. Moreover, *acute pain* differs from *chronic pains* in that the body is able to restore and obtain homoeostasis. Finally, according to this

classification, the PhD study relates to *transient pain*. However, as appears from the paediatric literature, transient pain is often referred to as acute pain.

2.3.3 The Neuromatrix Theory of Pain

The *Neuromatrix* theory of pain was proposed by the Canadian physchologist and pain researcher Melzack (Loeser & Melzack, 1999; Melzack, 1999; Melzack 2001). The theory is a revision of the *Gate Control* theory of pain (Melzack & Wall, 1965). In short, the *Gate Control Theory* broke with prevous pain theories that claimed a one-to-one linear relationship between noxious stimuli and direct neurologic pathway transformation of pain signals to a passive receptive brain, which ultimately resulted in the experience of pain. On the contrary, Melzack & Wall (1965) viewed the central nervous system and the brain as active systems that filter, selecte, and modulate sensory pain stimuli and thus pain experience. The Gate Control theory shed light on the dynamic peripheral, spinal and brain mechanisms involved in the processing and controlling of noxious stimuli in relation to acute and chronic pain. The authors theorised that nociception and pain experience are modulated by two parallel simultaneously operating up- and downstream neural circuits (i.e. the *Gate control system* and the *Central control*, respectively).

But as opposed to the gate control theory, the neuromatix theory of pain (Melzack, 1999; 2001) highlights the interplay among the brain structures, brain functions (including cognitive and affective brain activities), and the body´s stress-regulation system as important components in relation to the processing and experience of acute and chronic pains, in addition to noxious sensory inputs from somatic receptors. In addition, as to chronic pains, the neuromatrix theory emphasises the significance of the interplay between long-term changes in the central nervous system and somatosensory inputs. According to Melzack, neuromatrix refers to a genetically built-in matrix or template of neurons for the whole body. The neuromatrix comprises widely distributed neural networks, including emotional-related areas of the brain (e.g. components of the limbic system, the amygdela), cognitive-related areas of the brain (associated with meaning, attention, memories), thalamocortical, and somato-sensory components. Melzack theorises that through genetic programmes and past experience, the neuromatrix creates and sustains a body-self image. Moreover, the neuromatrix is initially determined genetically, but is dynamic and eventually *sculptured* by experience.

Besides that, Melzack (2001) proposes that the neuromatrix generates output patterns termed *neurosignature* as a result of cyclic processing and synthesis of nerve impulses in the neuromatrix. The neuromatrix-patterns are produced by neural programmes that are genetically built into the neuromatrix. In that connection Melzack (2001) states that the neuromatrix is:

> ...the origin of the neurosignature; the neurosignature originates and takes form in the neuromatrix....
> The neuromatrix, distributed throughout many areas of the brain, comprises a widespread network of neurons that generates patterns, processes information that flows through it, and ultimately produces the pattern that is felt as a whole body possessing a sense of self. The stream of neurosignature output with constantly varying patterns riding on the main signature pattern produces the feelings of the body-self with constantly changing perceptual and emotional qualities. (p. 180)

In addition, based on research on phantom limb pain, he points out that these patterns may be triggered by stimuli, but not *produced* by them. Melzack (2001) stresses that the body´s stress-regulation system plays an important role in relation to pain, especially in chronic pains. He points out that:

> ...stress is a biological system that is activated by physical injury, infection, or any threat to biological homeostasis as well as by psychological threat and insult of the body-self. Both are correct and important. The disruption of homeostasis by injury activates programs of neural, hormonal, and behavioral activity, which aim at returning to homeostasis. The particular programs that are activated are selected from a genetically determined repertoire of programs and are influenced by the extent and severity of the injury. When injury occurs, sensory information rapidly alerts the brain and begins the complex sequence of events to reinstate homeostasis. (Melzack, 2001, p. 1380)

Finally, he states that specific quality and other properties of the pain experience and behaviour are determined by the neurosignature. Melzack (1999) proposes five elements that influence the neuromatrix programme and contribute to the output neurosignature, which are:

> Sensory inputs from somatic receptors (phasic cutaneous, visceral and tonic somatic inputs)
>
> Visual and other sensory inputs that influence the cognitive interpretation of the situation
>
> Phasic and tonic cognitive and emotional inputs from other areas of the brain
>
> Intrinsic neural inhibitory modulation inherent in all brain function
>
> The activity of the body's stress-regulation systems, including cytokines as well as the endocrin, autonomic, immune and opioid systems. (p. 125)

Figure 2.3 contains a schematical illustration of the body-self neuromatrix. The left side of the figure relates to the many inputs that influence the neuromatrix, whereas the left side of the figure relates to the neurosignature output.

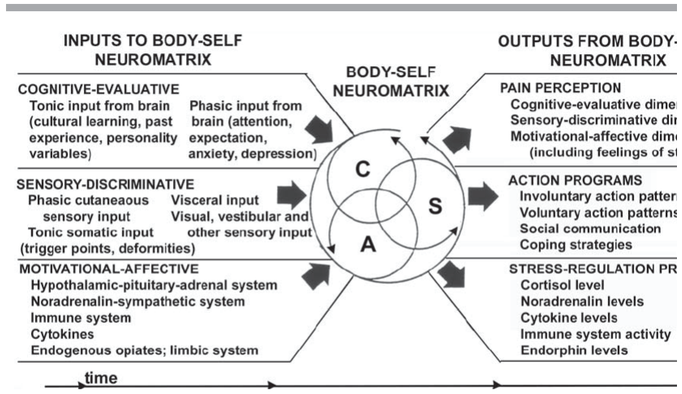


Figure 1. Factors that contribute to the patterns of activity generated by the body-self neuromatrix, w sensory, affective, and cognitive neuromodules. The output patterns from the neuromatrix produce th dimensions of pain experience as well as concurrent homeostatic and behavioral responses.

As we can see from figure 2.3, the body-self neuromatrix is influenced by a variety of possible inputs and parallel cyclic processes, which result in neurosignature output patterns contributing to the multiple dimensions of pain experience (i.e. the sensory-discriminative (S), affective-motivational (A), and cognitive-evaluative (C) dimensions) plus stress-regulation programmes related to homeostatic and behavioral responses.

In the context of the PhD study, I find the neuromatrix theory a useful conceptual framework of pain. It provides a holistic and multi-dimensional understanding of pain, which among other things emphasises the influence of cognitive, affective, and sensory inputs in addition to the bio-physiological dimensions. Specifically, in the context of MTPS under painful medical procedures, the theory provides an explanation of how music can be used therapeutically to alter the *cognitive-evaluative* and the *motivational-affective* dimensions of pain. For instance, familiar music may elicit and promote positive memories, mood states, and associations. Similarly, while provision of information related to the procedure, distraction, or re-direction of attention to the music may influence the *cognitive-evaluative* dimension and reduce the child´s experience of pain or the suffering associated with it.

2.4

Theoretical Framework for Understanding Trauma

In addition to the infliction of pain, needle procedures can cause significant elevated levels of acute anxiety and distress in children as well as the experience of hopelessness and loss of control, as described in Chapter 3 (Cohen, 2008; Young, 2005). Furthermore, as put forward by Young (2005), if procedural-related pain, distress, and anxiety are not adequately managed, painful procedures can cause detrimental long-term effects, including distorted traumatic memories and future medical fears. Consequently, in the development of the MT intervention of the PhD study, I found it clinically relevant and meaningful to include aspects of the trauma theory in the present overall theoretical framework of the study. Specifically, as a point of departure, I used the conceptual framework of the Somatic Experiencing (SE) method in the form of the references Levine & Kline (2007) and Levine (2006). This conceptual framework was recommended to me by my clinical supervisor Maiken Bjerg, who is a trained and experienced music and SE therapist.

2.4.1 The Trauma Theory of Peter Levine

SE is rooted in a primarily biological/evolutional conceptual framework and is a psychological method for bodily release of traumas, which aims at re-establishing the nervous system´s natural balance and inherent ability to secure homeostasis. The method was developed by Peter Levine, a medical bio-physician and psychologist, on the basis of extensive observation of wild life animals´ behaviour and inherent ability to recover from repeated stressing and life-threatening experiences. According to Levine, humans have a similar instinctive preparedness, which may lead to resolution of post-traumatic stress reactions (Levine, 2006; Levine & Kline, 2007). According to the theoretical

concept of the SE method, a traumatic reaction is understood regardless of its cause. Levine & Kline (2007) put foreward that trauma is a *physiological* enterprise rather than a psychological one and occurs when a situation affects the organism without being resolved. They state that:

> Trauma is not in the event itself; rather, trauma resides in the nervous system. Because there is no time to think when facing threat, or primary responses are instinctual. Our brain´s main function is survival!....At the root of traumatic reaction is our 280-million-year-heritage – a heritage that resides in the oldest and deepest structures of the brain known as the reptilian brain. (Levine & Kline, 2007, pp. 4-5)

The theoretical concept of the SE method relates to the flight or flee mechanisms elicited by the nervous systems. When experiencing a traumatic event, more than 20 physiological survival responses are activated in order to prepare the organism to get ready for action. These reactions are strongly related to the evolutionary development of the brain structure and are designed to maintain survival, integrity and the ability to defend ourselves and our nearest ones. The first main physical reactions to a traumatic experience are the fight or flee response. The reaction secures the advantage of mobilising a physical energetic boost, which allows us to fight or flee from the threatening situation. When the fight or flight reactions are impossible, the autonome nervous system instinctively shifts to its last option in response to the overwhelming experience of danger, the *freeze reaction*. In that connection, Levin & Kline (2007) stress that "There is no conscious choice. We are biologically programmed to freeze (or go limp) when fight or flee is either impossible or perceived to be impossible. Freeze is the last-ditch, "default" response to an inescapable threat" (p. 5). In continuation of this, the authors say:

> Underneath the freeze response is a variety of physiological effects. What must be understood about the freeze response is that although the body looks inert, those physiological mechanisms that prepare the body to escape may still be on "full charge". The sensory-motor-neuronal blueprint that was set into motion at the time of threat is paradoxically thrown into a state of immobility or "shock"....Underlying this situation of helplessness there is an enormous vital energy. This energy lies in wait to finish what has been started....When the energy is not fully discharged, it does not simply go away; instead it stays trapped creating the potential for traumatic symptoms". Levin & Kline (2007, p. 6)

Levine & Kline (2007) state that the initial universal symptoms of trauma are:

(1) Hyper-arousal (e.g. panic attacks, anxiety, flashbacks, hyper-activity, regressive behaviour)

(2) Constriction (e.g. headaches, digestive problems, feelings of shame, guilt, and helplessness)

(3) Dissociation (e.g. feelings of isolation and detachment, diminished emotional responses)

(4) Freeze (i.e. feelings of numbness and shutdown that can result in a sense of helplessness and hopelessness plus similar symptoms as dissociation)

According to the theoretical framework of the SE method, the fight, flight, and freeze reactions are congenital components of our overall defence system, which we humans share with the animals. Levine & Kline (2007) state that if the freeze reaction gets too overwhelming, the organism goes to the level of shutdown. Furthermore, the likelihood of developing traumatic symptoms is related to the level of shutdown and the un-discharged survival energy, which was originally mobilized to fight or flight.

Finally, Levine & Kline (2007) stress that infants and children are more vulnerable to traumatic reactions than adults. However, their reaction differs from adults. When fight is impossible, children do not flee. Instead, they seek comfort and security in an adult attachment figure when feeling threatened. Furthermore, children share this self-protecting behaviour with all mammal cubs. Likewise, children are dependent on a safe adult in order to resolve from a trauma. If the adult takes part of the cause of the traumatic experience, double-bind situations may occur. According to the authors, this can ultimately undermine a basic sense of self and trust in the child´s own instincts.

2.5

Coping & Coping in Children Undergoing Medical Procedures

A key objective in MT as procedural support for children is provision and support of coping strategies. This section will address theoretical aspects Richard Lazarus´ and Susan Folkman´s cognitive-phenomenological theory of psychological stress and coping (Lazarus & Folkman, 1984). Initially, I will outline their theory. After that I will illuminate aspects of children´s strategies for coping with hospital-related pain, as described by Siegel & Smith (1989). I have used the coping paradigm of Lazarus & Folkman, since their theoretical contribution to the coping literature has been influential and widely acknowledged. Moreover, I find their theory precise in terms of my clinical experience as a music therapist and observer during painful medical procedures.

2.5.1 The Coping Theory of Lazarus and Folkman

Lazarus & Folkman (1984) define coping as “constantly changing cognitive and behavioural efforts to manage specific external and/or internal demands that are appraised as taxing or exceeding the resources of the person” (p. 141). As the definition indicates, this theory of coping is process-oriented. Hence, the process of coping involves efforts in terms of what a person actually thinks and does in a given demanding encounter and how his/her efforts may change as the encounter unfolds. Another key concept of the theory is that coping is regarded as a contextual enterprise, which is influenced by various variables (e.g. developmental level, individual preferences, individual

resources). Third, the theory does not define a priori assumptions about types of good and bad coping. Besides that, psychological stress is a central notion in this theory, which the authors define as "the relationship between the person and the environment, which take into account characteristics of the person on the one hand, and the nature of the environmental event on the other hand" (Lazarus & Folkman, 1984, p. 21). In addition, coping differs from mastery, as the authors point out "not all sources of stress in living are amenable to mastery, or even fit within a problem-solving framework. Examples include natural disasters, inevitable losses, aging and diseases" (Lazarus & Folkman, 1984, pp. 138-139). Finally, the authors distinguish between coping styles and coping strategies. The former refer to broad, pervasive, encompassing ways of relating to particular types of people or situations (e.g. persons that are powerful or powerless, friendly or hostile, controlling or permissive; or situations that are temporary or chronic, ambiguous or clear) (Lazarus & Folkman, 1984, pp. 120-121). On the other hand, coping strategies refer to the specific strategy a person may use in the encounter (e.g. avoidance, active approach, denial, information seeking).

Lazarus & Folkman (1984) understand coping as a process that unfolds by means of two inter-related and cyclic processes i.e. *cognitive appraisal* and *implementation/application* of coping efforts. According to this theory, cognitive appraisal covers two basic forms of appraisals termed *primary* and *secondary* appraisals[2], respectively. Similarly, the *function* and *immediate outcome* of coping also constitute essential elements, which I will clarify further below. Lazarus & Folkman (1984) theorise that coping is unfolds through primary and secondary appraisals, which mutually "interact with each other in shaping the degree of stress and the strength and quality (or content) of the emotional reaction" (p. 35). *Primary appraisals* relate to the evaluations a person makes in order to determine whether anything is at stake in the encounter in relation to his/her commitments, values, or goals. The authors classify three types of primary appraisals, which are *irrelevant*, *benign-positive*, and *stressful*. *Irrelevant* appraisals include encounters that are interpreted as having no implications for the person´s well-being. *Benign-positive* appraisals relate to encounters that are perceived to enhance or maintain the person´s well-being. Finally, *stress* appraisals relate to loss, harm, threat, and challenge. As to *secondary appraisal*, the authors point out: "Secondary appraisal activity is a crusial feature of every stressful encounter because the outcome depends on what, if anything,

2 *Although these terms indicate a hierarchical order, the authors state that these processes are equally important (Folkman & Lazarus, 1984, p. 31).*

can be done, as well as what is at stake" (Lazarus & Folkman, 1984, p. 35). In short, secondary appraisals relate to the considerations a person makes in order to evaluate if anything can be done to manage, prevent, or reduce possible harms or, on the other hand, improve the degree or range of perceived benefits.

According to Lazarus & Folkman (1984), coping has two major *functions*. These are regulating stressful emotions and altering the cause of the problem, which are classified as *cognitive-focused forms* of coping and *behavioural-focused forms* of coping, respectively. Finally, *immediate outcomes* of an encounter relates to the extent to which the person finds that the encounter was resolved successfully. This judgement relates to the commitment, values, and goals of the person as well as his/her expectations with regard to aspects of the encounter (Folkman, Lazarus, Dunkel-Schetter, DeLongis, & Gruen, 1986).

However, the classification of *cognitive-focused* versus *behavioural-focused forms* of coping has been critisised. Based on a systematic literature review, Skinner, Edge, Altman, and Sherwood (2003) identified 400 specific ways of coping. Skinner et al. argue that the above-mentioned dichotom classification is neither conceptually clear nor mutually exclusive in that some coping strategies comprise components of both cognitive- and behavioural-focused approaches. Morevover, many coping strategies may serve similar functions. Hence, this dichotomy classification poses for research purposes, which has also been acknowledged by Lazarus (2000). Instead, Skinner et al. (2003) suggest another hierarchical classification for higher orders of categories, referred to as *hierarchical systems of action*, which are sub-divided into *core families*. However, in spite of that, I find the original theoretical framework of Lazarus & Folkman clinically relevant and useful in the context of the PhD study in that the children´s "repertoire" of *behavioural-focused* forms of coping strategies is reduced to a great extent due to the medical procedure. Consequently, children cannot use active *behavioural-focused* coping strategies with an eye to changing or preventing the cause of the stressor, since they cannot prevent the medical procedure from being performed.

2.5.2 Coping Strategies in Relation to Painful Medical Procedures Involving Children

Rooted in the coping paradigm of Lazarus & Folkman (1984), Siegel & Smith (1989) address children´s strategies for coping with pain in a medical context. In addition to the two functions of coping suggested by Lazarus & Folkman (i.e. regulating stressful emotions and altering the cause of the problem), Siegel & Smith (1989) point out a third function, which "involves perceptually controlling the meaning of the experience so that the problem is perceived as less of of a problem" (p. 110). In that connection, the authors suggest that when it comes to painful events involving children in a medical context (e.g. procedural pain, post-operative pain), it may be impossible or difficult to change or avoid the situations that cause pain, as I pointed out above. Consequently, this leaves the child poor opportunities to employ coping efforts that seek to manage external demands in terms of the coping definition suggested by Lazarus & Folkman (1984). Thus, this narrows down the children´s array of coping strategies to the ones that serve the function of *regulating emotions* and *controlling the perceived meaning* in relation to the painful event. In addition, Siegel & Smith (1989, p. 111) point out that painful experiences (e.g. procedural pain) are most likely to be appraised by children as stressful (and not benign or irrelevant). In that connection, Siegel & Smith identify the following factors that may influence children´s strategies for coping with pain (e.g. under medical procedures), which I will address below. These are:

- The child´s general cognitive-developmental level
- Meaning ascribed to the painful encounter
- The child´s perceived ability to manage pain in terms of self-efficacy
- Previous experience
- Support from parents
- Contextual factors related to the pain situation

As to the child´s general cognitive-developmental level, Siegel & Smith (1989, pp. 111-112) point out that this facor is typically related to the child´s age. As opposed to school-aged children, pre-schooled-aged children are more vulnerable in that they rely on a global and undifferentiated understanding of illness involving magical thinking and circular logic. As to the ascription of meaning, young children base their understanding of illness on observable and external cues. Moreover, since their sense of time is poorly developed, it may not be effective to reassure the

child that the painful experience may decrease after a short period of time. As to the perceived ability to manage pain, the authors emphasise that previous experience can have negative as well as positive effects in the form of sensitisation and development of adaptive coping strategies that minimise the suffering of the pain experience, respectively. According to the authors, self-efficacy relates to the belief that the person is able to achieve the desired objectives, for instance decrease pain and/or anxiety). As to the role of the parents, Siegel & Smith (1989) state:

> "Parents play an important role in facilitating their child´s adaptive coping with pain. Parents´ response to a child´s verbal or nonverbal expression of pain can also influence a child´s experience and/or report of pain.... Parental anxiety and distress can be transmitted to the child, resulting in maladaptive coping. This may be due in part to a child´s attempt to elicit support and emotional comfort from a significant attachment figure during a stressful event, and/or that parent anxiety has been transmitted to the child through nonverbal means". (p. 112)

Finally, as to the contextual factors of the painful event, the authors state that the degree of the control that a child has over a painful event may influence the applied coping strategies and ultimately the child´s experience of pain, anxiety, and distress. In that connection, they emphasise that appropriate provision of information in relation to the pain event may be fruitful in terms of increasing the child´s sense of control. Likewise, if appropriate, it may be beneficial to involve the child in the treatment and decision-making.

Based on a clinical study (Siegel, 1983), the authors sum up a list of specific coping strategies that were applied by 80 children at the ages of 8 to 14 in response to needle procedures and surgery (e.g. blood drawings, pre-operative injections). The study showed that successful copers had more accurate information about their admission and applied a greater extent of different coping strategies that did unsuccessful copers. In table 2.1, I have displayed a summation of selected coping strategies used by the successful copers in the study.

Table 2.1. Summation of selected coping strategies reported in Siegel & Smith (1989, p. 114).

Distraction	External: efforts to divert attention away from the procedure by focusing on aspects of the enviromnment Internal: efforts to divert attention away from the procedure by focusing on body parts or sensation that are not related to the medical procedure Imagery: imagination of a pleasant experience or activity
Re-interprets sensations	Attempts to re-interpret or alter the sensory stimuli related to the medical procedure through cognitive process other than distraction (e.g. thinks about it as pressure instead of pain)
Fantasy	Imagination and identification with an imaginary character who does not feel pain (e.g. Superman) or pretending that a magical event is occurring (e.g. use of a magic wand) to eliminate the pain
Mental rehersal	Attempts to prepare oneself by mentally planning how the child will confront the painful stimuli/experience
Information seeking	Relevant: attempts to ask questions regarding the medical procedure Irrelevant: attempts to ask questions not related to the medical procedure
Positive self-statements	Thinking about positive aspects of the medical procedure; thinking about how he/she had managed successfully previous procedures; reassures self that he/she can tolerate the procedure; thinking about the experience (e.g. It does not hurt so bad; I can get through the procedure all right)
Seeking help and/or emotional support	Thinking of asking for help, comfort, sympathy, or emotional support from parents or medical personel (e.g. holding his/her hand)

2.6

Music Therapy in Paediatrics

The literature bears witness to clinical application and research involving a wide range of music interventions in general hospitals, including paediatrics. I will start this section by clarifying the boundaries of medical MT and music medicine (MM). Next, I will provide an overview of applied overall therapeutic approaches, methods, and objectives in paediatric MT, as described in the literature. After that I will exclusively address *music therapy as procedural support involving children*, which is the primary focus of the PhD study. Hence, as mentioned in the introduction of this chapter, related literature on music medicine (MM) will only by accounted for to a minor extent. Similarly, the literature on the application of MT and MM within the neo-natal medical specialty is also beyond the scope of the PhD study.

2.6.1. Definitions of Medical Music Therapy

The term *medical music therapy* covers a variety of MT practices with paediatric and adult in-/outpatients in the context of general hospitals. In the following, I will shortly present two internationally recognised definitions of medical MT suggested by Bruscia (1998) and Dileo (1999), respectively. Bruscia (1998) defines medical music therapy as:

> ...all applications of music or music therapy where the primary focus is on helping the client to improve, restore, or maintain physical health. This includes all those approaches that focus on direct treatment of biomedical illness, disease, or injury, as well as those that address related psychosocial factors. When the focus is biomedical, the goals are to effect changes in the client´s physical condition; when the focus is psychosocial, the goals may be to modify those mental, emotional, social, or spiritual factors that contribute to the biomedical problem, or to provide psychosocial forms of support to the client during the course of illness, medical treatment, or convalescence". (p. 193)

In continuation of this, he differentiates between practises, which:

> ...seek psychological changes in the client as a means to an end, that is, ultimately to ameliorate the biomedical problem, and those practices that seek psychological changes in the client as an end in itself, quite apart from any biomedical problems the client might have. (Bruscia, 1998, p. 193)

In other words, Bruscia defines the former practices as medical MT, whereas he regards the practices, which seek psychological changes as an end in itself as *music psychotherapy*. Furthermore, Bruscia (1998) classifies medical MT practices according to the following four overall levels of practices: the *Auxiliary level*, *Augmentative practices*, *Intensive practice*, and the *Primary level*. Table 2.2 holds a summation of Bruscuscia´s classification of *Augmentative music therapy practices*. In addition, an outline of all four categories is provided in appendix 1.

Table 2.2: Summation of Bruscia´s classification of Augmentative music therapy practices (Bruscia, 1998, pp. 195-196).

Augmentative practices	• *Music in medicine*: the use of music as distraction and to reduce anxiety, stress, and discomfort before, during, and after surgery and other medical procedures • *Music in palliative care*: the use of music to provide comfort, diversion, managing pain, anxiety and stress

In the *augmentative* music therapy practices, the music takes precedence over the therapeutic relationship, which is supportive and has a short-term duration (Bruscia, 1998, pp. 195-196).

Dileo (1999) proposes another simpler definition. She differentiates between music therapy and music medicine in terms of whether a therapeutic relationship exists or not. According to her definition, music therapy "...involves a therapeutic relationship, a music therapist, and a relationship that develops through the music and the process. It includes all types of music experiences", that is receptive, improvisation, recreation, composition, activities, combined arts" (Dileo, 1999 pp. 4-5). On the contrary, music medicine does not include a trained music therapist

and a therapeutic relationship that develops through the music (e.g. music administered by the patient or medical staff). In addition, Dileo (1999, p. 8) suggests a model which classifies MT practices into three levels. The model is reprinted in table 2.3 and exemplifies a patient in pain.

Table 2.3. Reprint of Dileo´s classification of music therapy practices, illustrated by an example of pain management (Dileo, 1999, p. 8).

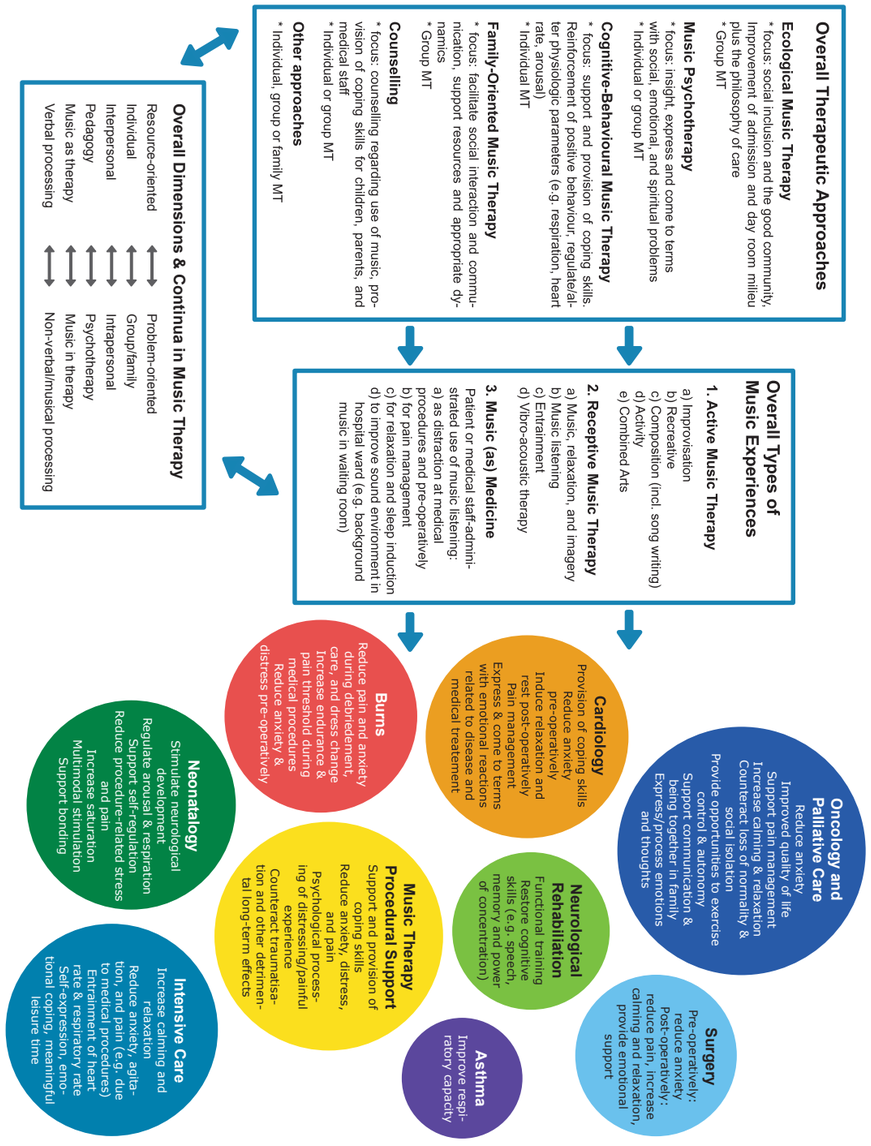
	1. Supportive level	2. Specific level	3. Comprehensive level
Needs of client:	Temporary relief of pain.	Understanding of pain	Resolution of pain
Level of therapist:	Beginning, intermediate	Intermediate, experienced, graduate studies	Advanced, experienced. Graduate/specialised training
Depth:	Distraction, provision of coping skills	Dialogue with or confrontation of pain	Resonance with pain
Function:	Supportive of medical intervention	Equal with medical intervention	Primary
Common music therapy interventions:	Music and biofeedback, music-based relaxation strategies, vibroacoustic therapy, recreative techniques	Improvisation, music and imagery techniques	Entrainment, guided imagery and music

I find both definitions useful in that they provide a good overview of the application of medical MT. The model proposed by Dileo gives a simple and clear picture and holds information on MT practices plus the level of training of the music therapist. On the other hand, Bruscia´s model gives a more comprehensive and detailed overview of the variety of MT services. In conclusion, the two models both have some distinguished important qualities and will be referred to in the thesis.

2.6.2 Overview of the Use of Music Therapy in Paediatrics

As we saw above, Bruscia (1998) and Dileo (1999) illustrate that MT is practiced at many levels within the medical setting meeting a variety of clinical needs (e.g. physical, psychological, social, cognitive). What follows now is an overview of the use of MT within paediatrics, including the overall therapeutic approaches, methods, and objectives of the MT (table 2.4). The overview is not exhaustive and is based on various forms of clinical and research texts (e.g. articles, books, abstracts) that I came across in my literature search.

Figure 2.4. Overview of overall approaches, methods, and objectives in paediatric MT as described in the literature.



As appears from table 2.4, the literature shows that MT is used in many ways and on many levels in paediatrics, meeting myriads of clinical needs and therapeutical objectives. In the following section, I will narrow down the scope of the presentation to *Music therapy as Procedural Support*.

Asthma: Marks (1974), Wade (2002)

Burns: Bishop, Christenberry, Robb, and Rudenberg (1996), Daveson (1999), Edwards (1994, 1995), Fratianne et al. (2001), Neugebauer & Neugebauer (2003), Prensner, Yowler, Smith, Steele, and Fratianne (2001), Rudenberg & Royka (1989)

Cardiology: Dun (1995), Micci (1984)

Intensive Care: Dun (1995), Kennelly and Edwards (1997), Stouffer and Shirk (2003)

Music Therapy Procedural Support: Barry, O'Callaghan, Wheeler, and Grocke (2010), Caprilli, Anastasi, Grotto, Abeti, and Messeri (2007), Ghetti (2012), Loewy (1997), Loewy, Hallan, Friedman, and Martinez (2005), Loveszy (1991), Malone (1996), Nguyen, Jarred, Walworth, Adams, and Procelli (2005), O´Callaghan, Baron, Barry, and Dun (2007), O´Callaghan, Sexton, and Wheeler (2007), Pfaff, Smith, and Gowan (1989), Turry (1997, 1999), Walworth (2003; 2005) Whitehead-Pleaux, Baryza, and Sheridan (2006), Whitehead-Pleaux, Zebrowski, Baryza, and Sheridan (2007)

Neonatalogy: Abromeit (2003), Cassidy and Standley (1995), Gilad and Arnon (2011), Nöcker-Ribaupierre (1999; 2004), Shoemark (1999), Standley (2001, 2003), Standley and Whipple (2003), Whipple (2000, 2005)

Neurological Rehabilitation: Edwards and Kennelly (2004), Hurt-Thaut and Johnson (2003), Kennelly and Brien-Elliott (2001), Robb (1996), Rosenfeld and Dun (1999)

Oncology & Palliative Care: Aasgaard (2001, 2002, 2004, 2012), Barrera, Rykov, and Doyle (2002), Brodsky (1989), Daveson (2001), Daveson and Kennelly (2000), Kennelly (2011), Lindenfelser (2005), Loewy (1999), Robb (1999, 2000, 2003), Robb and Ebberts (2003a, 2003b) Robb et al. (2007), Sheridan and McFerran (2004), Slivka and Magil (1986), Turry and Turry (1999)

Surgery: Aldridge (1993), Bradt (2010), Chesky and Michel (1997), Chetta (1981), Jarred (2003), Kain et al. (2004), Robb, Nichols, Rutan, and Bishop (1995), Sims and Burdett (1996), Whipple (2003)

Additional literature: Avers, Mathur, and Kamat (2007), Burns, Robb, Phillips-Salimi, and Haase (2010) Darsie (2009), Douglas (2006), Edwards (1999, 2005), Froelich (1986), Kennelly (2000), Loewy (1997, 2005), McCauley (1996), Robb (1999, 2000, 2003), Standley and Hanser (1995), Stouffer, Shirk, and Polomano (2007), Turry (2009), Whitehead-Pleaux, Clark, and Spall (2011)

2.7

Theoretical Aspects of Music Therapy as Procedural Support for Invasive Medical Procedures

This section relates specifically to the literature on *music therapy as procedural support*. The applied MT intervention of the PhD study was based on a multi-faceted and integrative theoretical framework. The framework is based on the theories and literature presented in Chapters 2 to 4, prior clinical experience, and two pilot studies. Originally, when I outlined and described the theoretical and clinical aspects of MTPS under *needle procedures involving children*, I found fragmented pieces of literature of varying relevance. As a result, my description of the theoretical framework of MTPS under needle procedures ended up being a patchwork, which comprised several minor descriptions that constituted a fragmented and unrelated unity. Eventually, some years later, I identified the theoretical study by Claire Ghetti (2012). On the basis of a systematic literature review, Ghetti included 19 clinical practice articles, practice books, and research articles that were subjects to a theoretical analysis. Based on the analysis, Ghetti proposes the first comprehensive, clear, and coherent theoretical framework of MT as procedural support under *various medical procedures*, primarily involving children. Although my original description had a less comprehensive scope and/or level of details, it concurred with Ghetti. Moreover, Ghetti synthesises and confirms my original

description, but in a much more comprehensive and structured way. In order to provide a clear structure and overview of the theoretical aspects, I have revised this section by using her findings and structure as a point of departure. In that connection, I have also deselected some of my original minor sub-sections in that they only held limited information regarding the specific theoretical aspects and were more comprehensively described by Ghetti. I made the revision before writing the discussion chapter. Besides a clearer and more comprehensive overview of the theoretical aspects, this choice also enables me to include the newest knowledge in the thesis. Finally, I revised this section with a view to improving the discussion even more.

In the following I will provide a definition of music therapy as procedural support as well as an overview of the use of MTPS in paediatrics. Next, I will address three main approaches MTPS, followed by a summation of Ghetti´s (2012) findings in terms of 15 key concepts of MTPS. After that, I will add sub-sections from my original description. Next, I will present Ghetti´s working model of MTPS, which summarises most of the theoretical aspects described in this section. Finally, I will provide a chapter summary.

2.7.1 Defining Music Therapy for Invasive Medical Procedures

As a point of departure, Ghetti (2012, p. 5) defines four important terms in relation to her theoretical study on MT as procedural support for invasive medical procedures. These are: invasive medical procedures, procedural support, music therapy, and music therapy as procedural support. Below, I will address some of these.

Invasive Procedures: Ghetti refers to Stedman´s Medical Dictionary (2000), which defines an invasive procedure as "a procedure requiring insertion of an instrument or device into the body through the skin or a body orifice for diagnosis or treatment". Examples of invasive medical procedures are provided further below in table 2.4.

As to *Music therapy as Procedural Support*, Ghetti (2010, pp. 5-6) states that the term *procedural support* originates from the *Child Life* literature, which first labelled it as "support during medical procedures" and described it as "remaining with a child during a medical procedure, when appropriate, to provide support, and to help the child use effective coping behaviours" (Gaynard et al., 1990, p. 131). However, Ghetti (2012, p. 6) stresses that procedural support may also be offered to adults. In addition, Ghetti defines MT on the basis of the American Association of Music Therapy (2010). Finally, she calls for an more adequate definition of MT as procedural support and proposes this definition, "For the purpose of this papir, *music therapy as procedural support* is defined as the use of music and aspects of the therapeutic relationship to promote healthy coping and decrease of distress in individuals undergoing medical procedures" (Ghetti, 2012, p. 6).

2.7.2 Overview of Music Therapy as Procedural Support under Various Medical Procedures in Paediatrics

In order to clarify the scope of the use of MT as procedural support under various types of medical and diagnostic procedures in paediatrics, I have provided an overview in table 2.4. The table lists 22 clinical- and/or research-related references, which I found on the basis of my literature search. Of these, 11 are included in my literature review, which I will present in Chapter 4.

Table 2.4. Overview of the use of music therapy as procedural support under various medical procedures in paediatrics.

Medical & Diagnostic Procedures	Clinical- & Research-Related Music Therapy References
Non-invasive and non-painful procedures • e.g. temperature, blood pressure, CT, EKG, EEG, X-ray, ventilator and emergency services	Loewy et al. (2005), Nguyen et al. (2005), Walworth (2003, 2005).
Invasive and painful procedures • e.g. IV-starts, finger sticks, injection, lumbar punctures, bone marrow aspiration, debridement, temperature (rectal, oral), emergency services	Bishop et al. (1996); Caprilli et al. (2007), Edwards (1994, 1995), Ghetti (2012), Kain et al. (2004), Loveszy (1991), Malone (1996), Neugebauer and Neugebauer (2003), Nguyen et al. (2005), O´Callaghan et al. (2007), Pfaff et al. (1989), Prensner et al. (2001), Turry (1997, 1999), Walworth (2003, 2005), Whitehead-Pleaux et al. (2006, 2007).
Surgery • Pre- and post-operative	Aldridge (1993), Bradt (2010), Chetta (1981), Chesky and Michel (1997), Jarred (2003), Kain et al. (2004), Micci (1984), Robb et al. (1995), Sims and Burdett (1996), Whipple (2003)

As appears from table 2.4, MT is used as procedural support in an array of medical and diagnostic procedures.

2.7.2.1 Approaches to Music Therapy as Procedural Support

Based on a comprehensive literature review, Ghetti (2012) classified three different overall approaches to MT as procedural support for invasive medical procedures in paediatric and adult patients. These are Music alternate engagement (MAE), Integration, and Music-assisted relaxation (MAR).

Music alternate engagement (MAE). According to Ghetti, MAE has been described or labelled as such in three articles (Bishop et al., 1996; Prensner et al., 2001; Fratianne et al., 2001). MAE is closely related to distraction, but differs in that:

> In MAE music is used to motivate and structure the patient´s active engagement with music and therapist in order to reduce awareness of painful or anxiety-provoking stimuli. Various clinical approaches fall within the realm of MAE by drawing the patient´s attention to the musical interaction. Ghetti (2012, p. 7)

In MAE, the patient is encouraged to participate musically and to follow cues of the music therapist to the extent feasible or permitted in the context of the medical procedure. In the context of the PhD study, I based the MT intervention of the MAE approach. Specifically, the MT intervention was informed by the MAE sub-interventions proposed by Fratianne et al. (2001) and Prensner et al. (2001), which the authors used in their clinical work with burn patients during debridement. The MAE sub-interventions are displayed in table 2.5, which also clarifies the level of involvement required from the child.

Table 2.5. Reprint of musical alternate engagement sub-intervention (Fratianne et al., 2001, p. 50).

Sub-interventions	**Level of Involvement**	**Description**
Music listening	Low	Listening to specifically selected music
Deep rhythmic breathing	Low	Using music´s rhythm to structure deep breathing
Preference expression	Low	Selecting music styles/songs/instruments to be used
Song identification	Low – moderate	Identifying songs played by the therapist
Song phrase cued response	Moderate	Giving a specific response to a specific music cue
Therapeutic instrument playing	Moderate – high	Playing a simple instrument with the beat of the music
Songs encouraging compliance	Moderate – high	Complying with treatment described/structured by the music
Therapeutic singing	High	Singing familiar songs
Musical games	High	Participating in music games

Based on their study on the use of MT during debridement, Fratianne and collaegues (2001) describe how the MAE sub-interventions can be used in practice. During painful procedures such as debridement, the music therapist continuously evaluates the patient´s interaction and responsiveness, his/her ability to focus plus acute needs in order to choose the most appropriate sub-intervention. The sub-interventions aim at engaging the participants as much and as actively as possible. According to Fratianne et al., the sub-interventions should be adapted in accordance with the patient´s acute and shifting needs, which facilitate variations and provide opportunities of redirection of attention. If the patient exhibits moderate to high level of responsiveness and becomes more anxious or stressed, the therapist can easily change to sub-interventions that require a lower level of involvement. Eventually, the therapist can gradually shift back to sub-interventions requiring high levels of involvement and interaction. In short, the MAE sub-interventions offer a flexible and adaptable means and contain several forms of musical interaction as well as music experiences.

Integration: According to Ghetti (2012, pp. 7-8), *integration* as an MT pain management technique was defined by Loewy et al. (1997), who describe this approach as an alternative to distraction. Contrary to MAE, *integration* implies that the patient focuses on the bodily, sensory, and affective dimensions of his/her pain experience, which are subsequently externalised or released by musical means. Loewy et al. (1997) write that integration "calls upon the child to come into the body by focusing on the breath, heart rate, emotional intention, and resonance, i.e. the feeling of the pain itself" (p. 48). Through a harmonic, rhythmic, and tonal synthesis, the four above-mentioned dimensions are integrated. She describe integration as a two-fold process:

> At the first level, rhythm, air, and tone enhance a vibration of connection physiologically. At the second level, the painful music of the body encourages integration at the affective level, which connects the mind to the body and the spirit. (Loewy et al. (1997, p. 48)

In addition, the musical expression and release of the patient´s multi-dimensional focus/experience of the pain, facilitate physical release for the pain and support enhanced feelings of control (Ghetti, 2012, p. 8). In addition, as to the process of *integration*, the music and patient-therapist relationship are equally important in terms of providing support during the medical procedure. Finally, *integration* obviously requires active participation by the child. Furthermore, it also requires that the child is able to express his/her bodily-emotional experience and needs during the medical procedure.

As to *Music-assisted relaxation (MAR)*, Ghetti (2012, p. 8) cites Bishop et al. (1996, p. 92) for the following definition, MAR is:

> ...the use of music that has been selected for its characteristics of tempo, fluid and predictable movement of melody and dynamics, and pleasing harmonics. The music therapist utilizes the music to structure and teach deep diaphragmatic breathing, progressive muscle relaxation, and to facilitate imagery. (Bishop et al., 1996, p. 92)

According to Ghetti, MAR can serve two main functions, to reduce pain and to reduce anxiety by means of entrainment and the ISO-principle. She says:

> The therapist may direct the patient to focus on breathing or elements of the music as a form of attention control, or may allow the patient to attend to anything he or she desires, but will continue to employ the iso-principle to decrease arousal. (Ghetti, 2012, p. 9)

Finally, some forms of MAR require active engagement of the patient, whereas other forms may not.

2.7.3 Key Concepts of Music Therapy as Procedural Support

As mentioned previously, Ghetti (2012) analysed 19 MT texts that met the inclusion criteria of her theoretical study. The analysis aimed at identifying important theoretical aspects of MT as procedural support for invasive procedures, which resulted in a classification of the following 16 key concepts:

- Assessment
- Multi-faceted moderators
- Reflexivity
- Individualized approach
- Preparation
- Modification of environment
- Level of patient engagement
- Focus of attention
- Type of music used
- Role of the therapist
- Role of the music
- Role of the patient
- Sense of control
- Facilitation of healthy coping
- Additional functions
- Limitations

In table 2.6, I have provided a summative description of these 16 key concepts, which constitute a major result of her study (Ghetti, 2012, pp. 19-27). For general information my numbering of these aspects (in the table) does not reflect any suggestion for precedence. Below the table, I will supplement her result with my original descriptions of theoretical aspects of MT as procedural support.

Table 2.6. Summation of key concepts of music therapy as procedural support after Ghetti (2012, pp. 19-27).

Key concepts	**Summative description**
1. Assessment:	- was consistently emphasised as an ongoing and essential element of the procedural support process, both before and during (see *Reflexivity*) the medical procedure
2. Multi-faceted moderators:	- comprise several factors including developmental level, coping tendencies, personality traits, the child´s appraisal of medical procedure and illness, possible anticipatory distress/anxiety, the nature of the child´s past experience with medical procedures and admissions, sensitivity of pain, family support, relationship to medical personel, use of medication (e.g. sedatives)
3. Reflexivity	- was suggested and defined by Ghetti (2012) as a term describing "a process of ongoing assessment in which a music therapist alters clinical approaches over time in reaction to a patient´s responses and changing needs" (pp. 19-20). The importance of using reflexivity throughout the entire medical procedure was stressed by more authors
4. Individualized approach	- was emphasised as very important and necessary in order to tailor and maximise the effects of the MT intervention in question when meeting a patient´s idiosyncratic and shifting needs in relation to medical procedure
5. Preparation	- prior to the procedure was often recommended in the literature in order to assess child, establish rapport, prepare child and parents about the procedure, and rehearse coping skills. In addition, preparation could take place some time before or immediately prior to the procedure
6. Modification of environment/context	- covered inclusion of parents and medical personel with a view to alleviating stress, encouraging positive interaction during medical procedure and *humanizing* medical personel

7. Level of patient engagement	It is important that the MT intervention is sensitive and adaptable to the child´s needs and the context of the medical procedure. Optimally, the intervention can strike "a balance between demanding attention, but not being too challenging, in order to promote sustained engagement with the music and the therapist" Ghetti (2012, p. 22). Ghetti exemplifies that the use of MAE sub-interventions that require low levels of engagement can be useful as a *point of entry*. Subsequently, the child´s level of active engagement can be modified. Besides that, the music therapist may use variation in stimuli and the aspect of novelty in order to promote engagement, which may include visual or tactile appealing (musical) objects
8. Focus of attention	The result of the analysis showed a difference of clinical relevance with regard to where attention should be focused. Two overall diverse approaches were argued i.e. *away* and *on* the medical procedure, respectively. Specifically, attention could be focused on the music, the music and the music therapist, on an assigned task, on inner sensations and emotional responses, and on the medical procedure
9. Type of music used	- varied, but was carfully considered before being selected. The majority of the authors recommended live music in that it can be adjusted according to the child´s needs and preferences as well as the course of the medical procedure. Likewise, the majority of the authors stressed the use of familiar or preferred music. Besides that, several used improvised music or adjusted lyric contents of familiar music in order to provide reassurance
10. Role of the therapist	According to Ghetti (2012), the role of the music therapist were various and included the following functions: ...providing cues for desired response....redirecting attentions to the music when the patient orients to the procedure....providing positive reinforcement when patient attends to music of task....synergizing with patient during active music making...providing reassurence and emotional support...providing positive suggestions or clarifications through sung lyrics or spoken words....validating patients´ emotions and sensations, and eliciting patients´emotional experiences....being emergent and responsive to patient needs as they evolve over time. (p. 24)

11. Role of the music	According to Ghetti, the role of the music is multi-facteted and constitutes a key aspect of MT as procedural support. In short, the role of the music had many functions. In addition, these varied according to the overall stage of the procedure (i.e. before, during, and after) or the stages within a procedure. Specifically, Ghetti (2012) identified the following functions: ...enabling engagement...providing integration of body-mind sensations and perceptions...providing resonance and vibration...cueing and supporting deep breathing/oxygenation...promoting relaxation and decreasing arousal...promoting comfort...triggering positive associations...conveying a sense of structure...masking environmental noise...providing a means of connecting with others...providing a sense of grounding through structure and familiarity...functioning as a transitional object...and serving as a projective technique. (pp. 24-25)
12. Role of the patient	- was only described explicitly to a minor extent, but some authors "acknowledged the importance of the patient engaging in the music, expressing needs, and serving as an empowered decision-maker" (Ghetti, 2012, p. 25).
13. Sense of control/ empowerment	The ability of promoting empowerment and increasing sense of control through MT were addressed to a great extent in the literature. In hat connection, the provision of choices within the mucial interaction was found to be significant.

15. Facilitation of healthy coping	- was described by several authors. Ghetti (2012) sums up that " MT can reinforce exising coping strategies (e.g. avoidance, information-seeking, emotional expression)…introduce and rehearse new coping strategies (e.g. relaxation strategies, integration, focusing attention)… and facilitate cognitive re-framing of a situation" (p. 26). Besides that, some authors described MAE and MAR as coping strategies in the context of pain management in that: MT may help improve a patient´s tolerance of the pain experience, but not necessarily render the sensation of pain any less intensive….MT may not be able to diminish the sensation of pain at moments of peak intensity (e.g. during needle insertion), but it may help increase the patient´s use of adaptive coping stregies to deal with the pain. (Ghetti, 2012, p. 26)
15. Additional functions	Ghetti (2012) found the following additional processes and functions of MT during procedural support: …the use of ISO-principle or entrainment… MT functioned as a container for a patient´s emotional expression and experience…use of musical and interpersonal elements to provide a stable sense of "holding", and MT to improve a patient´s ability to rebound to a stress-free state following a stressful procedure. (pp. 26-27)
16. Limitations	- of MAE and integration in relation to procedural pain were also pointed out in the literature. For instance, as to MAE, Fratianne et al. (2001) write that "Music therapy interventions seemed less effective during the most painful aspect, debridement, than compared to the beginning and the end of the process" (pp. 51-52). In addition, Loewy et al. (1999) point out that "distracting the child to the degree that the puncture is a surprise may not always be useful" (p. 55).

2.7.4 Additional Descriptions of Aspects related to Music Therapy as Procedural Support

In addition to the overview and contents provided in table 2.6, I will now add some supplementary descriptions, which relate to medical procedures involving children. These are: the role of the music therapist, the role of the music, sense of control, and facilitation of healthy coping.

2.7.4.1 The Role of the Music Therapist

In addition to the Ghetti´s (2012) finding regarding the role of the music therapist, I would like to add the following roles, which were proposed by Nguyen et al. (2005, p. 216):

- Patient advocate
- Patient/family educator
- Relieve patient/family anxiety
- Reduce need of sedation of children

As appears, these roles are exclusively supportive, which is in agreement with Ghetti (2012).

2.7.4.2 The Role of the Music

Likewise, in this this sub-section, I would like to add descriptions of the following roles and functions of music: the ISO-principle and the compensational principle, psychological meanings of music, and the musical characteristics of sedative and anxiolytic music.

The ISO principle and the *compensational principle* are two important complementary principles in MT practice and other application of music (e.g. music medicine). The *ISO-principle* was proposed by Ira Altschuler (1948) and can be used to alter a client´s mood states and/or physiologic reactions to stimuli. According to this principle, music is first matched to the client´s mood state or behaviour, and is then gradually altered in the direction of the desired mood or therapeutic objective (Walworth 2003). On the contrary, the *compensational principle* involves that music

with opposed qualities to the client´s mood or behavioural state is applied as a starting point (Wigram, Pedersen, & Bonde, 2002, p. 319). An example would be an application of vivid or happy music to a depressed client. When using either principles, the music can either be pre-recorded or performed live. However, the use of live music in the context of medical procedures, obviously adds more flexiblility and adaptability in meeting children´s changing needs and moods (Turry, 1997).

Moreover, music has distinct qualities and functions that are beneficial in the context of medical procedures involving children, which will be address in the following.

Edwards (1999) puts forward that many children have an existing relationship to music, which is often positive. She emphasises that "…children are able to indicate their preferences and interests….The child patient may already have positive, well established musical associations, linking certain songs to family members, as well as connecting previous music experiences with fun and play" (Edwards 1999, p. 71).

In the clinical context of medical procedures, this may ease or promote the process of establishing rapport. In continuation of this, several authors emphasise the importance of using music that is preferred by or familiar to the child in order to benefit from the positive associations the child may have to specific songs and music. In addition, improvised music may also be beneficial in MTPS (e.g. Edwards, 1995; Loewy, 1997; Walworth, 2003; Whitehead-Pleaux et al. 2007).

One of the outcomes of the PhD study is *Child Anxiety*. As to the development of the applied MT intervention, I found Wigram, Pedersen, and Bonde (2002, p. 144) clinically very relevant in that they provide an overview of musical parameters in *relaxing* and *anxioalgolytic* (i.e. anxiety reducing) music, respectively. The musical parameters are based on an unpublished conference presentation about the use of music medicine under surgery (Spintge, 1993). The parameters are listed in table 2.7.

Table 2.7. Musical parameters in relaxing and anxioalgolytic music. Reprint of Wigram et al. (2002, p. 144).

Musical elements	**Relaxing music**	**Anxioalgoytic music**
Frequency	600 Hz to 900 Hz	20 Hz to 10.000 Hz
Dynamics	Little change in dynamics	Little change in dynamics
Melody	Regular, continuous	Regular, continuous
Tempo	60 to 80 beats per minute	50-70 beats per minute
Rhythm	Constant: little contrast	Floating: no contrast

In continuation of this, Wigram (2004, p. 115) proposes a list of similar musical parameters in the tool **P**otentials in **S**timulatory and **S**edative **M**usic (PSSM). However, the PSSM provides guidelines for both potential stimulatory and sedative music. As to sedative music, Wigram emphasises the following musical parameters:

- Stable tempo and structure
- Stable or gradual change in: volume, rhythm, timbre, pitch, and harmonics
- Stable texture
- Predictable harmonics (modulations)
- Predictable cadences and ending of phrases
- Predictable melodic progresses
- Repetition of different parts
- Clear and transparent form
- Pleasant timbres
- Few accents

In summation, the musical parameters in sedative music proposed by Wigram et al. (2002, p. 144) and Wigram (2004, p. 115) illuminate different aspects of sedative music. In short, a slow tempo and predictability in terms of few or subtile changes in dynamics and melody are important components of sedative and anxiety reducing music, which I applied clinically in the MT intervention of the PhD study.

2.7.4.4 Healthy Coping

One of the key objectives of MTPS is to facilitate and support healthy coping. Brown, Chen, and Dworkin (1989) identify two important theoretical aspects with regard to the use of music as a cognitive coping strategy in controlling pain. They emphasise two distinct qualities inherent in music, namely an *attention-distraction* and an *affect-regulative* property. As to the *attention-distraction* property, they stress that music unfolds in time, whereby music potentially enables to hold the listener´s attention while challenging the intellect. Likewise, music may alter the emotional state of the listener, regardless of his/her music preference. In addition, music has also the ability to alter the listener´s perception of time and place. Hence, Brown et al. state that when the listener loses him-/herself in the music, the suffering related to a pain experience may be reduced. As to the *affect-regulative* property, the authors put forward that music is mood evoking and can potentially recal emotional experiences which in turn may provide heightened meaning to a situation (Brown et al., 1989, p. 56). In summary, Brown et al. state that structured music listening can serve many cognitive and emotional functions, which can potentially affect the listener´s perception of and suffering from pain.

During the preparatory pilot studies related to the PhD study, I found the two above-mentioned concepts clinically useful. Specifically, it seemed to me as if the participants´ behaviours and responses to the medical procedure were modified by the cognitive and emotional functions of the music that I played for/with them.

2.7.4.5 Sense of Control

I would also like to address the importance of supporting the sense of control and empowerment in (young) children under medical procedures. This topic is emphasised by several authors in the MT literature (e.g. Edwards, 1999; Loewy, 1997; Robb, 1999). In that connection, Sheridan & McFerran (2004) emphasise the value of opportunities, choices, and control in the context of paediatric hospice. They state: "Similar to paediatric medical settings, the actual experience of control over the environment is fostered through opportunities for choice that promote control and mastery. Similar to adult palliative care, the perceived loss of control experienced due to the nature of their chronic illness is addressed through metaphoric opportunities to experience control: over music making, another´s actions, and the level of responsibility assumed by the child" (Sheridan & McFerran, 2004, pp. 29-30).

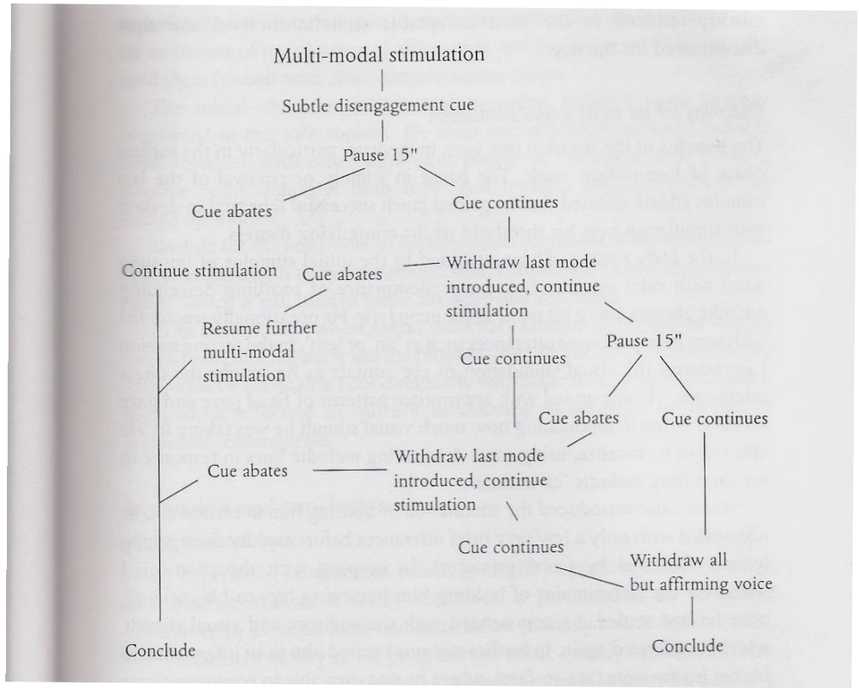
Although Sheridan & McFerran describe the value of opportunities in the context of palliative care, they point out the similarities to paediatric medical setting and argue that MT can offer a wide range of musical and other symbolic options, which may be beneficial for the child´s sense of control.

2.7.4.6 Informing Clinical Practice by Decision Trees

Shoemark (1999, p. 41) advocates the use of decision trees as a precautionary measure to guide clinical MT practice during multi-modal stimulation with premature babies. Specifically, she adapted the decision tree suggested by Burns et al (1994[3]). In figure 2.5, I have provided a reprint of her decision tree.

3 *Burns, K., Cunningham, N., White-Traut, R., Silvestri, J. and Nelson, M. (1994) `Infant stimulation: Modification of an intervention based on physiologic and behavioural cues`. Journal of Gynaecological and Neonatal Nursing 23, 7, 586.*

Figure 2.5. Decision tree suggested by Shoemark (1999, p. 41).

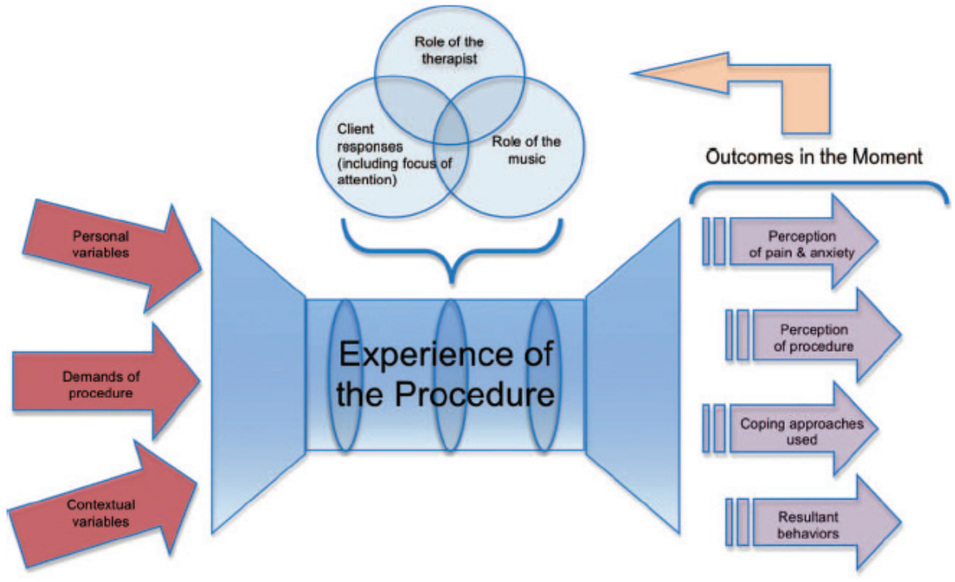


As appears from figure 2.5, the decision tree is meant to be used if the premature baby exhibits cues of disengagement during multi-modal stimulation. If so, the decision tree clearly guides the music therapist when to withdraw the last mode introduced, to resume again, or ultimately to conclude multi-modal stimulation. In addition, the decision tree involves short pauses of 15 seconds during which the music therapist watches and appraises the cues of the premature baby. This cyclic process of appraisal relates to Ghetti´s (2012) concept of *reflexivity*, described further above.

2.7.5 Theoretical Working Model of Music Therapy as Procedural Support

As described previously, I will now present Ghetti´s (2012, p. 28) working model of MTPS, which to a large extent summarises the present section on theoretical aspects of MTPS. The theoretical working model is multi-dimensional and illustrates the interactions among the 16 key concepts, which were described in this section, and various components, including personal variables, demands of the procedure, contextual variables etc. The model is displayed in figure 2.6.

Figure 2.6. Reprint of working model of music therapy as procedural support (Ghetti, 2012, p. 29).



Ghetti (2012, p. 29) defines the working model of MTPS (i.e. figure 2.6) as a *transactional model* in that it reflects complex non-linear interactions among the various components (e.g. patient, music therapist, the medical procedure in question, contextual variables). Specifically, the components depicted by arrows on the left side influence the child´s *immediate* experience of the procedure, which in turn is modified by the *role of the therapist and music* plus the *child´s responses*, which serve as a "lens that filters the individual´s experience of the procedure" (Ghetti, 2012, pp. 28-29). According to Ghetti, this filtering process results in the child´s perception of pain, distress, coping approaches used, the procedure, and the resultant behaviour. Based on these *outcomes in the moment*, the music therapist applies the process of *reflexivity* by which the she/he continuously re-assesses and re-focus the MTPS *intervention lens* in order to positively alter outcomes (Ghetti, p. 28). Finally, Ghetti states that the theoretical working model accommodates the three overall MT approaches to MTPS (i.e. MAE, integration, and MAR). In addition, the model supports multi-dimensional models of pain perception, including the Gate Control Theory of Pain and the Neuromatrix Theory of Pain. In the context of MTPS in children, these two pain theories are useful in that they provide a theoretical framework that explains how MTPS may modify and reduce the experience of pain in children undergoing medical procedures. In conclusion, as to the *motivative-affective* aspects of pain perception, MTPS may promote positive mood states and associations by means of familiar songs/music, inclusion of parents etc. Likewise, the *cognitive-evaluative* aspects of pain may be modified through provision of clear information related to the medical procedure, validation of the child´s successful coping efforts among other things.

2.7.6 Chapter Summary

In this first chapter of the theoretical framework of the MT intervention, I initially provided information about nephro-urological diseases and described the current practice regarding IV-access procedures at AUH. Next, I presented theoretical aspects of pain (Loeser & Melzack, 1999; Melzack, 1999; Melzack, 2001), trauma (Levine, 2006; Levine & Kline, 2007), and coping (Lazarus & Folkman, 1984; Siegel & Smith, 1989), which informed the development of the MT intervention of the PhD. Then, I outlined the boundaries of medical MT and provided an overview of the use of MT in paediatrics in general as well as a specific overview of the use of MT as procedural support in paediatrics. After that I illuminated important theoretical aspects of MT procedural support. This

was partly done by summating the classification and results of Ghetti (2012) with a view to revising my original somewhat incoherent description, including the newest knowledge, and providing a research-based comprehensive theoretical overview of MT as procedural support. Specifically, I described three overall MT approaches and 16 specific overall key concepts of MT procedural support. Finally, these theoretical aspects will now be complemented by clinical-based descriptions of MT as procedural support plus research-based recommendations of cognitive-behavioural interventions under various medical procedures involving children (Chapter 3). After that follows a literature review of the 11 outcome studies on the effects of MT as procedural support under various medical procedures involving children (Chapter 4).

CHAPTER 3
Theoretical FrameWORK:

RESEARCH-BASED CLINICAL RECOMMENDATIONS & CLINICAL ASPECTS OF MUSIC THERAPY AS PROCEDURAL SUPPORT

In the previous chapter (Chapter 2), I presented some overall theoretical aspects of invasive painful medical procedures and MT as procedural support. As illustrated in figure 3.1, this chapter relates to research-based clinical recommendations regarding non-pharmacological techniques that aim at reducing pain and distress in children under painful medical procedures. First, I will provide a summative overview of the quite substantial body of research literature on the detrimental short- and long-term effects of medical procedures involving paediatric patients, including studies on non-pharmacological interventions. Next, I will address myself to clinically related aspects of MT as procedural support as described by Turry (1997). However, it is beyond the scope of this PhD study to present a detailed review of the many individual studies. Instead, the objectives in this chapter are to provide a summative overview of the literature on the detrimental effects and to sum up specific research-based clinical recommendations that informed the development of the MT intervention of the PhD study. The description of the theoretical framework in this chapter is rooted in three main references that I found clinically very relevant for the PhD study in that they illuminate the comprehensive literature on medical procedures from different clinical and/or theoretical perspectives (Cohen, 2008; Turry, 1997; Young, 2005).

Figure 3.1. Overview of Contents of Chapter 3

3.1 Theoretical Perspectives and Research-Based Clinical Recommendations

Young (2005) provides a summation of the evidence of potential long-term negative effects of medical procedural pain in paediatric patients. Among other things, the article contains a summation of individual determinants of pain responses, pain assessment methods, and non-pharmacological interventions, respectively. Furthermore, Young presents a theoretical model that incorporates individual determinants of pain responses, procedure-related factors, and the Gate Control Theory. Finally, Young provides illustrative and summative user-friendly tables with practical clinical guidelines, which I found very useful in my preparation of the MT intervention of the PhD study. In this section, I will sum up these items except for the pain assessment part.

With reference to the pain definition proposed by the International Association for the Study of Pain (see section 2.3.1), Young states that pain is subjective, and pain response is individual and learned through social learning and experience. She puts forward that:

> Common routine and emergency childhood painful medical procedures, such as immunizations, blood tests, circumcision, dental care, and laceration repair, along with minor everyday pain experiences, such as falls, bumps, and cuts, compose the majority of the typical child's pain events. Thus, a child's experience during painful medical procedures likely plays a significant role in shaping that individual's pain response to future event…Even minor medical procedures such as finger sticks and venipuncture cause significant pain and fear in children, yet interventions to reduce pain and distress are infrequently used. Improved emergency department care is a key link in the chain of improved overall pediatric pain management. (Young, 2005, pp. 160-161)

Table 3.1 shows Young´s summary of the clinical research-based determinants that influence children´s pain response to medical procedures. The determinants are temporally divided according to the process of the medical procedure (that is before and during the procedure), and furthermore categorised as modifiable and not modifiable, respectively. Finally, please note that the right column lists the characteristics in group/individuals that show greater pain response.

Table 3.1. Copy of Young´s summary of current evidence for determinants of a child´s pain response to painful procedures, illustrated in (Young, 2005, p. 162).

Determinant	Proposed Effect: Group With Greater Pain Response
Preprocedural - not modifiable	
Age	Younger
Developmental level of understanding	Less complex understanding
Sex	Female
Race/ethnicity/culture	Non-Caucasian
Temperament	Difficult (adaptable=lesser pain response)
Birth order	Unknown
Pain sensitivity	More sensitive
Symptom monitoring	Higher level of symptom monitoring
Pain expressivity	More expressive, more pain reporting
Locus of control	Internal locus of control
Anxiety level: trait (overall)	High anxiety
Experiences	Variable effect, no evidence for habituation or sensitization
Systolic blood pressure	Lower blood pressure
Preprocedural - modifiable over time	
Pain coping style	Internalizing, catastrophizing (distraction, problem-focused=lesser pain response)
Familial role models	Pain-sensitive family members
Social learning from peers, media, authority figures	Variable
Perceived secondary gains	Increased desirable secondary gains
Medical fears	Increased medical fears
Procedural - not modifiable	
Procedure invasiveness, noxiousness, duration	Increased noxious stimulus, invasiveness, duration
Sex and ethnicity of person performing procedure	Unknown
Procedural - modifiable	
Preparation and information given	Inadequate information and preparation
Appraisal of meaning & context of procedure	Less positive meaning (eg, medical procedure vs ear piercing)
Anxiety level: state (current)	More anxious
Sense of control	Decreased sense of control
Use of pain-coping skills	Not using pain-coping/promoting behavior
Parental presence	Mixed effects
Parent and staff behavior	Reassurance, apology, criticism, giving general control to child (not specific choices); decreased pain response with distraction, direct commands to use coping skills, and praise
Environment	Chaotic, noisy environment
Child's physiologic state (eg, hunger, fatigue, nausea, baseline pain)	Variable
Use of non-pharmacologic and pharmacologic interventions	No or ineffective interventions

Table 3.1 reflects a multi-dimensional framework and provides a user-friendly summation of guidelines for clinical practice. According to Young´s (2005) summative table, a child´s pain response is formed by both genetic factors and environmental influences. Some pain response determinants are considered fixed (e.g. age, gender, temperament). Some can be modified over time (e.g. state anxiety, pain, coping skills, medical fears), and others can be modified prior to or during the procedure (e.g. environment of the procedure, use of pain reducing interventions).

Pre-procedural non-modifiable determinants: According to Young (2005), the research literature indicates that younger children exhibit more distress and rate higher pain levels compared to older children. Likewise, younger children are more vulnerable to painful medical procedures, since they cannot use cognitive coping skills due to limited developmental stage. However, they can use non-cognitive coping skills like seeking comfort. Contrasting findings regarding gender differences to pain response, have been reported in the research literature as opposed to the research literature on adults. Furthermore, evidence for ethnical differences is sparse. However, Blacks and Hispanics are generally associated with higher pain levels compared with whites (Young, 2005, pp. 161-162).

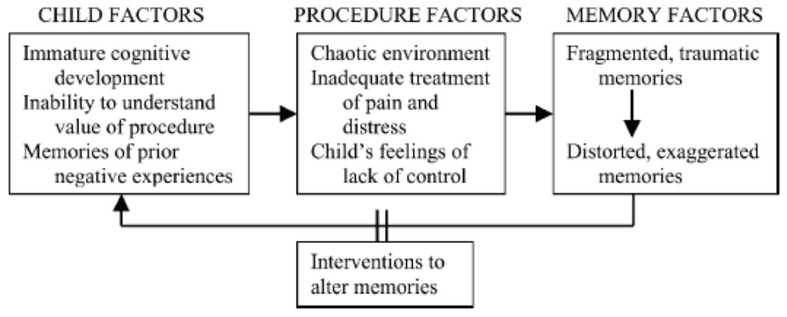
Pre-procedural determinants modifiable over time: As to this category, Young (2005) puts forward these determinants that can modify a child´s pain response over time: coping style, medical fears, familial role model, and social learning. For example, anxiety and coping style influences the pain response, with those having high anxiety levels and those using distraction reporting lower pain responses. Moreover, Young states that the effects of parental presence have been well researched and show mixed results in terms of child pain and distress (Young, 2005, pp. 162-163).

Procedural modifiable determinants: Preparation and information regarding the procedure is associated with reduction of child distress as well as the use of coping skills. Based on the research literature, Young stresses the importance of parent and medical staff behaviour. Distraction and direct commands to use a coping strategy stated by parent and medical staff, is found to be beneficial in reducing child pain and distress. On the contrary, reassurance, criticism, apology, and giving control of the procedure to the child, are associated with higher levels of child pain (Young, 2005, p. 163).

Based on the research literature, Young (2005) stresses that the child´s age and brain development at the time of the painful medical procedure(s) are believed to influence the nature, severity, and permanence of the possible negative long-term effects. Hence, she emphasises the importance of adequate pain relief for premature born infants, since the development of the neuronal architecture of the brain may be permanently altered due to repeated pain stimuli, such as needle procedures. As to children as young as three years old, memory of painful medical procedures plays a significant role in the development of negative long-term effects. According to Young (2005), special attention should be given to young children since studies have shown they can remember details of painful procedures and pain events, and not least due to their immature cognitive development and inability to understand the purpose and meaning of medical procedures. Consequently, fragmented traumatic memories of painful events can easily become distorted and exaggerated, generating higher levels of distress and anxiety under future medical procedures, which is illustrated in figure 3.2 (Young, 2005, p. 161).

Figure 3.2. Simple theoretical model regarding traumatisation due to medical procedures. Reprinted after Young (2005, p. 161).

The model sums up illustratively the possible interactive domino reactions in young children during medical



procedures, which, however, can be modified by non-pharmacological interventions. In addition, Young gives a summation of such interventions and simple techniques documented in the research literature on paediatric patients during various medical procedures (see table 3.2).

Table 3.2. Non-pharmacologic interventions to reduce pain and distress at procedures. Reprint of Young (2005, p. 166).

Technique	**Description**
Distraction	Infant: pacifier, bubbles, toys Toddler: bubbles, songs, pop-up books, party blower, kaleidoscope, toys School-age: videos, video games, search for objects in pictures, stories, jokes, counting, nonprocedural conversation Adolescent: music by headphones, video games, nonprocedural conversation, focusing on objects
Deep breathing	Have the child breathe rhythmically with slow deep breaths.
Blowing	Have the child blow out imaginary candles or take a deep breath and "blow away the pain". Party blowers have been used successfully.
Suggestion	Help the child put on a "magic glove" that does not allow pain, or apply "magic invisible cream", or turn off a "pain switch."
Superhero imagery	Have the child imagine that he or she is a superhero and the procedure is a special mission.
Guided imagery	Help the child imagine a favourite place/activity, concentrating on all the associated sensations.
Thought-stopping and positive self-statements	Teach the child to think or say "Stop!" when feeling pain and then to think or say, "I can handle this," or similar positive self-statements.
Rewards	Let the child know that rewards such as stickers, decorative bandages, small trophies, certificates, or prizes are available. Make behavior such as cooperation a goal, but give all children the reward.
Spot pressure or counterirritation	Rub the surrounding skin or provide spot pressure to the surrounding skin.
Sweet solution or pacifier	Useful for infants for minor procedures. Give 2 mL of 30% sucrose or 30% glucoseor breastfeeding immediately before or during the procedure. Allow sucking on pacifier or breastfeeding during the procedure.
Cognitive behaviour	Preparation with dolls or other materials, role playing, role modelling, practicing therapy desirable behaviour, desensitization (slow introduction to subparts of procedure), hypnosis, guided imagery, progressive muscle relaxation, memory alteration.

As appears from table 3.2, Young (2005, p. 166) provides a summative overview of 11 non-pharmacological interventions/techniques that are easily applicable in clinical practice with child and parent(s) during painful medical procedures. Furthermore, the table holds informative descriptions, recommendations, and wordings.

Table 3.3. Copy of environmental methods to decrease pain and distress during procedures (Young, 2005, p. 165).

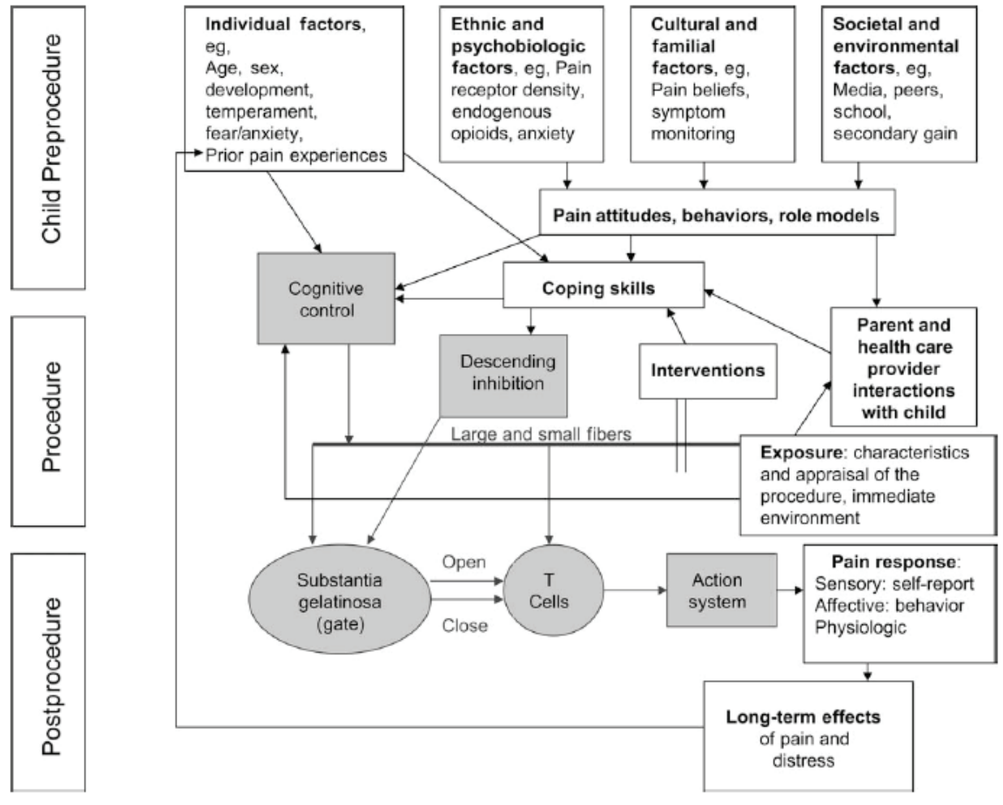
Provide Information and Prepare Parent & Child	**Parental Involvement**
• Give step-by-step information of what will occur during the procedure • Give sensory information about what the child will see, hear, and feel • Use age-appropriate language and terminology and avoid medical jargon • Avoid high-anxiety words such as pain, hurt, cut, shot • Use words such as poking, freezing, squeezing instead • Do not insinuate that the procedure will definitely hurt • Be aware of possible misinterpretations of words and phrases such as ''dye'' or ''put to sleep'' • Address children's concerns (eg, ''taking all my blood'') • Consider using books describing the procedure the child can read with the parent • Give information before and during the procedure • Be honest	• Ask the parents how much distress they expect from the child • Allow parents to remain present • Do not ask the parent to help restrain the child • Instruct the parent not to threaten the child (eg, with additional shots) • Instruct the parent on coping-promoting behaviors (eg, distraction) and to avoid distress-promoting behaviors (eg, reassurance)

Health Care Worker Behavior	**Hospitalized Children**
• Be calm, confident, and in control • Avoid reassurance, apology, criticism • Avoid conversation with other health care workers and parents that may be distressing (eg, describing possible adverse events) in front of the child • Teach students how to perform the procedure outside the room to minimize discussion in front of the child	• Use a treatment room; keep the patient's room/bed as a ''safe place'' • Give hospitalized children a predictable ''safe'' time when procedures will not occur and a predictable time for procedures • Plan ahead and draw all blood samples at once if possible • Do not give pain medications by a painful route (intramuscular)

Procedural details	**Health care setting**
• Allow comfort items such as favorite stuffed animals or blankets • For venipunctures and intravenous cannulation in thumb-sucking children, avoid the arm of the preferred thumb • Do not force the child to lie down if he or she does not want to and is not required to • Consider giving the child a ''job'' (eg, holding a gauze) • Give the child choices to increase the perception of • control (eg, right arm or left) • For long procedures (eg, burn dressing changes), allow the child ''time outs'' of a predetermined number and duration (eg, three 20-second time outs) • Allow the child to ''count down'' from 10 to 1 before a brief procedure • Use automatic lancets for finger sticks • Venipuncture, when feasible, may be less painful than heel lance	• Maintain a quiet, calm environment. • Avoid stressors such as beeping monitors • Avoid long delays between informing the child of the procedure and performing it • Avoid situations in which children can see or hear procedures performed on other children

Finally, Young (2005, p. 167) proposes a framework containing the complexity and many dynamics of painful medical procedures in paediatric patients (figure 3.3). This conceptual model integrates the above-mentioned research-based individual determinants of child pain responses, procedure-related factors, and the Gate Control Theory.

Figure 3.3. Complex theoretical conceptual model of important factors involved in medical procedures and detrimental long-term effects. Reprinted after Young (2007, p. 167).



According to figure 3.3, the model is temporally divided into three phases according to medical procedure (i.e. before, during, and after). According to the model, each child has specific pain attitudes, behaviour, and coping skills, which are influenced by individual, psychobiologic, cultural, and societal factors before the procedure. Of special importance here are age, developmental stage, and prior pain experiences. During the procedure the characteristics of the specific procedure, the environment, interaction with parent(s) and medical staff, and possible use of non-/pharmacological interventions contribute additional stimuli. The grey boxes in the figure represent the Gate Control Theory. As described in section 2.3.3 this theory argues that sensory inputs are controlled by inhibiting or "gating" mechanisms before pain perception occurs. Thus, the child´s pain attitudes and coping skills potentially regulate the level of cognitive control and the descending inhibition exerted on the substantia gelatinosa pain gate. Finally, the child´s experience of the medical procedure influences the long-term effects on his/her pain response in future procedures. If adequate pain relief intervention is provided, possible negative and distorted traumatic memories can be modified.

In conclusion, Young (2005) illuminates important clinical and theoretical aspects contributing to potential negative long-term effects due to painful medical procedures seen from a healthcare worker´s perspective. Young manages to combine theoretical and practical sides of the multi-faceted phenomenon. Based on the clinical research literature, she provides a summation of important information and considerations in terms of painful procedures, and combines this with the Gate Control Theory in the form of practical user-friendly straightforward recommendations. In accordance with her proposed summative multi-dimensional pain response model, Young advocates for a multi-stringed pain relief approach combining non-pharmacological and pharmacological interventions.

3.2 Research-Based Clinical Recommendations and guidelines under Venipuncture Procedures in Hospitalised Children

In addition to Young (2005), I will now present additional research-based clinical recommendations and guidelines regarding venipuncure involving young children, as described by Cohen (2008). Cohen provides summative clinical recommendations of behavioural approaches and techniques for anxiety and pain management in children during venous access in the form of concrete user-friendly wordings that are directly applicable in practice. Due to its

clinical relevance, I used this article to inform the MT intervention in the form of development of the decision trees, therapeutic objectives, and specific supportive wordings as described in the method chapter (section 5.10).

According to Cohen (2008), studies indicate that pain due to medical procedures may not only result in short-term suffering, but also in long-term harmful effects. However, studies on behavioural interventions and techniques have indicated robust and consistent findings as to positive effects of adequate preparation under various medical procedures including induction of anaesthesia, surgery, magnetic resonance imaging, hospitalization, and dental care. Though fewer studies have been conducted on venous access, the findings of these studies are consistent with the larger before-mentioned preparation literature. Thus, based on the compounded findings, he formulates general recommendations applicable to venous access (Cohen, 2008, p. 134). Generally seen, behavioural approaches can be categorised into two groups, that is before, during, and after the medical procedure. In his article, Cohen summarizes the research literature by grouping the recommendations with regard to timing, format, and content of preparation. In addition, guidelines for advice for parents, positioning, and distraction are provided.

Timing: Information should be balanced according to age and type of medical procedure. Information provided far in advance might increase anxiety due to exaggeration of the upcoming procedure. On the other hand, information provided immediately before the procedure might not give the child enough time to process information and prepare for procedure. If venous access is part of a major medical procedure (e.g. surgery), information provide a few days before might be ideal. On the other hand, if venous access serves the purpose of minor procedures (e.g. blood draw), information provided on the same day should be adequate (Cohen, 2008, p. 135).

Format: Computer programmes, videogames, puppets, and written summaries have been used for the provision of information. If verbal or written information is used, the findings suggest that photographs or other illustrations will improve memory. Regardless of the type of format, an interactive dialogue where the child is encouraged to ask questions is important. When it comes to who should provide the preparation, there are few data to support clear guidelines. However, information can be provided by parents, medical staff, or other personnel. Peer models as well as adult models are beneficial with regard to teaching coping skills (Cohen, 2008, p. 135).

Content: The content of the information is likely to be the most critical consideration. The content must be clear, simple, detailed, and concrete containing information about sensory as well as procedural expectations, since accurate expectations will enhance he sense of control and mastery. Depending on age and cognitive abilities, information about the procedure should be provided continuously during the procedure in a calm voice and in age-appropriate language (Cohen, 2008, p. 135).

Advice for parents: Parent anxiety is strongly predictive of child procedural anxiety, and research suggests that parents´ behaviour notably influences the variability of children´s coping and distress. Adult distraction and coaching in coping behaviour have positive effects on reducing child distress contrary to criticism, apologising, or giving control (Cohen, 2008, pp. 135-136).

Positioning: Though there are few data on the optimal positioning, Cohen provides tentative guidelines. Initially, he points out that the studies show mixed result as to the presence/absence of parents during procedures. In general, both child and parents prefer that parents are present. During venous access procedures, studies indicate that the child should be hold by a parent. The ideal position is thought to be in the parent´s lap facing him/her with while the child´s arm and hand are placed under or above the parent´s shoulder on a secure and stable surface (Cohen, 2008, p. 136).

Distraction: A number of studies have demonstrated positive effects of distraction on pain and anxiety reduction during venous access. Some of the distraction techniques documented in the literature include movies, interactive toy robots, bubble blowing, short stories, virtual-reality goggles, and music. On the basis of a meta-analysis, Cohen (2008) puts forward that distraction has the same effect on pain reduction across gender and ethnic groups, but yields most effects in children up to 7. From a theoretical perspective, optimal distraction stimuli should involve multiple modalities, produce positive affective states that are irreconcilable with anxiety, pain, and distress. According to Cohen, the distraction stimuli should be age-appropriate, include parents as coaches, and be applied before, during, and after the procedure. However, the child´s coping style should be taken into account, since active involvement and observation of the procedure can be beneficial to some children, resulting in enhancement of

feeling of control, and reduction of anxiety and pain (Cohen, 2008, p. 136). Table 3.4 holds a summation of the above-mentioned recommendations.

Table 3.4. Specific recommendations related to preparation of child under medical procedure. Copy of table provided in Cohen (2008, p. 137).

Pre procedure (days to hours before procedure)	**During procedure** (immediately before, during and several minutes after procedure)	**Post procedure** (from several minutes after procedure and up to hours later)
Provide clear, non-emotive detailed age-appropriate sensory, and procedure information	Distraction	Praise coping efforts
	Encourage coping	Distraction as necessary
Train in coping skills	Avoid negative behavior	Encourage coping as necessary
Select distraction stimuli	Breastfeed and provide skin-to-skin contact for young infants	
	Position children facing parents and in laps with arm secured; young infants should he held by parents and swaddled	

Table 3.5. Suggestions for specific beneficial language and wordings. Reproduction of Cohen (2008, p. 136).

Language to avoid	Language to use
1. You will be okay; there is nothing to worry about (reassurance)	1. What did you do in school today? (distraction)
2. This is going to hurt/this won't hurt (vague; negative focus)	2. It might feel like a pinch (sensory information)
3. The nurse is going to draw your blood (vague information)	3. First, the nurse will clean your arm, you will feel the cold alcohol pad, and next . . .(sensory and procedural information)
4. You are acting like a baby (criticism)	4. Let's get your mind off of it; tell me about that movie . . . (distraction)
5. It will feel like a bee sting (negative focus)	5. Tell me how it feels (information)
6. The procedure will last as long as . . . (negative focus)	6. The procedure will be shorter than . . . (television program or other familiar time for child) (procedural information; positive focus)
7. The medicine will burn (negative focus)	7. Some children say they feel a warm feeling (sensory information; positive focus)
8. Tell me when you are ready (too much control)	8. When I count to 3, blow the feeling away from your body (coaching to cope; distraction; limited control)
9. I am sorry (apologizing)	9. You are being very brave (praise; encouragement)
10. Don't cry (negative focus)	10. That was hard; I am proud of you (praise)
11. It is over (negative focus)	11. You did a great job doing the deep breathing, holding still . . . (labeled praise)

3.3. Theoretical and Clinical aspects of Music Therapy under Painful Medical Procedures involving Hospitalised Children

Ann Turry´s (1997) clinical descriptions of MT under painful needle procedures served as a major source of inspiration in the development of the MT intervention in the PhD study. Turry addresses both theoretical and practical aspects in terms of clinical improvisation to alleviate procedural distress in young children. Among other things, she addresses some common needs of children under medical procedures, the role of the MT in addressing these needs, key elements of the music intervention, and the importance of precaution of balancing the needs of the child, parents, and medical staff involved.

As it appears from table 3.6, MT can provide support in a variety of quite different procedures. But whether the procedure is painful or not, Turry (1997) points out that the child´s perception of the event is crucial:

> It is the child´s appraisal of the impending procedures, which influences his/her pain experience and emotional response. It is well documented that even non-invasive procedures, such as temperature and blood pressure, can be perceived as threatening and frightening to a child. (p. 89)

Furthermore she describes the procedure room as a unique setting "…in which tension can be high and the child may escalate to a point beyond his capacity to reason or utilize effective coping strategies" (Turry 1997, p. 90).

So the therapist should carefully consider factors, which influence the child´s level of distress experienced during a painful procedure. In order to assess the individual need of the child, Turry emphasises these aspects:

- The child´s developmental stage
- The child´s and parents´ current coping styles
- Environmental influences (including persons present in the room)
- Parental support
- The dynamics of the environment
- Level of preparation and expectations regarding the procedure

According to Turry (1997), loss of control, helplessness, lack of emotional support and fear of bodily disintegration are potential realities for a child faced with impending pain. Another circumstance that should be taken into account is that younger children often do not have the cognitive abilities to understand the cause and effect relationship justifying the need for injections. Hence, the child can appraise the medical procedures as a punishment.

The improvisational approach proposed by Turry integrates the process of what happens during the procedure within the structure of lyrics and music. She stresses:

> By improvising music based on the unique qualities and needs of the situation, providing an important role for the child within context of an aesthetic form, the therapist engages and motivates him into active participation. The musical interaction becomes a purposeful and enjoyable activity rather than a task of distraction….As the therapist accepts and supports a child´s feelings, while providing an opportunity for creative expression, he becomes able to re-frame the situation, potentially acknowledging an understanding of the need for an IV or needle stick. (Turry 1997, pp. 91-92)

As appears from table 3.6**,** Turry makes it clear that the objectives and techniques of the MT intervention differ according to the phase of the procedure. In the following I have summated Turry´s descriptions of the MT intervention before, during, and after the medical procedure (Turry 1997, pp. 89-96).

Table 3.6. Summation of therapeutic objectives in music therapy under medical procedures involving paediatric patients (after Turry, 1997).

MT used before the procedure	Goals: preparing the child before the procedure Function of MT intervention: induce relaxation, soothe, help the child focus, and empower child
MT used during the procedure	Goals: support during pain, distraction, soothe, facilitate active engagement, validate feelings and empower the child Sub-strategies: Incorporating procedure into the music or/and singing fun and playful songs not related to the event Psychological function of the MT intervention: • Distraction • Engagement in music activity and choice making in songs, which increases sense of control and autonomy • Relaxed, quite and elongated tones can provide a sense of grounding • Re-framing the child´s perception of the situation through improvised songs • Creating meaningful individualised improvised songs for self-affirmation, empowerment, increased sense of control and creative expression of feelings (e.g. "A Brave Song", and "A I hate the Needles Blues") Aspects of the child´s coping strategy: some children need distraction, whereas others need information of each step of the procedure, while others need a combination hereof
MT used after the procedure	Goals: process feelings and recovery: • Containment of the child´s feelings and creating a holding environment, which can foster a sense of safety • Re-framing the child´s perception of the situation through improvised songs Function of MT intervention: • Containment of the child´s feelings and creating a holding environment, which can foster a sense of safety • Re-integration • Recovering

Inspired by elements of trauma/recovery theory, Turry (1997) lists three tasks/steps in the recovery process in traumatised children after painful medical procedures:

- To establish a sense of safety
- To tell their story
- To reconnect relationships with others

According to Turry (1997), the feeling of safety is essential in order to reconnect with others. She puts forward that creating songs like "a Needle Song" or "a I Hate the Nurse song" can express the child´s perception of situation and offer the child a means of telling his story. Improvisation and active music making can provide a means of neutralising withdrawal, regaining a sense of self, and reconnecting with others.

As to the inter-personal dynamics in the treatment room, several factors must be appraised. The feeling of guilt, anger, and helplessness as well as coping strategy of the child and parent must be taken into account. In the case of discrepancy, the emotional dynamics can be magnified. Furthermore, the music therapist should also balance the staff members´ feelings about inflicting pain and distress in the child.
Including parents and staff members in active music making or the musical process can be one helpful way of reducing the inter-personal dynamics.

3.4 Chapter Summary

This second part of the theoretical framework of the PhD study is rooted in four main references that I selected due to their clinical relevance and applicability for the MT intervention applied in the PhD study. The references illuminate important aspects of the research/literature on children undergoing various medical procedures in terms of different theoretical, clinical, and practical aspects. Initially, the first reference provided a multi-dimensional framework of modifiable and non-modifiable factors before, during, and after conduction of medical procedures in children (Young, 2005). This reference also gave an overview of concrete simple non-pharmacological techniques that can be used to reduce pain and stress plus subsequent practical guidelines for parent and staff-member behaviour in regard to medical procedures. Finally, Young (2005) provided a summative conceptual model that

graphically illustrates the complexity and dynamics of the many possible factors that potentially can lead to long-term effects of pain and distress.

Next, I summated Cohen´s (2008) user-friendly clinical recommendations and concrete wordings for pain and anxiety management of paediatric venous access. Finally, I illuminated some of these above-mentioned aspects from a clinical and practical MT perspective in the form of the MT techniques and guidelines suggested by Turry (1997). From an overall perspective, these three references concurred and supported each other in that they illuminated related and/or different theoretical and clinical aspects relevant to the MT intervention in the PhD study.

In addition to the above-presented theoretical framework, clinical aspects, and research-based recommendations, I will now present a review of the MT research literature on outcome studies reporting the effect of MT under needle procedures and related medical procedures involving paediatric patients.

CHAPTER 4
Theoretical FrameWORK:

OUTCOME STUDIES REPORTING THE EFFECTS OF MUSIC THERAPY UNDER MEDICAL PROCEDURES IN PAEDIATRIC PATIENTS

4.1

Introduction

The overall objectives of the theoretical framework of the PhD thesis (i.e. *Chapters 2 to 4*) are to identify, define, and illuminate a multi-faceted theoretical understanding of invasive painful medical procedures involving children plus the role and function of music therapy as procedural support within this clinical context. I have divided the theoretical framework into three inter-related chapters that informed the development of the applied MT intervention of the PhD study. In *Chapter 2*, I provided an overview of theoretical aspects of invasive painful medical procedures and MT as procedural support under medical procedures involving paediatric patients. Next, in *Chapter 3*, I provided an overview of research-based clinical recommendations and clinically related aspects of MT as procedural support.

The primary objective of this chapter is to provide an overview and a review of outcome studies reporting the effects of MT under *needle procedures* in paediatric patients, including nephro-urological patients. In addition, the review also includes similar outcome studies on MT procedural support under other related medical and diagnostic procedures that are potentially painful and/or stressing (i.e. invasive and non-invasive procedures). Since the PhD study relates to the evaluation of the effects of a specific MT intervention, this chapter primarily focuses on Music therapy studies. On the contrary, due to the scope of the study, the research literature on similar music medicine studies will not be reviewed as thoroughly. Instead, the research literature on music medicine will be provided in the form of a summation of the results of the meta-analysis Klassen, Liang, Tjosvold, Klassen, and Hartling (2008).

Figure 4.1. Graphical illustration of the three chapters that constitute the theoretical framework of the PhD study.

4.1.1 Strategy of Literature Search

The literature review in this chapter is based on a systematic literature search conducted in several public Internet databases (e.g. Medline, PsychInfo, Cochrane Database), private, and other public databases, Internet search in specific MT journals (e.g. Nordic Journal of MT, Journal of MT etc.). In addition, I consulted with leading music therapy researchers and applied manual search in reference lists. I used combinations of key words such as: "music therapy + distress + child" in my literature search (see appendix 2). Based on the results of the specific combination of search words, I then screened all abstracts that seemed relevant for the study. If so, I retrieved and reviewed the full text article, books etc. The literature review is based on the criteria listed below. Finally, a total of 11 studies were included in the review. Detailed descriptions of the literature search process can be found in appendix 2:

Inclusion criteria

- Published articles and book chapters
- No limitation with regard to publication year
- English and Danish texts
- MT outcome studies
- Meta-analyses of medical MT
- Review articles on MM under needle procedures
- Paediatric populations at the ages of 0-18
- Use of MT as procedural support under specific medical procedures (e.g. needle procedures, surgery, X-rays) involving and/or in- and outpatients

Exclusion criteria

- Studies that included both paediatric and adult populations
- MT studies in neonatalogy
- Interventions for paediatric rehabilitation

The following sections provide a presentation of the research literature regarding outcome studies of the effects of MT under various medical and diagnostic procedures and surgery in paediatric patients. The 11 reviewed MT

studies cover MT under non-invasive, invasive[1], painful, and non-painful medical procedures and surgery. In the first section of the review, I will sum up some overall clinical research findings based on two meta-analyses. These constitute an overall rationale for the use of music interventions in paediatrics. Next, table 4.3 provides an overview of the 11 MT studies that I identified on the basis of the literature search. Next, three studies on MT under needle procedures will be presented, followed by a supplementary overall summation of a survey article of the effects of MT and MM under needle procedures. Hereafter the remaining 8 MT studies will be presented one by one. The review concludes with a summary of this third part of the theoretical framework of the PhD study. To sum up, the following sections provide an overall rationale for the general benefits of music interventions in paediatrics and then present studies of MT interventions relevant to the PhD study.

1

Invasive refers to a medical procedure during which a part of the body is entered (e.g. puncture, incision)

4.2

Medical Music Therapy in Paediatrics – Overall Research Findings

In this section, I will present some overall clinical research findings based on two meta-analyses (Standley & Whipple 2003; Dileo & Bradt 2005), which give a general rationale for the use of music interventions in paediatric patients. At present, Standley & Whipple (2003) is the only specific meta-analysis of MT and MM with hospitalised children at the ages of 0 to 18 years. (In addition, Standley (2002) made a meta-analysis of MM and MT with premature born infants). The meta-analysis by Standley & Whipple (2003) comprises 29 outcome studies, which include 17 studies with premature infants. When the 29 studies were pooled and analysed together, the meta-analysis revealed a statistically significant (p=0.00) overall mean positive medium-large effect of MT and MM (d=0,64[2] with a 95% confidence level between 0.52 to 0.76). Based on the results of the meta-analysis, the authors formulated the following eight overall conclusions (table 4.1):

2 *Interpretation of Cohen´s d (effect sizes): d= 0.20 (small effect), d= 0.50 (moderate effect), and d= 0.80 (large effect).*

Table 4.1. Overall conclusions formulated in the meta-analysis Standley & Whipple (2003, p. 11).

- MT & music medicine were significantly better compared to control group conditions with no music in paediatric medical treatment, except for one study
- Active music participation (*d*= 0.89) was more effective than passive music listening (*d*= 0.44)
- Live music was more effective (*d*= 0.82) than recorded music (*d*= 0.55)
- There were no substantial differentiated effects by the individual selecting the music (patient vs. music therapist vs. medical personnel)
- MT & MM were most effective for major invasive procedures (*d*= 0.91) and non-invasive (*d*= 0.83) than for minor invasive procedures (*d*= 0.37)
- Greatest effects were achieved for adolescents (*d*= 1.36), then infants up to 4 years (*d* = 0.74). Least effect was indicated for children aged 4-12 years (*d*= 0.43)
- The effects were not differentiated by gender
- Observed pain and distress showed modest effect sizes in comparison to self-report and physiologic measures of the same outcome variables

In relation to the present PhD study, the meta-analysis holds one study on MT as procedural support at needle procedures (Malone, 1996). This study will be presented separately later in the literature review.

The most recent meta-analysis of medical MT is Dileo & Bradt (2005), which includes a total of 183 outcome studies across 11 medical specialties on children and adults patients. Of the 183 studies, 11 include various medical procedures and medical conditions in paediatric patients. (The meta-analysis also comprises 17 studies on premature infants. But these are not included in this literature review cf. the inclusion criteria of the literature review). As to the 11 studies on paediatric patients, five studies can be defined as MT studies and six as MM studies. The 11 studies differ in regard to the type of music intervention (e.g. active music making, music listening), and number of participants (between 10 and 40). Two overall results of the meta-analysis are important to put forward. First, a

sample-level effect size analysis was performed with an eye to estimating an overall mean effect of the total outcome variables of the paediatric studies. After removal of one study (an outlier), this analysis showed a statistically significant (p=0.00) mean moderate to large positive effect of MT and MM (r=0.34[3] with a 95 % confidence interval between 0.15 to 0.51). However, the samples were not homogeneous. Second, the meta-analysis indicated that the five MT studies displayed a statistically significant larger effect (r= 0.49) compared to the five MM studies (r=0.13) (Dileo & Bradt, 2005, p. 29). In addition, this finding was consistent with the results of the global estimated effects based on the total 183 outcome studies comprised in the meta-analysis, as well as the overall results of the meta-analysis made by Standley & Whipple (2003).

On the basis of the above-presented overall clinical research findings, it is now time to take a closer look at results of selected outcome measures provided in Dileo & Bradt (2005), namely outcome measures that are specifically related to those of the PhD study. In their meta-analysis, Dileo & Bradt (2005) provide moderator analyses of paediatric patients according to the following outcome variables: pain, distress, mood, and feelings of control. These overall estimated effects are calculated based on ten pooled MT and MM studies on paediatric patients. The results are summed up in table 4.2.

3 *Interpretation of r effect sizes: r=0.10 (small effect), r=0.25 (medium effect), r=0.40 (large effect).*

Table 4.2. Summation of pooled estimated effects of MT and MM on pain, distress, mood, and feelings of control as described in Dileo & Bradt (2005).

Pain (Dileo & Bradt, 2005, p. 45)
Based on three studies including 66 paediatric patients, the moderator analysis showed:

- A large mean effect of $r = 0.45$[3] with a 95% confidence interval between -0.30 to 0.86
- This finding was not statistically significant ($p = 0.23$)
- The sample was not homogenous

Distress (Dileo & Bradt, 2005, p. 52)
Based on one study including 40 paediatric patients, the moderator analysis showed:

- A large mean effect ($r = 0.45$)
- Note: 95% confidence level and p-level were not provided

Mood (Dileo & Bradt, 2005, pp. 55-56)
Based on two studies including 42 paediatric patients, the moderator analysis showed:

- A very large mean effect ($r = 0.64$ with a 95% confidence interval between 0.40 to 0.79
- This finding was statistically significant ($p = 0.00$)
- The sample was homogenous

Feelings of control (Dileo & Bradt, 2005, pp. 56-57)
Based on one study including 32 paediatric patients, the moderator analysis showed:

- A large mean effect ($r = 0.48$)
- Note: 95% confidence level and p-level were not provided

As appears from table 4.2, large effects of MT and MM were demonstrated as to pain, distress, mood, and feeling of control. However, as underlined by the authors these results should be interpreted with precaution due to among other things the small numbers of studies, small samples sizes, and the diversity of medical specialty as well as music techniques used in the experimental conditions. However, statistical information (e.g. confidence intervals, p-values, homogenous) was not sufficiently provided, which weakens the estimates of the meta-analysis.

In conclusion, Standley & Whipple (2003) and Dileo & Bradt (2005) constitute an overall rationale for the application of MT and MM in paediatrics (and the somatic area in general as well) although statistical and methodological weaknesses could be pointed out. Only one study on MT under needle procedures was comprised in the meta-analyses. In short, with regard to the PhD study the most relevant overall findings of the meta-analyses are:

- MT was more effective than MM
- The effect of MT and MM did not differ with regard to gender as opposed to age. Here the music interventions were most effective in infants <4 years old (almost a large effect) compared to children aged 4–12 (almost a moderate effect)
- MT and MM were least effective under minor invasive procedures including IV-starts (small effect)
- Large effects were reported in regard to pain, distress, mood, and feelings of control

What follows now is an overview of the 11 MT studies identified on the basis of the literature search. In table 4.3 I have categorised and listed the studies according to overall type of procedure. From the left to the right side of the table, the following information is provided: overview of author(s) and year of publication, specific type of medical procedure, sample size, age of participants, type of music intervention, type of design, outcome variables, and measurement instrument used. According to the original articles in which these studies were reported, the music interventions comprised a variety of techniques and approaches, among other things active music making, passive music listening, music-assisted relaxation, and music-assisted imagery. However, according to Ghetti´s (2012) classification, the applied approaches to MTPS included *Music Alternate Engagement* (MAE) and *Music-Assisted Relaxation* (MAR). Furthermore, the music interventions were conducted individually by one and the same music therapist.

Table 4.3. Overview of reviewed outcome studies reporting the effects of music therapy under various medical procedures and surgery with paediatric patients.

	Authors	Type of procedure	Sample	Age	Music intervention	Design	Outcome variables
Needle procedures	Malone (1996)	Various needle procedures	(*n*=41)	0-7	Receptive (& active) MT: ML (preferred songs); MAR & MAE	Match control w. two groups: MT/Control	Distress (PBCL, RDOS), duration of procedure, number of needle pricks
	Caprilli et al. (2007)*	Venipuncture for routine blood test	(*n*=108)	4-13	Receptive (& active) ML, playing instrument (prof. musicians)	RCT w. two groups: Music/Control	Distress (OSBD-A), Pain (FPS)
	Pfaff et al. (1989)	Bone marrow aspiration (MBA)	(*n*=6)	6-15	Receptive MT: ML, imagery & progressive relaxation; MAR	Within subject: baseline versus subsequent BMA	Distress (OSBD), Fear (Faces Scale for Fear), Pain (Faces Scale for pain)
Other painful procedures	Whitehead-Pleaux et al. (2006)	Donor site dressing change (burn patients)	(*n*=14)	6-16	Receptive MT: ML (preferred songs), improvised music; MAE (integration)	RCT w. two groups: MT/Control	Pain (FPS), Distress (NAPI), Anxiety (Fear Thermometor), Physiological (heart/respiration rate)
	Whitehead-Pleaux et al. (2007)	Various painful procedures (burn pt.)	(*n*=9)	7-16	Receptive/active MT: ML (preferred songs), improvised music; MAE (elements of integration)	Exploratory multiple case studies w. mixed methods	Pain (FPS), Distress (NAPI), Anxiety (Fear Thermometer) & Physiological (heart rate, blood oxygenation level), qualitative interviews
Surgery (pre & post)	Chetta (1981)	Pre-operative	(*n*=75)	3-8	Receptive MT: ML plus preparatory info. about operation	RCT w. 3 groups: 2 MT/1 Control	Anxiety (RDOS/OBTSF)
	Robb (1995)	Pre-operative	(*n*=20)	8-20	Receptive MT: ML, imagery and progressive relaxation; MAR	RCT mixed methods w. two groups: MT/Control	Anxiety (STAIC), (physiological), Qualitative comments
	Kain et al. (2004)	Pre-operative	(*n*=123)	3-7	Active/receptive MT: singing, ML Instruments playing, song writing	RCT w. 3 groups: MT/Control/Midazolam	Anxiety (YPAS) & baseline data: STAI, ICC, EASI
	Bradt (2010)	Post-operative	(*n*=32)	8-18	Receptive MT: Entrainment	RCT: cross-over	Pain (VAS), Emotional state (RDS)
Various mainly non-painful procedures	Loewy et al. (2005)	EEG (non-invasive/ non-painful)	(*n*=58)	0-5	Receptive MT: ML (preferred songs and soothing music)	Two groups: MT/Chloral hydrate (not randomised)	Level of sedation (LS), duration of sedation, completion rate of procedure
	Walworth et al. (2005b)	ECG, CT etc. (mainly non-painful procedures)	(*n*=156)	0-13	Receptive MT: ML (preferred music)	Comparative analysis	Need of sedation, cost-benefit

*) The intervention was provided by professional musicians (not trained music therapists).

Note. CDI= Children´s Depression Inventory. EASI= Emotionality Activity Sociability and Impulsivity Scale. FPS= Wong-Baker Faces Pain Scale. ICC= Induction Compliance Checklist. LS= Likert-type Scale. Midazolam= a short-acting drug viedly used before medical procedures due to its profoundly anxiolytic and sedative properties. ML= music listening. MT= Music Therapy. NAPI= Nursing Assessment of Pain Intensity. OSBD= Observation Scale of Behavioral Distress. OSBD-A= Observation Scale of Behavioral Distress Amended version. PBCL= Predominant Behaviors Category List. RDOS=Researcher Developed Observation Scale. OBTSF= Observed Behavior Time-Sampling Form (Researcher Developed). Pt.= Patient(s). RCT= Randomised Controlled Trial. RDS= Researcher Developed Scale. STAI= State-Trait Anxiety Inventory. STAIC= State-Trait Anxiety Inventory for Children. VAS= Visual Analogue Scale.

4.3

Outcome Studies Reporting the Effect of Music Interventions Under Needle Procedures and other Medical Procedures

The present PhD study is about MT procedural support under intravenous access procedures in children with various nephro-urological diseases. Based on my comprehensive literature search, I did not identify any outcome studies on this specific population during needle procedures. However, three studies met the criteria of the review and are highly relevant for the PhD study. Malone (1996) made a study on MT and Caprilli et al., 2007 on music distraction (performed by professional musicians) under various needle procedures involving various paediatric patients. The third study is Pfaff (1989), who examined the effect of MT during bone marrow aspiration, which involves a needle procedure. I will now present these studies.

4.3.1 Outcome Studies on Music Therapy under Needle Procedures

In a matched controlled study, Malone (1996) evaluated the effect of MT (i.e. MAE and MAR cf. Ghetti, 20012) on distress in children undergoing various needle procedures (i.e. intravenous starts, restarts, venipunctures, injections, and infant heel sticks). The study included 40 children (new admissions) at the ages of 0 to 7, of whom the majority (68%) were 0 to 3 years old. The participants were assigned to either a music therapy group or a comparable control group matched on the basis of age, site of procedure, and type of needle procedure. The music intervention consisted of age-appropriate children´s song, and requested songs accompanied by steel string guitar performed by the researcher, who was a postgraduate student of MT. Moreover, the researcher used an original song with assumed therapeutic benefits made for the study. To the extent possible, subjects were encouraged to sing along, and were provided with opportunities to request and choose preferred songs with the intention of increasing their sense of control. As to the youngest children, the parent(s) provided suggestions for songs. The MT commenced as soon as the child entered the treatment room, and lasted throughout the entire medical procedure.

Likewise, the researcher was present during all procedures in the control group, but did not provide MT. Data were collected at three stages operationally defined as 1. *Pre-needle stage*, 2. *Needle stage*, and 3. *Post-needle stage*. Data consisted of video recordings of each child throughout these phases. The effect of the MT intervention was evaluated by means of two observational measurement instruments, i.e. an observation scale developed by Chetta (1981) and an adapted version of the Predominant Behaviors Category List. The former assessed observed behavioural distress duration (noise, motor, and restraint) rated in ten-second observation intervals, whereas the latter assessed overall observed intensity of distress. In the data analyses participants were divided into three age groups. Total scores were computed as well as scores for each of the three stages with regard to observed distress behaviour duration and observed distress intensity. Results regarding behavioural distress duration indicated:

- Statistically significant less total distress duration in the children between 0 and 1 year allocated to the MT group
- As to the two other age groups no other statistically significant results were found with regard to total distress duration
- The children between 3 and 7 years scored similar pre-needle scores in both groups. But during the needle stage (the medical procedure) the children in MT group scored higher (worse) distress duration than did the control group
- Children between 5 and 7 years exhibited minimal observed behavioural distress compared to the younger participants
- No statistically significant difference was found in total distress duration due to type of needle procedure (intravenous starts, restarts etc.)

Results regarding overall observed distress intensity indicated:

- A statistically significant difference ($p<0.05$) between the groups in regard to the pre-needle and post-needle stages in favour of the MT group when compared to the needle insertion stage
- No statistically significant difference was found in overall distress duration due to type of needle procedure (intravenous starts, restarts etc.)

In addition, the two groups did not differ significantly with regard to length of procedure or number of needle pricks.

In conclusion, the distribution of mean scores of the study varied within and across the three operationally defined stages as well as among the three age groups. The results of the study were conflicting. The infants allocated to the MT group exhibited statistically significant less distress duration, whereas children at the ages of 3 to7 in the MT group did worse during the needle procedure. Age seemed to be a crucial factor for distress with the youngest children exhibiting most distress. From a clinical point of view the MT intervention was limited in that this intervention was only provided for the participants *during* the needle procedures. Consequently, there was no time to establish rapport prior to the commencement of the medical procedure. This could partly explain the conflicting results along with the limited clinical experience of the music therapist.

From a methodological perspective the study was limited in several ways. Baseline data and important demographical/clinical data, for instance number of previous needle procedures were not recorded and compared statistically between the two groups in order to assess whether the two groups were similar and consequently directly comparable. Likewise, the sample size was relatively small, especially when the skewness of age distribution was taken into account. Furthermore, variations of the duration of the procedure (i.e. *Needle stage*) among participants were not taken into account in the computation of mean distress scores nor in the following statistical analyses. In addition, no important information was provided whether or not participants received topical anaesthetic (e.g. EMLA/numbing cream). Use of validated measurement tools would be preferable. However, the study was carried out 16 years ago, consequently before a variety of validated tools were available. A final comment related to my review of this study is the discrepancy in the MT research literature on the estimation of effect size of the Malone (1996) study. In their meta-analysis Standley & Whipple (2003) state that the Malone (1996) study has a small non-statistically significant effect (d=0.14) as opposed to Dileo & Bradt (2005), who reported a large effect (r=0.45).

In a more recent Italian RCT study, Caprilli and colleagues (2007) trialled the effect of active *music distraction* on observed behavioural distress and self-reported pain during venipuncture for routine blood test. The sample consisted of 108 un-pre-medicated children aged 4-13 years old, who were randomly assigned to either a music group (n = 54) or a control group (n = 54). In the former group music was used as a distraction strategy. The music was provided by one of two professional musicians involved in the study, who had received specific training in working in medical settings before the commencement of the study. The music intervention was initiated in the waiting room prior to the blood test, and was provided before, during, and after the venipunctures. The intervention comprised singing songs accompanied by guitar and proposing sonorous objects to the child and parent, who were invited to join the performance. In both groups the venipuncture procedures were performed by one and the same physician and nurse, who were instructed to maintain their usual way of distracting and comforting children. Data collection

started in the treatment room, and lasted during three operationally defined phases corresponding to immediately before, during, and after the blood test procedure. Distress was evaluated by means of the Amended Form of the Observation Scale of Behavioral Distress (OSBD-A)[4]. Self-report of pain was rated by the child immediately after the conclusion of the procedure using the FACES Pain Scale (Wong & Baker, 1988). Data from the three phases were analysed separately. Results showed that:

- The music intervention had a statistically significant positive small-moderate effect (Cohens´ d) on observed distress before, during, and after the blood test procedure compared to the control group
- Age turned out to have a statistically significant effect (negative correlation) on observed distress in all three phases of the procedure, showing most distress in the youngest children
- In the music group, children reported statistically significantly less procedural-related pain
- Age was not statistically significant associated with pain
- No statistically significant gender differences were found in relation to the effect of the music intervention

In conclusion, Caprilli et al. (2007) showed that music performed by professional musicians under venipunctures for blood tests yielded a small-moderate statistically significant effect on observed distress and self-reported pain. Age was found to have an effect on distress, but not on pain. Furthermore, gender did not have an effect on these outcome variables. Contrary to the study by Malone (1996), unambiguous positive effects of music was reported in all three phases of the needle procedure. However, as in Malone (1996) the study was limited in that baseline data or clinical data on previous needle procedures etc. were not registered and used to evaluate whether the two groups were directly comparable.

The third and last MT study in this literature review that implied needle procedures is the study by Pfaff and colleagues (1989). They trialled the effect of music-assisted relaxation (MAR) on observed distress, anticipated and experienced fear and pain in children with cancer undergoing bone marrow aspirations (BMA). For general information, BMA implies insertion of an aspiration needle through the skin and all the way into the cavity of the bone. Hereafter liquid bone marrow is aspirated. The entire procedure typically lasts about 10 to 15 minutes. In addition, it should be noted that there are national differences regarding practice and guidelines in terms of

4 In the reference list, the authors refer to a website that is not (currently) available.

whether or not anaesthesia is used under this procedure. According to the head physician at the child oncology ward at Aarhus University Hospital Skejby, BMAs (in children) are always performed under general anaesthesia in a Danish context. The same tendency accounts most other European countries, and gradually also for the USA (H. Hasle, personal communication, March 15, 2012).

However, as appears from Pfaff et al. (1989), the BMA procedures in the study were performed under local anaesthesia. Consequently, the participants remained conscious before, during, and after the procedure. In the study by Pfaff et al. (1989), six children aged 6 to 15 participated in two consecutive BMA procedures. The first BMA procedure served as baseline. A within-subjects experimental design was applied, in which the participants served as their own control. In both BMA procedures self-report of anxiety and pain were recorded pre and post BMA procedure by means of the Faces Scale for Fear and the Faces Scale for Pain, respectively. Observed distress was measured by the Observation Scale of Behavioral Distress (Jay & Elliot 1986), and inter-rater reliability was established. The MT intervention was provided individually during the bone marrow aspiration by one and the same music therapist. The intervention consisted of pre-recorded instrumental music (forced choice selection) in conjunction with verbal relaxation guiding. The results were:

- No statistically significant reduction of observed distress
- Trends towards a decrease in median: anticipatory fear, experienced fear, and experienced pain
- No age or gender differences were found

Although not statistically significant, the MT intervention in the present study had a large effect (r=0.49) according to Dileo & Bradt (2005).

As to the limitations of the study and recommendation for future research, the author stresses a need for a larger sample size, use of an RCT design plus continual improvement of the intervention.

4.3.2 Systematic Literature Review of MT & MM Randomised Controlled Trials during Various Medical Procedures in Paediatric Patients

As described above, Dileo & Bradt (2005) and Standley & Whipple (2003) clearly show that MT is more effective compared to MM with regard to various outcome measures in medical patients. However, Klassen et al. (2008) report a contrasting finding on the effect of MT versus MM on anxiety and pain in children under various medical and dental procedures. Their article holds a systematic literature review and a meta-analysis. The review comprises 19 studies that meet the inclusion criteria. Of these, 9 are included in the additional meta-analysis, which provides overall estimates of the effects of MT and MM on anxiety and pain. I found this systematic review (Klassen et al. 2008) relevant in the context of the PhD study. It illuminates the effects of both MT and MM randomised controlled trial studies under various medical procedures involving paediatric patients. Furthermore, the article gives an overview of the methodological properties of these studies and identifies important methodological challenges within this field of research.

In the following sections, I will provide a summation of their systematic review. I will start with a short qualitative summation of the 19 studies included in the review. Next, I will sum up the methodological properties of the studies, which I used to inform the preparation of the present PhD study. Then a short summation of the results of the meta-analyses follows. Subsequently, I will sum up some of the article´s overall findings and recommendations for future research, which I also took into consideration when planning the PhD study.

In their review (Klassen et al., 2008), the authors make a distinction between MT and MM in their systematic review and meta-analysis of RCT studies[5]. They assess the quality of the studies in terms of randomisation, allocation concealment, withdrawals, double blinding, and follow-up. Data are extracted by means of a standardised form that captures the type of intervention, quality of outcome measure etc. As to the 9 studies included in the meta-analysis, standardised mean differences (SMD) are calculated with 95 % confidence intervals. Here, changes from baseline data are used in available. For general information, the results of the meta-analysis reflect a conservative estimate (Klassen et al., p. 118).

5 They define MT as a music intervention that involves a music therapist and is used as a medium for interactive communication. MM is defined as music listening without a music therapist. However, in the article the authors refer incorrectly to these terms as active and passive MT, respectively.

4.3.2.1 Qualitative Summation of the Included Studies

The 19 included studies comprise 1513 paediatric patients undergoing various medical and dental procedures. The age ranged from 8 months to 20 years. Five of the 19 studies were MT studies, whereas the remaining 14 were MM studies. All five MT studies measured anxiety (Chetta 1981; Robb et al. 1995; Robb et al. 2003; Kain et al. 2004; Whitehead-Pleaux et al. 2006). In addition, one of these MT studies also measured pain (Whitehead-Pleaux et al. 2006). As to the 14 MM studies, eight studies measured pain, two studies measured anxiety, and four measured both pain and anxiety. Some additional overall characteristics relevant for the PhD study were as follows:

- A total of 12 MT/MM studies compared the music intervention to standard care
- Six studies compared the MT/MM intervention to another intervention
- Two studies compared MT/MM to a pharmacological agent
- Four studies combined MT/MM with other modalities
- Two MM studies incorporated an additional active element

4.3.2.2 Methodological Properties of the Included Studies

From a methodological perspective, the 19 studies varied in many regards, among other things (Klassen et al., 2008, p. 118-119):

- The majority of the studies had low quality (e.g. none of the studies stated concealment of allocation, and only 4 studies used blinding of outcome raters)
- Self-report and observation were the most common methods used
- Outcome measures of anxiety varied, whereas measures of pain varied slightly less. The measurement instruments also varied in terms of validity and reliability
- Observational measures of pain were generally validated and indicated good inter-rater reliability. However, their discriminant validity was questioned
- Self-report measures of pain showed bimodal distribution in young children in spite of established validity and reliability. This could be explained by a possible lack of cognitive ability in young children

Based on the meta-analysis, which comprised nine of the 19 studies, three estimates of MT and MM were made. One as to to anxiety, one as to pain, and a third combined estimates of these two measures. Moreover, additional subgroup analyses were performed, in which a number of variables were controlled for in order to check for possible sources of heterogeneity (e.g. MT versus MM, type of measurement and control etc. Klassen et al., p. 118).

4.3.2.3 Descriptive Summation of MT Studies Included in Meta-Analysis

The analysis of the five MT studies showed mixed results. In some of the MT studies a statistically significant difference between experimental and control groups was shown (e.g. Robb et al. 1995). Other studies had small sample sizes, which hindered definitive conclusions (e.g. Robb et al. 2003). Klassen and colleagues (2008, p. 125) states that the five MT studies as a whole did not demonstrate any clinical importance.

4.3.2.4 Descriptive Summation of MM Studies Included in the Meta-Analysis

As to the 11 MM studies measuring pain, mixed findings were found in terms of statistical significance between experimental and control groups. Likewise, this overall conclusion was made in relation to the six MM studies that measured anxiety. The authors state that clinical importance was found in three of the 11 MM studies (Klassen et al. 2008, p.119).

4.3.2.5 Summary of Estimates Regarding the Effects of MT & MM on Anxiety & Pain in combination

The meta-analyses comprised two MT studies and seven MM studies. Based on these nine MT/MM studies (704 participants) an estimate was made in order to evaluate the combined effect of MT and MM on pain and anxiety. This analysis revealed a statistical significant difference showing an estimated standard mean difference (SMD) of -0.35, 95% CI -0.55 to -0.14 in favour of these music interventions. However, a subsequent subgroup analysis showed a significant effect for MM as opposed to MT. However, this subgroup analysis included seven MM studies and only two MT studies (Robb et al. 1995; Kain et al. 2004). Moreover, in the latter study a substantial therapist effect was reported. From an overall perspective the results based on the nine studies showed that MT/MM had an overall estimated mean small to moderate positive effect on anxiety and pain. Moreover, clinical implications were demonstrated regarding MM in the form of less need for sedatives and greater compliance (Klassen et al., pp. 125, 127). The analysis also revealed statistically significant results in favour of MT/MM in studies in which observation was used as evaluation method. A similar non-significant tendency was noted in studies using self-report. Finally, studies of higher methodological quality showed a larger effect than did studies of low quality. Based on this combined estimate, Klassen and colleagues (2008) state that there was evidence to support the application of MT and MM for children under various anxiety and pain related medical procedures. They also state that this finding concurs with their qualitative synthesis of the 19 studies. Furthermore, they find that music was clinically important as an adjective intervention in reducing the amount of pharmaceutical interventions needed. However, the latter was based on three MM studies (Klassen et al., 2008, p. 127).

4.3.2.6 Summary of Estimate Regarding the Effects of MT & MM on Anxiety

The meta-analysis comprised two MT studies (Robb et al. 1995; Kain et al. 2004) and three MM studies, which measured anxiety and used comparable control conditions. These studies comprised a total of 284 research subjects. Results yielded a statistically significant estimated standard mean difference of -0.39, 95% CI -0.76 to -0.03 in favour of these music interventions. However, this combined estimate was associated with a substantial heterogeneity (e.g. diversion in type of music intervention), which limited the finding.

4.3.2.7 Summary of Estimate Regarding the Effects of MM on Pain

The third main analysis included four MM studies but no MT study. These four MM studies comprised a total of 465 paediatric patients. Results showed that a significant estimated mean effect of -0.39, 95% CI -0.66 to -0.11 in favour of the MM interventions.

4.3.2.8 Summation of Overall Findings with Regard to the PhD Study

Klassen et al. (2008) report several findings that relate to the context of the present PhD study. Among other things they state that:

(1) There was evidence to support the application of MT and MM as a whole for children under various anxiety and pain related medical procedures

(2) However, they found that MT and MM yieled an equal effect on anxiety and pain (combined calculations) contrary to previous meta-analyses of medical MT (Dileo & Bradt, 2005; Standley, 1986; Standley & Whipple, 2003)

(3) Furthermore, this effect was equal, but only statistically significant for MM, not for MT

(4) As opposed to the five MT studies, two MM studies were found clinically important as an adjective intervention in reducing the amount of pharmaceutical interventions needed

(5) MT/MM yielded greater effect when compared to standard care versus other interventions, including placebo

(6) Multi-faceted music interventions that combined other modalities (e.g. relaxation) were more effective than MT/MM alone

(7) Due to variety across studies in terms of type of music intervention etc., conclusive recommendations could not be outlined in terms of which specific medical procedures MT and MM interventions would be most efficient for

4.3.2.9 Summary of Recommendations for Future Research

Based on their findings, the authors (Klassen et al., 2008) formulated a number of recommendations for methodological improvements in future research. In relation to the PhD study the most relevant recommendations are:

- A need for consistency in types of measurement instruments and the way of measuring
- Double blinding etc. was difficult due to the nature of the music interventions. But as a minimum the outcome assessor should be blinded
- Use of adequate concealment of allocation
- Use of control conditions similar to music intervention
- A need to examine the effect of type of music and how music is delivered

As mentioned above, the authors´ findings regarding the efficacy of MT versus MM contradict the conclusions drawn by Dileo & Bradt (2005) and Standley & Whipple (2003). In the context of the PhD study, one should bear in mind that Klassen et al. colleagues (2008) included and compared MT and MM under a variety of medical and dental procedures, including needle procedures. The two studies on MT and needle procedures by Malone (1996) and Caprilli et al. (2007) are not included. Furthermore, the meta-analyses held an imbalance in terms of numbers of MT and MM studies. The meta-analysis by Klassen et al. (2008) only comprised two MT studies, which were compared to seven MM studies. Consequently, it is plausible to infer that this imbalance led to a misleading picture. Also, some of the MT studies included had small sample sizes. Moreover, this could affect the estimates in favour of the MM interventions. Furthermore, only RCT studies were included in the meta-analysis made by Klassen et al. as opposed to the previous medical MT meta-analyses (Dileo & Bradt, 2005; Standley, 1986; Standley & Whipple, 2003). Hence, relevant data and results from outcome studies other than RCT studies were not taken into consideration (e.g. the study Malone 1996).

In conclusion, one could argue on the one hand that the previous meta-analyses provide a more accurate picture of the overall effects of MT and MM in medicine, respectively. For instance, the latest meta-analysis by Dileo & Bradt (2005) is based on 183 studies, which gives statistical weight as opposed to Klassen et al. (2008). However, the present PhD is about needle procedures, which only constitute a minority of the studies comprised in Dileo & Bradt (2005). But on the other hand, the estimates provided by Klassen et al. are based on studies that relate directly to medical procedures in paediatric patients.

The following sections hold a summative presentation of the remaining 8 MT outcome studies under various medical procedures that are included in this third part of the theoretical framework of the PhD study. The review comprises all of the five MT studies that are included in the above-presented systematic survey by Klassen et al. (2008).

4.3.3 Additional Outcome Studies on Music Therapy under other Painful Medical Procedures

Now I will present my review of two outcome studies on MT in paediatrics burn injury patients undergoing painful and potentially anxiety provoking medical procedures (Whitehead-Pleaux et al. 2006; Whitehead-Pleaux et al. 2007). The medical procedures are not directly comparable to the present PhD study due to the type of the medical procedures, type of MT intervention, and outcome variables. However, these studies still contain possible similar aspects and therapeutic mechanisms of MTPS, which could be relevant for the development of the MT intervention used in the present PhD study.

In an exploratory pilot study, Whitehead-Pleaux and colleagues (2006) examined the effect of music therapy (i.e. MAE and integration cf. Ghetti, 20012) on anxiety, distress, and pain during donor site dressing change. Sixteen children at the ages of 6 to 16 with burn injuries participated in the study the day after surgery. The participants were randomly assigned to a music therapy group or a control group. The Nursing Assessment of Pain Index was used during the donor site dressing change to measure observed distress. The FACES Scale (Wong Baker, 1988) was applied to evaluate self-reported pain before, during, and after the procedure. Anxiety was measured by means of the Fear Thermometer before, during, and after the procedure. In addition, physiological data in the form of heart rate and respiration rate were also recorded as measures of stress due to pain and/or anxiety. These physiological data were collected before and after the medical procedure.

The children in the MT group received individual MT conducted by one and the same music therapist. The MT was provided during the medical procedure, and consisted of preferred songs and psychological support in the form of improvised songs with lyrics that expressed support. The children in the control group received standard treatment with no music, only verbal support given by the music therapist. A number of explanatory variables were controlled for. These analyses proved to have no statistically significant influence on the main and secondary outcome measures. The results of the study were as follows:

- Nurse-rated child distress: The children in the MT group had statistically significant higher distress scores compared to the control group
- Self-reported pain: Children in the MT group had higher pain scores before, during, and after the medical procedure, which were not statistically significant
- Self-reported anxiety pre/peri: Compared to the control group children in the MT group had statistically significant higher anxiety levels before and during the procedure.
- Self-reported anxiety post: After the procedure, the MT group exhibited a decrease in anxiety level as opposed to an increase in the control group. But in spite of this, the MT group still exhibited a higher anxiety level after the procedure. The latter finding was not statistically significant
- Physiological measures: The MT group had a higher heart rate and respiration rate before the procedure. However, this finding was not statistically significant. But when the pre- and post- scores were compared in both groups, the MT group had a statistically significantly lower heart rate

In conclusion, the study showed conflicting results, some in favour of the control group and others in favour of the MT group. In addition, in spite of the use of randomisation the children in the MT group had statistically higher anxiety scores before the onset of the medical procedure. Likewise, although not statistically significant their respiration rate was also higher before the procedure. As to limitations of the study, the authors put forward the small sample size and the fact that some participants were confused about how to administer the Fear Thermometer. The authors suggest that a variety of painful medical procedures could be included as inclusion criteria in future studies on this population. As to the MT intervention, they stress that the music intervention should start five minutes before commencement of the donor site dressing change in order to avoid classical conditioning. They also recommend the use of pulse oximeter measures and continuous evaluation of observed distress throughout the entire medical procedure. Finally, they state that no conclusions regarding the effect of the explorative variables such as gender, age etc. could be drawn due to the small sample size.

Based on the above-presented pilot study, Whitehead-Pleaux et al. (2007) carried out an MT (i.e. MAE and elements of Integration cf. Ghetti, 20012) study with nine paediatric burn patients at the ages of 7 to 16 undergoing various painful medical procedures (e.g. IV-starts, donor site dressing change, suture removal). The purposes of the study were to explore if higher levels of engagement in the MT reduced self-reported pain, self-reported anxiety, and observed distress. The study design was an exploratory multiple case study design with mixed methods. As to the quantitative part of the study, the Nursing Assessment of Pain Index the Fear Thermometer, and the FACES Pain Scale (Wong & Baker, 1988) were used to measure distress, anxiety and pain, respectively. Likewise, physiological data (heart rate and blood oxygenation) were collected. The qualitative part consisted of interviews with participants, parents, staff, and music therapist with regard to each child. Each child received individual MT conducted by one and the same music therapist. The music intervention began five minutes before the medical procedure, lasted throughout the procedure, and consisted of preferred music and improvised music. The child was encouraged to participate actively (sing along) or listen actively to the music. Results showed:

- A statistically significant relationship was found between level of engagement and nurse-ratings of child distress
- No statistically significant relationships were found between level of engagement and anxiety and pain (quantitative part)
- A discrepancy between the quantitative and qualitative data as to the effect of MT was reported
- The qualitative interview data showed that MT was beneficial to the reduction of pain, which was reported by the participants, parents, nurses, and music therapist

In conclusion, the hypothesised effect of higher engagement in MT leading to reduced anxiety, pain, and distress could not be confirmed statistically. As to the qualitative part, the authors state that the interviews could not prove a positive effect of music therapy. They emphasise that the qualitative data could be used as a starting point for further research. Furthermore, they stress the importance of the use of larger sample sizes in future studies. In addition to these limitations, the authors´ emphasis on the *effect* of the MT intervention and their choice of an explorative design with no controlled data (e.g. lack of baseline data, pre- and post-measures, control group) seems unclear to me.

4.3.4 Additional Outcome Studies on Music Therapy and Surgery

In the following sub-sections, I will present a summary of four MT studies related to surgery (Chetta, 1981; Robb et al. 1995; Kain et al., 2004; Bradt, 2010).

In one of the oldest studies on MTPS, Chetta (1981) examined the effect of MT on pre-operative anxiety in 75 hospitalised children aged 3 to 8. An RCT design with three groups was utilised comprising a control group, music therapy group 1 (MTgr 1), and MT group 2 (MTgr 2). In the control group only verbal pre-operative information was given. Participants in the two MT groups received the same pre-operative preparation, but with the addition of subsequent MT in the form of songs conveying and reflecting the information given in the initial verbal presentation. Furthermore, the MT intervention incorporated an element of medical play therapy in that children were invited to give a doll a needle injection. The two MT groups differed in that MTgr 1 received MT the evening before the operation, whereas children randomised to MTgr 2 received the music intervention immediately prior to induction

of preoperative medication on the morning of surgery. The primary outcome variable was anxiety measured by the Observed Behavior Time-Sampling Form (OBTSF), which was developed by the researcher. The OBTSF measures noise (i.e. crying, screaming, verbal resistance to procedure) and motor (i.e. physical resistance) behaviours that are rated in ten-second intervals. Data collection took place immediately prior, during, and immediately after induction of pre-operative medication. The results of the study showed:

- No statistically significant difference in anxiety between the C and either MT groups
- A statistically significant difference between the two MT groups in favour of MTgr 2 showing less anxiety
- Children in MTgr 2 were consistently rated as less anxious before and during induction of pre-operative medication

The study was limited in that non-validated measurement tools were used. Furthermore, inter-rater reliability was only established in 4% of the sample. However, data regarding parent-reported previous overall anxiety level at certain times during hospitalisation were obtained and compared among groups.

In a later study, Robb et al. (1995) trialled whether music-assisted relaxation (MAR) could reduce pre-operative anxiety in paediatric burn patients. The sample consisted of 20 burn patients aged 8 to 20, who underwent reconstructive surgeries. The participants were randomly assigned to either an MT or control group. Both groups received standard treatment and care. In addition, children in the MT group received individual MT, which consisted of receptive music-assisted relaxation (MAR) combined with subsequent music listening. The MT was conducted by one and the same music therapist. On the night before surgery, the child was given a presentation of the MT intervention, including a demonstration of relaxation exercises. The music intervention (MAR) was provided in the child´s room the following day, 30 to 50 minutes before transportation to the operation theatre comprising music listening, deep diaphragmatic breathing, progressive muscle relaxation, and imagery to facilitate relaxation. Upon departure music listening was provided via headphones during transportation to the operation theatre area. During the induction of anaesthesia, the children listened to music coupled with emotional support offered by the music therapist. During both parts of the music intervention, subject selected music was used (i.e. forced choice: sedative music and lullabies).

Data comprised pre- and post-measurements. Anxiety was measured by the State-Trait Anxiety Index for Children (STAIC) plus physiological indicators of stress in the form of blood pressure, respiratory rate, heart rate, and temperature. Finally, qualitative comments from children and staff were collected. Results of the study showed:

- Physiological indicators of stress: no statistically significant differences between groups
- A statistically significant decrease of anxiety in the MT group (pre-post) the MAR intervention, which took place before transportation to operation theatre
- Post-tests revealed statistically significant less anxiety in the MT group
- During transportation children in the MT group displayed significant less anxiety
- No significant changes between groups during induction of anaesthesia
- All 10 children confirmed a wish for MT under future surgeries

As to the limitation of the study, the authors put forward that future studies should also include post-operative measurements in the design, among other things the amount of pain medication, rate of emergence, registration of pain, and behavioural signs of distress during the recovery phase.

In their most recently published study, Kain et al. (2004) examined the effect of active MT on preoperative observed anxiety and compliance. However, as opposed to Robb et al. (1995) they investigated the effect of MT versus the conventional pharmacological treatment midazolam. The sample consisted of 123 children aged 3 to 7, who underwent anaesthesia and elective outpatient surgeries. They were randomly assigned to one of these three conditions:

(1) Midazolam group (n=34): only receiving oral midazolam 30 min. before surgery

(2) MT group (n=51): only receiving active MT (no midazolam)

(3) Control group (n=38): neither receiving midazolam nor MT

The MT intervention was conducted individually by one of the two music therapists involved in the study comprising active and receptive MT (preferred music, playing instruments, singing, and song writing). The MT started in the holding area and lasted about 20 to 30 minutes, after which the music therapist accompanied each child into the

operating theatre. Parents, on the other hand, were present in the pre-operative holding area. Data consisted of video recordings of the participants in the pre-operative area and during induction of anaesthesia. Anxiety was measured by the Yale Preoperative Anxiety Scale (YPAS), (Kain et al., 1995; Kain et al. 1997). Furthermore, the following evaluation instruments were used: the State-Trait Anxiety Inventory (STAI), the Induction Compliance Checklist (ICC), the Emotionality, Activity, Sociability, and Impulsivity Scale (EASI) of child temperament. Anxiety was rated at four time points: 1. in the pre-operative holding area, 2. during separation with parents at operation theatre, 3. entrance into operation room, 4. during the induction of anaesthesia mask. Analyses of demographical and baseline data revealed no statistically significant difference among the three groups. The results of the study were:

- Anxiety level of the three groups increased statistically significant over the four time points
- The Midazolam group had statistically significant less overall anxiety scores compared to the MT and control group
- A statistically significant music therapist effect was reported. Children receiving MT from therapist two had statistically significant lower anxiety scores than children receiving intervention from therapist one
- Anxiety scores in therapist 2 group had almost same mean and standard error as those in the Midazolam group during holding area, separation, and entrance to operation theatre, except during induction of mask
- Anxiety scores were statistically significant lower in children receiving MT from therapist 2 compared to the control group: during separation at entrance into operation theatre and until the children were induced
- Children in the Midazolam group were statistically significant more compliant during the induction of anaesthesia
- No difference in compliance was found neither between MT and control group nor among children receiving MT from therapist one and two

Contrary to Chetta and Robb, Kain et al. (2004) applied validated measuring instruments, which strengthened the validity of the results. As to the results, a considerable statistically significant effect was noted in the Midazolam group compared to both the MT and standard care groups. However, as mentioned above a statistically significant therapist effect was noted between the two therapists involved in the study. This difference occurred in spite of appropriate preparatory training and observation in order to ensure that both therapists performed the MT

intervention in a similar manner. In addition, it should be noted that the therapist effect was statistically significant during three of four time points (i.e. preoperative holding area, separation to operation theatre, and entrance into operation theatre), except during anaesthesia induction. Based on the results (including a rough calculation of cost-effectiveness), the authors conclude that in general the provision of pre-operative MT could not be supported. However, they subsequently point out that some children may benefit from MT. Hence, they stress that future studies should aim at identifying such a population.

Bradt (2010) carried out a study evaluating the effects of MT in the form of music entrainment on post-operative pain and emotional state in children and adolescents. In the study, 32 orthopaedic inpatients at the ages of 8 to 18 participated. A cross-over design was used comprising four treatment sequences, to which the children were randomly allocated. Each child participated in two music entrainment conditions and one standard care (control) condition over a period of two consecutive days, starting within 24 hours following the operation. The music entrainment sessions were individually conducted in the child´s hospital room, provided by one and the same music therapist. Each music entrainment session lasted 30 to 45 minutes, and a variety of musical instruments were used. Self-reported pain was measured by a Visual Analogue Scale (VAS). Self-reported emotional state was rated by eight bipolar five-point scales developed by the researcher. Results showed a statistically significant large effect (Cohens´ *d*) of music entrainment on self-reported pain when compared to the control condition. Likewise, children in both music entrainment conditions reported statistically significant improved emotional states (higher degrees of happiness, peacefulness, relaxation, comfort, and calmness). Moreover, a significant correlation between emotional state difference scores, and pain intensity difference scores was found. In both MT conditions a strongly positive association between mood improvement and pain reduction was found contrary to the control condition. The authors put forward two main limitations. That was the small sample size and generalisability of results in that only orthopaedic patient suffering from post-operative pain were included in the study.

4.3.5 Additional Outcome Studies on Music Therapy under various Mainly Non-Painful Medical Procedures

In the following sections I will provide a review of two studies related to mainly non-invasive and non-painful medical procedures (Loewy et al., 2005; Walworth, 2005).

Loewy et al. (2005) compared the effect of MT versus pharmacological sedation (i.e. chloral hydrate) on sleep/sedation in young babies and toddlers undergoing electroencephalogram (EEG). The study was initiated on the basis of a pilot study, and parental requests for MT to assist relaxation during medical diagnostic tests due to the concern about potential side effects and risks related to sedation. The aim of the study was to evaluate feasibility of MT as a cost-effective, non-invasive and risk-free alternative to sedation by comparing the effect of MT versus chloral hydrate on the level of sleep/sedation, length of sleep/sedation, and successful completion of EEG. In the study, 58 children ranging in age from one month to five years participated in the study. Of these, 34 were assigned to the MT group and 24 to the chloral hydrate group. The parents and nurses were instructed to sleep-deprive the children the night before the EGG test. The level of sleep/sedation was measured using the Beth Israel Medical Center flow sheet sedation scale (i.e. 5-point Likert-type scale). Furthermore, duration and number of subjects completing the EEG test were registered. The MT intervention was individually delivered by one of the seven music therapists participating in the study comprising music requested by the parent(s), the therapist´s choice of soothing music, using voice, guitar, and soft percussion instruments. Baseline characteristics (e.g. age, sleep-deprivation) were not statistically significantly different between groups, and were moreover controlled for in the analyses. The following results were reported:

(1) Level of sleep/sedation: a statistically significant (p= 0.00) median difference of one point on the five-point scale in favour of the MT group, also when controlled for age

(2) Length of sleep/sedation: when the two groups were compared, children in the MT group needed nine minutes less to be sedated, which however was not statistically significant (p= 0.24). On the contrary, a very large (d=1.33) and statistically significant (p= 0.00) effect was reported in the form of a 160 minutes reduction in mean length of sleep, which was in favour of the MT group, also when controlled for age

(3) Completion rate of EEG: yielded a statistically significant difference between the groups in favour of the MT group. In the MT group (n=34) 97% of the children completed the EEG test without additional treatment (i.e. chloral hydrate) as opposed to the Chloral hydrate group (n=12), in which 50% completed the EEG test without additional treatment (i.e. MT)

The results of the study have clear and directly applicable implications. However, generalisation and extrapolation of the results to other regional or national contexts requires that the EEG procedure is carried out in a similar way.

Walworth (2005b) made a comparative analysis of the cost-effectiveness of MT as a procedural support intervention in paediatric patients under various medical procedures. The main objectives of the study were to evaluate to what extent MT could reduce the use of sedation avoiding potential harm, reduce anxiety, and the cost-benefit of MT. A total of 156 children ranging in age from one month to 13 years participated in the study. Of these, n=92 attended echocardiograms (ECG), n=57 computerized tomography (CT), and n=17 other non-invasive and invasive procedures. Hence, the procedures were mainly non-invasive, and did not include elements of inflicted pain. However, they posed a potential element of anxiety. The MT intervention was individual, and consisted of preferred music played on classical guitar and sung by a music therapist. The children who received CT and ECG were sleep-deprived in order to reduce or avoid the use of sedation due to its possible side effects. Thus, the objectives of the MT intervention were to facilitate and induce sleep during these scans. The results of the study were:

1. Need of sedation and completion of procedure:

- 100% success rate in eliminating the need for sedation for the children receiving ECG (n=92)
- 80,7 % success rate for completion of CT scannings (n=57)
- 94,1 % success rate for completion of the remaining procedures (n=17)

The researcher defined the MT intervention as successful if the procedure was completed without sedation and if the child´s behaviour did not disturb the procedure. In addition, successfully completed medical procedures did require the involvement of a registered nurse. Regarding the cost-benefit analysis, the effect of MT also yielded encouraging results from an economical perspective. The MT-assisted procedures saved money, time, and staff/equipment resources, especially at Echocardiograms (ECG). The 100% success rate in eliminating the use of sedation in the 92 participants revealed the following benefits:

- $76.15 worth saving per patient or $70.005 in total (incl. the costs of the music therapist), since sedation was unnecessary, and the assistance of a nurse that was obviated plus a 2/3 time reduction of the sonographer per child
- In total the MT-assisted ECGs resulted in a reduction of 184 registered nurse-hours
- This substantial time saved potentially allowed the equipment and staff to be scheduled for three times as many procedures
- In addition, space in the recovery rooms was increased

The above-mentioned highly successful completion rates and economical savings are encouraging. However, the author points out some essential limitations in the study. First, the study was launched shortly after new sedation standards were initiated (by the Joint Commission on Accreditation of Healthcare Organizations). Second, the author stresses that future studies should use an RCT design in order to provide comparable data on distress and anxiety from patients, family members, and staff, length of procedure, and staff resources used. The reason for not doing so in the study was that the MT procedural support was given during the total 166 procedures as part of the standard clinical MT service. Consequently, no child was refused MT or allocated to a comparable control group. Hence, the results are not directly comparable to standard treatment or other conditions. The study also raises the

question to which degree the results can be generalised to other regional and national contexts and practices, which requires that the EEG procedure is carried out in a similar way.

4.3.6 Studies Not Accessible or Not Meeting Inclusion Criteria of the Literature Review

I did not include the following 13 studies in that they were either not accessible or did not meet the criteria of the review due to the reasons specified in appendix 3 (Aldridge, 1993; Barrera et al., 2002; Fratianne et al., 2001; Hendon and Bohon, 2007; Longhi and Pickett, 2008; Micci, 1984; O´Callaghan, Sexton, and Wheeler, 2007; Prensner et al., 2001; Robb and Ebberts 2003; Robb et al., 2007; Ryan, 1989; Sahler, Hunter, and Liesveld, 2003; Walworth, 2010).

4.3.7 Chapter Summary

The primary objective of this chapter was to provide an overview and a review of outcome studies reporting the effects of MT under *needle procedures* in paediatric patients, including nephro-urological patients. In addition, outcome studies on *related* medical and diagnostic procedures and surgery are also included. The review of the presented research literature was based on an initial systematic literature search. I identified three outcome studies that implied a *needle procedure* involving children with different diseases (Caprilli et al., 2007; Malone, 1996; Pfaff et al., 1981). Due to the nature of the PhD study, I gave these studies precedence over the supplementary MT 8 outcome studies on *related* medical procedures in children. Hence, a total of 11 studies were reviewed. Contrary, 13 studies were deselected in that they did not meet the inclusion criteria of the review. Moreover, the review was aided by three meta-analyses (Standley & Whipple, 2003; Dileo & Bradt, 2005; Klassen et al., 2008).

Initially, I outlined an overall rationale for the use of MT and MM in paediatrics based on two of the meta-analyses (Dileo & Bradt, 2005; Standley & Whipple, 2003). In addition, the former meta-analysis showed positive effects on outcome measures related to the ones in the present PhD study. Next, I reviewed the three studies that implied needle procedures (Caprilli et al., 2007; Malone, 1996; Pfaff et al., 1989). In short, Malone (1996) found statistically significant less total distress duration in the children between 0 and 1 years as well as in favour of the MT group. Moreover, the remaining outcome measures did not show a statistically significant difference between groups. In addition, negative effects of the MT intervention were reported, which, however, were not statistically significant.

Caprilli et al. (2007) found only statistically significant and positive effects of music distraction (i.e. less distress and pain compared to the control group). Pfaff et al. (1989) reported trends for a decrease in median as to anticipatory fear, experienced fear, and experienced pain. The review of these three studies, which related to venous access, was aided by a meta-analysis of RCT studies on MT and MM involving procedural anxiety and pain in children (Klassen et al. 2008). The authors conclude that MT and MM as a whole had a mean small to moderate positive effect on anxiety and pain under various medical procedures. However, when comparing the effect of MT versus MM, the authors only found a statistically significant effect for MM. This finding was not consistent with previous meta-analyses of medical MT (Dileo & Bradt, 2005; Standley & Whipple, 2003).

Next, I presented a review of the 8 supplementary MT studies that related to *various* medical and diagnostic procedures and surgery. Of these, two studies related to painful procedures involving children with burn injuries (Whitehead-Pleaux et al., 2006; Whitehead-Pleaux et al., 2007). These two studies found conflicting results, including negative effects of MT on anxiety and pain (Whitehead-Pleaux et al., 2006). Subsequently, I presented four studies that evaluated the effect of MT in the context of surgery (Bradt, 2010; Chetta, 1981; Kain et al., 2004; Robb et al., 1995). In short, these studies found conflicting results in terms of statistically significant difference in favour of the MT groups. Here, statistically significant differences were found in favour of the MT group in terms of anxiety (Robb et al., 1995), pain, and emotional states (Bradt, 2010) as opposed to Chetta (1981). Moreover, Kain et al. (2004) found statistically significant less pre-operative anxiety in the Midazolam group contrary to the MT group. Finally, I reviewed two MT studies that related to various mainly non-invasive and non-painful procedures (Loewy et al., 2005; Walworth, 2005). These two studies found statistically significant differences in favour of the MT group, which were furthermore clinically and economically encouraging.

In conclusion, the review of the 11 outcome studies shows inconsistent results regarding the effect of MT as procedural support. Similarly, conflicting results were found as to the effectiveness of MT versus MM. Consequently, the review shows a somewhat mixed picture that does not render definitive conclusions. Moreover, from a methodological perspective the review identifies weaknesses and a considerable diversity across studies. Consequently, these inconsistencies complicate the interpretation of results. Likewise, these conclusions call for further valid and good quality research in the complex field of MT procedural support of paediatric patients.

4.4

Summary of the Theoretical Framework of the PhD Study

I divided the theoretical framework of the PhD study into three parts. The first part comprised a presentation of the epidemiology of nephro-urological diseases and current practice regarding venous access in children in a Danish context. Next, I provided an overview of the use of MT in paediatrics as described in the literature. This was followed by definitions and descriptions of overall theoretical aspects of pain, trauma, coping, theoretical aspects of MT as procedural support, and other theoretical core elements related to the PhD study. In the second part of the theoretical framework, I focused on the relation between theory, research, and clinical practice. Initially, I presented theoretical aspects, subsequently accompanied by specific research-based recommendations related to concrete clinical practice. The progression from overall aspects to clinically related descriptions culminated in user-friendly suggestions regarding specific techniques and assumed preferable wordings. In the third and last chapter of the theoretical framework of the PhD study, I provided a review of 11 outcome studies on the effect of MT under various medical and diagnostic procedures in paediatric patients. The review of these outcome studies was aided by three meta-analyses (Standley & Whipple, 2003; Dileo & Bradt, 2005, Klassen et al., 2007). In addition, I defined outcome studies on MM under painful and anxiety related medical procedures in children as beyond the scope of the PhD study, since this study involves an MT intervention. However, I included related overall results of MT and MM studies in the form of a summation of a meta-analysis (Klassen et al., 2007).

The three chapters (i.e. Chapter 2 to 4) helped me identify and form a multi-faceted theoretical framework for the PhD study. The first part illuminated overall important theoretical aspects related to the PhD study. The second

and third parts guided me to inform, develop, and shape the MT intervention. In addition, the third part gave an important overview of the current research literature, including the methodological weaknesses and challenges within this field of MT research. To conclude, I used the findings and results from these three parts to develop the specific research questions and hypotheses, which defined and narrowed further down the scope of the PhD study. In the following chapter (chapter 4), I will address myself to the method of the study.

CHAPTER 5 Method:

IN THIS CHAPTER, I WILL ACCOUNT FOR THE VARIOUS METHODOLOGICAL ASPECTS OF THE RESEARCH STUDY. THE CHAPTER STARTS WITH A SUMMATIVE INTRODUCTION, AFTER WHICH I WILL PRESENT THE RESEARCH QUESTIONS AND RESEARCH HYPOTHESES. AFTER THAT THE METHODOLOGICAL ASPECTS ARE ACCOUNTED FOR. IN ORDER TO PROVIDE AND MAINTAIN A CLEAR OVERVIEW OF THE METHODOLOGY, I WILL PROVIDE SUMMATIVE TABLES AND FIGURES ALONG THE WAY, AS WELL AS IN THE END OF THE CHAPTER. AN OVERVIEW OF THES CHAPTER IS PROVIDED IN THE FOLLOWING

Figure 5.1. Overview of Contents of Chapter 5

Introduction

Research Questions and Hypotheses

Study Design

Development of Study Protocol

Measuring Instruments

Participants

Protocol for Recruitment

Protocol for Randomisation

Protocol for the Applied Music Therapy Intervention

Ethics

Protocol for Data Analyses

5.1

Introduction

The objective of the study was to examine the effect of a designed MT procedural support intervention in relation to distress and a number of related outcome measures in young children undergoing peripheral intravenous access procedures (e.g. IV-start, intravenous catheter, cannulisation). The IV-access procedure can be defined as invasive in that the procedure requires insertion of a needle into a vein. Consequently, the procedure often causes pain, distress, and elevated anxiety states. A description of the procedure is provided in section 2.2.2. Based on Chapter 2 and 3, I identified important theoretical and clinical aspects with regard to distressing and painful medical procedures. Likewise, the literature review (i.e. Chapter 4) revealed three outcome studies that specifically related to music interventions in connection to various types of needle procedures (Caprilli et al., 2007; Malone, 1996; Pfaff et al., 1989). The 16 outcome measures (including the MT satisfactory survey) are based on the research literature and the overall theoretical framework of the study, which will be explicated in the respective sub-sections related to each outcome measure. Likewise, based on the research literature, I chose to regard the four types of raters (i.e. research-assistant, child, parents, physician), who assessed *child anxiety* and *child pain*, as four separate outcome measures. This will also be clarified later in this chapter.

As described in the introduction chapter (i.e. Chapter 1), the study was rooted in an already existing co-operation between the paediatric department at Aarhus University Hospital (AUH) and me, which was beneficial for the course of the study. In the preparatory planning phase, we formed an MT working party that provided ongoing discussion with regard to the development of the study, including choice of outcome measures, practicalities and feasibility of the study. Besides the working party, the methodological aspects of the study (e.g. choice of design, outcome measures, MT intervention) were based on the presented clinical and research literature (i.e. Chapters 2 to 4), discussions with my PhD supervisor and Tony Wigram, clinical experience plus peer group discussions during the PhD seminars at AAU. In addition, the CONSORT statement (Moher et al., 2010), informed the

study and served as an ideal in terms of design and methodology. Likewise, I used the CONSORT statement as a checklist to obtain an appropriate methodology as well as an overall checklist in the writing of the PhD thesis.

After obtaining the required formal ethical approvals, I launched two preparatory pilot studies. The objectives of these pilot studies were to shape and refine the MT intervention, gain clinical experience, and establish new common work routines between medical personnel and the music therapist with regard to the practical implementation of the MT intervention. Besides that, the pilot studies served to try out measurement instruments and assess feasibility aspects in relation to the study. The pilot studies and the main study were conducted in the outpatient day unit at the paediatric nephro-urological ward at AUH. The data collection period of the main study started on 21 May 2010 and ended on 7 March 2011. All the research subjects/families participated voluntarily in the study. A co-ordinating nurse administrated the recruitment of eligible children. Children/families who wished to participate gave written informed consent prior to enrolment in the study. Likewise, a verbal confirmation hereof was obtained in the waiting room before final enrolment in the study and prior to commencement of the IV-procedure. After written and verbal consent was secured, the children were randomly allocated to either the MT group or control group.

5.2

Research Questions and Hypotheses

This section holds the research questions and hypotheses.

5.2.1 Research Questions

Based on the theoretical framework of the study (chapters 2 to 4), I formulated this primary research question:

(1) *What are the effect of music therapy procedural support under a single peripheral intravenous access procedure on distress, anxiety, pain, compliance, overall satisfaction with medical procedure, number of needle pricks, duration of medical procedure, and positive child behaviour in young children having various nephro-urological diseases?*

As will be clarified in this chapter, each outcome domain was based on specific studies and/or research-based recommendations. In addition, I formulated this secondary research question:

(2) To what extent will the parents and children find the music therapy intervention supportive in relation to the intravenous access procedure?

5.2.2 Research Hypotheses

These research questions subsequently generated the following 16 research hypotheses that I have classified into nine overall outcome domains:

(1) Children having various nephro-urological diseases who receive music therapy procedural support under a single peripheral intravenous access procedure will score less mean research-assistant-rated ***Child Distress*** than children having various nephro-urological diseases who undergo a standard peripheral intravenous access procedure *without* music therapy (main outcome).

(2) Children having various nephro-urological diseases who receive music therapy procedural support under a single peripheral intravenous access procedure will score less mean Child Anxiety than children having various nephro-urological diseases who undergo a standard peripheral intravenous access procedure without music therapy, as rated by:

a) the research-assistant
b) the child
c) the parents
d) the physician

(3) Children having various nephro-urological diseases who receive music therapy procedural support under a single peripheral intravenous access procedure will score less mean Child Pain than children having various nephro-urological diseases who undergo a standard peripheral intravenous access procedure without music therapy, as rated by:

a) the research-assistant
b) the child
c) the parents
d) the physician

(4) Parents of children having various nephro-urological diseases who receive music therapy procedural support under a single peripheral intravenous access procedure will report greater ***Overall Satisfaction with the Medical Procedure*** than parents of children having various nephro-urological diseases who undergo a standard peripheral intravenous access procedure *without* music therapy.

(5) Children having various nephro-urological diseases who receive music therapy procedural support under a single peripheral intravenous access procedure will score better physician-rated ***Child Compliance*** in relation to the needle procedure than children having various nephro-urological diseases who undergo a standard peripheral intravenous access procedure *without* music therapy.

(6) Parents of children having various nephro-urological diseases who receive music therapy procedural support under a single peripheral intravenous access procedure will score better physician-rated ***Parent Compliance*** in relation to the needle procedure than children having various nephro-urological diseases who undergo a standard peripheral intravenous access procedure *without* music therapy.

(7) A smaller ***Number of needle pricks*** will be needed to obtain peripheral intravenous access in children having various nephro-urological diseases who receive music therapy procedural support than children having various nephro-urological diseases who undergo a standard peripheral intravenous access procedure *without* music therapy.

(8) The ***Duration*** of the peripheral intravenous access procedure will be shorter in children having various nephro-urological diseases who receive music therapy procedural support than children having various nephro-urological diseases who undergo a standard peripheral intravenous access procedure *without* music therapy.

(9) Children with various nephro-urological diseases receiving music therapy procedural support under a single peripheral intravenous access procedure will score better research-assistant-rated ***Positive Child Behaviour*** than children having various nephro-urological diseases who undergo a standard peripheral intravenous access procedure *without* music therapy.

(10) The majority of the parents and the children having various nephro-urological diseases who receive music therapy procedural support at a single peripheral intravenous access procedure will find the music therapy intervention supportive and helpful in relation to the medical procedure.

5.3

Study Design

The study can be defined as a clinical, experimental, not blinded, randomised controlled trial (RCT), which was conducted in a natural paediatric outpatient setting. The study investigates the effect of a specific MT procedural support intervention before, during, and after IV-access in relation to 16 outcome measures. Since the objective of the study was to examine the effect of an intervention, I applied a fixed method design in the form of an RCT. According to Robson (2011, pp. 81-93), well-performed randomised controlled trials (RCT) generate trustworthy data and are highly appropriate for the purpose of measuring effects. In addition, RCT designs justify use of inferential statistics. Hence, the overall research paradigm follows the bio-medical standards of effect research with quantitative measures, causality, and generalisation based on a large sample. Furthermore, according to this research tradition, double- or triple-blinded RCT designs are regarded as the gold standard (i.e. blinding of participants, practitioner, and outcome rater) (Robson, 2011).

The sample consisted of 41 children with various nepho-urological diseases, who were randomly assigned to one of these two conditions:

(1) Control group with standard PIVA: Children randomised to the control condition underwent a standard PIVA procedure without any MT intervention or presence of the music therapist/researcher (see description in section 2.2.2). To the extent possible, local anaesthesia in the form of Eutectic Mixture of Local Anaesthetic (EMLA plaster) was provided for all participants prior to the IV-access procedures. In a few cases a medical kit was used with a view to preparing the child and supporting his/her coping skills during the approaching IV-access procedure. The medical kit intervention was administered by the co-ordinating nurse, who assisted the physician in obtaining PIVA

(2) Music Therapy Group: Children randomised to the MT condition receiving a standard PIVA procedure similar to the control group, with the addition of a single MT procedural support session individually provided before, during, and ten minutes after completion of the IV-access procedure. The MT intervention can be defined as *supportive* according to Dileo (1999, p. 8) and/or as *music therapy as procedural support* in the form of a *Music Alternate Engagement*-based intervention, which comprised receptive and active music experiences according to the child´s wishes (se description in section 5.10).

5.3.1 Overview of Outcome Measures and Additional Variables

In this subsection, I will outline the intervention, outcome measures, recorded explanatory variables, and unregistered possible explanatory variables.

The 16 *outcome measures* can be grouped as follows:

- **Observed Child Distress** (main outcome measure) as rated by the research-assistant
- **Child Anxiety** as rated by the research-assistant, child, parents, and physician
- **Child Pain** as rated by the research-assistant, child, parents, physician
- **Overall Satisfaction with IV-procedure** as rated by the parents
- **Child Compliance** and **Parent Compliance** as rated by the physician
- **Number of pricks** as registered by the research-assistant
- **Duration of needle procedure** as registered by the research-assistant
- **Positive Child Behaviour** as rated by the research-assistant
- **Satisfaction with MT intervention** as rated by parents (and child)

In addition, the research-assistants registered data in relation to these explanatory variables:

- Randomisation group
- Age
- Gender
- Diagnosis
- Course of disease
- Number of previous in- and outpatient admissions
- Number of previous needle procedures
- Administration of topical anaesthesia (i.e. numbing cream in the form of EMLA)
- Use of sedative medication

Furthermore, the research-assistant recorded these data:

- Use of medical play kit during the *Pre-Needle Period* and the *Needle Period*
- Number of needle pricks *with/without* EMLA
- Type/size of needle
- Possible blood drawing prior to the needle procedure
- Use of toys, stuffed animals etc. during *Pre-Needle Period* and the *Needle Period*
- Duration of *Phases 1* to *5*
- Name of the physician who performed the needle procedure

The following explanatory variables were not registered in the study:

- Trait anxiety
- Level of general fear regarding medical procedures
- Type of coping style and preferred/applied coping style
- Possible positive/negative interaction patterns between child and medical personnel
- Possible positive/negative interaction patterns between child and parents

5.4

Development of Study Protocol

In this section, I will shortly outline the preparation and further development of the overall study protocol, which proceeded in the following four overall stages: an initial preparation stage, a subsequent elaborated preparation, and two pilot studies. In addition, the pilot studies as well as the main study were carried out in the nephro-urological outpatient unit at AUH.

As suggested by the English Medical Research Council, (MRC, 2006, p. 13), during the planning phase of the study I took measures to ensure relevance and possible subsequent implementation of MT intervention into the overall interdisciplinary treatment strategy. Specifically, I initially consulted the head nurse, who is the stakeholder of the paediatric department. The two of us commissioned an MT working party with a view to discussing important aspects related to design, method, feasibility, and in order to focus the study on the specific context and needs of the Paediatric Department. Furthermore, as put forward by the MRC (2006) recommendations:

> Best practice is to develop interventions systematically, using the best available evidence and appropriate theory, then to test them using a carefully phased approach, starting with a series of pilot studies targeted at each of the key uncertainties in the design, and moving on to an exploratory and then definitive evaluation. (p. 8)

5.4.1 Stage 1: Background of the Study

As described in Chapter 1, the PhD study was based on an existing co-operation between the paediatric department at AUH and me. The co-operation started in 2005 when I was studying MT at the Masters program at Aalborg University. Until the commencement of the PhD study, our co-operation comprised the following activities:

- An 8th semester written project in the form of a qualitative interview study in the child oncology ward preparatory to
- A four months´ internship at the child oncology ward
- My master´s thesis
- A pilot study, which was a continuation of the master´s thesis

In 2007, the head nurse of the paediatric department and I commissioned an MT working party. Besides the two of us, two physicians and two leading charge nurses constituted the working party. The objective of the working party was to discuss and outline a number of possible MT research studies that could be carried out in the paediatric department. With support from the working party, I outlined sketches for four research studies. We selected the present study. After about eight months´ preparations, the study was transformed into a PhD project in the context of Aalborg University.

5.4.2 Stage 2: Elaborated preparation of the study

After the study was transformed into a PhD project, I began to elaborate on the research protocol and the clinical protocol related to the applied MT intervention. My initial outline, which we discussed in the working party, served as a point of departure for the further course of my elaboration of the overall methodology. At that point in the process, I had limited clinical experience with MT as procedural support, which originated from the internship. Therefore, I visited the paediatric nephro-urological in- and outpatient unit numerous times in order to observe many IV-access procedures. Through observation and discussions with the medical staff, I got thorough knowledge of the carrying out of this specific medical invasive procedure as well as their working routines. In that connection, I quickly discovered the importance of establishing a good professional as well as social relationship with the staff members. As to the social aspect, I participated in a number of social activities in the nephro-urological unit as well as in the additional part of the paediatric department and played in the medical staff´s band, which was cosy and resulted in joyful social and musical experiences.

In elaborating the research protocol, I carried out the following activities:

- Reviewed the clinical and research-based MT literature
- Submitted my elaborated proposal
- Visited the nephro-urological in- and outpatient unit
- Observed numerous IV-access procedures
- Discussed issues regarding outcome measures, measurement instruments in various professional contexts - with my supervisor, Tony Wigram, peers at the AAU PhD seminars as well as with the MT work party at the hospital

At that point of the research process, the most pressing issues related to the practical, clinical, and methodological aspects as well as feasibility in general. In continuation of this, some of the prevailing unsolved questions were:

- Which and how many outcome measures should I include in my study?
- How, when, and by whom should the data be collected in practice?
- How could I design the MT intervention to fit the course of the IV-access procedure and the working routines of the medical staff who performed it?
- How could I secure that the IV-procedure would be carried out similarly in the two groups?
- In continuation of this, could the MT intervention to be started in practice before the IV-procedure commenced or would that interfere with the working routines in the outpatient unit?

In order to clarify these important questions, I prepared and carried out a pilot study. In addition, preparatory to the pilot study, I carried out a two-way translation of the Faces Pain Scale-Revised, which I have described in section 5.5.3.

5.4.3 Stage 3: Pilot study 1

Based on the results of the above-described elaborated preparation phase, I launched a preparatory pilot study in the period from June to October 2009. In accordance with the recommendations suggested by the English Medical Research Council (MRC, 2006, p. 10), I employed a feasibility/piloting stage. It consisted of two separate pilot studies. The main objectives of these preparatory studies were to address the main uncertainties of the study

protocol and to test the study protocol with a view to an appraisal of feasibility aspects. In short, pilot study 1 served the purpose of developing and testing the overall research protocol including the MT protocol in practice. Specifically, the objectives of the pilot study were:

- To formulate and select final hypotheses, research questions, and outcome measures for the main study
- To choose final measuring instruments and test them in practice prior to the main study
- To test the protocol for the MT intervention with an eye to adjustments, including an appraisal of the suitability of the MT intervention in terms of age range and repertoire
- To appraise a possible need for further ethical precaution initiatives
- To gain insight from the participants as to the process and meaning of the MT intervention
- To test and appraise different practical aspects and feasibility in terms of recruitment, data collection, and the MT intervention

As appears from above, the objectives of this first pilot study both related to the scope of the study (i.e. research questions), measuring instruments, practicalities, feasibility, and the MT intervention. As to the measuring instruments, I developed two measuring instruments prior to the pilot study due to the lack of such available validated tools (i.e. self-reported Child Pain, Overall Satisfaction with IV-access procedure). As to the MT intervention, I received clinical supervision by an experienced music therapist (Maiken Bjerg, a trained music and SE therapist). Based on live observation, we discussed how the MT intervention could be further developed and more efficient. In addition, I also used qualitative data to a lesser extent. I applied brief open qualitative interviews with some of the participants about their thoughts and experiences with regard to the MT intervention. The interviews were brief and methodologically informal and did not contain traditional measures of validation etc. (member-check) or formal analysis.

5.4.4 Stage 4: Pilot study 2

I carried out the second pilot study in the period from January to March 2010. The overall objective of the pilot study was to test out the final revision of the research protocol. As opposed to the first pilot study, all data collection was managed by a research-assistant. Besides the actual training and management of the data collection tasks, she was envolved in ongoing discussions, improvements, and testing of the data collection protocol including feasibility aspects. Hence, some of the specific objectives of this pilot study were to establish routines and test practical aspects regarding the protocol for the data collection. Likewise, the pilot study targeted towards continuous improvements of the MT intervention and the testing of a revised choice of measuring instruments for observed Child Distress (i.e. OSBD-R). Furthermore, in this pilot study I developed a measuring instrument for observed Positive Child Behaviour (see section 5.5.8). In addition, the pilot study provided me with important information and trends regarding the recruitment and occurrence of possible dropouts.

5.4.5 Outline of Revision of Study Protocol

After the commencement of the data collection, I made one major change in the study protocol in the form of extending the course of the data collection period with eigth month. Besides that, I made the following minor adjustments:

- Time measuring in Phases 1 and 2 in both groups (beginning from the 5th enrolled child)
- A separate sheet for optional written comments in the MT group (beginning from the 15th enrolled child)
- I changed the procedure for filling in of the additional MT satisfactory questionnaire. From the 15th enrolled child, only children 5 years and above rated *use-value* of the MT intervention together with their parents
- Registration of the child´s general level of anxiety/fear for previous needle procedures as rated by the parents group (beginning from the 38th enrolled child)
- A separate sheet for optional written comments in the control group (beginning from the 39th enrolled child)

In this section, I have outlined the overall development of the research protocol. In the following sections, I will present and clarify my choice of measuring instruments.

5.5

Measuring Instruments

In this section, I will account for the measuring instruments applied in the study. Initially, I will outline how the research literature was used to inform the choice of outcome domains and measuring instruments. Hereafter, I will present each of the applied measuring instruments[1].

The objective of the study was to examine the effects of MT as procedural support on acute and situational distress, anxiety, and pain among other things in response to a specific invasive medical procedure (i.e. IV-access). In short, I aimed at using valid tools, preferably ones that had already been translated into Danish and used in a Danish context. During the elaboration of the study protocol, the revision of outcome domains and measuring instruments were to a great extent informed by the recommendations proposed by:

- The English Medical Research Council, (MRC, 2006)
- The Pediatric Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials, PedIMMPACT (von Baeyer & Spagrud, 2006; McGrath et al., 2008; Stinson, Kavanagh, Yamada, Gill, & Stevens, 2006)
- The Society of Pediatric Psychology task force, SPP-ATF, (Blount et al., 2008; Cohen et al., 2008)
- van Dijk et al. (2002)
- Overview article of test instruments used by Journal of Music Therapy authors from 1984-1997 (Gregory, 2000)
- Plus clinical experience as a music therapist from the two pilot studies

In addition, during the elaboration of the study protocol, I discussed the choice of measuring domains and outcome measures with my supervisor, the MT working party at AUH, professor Cheryl Dileo, and peer researchers at the doctoral program for MT at Aalborg University (AAU).

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1 Througout the chapter, I will use the following terms synonymously in order to make variation: measuring instruments, tool, measuring tool, and measures.

In my effort to obtain a rigorous methodology, I gradually realised the complexity and many methodological challenges connected to the carrying out of this type of clinical *real world* research study. For example the nature of the IV-access procedures is obviously potentially unpleasant and painful. Therefore, the pain dimension of the procedures is likely to influence the remaining outcome measures (e.g. distress, anxiety, child compliance). Likewise, the age span of the participants (one to ten years) posed methodological challenges. Therefore, I aimed at using a methodology that was sensitive and able to capture this complexity. As to the pain dimension, Stinson et al. (2006) summarise three overall methodological approaches to the measuring of pain in relation to medical procedures involving paediatric patients. These are self-report, observation, and physiological measures. Consequently, it would be preferable to include all three approaches in an ideal study. However, the process of finding an optimal balance between a rigorous methodology and practicability, implied many trade-offs among methodological ideals, feasibility aspects, economics, and overall premises of the study. In short, as appears from the outline below, I used a combination of self-report and observation data. It turned out that I could not apply exclusively valid and reliable tools, mainly due to feasibility reasons. Moreover, my search for valid and feasible measuring tools did not identify Danish appropriate tools. Finally, blinding was not feasible partly given the nature of the MT intervention and partly due to economic reasons.

In summation, I applied the following measuring instruments in the study: the Observation Scale of Behavioural Distress-Revised (OSBD-R) (Elliott, Jay, & Woody, 1987), the single-item 100mm bipolar Visual Analogue Scale (VAS) (Wewers & Lowe, 1990), the Faces Pain Scale-Revised (FPS-R), (Hicks, von Baeyer, Spafford, van Korlaar, & Goodenough, 2001), a modified version of the latter, and a single-item 5-point Likert-type scale (Robson, 2011, pp. 304-305). Furthermore, I used count data, time measuring, and the Observation Scale of Positive Child Behavior (OSPCB). The latter is a scale made by the researcher for the purpose of the study. In the outline below, I have grouped the above-mentioned measuring tools according to the type of outcome domain following this progress:

- **Observed Child Distress**: as rated by the research-assistant (OSBD-R)
- **Observed and self-reported Child Anxiety**: as rated by research-assistant, parents, and physician (VAS, single-item) & Child (FPS-R, modified version)
- **Observed and self-reported Child Pain intensity**: as rated by research-assistant, parents, and physician (VAS, single-item) & Child (FPS-R)
- **Observed Child Compliance & Parent Compliance**: as rated by physician (VAS, single-item)
- **Self-rated Overall Satisfaction with IV-access Procedure**: as rated by the parents (5-point Likert-type scale, single-item)
- **Number of needle pricks**: as counted by research-assistant (count data)
- **Duration of Needle Procedure**: as measured by research-assistant (minutes/seconds)
- **Observed Positive Child Behaviour:** as rated by research-assistant (OSPCB)
- **Satisfaction with MT intervention:** as rated by parents and child

In short, based on the recommendations suggested by Stinson et al. (2006) and Cohen, Blount, Cohen, and Johnson (2004), I applied a combination of self-report and observational approach. Of these, three were single-item scales (e.g. VAS, FPS-R). In addition, I used hard measures in the form of count data (i.e. *Number of needle pricks* and *Duration* of medical procedure), which were based on observation other than overt child behaviour. As to *Child Anxiety* and *Child Pain intensity*, these outcome measures were recorded from four perspectives, namely as rated by the research-assistant, parents, physician, and children at the ages of five to ten. The rationale for this triangulation of raters was based on studies showing conflicting findings regarding (child) pain intensity when comparing self-report, observational measures, and nurse ratings (Beyer, McGrath, & Berde, 1990; Chambers, Giesbrecht, Craig, Bennett, & Huntsman, 1999; van Dijk et al., 2002). In continuation of this topic, Cohen et al. (2004) suggest, on the basis of their study, that such conflicting results are likely to reflect that these overall methodological approaches (e.g. self-report, observational measures) discriminate between different *constructs* of pain and anxiety rather than expressing a true incongruence. In continuation of this, the PedIMMPACT (McGrath et al., 2008) recommendations stress the importance of including multiple outcome domains in relation to the measuring of transient pain during invasive medical procedures in paediatric patients. In short, based on the above-mentioned considerations, I chose

to apply a combination of self-report and observation. Similarly, as put forward by the MRC, I applied a range of measures in order to grasp and identify a broader range of the possible effects of the MT intervention (MRC, 2006, p. 7).

5.5.1 Observed Child Distress

I chose distress as the primary outcome measure for several reasons. Based on the theoretic framework of the study (Caprilli et al., 2007; Malone, 1996; Pfaff et al., 1989; Whitehead-Pleaux et al., 2006; Whitehead-Pleaux et al., 2007) plus my clinical experience from the pilot studies, I found distress very relevant in the context of the PIVA procedure. Furthermore, observed distress can be assessed by a standardised measure that is valid for all the participants in the study regardless of the age span. Finally, observed distress comprises aspects of both pain behaviour and anxiety.

As to the measuring of distress, I initially considered a number of standardised tools. In the previous chapter, the literature review showed an application of a variety of tools in the MT studies (e.g. Caprilli et al., 2007; Malone, 1996; Pfaff et al., 1989), among other things the Predominant Behaviors Category List (PBCL), the Amended Form of the Observation Scale of Behavioral Distress (OSBD-A), the Nurse Assessment of Pain Inventory/Index (NAPI), and the Observation Scale of Bahavioral Distress (OSBD), (Elliot et al., 1987). In my search of measuring instruments, I also consulted my supervisor Søren Rittig, the head physician of the unit. However, he was not familiar with this kind of tools. Eventually, during the elaboration of the study protocol, I identified the review article of the SPS-ATF group (Cohen et al., 2008). Based on a comprehensive systematic review, the authors propose appropriate measuring tools for paediatric pain. Informed by this article, I applied the revised version of the Observation Scale of Behavioural Distress (OSBD-R), which they classify as a well-established tool (Cohen et al., 2008, p. 9)2. The OSBD-R is an observational scale developed to measure children´s behavioural responses in the context of painful medical procedures. It consists of eight operationally defined behaviour categories. The tool was originally

2 *Please note, in their article, the PedIMMPCT group does not recommend the OSBD-R as a well-established tool (von Bayer & Spagrud, 2006, p. 146). This disagreement is due to differences in terms of focus, objectives, and field of application of the two articles.*

developed for children with cancer undergoing bone marrow aspiration. The behavioural categories were originally continuously rated in 15-second intervals by a trained observer by means of live observation. The eight categories are: Information seeking, Cry, Scream, Physical restraint, Verbal resistance, Seeks emotional support, Verbal pain, and Flail (Elliott et al., 1987, p. 546). However, I added an extra behavioural category, Apathy, which I will account for below. The operational definitions of the nine behavioural categories are provided in table 5.1, which illustrates the time sampling version of the OSBD-R used in Phases 3 to 5.

Table 5.1. Illustration of the time sampling version of the OSBD-R data collection sheet, including definitions of behavioural categories. Reprint from Elliott et al. (1987, p. 546).

Category	**Definition**	**Examples**	**30 sec**	**1 min**	**etc.**
1. Information seeking	Any question regarding medical procedure	"Is the needle in?"			
2. Cry	Onset of tears and/or low-pitched nonword sounds of more than 1-second duration				
3. Screem	Loud, nonword, shrill vocal expressions at high pitch intensity				
4. Physical restraint	Child is physically restrained with noticeable pressure and/or child is exerting bodily force and resistance in response to restraint				
5. Verbal resistance	Any intelligible verbal expression of delay, termination, or resistance	"Stop" "I don´t want it"			
6. Seeks emotional support	Verbal or nonverbal solicitation of hugs, physical or verbal comfort from parents or staff	"Mama, help me" Pleading to be held			
7. Verbal pain	Any words, phrases, or statements in any tense which refer to pain or discomfort	"Ouch" "My leg hurts" "That hurt"			
8. Flail	Random gross movements of arms, legs, or whole body	Kicking legs; pounding fists			
Additional 9th category: Apathy	Shutting off, foraway look in the eye and/or resigned				

According to Cohen et al. (2008), the OSBD-R and the original non-revised version of this (OSBD) are among the most widely applied observational measuring tools in paediatric procedural studies. Furthermore, Cohen et al. recommend the OSBD-R and classify it as a *well-established* measuring instrument, which has proved valid and reliable (i.d. internal consistency r=0.72, inter-rater reliability = 80 to 91%, concurrent validity = 0.20 to 0.76 (Cohen et al., p. 5).

I translated the OSBD-R into Danish, but did not make a back-translation by means of a skilled bi-lingual person (as opposed to the FPS-R, Hicks et al., 2001). Specifically, the OSBD-R was rated using live/direct observation before, during, and after the IV-access procedure. This choice related to ethical concerns as well as logistics and economic aspects. As to the former, I feared that the use of video recordings would reduce the families´ willingness to participate in the study in that their children would be recorded under potential distress and pain. I feared that the economic limit of the PhD study would be exceeded if the following costs were added: the costs of video ratings made by two extra persons plus the costs of research-assistants collecting the data and finally the unknown sum multiplied by 124 participants.

5.5.1.1Modifications:

In the context of the PhD study, I applied the OSBD-R with the following modifications. Based on the clinical experience from the pilot studies, I added *Apathy* as an extra behaviour category. Besides that, I partly used time sampling in the form of 30-second interval ratings of the OSBD-R in order to obtain more precise data, as recommended by the PedIMMPACT group (von Baeyer & Spagrud, 2007). However, on the basis of the second pilot study, I found that time sampling across all phases was not manageable for the research-assistants. Therefore, I restricted to use of time sampling to the phases that I found most critical in relation to the IV-access. These were *Phases 3* to *5*, which will be explicated later in section 5.6. To obtain adequate precision, the research-assistants were cued every 30 seconds by an mp3 player (Philips GoGear 2 GB and Sweex 2 GB). As to the remaining phases (i.e. *Baseline Phase*, *Phases 1* and *2*), each behaviour category of the OSBD-R was rated as occurring or non-occurring. Finally, I did not use weighting of the OSBD-R behavioural categories.

5.5.1.2 Scoring Procedure:

As appears from figure 5.7, in accordance with the OSBD-R definitions, the research-assistants recorded overt child distress behaviours continuously in all phases by means of marks on the OSBD-R data collection sheet (table 5.1). The statistical preparation and calculation of the OSBD-R scores will be described in the last part of the method chapter (section 6.6).

5.5.2 Child Anxiety

Based on the literature review, the reviewed studies (Pfaff et al., 1989; Whitehead-Pleaux et al., 2006; Whitehead-Pleaux et al., 2007), my clinical experience from the pilot studies, and the PedIMMPACT recommendations (McGrath et al., 2008; p. 777), I measured *emotional response* in addition to pain intensity. This was done in the form of acute anxiety, distress, and positive child behaviour. As to acute anxiety, I searched for standardised measuring instruments during the preparation of the study. A number of observational and self-report anxiety tools were applied in the needle procedure-related MT studies that were included in the literature review (Kain et al., 2004; Pfaff et al., 1989; Robb et al., 1995; Whitehead-Pleaux et al, 2006; Whitehead-Pleaux et al. 2007). Among these were the Faces scale for Fear (Katz, Kellermann & Siegel 1982), the Fear Thermometer, the State-Trait Anxiety Index for Children (STAIC), and the Yale Preoperative Anxiety Scale (Kain et al., 1995; Kain et al., 1997). Of these, I found the STAIC relevant and in accordance with my aim at applying standardised tools. However, during the second pilot study, I appraised that inclusion of the STAIC in addition to the battery of measures would result in overload of the already busy research-assistants. Likewise, I feared that the parents would feel overburdened. After thorough consideration, I chose another solution, which was feasible but methodologically inferior.

I used a combination of 100mm bipolar Visual Analogue Scales (VAS) and a modified version of the Faces Pain Scale Revised (Hicks et al., 2001). I applied the VAS[3] as a global scale or proxy measure for child anxiety. The VASs were filled in by the research-assistant, parents, and physician. Originally, the FPS-R is developed for measuring pain.

3 *In the remaining part of the thesis, I will refer to the VAS as a global scale or a proxy measure (and not as a self-report measure), unless otherwise specified.*

Due to lack of a similar easily manageable measure for anxiety, I modified and translated the original English version of the FPS-R (5th version, August, 2007, www.painsourcebook.ca) into Danish and applied it as a self-report measure for anxiety in the participants, who were five to ten years old. Specifically, the valid version of the FPS-R was used to measure pain. Next, anxiety was measured using the modified version. Although the solution of using a modified version of the FPS-R for anxiety and VAS as a global scale implied a methodological weakness, it had important practical advantages. First, the VAS made it feasible to measure anxiety in all the children. Second, use and re-use of the same scale for the measuring of anxiety and pain eased the instruction and demand for the participants and parents. Now I will account for the use of the FPS-R and VAS in the mentioned order.

5.5.2.1 Self-Report of Anxiety:

I applied a modified version of the FPS-R as a measuring tool for children´s self-report for acute anxiety. As will be described further below (section 5.5.3), the FPS-R is a standardised tool for the measuring of acute pain intensity. It is valid for children from age 4 and upwards (Hicks et al., 2001) and has been used in several medical studies (Stinson et al., 2006). Further details are provided in section 5.5.3. The FPS-R consists of six line drawn faces ranging from a face with a neutral expression to a face of intense pain (see figure 5.2).

Figure 5.2. Illustration of the Faces of the Faces Pain Scale-Revsed.

In the study, the research-assistant managed the instruction and use of the modified version of the FPS-R scale for the measuring of anxiety. The actual wording of the Danish version is provided in Appendix 5. In the following, I have provided an English translation of the applied wording:

Introduction: Now I would like to show you the same drawing again.

Now the faces show how afraid one can be – that is not what one looks like, but how one feels inside!

Wording/instruction: **This face** [point to left-most face] **shows that one is not afraid at all**.

The faces show that one is gradually more afraid [point to each from left to right] **up to this face** [point to right-most face], **it shows that one is very much afraid.**

If these faces were you, how afraid were you when the physician stuck you? That is not what you looked like, but how you felt inside? (Hicks et al., 2001)

As described above, I used the 100mm bipolar Visual Analogue Scale as a global observation scale with a view to measuring acute anxiety. The VASs were rated by the research-assistants, parents, and physicians, respectively. I searched the literature for valid and easily applicable tools for measuring observed anxiety. I chose to measure anxiety by means of a VAS due to the lack of a more feasible and better measure. From a practical point of view, the VAS has a number of weighty advantages. The VAS is widely used and is free for use. It is easy to use in practice and yields data at interval/ratio level. But, as described further below there are no research-based recommendations to support the use of the VAS for this purpose. As to the use of the VAS as a global scale for observed *pain*, van Dijk et al. (2002) pointed out important validity and reliability drawbacks. Thus, I find it reasonable to assume a similar methodological drawback in the use of VASobs for observed *anxiety*. However, this approach and usage of the VASobs also had important advantages. First of all, I chose the VAS for pragmatic reasons and feasibility (e.g. ease of use, low cost, widely used in a Danish context). The use of the VAS with an identical wording also allowed me to assess, compare, and triangulate anxiety ratings from three different types of adult raters (i.e. research-assistant, parents, physician). As to the above-mentioned methodological downsides, I took measures to partly counteract observer bias by providing global rating questionnaires with the following introduction. The VAS is depicted in figure 5.3, which also holds a short introduction text plus the specific applied wordings.

Figure 5.3. Visual Analogue Scale for adult-rated Child Anxiety plus introduction text and specific wording.

(Put one clear cross (right) on the line).

To what extent did you experience that the child was afraid during the needle procedure (average/overall evaluation of the child´s behaviour, body language, and verbal expressions)?:

Not afraid at all *Much afraid*

As to the calculation of the VAS scores, I measured the distance in millimetres (i.e. from the left endpoint up til the mark drawn by the rater).

5.5.3 Child Pain Intensity

Based on the literature review, the reviewed MT outcome studies (Caprilli et al., 2007; Pfaff et al., 1989; Whitehead-Pleaux et al., 2006; Whitehead-Pleaux et al., 2007), my previous clinical experience, and not least the recommendations proposed by the PedIMMPACT group (McGrath et al., 2008; p. 777), I measured *pain intensity*. Furthermore in the PhD study, pain intensity constituted one of the core outcome measures, which had the potential of influencing the scores of the remaining outcome measures (e.g. distress, anxiety etc.). Initially, I considered a number of faces pain scales that were applied in the pain related MT studies in the literature review as well as in the broader paediatric research literature (Caprilli et al., 2007; Malone, 1996; Whitehead-Pleaux et al., 2006; Whitehead-Pleaux et al., 2007). In these MT studies, the Wong-Baker FACES Pain Scale (Wong & Baker, 1988), the Fases Pain Scale (Bieri, Reeve, Champion, Addicoat, & Ziegler, 1990), and the Faces Scale for Pain (Katz, Kellermann, & Siegel 1982) were referred to. Furthermore, I also considered the institutionally applied faces pain scale of the paediatric department at AUH, which is used for clinical pain for pain management purposes. But it turned out to be the Faces Pain Scale by Bieri et al. However, I deselected these pain scales in that they comprise a *smiling* face

reflecting “no pain”, which has been found to compromise their validity (e.g. Chambers et al., 1999; Chambers & Craig, 1998; Keck, Gerkensmeyer, Joyce, & Schade, 1996, p. 25). Furthermore, during the elaboration of the study protocol, I subsequently discovered the PedIMMPACT and SPP-ATF review articles (e.g. Cohen et al., 2008; Stinson et al., 2006). Based on these recommendations, I finally chose the Faces Pain Scale Revised (FPS-R) (Hicks et al., 2001) due to its psychometric properties and superiority and translated it into Danish. However, in addition, I used 100mm bipolar Visual Analogue Scales (VAS) as a global observational scale of pain intensity, since the FPS-R is not feasible or valid for the youngest participants in the study. Hence, the VASs allowed to record observed pain intensity in all the participants and were rated by the research-assistants, parents, and physicians using an identical wording. In the following, I will now account for the choice of these two measures.

Self-Report of Pain Intensity: Following the PedIMMPACT and SPP-ATF recommendations (Stinson et al., 2006), I measured pain intensity via self-report, using the FPS-R (Hicks et al., 2001) in participants at the ages 5 to 10 years. The FPS-R is a standardised self-report measuring tool of acute pain intensity in children aged from 4 or 5 and upwards (Hicks et al., 2001). It has been widely used in a number of studies to measure acute procedural pain as well as post-operative and disease-related pain (Stinson et al., 2006). It consists of six line drawn faces ranging from a neutral face to one of intense pain (see figure 5.4).

Figue 5.4. Illustration of the Faces of the Faces Pain Scale - Revised.

Specifically, I used the Danish version of the FPS-R, which is provided in Appendix 4. A reprint of the original instruction and wording of the English version of the FPS-R (www.painsourcebook.ca, Edition 5, August 2007) is provided in the following:

In the following instruction, say “hurt” or “pain” whichever seems right for a particular child.

“These faces show how much something can hurt. This face [point to the left-most face] **shows no pain. The faces show more and more pain** [point to each from left to right] **up to this one** [point to the right-most face] **– it shows very much pain. Point to the face that shows how much you hurt** [right now].”

Score the chosen face **0**, **2**, **4**, **6**, **8**, or **10**, counting left to right, so “0” = ”no pain” and “10” = “very much pain”. Do not use words like “happy” and “sad”. This scale is intended to measure how children feel inside, not how their face looks.

The SPP-ATF (Cohen et al., 2008) classifies the FPS-R as a well-established measure for pain. Likewise, it is recommended by the PedIMMPACT (Stinson et al., 2006; McGrath et al., 2008). According to Cohen et al. (2008) and Stinson et al. (2006) it has proved valid and reliable in a number of studies (e.g. concurrent validity 0.84 to .99; inter-rater reliability 0.84 to .99). Besides the psychometric and methodological properties, the FPS-R has additional advantages. It has been translated into more than 30 languages and can be obtained and used for free (www.painsourcebook.ca).

Translation and Validation of the FPS-R: As mentioned, the FPS-R is translated into 30 languages, but not into Danish. Hence, preparatory to the first pilot study, I performed a two-way translation. In accordance with the official translation requirements stated by the www.painsourcebook.ca, I followed this progression:

(1) I translated the FPS-R (5th version, 2007) instruction and wording from English into Danish. In that process, I adapted the instruction and wording to the context of the study

(2) I secured that the translation was suitable for children at the ages three to eight in the form of two group discussions with nurses at AUH

(3) I had the Danish version back-translated by a skilled bilingual person (i.e. professor Lars Ole Bonde) in order to detect accuracy and possible misinterpretations (Appendix 6)

(4) I compared the two versions and tested out the Danish version in 7 children at the ages six to 11 plus their parents (Appendix 7)

Global Observational Scale Rating of Pain Intensity: as mentioned above, the FPS-R is not feasible or valid in children under four years. Therefore, I also applied 100mm bipolar VASs as a global observational scale for ratings of child pain intensity. The VASs served as a proxy for child pain intensity and were rated by the research-assistants, parents, and physicians. The VAS is a validated measuring tool for children´s self-report of pain intensity (Cohen et al., 2008; Stinson et al., 2006, pp. 151-153). However, its psychometric properties as a global observational scale is still unclear due to the lack of sufficient studies examining its psychometric properties (van Dijk et al., 2002). Based on the their review on the use of the VAS as a global scale in paediatric pain literature, van Dijk et al. (2002) found great variability in terms of inter-rater reliability (i.e. 0.36 to 0.91), correlation between VAS and self-report (0.23 to 0.83), and concurrent validity (0.42 to 0.86). Consequently, the PedIMMPACT do not at present recommend the use of the VAS as a global scale (McGrath et al., 2008). But in spite of that, I chose to use the VAS due to pragmatic and feasibility reasons including its simplicity and ease of use. However, I took measures to partly counteract observer bias by providing the VAS with the introduction text and specific wording depicted in figure 5.5.

Figure 5.5. Visual Analogue Scale regarding adult-rated Child Pain plus introduction text and specific wording.

(Put one clear cross (right) on the line).

To what extent do you think that the child experienced pain during the needle procedure (give an average/overall evaluation of the child´s experience of pain):

No pain ——————————————— *Worst imaginable pain*

As to the calculation of the VAS scores, I measured the distance in millimetres (i.e. from the left endpoint up to the mark drawn by the rater).

5.5.4 Child Compliance & Parent Compliance

Although *compliance* was not included as an outcome measure in the reviewed MT outcome studies the PedIMMPACT recommendations (McGrath et al., 2008), I found *child compliance* and *parents compliance* important on the basis of the two pilot studies. In the study, the physicians rated Child Compliance and Parent Compliance by means of 100mm bipolar Visual Analogue Scales. In spite of the validity problems described above (cf. van Dijk et al., 2002), I chose to use the VAS as a global observational scale due to pragmatic reasons given above (i.e. its simplicity and feasibility). In practice the physicians received a document comprising four VASs i.e. one for anxiety, pain, child compliance, and parent compliance. The VAS regarding Child Compliance is depicted in figure 5.6, which also holds the specific wordings. For general information, the VAS for Parent Compliance was identical except that “child” was changed to “parent”.

Figure 5.6. Visual Analogue Scale regarding physician-rated Child Compliance plus introduction text and specific wording.

Please put four clear crosses in all (right) on the line below the following questions and then return this document to the research-assistant before you leave the treatment room.

During the IV-access procedure, I experienced the child as:

Very compliant Very non-compliant

As to the calculation of VAS scores, I measured the distance in millimetres (i.e. from the left endpoint up til the mark drawn by the physician).

5.5.5Overall Satisfaction with the Intravenous Access Procedure

On the basis of the pilot studies and in accordance with the consensus statement proposed by the PedIMMPACT group (McGrath et al., 2008, p. 776), I measured *Overall Satisfaction* with the IV-access procedure in the form of parents´ ratings. However, the consensus statement does not provide any specific recommendations in terms of standardised tests for *Overall Satisfaction*. Thus, I made a balanced five-point Likert-type scale, which consisted of a single Likert item[4], which I planned to analyse as ordinal data. Specifically, I used the following wordings in the satisfactory questionnaire and Likert-item:

We kindly ask you to fill in this questionnaire, and only make one mark. How satisfied are you generally seen with the way the needle procedure was performed?: *Very satisfied*, *Satisfied*, *Neither/Nor*, *Unsatisfied*, and *Very Unsatisfied*".

4 *A Likert item is a question or statement that the research subject is asked to answer on the basis of subjective or objective criteria in terms of his/her level of agreement or disagreement. The Likert item is bipolar in that it contains a number of positive and negative categories (Robson, 2011, p. 304-305).*

5.5.6 Number of Needle Pricks

With inspiration from Malone (1996), which I reviewed in section 4.3.1, I recorded the *Number of needle pricks* during the IV-access procedure (i.e. Phase 3). Data were collected by the research-assistant by simple counts. In the study, I defined a *needle prick* as each time the needle was inserted through the skin and subsequently removed entirely again.

5.5.7 Duration of the Intravenous Access Procedure

Likewise, inspired by the Malone (1996) study, I recorded their duration of the IV-access procedure. This was done by the research-assistant in minutes and seconds using a simple digital stopwatch. In the recording of duration, two different types of digital stopwatches were used (i.e. Select).

5.5.8 Observed Positive Child Behaviour

Based on the experience gathered during the pilot studies and the recommendations of the PedIMMPACT group (McGrath et al., 2008), i.e. *emotional response* in the form of *maintenance of positive affects*, I found it important to include an outcome measure related to *positive affect* (as opposed to the 11 MT studies contained in the literature review). Initially, during the second pilot study, I considered inclusion of observational coping measuring instruments such as the Behavioural Approach-Avoidance and Distress Scale (BAADS), (Hubert, Jay, Saltoun, & Haye, 1988), the Child Adult Medical Procedure Interaction Scale- Revised (CAMPIS-R), (Blount et al., 1997) and the short form of this tool the CAMPIS-SF (Bount, Bunke, Cohen, & Forbes, 2001). However, I deselected these scales due to two main reasons. First, I appraised that they would require too much additional time for training, which my time schedule did not allow. Second, I did not use video clips but direct/live observation for the rating of distress. Thus, I feared that adding another type of observational scale would be impossible to manage in practice for the research-assistants. Consequently, during pilot study 2, the research-assistant and I discussed how the ratings of positive affects could be added in the design in a feasible manner. Finally, I chose a non-validated methodological weak but feasible solution in the form of the Observation Scale of Positive Child Behaviour (OSPCB), which I developed with

assistance from the research-assistance during the second pilot study. Specifically, we found a practical solution that enabled us to incorporate the distress scale (OSBD-R, Elliott et al., 1987) and the OSPCB into the same rating sheet, which made simultaneous ratings of both measuring instruments manageable.

Due to the feasibility reasons given in section 5.5.8, the OSPCB was recorded with 30-second intervals during the IV-access procedure (i.e. Phase 3) and the subsequent *Recovery Post-Needle Period* (i.e. *Phases 4* and *5*) similarly to the distress scale (OSBD-R, Elliot et al., 1987). The purpose of prioritising the use of interval ratings during most phases was to obtain more precise data in these critical phases of the IV-access procedure. The registration of the OSBD-R and the OSPCB was synchronised and cued every 30 seconds by means of a musical cue via an mp3 player (GoGear 2 GB and Sweex 2 GB). As to the *Baseline Phase* as well as *Phases 1* and *2*, each behaviour category of the scale was rated as occurrence or non-occurrence.

The OSPCB consists of the seven operationally defined behavioural categories *Smile*, *Laughter*, *Humour*, *Positive vocal/verbal comments*, *Play*, *Physical activity,* and *Music and singing*. The operational definitions of the seven behavioural categories are provided in table 5.2, which illustrates the time sampling version of the OSPCB used in *Phases 3* to *5*.

Table 5.2. Illustration of time sampling version of the OSPCB data collection sheet, including definitions of behavioural categories.

Category	Definition	Examples	30 sec	1 min	etc.
1. Smile	Child smiles				
2. Laughter	Vocal sounds				
3. Humour	Funny comments or jokes				
4. Positive vocal/ verbal comments	Positive vocal or verbal comments	"Yippiee! The needle prick, I made it"			
5. Play	Play (exclusive musical play) with toys or objects alone or with others				
6. Physical activity	Voluntary bodily display alone or with others	Dance			
7. Music and singing	Active musical behaviour	Any initiative/ suggestion and/or musical participation for instance move the foot/body in time to the music			

5.5.8.1 Scoring Procedure:

As will be explicated in section 5.6 and graphically illustrated in figure 5.7, the OSPCB was rated continuously before, during, and after the IV-access procedure by by means of live/direct observation. The research-assistant scored the OSPCB as follows. In accordance with the OSPCB definitions, the research-assistant recorded all overt positive behaviours by a mark on the OSPCB data collection sheet (table 5.2). The statistical preparation for and calculation of the OSPCB scores are accounted for in section 6.20.

5.5.9 Satisfaction with Music Therapy Intervention

In order to examine the participants´ satisfaction with the MT intervention, I carried out a satisfactory survey in the MT group. The survey consisted in a questionnaire with the following three questions:

- Would you prefer music therapy during a future IV-access procedure?

  No__ Yes__ Don´t know__

- Would you recommend music therapy during IV-access procedures to others?

  No__ Yes__ Don´t know__

- Giv an overall appraisal of how useful the music therapy has been for your child in relation to your visit in the day unit (during the waiting period, needle procedure, and until now):

  Very useful__ Useful__ Neither useful nor unuseful__ Unuseful__ Very unuseful__

5.6

Protocol for Data Collection

Based on the theoretical framework of the study and the two pilot studies, I developed the protocol for the data collection. In the first pilot study, I collected all data as opposed to the second pilot study in which this task was managed by research-assistant 1. As to the subsequent main study, all data were collected by four trained research-assistants following three overall *periods* i.e. *Pre-needle Period*, *Needle Period*, and *Recovery Post-Needle Period*. These three overall *periods* comprised seven specific pre-defined *phases* or time points (i.e. *Introduction Phase*, *Baseline Phase*, and *Phases 1* to *5*, respectively). During these seven *phases* or measuring points the research-assistant recorded various data, which I will clarify in this section. Initially, I will define each of the seven *phases* in table 5.3. In addition, I will present a corresponding graphical illustration of these *periods* and *phases*, including an overview of when and with which tools data for the 16 outcome measures were assessed. Next, I will clarify how the research-assistants were trained. Finally, I will shortly describe how the research-assistants instructed the children, parents, and physicians to fill in the questionnaires. For general information, the data collection process in the two groups was identical. Furthermore, during the course of data collection (period), no changes were made in the routine of the carrying out of the IV-access procedures at the nephro-urological outpatient unit at AUH. But initially, as mentioned, I will now provide an outlined the three *overall periods* and seven *phases* during which the data were collected.

Table 5.3. Overview of sequence of periods and phases during the data collection.

PRE-NEEDLE PERIOD

Introduction Phase

Introduction to study, incl. verbal confirmation of consent and information regarding result of randomisation

Starts: in the waiting/treatment room before Baseline Phase

Ends: immediately before Baseline Phase

Baseline Phase

Starts: in the waiting or treatment room approximately 5 minutes before either:

1) the onset of the MT intervention (MT Group only) or

2) before the medical personnel calls the child to the treatment room (Control group only)

Ends: after 3 minutes´ observation (by research-assistant)

Phase 1: Waiting phase

Starts: immediately after Baseline Phase, in the waiting or treatment room

Ends: when the physician enters the treatment room

Phase 2: The physician´s information phase

Starts: when the physician enters the treatment room

Ends: at the commencement of the positioning of the child (i.e. in a lying position in the hospital bed, where the IV-access procedure is performed)

NEEDLE PERIOD

Phase 3: The actual needle procedure

Starts: when the child has been positioned in the hospital bed

Ends: after completion of IV-access procedure, when the bandage has been placed

RECOVERY POST-NEEDLE PERIOD

Phase 4: Recovery phase

Starts: when the bandage has been placed and after completion of questionnaires

Ends: after 3 minutes´ observation (by research-assistant)

Phase 5: Recovery phase, continued

Starts: immediately after Phase 4

Ends: after seven minutes´ observation (by research-assistant)

Based on table 5.3, I will now clarify when and which data the research-assistant collected during the *seven phases*. Please remember that the data collection in the two groups followed the same sequence and procedures. In the *Introduction Phase*, the research-assistant met with the enrolled children and parents in the waiting room. Initially, the research-assistant obtained verbal consent, summated important aspects of the information brochure including that participation in the study was voluntary and the right to withdrawal, and that only 50% of the participants would be allocated to the MT group. Next, the research-assistant clarified his/her role and independence of the hospital. Subsequently, she/he recorded the following demographical and medical data:

- Name
- Gender
- Age
- Nephro-urological diagnoses
- Duration of course of disease
- Number of previous in- and outpatient admissions
- Number of previous needle procedures
- Administration of EMLA cream prior to the IV-access procedure

After completion of the *Introduction Phase*, the research-assistant observed the participants individually throughout the *Baseline Phase* and *Phases 1* to *5*. Besides making his/her own ratings and recordings of the data, the research-assistant guided the child, parents, and physician how to fill in the questionnaires, which I will clarify later in this chapter. The *Baseline Phase* was employed to examine whether the initial levels of observed *Child Distress*, *Child Anxiety*, and *Positive Child Behaviour* in the two groups were somewhat similar with an eye to informing the subsequent statistical analyses. In short, data were collected via a battery comprising observation scales, self-report questionnaires, and count data. Of the 16 outcome measures, 14 were related to Phase 3 (i.e. the actual needle procedure) and were rated upon completion of this phase (i.e. Child Distress, Child Pain, Child Anxiety, Child Compliance, Parent Compliance, Number of needle pricks, During of needle procedure, Positive Child behaviour). Of these 14 outcome measures, three were also registered during the *Baseline Phase* and *Phases 1* to *5* (i.e. research-assistant-rated: Child Distress, Child Anxiety, Positive Child Behaviour). Finally, parent-rated *Overall Satisfaction* with IV-access procedure was rated upon completion of *Phase 5*. Likewise, data for the supplementary *MT satisfactory survey* were collected upon completion of *Phase 5*.

Cf. section 5.5, the measuring time point of the 16 outcome measures can shortly be outlined as follows:

- **Observed Child Distress (OSBD-R)** (main outcome measure): rated throughout Baseline Phase and Phases 1 to 5 by the research-assistant
- **Child Anxiety (VAS & FPS-R)**: rated upon completion of Phase 3 by the research-assistant, parents, physician & child. Moreover, the research-assistant rated Child Anxiety in relation to Baseline Phase and Phases 1, 2, 4, and 5
- **Child Pain (VAS & FPS-R)**: rated upon completion of Phase 3 by the research-assistant, parents, physician & child
- **Overall Satisfaction with IV-procedure (5 point Likert-type Scale)**: rated upon completion of Phase 5 by the parents
- **Child Compliance** and **Parent Compliance (VAS)**: rated upon completion of Phase 3 by the physician
- **Number of needle pricks**: registered during Phase 3 by the research-assistant
- **Duration of needle procedure (minutes/seconds)**: registered during Phase 3 by the research-assistant
- **Positive Child Behaviour (OSPCB)**: rated throughout Baseline Phase and Phases 1 to 5 by the research-assistant
- **Satisfaction with music therapy intervention:** rated by parents (and child)

In addition to the description above, I have illustrates the applied measuring instruments and time points of assessment related to the 16 outcome measures graphically in figure 5.7. Please recall, that in both groups data were collected following the same sequence.

Figure 5.7. Overview of measurement instruments and time measuring points of assessment of the 16 outcome measures.

I aimed at obtaining a methodology as systematic and consistent as possible. In that connection, some of the initiatives taken were a thorough training of the involved research-assistants, clear guidelines for their interaction with participants and the involved medical personnel, and standardised instructions regarding the questionnaires, which I will now clarify.

5.6.1 Training of Research-Assistants

Four trained research-assistants managed the data collection in the main study. They were neither music therapists (students) nor affiliated to the hospital. The research-assistants were recruited on basis of grapevine via my social network. As described below, all research-assistants received adequate training before they were practically involved in the management of the data collection. Research-assistant no. 1 (Tine Espelund Klausen) collected data in relation to the nine first enrolled participants. Research-assistant no. 2 (Birgitte Uggerhøj) collected data in relation to three children and functioned as substitute for assistant no. 3 and 4. Research-assistant no. 3 (Maria Munkholt) observed 12 children and finally assistant no. 4 (Ole Madsen) observed 13 children.

Research-assistant no. 1 (Tine Espelund Klausen) not only underwent training with an eye to collecting data. She was also involved in the process of testing methodological refinements and feasibility issues during the second pilot study. Altogether, she was trained and involved in a 10-weeks´ period prior to the commencement of the main study. In this period she received the following training:

(1) Employment interview including introduction to study

(2) Second employment interview including further elaboration of the work tasks, video excerpts illustration of IV-start procedure etc.

(3) Initial exhaustive survey of observation scales and questionnaires

(4) Four visits and guided tours to the nephro-urological in- and outpatient unit at AUH

(5) Passive observation of three IV-access procedures without filling in measurement tools

(6) Training in filling in observation scales and questionnaires in practice during three IV-access procedures

(7) Ongoing debriefings in order to improve practical aspects of the data collection process

(8) Discussions related to revision of tool including layout aspects

(9) Ongoing debriefing with an eye to improving practical aspects of the data collection process and cooperation with medical personnel

Research-assistant no. 2 (Birgitte Uggerhøj) received the following training over a period of four consecutive days:

(1) Day one: initial exhaustive survey of observation scales, and questionnaires

(2) Day two: (next day) observation of two IV-access procedures

(3) Day two: subsequent debriefing and survey of the battery of measures (after observation of medical procedure)

(4) Day three: (two days later): a last survey of the battery of measures immediately before the start of data collection

Research-assistant no. 3 and 4 (Maria Munkholt and Ole Madsen) received the following training over a three to four weeks´ period:

(1) An individual employment interview including introduction to study

(2) Second individual employment interview including further elaboration of the work tasks, illustration of video excerpts of IV-access procedures

(3) Initial exhaustive survey of measures

(4) Four visits and guided tours to the nephro-urological out- and inpatient unit at AUH

(5) Passive observation of five IV-access procedures without filling any measuring tools

(6) Testing out of questionnaires in practice at six IV-access procedures

(7) Ongoing debriefings with an eye to improving practical aspects of the data collection process and cooperation with medical personnel

5.6.2 The Role of the Research-Assistants

Based on the two pilot studies, I defined the role of the research-assistants as stated below. This was explained and stressed during the training of the research-assistants. In addition, as a precautionary measure, I explicated the role of the research-assistants as the first item on the front page of the research-assistants´ data collection sheets. On this first page, I stated the following:

- As an observer you are supposed to be present as a fly on the wall, but you may “fly around”
- You may not join in singing
- You may not comment or appraise the process nor the children´s reactions e.g. encourage or praise the child if he/she is doing fine during the needle procedure
- You may not initiate conversations, but only give short polite answers to questions asked by the child, family, and staff

5.6.3 Additional Aspects of the Protocol for the Data Collection

Besides the methodological measures described above, I employed other means to secure a consistent methodology in relation to the collection of data. As to the research-assistants, I provided clear short written descriptions, instructions, and reminders on every sheet of the data collection battery (i.e. data collection sheets). Likewise, as to the questionnaires filled in by the children, parents, and physicians, I provided a standardised short concise written introductory description plus practical instruction in regard to how the questionnaire should be filled in. The intention of this measure was to improve the validity of the questionnaires. In relation to the handing out of questionnaires, I instructed the research-assistants to speak shortly and friendly using terms such as "*Now, I will ask you to fill in this questionnare*" and subsequently "*Thank you very much*". In the case parents raised questions regarding the filling in of the questionnaires, the research-assistants were instructed to give a short adequate explanation. As opposed to this, the instructions to the children´s ratings of anxiety and pain were given exclusively orally. But still, the research-assistants read out a fixed written instruction (see sections 5.5.3 and 5.5.2.1).

As to the rating of Observed Child Distress and Positive Child Behaviour during Phases 3 to 5 in 30-second intervals, I equipped the research-assistants with an mp3 player. For this purpose, I made a sound track, which contained musical cues that were faded in every 30 seconds. However, the musical cues were faded out again after five seconds in order to allow the research-assistants to hear any sounds in the treatment room.

As mentioned above, research-assistants no. 3 and 4 managed the data collection in relation to the majority of the participants. As will be addressed later in sections 5.12.3.5 and 6.22, I computed inter-rater reliability between these two assistants. However, the calculation was done retrospectively and based on data collected in the last part of the data collection period. Finally, as clarified, I chose to use in vivo rating. Consequently, the research-assistants were present before, during, and after the IV-access procedure and could not be blinded.

5.7 Participants

The participants were 41 children at the ages of one to ten having various nephro-urological diseases. All participants were admitted to the outpatient day unit at the paediatric nephro-urological unit at AUH in the period between May 21 2010 and March 7 2011. The children were admitted for a planned initial IV-access procedure preparatory to a subsequent scheduled diagnostic kidney scanning at the medical nuclear department elsewhere in the hospital. Two third of the participants had various nephrological diseases, whereas the remaining third had various urological diseases. Moreover, the duration of their course of disease varied. The participants came from different parts of Jutland, but were admitted at the nephro-urological unit at the paediatric department at AUH, which serves as a regional medical centre for children with these diseases. The 41 participants consisted of 14 (34%) boys and 27 (66%) girls. The majority of the children were between one and five years old. In the total sample, the mean and *SD* for age were 3.91 (2.54) years. Of the 41 children, 21 were randomised to the MT group and 20 to the control group. In addition, as will be addressed in the result chapter (section 6.3), the demographical characteristics and medical history of the participants did not differ statistically significantly between the two groups in terms of duration of course of disease, numbers of previous inpatient admissions, and number of previous needle procedures. However, the numbers of previous outpatient admissions between the two groups differed statistically significantly.

In the following subsection, I will account for the inclusion and exclusion criteria, the specific diagnoses, and the prospective calculation of sample size.

5.7.1 Inclusion and Exclusion Criteria

The inclusions criteria were:

- Children one to ten years old with various nephro-urological diseases
- Outpatients admitted at the nephro-urologic outpatient unit at AUH
- Speak and/or understand Danish (parents/guardians and child if verbal)
- Normal hearing
- Parents/guardians have received written and oral information about the study
- Obtained written and oral consent with signature of parents/guardians

The exclusion criteria were:

- Previous participation in the study
- Known psychiatric diagnose(s)
- Chronic pains
- Significant visual and auditory impairments
- Significant cognitive deficits

5.7.2 Diagnoses

Of the 41 children, 29 had various nephrological diseases, whereas the remaining 13 children had various urological diseases. However, four of the children had two nephrological diagnoses. Finally, the diagnoses of three of the participants were not recorded. The medical terms of the specific diseases (Latin) are listed below according to the frequency with which they occurred in the participants:

Nephrological Diseases

- Urinary tract infections Acute infection in the upper urinary system (Acute Pyelonephritis) (20 children)
- Other diseases erroneously recorded (four children)
- Glomerulonephritis chronica without specification (two children)
- Hæmolytisk uræmisk syndrome (one child)
- Tubulointerstitiel kidney disease other type(one child)
- Morbus cysticus renis without specification one child)

Urological Diseases

- Congenital and functionally related deformities in the form of congenital hydronephrosis (dilatation of the urinary tract) (ten children)
- Duplex kidney (two children)
- Neoplasma benignum renis (one child)

5.7.3 Protocol for Dropouts

As will be described in section 5.11, the parents of the participants were informed verbally and in written about their right to withdraw from the study at any point without consequences for the child´s present or future treatment. The protocol for attrition was as follows. In the case a child or his/her parents wished to withdraw from the study, the child would keep his/her assigned randomisation number and the research-assistants were to record all voluntary and involuntary cases of withdrawals. In addition, as long as the child and/or parents wished to explain their reasons for withdrawal in a voluntary way, the research-assistants were instructed also to record their reasons.

5.7.4 Power Calculation

Before commencement of the pilot studies and the main study, I made a power calculation in order to determine the size of an appropriate sample. For this purpose, I used the Italian study by Caprilli et al. (2007)[5] on music distraction during venipuncture in paediatric patients, which I reviewed in section 4.3. In their study, Capprilli et al. applied an amended version of the Observation Scale of Behavioral Distress-Revised. Their results showed a positive small to moderate effect of music distraction on observed distress (Cohen´s *d*=0.39). I calculated the sample size with consultancy from a skilled MT researcher (i.e. Christian Gold). Specifically, we based our calculation on the distress scores from the above-mentioned *During venipuncture phase* (Caprilli et al., p. 401). However, I used a more conservative effect size combined with a power level of 90% and a significance level of 5%. The result of the power calculation was (*n*=124), 62 children in the MT and the control group, respectively. The sample size calculation was made in STATA, release 10.1 for Macintosh.

5 *Caprilli et al. (2007) is an outcome study on the effect of active music at venipuncture in 108 un-premedicated children 4-13 years old.*

5.8

Protocol for Recruitment

During the two pilot studies, I developed the protocol for the recruitment. In the first pilot study, I administrated the recruitment myself as opposed to the second in which I trained the co-ordinating nurse (Anne Aagaard Laursen) to manage this task with a view to the main study. She worked in the paediatric nephro-urological unit as well as in the related outpatient day unit. The latter was the site where the data were collected. In order to maximise the number of enrolled participants, I made great efforts to optimise the recruitment protocol. One of the initiatives was to make a professional information brochure about participation in the study (Appendix 8). The brochure was made by a photographer and a graphical designer affiliated to AUH´s communication department. Another measure to enhance the recruitment was to specify a deadline for feedback in the brochures that were sent to all eligible children. In continuation of this, in the case they did not reply before the specified deadline, a telephonic call was made by the co-ordinating nurse.

In the main study, the co-ordinating nurse mainly managed the recruitment. If she was ill, on holiday or if a family needed to be contacted hastily, I functioned as a backup measure. Specifically, the recruitment procedure was carried out as follows. Seven to ten days ahead the co-ordinating nurse screened the list of children who were scheduled to attend the nephro-urological outpatient unit in order to undergo an IV-access procedure. Based on the inclusion and exclusion criteria, she assessed whether they could be included in the study. During the data collection period, all eligible children were invited to participate in the study by means of a physical or electronic copy of the information brochure. Furthermore, the brochure contained the consent form (appendix). As mentioned above, a deadline for feedback was specified in the brochure. In the few cases where families could not be contacted in advance, they were invited to participate in the study after arrival at the unit. In these cases, the research-assistant gave a short initial verbal summation of the information brochure in the waiting room. Next, she/he obtained written consent before the child was enrolled in the study.

Some days, up to five children were scheduled for kidney scanning's in the same morning. In practise, this meant that the physicians sometimes needed to perform more IV-access procedures at the same time or within a limited time frame. This meant that in some cases more eligible children were admitted to IV-access procedures than was feasible to manage for the research-assistants and the music therapist. Consequently, the co-ordinating nurse made an additional prospective appraisal of the logistic aspects in terms of enrolment. In case all eligible children could not be enrolled, we chose the combination of children that secured the largest number of participants feasible on the day in question. In addition, we deselected or rather postponed children who seemed likely to be scheduled for further IV-access procedures in the outpatient unit during the data collection period. Hence, to the extent possible, these children were invited to participate in the study at a later point. Finally, after the co-ordinating nurse had clarified the number of eligible children and estimated a likely time schedule, she notified the research assistants and the music therapist. Likewise, on the day of the IV-procedure(s), she indicated the number of enrolled children on the schedule list of the outpatient unit in order to let the medical personnel plan their work more efficiently. However, the result of the randomisation was not revealed to the medical personnel before the onset of the IV-access procedures.

5.9

Protocol for Randomisation

Random allocation is a key feature in randomised controlled trials (RCT). According to Robson (2011, pp. 81-93), adequate random allocation secures that participants are assigned by chance to the different conditions in a study. Hence, in well-performed RCT studies, selection biases can be avoided and possible group differences will be washed out. Consequently, this allows the researcher(s) to assume equality between groups, which has important methodological and statistical implications.

In the context of the PhD study, I used the CONSORT statement (Moher et al. 2010) as a methodological checklist to inform the choice of an adequate randomisation strategy. I used the SNOSE method as described by Doig and Simpson (2005). SNOSE stands for the abbreviation of **S**equentially **N**umbered **O**paque **S**ealed **E**nvelopes. It is a simple, cheap, and easily manageable randomisation method. According to Doig & Simpson (2005), the SNOSE method meets all the randomisation precautions outlined in the CONSORT statement (Moher et al. 2010). As the titel indicates, the SNOSE method both generates a sequentially numbered order and conceals this information cf. the opaque sealed envelopes. Besides the simplicity and applicability, the SNOSE method also has other practical advantages. The method is not dependent on a third party or any form of technology neither in order to generate the randomisation sequence nor in revealing the result hereof. Due to these advantages, I applied the SNOSE method to produce a simple restricted block randomisation, which I made in blocks of eight. In the second pilot study, I tried out the randomisation protocol in practice preparatory to the main study.

Specifically, I generated the random sequence and concealed envelopes following the SNOSE method. In short, I initially prepared two piles each with four pieces of carbon paper. As to the first pile, I wrote "*MT*" for music therapy on each carbon paper. As to the second pile, I wrote "*KT*" for control group on the remaining four carbon papers. Then, I wrapped the eight pieces of carbon paper in tin foil and returned them to their respective pile from which I

took them. Subsequently, I put each tin foil-wrapped carbon paper in separate envelopes, closed them, and shuffled the eight envelopes thoroughly. Next, I piled the eight envelopes. On the front side on each, I wrote a number in chronological order (starting with #1). These numbers functioned as the children's ID-numbers. Hereafter, I stamped the backside of each envelope.

During the course of the data collection period, the majority of the envelopes were opened by the co-ordinating nurse and the remaining envelopes by me. In practice, only three to five envelopes were opened at a time. The result of the randomisation sequence of the following three to five envelopes was communicated in advance to the research-assistants and the music therapist in order to improve planning and due to feasibility reasons. Likewise, one week in advance, the co-ordinating nurse also communicated the number of children, who were scheduled to undergo IV-access in the nephro-urological day unit. However, participants were not enrolled in the study, nor allocated to one of the two conditions until written and oral consent were obtained, in practice, this meant in the waiting room on the day in question. In addition, information regarding the result of randomisation was neither communicated to the medical personnel nor the participants. In the case that eligible participants could not be enrolled in the study contrary to expectation (e.g. due to cancellations of IV-procedures, business in the day unit etc.), the families were offered participation in the study at a later point if possible.

To sum up, the concealed envolopes were mainly opened by the co-ordinating nurse, who subsequently communicated the upcoming three to five results of the randomisation sequence. The result of randomisation sequence remained secret for the child and medical personnel until a few minutes before the onset of the MT intervention (MT group) and IV-access procedure (control group), respectively.

5.10

The Music Therapy Intervention

In this section, I will describe the applied MT intervention. I aim at providing a transparent and adequate description of the MT intervention following the recommendations for music-based intervention reporting as suggested by Robb and Carpenter (2009) and Robb, Burns, and Carpenter (2011).

5.10.1 Introductory Summation

In short, the MT intervention was designed to meet the clinical needs of the children and fit the IV-access procedure in the context of AUH. It was based on a multi-faceted theoretical framework as well as tested and adjusted during the two pilot studies. The MT intervention was performed individually and provided before, during, and after the IV-access procedure. The MT intervention was therapeutically guided by two clinical navigation tools in the form of an outline of therapeutic objectives and decision trees. The intervention can be defined as *Medical Music Therapy at a Supportive level* according to Dileo (1999, p. 8) and as *Music in Medicine on an augmentative level* according to Bruscia (1998, pp. 195-196). In addition, the specific MTPS approach can be defined as music alternaive engagement (MAE) according to Ghetti, (2012). Finally, according to English Medical Research Council (MRC, 2006, p. 7), the MT intervention is complex. It comprises several dimensions of complexity in terms of:

(1) The degree of flexibility of the intervention (e.g. individualised approach, several kinds of music experiences, use of verbal and musical interventions)

(2) The number of behaviours required by the music therapist (e.g. reflexivity, flexibility in the role and function of the music therapist, and flexibility in the tailoring of the overall therapeutic decisions and specific musical and verbal interventions)

The MT intervention was carried out in accordance with the rules and guidelines of The Danish Music Therapy Association by a trained music therapist (i.e. the undersigned), who has undergone a five-year Master´s programme in MT. Inspired by Robb´s (2000) contextual support model plus the MRC (2006), the MT intervention is designed on the basis of a clear and comprehensive theoretical framework, which is multi-faceted and integrative. In summation, the intervention was rooted in the following theoretical, clinical, and research-based perspectives and elements:

- The Gate Control Theory of Pain (Melzack & Wall, 1965)
- The Neuromatix Theory of Pain (Loeser & Melzack, 1999; Melzack, 1999; 2001)
- Trauma theory (Levine, 2006; Levine & Kline, 2007)
- Coping theory (Lazarus & Folkman, 1984; Siegel & Smith, 1989)
- Theorical aspects of MT as procedural support for invasive medical procedures (Fratianne et al., 2001; Loewy et al., 1997; Nguyen, 2005; Prensner et al., 2001; Shoemark, 1999; Turry, 1997; Walworth, 2003)
- Theoretical aspects of the role and functions of music (Altschuler, 1948; Brown et al., 1989; Edwards, 1999; Sheridan & McFerran, 2004)
- Properties of sedative music (Wigram et al., 2002; Wigram, 2004)
- Outcome studies on MT interventions during needle procedures involving paediatric patients (Caprilli et al., 2007; Malone, 1996; Pfaff et al., 1989)
- Theoretical aspects of distress, pain, and stress related to clinical practice in the form of behavioural-cognitive interventions for the reduction of suffering during medical procedures involving paediatric patients (Yong, 2005)
- Research-based clinical recommendation for venipuncture procedures involving paediatric patients (Cohen, 2008)
- Clinical MT supervision during the pilot studies and the main study (Maiken Bjerg, trained music therapist and SE therapist)

Finally, the description of the MT intervention is aided by video an excerpt, which illustrates the MT intervention in practice. The video excerpt is contained on the enclosed DVD (track 1).

5.10.2 Elaborated Description

After this above-mentioned summated presentation of the MT intervention, it is time to provide more detailed descriptions. Based on the literature presented in Chapters 2 to 4 and clinical experience from the two pilot studies, the MT intervention was individualised and provided before, during, and after the IV-access procedure (Caprilli et al., 2007; Cohen, 2008; Ghetti, 2012; Turry, 1997; Young, 2005). The objective of starting the MT intervention before the medical procedure was to establish rapport and resources more effectively as well as to facilitate the development of a musical relationship and musical experience in a non-threatening atmosphere (Dileo, 1999). According to the applied literature, initiation of the MT intervention prior to the medical procedure is stressed in order to minimise a possible conditioning between the MT intervention and the subsequent medical procedure (Cohen, 2008; Ghetti, 2012; Whitehead-Pleaux et al., 2007; Young, 2005). In practice, the MT intervention was initiated in and lasted throughout the *Pre-Needle Period* (i.e. *Phases 1* and *2*) in the waiting/or treatment room. It continued during the IV-access procedure (i.e. *Needle Period* alias *Phase 3*) and was likewise provided in the *Recovery Post-Needle Period* (i.e. *Phases 4* and *5*), which was defined as ten minutes after completion of IV-access procedure.

5.10.2.1 Music & Repertoire

The MT intervention was performed individually by one music therapist and can be defined as person-centered (Wigram et al, 2002, p. 66). Consequently, the intervention was primarily based on the child´s age, interests, preferences, type of coping style etc. The MT intervention comprised active and receptive types of music experiences (Dileo, 1999):

- Receptive (music listening)
- Re-creative (singing and/or playing pre-composed songs)
- Improvisation (on instruments)
- Composition (improvised songs)

The combination of these types of music experiences was coupled with a containing, warm and age-appropriate therapeutic approach to the child. This served the purpose of inviting and allowing the child (and parents) to

participate in different ways and to the extent suitable for the child in case the child was shy or introvert. Specifically, the music mainly consisted of preferred music in the form of well-known children´s songs and songs proposed or requested by the child and/or parents. In addition, the intervention comprised improvised songs and instrument playing. Almost all songs and music were accompanied by the music therapist on a guitar. In addition, the child and parents were provided with a small selection of instruments in order to support establishment of rapport, develop a music relationship, facilitate active engagement, and create an inclusive atmosphere. The instruments gave the child a non-verbal means of engaging her-/himself actively and of providing metaphorical opportunities to exercise control as emphasised by Sheridan & McFerran (2004, pp. 29-30). The selection of instruments counted a wooden xylophone, a small metalophone, a bongo drum, a couple of maracas, and a few other small percussion instruments. In addition to the musical equipment, colourful balloons were offered to the child when appropriate before, during, or after the medical procedure. Furthermore, small plastic toy animals and a magic wand were integrated into the musical experience to a minor extent.

During the two preparatory pilot studies and the main study, I developed a repertoire list, which I continuously updated during the main study. Appendix 9 provides a list of the songs according to the frequency by which they were sung. Occasionally, I used the repertoire list as an inviting catalogue from which the child and parents could choose their preferred songs. As to shy or introvert children, the repertoire list often had great use-value and served as a more secure means of communication, engagement, and autonomy. In addition, confer the decision trees (figures 5.9, 5.10, and 5.11), I often used the ISO-principle and the musical parameters for sedative music as suggested by Wigram et al. (2002, p. 144) and Wigram (2004, p. 115) with a view to regulating the child´s emotional state and arousal. To a minor degree, I used the complementary principle (Wigram et al. 2002).

5.10.2.2 The Role of the Music Therapist

The role of the music therapist was informed by Nguyen (2005) and Walworth (2003, 2005) plus clinical experiences from the two pilot studies, and the role can be defined as the child´s advocate. I met each child with a supportive, empathic, cheering, and encouraging holding. My role as a leader and follower was flexible and based on continuous appraisals (i.e. *reflixivity*) of the child´s personality, changing needs, type of coping style, applied coping skills and efforts etc.

5.10.2.3 Duration of the Intervention

The duration of the MT intervention varied from child to child since Phases 1, 2, and 3 were not limited in time as opposed to the remaining phases (i.e. Phases 4 and 5). Phases 1 and 2 depended exclusively on logistical and practical circumstances, which also applied to the control group. As will be presented in the Result Chapter (section 6.25.1) the mean and *SD* for durations of the MT intervention during Phases 1 and 2 were 17.93 (11.78) and 2.72 (2.65) minutes, respectively. Furthermore, the mean and *SD* for duration in Phase 3 were 7.28 (4.05) minutes. Finally, in both conditions Phases 4 and 5 were pre-defined to last three and seven minutes, respectively.

5.10.2.4 Therapeutic Objectives of the MT Intervention

The objectives of the MT intervention were based on the needs of the children before, during, and after the medical procedure as described in the theoretical framework that is Chapters 2 and 3 (e.g. Cohen, 2008; Ghetti, 2012; Turry, 1997; Young, 2005). These needs changed rapidly during the progression of the procedure (i.e. *Pre-needle period*, the *Needle Period*, and *Recovery Post-Needle Period*). In short, the overall therapeutic objectives of the MT intervention across these three overall periods were:

- To establish resources during the *Pre-Needle Period* and subsequently draw on them during the needle procedure
- Provision and support of the child´s coping skills
- Provide distraction in order to reduce perceived distress, anxiety, and pain
- To counteract possible short- and long-term detrimental effects and traumatisation
- Re-orientation

5.10.2.5 Clinical Navigation Tools

The MT intervention consisted of verbal and musical techniques and strategies. These were used in combination and supported each other mutually. Specifically, the MT intervention was to a great extent guided by two clinically navigation tools in the form of an outline of therapeutic objectives and three decision trees. These two tools were a clinically oriented condensed synthesis of the theoretical framework of the PhD study (cf. Chapters 2 to 4). Both tools were temporally divided equally before (*Phase 1* and *2*), during (*Phase 3*), and after (*Phases 4* and *5*)

the IV-access procedure. I used the outline and the decision trees in combination as a clinical navigation tool to inform the ongoing process of therapeutic assessment and appraisal of the child´s response and needs, referred to as *reflexivity* by Ghetti (2012). The outline mainly contains overall clinical objectives and suggestions for verbal techniques, whereas the decision trees mainly give an overview of useful musical techniques. In combination, they give an effective and clear overview of commonly prevailing clinical needs as well as suggestions for how these could be met by verbal and musical approaches and techniques.

The outline of therapeutic objectives is displayed in figure 5.8. The specific verbal techniques and wordings were based on clinical supervision and the theoretical framework as presented in Chapter 3 (Cohen, 2008; Turry, 1997; Young, 2005).

Phases 1 & 2

1. Introduction and information
Presentation to the family

Possible questions and additional information

Explication:
- MT will be offered in all 4 phases, and can be paused/stopped on request
- No expectations for the child: Let´s see how (the child) reacts to the music without expecting that he/she shall act in a specific way.
- The important thing is that your child feels safe, and senses that he/she is not expected to participate or react in a certain way when I begin to play

2. Establishing rapport
- Establishing rapport with emphasis on security and trust
- Gain insight in the child´s live-world, family, interests, wishes & personality

3. Establishing resources
Relationship to music/music preferences
- Which songs/what music do you like?

Identify interests, preferences and leisure activities
- What makes you happy?
- What do you like the very best?

Relationship to favourite pets, teddy bears & transitional objects:
- Discussion about the qualities that they contain (faithful, power, wildness, comfort etc.).
- How do you du notice that it/they love you?

Ability to demonstrate boundaries between power and wildness
- Identification with hero icons e.g. Superman
- Fencing, karate etc.

Identify favourite physical activities:
Dance, play, playground, sucker etc. regarding establishment of joint references focusing on vigour, possibilities, joy and power in using ones body freely.

Possible current special occasions:
Important events, birthday, feasts, vacations etc.

4. Establishment of a musical relation
- Singing, musicking, improvising on instruments

5. identifying the child´s feelings/thoughts
- Have you tried to be stuck (in the hand) before?
- How do you feel about getting stuck - are you nervous or scarred?I know you are to be stuck, and/so I will be here to help you
- Are there particular songs you would like to hear during the procedure

6. Offering help
- I will accompany you in the treatment room
- If we help each other everything will be easier
- When the physician sticks you your role will be to focus on me and/or to the music.

Phase 3

1. Draw on resources established in phase 1 & 2
Refer to music, songs, pets, stuffed bears, family members etc.
e.g.:
- Do you remember that you liked the X-song?
- Let´s play it again shall we?/Would you like to ply it again?
- Can you think of a song that can comfort you/make you feel better?

2. Create calmness and counterpoise
Create calmness as counterpoise to possible changes of pace and in interpersonal dynamics (child, parents & staff).

3. Re-orientation
Support the child in re-orientating in time and place in connection to positioning on the hospital bed:
- Look, now you will be sitting/laying on the bed.
- Mom and dad are right beside you.
- I would like to sing a song for you while you are in the bed.

4. Regulation of emotions and arousal level
Use of ISO principle to regulate emotions, arousal level and respiration via the structure, rhythm and pace of the music.

5. Explanation of the necessity of the procedure
- It is necessary that you are stuck so the physicians can help your kidneys feel better
- Nu you will get a tap in your hand so the kidneys can drink some water.

6. Containment and validation of the child´s experience
Mirroring and containment of the child´s emotions verbally and musically with an eye to support and empathy:
- Year, it is strenuous, but necessary.
- Yes, we/I know that it hurts but/so I will try to make it more pleasant for you.

6. Refocusing
- Many children here in the hospital find it helpful to watch me or to listen to the music during the procedure.
- Try to look at your mother/father/bear (and listen to the music) until it is over.

7. Promotion of control
Information about the course of the procedure:
- I´ll inform you when the physician is finish with the procedure.
- In a moment every thing will be just fine (again).
- In a moment there will be no more sticking.

8. Reassurance & comfort
- Shouldn´t we ask the physician to stick as gentle as possible?
- Do you want mom/dad to comfort/hug you now?

Phases 4 & 5

1. Placing the procedure in the past
- Now it is ***completely*** over
- Now the physician is ***completely*** done
- Now you will not be stuck anymore.
- Now it will not hurt anymore.

2. Create calmness, regulation of emotions & arousal
Singing songs associated with safety:
- Do you remember the for X-song that you liked?
- Shall we sing it again (before I have to go in a while)?

Use of ISO to regulate emotions, arousal & respiration.

3. Comfort & praise
- Do you know how you could feel glad again/better again?
- Would you like mom/dad to comfort you?
- Is there a song that can comfort you
- Is there a song that you would like to hear now?
- You made it so good (even though it was hard/difficult).
- You are just brave/cool (even though it was hard/difficult).
- If someone asked me to make a song about you it would be about how brave you were. For even though it hurt you made it so good. I think it would be/sound like this…..

4. Re-orientation in time and place
- Now it is over with the sticking part.
- Now the needle is placed in the yellow box
- Now the physician says goodbye.
- Now there will only be us in the room.
- You can stay here until you go to the other unit in the hospital.

5. Re-integration of senses
- How is the arm now?
- Is it better/good again?
- Does it still hurt?

6. Re-framing & processing of the procedure
About the necessity and goal of the procedure:
- I know it was hard/annoying for you. But it was necessary in order to the physician to help your kidneys feel better.
- Encourage the parents to debrief about the process of the procedure with the child after arrival to home.
- And ask the child when he/she began to relax/realised that the procedure ended.

7. Restoration of safe relation to parents
- Would you like mom/dad to comfort/hug you now?
- Would it be pleasant for you if mom/dad joined singing now?

8. Finally restoration of resources
Refer to resources (songs, pets, bears, family members etc.):
- Do you remember that you liked the X-song?
- Would you like to sing it again (before I will/shall go to another child at the hospital in a while)?
- What are your plans for today after you finish at the hospital?
- Do you look forward to go home after the kidney scanning?

Figure 5.8. Overview of overall and specific phase-wise therapeutic objectives of the MT intervention.

In practice, the objective and choice of strategy were highly dependent on the child´s age, its previous history of invasive medical procedures, and type of coping style and coping skills. In the following, I will restrict myself to describe some of the most commonly prevailing needs exhibited by the children in the MT group. During Phases 1 and 2 (i.e. before the IV-access procedure), the MT intervention was primarily concerned with establishing rapport and resources as well as building up a musical relationship. During Phase 3 where the children were pricked, some of the overall objectives were to counterbalance possible stressful implications of the medical procedure, provide distraction and to promote the child´s sense of control. Specifically, these therapeutic goals were met by drawing on resources established in Phases 1 and 2. Likewise, reassurance plus regulation of emotions and arousal played an important role during the medical procedure (i.e. Phase 3).

After completion of the IV-access procedure, the overall objectives of the MT intervention changed. Dependent on the coping style and age, some children needed to process their experiences in relation of the medical procedure, whereas other needed to place the procedure in the past. Furthermore, some children needed support for re-integration of senses before they were ready to change focus and draw on recourses established prior to the medical procedure. Likewise, some children needed support in order to re-orientate properly in time and place due to the rapid change in pace experienced between Phases 2 and 3. As to the most vulnerable or affected children, regulation of emotions and arousal was useful as an initial strategy.

As mentioned by way of introduction above, the outline of therapeutic objectives and strategies was supplemented by and used in combination with three decision trees. The decision trees are a synthesis of the decision tree proposed by Shoemark (1999, p. 41) and the MAE-based sub-interventions proposed by Fratianne et al. (2001, p. 50). The decision trees structured the process of reflexivity and informed the therapeutic choices in terms of my musical behaviour and intervention. Specifically, I implemented seven of the nine specific MAE-based sub-interventions suggested by Fratianne et al. (2001, p. 50). In accordance with Fratianne et al., I incorporated the musical sub-interventions with an eye to facilitating and supporting active engagement (i.e. boxes 4 to 7). The sub-interventions offered the child a means of interacting regardless of which level he/she was able to or felt comfortable about. Likewise, the sub-interventions offered the child to engage in different types of musical experiences (Dileo, 1999, p. 6) and supported different types of coping styles (e.g. approach-avoidant). Consequently, the musical

sub-interventions functioned as a means of inclusion, promotion of emotional support, and active engagement in various ways, which turned out to be very useful in practice. In addition to the MAE sub-interventions (boxes 4 to 7), the decision trees contain three important elements. These are *Temporary pauses from MT* (box 1), *Establishing rapport* (box 2), and *Identifying child´s thoughts about procedure* (box 3). The decision trees are displayed in figures 5.9 to 5.11. They graphically illustrate the repeatedly circular process of reflexivity, which starts at the top of the decision trees diagrams.

Figure 5.9. Decision Tree Related to Phases 1 & 2.

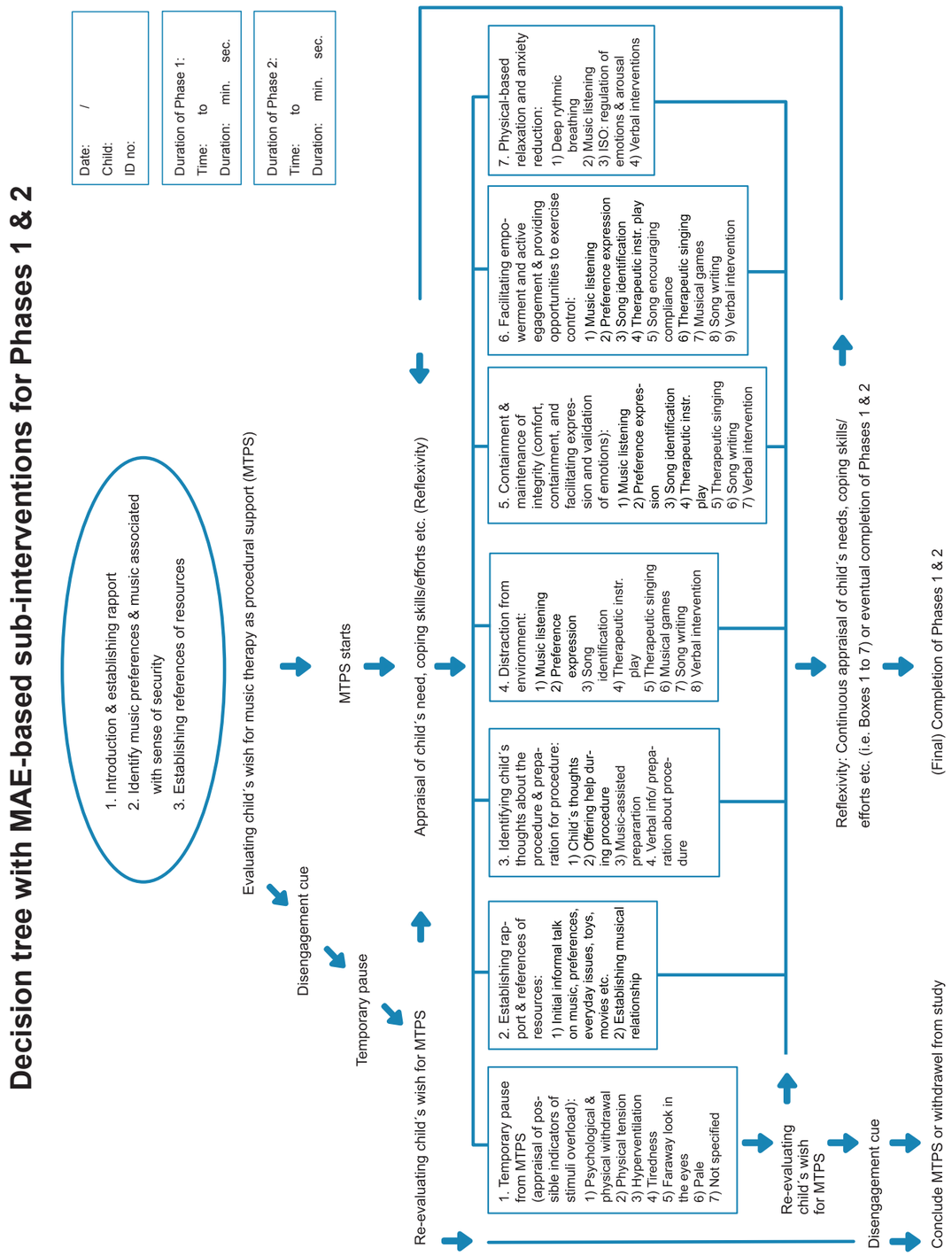


Figure 5.10. Decision tree for Phase 3.

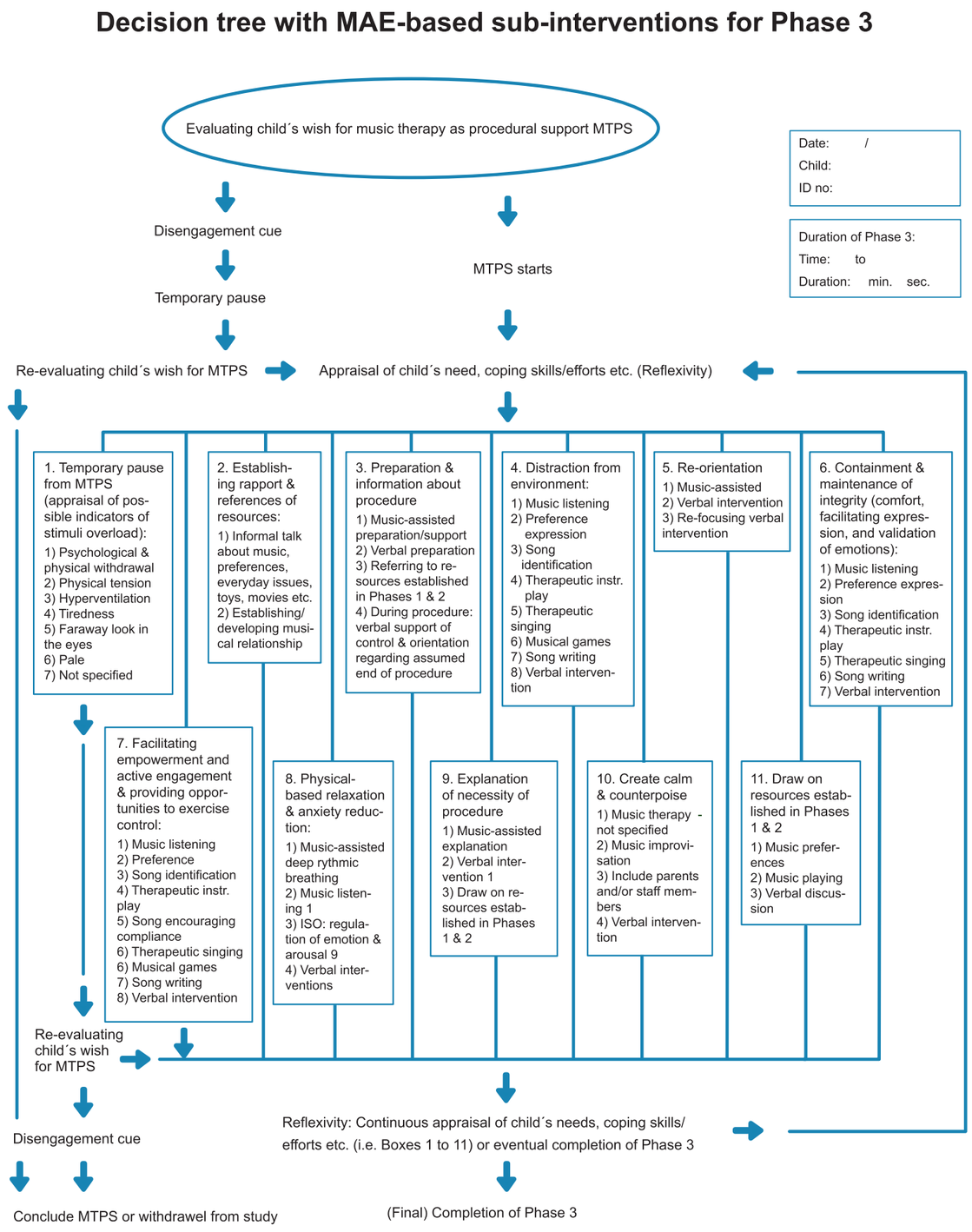
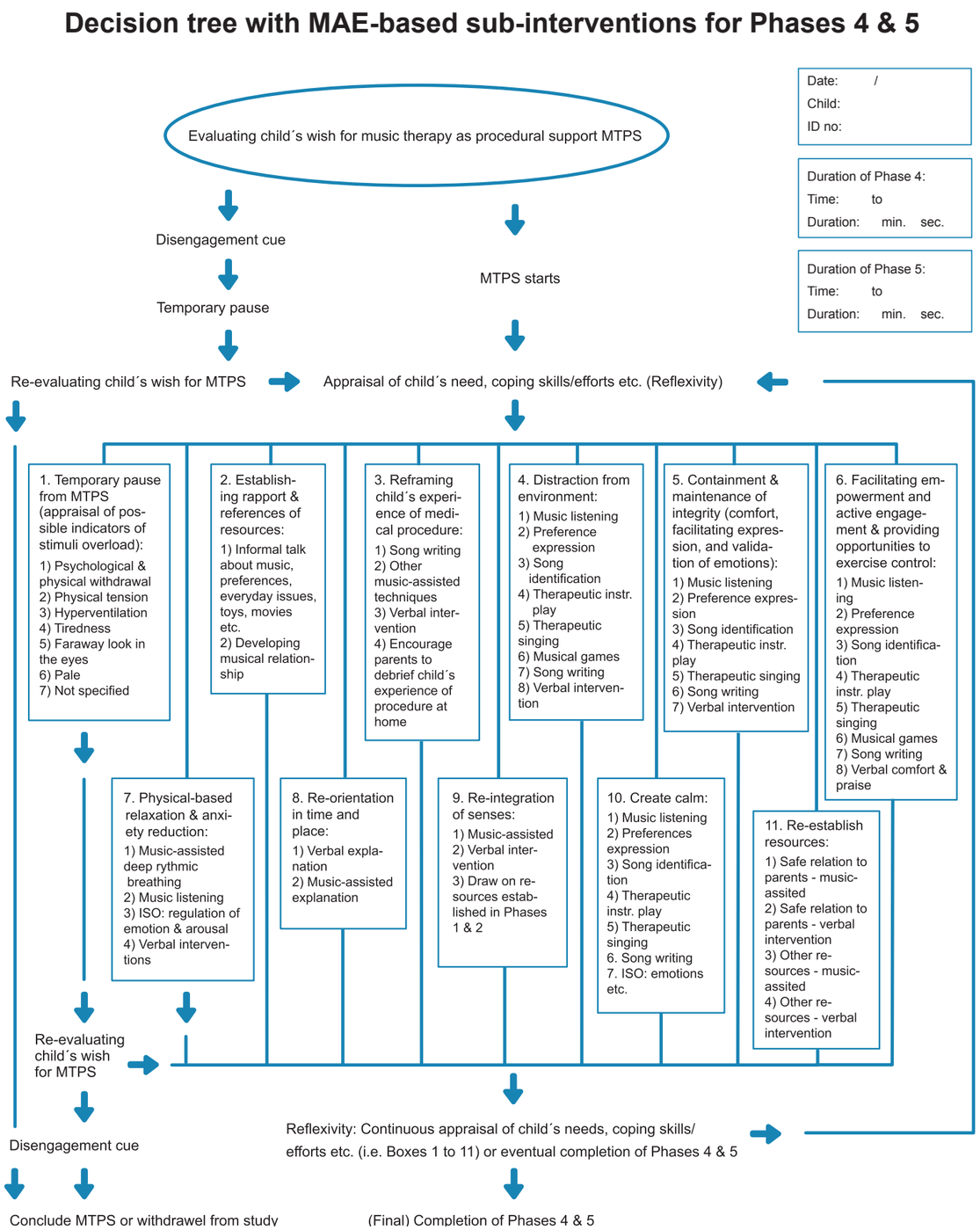


Figure 5.11. Decision Trees for Phases 4 and 5.



In conclusion, the applied MT intervention can be classified as a complex intervention, which was rooted in a multifaceted integrative theoretical framework plus clinical experience. The MT intervention was performed individually by a trained music therapist and provided before, during, and after the IV-access procedure. The intervention was child-directed, supportive, and age-appropriate in terms of music and verbal interventions. Finally, the MT intervention and the continuous process of reflexivity were guided by two clinical navigation tools, which supported each other mutually.

5.11

Ethics

In this section, I will present the ethical aspects of the PhD study. Initially, I will address myself to general ethical principles and precautions regarding research. Then follows an overview of ethical considerations and precautions taken in planning and carrying out the present PhD study. Next, I will shortly describe my applications for formal ethical approvals, which are followed by a short section holding a disclosure of rewarded fundings for the PhD project. Finally, in the last part of this ethics section, I will sum up the patient information material/brochure and consent form that were applied in the study. For general information, *translated excerpts from the information brochure and consent form are put in italics*.

5.11.1 General Research Ethics

Ethical considerations and precautions are crucial and mandatory components in all scientific research on humans. Within the international music therapy research community Cheryl Dileo has made important contributions to research ethics (Dileo, 2005). She stresses the importance of ethical reflections, considerations, and precautions as integral parts throughout the entire research process. Consequently, ethics should influence subject recruitment and selection, the treatment intervention(s), the overall implementation of the research study, research design and methodological aspects as well as the data analysis, and communication of the research project (Dileo, p. 226). Moreover, Dileo argues that the ethical responsibility of the researcher should embrace both the subjects of the study and the scientific community to whom the research is reported. She puts forward three overall ethical principles (based on the Belmont Report):

(1) Respect for persons - individual autonomy and protection of individuals having reduced autonomy

(2) Beneficence - maximising benefits and minimising harm

(3) Justice - fairness in distribution of research burdens and benefits

In practice the three principles entail the following research procedures: informed consent, privacy, confidentiality (respect for persons), risk/benefit analysis and evaluation of scientific merit (beneficence), and review of subject selection (justice) (Dileo, 2005, p. 226).

5.11.2 Ethical Approvals and General Ethical Precautions

In the present PhD study, the above-mentioned ethical considerations and precautions served as ideals for me. The research protocol was approved by the following agencies and conducted in accordance with the ethical standards listed below:

1. Institutional Review Boards at Aalborg University

- The board affiliated to the doctoral school in music therapy at Aalborg University (AAU) (review of the initial elaborated proposal including the ethical aspects)
- Human Research Ethics Board (HREB) at the Faculty of Humanities, AAU

2. Approvals from Official Danish Research Agencies

- The Scientific Ethical Committee for Central Denmark Region
- The Danish Data Protection Agency

3. Other Ethical Standards Followed

- Helsinki II declaration
- Research ethics guidelines and rules of the Danish Music Therapy Association (MTL)

Based on the above-mentioned initiatives, I aimed at securing an ethical codex as high as possible during the entire research process for many reasons. First of all, the study subjects were sick children and the research took place in a naturalistic setting, in which illness and the IV-access procedures could pose potentially serious stressors to the children consequently causing pain, distress, and general inconveniences. This meant that the participants in the study were potentially vulnerable, which was reflected in the ethical considerations in general as well as in the clinical music therapy intervention. Therefore the ethical objectives were to reduce harm (and inconvenience) and maximise benefits as much as possible. Furthermore, I informed the participants that they would receive debriefing regarding the final results and conclusion of the study after completion of PhD defence. In this regard I stated that anonymity would be secured in all aspects in the communication of the study. Finally, all data containing personal information were stored in accordance with national laws (in a locked place).

5.11.3 Formal Statutory Ethical Acceptances

In agreement with The Scientific Ethics Committee of Central Denmark, Region, I sent a descriptive overview of the proposed study with an eye to applying for an initial evaluation of duty of notification. This enquiry (no. 112/2008) was made on 10, October 2008. On October 28 the committee replied saying that since the research project could not be classified as *Biomedical research*, a formal consent procedure was unnecessary according to the committee (cf. paragraph 8, subsection 1) (Appendix 10).

Furthermore, I obtained approval from The Danish Data Protection Agency to collect and store data with connection to the study (Appendix 10**)**.

Finally, I sent a post hoc application to the Human Research Ethics Board (HREB) at Faculty of the Humanities, Aalborg University. Note, the HREB was first commissioned after onset of the data collection in the PhD study. Hence, the application could not be sent prospectively.

5.11.4 Economic Transparency

The Danish Council for Independent Research, Humanities (FKK) financed almost the entire PhD project (salary, overhead, conference costs etc.). Furthermore, The Obel Family Foundation donated a supplementary part of the costs related to the data collection. A part from salary I had no economic or commercial interests the present research project.

5.11.5 Summated Presentation of Information Material

Prior to enrolment in the study, the associated co-ordinating nurse sent a copy of the information brochure (Danish), including the consent form (see Appendix 8) to the eligible participants. However, in a few cases families could not be contacted in practice before they attended the ward. In these cases the research-assistant gave a short verbal summation of the information brochure and the consent form was filled in before possible enrolment in the study. The topics and guideline provided in Dileo (2005) served as inspiration for the preparation of the information brochure. Here, I aimed to secure adequate (i.e. understandable and non-technical) and full information regarding the purpose of the study, procedures, risks, benefits, and other relevant aspects. What follows now are translated excerpts from the information brochure, relating specifically to the ethical aspects (Appendix 8, pp. 2-3):

"Month, date 2010 _____ (name of child) is to undergo a diagnostic kidney scanning at Aarhus University Hospital Skejby. The scanning implies an initial needle procedure at unit A8. In that connection we take the liberty of asking whether you would like to participate in a research study. The intention of the research study is to evaluate if music therapy has a positive impact on a child´s well-being, and ability to cope with the needle procedure….The information brochure describes what the study is all about, and what participation in the study will imply for you. You have at least two days for reflection. So do not feel pressed to answer right away. Participation in the study is voluntary. Regardless of your decision, your child will receive the same medical treatment".

Then I described the MT intervention and its objectives followed by this description of expected benefits and possible harms (Appendix 8, page 3):

"The music therapy offered in the research study intents to support child (and parents) emotionally and mentally with regard to the needle procedure. The music therapy is expected to help the child to reduce his/her experience of anxiety and pain…There are no expected harms in relation to the music therapy…However, it is important that especially the child is not negatively about music therapy or being exposed to music, which he/she does not like. If so, you have the right to either stop the music or completely withdraw from the study at any time without warning or reservation".

In the information brochure I also stated that participation in the study would imply only 50% probability of receiving music therapy, and a questionnaire´s burden of approximately five minutes´ duration. Likewise, I clarified that I had the obligation of confidentiality as well as access to the childrens´ medical records. The information brochure also stated that I would obtain information regarding name, age, date of birth, and diagnoses. The brochure also briefly outlined a plan for possible subsequent publication (articles in international and national journals, communication via the press etc.). In this connection anonymisation of the participant´s identity was explained. Next, I disclosed the receipt of financial support and made a final repetition of the right of cancellation additional practical information.

5.11.6 Consent Form

In accordance with official laws regarding research ethics, all participants should give written consent, which was stated in the information brochure. Here the participants were asked to indicate whether they wanted to participate in the study or not, and then return the consent form before the specified deadline in an enclosed pre-paid envelope. With inspiration from the topics addressed and described in Dileo (2005), the consent form was made. The overriding aim was to use an adequate, rather easily understood, and non-technical language. In addition, the research-assistant secured orally confirmation hereof after arrival to the outpatient unit on the day of the medical IV-access procedure. What follows now is a translated excerpt from the consent form reflecting the above-mentioned ethical aspects (Appendix 8, page 7):

"With our signature (parent/guardian) we hereby give informed consent to participate in the described scientific study: Music therapy as coping strategy at IV-starts in children (one to ten years) with kidney diseases. With our signature we moreover confirm that:

- We have read the above-mentioned information brochure
- We are informed that participation in the study is voluntary
- We are informed that we can withdraw our consent any time without any consequences for our child´s current or possible future medical treatment
- We are informed that there is only 50% probability of receiving music therapy under the IV-access procedure"

In the previous subsections, I addressed myself to and clarified important ethical aspects. Among other things, I described general ethical principles, attainment of formal ethical approvals along with ethical considerations and precautions taken in planning and carrying out the PhD study. Based on the various methodological aspects described so far in this chapter, I will now provide a summative methodological overview (table 5.4). Subsequently, I will present the prospective data analysis plan, according to which the statistical analyses were performed.

5.11.7 Methodological Outline

So far in this chapter, I have accounted for myriads of methodological aspects. In order to help the reader maintain an overview, I will now provide a summary in table 5.4.

Table 5.4. Summative methodological outline of the PhD study.

Outcome Measures & Measuring Tools	• **Observed Child Distress (OSBD-R)** (main outcome measure): rated throughout Baseline Phase and Phases 1 to 5 by the research-assistant • **Child Anxiety (VAS & FPS-R)**: rated upon completion of Phase 3 by the research-assistant, parents, physician & child. Moreover, the research-assistant rated Child Anxiety in Baseline Phase and Phases 1, 2, 4, and 5 • **Child Pain (VAS & FPS-R)**: rated upon completion of Phase 3 by the research-assistant, parents, physician & child • **Overall Satisfaction with IV-procedure (5 point Likert-type scale)**: rated upon completion of Phase 5 by the parents • **Child Compliance** and **Parent Compliance (VAS)**: rated upon completion of Phase 3 by the physician • **Number of needle pricks**: registered during Phase 3 by the research-assistant • **Duration of needle procedure (minutes/seconds)**: registered during Phase 3 by the research-assistant • **Positive Child Behaviour (OSPCB)**: rated throughout Baseline Phase and Phases 1 to 5 by the research-assistant • **Satisfaction with applied MT intervention:** rated after Phase 5 by parents (and children at the ages of five to ten)
Design & Randomisation	Design: Fixed/RCT pre-test/post-test and post-test experimental-control group design (Robson 2011). Participants were randomised to either group: 1. Control Group (standard IV-access procedure) or 2. MT Group (Standard IV-acces procedure plus MT procedural support) Randomisation: Simple randomisation in blocks of eight. Random allocation and concealment secured by means of the SNOSE method (Doig & Simpson, 2005).
Participants	Participants were 41 children having various nephro-urological diseases, who were admitted to the outpatient section at the nephro-urological paediatric unit at AUH. Inclusion criteria • Children 1-10 years old with various nephro-urologic diseases • Outpatients admitted for planned IV-access preparatory to kidney scanning • Speaks and understands Danish (parents/guardians and child if verbal) • Normal hearing (child and parents) • Adaquate information regarding participation in the study provided • Obtained written and oral informed consent from parent(s)/guardian(s)

	Exclusion criteria • Previous participation in the study • Known psychiatric diagnosis/diagnoses • Chronic pain • Significant visual and auditory impairments • Significant cognitive deficits
Recruitment	Participants were mainly recruited by the associated co-ordinating nurse, who worked at the outpatient unit. Otherwise, the researcher served as backup.
Setting	The IV-access procedures were performed by a physician and an assisting nurse in treatment rooms at the paediatric nephro-urological outpatient section at AUH.
MT intervention (independent variable)	A single individualised MT procedural support session performed by one and the same trained music therapist. The MT was provided before, during, and after the IV-access procedures. The intervention can be defined as *Medical MT at a supportive level* (Dileo, 1999, p. 8) and as *Music in Medicine at an augmentative level* (Bruscia, 1998, pp. 195-196). Sepcifically, according to Ghetti (2012), the applied intervention can be defined as *music therapy as procedural support* using an *MAE-based approach*.
Procedure	The IV-access procedures were performed by a physician and an assisting nurse. Data were collected by one of four trained research-assistants during seven pre-defined (i.e. *Introduction Phase*, *Baseline Phase*, and *Phases 1* to *5*), which can be classified in three overall periods (i.e. *Pre-Needle Period*, *Needle-Period*, *Recovery Post-Needle Period*). The MT intervention was performed by the one and same trained music therapist. All children were together with parent(s) before, during, and after the medical procedure.
Ethics	Before commencement of the study was launched, the following approvals were obtained: • The Scientific Ethical Committee for Central Denmark Region • The Danish Data Protection Agency • Human Research Ethics Board (HREB), Faculty of Humaities, Aalborg University (retrospective approval) In addition, written and orally informed consent from parents was obtained.

5.12

Protocol for Data Analyses

In this section I will present the protocol for the data analyses. It addresses and clarifies important aspects including data entry, data management, and the prospective data analysis plan.

5.12.1 Data Entry and Data Management

I entered data into my private laptop, using the computer programme Excel (release 12) for Macintosh. Next, I double-checked 100% of the data after 1-3 weeks assisted by one of the research-assistants. A comma separated version of the Excel data file was then loaded into SPSS version 19 for Macintosh as well as STATA release 10.1 for Macintosh. Along the data analyses process I computed new variables, which I made in SPSS and in the Excel file. In order to avoid possible mistakes I also subsequently double-checked this data. I made the statistical analyses in SPSS, whereas all figures were made in STATA.

5.12.2 Prospective Data Analysis Plan

Before analysing data, I formulated a prospective data analysis plan. The plan was based on the CONSORT statement (Moher et al. 2010), two preparatory pilot studies, discussions at PhD seminars, and statistical consultancy (Kasper Klitgaard Berthelsen, associate professor, Department of Mathematical Sciences, AAU). Likewise, data analyses were performed under supervision of the same statistician. The purpose of the analysis plan was to clarify and define how data should be analysed appropriately in order to evaluate the effect of MT. In short, I inspected the data set graphically and by means of descriptive analyses. Then followed the main analyses, which were meant to evaluate the effect of MT on the selected outcome measures. In addition, I estimated and tested each outcome

variable under correction for four pre-defined explanatory variables in order to examine whether the effects were due to other reasons than group differences (MT versus control group). The four explanatory variables were *Age*, *Previous number of Needle procedures*, and *Needle pricks with/without EMLA*. In addition to these main analyses the prospective data analysis plan contained a supplementary satisfactory survey of the MT intervention, which I analysed by means of descriptive statistics.

I selected the applied explanatory variables based on a combination of the clinical research literature, clinical observations during pilot and main study, statistical consultancy, discussions with supervisor and the physician associated to the study as well as discussions at PhD seminars. In short, I controlled for *Age*, since the clinical research literature indicates that younger children exhibit more observed distress, anxiety, and pain than do older children (e.g. Malone 1996; Caprilli et al. 2007; Young 2005; Fowler-Kerry & Lander 1989; Cohen 2008). In addition, these research findings were also consistent with the researcher´s clinical experience from the pilot and main studies.

On the basis of the clinical research literature *Needle pricks with/without EMLA* was chosen as an explanatory variable due to the researcher´s clinical experience as well as the research literature where this topical anaesthesic has been found effective in reducing pain (Arts et al. 1994; Fetzer 2002). Pain was one of the central outcome measures in the study, which furthermore was assumed to have a potential impact on all other outcome variables. *Previous number of needle procedures* was chosen due to the clinical research literature demonstrating the imminent danger of traumatisation due to painful medical procedures (e.g. Young 2005; Cohen 2008). The results of the classification, and statistical definition of the explanatory variables are described in section 6.5. Finally, I deselected the following variables as explanatory variables based on the research literature: size of needle, duration of course of disease, gender, numbers of previous admissions, physician, and use of toys during IV-procedure (e.g. Malone 1996; Caprilli et al. 2007) as well as discussions and professional inputs (e.g. my supervisors, statistician, group discussion at PhD seminars).

Table 5.5 displays the 16 outcome variables, their characteristics according to which phase(s) they were analysed.

Table 5.5. Summation of the prospective analysis plan of the 16 outcome variables.

Outcome variable	**Measure,** measurement level	**Analyses according to phase(s)** (time measuring point)
1. Research-assistant-rated Child Distress	OSBD-R, interval	Phase 3 & Phases 1-5
2. Research-assistant-rated Child Anxiety	VAS, interval	Phase 3 & Phases 1-5
3. Research-assistant-rated Child Pain	VAS, interval	Phase 3
4. Child-rated Anxiety	FPS-R, interval	Phase 3
5. Child-rated Pain	FPS-R, interval	Phase 3
6. Parent-rated Child Anxiety	VAS, interval	Phase 3
7. Parent-rated Child Pain	VAS, interval	Phase 3
8. Overall satisfaction w. procedure	Likert-type Scale, ordinal	Upon completion of Phase 5
9. Physician-rated Child Anxiety	VAS, interval	Phase 3
10. Physician-rated Child Pain	VAS, interval	Phase 3
11. Physician-rated Child Compliance	VAS, interval	Phase 3
12. Physician-rated Parent Compliance	VAS, interval	Phase 3
13. Number of needle pricks	Counts, interval	Phase 3
14. Duration of medical procedure	Minutes, interval	Phase 3
15. Positive Child Behaviour	OSPCB, interval	Phase 4 & Phase 5
16. Satisfaction with MT intervention	Yes/no/don´t know and 5-point Likert-type scale	Phase 5

Note: FPS-R= Faces Pain Scale Revised, OSBD-R= Observation Scale of Behavioural Distress-Revised, OSPCB= Observation Scale of Positive Child Behaviour, VAS= Visual Analogue Scale.

As appears from table 5.5, 14 of the 16 outcome measures were recorded in Phase 3 and compared between the two groups according to this phase. Satisfaction with medical procedure and satisfaction in regard to the MT intervention were registered at the end of Phase 5. In addition, distress, anxiety, and positive child behaviour were measured throughout all phases (Baseline Phase, and Phases 1-5). The prospective plan for the data analyses was as follows. On the basis of results of graphical inspections of the data set, I chose appropriate statistical analyses. In the case data could not meet the assumptions of parametric statistics, non-parametric statistics were applied. Here, I provided means (*M*), standard deviations (*SD*), and p-values. In addition, supplementary analyses with correction for the selected explanatory variables were also made. Results of the supplementary analyses were reported with mean differences, 95% confidence intervals (CI), and a significance level of 5%.

As to outcome measures that were rated during all six phases (i.e. distress, anxiety, positive child behaviour), the effect of MT was calculated across Phases 1 to 5 (except for Baseline phase) under correction for the pre-defined explanatory variables. The results of these analyses were reported with mean differences, 95% confidence intervals (CI), a significance level of 5%, and effect sizes (Cohen´s *d*). Finally, I summated the addition satisfactory survey regarding the MT intervention using descriptive statistics.

5.12.3 Short Description of the Applied Statistical Models and Tests

This section provides a short summative description of the statistical test used in the data analyses. These were Pearson´s chi-squared test, Mann-Whitney U-test, General Linear Model, and Linear Mixed Effects Model, Pearson Correlation, and R^2.

5.12.3.1 Pearson´s Chi Squared Test

The Pearson´s Chi Squared test (also denoted X2 test) is a non-parametric significance test using unrelated data at a nominal level for testing the association between two categorical variables (i.e. qualitative values), (Kirkwood & Sterne 2008, pp. 165-167). In the statistical analyses I used the Pearson´s Chi Squared test to determine whether the gender distribution was significantly different between the two groups.

5.12.3.2 Mann-Whitney U-Test

The Mann-Whitney U-test (also called Wilcoxon rank-sum test) is a non-parametric test based on rank order (as opposed to absolute numeric values used in parametric statistics). The Mann-Whitney U-test is a significance test used to compare two unrelated sets of scores. The test requires data at at least ordinal measurement level (e.g. a 5-point Likert-type scale) including non-normally distributed data on interval scale level. In the analyses I used two-sided Mann-Whitney U-tests for ordinal data and non-normally distributed data on interval scale level (Kirkwood & Sterne 2008, pp. 347-249). In the statistical analyses, I used the Mann-Whitney U test for ordinal data as well as non-normally distributed data related to the outcome measures, except for the MT satisfactory survey.

5.12.3.3 General Linear Model

A General Linear Model (GLM) is a statistical model that assumes linear relationship between the outcome/dependent variable and one or more explanatory variables, where the explanatory variables can be both categorical and continuous. The use of the GLM requires that the following statistical assumptions are met: data on at least interval scale level, a normal distribution, homogeneity of variance, and independence among observations (Kirkwood & Sterne 2008, p. 316). In the PhD study, I applied the GLM supplementary to the Mann-Whitney U test in order to estimate the effects of the four pre-defined explanatory variables in relation to the dependent variables, except for satisfaction with MT.

5.12.3.4 Linear Mixed Effects Model

A Linear Mixed Effects Model (LMEM) is a statistical model that assumes linear relationship between the outcome/dependent variable and one or more explanatory variables, where the explanatory variables can be both categorical and continuous. In continuation of this, the LMEM includes both fixed and random effects. The use of the LMEM requires data on at least interval scale level, normality, homogeneity of variance, and independence among observations (Verbeke & Molenberghs, 2009). An LMEM can be used to estimate the effects of one or more explanatory variables, possible interaction terms, and in repeated measures designs with two or more conditions. The overall concept of these models is the calculating of a mean "profile" across all measuring points for each separate observation as well as the mean of each condition/randomisation group. The important thing here is the shape and deviations of the observations´ profiles including possible major curves or deviations. On the basis of the profiles, the LMEM estimates a mean of each measuring time point and a mean across time points separately for each observation plus each condition. Hence, a LMEM can account for the variability in the data set by analysing each observation´s general/relative level across all measuring points Verbeke & Molenberghs (2009). In the PhD study, I applied the an LMEM with a view to estimating the effects of the four pre-defined explanatory variables in relation to the repeated measures of research-assistant-rated Child Distress, Child Anxiety, and Positive Child Behaviour.

5.12.3.5 Pearson Correlation

The Pearson correlation is a significance test that provides a measure of correlation (linear association) between two variables on an interval scale level. The measure of correlation is termed *r* or Pearsons´ correlation coefficient. The test gives a value between -1 to +1. A value of 0 indicates no correlation between the two variables, whereas -1 and +1 reflect a perfect negative and perfect positive linear correlation, respectively, between the two variables of interest (Kirkwood & Sterne 2008, p. 94). I used Pearson correlations to calculate a measure for inter-rater reliability (i.e. the degree of agreement) between the ratings of the two main research-assistants.

5.12.3.6 R^2

R^2 is a measure of the percentage of the variance of the outcome measure that can be explained by the exploratory variables.

5.12.4 Chapter Summary

The objective of the PhD study was to examine the effects of an MT intervention on 16 outcome measures under peripheral IV-access procedures in nephro-urological paediatric patients. In order to examine effects, I applied a fixed method RCT design with two conditions (Robson, 2011). As to the study protocol, the choice of outcome domains, outcome measures, and measuring instruments were informed by (research-based) recommendations suggested by:

- The English Medical Research Council, (MRC, 2006)
- The Pediatric Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials, PedIMMPACT (von Baeyer & Spagrud, 2006; McGrath et al., 2008; Stinson et al., 2006)
- The the Society of Pediatric Psychology Task Force, SPP-ATF (Blount et al., 2008; Cohen et al., 2008)
- van Dijk et al. (2002)
- The paediatric research literature on medical procedures (Cohen, 2008; Young, 2005)
- Overview article of test instruments used by Journal of Music Therapy authors from 1984-1997 (Gregory, 2000)
- Clinical experience from two pilot studies
- The MT working party´s appraisal of clinical needs of the paediatric department

In addition, the CONSORT statement (Moher et al., 2010) was used as a methodological checklist in the elaboration of the study protocol. In short, a combination of three methodological approaches was applied (i.e. self-report, observation, and count data). I aimed at using valid measuring instruments that were already translated and used in a Danish context. However, it turned out only to be possible to some extent due to more reasons. In the method chapter, the protocols for data collection, randomisation, and recruitment were presented. Likewise, the participants were also described.

The MT intervention was rooted on a multi-faceted integrative theoretical framework. It was developed, tested out, and continuously improved over a longer period, which included two pilot studies. The MT intervention was child-directed and to a great extent informed by two clinical-oriented navigation tools. Finally, following the recommendations suggested by Robb & Carpenter (2009) and Robb et al. (2011), I aimed at providing a transparent and sufficient description of the MT intervention. As to the ethical aspects of the study, all mandatory ethical approvals were obtained appropriately and prospectively. Likewise, the study was carried out in accordance with common and specific research ethics and ethical rules related to research stated by the Danish music therapy association (MTL). In accordance with the ethical standards addressed by Dileo (2005), I took initiatives and measures in order to secure and maintain as high an ethical codex as possible throughout the entire research process. Among other things, the parents of all potential children received adequate information and consent form. The information material comprised an easily understandable and a non-technical explanation of the purpose, procedures, burdens, risks, benefits etc. of the study. Besides that, before enrolment in the study parents of the participating children gave written consent, which was moreover verbally confirmed upon arrival at the nephro-urological outpatient unit on the day of the procedure. The data collection took place between May 21, 2010 and March 8, 2011. During the course of the data collection (period), all children who met the study criteria were invited to participate in the study. Finally, I clarified the method for data entrance plus preparation and analyses of data. In the following chapter, the results of the study will be presented.

CHAPTER 6 Results

IN THIS CHAPTER I WILL PRESENT THE RESULTS OF THE STATISTICAL ANALYSES. THE OBJECTIVES OF THE ANALYSES WERE TO EXAMINE THE EFFECTS OF MT, WHETHER OR NOT GROUP DIFFERENCES WERE STATISTICALLY SIGNIFICANT, AND THE DEGREE TO WHICH THE EFFECTS WERE INFLUENCED BY OTHER VARIABLES.

6.1 Introduction

I will present the results of the statistical analyses according to this progress:

- Results regarding each research hypothesis (sections 6.6 to 6.23)
- Results regarding additional findings related to the 16 outcome measures (section 6.24)
- Results regarding additional findings related to the applied music therapy intervention (section 6.25)

Please recall, I hypothesised that children randomised to the MT group would report:

- Less Research-assistant-rated Child Distress, Child Anxiety, and Child Pain
- More Research-rated Positive Child Behaviour
- Less Child-rated Anxiety and Child Pain
- Less Parent-rated Child Anxiety and Child Pain
- Better overall Parent-rated Satisfaction with IV-access procedure
- Less Physician-rated Child Anxiety and Child Pain
- Better Physician-rated Child Compliance and Parent Compliance
- Fewer Needle pricks
- Shorter Duration of IV-access procedure
- The majority of the families will find the music therapy intervention supportive and helpful

I defined research-assistant-rated *Child Distress* as the primary outcome variable, which was measured by the OSBD-R. In addition, research-assistant-rated Child Distress and *Positive Child Behaviour* were calculated separately and not by subtraction, since the scale measuring Positive Child Behaviour is not valid. Besides that, I have reported

the results on the basis of the recommendations suggested and defined by the CONSORT Statement (Moher et al. 2010). Finally, throughout this chapter, I will refer to the term *significant* meaning *statistically significant*, unless otherwise specified.

6.1.2 Structure of the Result Chapter

The structure of the chapter is as follows. Initially, I will clarify abbreviations used in this chapter. Subsequently, I will provide an overview of the measuring time points for the outcome measures during the data collection process. In the next section I will give a summative description of the data analysis process. Next, I will outline the structure of the presentation of results related to the 16 outcome measures. Hereafter, I will provide a short description of the graphical methods used in this chapter.

After these initial descriptions, I will move on to the presentation of the actual results starting with the results of eligible participants, randomisation, demographic characteristics, baseline data, and classification of explanatory variables. After these sections I will present the results of the main statistical analyses, which relate to the 16 research hypotheses. The two final sections of this chapter hold a presentation of additional results indirectly related to the 16 outcome measures as well as additional results regarding the MT intervention. In order to give and maintain a clear overview of the results I will provide summative tables and figures along the way. The contents of this chapter are graphically illustrated below in figure 6.1.

Figure 6.1. Overview of contents of the Result Chapter.

Results Introduction

Structure of Chapter

Definitions of Abbreviations & Overview of Phases and Measurement Time Points

Description of Data Analysis Process

Structure of Presentation Regarding Results of Outcome Measures

Interpretation of Figures

Results with relation to Eligible Patients

Results with regard to Randomisation

Presentation of Results of Demographical Characteristics

Presentation of Results of Baseline Data

Results of Classification of Explanatory Variables

Results of 16 Outcome Variables

6.1.2 Abbreviations and Overview of the Data Collection Process

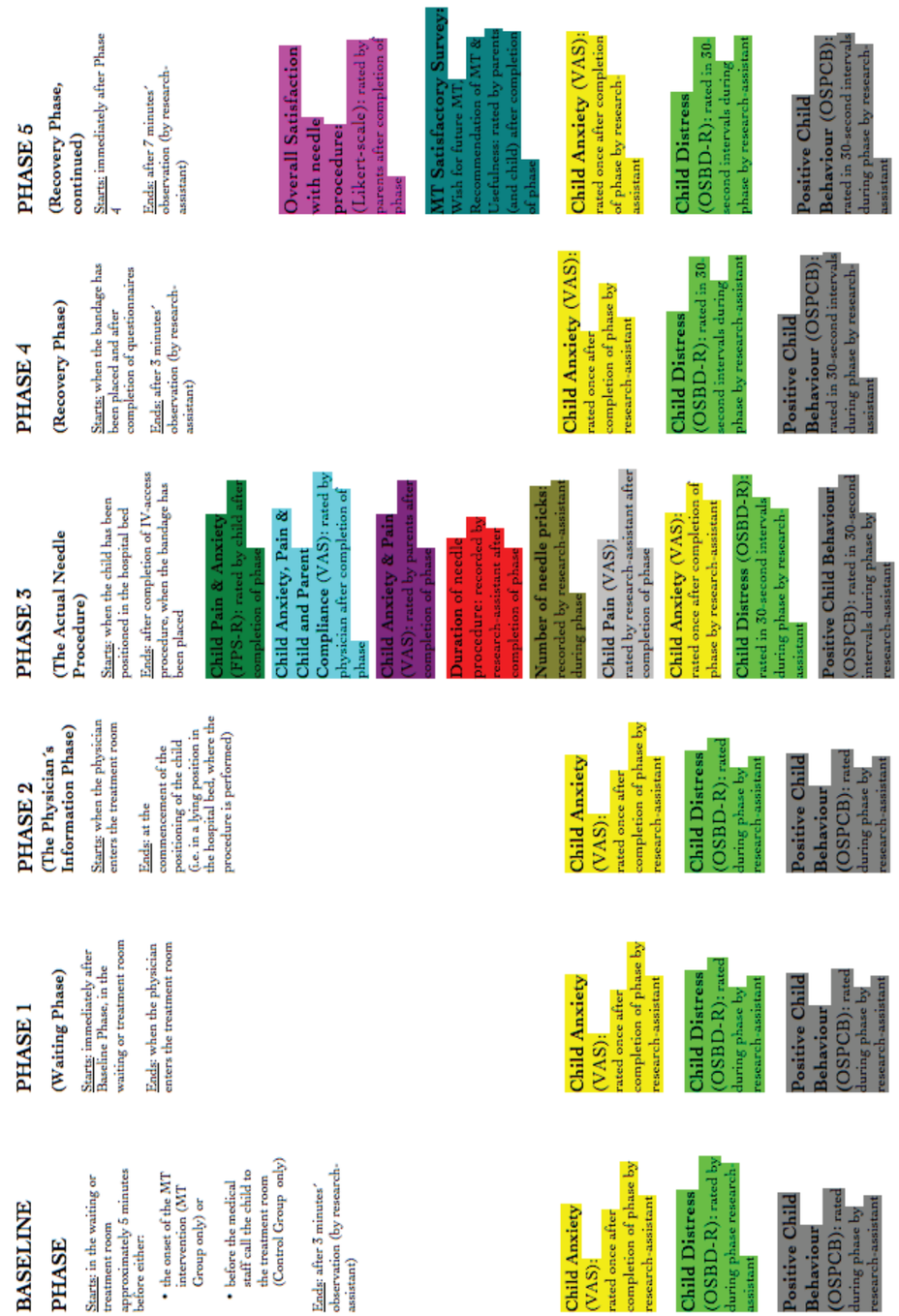
In order to maintain an overview for the reader, I will now list the abbreviations used in this chapter. Then, I will repeat the outline of the phases and measuring time points during the data collection process.

Throughout the present chapter I will use these abbreviations in the text, tables, and figures:

CI	95% **C**onfidence **I**nterval
GLM	**G**eneral **L**inear **M**odel
LMEM	**L**inear **M**ixed **E**ffects **M**odel
OSBD-R	**O**bservational **S**cale of **B**ehavioural **D**istress - **R**evised
OSPCB	**O**bservational **S**cale of **P**ositive **C**hild **B**ehaviour
Phase(s)	Measuring time point(s) during data collection process
SD	**S**tandard **D**eviation
VAS	**V**isual **A**nalogue **S**cale (100mm bipolar)

As described in the previous Method Chapter (section 5.6), data were collected during seven pre-defined phases, which I categorised into three overall *periods* (i.e. *Pre-Needle Period*, *Needle Period*, *Recovery Post-Needle Period*). Figure 6.2 graphically illustrates the applied measuring instruments and time points of assessment of the 16 outcome measures. Please recall, that the data collection in both groups followed this sequence.

Figure 6.2. Overview of measurement instruments and time points of assessment of the 16 outcome measures.



6.1.3 Description of the Data Analysis Process

The analyses of the data have the following progression. I checked the distribution of scores graphically for each outcome variable in order to get an overview of the data set, to detect possible errors, and to check whether the assumptions of normality and equal variance could be met. I made graphical inspections by means of normal probability plots, dot plots, histograms, and box plots. Furthermore, I used scatter plots to clarify possible relations between relevant variables with an eye to informing the statistical analyses.

The distribution of demographical characteristics was compared between the two groups to check whether the groups were directly comparable. This consequently informed decisions whether these characteristics should be controlled for in the subsequent statistical analyses.

I transformed data that were not normally or rather normally distributed. Specifically, I log-transformed data and took the square root. If data were still not normally distributed, I applied non-parametric statistics. As described in section 5.12, I used the following statistical models and a level of significance of p=0.05:

- Pearsons Chi-Square test for dichotomous variables
- Mann-Whitney U-test for ordinal variables as well as for
- non-normally distributed outcomes on interval measurement level
- General Linear Model (GLM)
- Linear mixed effects model (LMEM)
- Pearson´s Correlation

However, as defined in the prospective data analysis plan (section 5.12), a supplementary General Linear Model (GLM) was used in regard to 15 of the outcome variables (except for satisfaction with MT intervention). This analysis was made in spite of violation of the statistical assumptions in order to control for the pre-defined explanatory variables. Likewise, a Linear Mixed Effects Model (LMEM) was used in order to analyse repeated measures of research-assistant-rated Distress (OSBD-R), Child Anxiety (VAS), and Positive Child Behaviour (OSPCB). The LMEM and GLM were used due to lack of existing equivalent non-parametric tests as well as the pragmatic choice of getting a sense of the effects, knowing that the p-values could not be taken at face value. In addition, the LMEM analyses

were made in order to make estimates by using most possible data points available recorded across the repeated time points. Finally, estimates are reported with 95% CI. Moreover, effect sizes (Cohen´s d) are provided as a measure of clinical significance. However, effects sizes were only provided with regard to outcome variables, which had values on scales that were not intuitively understandable (OSBD-R and OSPCB).

6.1.4 Structure of Presentation Regarding Results of Outcome Measures

In this section, I will describe the structure of the presentation of the results of the 16 outcome measures in this chapter. Each presentation begins with a descriptive summation accompanied by graphical illustrations of the raw data in the form of histograms and to a minor degree supplementary box plots. Then, I will provide mean difference between the groups plus the result of the applied significance test. Next, as to the research-assistant-rated outcome measures, I will state result of inter-rater reliability test. Hereafter follows the results of a supplementary analysis using a General Linear Model. Please note, that in addition to the analyses of Observed Child Distress (Phase 3), Observed Child Anxiety (Phase 3), and Positive Child Behaviour (Phases 4 and 5), I made a supplementary analysis across phases using a LMEM. Consequently, I will also provide estimates of the effects and p-values of the predefined explanatory variables.

As described in the previous section, the assumptions of normality and homogeneity as to the GLM and LMEM analyses were violated due to lack of equivalent non-parametric tests. However, the assumption of independence among observations (i.e. the participants) was secured due to an appropriate protocol for data collection procedure. In short, for instance there were no obvious systematic bias or methodological errors in the data collection procedures, and participants did not influence each other´s behaviour or self-reporting with regard to the IV-access procedure. Moreover, all of the involved physicians performed a somewhat equal number of IV-access procedures in both groups (cf. section 6.24.4). Likewise, all of the research-assistants observed a somewhat equal number of children in both groups (cf. section 6.24.3).

In order to provide and maintain a clear overview for the reader, I have summated the results of the separate demographical data and baseline data in tables along the way (tables 6.4 and 6.5, respectively). Likewise, I have

summed up the results of the 16 separate outcome measures in the last part of the chapter (table 6.11). Here, the number of observations in the total sample is indicated with (*N*s), whereas (*n*s) denotes the number of observations in the two separate groups. Moreover, I have reported results as means (*M*s), standard deviations (*SD*s), mean differences with 95% confidence intervals (CIs), p-values. In addition, a calculation of Cohen´s *d* effect sizes (ESs) is provided to a minor extent. Finally, in the GLM and LMEM analyses, the estimated effects of the explanatory variables are only provided if the appertaining p-value was significant. Furthermore, in order to avoid endless enumerations of p-values I have referred to these significance levels in this way: highly statistically significant ($p \leq 0.01$), significant ($p < 0.05$), trends towards significance ($p < 0.10$), not statistically significant ($p \geq 0.10$).

6.1.5 Interpretation of figures

The following sections hold short explanations of the graphical methods that I used in my presentation of results in this chapter (as well as preparatory to the data analyses).

6.1.5.1 Histograms

I used histograms for most of the outcome variables in order to present the raw data, clarify the distribution of scores (normal, skew etc.), and for the purpose of conveying the descriptive summation graphically. Recall that a histogram is a non-parametric way of graphically displaying a set of numerical data by frequency (Kirkwood & Sterne 2008, pp. 18-19). In this thesis the y-axes depict the frequency of scores, whereas the x-axes depict the outcome variable of interest.

6.1.5.2 Box plots

In addition to the histograms, I used box plots in some of the 16 outcome variables, since they illustrate a number of descriptive information simultaneously. Moreover, it easily allows several (box) plots to be comprised in a single graph. Recall that a box plot is a non-parametric way of graphically displaying one or more sets of numerical data. It depicts the smallest value in the data set, the lower quartile, the median, the upper quartile, the largest value,

and possible outliers (i.e. extreme low and/or high values). The distance between the different parts of the box plot illustrates the distribution of the data. The box frames the inter-quartile range (the 50% middle scores), whereas the band in the box illustrates the median. Furthermore, outliers are represented separately as dots (Kirkwood & Sterne 2008, p. 24). In this thesis the whiskers depict the lowest and highest scores within a maximum of one and a half times the inter-quartile range beyond the lower and upper quartile.

6.1.5.3 Scatter plots

A scatter plot is a non-parametric graphical way of plotting two variables against each other in order to explore a possible relation e.g. a dependent variable versus an explanatory variable (Kirkwood & Sterne 2008, pp. 26-27). I used interaction plots with an eye to detecting possible relations between variables and to informing the statistical analyses.

6.2

Results in Relation to Eligibility & Randomisation

In the two following sections, I will present the results of eligibility and randomisation.

6.2.1 Eligibility

The data collection took place between May 21, 2010, and March 8, 2011. In this period the associated co-ordinating nurse assessed 458 children for eligibility with a view to participation in the study. Forty-one children were included in the study, whereas 417 were excluded. As to the latter, 396 children did not meet inclusion criteria, mainly because they were younger than one year or older than ten. In addition, four families declined to participate. Finally, 17 children were not enrolled in the study although they either met the study criteria or gave written consent due to the following reasons:

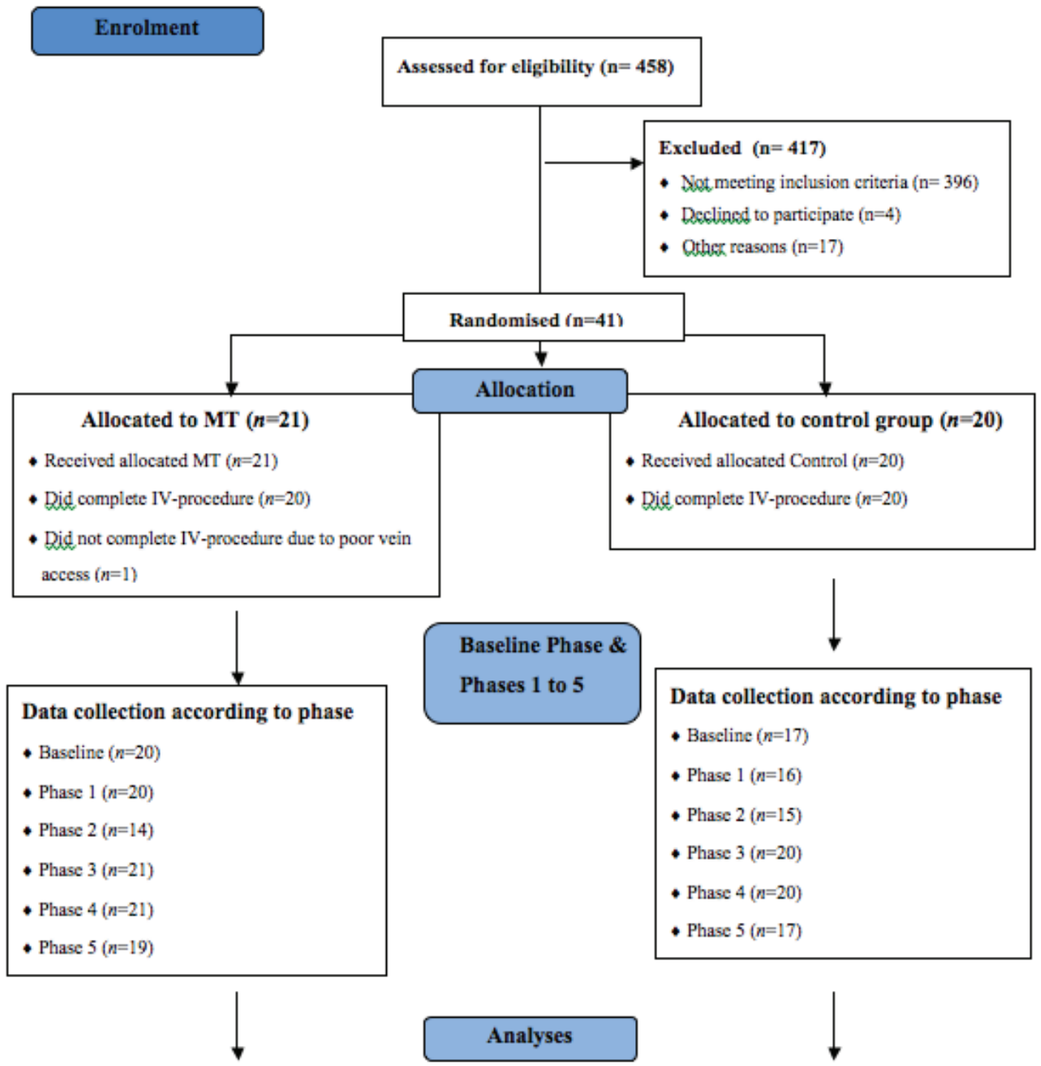
- Logistic and practical limitations regarding research assistant and music therapist resources on days when three or more eligible children underwent the IV-access procedure
- Cancellation of and/or changes of the date of kidney scanning and thereby also the IV-procedure
- Extraordinary business in the outpatient unit (among medical personnel)
- Failing attempts to contact family due to incorrectly announced contact information
- Did not respond after receiving the information brochure
- Responded or gave written consent too late

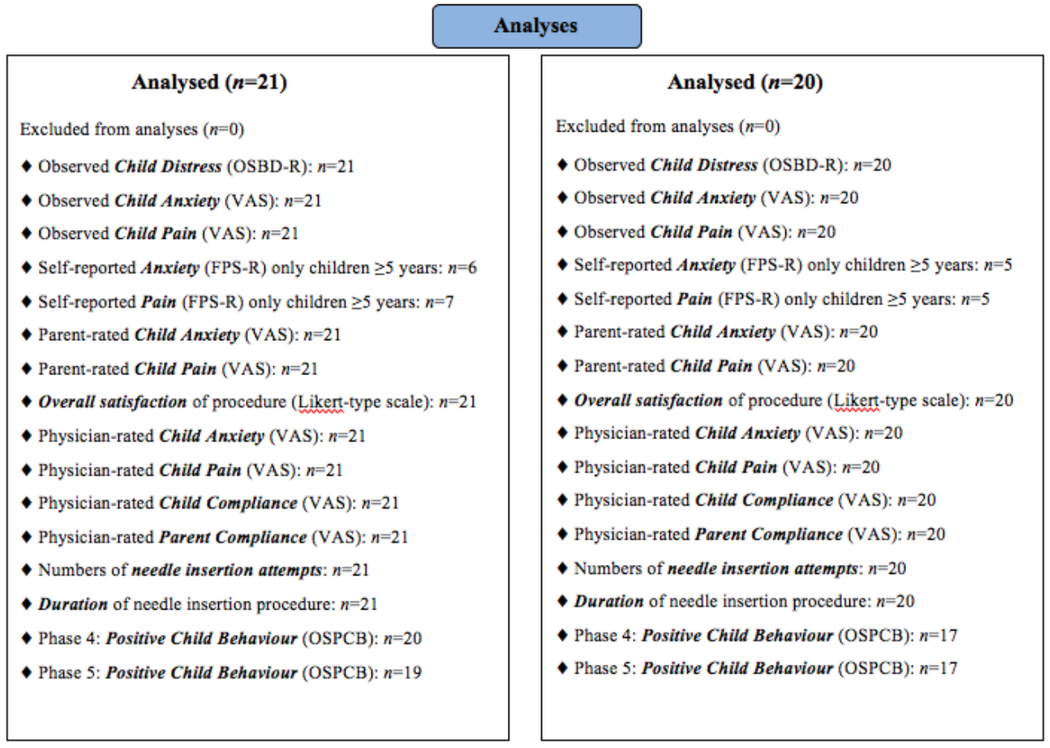
6.2.2 Randomisation

The total sample consisted of 41 children, who were randomly assigned to either the music therapy (*n*=21) or control group (*n*=20). Cf. section 5.9, I used the **S**equentially **N**umbered **O**paque **S**ealed **E**nvelope (SNOSE) method as described by Doig & Simpson (2005) to randomise the participants. None of the 41 participants withdrew their informed consent after enrolment in the study and consequently completed participation in the study. In addition, the IV-access procedures of 40 of the children were completed successfully. As to the remaining child, the physician was not able to succeed in the procedure. This child was randomised to the MT group. Figure 6.3 is a flow diagram, which illustrates the number of children, who were assessed for eligibility, allocated, and included in the statistical analyses. As appears from the figure, the number of participants varies across the six phases (Baseline phase and Phases 1 to 5), which was due to logistic circumstances and practicalities. For instance Phase 1 and/or Phase 2 were in some cases cancelled on days when more children participated in the study the same morning. It was mainly because the physicians were forced to commence the procedures as soon as possible in order to keep the time schedule. Likewise, the *Recovery Post-Needle Period* (i.e. *Phases 4* and/or *5*) was sometimes cancelled, for instance if children were collected by one of the hospital porters immediately after completion of IV-access procedure.

In accordance with recommendations stated and defined in the CONSORT statement (Moher et al. 2010), I made the following flow diagram (figure 6.3). Please note that the analyses listed in the box *Analyses* refer to Phase 3 unless otherwise specified.

Figure 6.3. Flow diagram of results of randomisation.





Please note: FPS-R= Faces Pain Scale Revised, 5-point Likert-type scale, OSBD-R= Observation Scale of Behavioural Distress, OSPCB= Observation Scale of Positive Child Behaviour, VAS= bipolar Visual Analogue Scale (100mm).

6.3

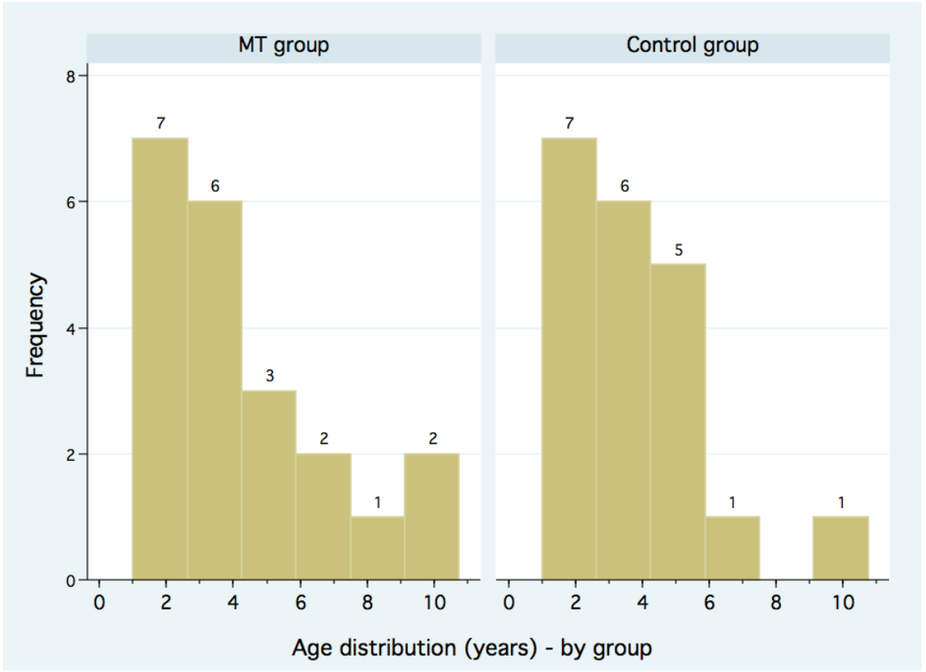
Presentation of Results of Demographic Characteristics

The total sample consisted of 41 children, who were randomly assigned to either the MT group (*n*=21) or Control group (*n*=20). Demographic characteristics of all 41 children were registered by the research-assistant. In the following presentation I have reported results of demographic data as means (*M*s) and standard deviations (*SD*s) accompanied by histograms and summative tables. Moreover, please note that throughout the chapter, I use the term significance meaning statistical significance unless otherwise specified. Finally, in order to provide and maintain a clear overview for the reader, I have summated the results of demographic data in table 6.4.

6.3.1 Results of Distribution of Age

The ages of all 41 children were registered. In the total sample (*n*=41), the mean and *SD* for Age were 3.91 and 2.54 years, respectively. In the MT group (*n*=21) the mean and (*SD*) for *Age* were 4.14 (2.82). In the Control group (*n*=20) they were 3.67 (2.26) years. In figure 6.4 I have graphically illustrated the distribution of age of the two groups.

Figure 6.4. Histogram of Age distribution - by group.

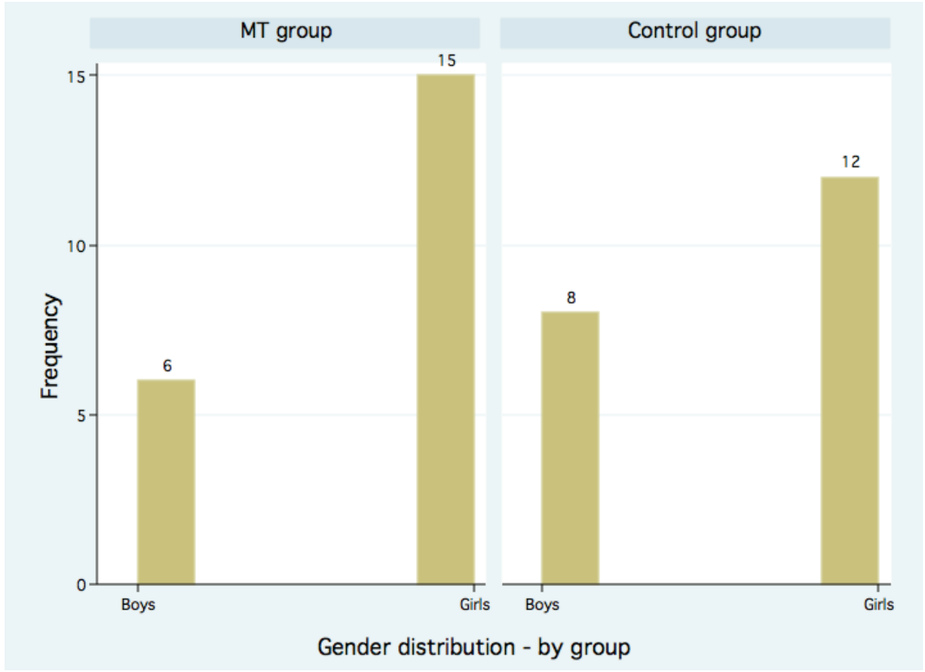


As appears from figure 6.4, the majority of the children were at the ages from one to five. Age was both unimodally and to a great extent similarly distributed in both groups, which could be confirmed by a Mann-Whitney U test (p=0.79).

6.3.2 Results of Distribution of Gender

The total sample (n=41) comprised 14 boys (34%) and 27 girls (66%). The distribution of gender in the MT group (n=21) was 6 boys (29%), and 15 girls (71%). The C group (n=21) consisted of 8 boys (49%) and 12 girls (61%). The gender distribution of the groups is illustrated graphically in figure 6.5.

Figure 6.5: Histogram of Gender distribution - by group.

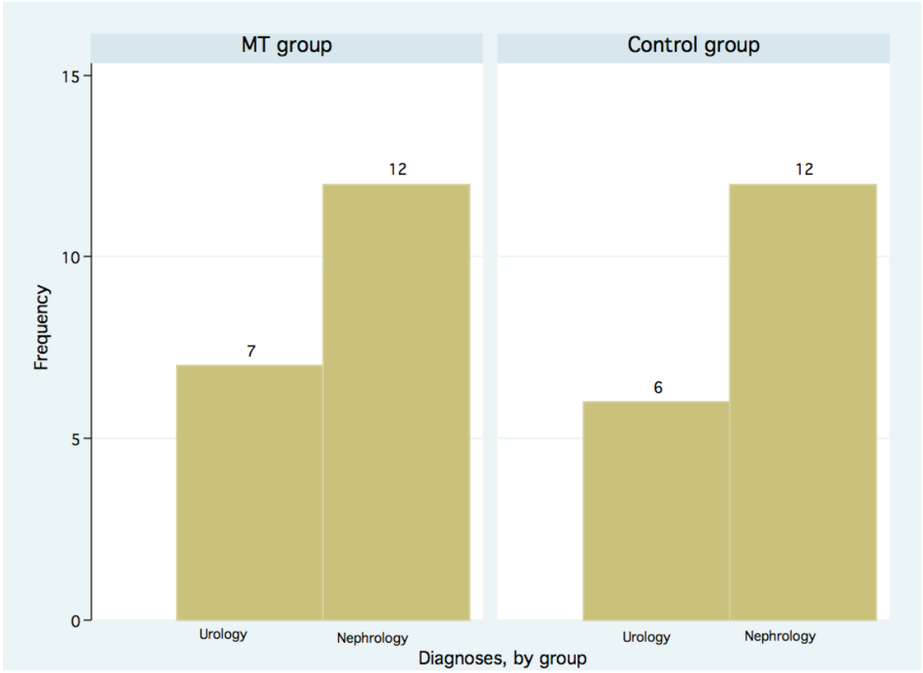


In figure 6.5 we can see that both groups had a female over-representation. However, the gender distribution did not differ notably between the groups, which could be confirmed by a Pearson Chi-Square test (p=0.44).

6.3.3 Results of Distribution of Diagnoses

The diagnoses of 37 ofthe children were registered. The diagnoses were dispersed as illustrated in figure 6.6.

figure 6.6. Histogram of diagnose distribution by groups.



Results of Distribution of Course of Disease

Course of disease was measured in years and registered in all 41 participants. In the total sample (*n*=41), the mean and *SD* for Course of Disease were 1.80 and 2.24 years, respectively. In the MT group (*n*=21) the mean and (*SD*) were 1.54 (2.32) years. In the Control group (*n*=20) they were 2.07 (2.17) years. The distribution of course of disease between the groups is graphically illustrated in figure 6.7.

Figure 6.7. Histogram of distribution of Course of Disease - by group.

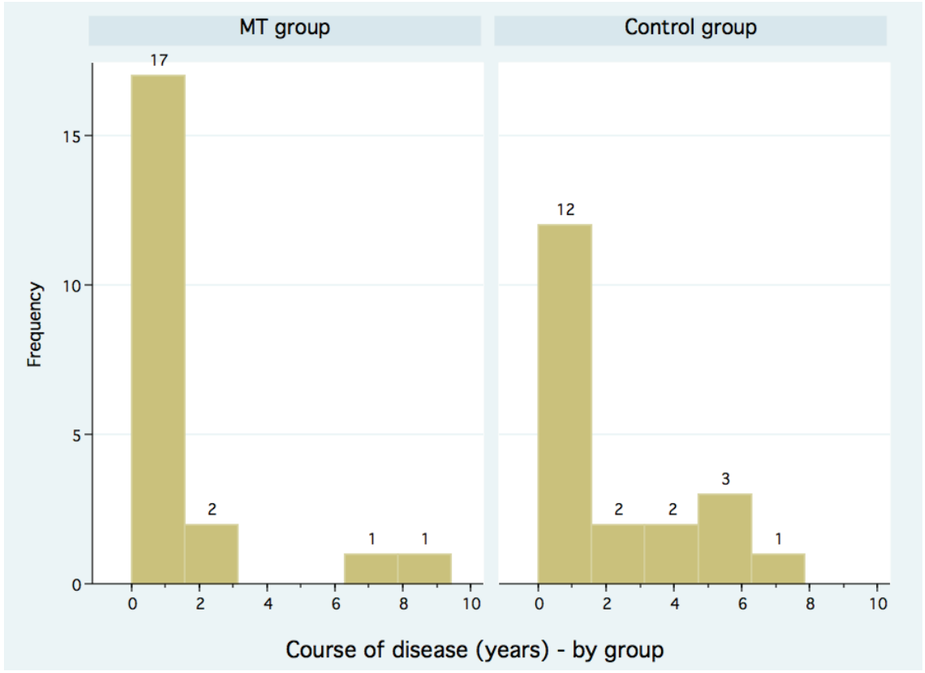


Figure 6.7 shows that most of the children had a relatively short course of disease, more precisely between 0 and 1 year. Data were unimodally distributed and did not differ considerably from each other. This could be confirmed by a Mann-Whitney U test (*p*=0.32) demonstrating no significant difference between the groups.

6.3.4 Results of Distribution of Previous Needle Procedures

The number of previous needle procedures minus ordinary vaccinations was registered for all 41 participants. The result is reported as categorical data (and not continuous), since it appeared early in the pilot studies that the parents could not remember the exact numbers. Hence, this classification proved to be more beneficial in practice. The distribution of the two groups is numerically summed up in table 6.1.

Table 6.1. Distribution of Previous Needle Procedures - by group.

Distribution of Previous Needle Procedures					
Likert-type scale	Never	1-5 times	6-10 times	11-15 times	16+
MT group (*n*=21)	2	9	2	2	6
Control group (*n*=20)	1	4	7	3	5

Table 6.1 shows that the distribution of Previous Needle Procedures varied in categories between the two groups. However, a Mann-Whitney U test showed no significant difference between the groups (p=0.37).

6.3.5 Results of distribution of Previous Inpatient Admissions

The number of Previous Inpatient Admissions was recorded for all 41 children. Due to the experience made in the pilot study as described above, these data were also categorical (and not continuous). The scores of the two groups were dispersed as illustrated in table 6.2:

Table 6.2. Distribution of Previous Inpatient Admissions - by group.

Distribution of Inpatient Admissions					
Likert-type scale	Never	1-5 times	6-10 times	11-15 times	16+
MT group (*n*=21)	4	16	0	0	1
Control group (*n*=20)	2	15	2	0	1

As one can see in table 6.2, the distribution between the two groups was almost similar. This was tested and confirmed by a Mann-Whitney U test, which showed no significant difference between the groups (p=0.23).

6.3.6 Results of Distribution of Previous Outpatient Admissions

Previous Outpatient Admissions were registered for all 41 children. This variable was reported as categorical data due to the same reason as described above. The distribution of the two groups is numerically summated in table 6.3.

Table 6.3. Distribution of Previous Outpatient Admissions - by group.

Distribution of Outpatient Admissions					
Likert-type scale	Never	1-5 times	6-10 times	11-15 times	16+
MT group (*n*=21)	5	15	1	0	0
Control group (*n*=20)	4	7	6	1	2

As appears from table 6.3, the distribution of scores varied in categories between the two groups. A Mann-Whitney U test showed a significantly difference between the two groups for previous inpatient admissions (p=0.04).

6.3.7 Results of Distribution of the Use of EMLA Cream

The use of EMLA cream was registered for all of the 41 children. The distribution of the use of EMLA cream was as follows. In the total sample, ELMA cream was applied by 37 of the 41 children. Of these, EMLA was applied in 19 and 18 children in the MT (n=21) and control group (n=20), respectively. Hence, the use of EMLA was practically identical in the two groups.

6.3.8 Results of Distribution of Previous Needle Procedure(s) on the Same Day

None of the 41 children received any form of Previous Needle Procedures on the same day as they participated in the study. Thus, there was no difference between the two groups.

6.3.9 Results of Distribution of the Use of Coping Medical Kit

Of the 41 children, three received a medical kit coping intervention provided by the nurse immediately prior to the IV-access procedure. One of these children was randomised to the MT group, whereas the remaining two children were randomised to the control group. As appears, this intervention was rarely used and the distribution between two groups was practically speaking identical.

6.3.10 Summation of Results of Demographic Characteristics

I have summated the above-presented demographic characteristics in table 6.4. The setting up of the table was inspired by Erkkilä et at. (2011, p. 4). The demographic characteristics were not statistically different between the two groups except for Numbers of Previous Outpatient Admissions

Table 6.4. Summative table of Demographical Characteristics of the participants in total sample and by group.

Summation of Demographical Characteristics					
Characteristics	**Total sample** (*N*=41)	**MT group** (*n*=21)	**Control group** (*n*=20)	**Mean difference** (95% CI)	***p*a**
Age, years, *M* (*SD*)	3.91 (2.54)	4.14 (2.82)	3.76 (2.26)	0.47 (-1.15 to 2.09)	0.79
Female, *n* (%)	27 (66)	15 (71)	12 (61)		0.44
Diagnoses					
A) Nephrological, *n* (%)	24 (65)	12 (63)	12 (67)		0.88
B) Urological, *n* (%)	13 (35)	7 (37)	6 (33)		
Course of disease					
years, *M* (*SD*)	1.80 (2,24)	1.54 (2.32)	2.07 (2.17)	-0.53 (-1.96 to 0.99)	0.32
Previous needle procedures					0.37
Never, *n* (%)	3 (7.3)	2 (9.5)	1 (5.0)		
1-5 times, *n* (%)	13 (31.7)	9 (42.9)	4 (20.0)		
6-10 times, *n* (%)	9 (22.0)	2 (9.5)	7 (35.0)		
11-15 times, *n* (%)	5 (12.2)	2 (9.5)	3 (15.0)		
16+ times, *n* (%)	11 (26.8)	6 (28.6)	5 (25.0)		
Previous inpatient admissions					0.23
Never, *n* (%)	6 (14.6)	4 (19.0)	2 (10.0)		
1-5 times, *n* (%)	31 (75.6)	16 (76.2)	15 (75.0)		
6-10 times, *n* (%)	2 (4.9)	0 (0.0)	2 (10.0)		
11-15 times, *n* (%)	0 (0.0)	0 (0.0)	0 (0.0)		
16+ times, *n* (%)	2 (4.9)	1 (4.8)	1 (5.0)		
Previous outpatient admissions					0.04*
Never, *n* (%)	9 (22.0)	5 (23.8)	4 (20.0)		
1-5 times, *n* (%)	22 (53.7)	15 (71.4)	7 (35.0)		
6-10 times, *n* (%)	7 (17.0)	1 (4.8)	6 (30.0)		
11-15 times, *n* (%)	1 (2.4)	0 (0.0)	1 (5.0)		
16+ times, *n* (%)	2 (4.9)	0 (0.0)	2 (10.0)		
Use of EMLA crème: yes/no	37/4	19/2	18/2		
Previous needle procedure same day: yes/no	0/41	0/21	0/20		
Coping medical kit: yes/no	2/41	1/21	2/20		

a) Mann-Whitney U-test for ordinal outcomes and non-normally distributed continuous data, Pearson's Chi Square test for dichotomous outcomes.
*) Statistically significant at $p \leq 0.05$ level

6.4

Presentation of Results of Baseline Data

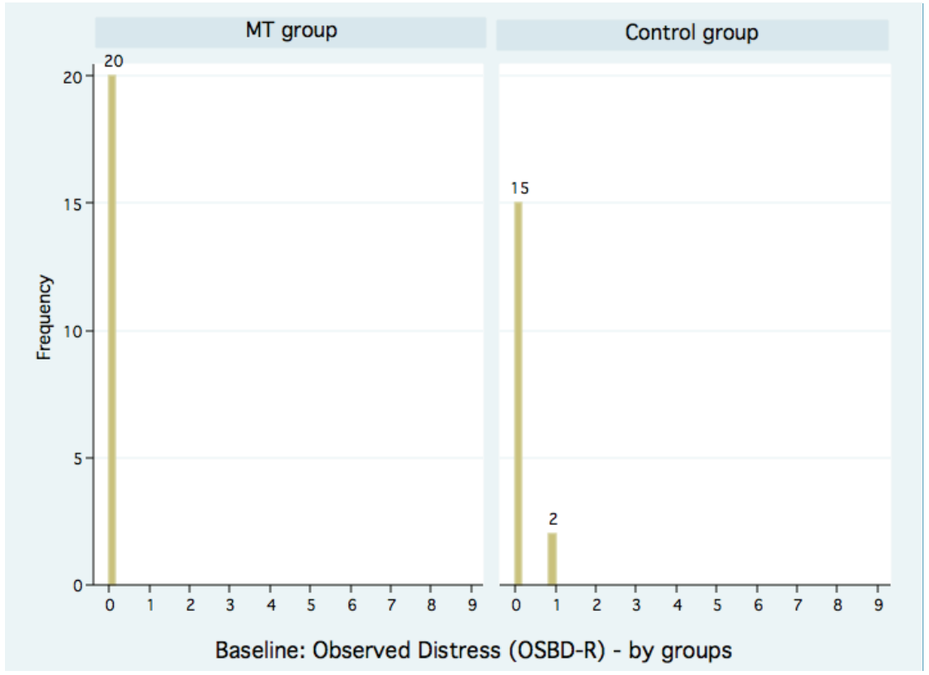
As mentioned previously, the total sample consisted of 41 children (MT group *n*=21; Control group *n*=20). Of these, baseline data were registered in 37 children divided between (*n*=20) in the MT group and (*n*=17) in the Control group. In the following presentation of results regarding Baseline data, I have reported descriptive data as means (*M*s), standard deviations (*SD* s) plus p-values. Estimates are reported with 95% confidence intervals (*CI*s) with a significance level of 5%. I have presented the Baseline measures separately according to outcome measure plus histograms. Please note that throughout the chapter, I use the term significance meaning statistical significance unless otherwise specified. Finally, in order to give and maintain a clear overview, I have summed up all baseline data at the end of the section (table 6.5).

6.4.1 Results of Baseline Research-Assistant-Rated Child Distress

Baseline measures of Research-assistant-rated Child Distress were registered in 37 of the 41 participants by means of the Observational Scale of Behavioural Distress – Revised (OSBD-R). As described in section 5.5.1, I added a supplementary behaviour category (*Apathy*) to this originally 8-item numerical scale. Hence, 0 and 9 depicted no and maximal observed Baseline Child Distress, respectively. The research-assistant filled in the OSBD-R continuously during the three-minute pre-defined *Baseline Phase*. During the *Baseline Phase*, each behavioural category was rated by occurrence or non-occurrence. In addition, each category could only be filled in once. In the total sample (*n*=41), the mean and *SD* for research-assistant-rated *Child Distress* were 0.05 and 0.23, respectively. In the MT group (*n*=20) the children had a score of 0. Consequently, the mean and *SD* of observed distress were 0.

In the Control group (n=17) two children scored one of nine possible distress points. In this group the mean and *SD* for observed *Child Distress* were 0.12 and 0.33, respectively. I have illustrated the distribution of observed *Child Distress* between the two groups graphically in figure 6.8.

Figure 6.8. Histogram of distribution of Research-assistant-rated Child Distress - by group.



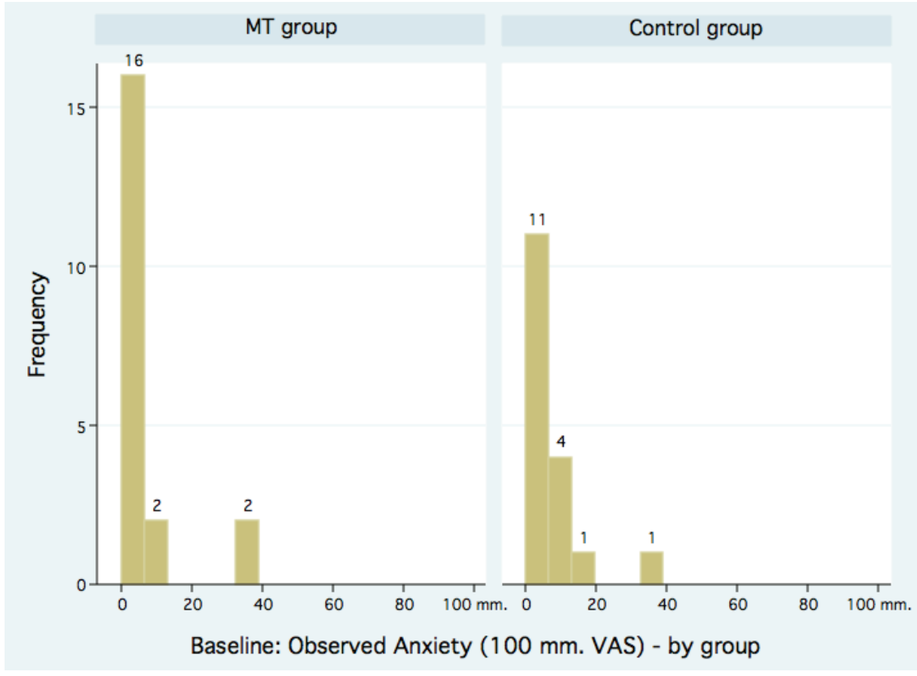
As we can see in figure 6.8, both groups did practically not exhibit distress during the Baseline Phase. The only difference consisted in the fact that the two (of the 17) children in the control group scored 1 (out of 9 possible) points on the OSBD-R scale. The appraisal of similarity could be confirmed statistically by using a Mann-Whitney U test (p=0.12).

6.4.2 Results of Baseline Research-Assistant-Rated Child Anxiety

The research-assistant registered baseline measures of Child Anxiety in 37 of the 41 participants. Child Anxiety was measured by means of a 100mm bipolar Visual Analogue Scale (VAS) with 0mm being *Not anxious at all* and 100mm being *Very anxious* (see section 5.5.2). Observation of Child Anxiety began in the start of the *Baseline Phase* and lasted throughout this pre-defined three-minute period. The VAS was filled in once retrospectively immediately upon completion of the *Baseline Phase*. The VAS scores were calculated from the 0mm anchor point.

In the total sample (n=41), the mean and *SD* for research-assistant-rated Child Anxiety were 6 and 10mm, respectively. In the MT group (n=20), the mean and (*SD*) were 6 (11) mm. In the Control group (n=17) the mean and (*SD*) were 6 (9)mm. I have provided a graphical representation of the distribution of the observed Child Anxiety levels in the two groups (figure 6.9).

Figure 6.9. Histogram of distribution of Research-assistant-rated Child Anxiety - by group.

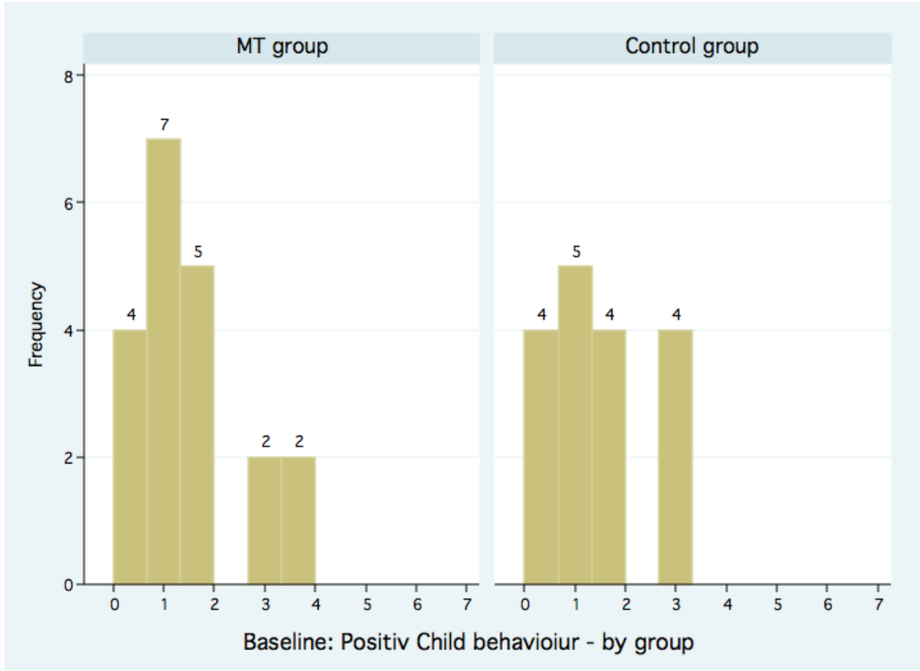


As appears from figure 6.9, almost all of the children had low observed Baseline anxiety scores (as expected by the researcher). Data were both unimodal, and to a great extent similarly distributed in the two groups. The latter could be confirmed by a Mann-Whitney U test showing no significant difference between the two groups (p=0.32).

6.4.3 Results of Baseline Research-assistant-rated Positive Child Behaviour

Baseline measures of Positive Child Behaviour were registered by the research-assistant in 37 of the 41 participants using the Observation Scale of Positive Child Behaviour (OSPCB). The OSPCB is a scale that I developed for the context of the PhD study. It is a numerical 7-item scale ranging from 0 to 7. The scores of 0 and 7 points representing *no* and *maximum* Positive Child Behaviour score, respectively. The OSPCB was filled in prospectively during this pre-defined three-minute *Baseline* observation *Phase*. Note that each OSPCB category/item could only be filled in once during the *Baseline Phase*. In the total sample (n=41), the mean and *SD* for research-assistant-rated *Positive Child Behaviour* were 1.51 and 1.17 points, respectively. In the MT group (n=20) the mean and (*SD*) were 1.55 (1.23) points. In the Control group (n=17) they were 1.47 (1.13) points. The distribution of observed *Positive Child Behaviour* of the two groups is graphically illustrated in figure 6.10.

Figure 6.10. Histogram of distribution of researcher-assistant-rated Baseline Positive Child Behaviour - by group.



When inspecting the histogram (figure 6.10), it appears that data were not normally distributed and furthermore not essentially different between the two groups. The latter appraisal was tested and confirmed by a Mann-Whitney U test (p=0.94).

6.4.4 Summation of results of Baseline Characteristics

I have summated the above-presented results of Baseline data in table 6.5. As mentioned, there were no statistically differences in Baseline measures between the two groups.

Table 6.5. Summation of Baseline Characteristics of participants in total sample and by group.

Summation of Baseline Characteristics					
Outcome	**Total sample**	**MT group**	**Control group**	**Mean difference**	***p*a**
	N, *M* (*SD*)	*n*, *M* (*SD*)	*n*, *M* (*SD*)	(95% CI)	
Observed Distress:	*37* 0.05 (0.23)	*20* 0.00 (0.0)	*17* 0.12 (0.33)	-0.12 (-0.29 to 0.05)	0.12
Observed Anxiety:	*37* 6 (10)	*20* 6 (11)	*17* 6 (9)	-3 (-7 to 6)	0.32
Observed Positive Child Behaviour:	*37* 1.51 (1.17)	*20* 1.55 (1.23)	*17* 1.47 (1.13)	0.08 (-0.71 to 0.87)	0.94

a. Mann-Whitney U test (two-sided) for non-normally distributed continuous data.

6.5

Results of Classification of Explanatory Variables

As defined in the prospective plan for the data analyses (section 5.12), 15 of the dependent variables (i.e. except for the music therapy satisfactory survey) were analysed statistically in two ways (except for satisfaction with the MT intervention). First, each dependent variable was analysed by randomisation (MT versus Control group) in order to evaluate possible group differences and effects (raw estimate). In addition, a supplementary General Linear Model (GLM) analysis was performed in order to control for the pre-defined explanatory variables listed below. In addition, Observed Child Distress, Observed Child Anxiety, and Observed Positive Child Behaviour were analysed by means of a Linear Mixed Effects Model (LMEM) analysis, in which these explanatory variables were also controlled for:

- Randomisation
- Age
- Previous Number of Needle procedures (exclusive ordinary heel sticks and vaccinations)
- EMLA Numbing Cream: Needle pricks with/without EMLA during the needle procedure

I classified these five explanatory variables based on descriptive analyses as well as graphical inspections of the data set. The results of the classification were as follows. I defined *Randomisation* as a dichotomous variable comprising the MT group (*n*=21) versus the Control group (*n*=20). As indicated by the brackets, this dichotomous variable contained 21 observations in the MT group and 20 observations in the control group. I calculated *Age* in full years. I defined *Previous number of needle procedures* as a dichotomous variable comprising *No previous procedures* (*n*=3) versus *1 to 16+ Previous procedures* (*n*=38). This decision was based on scatter plots, which revealed a tendency

towards traumatisation due to needle procedures caused after just one to five previous procedures (see section **6.24.6**). I defined EMLA as a dichotomous variable with the categories *Needle pricks with EMLA* (*n*=34) versus *Needle pricks without EMLA* (*n*=7), which contained 34 and 7 children, respectively. In addition, results revealed that three children received a combination of needle pricks *with* and *without* EMLA. These children were categorised as *Needle pricks on EMLA*.

Finally, as shown in (section 6.3.4**)**, the numbers of previous outpatient admissions were statistically significantly different between the groups. However, I did not include this variable as an explanatory variable due to an appraisal made by my supervisor (Søren Rittig) and me.

I will now present the results of the statistical analyses related to the 16 outcome measures. In that connection I will remind the reader that a clarification of the data analyses process and the structure of the presentations can be found in sections 6.1.3 and 6.1.4, respectively. Finally, please note that throughout the chapter, I use the term significance meaning statistcal significance unless otherwise specified.

6.6

Results regarding Research-assistant-rated Child Distress as measured by OSBD-R (primary outcome variable)

6.6.1 Results of Research-assistant-rated Child Distress - Descriptive Summary

The research-assistant recorded Observed Child Distress in all six phases by means of the Observation Scale of Behavioural Distress – Revised (OSBD-R). As described in section 5.5.1, I added a supplementary behaviour category to this originally 8-item numerical scale. The research-assistant filled in the OSBD-R prospectively in all six phases, which however differed notably in terms of duration and use of time interval ratings. Furthermore, as described in section 5.6, I defined the Baseline Phase to last three minutes, whereas Phase 1 and 2 were not time limited. These three phases were filled once (prospectively) and had a minimum and maximum score of 0 and 9, respectively.

In Phase 3 the research-assistant filled in the OSBD-R each 30 seconds throughout the entire phase, which varied in duration from one child to another. Likewise, the OSBD-R was filled in each 30-seconds in Phases 4 and 5, and these were predefined to last 3 and 7 minutes, respectively.

As mentioned in the introduction to this chapter, I calculated research-assistant-rated Child Distress and Positive Child Behaviour separately and not by subtraction. In addition, the minimum and maximum OSBD-R scores varied across the six phases due to the above-mentioned differences in terms of duration and time interval rating. Consequently, I computed comparable group scores in the form of ***mean*** scores and phase-wise ***average*** scores. I calculated ***mean*** scores by dividing each child´s total distress score by the number of children in the respective group. I computed the ***Average*** phase-wise scores by dividing each child´s total distress score by the number of observed 30-second interval ratings divided by the numbers of children in the respective group. Consequently, the ***mean*** scores reflect a value between 0 to 9 on the OSBD-R, whereas the ***average*** scores reflect the average distress level of the groups across the total numbers of 30-second interval ratings expressed by a value between 0 to 9 on the OSBD-R.

After this initial clarification, I will now move on to the actual presentation of results. Table 6.6 displays a descriptive summation of Observed Child Distress according to phase. Note that Baseline Phase, Phase 1, and Phase 2 are group ***mean*** scores as opposed to Phases 3, 4, and 5, which reflect ***average*** phase-wise group scores. In addition, note that the number of observations (i.e. observed children) in the six phases varied due to time pressure and logistic circumstances as described in section 6.2.2.

Table 6.6. Descriptive summation of Research-assistant-rated Child Distress scores by phases in the total sample and by group.

Research-assistant-rated Child Distress (OSBD-R) scores during all six phases.				
Measurement point	**Total sample**	**MT group**	**C group**	**Mean difference**	**(*p*a)**
	N, M (SD)	*n, M (SD)*	*n, M (SD)*	95% CI	
Pre-Needle Period					
Base line:	*37* 0.05 (0.23)	*20* 0.00 (0.00)	*17* 0.12 (0.33)	-0.12 (-0.29 to 0.05)	(0.12)
Phase 1:	*35* 0.29 (0.57)	*20* 0.30 (0.66)	*15* 0.27 (0.46)	0.03 (-0.37 to 0.44)	
Phase 2:	*29* 0.52 (0.91)	*14* 0.50 (0.94)	*15* 0.53 (0.91)	0.03 (-0.74 to 0.67)	
Needle Period					
Phase 3: Avarage score	*41* 0.88 (0.90)	*21* 0.78 (0.97)	*20* 0.98 (0.84)	-0.20 (-0.77 to 0.38)	
Recovery Post-Needle Period					
Phase 4: Avarage score	*37* 0.19 (0.44)	*20* 0.13 (0.32)	*17* 0.25 (0.55)	-0.12 (-0.42 to 0.17)	
Phase 5: Average score	*36* 0.14 (0.36)	*19* 0.06 (0.15)	*17* 0.22 (0.50)	-0.16 (-0.42 to 0.11)	

a. Mann-Whitney U test for non-normally distributed data/outcomes.

In addition to table 6.6, the Child Distress scores are also illustrated graphically in the form of box plots in figure 6.11.

Figure 6.11. Boxplot of Research-assistant-rated Child Distress by phases and group.

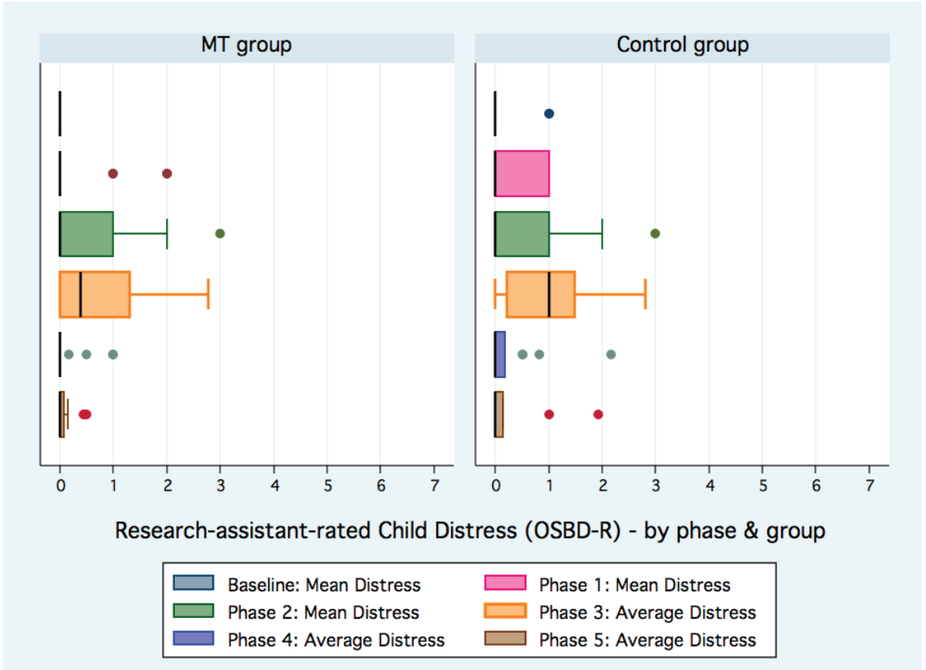


Table 6.6 and figure 6.11 illustrate ***mean*** and ***average*** research-assistant-rated Child Distress during all six phases by group. In figure 6.11 the x-axis displays the distress level as measured by the OSBD-R, whereas the six phases are represented on the y-axis. From the table and figure we can see that both groups had a similar distress progression across phases. As I assumed, the distress level was almost absent at Baseline and increased gradually towards a peak in Phase 3 whereupon it decreased again. Furthermore, when compared to the control group, the distress level of the MT group was lower in five phases except for Phase 2. However, it is not intuitively evident that the distress levels in Phase 3 were notably different compared to for instance Phases 1 or 2 in that medians are not substantially displaced from each other. This circumstance reflects the difference in the calculation methods in terms of ***mean*** and ***average*** distress scores as described above.

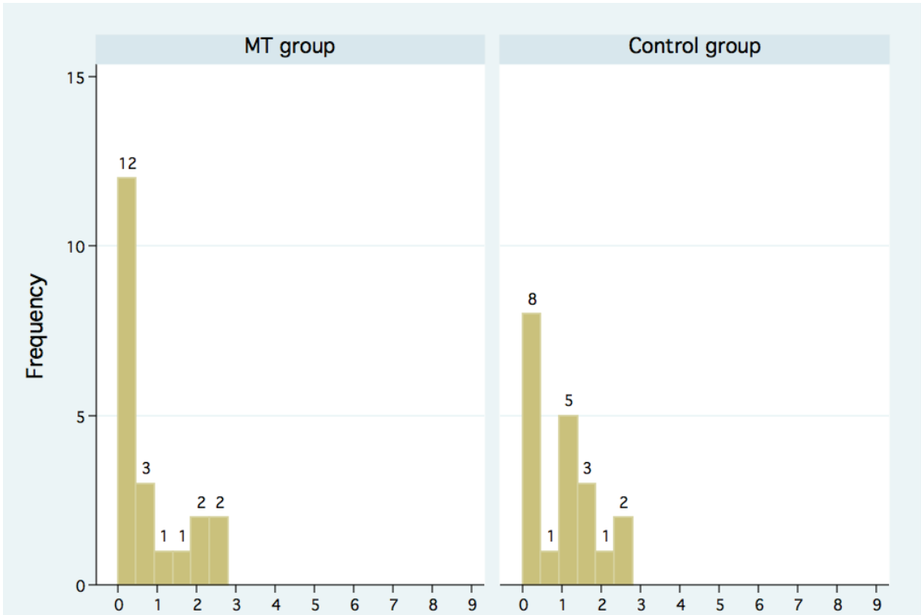
Finally, one can see an increase in Observed Child Distress in Phase 2 when compared to Phase 1. This indicates that children in both groups exhibited higher distress levels after the physician entered the treatment room, bear in mind, before commencement of the of placement of the child in a secure position in the hospital bed as well as commencement of the actual needle procedure.

6.6.2 Results of Phase 3 *Average* Research-assistant-rated Child Distress

The research-assistant rated child distress in relation to the IV-procedure (Phase 3) in all of the 41 children. Child distress was measured by means of the Observation Scale of Behavioural Distress – Revised (OSBD-R). As mentioned earlier, I added a supplementary behaviour category (Apathy) to this originally 8-item numerical scale. Moreover, the OSBD-R was filled in continuously at 30-second intervals throughout the entire phase, and comparable ***Average*** phase-wise distress scores were calculated for both groups. Consequently, the ***Average*** score reflects the average Child Distress scores during Phase 3 in the two groups expressed by a value between 0 to 9 on the OSBD-R.

In the total sample (n=41), the ***average*** and *SD* of Research-assistant-rated Child Distress during Phase 3 were 0.88 and 0.90, respectively. In the MT group, the ***average*** and (*SD*) were 0.78 (0.97). In the control group they were 0.98 (0.84). I have represented the distribution of *average* Research-assistant-rated Child Distress scores of the two groups graphically in figure 6.12.

*Figure 6.12. Histogram of distribution of **Average** Research-assistant-rated Child Distress in Phase 3 - by group.*



As appears from figure 6.12, it was unreasonable to assume that the data were normally distributed in either group. Attempting to alleviate this problem by a data transformation was unsuccessful. Specifically, I tried log-transforming the data and taking the square root. When comparing the two groups, the ***average*** score for the MT group was 0.20 points lower than for the control group, 95% CI (-39 to 3). Due to the non-normal distribution of data, I applied a Mann-Whitney U test (two-tailed), which revealed that the difference was not statistically significant (p=0.17). In addition, I calculated inter-rater reliability for research-assistant-rated Child Distress during Phase 3 based on 154 observations. Cf. Brace, Kemp, and Snelgar (2006), the result of the Pearson Correlation test yielded a moderate correlation (r=0.654), which was highly statistically significant.

Besides that, I performed a supplementary General Linear Model analysis (GLM) in order to control for the pre-defined explanatory variables. I carried out this analysis in spite of violations of the assumption of normality and homogeneity of variance. However, it was reasonable to assume that the assumption of independence was

met as described in section 6.1.4. The reason for using this parametric model in spite of the violations was due to the lack of an equivalent non-parametric test that could control for pre-defined explanatory variables. When the explanatory variables were controlled for, the result of the GLM analysis showed that *Age* had a highly significant effect on ***average*** Observed Child Distress. Specifically, when the remaining explanatory variables were taken into account, *Age* yielded an estimated mean effect of -0.15 point per year, 95% CI (-0.25 to -0.05). This means that if the youngest children included in the study (one year old) were compared to the oldest children (10 years old), we would expect a mean difference of 1.50 points Child Distress given that the these children were similar in all terms except for age. Despite the fact that p-values cannot be taken at face value if assumptions are violated (e.g. normality, equal variance), the highly significant effect of *Age* (p=0.01), however, gives indication of a somewhat trustful estimate.

Furthermore the result of the GLM analysis showed that *Previous number of needle procedures* and *Needle pricks with/without EMLA* had tendency towards significance. In addition, the GLM indicated that 35% of the variation of *Average* Observed Child Distress could be explained (cf. R Squared). Finally, the use of more complex models (e.g. including interaction terms) was not supported due to the limited amount of data in the study and violation of assumptions (e.g. normality and equal variance). A statistically experiment clearly confirmed this.

6.6.3 Results of Linear Mixed Effects Model analysis of Child Distress

I analysed the repeated measures of research-assistant-rated Child Distress across Phases 1 to 5 by means of a Linear Mixed Effects Model (LMEM). I made this analyse in spite of violation of assumptions as mentioned above and due to lack of an equivalent non-parametric alternative. However, it was reasonable to assume that the assumption of independence was met as described in section 6.1.4. I considered the defined explanatory variables and furthermore *Phases* as fixed effects. I regarded ID randomisation number (number of child) as random effects. I did not use interaction terms due to the reasons described above. The analysis comprised the total sample (n=41) and showed that *Phase 3* and *Age* (p=0.01) had a highly significant effect on ***average*** research-assistant-rated Child Distress. The estimated mean effect of *Age* was a reduction of -0.09 point, 95% CI (-0.16 to -0.02) per year on *Average* Child Distress. Results showed that the remaining explanatory variables were not statistically significant.

The use of more complex models (e.g. including interaction terms) was not supported due to the limited amount of data in the study and violation of assumptions (e.g. normality and equal variance). A statistical experiment clearly confirmed this. Finally, based on 321 observations, I calculated inter-rater reliability for research-assistant-rated Child Distress during all six phases. Confer Brace et al. (2006), the result of the Pearson correlation test showed a strong correlation (r=0.763), which was highly significant.

6.6.4 Summary of Results of Research-Assistant-Rated Child Distress

Results of the descriptive summation plus the statistical analyses showed that children in the MT had lower ***Average*** Child Distress scores during Phase 3 than did the children in the control group. However, this finding was not statistically significant in any of the three analyses. The Mixed Effects Model analysis showed a statistically significant effect of *Phase* and *Age*. As to *Age*, the GLM analysis also showed a highly significant effect. Finally, the GLM showed that 35% of the variance of the *average* distress is explained by the explanatory variables.

6.7

Results regarding Research-assistant-rated Child Anxiety (VAS)

6.7.1 Results of Research-assistant-rated Child Anxiety - Descriptive summary

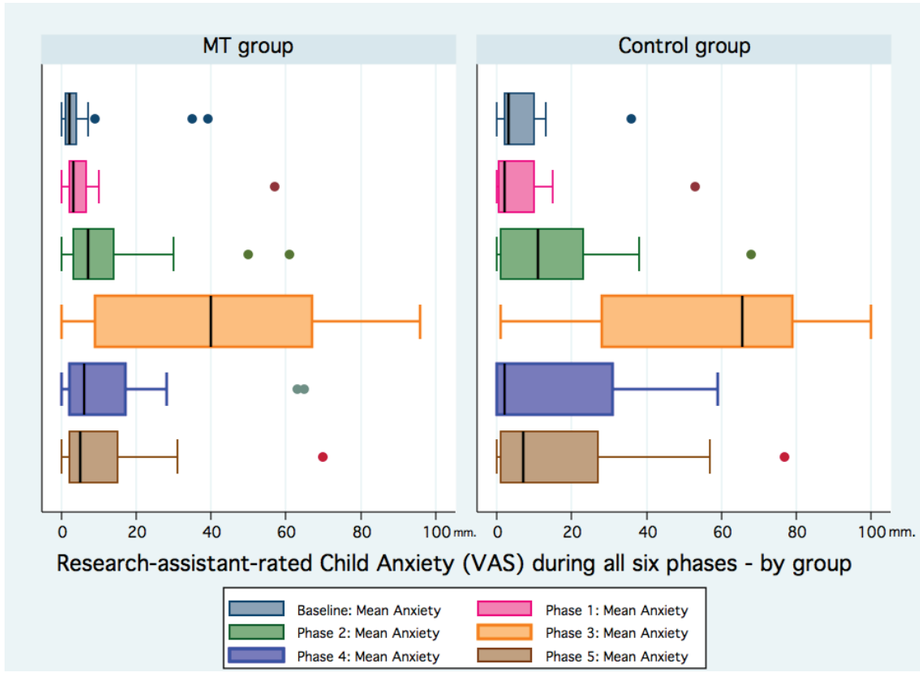
The research-assistant rated Child Anxiety in all six phases. Child Anxiety was measured by means of a 100mm bipolar Visual Analogue Scale (VAS) with 0mm being *Not anxious at all* and 100mm being *Very anxious* (see section 5.5.2). The research-assistant filled in the VAS once retrospectively immediately after completion of each phase. As I described in the *Method Chapter*, each phase differed in terms of duration (i.e. Baseline phase lasted three minutes; Phases 1, 2, and 3 had no pre-defined duration; Phase 4 lasted three minutes, and Phase 5 lasted seven minutes). I calculated the VAS scores from the 0mm anchor point. In addition, as appears in table 6.7 the number of participants varied in the six phases, which was due to time pressure and logistic reasons as mentioned earlier in section 6.2.2. In table 6.7 and figure 6.13, I have descriptively summated the research-assistant´s ratings of Child Anxiety scores of the six phases.

Table 6.7 Descriptive summation of Research-Assistant-Rated Child Anxiety (100mm VAS) in all six phases in total sample and by group.

Research-assistant-rated Child Anxiety (100mm VAS) scores during all six phases				
Measurement point	**Total sample** *N, M (SD)*	**MT group** *n, M (SD)*	**C group** *n, M (SD)*	**Mean difference** (95% CI)	**(*p*a)**
Pre-needle Period					
Baseline:	*37* 6 (10)	*20* 6 (11)	*17* 6 (9)	0 (-7 to 6)	(0.32)
Phase 1:	*36* 7 (12)	*20* 6 (12)	*16* 7 (13)	-1 (-9 to 8)	
Phase 2:	*28* 15 (19)	*13* 15 (20)	*15* 15 (19)	0 (-15 to 15)	
Needle Period					
Phase 3:	*41* 49 (33)	*21* 40 (33)	*20* 58 (32)	-18 (-39 to 3)	
Recovery Post-Needle Period					
Phase 4:	*41* 15 (19)	*21* 14 (18)	*20* 15 (21)	-1 (-14 to 11)	
Phase 5:	*36* 14 (20)	*19* 11 (16)	*17* 18 (24)	-7 (-21 to 7)	

a. Mann-Whitney U-test for non-normally distributed outcomes/data.

Figure 6.13. Box plot of mean Research-Assistant-Rated Child Anxiety during Baseline Phase & Phases 1 to 5, by group.



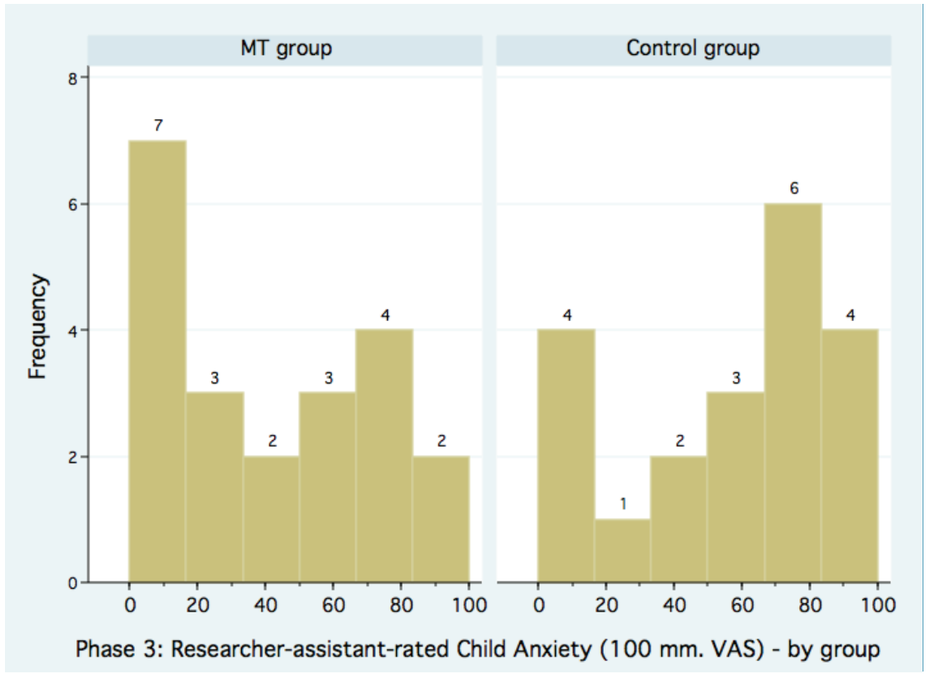
Tabel 6.7 & figure 6.13 illustrate research-assistant-rated Child Anxiety by group during all six phases. In figure 6.13 the x-axis displays the anxiety level as measured by the VAS, whereas the six phases are represented on the y-axis. From the graph we can see that both groups had a similar anxiety progression. As I expected the anxiety level was low at Baseline and increased gradually towards the peak in Phase 3. Hereafter it decreased. Furthermore, figure 6.13 and table 6.7 reveal that the Child Anxiety level and spread in the MT group were lower in all six phases compared to the control group. Finally, one can see an increase in Child Anxiety in Phase 2 when compared to Phase 1. This finding corresponded with the result of observed Child Distress scores during these two phases (figure 6.11 and table 6.6). Apparently, this indicates that the children in both groups exhibited higher anxiety levels after the physician entered in the treatment room, bear in mind before commencement of the positioning of the child in the hospital bed, as well as commencement of the actual procedure.

6.7.2 Results of *Phase 3* Research-Assistant-Rated Child Anxiety

The research-assistant rated Child Anxiety in relation to the IV-procedure (Phase 3) in all 41 children. Child Anxiety was evaluated by means of a 100mm bipolar Visual Analogue Scale (VAS) with 0mm being *Not anxious at all* and 100mm being *Very anxious* (cf. section 5.5.2). Observation of Child Anxiety began in the start of Phase 3 and lasted throughout this phase. The VAS was filled in once retrospectively immediately upon completion of the phase (i.e. after the bandage had been placed). I calculated the VAS scores from the 0mm anchor point.

In the total sample (*n*=41), the mean and *SD* for Research-assistant-rated Child Anxiety were 49 and 33mm, respectively. In the MT group (*n*=21) the mean and (*SD*) were 40 (33)mm. In the Control group (*n*=20) they were 58 (32)mm. The distribution of the Research-assistant-rated Child Anxiety level in the two groups is graphically illustrated in the histogram (figure 6.14).

Figure 6.14. Histogram and box plot of distribution of Researcher-assistant-rated Child Anxiety during Phase 3 (the IV-procedure) - by group.



As we can see in figure 6.14, data could not be assumed normally distributed in either group. Attempting to alleviate this problem by a data transformation was unsuccessful. Specifically, I tried log-transforming the data and taking the square root. When comparing the two groups, the mean score for the MT group was 18mm lower than the control group, 95% CI (-39 to 3). Due to the non-normal distributions, I used a Mann-Whitney U test (two-tailed). This analysis showed that the difference was not significant (p=0.092). In addition, I calculated inter-rater reliability for research-assistant-rated Child Anxiety during Phase 3 based on nine observations. Confer Brace et al. (2006), the result of the Pearson correlation test showed a moderate correlation (r=0.654), which had tendency towards being significant (p=0.068).

Besides that, I performed a supplementary GLM analysis. This analysis showed a tendcy towards a significant effect of *Age* and *Number of previous needle procedures* on research-assistant-rated Child Anxiety. The explanatory variables *Randomisation* and *Needle pricks with/without EMLA* were not significant. Moreover, for this model, the R squared showed that 23% of the variance of observed Child Anxiety is explained by the explanatory variables. The GLM was used in spite of violation of the assumptions of the model due to the reasons described in section 6.1.3 (i.e. due to the lack of an equivalent nonparametric alternative and the wish to control for pre-defined explanatory variables). Likewise, use of more complex models (e.g. including interaction terms) was not supported due to the limited amount of data in the study and violation of assumptions (e.g. normality and equal variance).

6.7.3 Results of Linear Mixed Effects Model Analysis of Child Anxiety

I analysed the repeated measures of research-assistant-rated Child Anxiety across Phases 1 to 5 using a Linear Mixed Effects Model (LMEM). I made this analysis in spite of violation of assumptions due to lack of an equivalent non-parametric alternative. However, it was reasonable to assume that the assumption of independence was met cf. section section 6.1.4. I considered the defined explanatory variables and furthermore *Phases* as fixed effects. I regarded childrens´ randomisation number (ID number of child) as random effects. The analysis comprised the total sample (*n*=41) and showed that *Phase 3* had a highly significant effect on research-assistant-rated *Child Anxiety*, in the form of an increase of distress as expected by the researcher. Moreover, the result of the GLM analysis

showed that *Number of previous needle procedures* had a tendency towards being significant (p=0.09). The use of interaction terms could not be supported due to the limited amount of data and violation of assumptions (e.g. normality and homogeneity of variance). In addition, I calculated inter-rater reliability for research-assistant-rated *Child Anxiety* during all six phases based on 48 observations. Confer Brace et al. (2006), the result of the Pearson correlation test showed a strong correlation (r=0.712), which was highly significant.

6.7.4 Summary of Results of Research-Assistant-Rated Child Anxiety

Results of the descriptive summation and the statistical analyses showed that the two groups had an equal mean *Child Anxiety* scores in the three phases before the IV-access procedure. On the contrary, as to the *Needle Period* and the *Recovery Post-Needle Period*, the children in the MT group had the lowest mean scores. However, the mean Child Anxiety score with regard to the *Needle Period* was not significantly different. The Mixed Effects Model analysis showed that *Phase 3* differed statistically significantly compared to the other phases, while the remaining explanatory variables did not have a significantly effect. The result of the GLM analysis showed that *Age* had a tendency towards being significance. In addition, 23% of the variance of *Child Anxiety* is explained by the explanatory variables.

6.8

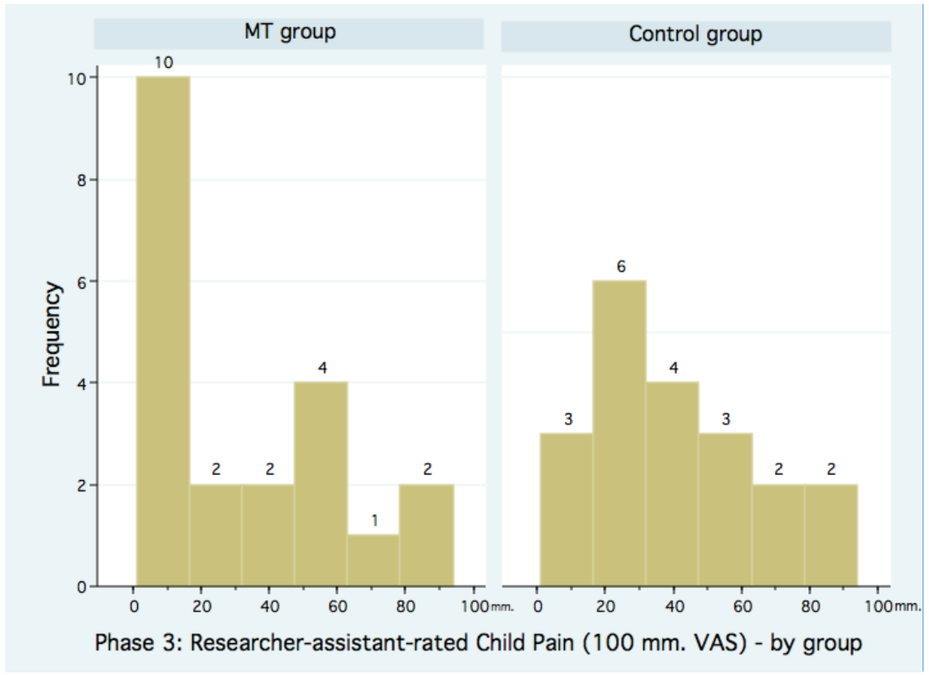
Results of Research-Assistant-Rated Child Pain

6.8.1 Results of Research-Assistant-Rated Child Pain

The research-assistant rated Child Pain in relation to the IV-procedure (Phase 3) in all 41 children. Child pain was measured by means of a 100mm bipolar Visual Analogue Scale (VAS) with 0mm being *No pain* and 100mm being *Worst imaginable pain*. Observation of Child Pain began in the start of Phase 3 and lasted throughout this phase. The VAS itself was filled in once retrospectively immediately upon completion of the phase (i.e. after the actual needle procedure ended). I calculated the VAS scores from the 0mm anchor point.

In the total sample (n=41), the mean and *SD* for Researcher-assistant-rated Child Pain were 35 and 26mm, respectively. In the MT group (n=21) the mean and (*SD*) were 31 (28)mm. In the control group they were 39 (25) mm. The distribution of Research- assistant-rated Child Pain of the two groups is graphically illustrated in figure 6.15.

Figure 6.15. Histogram of Researcher-assistant-rated Child Pain during the IV-procedure - by group.



Cf. figure 6.15, data were quite differently distributed in the two groups. Data could neither be assumed equally nor normally distributed in the two groups. Attempting to alleviate this problem by a data transformation was unsuccessful. Specifically I tried log-transforming the data and taking the square root. Therefore, I applied a Mann-Whitney U test (two-tailed). When comparing the two groups, the children in the MT group had a mean observed Child Pain score 8mm lower than did the children in the control group, 95% CI (-24 to 9). The result of the Mann-Whitney test showed no significant difference between the groups (p=0.262). In addition, based on 9 observations, I calculated inter-rater reliability for research-assistant-rated Child Pain during Phase 3. Confer Brace et al. (2006), the result of the Pearson correlation test showed a moderate correlation (r=0.681), which was significant (p=0.043).

Besides that, I performed a supplementary GLM analysis in order to control for the four pre-defined explanatory variables. This analysis was made in spite of a violation of assumptions due to the reasons described in section 6.1.4. The results of the GLM analysis showed that *Age* had a highly significant effect on research-assistant-rated Child Pain. Specifically, when I took the remaining exploratory variables into account, *Age* had an estimated mean effect of -4mm per year, 95% CI (-7 to - 1). Despite the fact that p-values cannot be taken at face value if assumptions are violated (e.g. normality, equal variance), the highly significant effect of *Age* (p=0.01), however, gives an indication of a somewhat trustworthy estimate. As to the remaining explanatory variables, *Number of previous needle procedures* yielded trends towards significance (p=0.06) as opposed to the remaining variables. In addition, for this model, the R squared showed that 29% of the variance of *Child Pain* is explained by the explanatory variables. Finally, the use of more complex models (e.g. including interaction terms) was not supported due to the limited amount of data in the study and violation of assumptions (e.g. normality and homogeneity of variance).

6.9

Results regarding Child-rated Anxiety (as measured by FPS-R)

6.9.1 Results of Child-rated Anxiety

11 of the 13 children, who were between five and ten years old, rated their anxiety in relation to the IV-procedure (Phase 3). I used a modified version of the Faces Pain Scale-Revised (Hicks et al., 2001) to assess self-reported Child Anxiety. The FPS-R is a numeric scale that ranges from 0 to 10 in steps of two points increase with 0 and 10 representing *Not afraid at all* and *Very much afraid*, respectively. The children filled in the FPS-R immediately after completion of Phase 3 (after the bandage had been placed upon completion of the IV-procedure). In the total sample (n=11), the mean and *SD* for Child-rated Anxiety were 2.73 and 3.38, respectively. In the MT group (*n*=6) the mean and *SD* were 1.33 (1.03). In the Control group (*n*=5) they were 4.40 (4.56). The distribution of scores is numerically summated in table 6.8 and in box plot labbeled figure 6.16:

Table 6.8. Distribution of Child-rated Anxiety during the IV-access procedure - by group.

Table 6.8.	**Self-reported Anxiety Scores**					
FPS-R scale	0 (Not afraid at all)	2	4	6	8	10 (Very much afraid)
MT group (*n*=6)	2	4	0	0	0	0
Control group (*n*=5)	2	0	1	0	1	1

Figure 6.16. Box plot of Child-rated Anxiety during IV-procedure - by group.

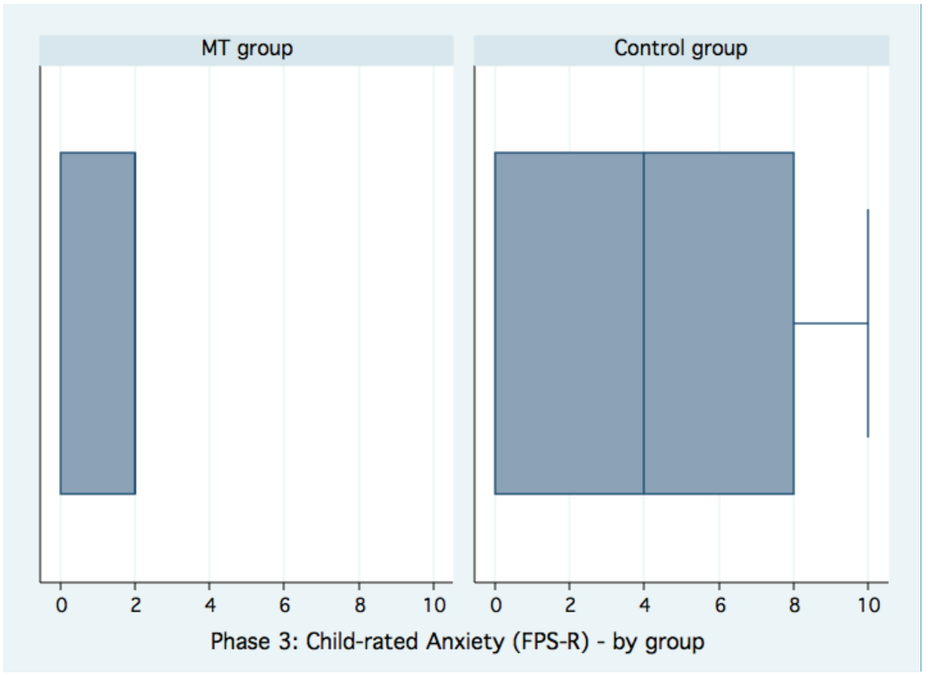


Table 6.8 and figure 6.16 show that data were neither normally nor identically distributed. Attempting to alleviate this problem by a data transformation was unsuccessful. Specifically I tried log-transforming the data and taking the square root. Thus, I applied a Mann-Whitney U test. When comparing the two groups, the mean Child-rated Anxiety score for the MT group was 3.07 points lower than for the control group. This difference was not statistically significant (p=0.338).

Due to the reasons given in section 6.1.3, I performed a supplementary GLM analysis. The result of the analysis showed trends towards a statistically significant effect of *randomisation* (p=0.075) on Child-rated Anxiety. When I took the remaining exploratory variables into account, *Randomisation* showed an estimated mean effect of -4.27 points, 95% CI (-9.13 to 0.59). The remaining four explanatory variables were not statistically significant. In addition, for this model, the R squared showed that 53% of the variance of self-reported anxiety is explained by the explanatory variables. Finally, use of more complex models (e.g. including interaction terms) was not supported due to the limited amount of data in the study and violation of assumptions (e.g. normality and homogeneity of variance).

6.10

Results Regarding Child-Rated Pain

6.10.1 Results of Child-rated Pain

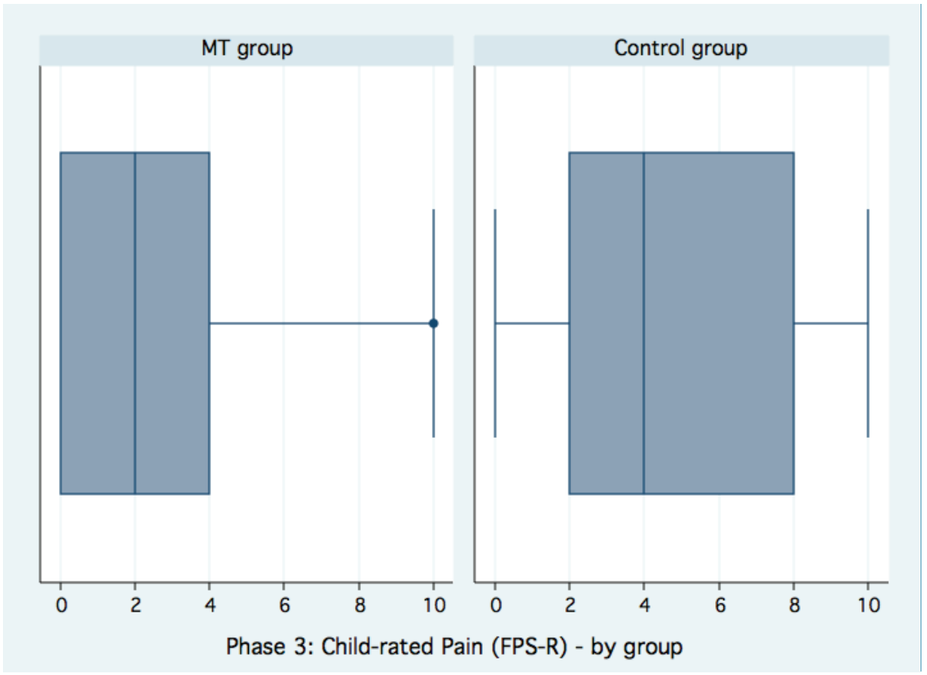
12 of the 13 children, who were between 5 and 10 years old, rated their pain in relation to the IV-procedure (Phase 3). The children rated their pain by means of the Faces Pain Scale-Revised (Hicks et al. 2001). This numeric scale ranges from 0 to 10 with a two points´ increase, with 0 and 10 representing *No pain* and *Very much pain*, respectively. The children filled in the FPS-R immediately after completion of the IV-access procedure (i.e. after the bandaged had been placed).

In the total sample (n=12), the mean and *SD* Child-rated Pain were 3.67 and 3.70, respectively. In the MT group (*n*=7) the mean and (*SD*) were 2.86 (3.43). In the Control group (*n*=5) they were 4.80 (4.15). The distribution of scores are provided in table 6.9 and figure 6.17:

Table 6.9. Distribution of Child-rated Pain during IV-access - by group.

Table xx.	**Self-reported Pain Scores**					
FPS-R scale	0 (No pain)	2	4	6	8	10 (Very much pain)
MT group (*n*=7)	2	3	1	0	0	1
Control group (*n*=5)	1	1	1	0	1	1

Figure 6.17 Box plot of Child-rated Pain during IV-access - by group.



As we can see in table 6.9 and figure 6.17, data were somewhat alike, but could not be assumed normally distributed. The assumption of homogeneity of variance was still not met after transformation. Specifically, I tried to log-transform the data and take the square root. Hence, I used the Mann-Whitney U test (two-tailed). The mean Child-rated Pain score of the MT group was 1.94 points lower than that of the control group, 95% (-6.82 to 2.93). The similarity between the groups was confirmed statistically in the analysis, which revealed no statistically significant difference between the groups (p=0.403).

In addition, due to the reasons given in section 6.1.3, I performed a supplementary GLM analysis. This analysis showed no statistically significant effect of the four explanatory variables. Moreover, for this model, the R squared showed that 20% of the variance of the Child-rated Pain is explained by the explanatory variables. Finally, the use of more complex models (e.g. including interaction terms) was not supported due to the limited amount of data in the study and violation of assumptions (e.g. normality and homogeneity of variance).

6.11

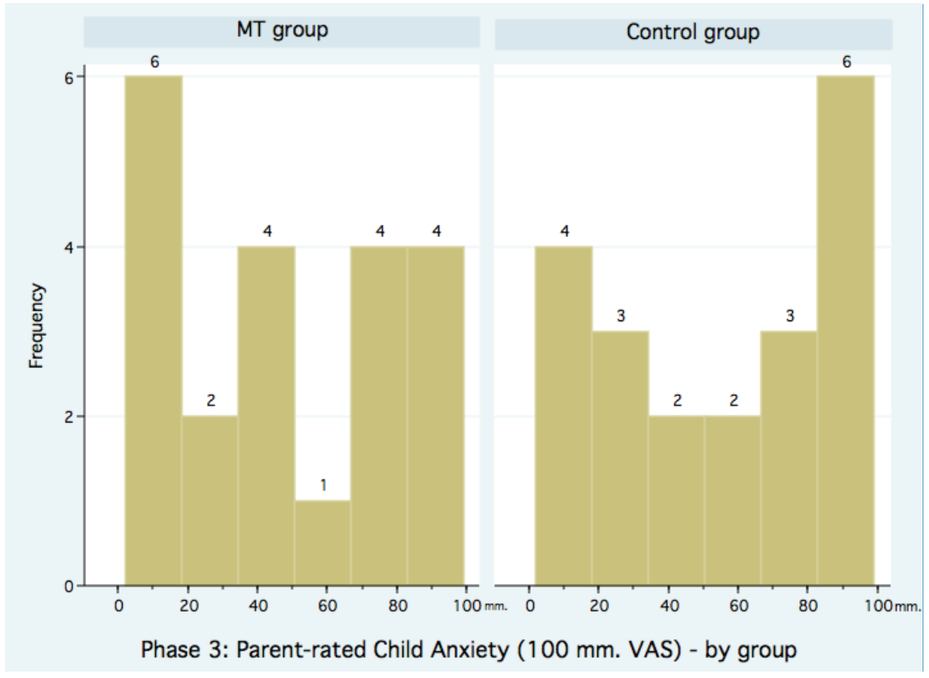
Results regarding Parent-rated Child Anxiety

6.11.1 Results of Parent-rated Child Anxiety

All parents of the 41 children rated their child´s anxiety in relation to the IV-access procedure (Phase 3). Parent-rated child anxiety was measured be means of a 100mm bipolar Visual Analogue Scale (VAS) with 0mm being *Not anxious at all* and 100mm being *Very anxious*. The parent(s) filled in the VAS once retrospectively immediately upon completion of Phase 3 (i.e. after completion of the IV-procedure). I calculated the VAS scores from the 0mm anchor point.

In the total sample (n=41), the mean and *SD* for Parent-rated Child Anxiety were 51 and 33mm, respectively. In the MT group (n=21) the mean and (*SD*) were 47 (33)mm. In the Control group (n=20) they were 55 (33)mm. The distribution of Parent-rated Child Anxiety of the two groups is graphically illustrated in the histogram (figure 6.18).

Figure 6.18. Histogram of distribution of Parent-Rated Child Anxiety during Phase 3 (the IV-access procedure) - by group.



As appears from figure 6.18, data were not normally distributed, but, however, somewhat similar. This was still the case after transformation of data. Specifically, I tried to log-transform the data and take the square root. When the two groups were compared, the mean score for the MT group was 8mm lower than that of the control group, 95% (-29 to 3). Due to the non-normal distribution of data, I used a Mann-Whitney U test (two-tailed). The similarity between the two groups was confirmed statistically in the analysis, which showed no significant difference between the groups (p=0.389).

In addition, due to the reasons given in section 6.1.3, I performed a supplementary GLM analysis. This analysis showed a tendency towards a statistically significantly effect of *Age* (p =0.06) and *Number of previous needle procedures* (p=0.10). The remaining explanatory variables were not statistically significant. In addition, for this model, the R squared showed that 17% of the variance of Parent-rated Child Anxiety is explained by the explanatory variables. Finally, the use of more complex models (e.g. including interaction terms) was not supported due to the limited amount of data in the study and violation of assumptions (e.g. normality and homogeneity of variance).

6.12

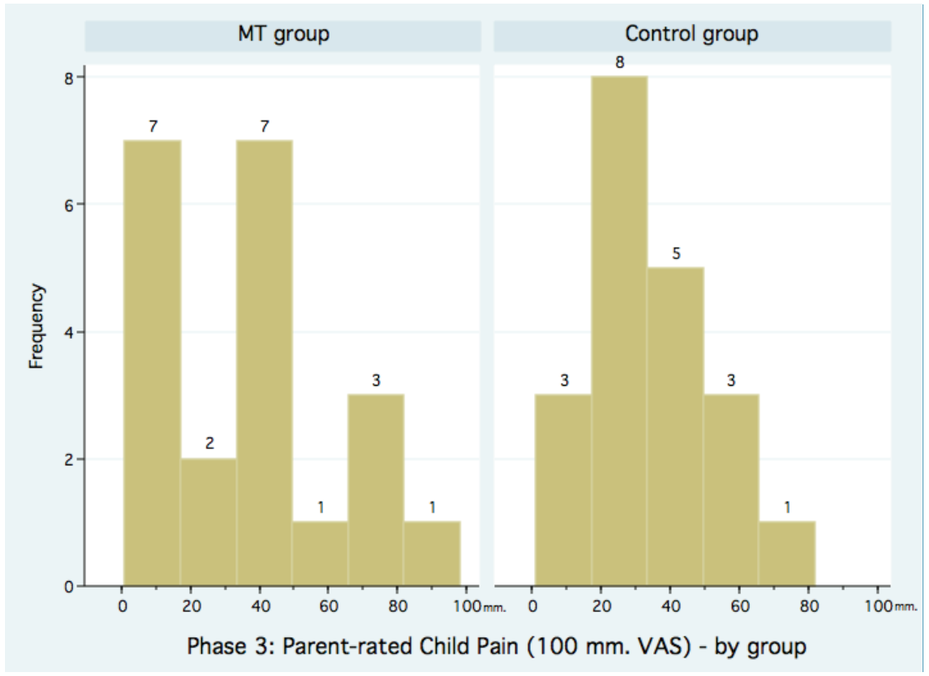
Results regarding Parent-rated Child Pain

6.12.1 Results of Parent-Rated Child Pain

All parents of the 41 children rated their child´s pain in relation to the IV-procedure (Phase 3). Parent-rated child pain was measured be means of a 100mm bipolar (No pain – Worst imaginable pain) Visual Analogue Scale (VAS) with 0mm being *No pain* and 100mm being *Worse pain imaginable*. The parent(s) filled in the VAS once retrospectively immediately upon completion of Phase 3 (i.e. the IV-procedure). I calculated the VAS scores from the 0mm anchor point.

In the total sample (n=41), the mean and *SD* for Parent-rated Child Pain were 35 and 23mm, respectively. In the MT group (n=21) the mean and (*SD*) for Child Pain were 37 (28)mm. In the Control group (n=20) they were 34 (17)mm. The distribution of Parent-rated Child Pain of the two groups is graphically illustrated in figure 6.19.

Figure 6.19. Histogram of distribution of Parent-Rated Child Pain during Phase 3 (the IV-access procedure) - by group.



As appears in figure 6.19, the distribution of scores differed between the groups. The scores of the control group were somewhat normally distributed as opposed to these of the MT group. Hence, the assumption of normality could not be met. Attempting to alleviate this problem by a data transformation was unsuccessful. Specifically I tried log-transforming the data and taking the square root. When the two groups were compared the mean score of the MT group was 3mm higher compared to the control group, 95% (-12 to 18). Therefore, I applied a Mann-Whitney U test (two-tailed), which showed no statistically significant difference between the groups (p=0.865).

Moreover, due to the reasons given in section 6.1.3, I performed a supplementary GLM analysis. This analysis showed that none of the four explanatory variables had a statistically significantly effect on Parent-rated Child Pain. In addition, for this model, the R squared showed that 9% of the variance of Parent-rated Child Pain is explained by the explanatory variables. Finally, the use of more complex models (e.g. including interaction terms) was not supported due to the amount of data in the study and violation of assumptions (e.g. normality and homogeneity of variance).

6.13

Results regarding Parent-rated Overall Satisfaction with Medical Procedure

6.13.1 Results of Parent-rated Overall Satisfaction with IV-Procedure

All parents of the 41 children rated their Overall Satisfaction with the IV-procedure by means of a 5-point researcher-developed Likert-type Scale. The scale ranged from *Very satisfied* to *Very dissatisfied* and was filled in once retrospectively immediately after completion of phase 5 (i.e. after completion of entire data collection). In case of cancellation of phase 4 or 5, the questionnaire was filled in after phase 3 or 4. In table 6.10 a summation of the results is provided:

Table 6.10. Distribution of Parent-rated Overall Satisfaction with IV-access procedure - by group.

Overall Satisfaction with Procedure					
Likert scale	**Very satisfied**	**Satisfied**	**Neither/nor**	**Dissatisfied**	**Very dissatisfied**
MT group (*n*=21)	14	4	2	1	0
Control group (*n*=20)	11	6	1	0	0

It appears from table 6.10, that the majority of the parents were satisfied with the procedure and that there was no essential difference of scores between the two groups. This could be confirmed statistically by means of a two-tailed Mann-Whitney U test (p=0.92).

6.14

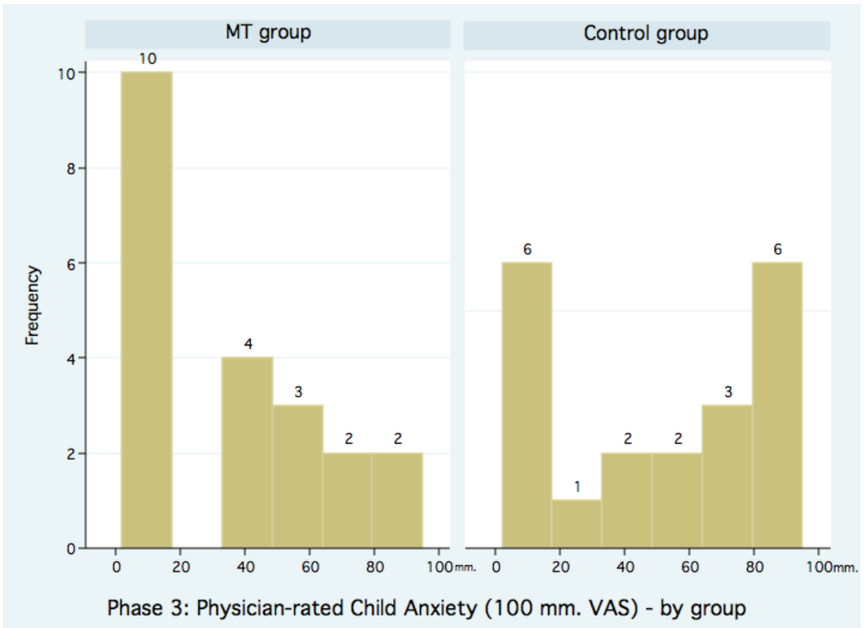
Results regarding Physician-rated Child Anxiety

6.14.1 Results of Physician-rated Child Anxiety

The physicians rated child anxiety in relation to the IV-procedure (Phase 3) in all 41 children. Physician-rated child anxiety was measured by means of a 100mm bipolar Visual Analogue Scale (VAS) with 0mm being *Not anxious at all* and 100mm being *Very anxious*. The IV-procedure was performed by one physician and an assisting nurse. The physician rated his/her rating once retrospectively immediately upon completion of Phase 3 (i.e. after the IV-procedure). I calculated the VAS scores from the 0mm anchor point.

In the total sample (n=41), the mean and *SD* for Physician-rated Child Anxiety were 43 and 33mm, respectively. In the MT group (n=21) the mean and (*SD*) for Physician-rated Child Anxiety were 34 (30)mm. In the Control group (n=20) they were 52 (33)mm. The distribution of Physician-rated Child Anxiety of the two groups is graphically illustrated in figure 6.20.

Figure 6.20. Histogram of distribution of Physician-rated Child Anxiety during the IV-access procedure - by group.



Based on figure 6.20, data were differently distributed in the two groups, unimodally in the MT group and bimodally in the control group. Hence, the assumption of homogeneity of variance was violated. Attempting to alleviate this problem by a data transformation was unsuccessful. Specifically I tried log-transforming the data and taking the square root. When the two groups were compared, the mean for Physician-rated Child Anxiety in the MT group was 19 mm lower compared to the control group, 95% (-39 to 2). Due to the non-normal distribution of data, I used a Mann-Whitney U test (two-tailed). This analysis showed that the mean difference was statistically significant (p=0.046).

Moreover, I performed a supplementary GLM analysis due to the reasons given in section 6.1.3. The result of the GLM analysis showed that *Age* had a statistically significant effect on Physician-rated Child Anxiety (p=0.04). Specifically, when I took the remaining exploratory variables into account, *Age* showed an estimated mean effect of -4mm per year, 95% CI (-7.89 to -0.16). Moreover, *Number of previous needle procedures* showed a tendency towards significance (p=0.06). On the contrary, *Randomisation* and *Needle pricks with/without EMLA* were not significant.

In addition, for this model, the R squared showed that 26% of the variance of the Physician-rated Child Anxiety is explained by the explanatory variables. Finally, the use of more complex models (e.g. including interaction terms) was not supported due to the limited amount of data in the study and violation of assumptions (e.g. normality and homogeneity of variance).

6.15

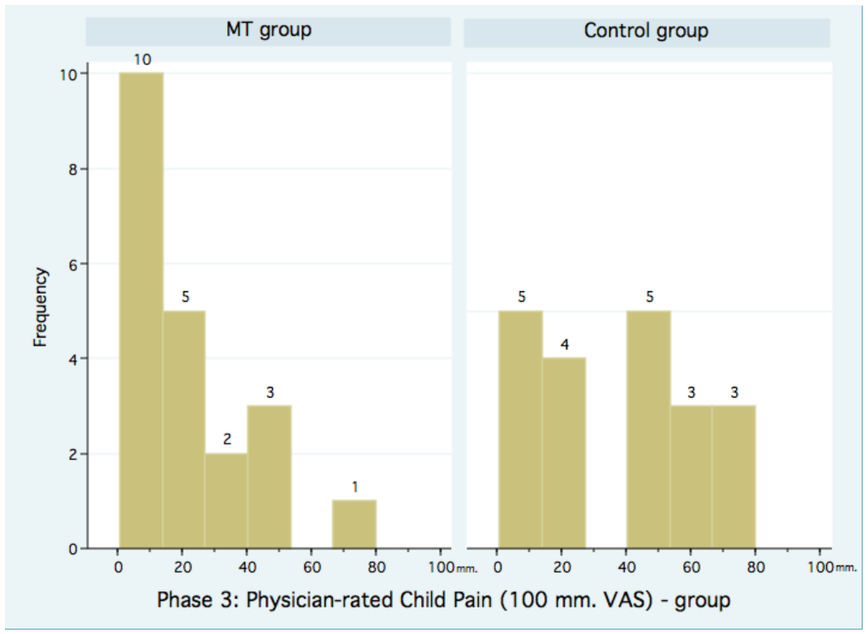
Results of Physician-rated Child Pain

6.15.1 Results of Physician-rated Child Pain

The physicians rated child pain in relation to the IV-procedure (Phase 3) in all 41 participants. Physician-rated child pain was measured by means of a 100 mm bipolar Visual Analogue Scale (VAS) with 0mm being *No pain* and 100mm being *Worst pain imaginable*. The IV-procedures were performed by one physician and an assisting nurse. The physician rated his/her rating once retrospectively immediately upon completion of Phase 3 (i.e. after the IV-procedure). I calculated the VAS scores from the 0mm anchor point.

In the total sample (n=41), the mean and *SD* for Physician-rated Child Pain were 30 and 24mm, respectively. In the MT group (n=21) the mean and (*SD*) for Child Pain were 22 (20) mm. In the Control group (n=20) they were 38 (26) mm. I have illustrated the distribution of Physician-rated Child Pain of the two groups graphically in figure 6.21.

Figure 6.21 histogram of distrubution of physician-rated child Pain during IV-procedure) - by group.



As appears from figure 6.21**,** the distributions of scores differed between the groups. The assumptions of normality and homogeneity of variance could not be met in either group. Attempting to alleviate this problem by a data transformation was unsuccessful. Specifically I tried log-transforming the data and taking the square root. When comparing the two groups, the mean score of the MT group was 16mm lower than the control group, 95% (-30 to -1). Since the assumptions of parametric tests could not be met, I applied a Mann-Whitney U test (two-tailed). The difference between the groups showed trends towards statistical significance (p=0.059).

Moreover, I carried out a supplementary GLM analysis due to the reasons given in section 6.1.3. The analysis showed that *Age* had a statistically significant effect on Physician-rated Child Pain (p=0.02). Specifically, when I took the remaining exploratory variables into account, *Age* had an estimated mean effect of -3 mm per year, 95% CI (-6 to -1). Furthermore, trends towards significance were shown with regard to *Randomisation* (p=0.061) with an estimated mean effect of -13mm, 95% CI (-26 to 1). Likewise, I found a trend towards statistical significance as to *Number of previous needle procedures*. In addition, for this model, the R squared showed that 31% of the variance of Physician-rated Child Pain is explained by the explanatory variables. Finally, the use of more complex models (e.g. including interaction terms) was not supported due to the limited amount of data in the study and violation of assumptions (e.g. normality and homogeneity of variance).

6.16

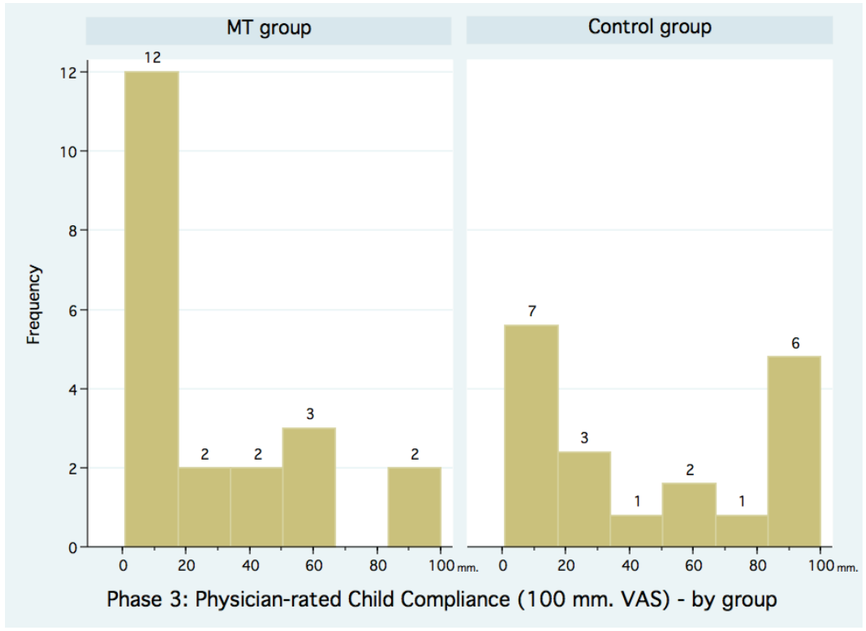
Results regarding Physician-rated Child Compliance

6.16.1 Physician-rated Child Compliance

The physicians rated Child Compliance in relation to the IV-procedure (Phase 3) in all 41 participants. Physician-rated child compliance was measured by means of a 100mm bipolar Visual Analogue Scale (VAS) with 0mm being *Very co-operative* and 100mm being *Very unco-operative*. The IV-access procedure was performed by one physician and an assisting nurse. The physician rated his/her rating once retrospectively immediately upon completion of Phase 3 (i.e. after the IV-procedure). I calculated the VAS scores from the 0mm anchor point.

In the total sample (n=41), the mean and *SD* for Physician-rated Child Compliance were 35 and 35mm, respectively. In the MT group (n=41) the mean and (*SD*) for Child Compliance were 26 (31)mm. In the Control group (n=20) they were 45 (37)mm. I have illustrated the distribution of Physician-rated Child Compliance scores graphically in figure 6.22.

Figure 6.22. Histogram of distribution of Physician-rated Child Compliance during Phase 3 (the IV-access procedure) - by group.



Based on figure 6.22**,** data differed between the two groups. However, data were not normally distributed. Attempting to alleviate this problem by a data transformation was unsuccessful. Specifically I tried log-transforming the data and taking the square root. Hence, I used non-parametric statistics in the form of a Mann-Whitney U test (two-tailed). When comparing the two groups, the mean score for the MT group was 19mm lower than for the control group. The Mann-Whitney U test revealed that the difference was not statistically significant (p=0.097).

Furthermore, due to the reasons given in section 6.1.3, I performed a supplementary GLM analysis. The result of this analysis revealed that *Age* had a highly statistically significant effect on Physician-rated Child Compliance (p=0.003). Specifically, when I took the remaining explorative variables into account, *Age* had an estimated mean effect of -6mm per year, 95% CI (-10 to -2). The three remaining explanatory variables were not significant. Moreover, for this model, the R squared showed that 34% of the variance of Physician-rated Child Compliance is explained by the explanatory variables. Finally, use of more complex models (e.g. including interaction terms) was not supported due to the limited amount of data in the study and violation of assumptions (e.g. normality and homogeneity of variance).

6.17

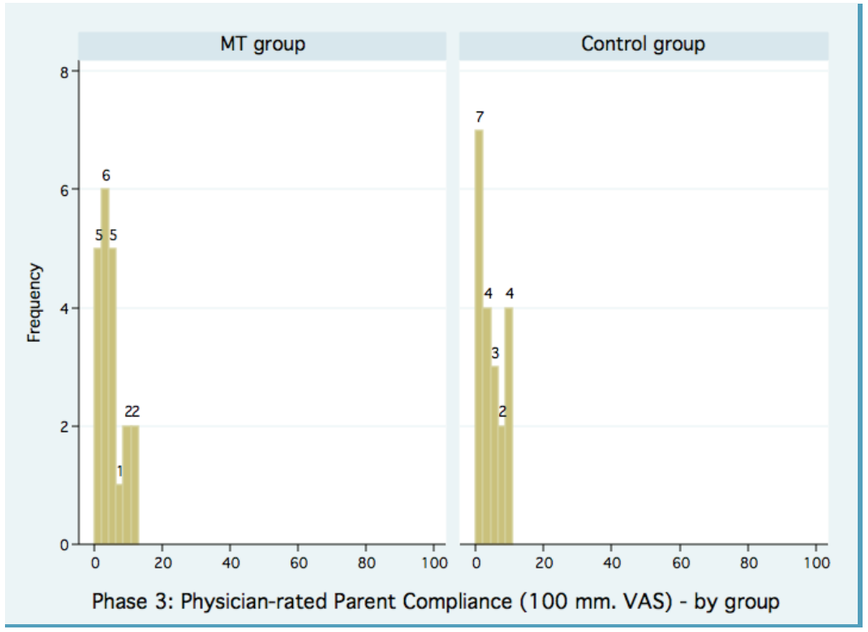
Results Regarding Physician-Rated Parent(s) Compliance

6.17.1 Results of Physician-Rated Parent(s) Compliance

The physicians rated Parent Compliance in relation to the IV-procedure (Phase 3) in all 41 participants´ parents. Physician-rated child anxiety was measured by means of a 100mm bipolar Visual Analogue Scale (VAS) with 0mm being *Very cooperative* and 100mm being *Very unco-operative*. The IV-procedure was performed by one physician and an assisting nurse. The physician rated his/her rating once retrospectively immediately upon completion of Phase 3 (i.e. after the IV-procedure). I calculated the VAS scores from the 0mm anchor point.

In the total sample (n=41), the mean and *SD* for Physician-rated Parent Compliance were 5 and 3mm, respectively. In the MT group (n=21) the mean and (*SD*) were 5 (4)mm. In the Control group (n=20) they were 5 (3)mm. In figure 6.23, I have illustrated the distribution of Physician-rated Parent Compliance scores graphically.

Figure 6.23. Histogram of distribution of Physician-rated Parent Compliance during Phase 3 (the IV-access procedure) - by group.



Based on figure 6.23, it was unreasonable to assume that the data were normally distributed in either group. However, data were somewhat similarly distributed in both groups. Attempting to alleviate this problem by a data transformation was unsuccessful. Specifically I tried log-transforming the data and taking the square root. Hence, I used non-parametric statistics in the form of a Mann-Whitney U test (two-tailed). When comparing the two groups, the means score were identical. The similarity could be confirmed statistically by a two-tailed Mann-Whitney U test (p=0.804).

Moreover, I made a supplementary GLM analysis due to the reasons given in section 6.1.3. The analysis showed that *Needle pricks with/without EMLA* had a statistically significant effect on Physician-rated Parent Compliance (p=0.046). When I took the remaining explorative variables into account, *Needle pricks with/without EMLA* had an estimated mean effect of plus 3mm, 95% CI (0 to 5) as to the children who were stuck without EMLA cream. On the contrary, the other three explanatory variables were not statistically significant. In addition, for this model, the R squared showed that 15% of the variance of Physician-rated Child Pain is explained by the explanatory variables. Finally, the use of more complex models (e.g. including interaction terms) was not supported due to the limited amount of data in the study and violation of assumptions (e.g. normality and homogeneity of variance).

6.18

Results Regarding Number of Needle Pricks

6.18.1 Results of Number of Needle Pricks

The research-assistant recorded the *Number of Needle Pricks* during the IV-access procedure (Phase 3) in all 41 participants. I defined a needle prick as each time the needle was inserted through the skin and subsequently removed entirely again. In the total sample (n=41), the mean and *SD* for *Number of Needle Pricks* were 1.61 and 0.97, respectively. In the MT group (n=21) the mean and (*SD*) were 1.57 (1.12). In the Control group (n=20) they were 1.65 (0.81). I have summated the distribution of *Number of Needle Pricks* numerically graphically in figure 6.24 and in table 6.11.

Table 6.11. Distribution of Number of Needle Pricks during IV-access procedure (Phase 3) – by group.

Numbers of Needle Pricks					
No. of Needle Pricks	1 Prick	2 Prick	3 Prick	4 Prick	5 Prick
MT group (n=21)	15	3	1	1	1
Control group (n=20)	11	5	4	0	0

Figure 6.24. Box plot of distribution of Number of Needle Pricks during the IV-access procedure (Phase 3) - by group.

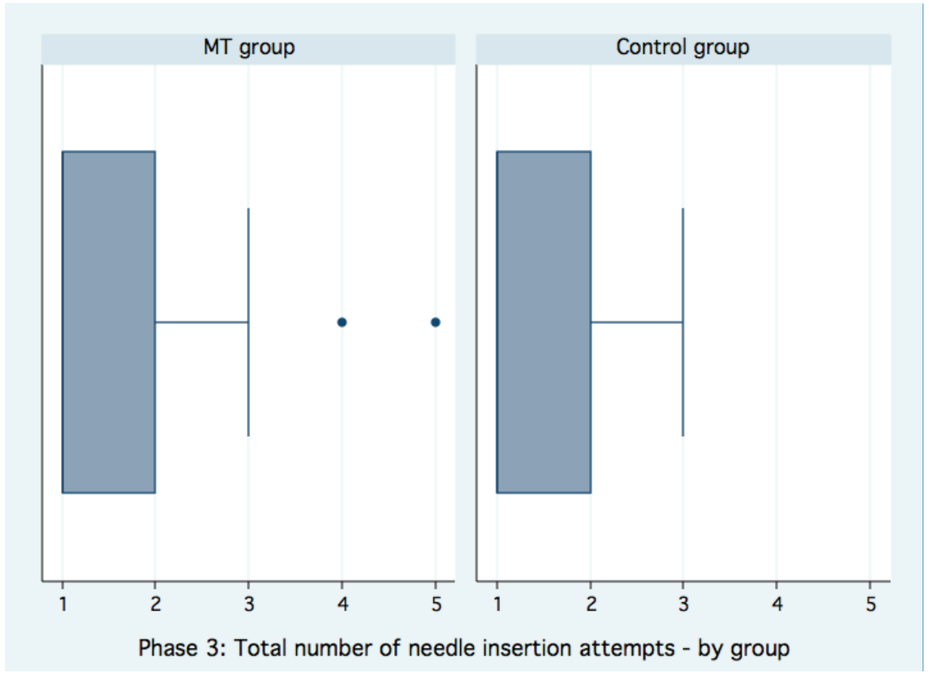


Table 6.11 and figure 6.24 show that the physicians completed the majority of the 41 IV-access procedures with only one needle prick. Consequently, data were unimodally distributed. After transformation, the assumption of normality and homogeneity of variance were still violated. Specifically, I tried log-transforming the data and taking the square root. Although the distribution of scores of the two groups differed to some extent, they had a somewhat similar mean score. When comparing the two groups, the mean score of *Number of Needle Pricks* for the MT group was 0.08 point lower than for the control group. Due to the unimodal distribution of data I applied a Mann-Whitney U test (two-tailed). This test confirmed my appraisal of similarity between the groups (p=0.378).

In addition, in each group I calculated the percentage of children, who completed the IV-procedure with only one versus more needle prick/insertions. The result of this descibtive analysis was a 71% percentage rate for children in the MT group as opposed to 55% in the control group.

Moreover, I conducted a supplementary GLM analysis due to the reasons given in section 6.1.3. Results indicated that *Age* had a statistically significant effect on Numbers of *Needle Pricks* (p=0.03). When the remaining explorative variables were taken into account, *Age* yielded an estimated mean effect of -0.14 needle prick per year, 95% CI (-0.27 to -0.02). The remaining three explanatory variables were not statistically significant (i. e. *Randomisation*, *Number of previous needle procedures*, and *Needle pricks with/without EMLA*. In addition, for this model, the R squared showed that 13% of the variance of *Number of needle pricks* is explained by the explanatory variables. Finally, the use of more complex models (e.g. including interaction terms) was not supported due to the limited amount of data in the study and violation of assumptions (e.g. normality and homogeneity of variance).

Based on my clinical experience as the music therapist in the pilot studies and main study, I appraised that *Number of needle pricks* was likely to have a major impact on the remaining 14 outcome variables. Therefore, I will now provide some additional information on this in the following. As described in section 2.2.2, the standard clinical practice guidelines for IV-access procedures at AUH are as follows. If the physician does not succeed in completing the IV-procedure after two (and absolutely no more than three) needle pricks, an additional more experienced physician is called for. The second physician then has only one attempt to succeed in the IV-access procedure. If both physicians fail, the IV-procedure and the subsequent kidney scanning are postponed to another day, when the child is sedated. As appears from table 6.11, two children in the MT group received four and five needle pricks, respectively, as opposed to the children in the control group. Although these cases did not strictly follow the normal clinical guidelines, the physician associated to the study advised me to include these children in the analysis.

Besides that, IV-access procedures *without* administration of EMLA cream are often more painful and stressful, which could also potentially influence the values of the other outcome measures in the study (e.g. child anxiety, child pain). Therefore I examined the distribution of *Needle pricks with/without EMLA* and the *combination of these* between the two groups. Cf. section 6.3.7, numbing cream in the form of EMLA plasters was administered to 39 of the 41 participants. However, in practice a total of seven children were stuck exclusively without EMLA (i.e. in other spots where EMLA had been administered). These children were equally allocated to the two groups, four to the MT group and three to the control group. I compared the distribution of demographical and baseline data of these children between the two groups and found that they were alike. The conclusion of similarity could also be

confirmed statistically. Besides that, three other children received a *combination* of needle pricks *with* and *without* EMLA administered spot. These children were also allocated equally to the two groups, one in the MT group and two in the control group. Likewise, when comparing the two groups, these three children did not differ in terms of distribution of demographical and baseline data.

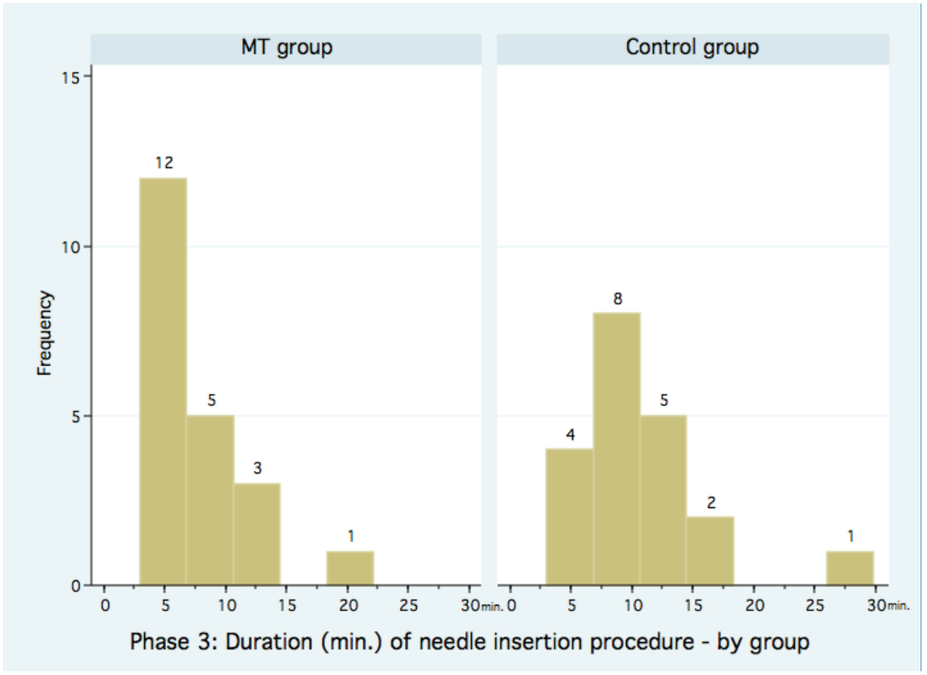
6.19

Results regarding Duration of IV-Procedure

6.19.1 Results of Duration of IV-procedure

The research-assistant registered the Duration of each child´s IV-procedure (i.e. Phase 3) in minutes and seconds. In the total sample (*n*=41), the mean and *SD* for the Duration of Phase 3 were 8.94 and 4.84 minutes, respectively. In the MT group (*n*=21) the mean and (*SD*) for Duration were 7.28 (4.05) minutes with a median of 5.59 minutes. In the Control group (*n*=20) they were 10.67 (5.09) minutes and had a median of 9.99 minutes. I have illustrated the distribution of Duration of the two groups graphically in figures 6.25.

Figure 6.25. Histogram of distribution of Duration of the IV-access procedure (Phase 3) - by group.



As appears from figures 6.25, the distribution of data differed between the groups. Moreover, data were somewhat normally distributed in the control group as opposed to the MT group. Due to the difference in data distributions, the assumption of normality could not be met, neither after transformation of data. Specifically, I tried log-transforming the data and taking the square root. Hence, I applied non-parametric statistics in the form of a Mann-Whitney U test (two-tailed). When comparing the two groups, the mean duration of Phase 3 (the actual IV-procedure) was 3.39 minutes shorter in the MT group compared to the control group. The appraisal of the difference between the groups could be confirmed statistically. A Mann-Whitney U test showed a highly statistically significant difference between the groups (p=0.009). In addition, I calculated inter-rater reliability for the duration of Phase 3 based on 9 observations. Confer Brace et al. (2006), the result of the Pearson correlation test showed a strong correlation (r=0.993), which was highly statistically significant.

Besides that, I made a supplementary GLM due to the reasons described in section 6.1.3. The analysis showed a statistically significant effect of *Randomisation* (p=0.037) on duration of the IV-procedure. Specifically, when I took the remaining exploratory variables into account, *Randomisation* yielded an estimated mean effect of -3.20 minutes in favour of the MT group, 95% CI (-6.20 to -0.20). The three remaining explanatory variables were far from statistically significant (i.e. *Age*, *Number of previous needle procedures,* and *Needle pricks with/without EMLA*). In addition, for this model, the R squared showed that 16% of the variance of the duration is explained by the explanatory variables. Finally, use of more complex models (e.g. including interaction terms) was not supported due to the limited amount of data in the study and violation of assumptions (e.g. normality and homogeneity of variance).

6.20

Results regarding Research-assistant-rated Positive Child Behaviour

6.20.1 Research-assistant-rated Positive Child Behaviour – Descriptive Summary

The research-assistant rated Positive Child Behaviour during all six phases by means of the Observation Scale of Positive Child Behaviour (OSPCB). As described in section 5.5.8, I developed the OSPCB for the purpose of this study. However, the scale was not valid. The OSPCB is a numerical scale with 7-items. The research-assistant filled in the scale prospectively during all six phases, which, however, differed notably in terms of duration and use of time interval ratings. As described in section 5.6, I pre-defined the Baseline Phase to last three minutes, whereas Phases 1 and 2 were not limited in duration. During these three phases the OSPCB was filled once (prospectively) and had a minimum and maximum score of 0 and 7, respectively. The research-assistant filled in the OSPCB every 30 seconds throughout Phase 3, which varied in duration from one child to another. Likewise, the OSPB was filled in every 30 seconds in Phases 4 and 5, which I pre-defined to last three and seven minutes, respectively.

As described in the Method Chapter, I calculated research-assistant-rated Child Distress and Positive Child Behaviour separately and not by subtraction. In addition, the minimum and maximum OSPCB scores varied across the six phases due to the above-mentioned differences in terms of duration and time interval rating (cf. section 5.6). Consequently, I computed comparable group scores in the form of ***mean*** scores and phase-wise ***average*** scores. In short, I calculated ***Mean*** scores by dividing each child´s total positive behaviour score by the number of children in

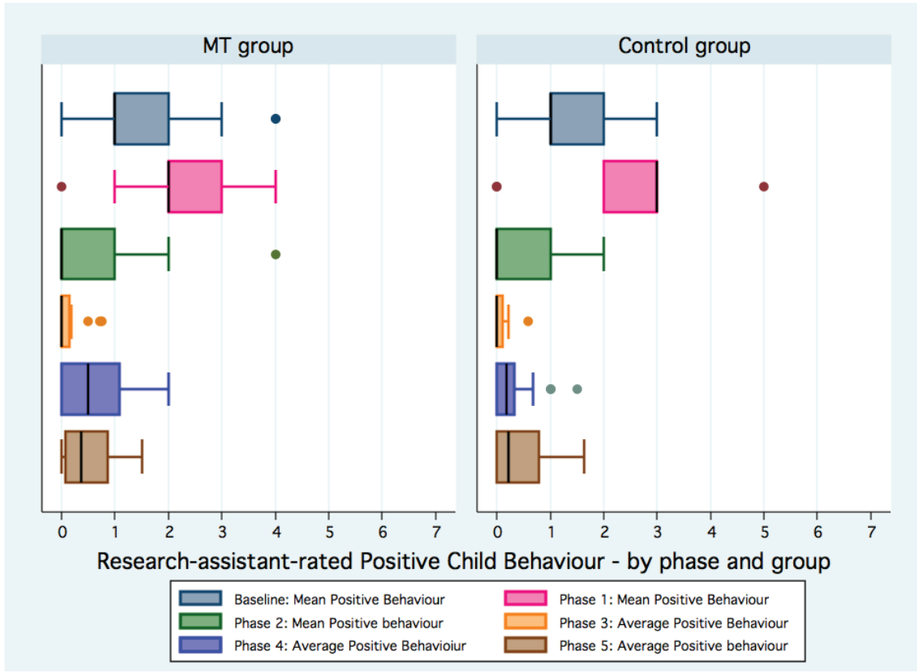
the respective group. I computed the ***Average*** phase-wise scores by dividing each child´s total positive behaviour score by the number of observed 30-second interval ratings divided by the number of children in the respective group. Consequently, the ***mean*** scores reflect a value between 0 to 7 on the OSPCB, whereas the ***average*** scores reflect the average positive child behaviour level of the groups across total number of 30-second interval ratings expressed by a value between 0 to 7 on the OSPCB.

After this initial clarification, I will now move on to the actual presentation of results. Table 6.12 and figure 6.26 display a descriptive summation and graphical illustration of research-assistant-rated positive child behaviour scores during all six phases. As appears from the table (table 6.12), the number of observations varied throughout the six phases due to time pressure and logistic circumstances as mentioned earlier in section (6.2.2).

Table 6.12 Descriptive summation of Research-assistant-rated Positive Child Behaviour across phases, in total sample and by group.

Research-assistant-rated Positive Child Behaviour according to phase					
Measurement point	**Total sample**	**MT group**	**C group**	**Mean difference**	***p*a**
	N, M (SD)	*n, M (SD)*	*n, M (SD)*	95% CI	
Pre-Needle Period					
Base line:	*37* 1.51 (1.17)	*20* 1.55 (1.23)	*17* 1.47 (1.13)	0.08 (-0.71 to 0.87)	(0.94)
Phase 1:	*35* 2.34 (1.08)	*20* 2.25 (0.97)	*15* 2.47 (1.25)	-0.22 (-0.98 to 0.54)	
Phase 2:	*29* 0.59 (0.95)	*14* 0.57 (1.16)	*15* 0.60 (0.74)	-0.03 (-0.76 to 0.71)	
Needle Period					
Phase 3: Average	*41* 0.10 (0.19)	*21* 0.12 (0.23)	*20* 0.07 (0.14)	0.05 (-0.08 to 0.17)	
Recovery Post-Needle Period					
Phase 4: Average	*37* 0.48 (0.57)	*20* 0.62 (0.62)	*17* 0.31 (0.46)	0.31 (-0.07 to 0.67)	
Phase 5: Average	*36* 0.43 (0.45)	*19* 0.47 (0.44)	*17* 0.39 (0.48)	0.08 (-0.23 to 0.39)	
a. Mann-Whitney U-test for non-normally distributed outcomes.					

Figure 6.26. Box plot of Research-assistant-rated Positive Child Behaviour during Baseline Phase & Phases 1 to 5, by group.



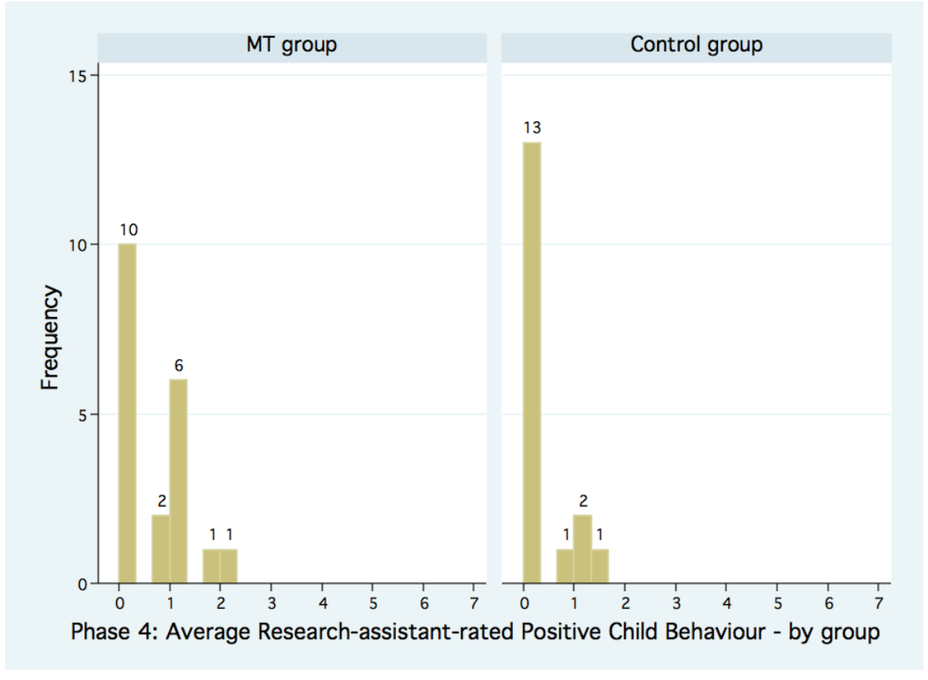
Tabel 6.12 & figure 6.26 illustrate research-assistant-rated Positive Child Behaviour by group during all six phases. In figure 6.26 the x-axis displays the level of positive child behaviour as measured by the OSPCB, whereas the six phases are represented on the y-axis. From the graph we can see that both groups had a somewhat similar progression in positive behaviour during the six phases. As appears from the figure, the highest level of positive behaviour was in Phase 5. Furthermore figure 6.26 and table 6.12 show that the level and spread of Positive Child Behaviour were somewhat equal in the two groups during the Baseline Phase and Phases 1 to 3, but higher in Phases 4 and 5 in the MT group. In addition, one can see a decrease in Phase 2 compared to Phase 1. This illustrates that the children in both groups exhibited less Positive Child Behaviour upon the physician´s entrance into the treatment room. This finding was consistent with the descriptive results regarding Observed Child Distress and Anxiety, however in reverse (sections 6.6 and 6.7).

6.20.2 Results of *Average* Phase 4 Research-Assistant-Rated Positive Child Behaviour

In Phase 4 the research-assistant rated Positive Child Behaviour in 37 of the 41 participants by means of the OSPCB. The OSPCB scale is a numerical 7-item scale ranging from 0 to 7 points. I pre-defined Phase 4 to last 3 minutes while the OSPCB was filled in continuously every 30 seconds. I computed comparable Phase 4 ***Average*** Positive Child Behaviour scores for both groups. This was done by dividing each child´s total Positive Behaviour score by the number of observed 30-second intervals. Consequently, the Phase 4 ***Average*** scores reflect the average Positive Child Behaviour scores in the two groups expressed by a value between 0-7 on the OSPCB.

In the total sample (n=41), the ***average*** and *SD* of Research-assistant-rated *Positive Child Behaviour* were 0.48 and 0.57, respectively. In the MT group (n=20) the mean and (*SD*) were 0.62 (0.62) and had a median of 0.33. In the Control group (n=17) they were 0.31 (0.46), and had a median of 0.13. The distribution of Research-assistant-rated Positive Child Behaviour of the two groups is graphically illustrated in figure 6.27.

Figure 6.27. Histogram of distribution of Average Phase 4 Research-assistant-rated Positive Child Behaviour by group.



Based on figure 6.27, it was unreasonable to assume that the data were normally distributed in either group. Attempting to alleviate this problem by a data transformation was unsuccessful. Specifically I tried log-transforming the data and taking the square root. When comparing the two groups, the mean score for the MT group was 0.32 point higher than for the control group, 95% CI (-0.07 to 0.67). Due to the skew distribution of data, I applied a Mann-Whitney U test (two-tailed). This test showed that the difference was not statistically significant (p=0.13). Furthermore, I computed effect in terms of Cohen´s d to provide a more intuitive measure of the effect of the MT intervention. The calculation revealed a positive small effect of the MT intervention (d=0.29). On the basis of 48 observations, I calculated inter-rater reliability for research-assistant-rated Positive Child Behaviour during Phase 4. Confer Brace et al. (2006), the result of the Pearson correlation test showed a strong correlation (r=0.810), which was highly statistically significant.

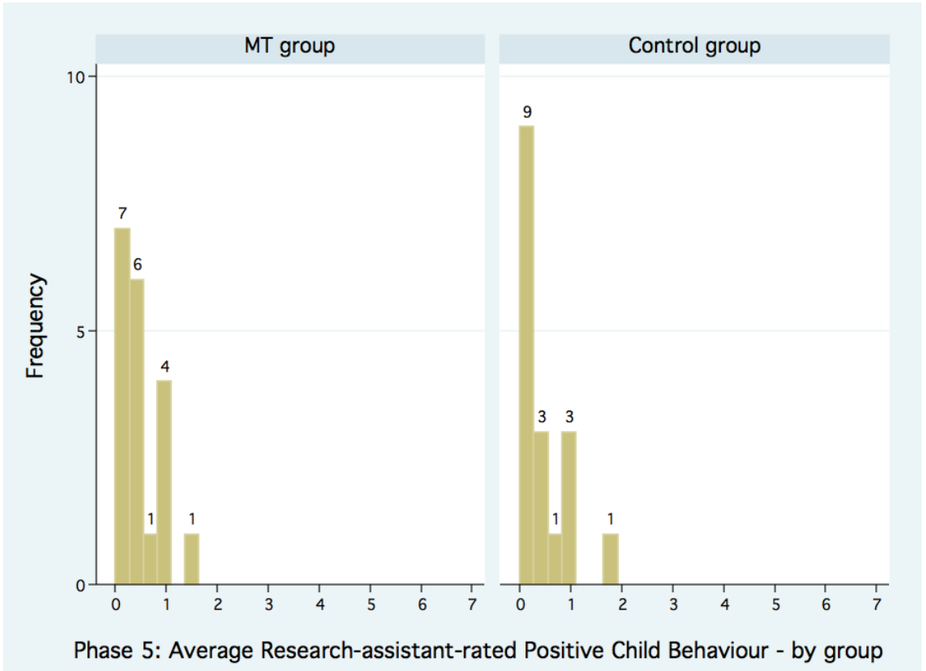
Moreover, I made a supplementary GLM analysis due to the reasons given in section 6.1.3. This analysis showed a tendency towards statistical significance with regard to *Needle pricks with/without EMLA* as opposed to the three remaining explanatory variables (i.e. *Age*, *Randomisation*, and *Number of previous needle procedures*). In addition, for this model, the R squared showed that 23% of the variance of the Positive Child Behaviour is explained by the explanatory variables. Finally, use of more complex models (e.g. including interaction terms) was not supported due to the limited amount of data in the study and violation of assumptions (e.g. normality and homogeneity of variance).

6.20.3 Results of Average Phase 5 Research-Assistant-Rated Positive Child Behaviour.

In Phase 5 the research-assistant rated Positive Child Behaviour in 36 of the 41 participants by means of the OSPCB. As described in, the OSPCB is a numerical 7-item scale ranging that ranges from 0 to 7 points. I pre-defined Phase 5 to last 7 minutes while the OSPCB was filled in continuously in 30-second intervals. I computed comparable Phase 5 ***Average*** Positive Child Behaviour scores for both groups. This was done by dividing each child´s total Positive Behaviour score by the number of observed 30-second intervals. Consequently, the Phase 5 ***Average*** scores reflect the average Positive Child Behaviour scores across all 30-second interval ratings in the two groups expressed by a value between 0-7 on the OSPCB.

In the total sample (*n*=36), the mean and *SD* for Research-assistant-rated Positive Child Behaviour were 0.43 and 0.45, respectively. In the MT group (*n*=19) the mean and (*SD*) were 0.47 (0.44) and had a median of 0.36. In the control group (*n*=17) they were 0.39 (0.48) and had a median of 0.21. The distribution of Research-assistant-rated Positive Child Behaviour of the two groups is graphically illustrated in figure 6.28.

Figure 6.28. Histogram of distribution of ***Average*** *Phase 5 Research-assistant-rated Positive Child Behaviour by group.*



As appears from figure 6.28, data were unimodally distributed in both groups. Hence, the assumption of normally could not be met. Attempting to alleviate this problem by a data transformation was unsuccessful. Specifically I tried log-transforming the data and took the square root. When comparing the two groups, the mean score for the MT group was 0.08 points higher than for the control group, 95% CI (-22 to 39). Since the assumptions of parametric statistics could not be met, I used non-parametric statistics in the form of a Mann-Whitney U test (two-tailed). This test confirmed the appraisal of similarity between the scores of the two groups (p=0.31). In addition, I calculated the effect (Cohen´s *d*) of the MT intervention in order to give a more intuitive measure of the possible benefit of it. The

calculation revealed a positive very small effect (*d*=0.09). In addition, I calculated inter-rater reliability for research-assistant-rated Positive Child Behaviour during Phase 5 based on 98 observations. Confer Brace et al. (2006), the result of the Pearson correlation test showed a moderate (*r*=0.645), which was highly statistically significant.

Moreover, due to the reasons given in section 6.1.3, I made a supplementary GLM analysis. This analysis revealed that none of the four explanatory variables had a statistically significant effect on Positive Child Behaviour. In addition, for this model, the R squared showed that 12% of the variance of Positive Child Behaviour is explained by the explanatory variables. Finally, the use of more complex models (e.g. including interaction terms) was not supported due to the limited amount of data in the study and violation of assumptions (e.g. normality and equal variance).

6.20.4 Results of Linear Mixed Effects Model Analysis of Positive Child Behaviour

I analysed the repeated measures of research-assistant-rated *Positive Child Behaviour* across Phases 1 to 5 by means of a Linear Mixed Effects Model (LMEM). I made this due to the lack of an equivalent non-parametric alternative with a view to controlling for the pre-defined explanatory variables. However, this meant that the assumptions of the model were violated. However, it seemed reasonable that the assumption of independence was met as described in section 6.1.4. Specifically, I considered the defined explanatory variables and furthermore *Phases* as fixed effects. I regarded ID randomisation number (number of child) as random effects. The analysis included the total sample (*n*=41) and showed a highly statistically significant difference regarding *phases* (i.e. Phases 1 and 3). I made the estimation of phase on the basis of Phase 5 (i.e. reference). Results showed that Phase 1 had an increase of Positive Child Behaviour, whereas Phase 3 showed a decrease as I expected. Moreover, *Age* was also statistically significant (p=0.015) and yielded an estimated mean effect of a 0.04 (0.01 to 0.08) point´s increase per year on research-assistant-rated Positive Child Behaviour on the OSPCB scale. In addition, the effects of *Number of previous needle procedures* showed trends towards statistical significance. The remaining explanatory variables were not statistically significant. Furthermore, I did not use more complex statistical models including interaction terms due to the limited amount of data in the study and violation of assumptions. Finally, based on 323 observations

made during the six phases, I calculated inter-rater reliability for research-assistant-rated Positive Child Behaviour. Confer Brace et al. (2006), the result of the Pearson correlation test showed a strong correlation (r=0.794), which was highly statistically significant.

6.20.5 Summary of Results of Research-Assistant-Rated Positive Child Behaviour

Results of the descriptive summation and the statistical analyses showed that children in the MT group had higher *average* Positive Child Behaviour scores compared to the control group including Phases 4 and 5. The mean difference between the groups was largest in Phase 4. However, these findings were not statistically significant in either of the two phases. Furthermore, the LMEM analysis showed that *Phase* and *Age* differed statistically significantly. On the contrary, none of the explanatory variables had a statistically significant effect, including the variable MT.

6.21

Results of Satisfactory Survey of MT-intervention

Now will present the results of the last outcome measure, *Satisfaction with the Music therapy Intervention*. As mentioned in the method chapter, I made a satisfactory survey of the MT intervention in which I examine whether the 21 families randomised to the MT group:

1) Would wish MT at possible future similar medical procedures
2) Would recommend MT to others
3) Found the MT Usefulness under the course the IV-access procedure

Specifically, the survey consisted of an additional questionnaire that was filled in by parents of children who were less than five years old. However, as to the 13 children who were between five and ten years old, the questionnaires were filled in by the parents and children in co-operation. Below, I will now present the results, which are summated in table 6.13.

6.21.1 Wish for MT at possible future procedures

Of the 21 participating children/families, 17 (81%) reported a wish for MT under possible future IV-access procedures. 3 (14%) answered *No* and 1 (5%) *Don´t know*.

6.21.2 Recommendation of MT

Of the 21 participating children/families, 18 (86%) answered that they would recommend MT to others under IV-access procedures. 1 (5%) answered *No* and 2 (10%) *Don´t know*.

6.21.3 Usefulness of MT

Of the 21 participating children/families, 20 answered this third question regarding the usefulness of the MT intervention. 11 (52%) rated MT as being *Very useful* and 7 (33%) as being *Useful*. 1 family (5%) answered that the MT was Neither/nor useful as opposed to 2 families (10%), who found it *Useless*. In addition, *0* families found it *very useless*.

Table 6.13 Results of satisfactory survey regarding the music therapy intervention.

Question	MT group
Wish for future MT (*n*=21)	Yes: 17 (81%) No: 3 (14%) Don´t know: 1 (5%)
Recommendation of MT (*n*=21)	Yes 18 (86%) No: 1 (5%) Don´t know 2 (10%)
Usefulness of MT (*n*=20)	Very useful: 11 (52%) Useful: 7 (33%) Neither/nor 1 (5%) Useless 2 (10%) Very useless 0 (0%)

As appears from table 6.13, the response of the questionnaire was mainly but not unconditionally positive. In total, three families did not wish MT under possible future procedures and one family answered *Don´t know*. One family would not recommend MT to others, whereas two families answered *Don´t know*. Finally, two families found MT useless and one answered *Don´t know*. In order to establish how many families these more or less negative answers represented, I subsequently summated the answers according to each family. In order to anonymise the families, I have referred to them by letters. The result is displayed in table 6.14.

Table 6.14 Summation of displeased response to MT by family.

	Future MT	Recommendation of MT	Usefulness
Family A	No	No	Very useful
Family B	Yes	Don´t know	Very useful
Family C	No	Don´t know	Useless
Family D	No	Yes	Useless
Family E	Don´t know	Yes	Neither/nor

Cf. table 6.14, it appears that the responses were not consistent across all three items of the MT questionnaire apart from Family C. For instance, family A neither wished future MT nor would they recommend MT to others. However, they responded that MT was *Very Useful*. As appears from table 6.14, 81% of the children randomised to the MT condition stated that they would wish MT under future procedures, 86% would recommend MT to others, and 85% stated that the MT was very useful or useful. Although these percentages are relatively high, it is still important to gain a greater understand of the remaining mixed responses both with an eye to improving the MT intervention, its effectiveness, and to examining possible contra indications as well as formulating clinical guidelines. Consequently, I wanted a further exploration of possible reasons for the mixed responses. Therefore, I took a closer look at the raw data (i.e. the actual document of written comments) and examined the written comments of the research-assistants and parents. In the following presentation I will link each family´s answer in relation to the satisfactory survey with their written comments and possible comments made by the research-assistants.

6.21.3.1 Family A

The girl in family A was 6.0 years old and had undergone 11 to 15 *Previous needle procedures*. The child answered the questions regarding future MT (*No*) and recommendation of MT (*No*), whereas the parents rated the usefulness of MT (*Very Useful*). Unfortunately, the document of written comments was not included in the data collection protocol at this point. It was only after participant number 15.

6.21.3.2 Family B

The girl in family B was 3.6 years old and had experienced 16 or more *Previous needle procedures*. Since the child was under 5 years old, the parents answered all three questions of the MT satisfactory questionnaire (Wish for future MT: *Yes*; Recommendation of MT: *Don´t know*; Usefulness of MT: *Very Useful*). Unfortunately, the parents did not give written comments.

6.21.3.3 Family C

The girl in family C was 1.2 years old and had experienced 1 to 5 *Previous needle procedures*. Since the child was under than 5 years old, the questions regarding the MT intervention were answered by her father (Wish for future MT: *No*; Recommendation of MT: *Don´t know*; Usefulness of MT: *Useless*). Written comments of the father as well as the research-assistant were recorded. The research-assistants wrote the following in the comment field after completion of *Phase 1*: "*The father is in someway a bit in opposition, but probably because he is a bit under pressure due to the situation*". As to the farther´s comments, he wrote the following after completion of the IV-procedure: "*My girl is rather afraid of strangers right now that is why she did not really fall for the music* ". Both written comments were in concordance with my experience as the music therapy clinician. Already from our first encounter I felt the farther was very sceptical about me and the concept of the music therapy intervention. During *Phase 1* which lasted 34 minutes, he kept a clear distance from me and only involved himself interactively to a minimum (e.g. participated musically, gave suggestions, encouraged the child to participate).

6.21.3.4 Family D

The girl in family D was 10.6 years old and had experienced one to five *Previous needle procedures*. The girl answered that she *did not wish* MT for future procedures. However, from the raw data sheet it did not appear who answered the question regarding recommendation of MT (*No*). On the contrary, the mother answered the question regarding the usefulness of the MT (*Useless*). Written comments from the mother as well as the research-assistant were recorded. The MT intervention was video recorded before, during, and after the IV-procedure. During the

Pre-Needle Period (i.e. *Phases 1* and *2*), there were five persons present in the treatment room besides the girl and her mother (i.e. two photographers, two research-assistants, the music therapist, and a nurse). After completion of *Phase 1* the research-assistant wrote: "*The child sits close to her mother. I note few smiles, but the child seems very conscious of the presence of the many people, and the video recordings*". In the written comment field of *Phase 3* the research-assistant wrote: "*The child is passive in relation to the music*". Furthermore, she wrote with regard to the recovery phase (Phases 4 and 5): "*Generally in Phases 4 and 5 the child seems almost apathetic. The child answers the questions that are asked, but does not react otherwise*".

These above-mentioned impressions of the girl were consistent with my experience as the music therapist clinician. I found the girl very introvert and reluctant towards me. She did not show any willingness to establish rapport, participate actively in music making or even talk about her preferred songs. In addition, the parent wrote: "*The music itself was ok, but as to my daughter there were too many people involved. She is a very private person. Maybe we should have rejected* (Ilan Sanfi: consent to) *the video recording*".

The video recording of the IV-procedure was initiated on my request with the purpose of complementing the written descriptions of the MT intervention in this thesis. For practical reasons I asked the mother to give her consent to the video-recordings just the evening before the IV-procedure. It proved problematic that the mother gave consent without having the opportunity to ask or even inform her daughter. In addition, they did not withdraw the consent to video-recording after arrival at the outpatient unit. In retrospective, it is understandable that it might have been difficult for the mother to see the consequences of taking part in video recordings as well as MT.

6.21.3.5 Family E

The girl in family E was a 3.4 year-old, who had a medical record of one to five *Previous needle procedures*. Due to the age of the child, the parents answered the questionnaires (Wish for future MT: *Don´t know*; Recommendation of MT: *Don´t know*; Usefulness of MT: *Neither/nor*). The parent of the child wrote: *"I think music therapy is really*

good. But in our case it has probably not had a big effect with regard to the IV-access procedure, since our daughter normally takes such things quite calmly". The research-assistant did not write any additional comments related to this. Furthermore, although introvert and clearly dependent of the security of being close to her mother, I noted as the clinician that the girl was engaged in the MT and rapport could be established

6.22

Results of Inter-Rater Reliability Tests

As mentioned in section 5.6.1, four research-assistants managed the collection of data in the study. In short, due to various reasons research-assistants numbers 1 and 2 observed 12 children joined together, whereas research-assistants numbers 3 and 4 observed 16 and 13 children, respectively. I calculated inter-rater reliability retrospectively and only between research-assistants numbers 3 and 4. The test was based on data collected in the last part of the course of the data collection period. Specifically, I used Pearson Correlation to calculate the inter-rater reliability based on nine children that were observed simultaneously by both research-assistants during *Baseline Phase* and *Phases 1* to *5*). I calculated inter-rater reliability for *Phase 3* and/or the above-mentioned six phases in relation to research-assistant-rated:

- Child Distress (OSBD-R): Baseline Phase and Phases 1 to 5 plus Phase 3 separately
- Child Anxiety (VAS): Baseline Phase and Phases 1 to 5 plus Phase 3 separately
- Child Pain (VAS): Phase 3
- Number of needle pricks: Phase 3
- Duration of the Needle Phase, Phase 3 (minutes and seconds)
- Positive Child Behaviour (OSPCB): Baseline Phase and Phases 1 to 5 plus Phase 3 separately

In table 6.15, I have displayed the results of the inter-rater reliability test.

Table 6.15. Result of inter-rater reliability tests between research-assistants 3 and 4.

Results of inter-rater reliability tests between observer 3 & 4			
Outcome measure	***n***	***r***	***p***
Observed Distress			
- all 6 phases	321	0.763	0.000**
- Phase 3 only	154	0.654	0.000**
Observed Anxiety			
- all 6 phases	48	0.712	0.000**
- Phase 3 only	9	0.632	0.068
Observed Pain (Phase 3)	9	0.681	0.043*
No. of Needle Pricks	9	0.972	0.000**
Duration (Phase 3)	9	0.993	0.000**
Observed Positive Child Behaviour			
- all 6 phases	323	0.794	0.000**
- Phase 4 only	48	0.810	0.000**
- Phase 5 only	98	0.645	0.000**
* Sign. at the 0.05 level (2-tailed)			
** Sign. at the 0.01 level (2-tailed)			

As appears from table 6.15, the inter-rater reliability test for research-assistants 3 and 4 showed values of *r* between 0.632 and 0.993. Furthermore, these tests were made on the basis of 9 to 323 observations, respectively. Except for Observed Child Anxiety in Phase 3, these results were significant. In relation to the results of the outcome measures in question, as presented previously in this chapter, the inter-rater test (i.e. Pearson correlation) as to *Observed Child Distress* during *Phase 3* showed a moderate correlation (r=0.654), Observed Child Anxiety in Phase 3 showed a moderate correlation (r=0.632), and Observed Child Pain in Phase 3 showed a moderate correlation (r=0.681). Contrary to the remaining outcome measures, Duration of Phase 3 showed a strong correlation (r=0.993). Finally, Observed Positive Child Behaviour showed a strong and a moderate correlation during Phase 4 (r=0.810) and Phase 5 (r=0.645), respectively.

6.23

Overall Summation of Results Regarding the 16 Outcome Measures

I have now presented the results of the main statistical analyses related to the 16 outcome measures, including the MT satisfactory survey. In these presentations I provided much statistical information. In order to provide an overview, I have summated most of the above-presented results in table 6.16**.** In the table I have grouped the results according to each outcome domain (i.e. anxiety, pain etc.). The table holds a summation of the results of number of observations, mean scores and *SD*, mean differences with 95% CI, *p*-values, possible effect sizes, and inter-rater reliability in relation to each of the outcome measures (except for satisfaction with the MT intervention). Please note that these *p*-values relate to the main statistical analyses and are based on non-parametric tests in the form of Mann-Whitney U tests. As to the GLM and MLEM analyses of explanatory variables, I have chosen to sum up primarily statistically significant results. As for these *p*-values these analyses of explanatory variables were based on parametric statistics. The table also comprises the results of inter-rater reliability tests related to Phase 3 and/or across all six phases. The corresponding *p*-values were based on the applied Pearson´s Correlations. Finally, all *p*-values in the table reflect the result of two-tailed tests.

Table 6.16. Overall summation of results of the 16 Outcome Measures.

Overall Summation of Results the 16 Outcome Measures

Child Distress	Total sample *N*, *M* (SD)	MT group *n*, *M* (SD)	Control group *n*, *M* (SD)	Mean difference (95% CI)	*pa*	Effect size (*d*)
Average Child Distress (OSBD-R, 0-9 point scale) Phase 3	*41* 0.88 (0.90)	*21* 0.78 (0.97)	*20* 0.98 (0.84)	-0.20 (-0.77 to 0.38)	0.17	0.11
Inter-rater reliability, Phase 3: *r*=0.654 (*n*=154)					0.00	
GLM analysis: effect of exploratory variable *Age* (per year)				-0.15 (-0.25 to -0.05)	0.00	
GLM analysis, R squared = 35%						
LMEM analysis: effect of exploratory variable *Age* (per year)				-0.09 (-0.16 to -0.02)	0.01	
LMEM analysis: effect of exploratory variable *Phase 3*					0.00	
Inter-rater reliability, all 6 phases: *r*=0.763 (*n*=321)					0.00	

Child Anxiety	Total sample *N*, *M* (SD)	MT group *n*, *M* (SD)	Control group *n*, *M* (SD)	Mean difference (95% CI)	*pa*
Observed Child Anxiety, (VAS, 100mm)	*41* 49 (33)	*21* 40 (33)	*20* 58 (32)	-18 (-39 to 3)	0.09
Inter-rater reliability, Phase 3: *r*=0.632 (*n*=9)					0.07
GLM analysis: R Squared = 23%					
LMEM analysis, exploratory variables: *Phase 3*					0.00
Inter-rater reliability, all 6 phases: *r*=0.712 (*n*=48)					0.00
Parent-rated Child Anxiety (VAS, 100mm)	*41* 51 (33)	*21* 47 (33)	*20* 55 (33)	-8 (-29 to 13)	0.39
GLM analysis, R squared = 17%					
Physician-rated Child Anxiety (VAS, 100mm)	*41* 43 (33)	*21* 34 (30)	*20* 52 (33)	-18 (-39 to 2)	0.05*
GLM analysis, exploratory variables: *Age*				-4 (-8 to 0)	0.04
GLM analysis, R squared = 26%					
Child-rated Anxiety (FPS-R, 0-10 point scale)	*11* 2.73 (3.38)	*6* 1.33 (1.03)	*5* 4.40 (4.56)	-3.07 (-8.67 to 2.54)	0.34
GLM analysis: exploratory variables: *Randomisation* (MT group)				-4.27 (-9.13 to 0.59)	0.08
GLM analysis, R squared = 53%					

Child Pain	Total sample *N*, *M* (SD)	MT group *n*, *M* (SD)	Control group *n*, *M* (SD)	Mean difference (95% CI)	*pa*
Observed Child Pain (VAS, 100mm)	*41* 35 (26)	*21* 31 (28)	*20* 39 (25)	-8 (-24 to 9)	0.26
Inter-rater reliability, Phase 3: *r*=0.681 (*n*=9)					0.04
GLM analysis, exploratory variables: *Age*				-4 (-7 to -1)	0.01
GLM analysis, R squared = 29%					
Parent-rated Child Pain (VAS, 100mm)	*41* 35 (23)	*21* 37 (28)	*20* 34 (17)	3 (-12 to 18)	0.87
GLM analysis, R squared = 9%					
Physician-rated Child Pain (VAS, 100mm)	*41* 30 (24)	*21* 22 (20)	*20* 38 (26)	-16 (-30 to 0.73)	0.06
GLM analysis, exploratory variables: *Age*				-3 (-6 to -1)	0.02
GLM analysis, exploratory variables: *Randomisation (MT group)*				-13 (-26 to 1)	0.06
GLM analysis, R squared = 31%					
Child-rated Pain (FPS-R, 0-10 point scale)	*12* 3.67 (3.70)	*7* 2.86 (3.43)	*5* 4.80 (4.15)	-1.94 (-6.82 to 2.93)	0.40
GLM analysis, R squared = 20%					

Overall satisfaction with IV-procedure	*pa*
Parent-rated Satisfaction with procedure	0.92

Compliance	Total sample *N*, *M* (SD)	MT group *n*, *M* (SD)	Control group *n*, *M* (SD)	Mean difference (95% CI)	*pa*
Physician-rated Child Compliance (VAS, 100mm)	*41* 35 (35)	*21* 26 (31)	*20* 45 (37)	-19 (-40 to 3)	0.10
GLM analysis, exploratory variables: *Age*				-6 (-10 to -2)	0.00
GLM analysis, R squared = 34%					
Physician-rated Parent Compliance (VAS, 100mm)	*41* 5 (3)	*21* 5 (4)	*20* 5 (3)	0 (-2 to 2)	0.80
GLM analysis, exploratory variables: *Needle pricks without ELMA*				3 (0 to 5)	0.05
GLM analysis, R squared = 15%					

No. of Needle Insertions	Total sample *N*, *M* (SD)	MT group *n*, *M* (SD)	Control group *n*, *M* (SD)	Mean difference (95% CI)	*p*[a]	
No. Needle Pricks	*41* 1.61 (0.97)	*21* 1.57 (1.12)	*20* 1.65 (0.81)	-0.79 (-0.70 to 0.54)	0.38	
Inter-rater reliability, Phase 3: *r*=0.972 (*n*=9)					0.00	
GLM analysis, exploratory variables: *Age*				-0.14 (-0.27 to -0.02)	0.03	
GLM analysis, R squared = 13%						
Duration	**Total sample** *N*, *M* (SD)	**MT group** *n*, *M* (SD)	**Control group** *n*, *M* (SD)	**Mean difference** (95% CI)	***p*[a]**	
Duration of IV-Procedure (minutes)	*41* 8.94 (4.84)	*21* 7.28 (4.05)	*20* 10.67 (5.09)	-3.39 (-6.29 to -0.49)	0.01	
Inter-rater reliability, Phase 3: *r*=0.993 (*n*=9)					0.00	
GLM analysis, exploratory variables: *Randomisation (MT group)*				-3.20 (-6.20 to -0.20)	0.04	
GLM analysis, R squared = 16%						
Observed Positive Child Behaviour	**Total sample** *N*, *M* (SD)	**MT group** *n*, *M* (SD)	**Control group** *n*, *M* (SD)	**Mean difference** (95% CI)	***p*[a]**	**Effect size**
Average Observed Positive Child Behaviour (OSPCB, 0-7 point scale)						
Phase 4	*37* 0.48 (0.57)	*20* 0.62 (0.62)	*17* 0.31 (0.46)	0.31 (-0.07 to 0.67)	0.13	0.29
Inter-rater reliability, Phase 4: *r*=0.810 (*n*=48)					0.00	
GLM analysis, R squared = 23%						
Phase 5	*36* 0.43 (0.45)	*19* 0.47 (0.44)	*17* 0.39 (0.48)	0.08 (-0.23 to 0.39)	0.31	0.09
Inter-rater reliability, Phase 5: *r*=0.645 (*n*=98)					0.00	
GLM analysis, R squared = 12%						
LMEM analysis: exploratory variables: *Age*				0.04 (0.01 to 0.08)	0.02	
LMEM analysis: exploratory variables: *Phase 1*				1.91 (1.55 to 2.27)		
LMEM analysis: exploratory variables: *Phase 3*				-0.34 (-0.46 to -0.22)		
Inter-rater reliability, all six phases: *r*=0.794 (*n*=323)					0.00	

Satisfaction survey of the MT intervention	
Whish for future MT (*n*=21)	Yes: 17 (81%) No: 3 (14%) Don´t know: 1 (5%)
Recommendation of MT (*n*=21)	Yes 18 (86%) No: 1 (5%) Don´t know 2 (10%)
Usefulness of MT (*n*=21)	Very useful: 11 (52%) Useful: 7 (33%) Neither/nor 1 (5%) Useless 2 (10%) Very useless 0 (0%)

6.23.1 Section Summary

Initially, I gave an introduction to the result chapter and provided an overview of the time points of the assessment of the outcome measures during the data collection process. I clarified how data were analysed and shortly addressed interpretation of figures applied in the chapter. Then I presented the results of the demographical characteristics and baseline data. I found that these were not statistically significantly different between the two groups, except for previous outpatient admissions. After accounting for the classification of explanatory variables, I presented the results of the main statistical analyses of the 16 outcome measures. Of these, 14 related to *Phase 3*, whereas data regarding *Overall Satisfaction with medical procedure* were recorded upon completion of *Phase 5*. Likewise, data related to the *satisfactory survey* of the MT intervention were collected after *Phase 5*. As to all of the outcome measures (except for satisfaction with the MT intervention), I calculated means, standard deviations, group differences, and 95% confidence intervals plus *p*-values. In addition, I calculated effect sizes. Based on the literature, discussions, and my clinical experience from the preparatory pilot study, I pre-defined four explanatory variables in the prospective data analysis plan. Due to the non-normally distributed data, the primary analyses of the 16 outcome measures consisted of Mann-Whitney U tests (two-sided). However, the assumption of independence could be met. But due to lack of a nonparametric equivalent test, I performed a supplementary GLM analysis in relation to 14 of the outcome measures, in which I controlled for the four explanatory variables. Besides that, I analysed the repeated measures of *Child Distress*, *Child Anxiety*, and *Positive Child Behaviour* collected during Phases 1 to 5 by means of an LMEM, in which I controlled for the four explanatory variables and phases. Finally, I analysed the *MT satisfactory survey* by means of descriptive statistics.

In short, when analysed with a Mann-Whitney U test, results showed that the mean duration to complete the IV-procedures in the MT group was a third shorter compared to the control group, which was highly statistically significant. Likewise, the physicians rated statistically significant less Child Anxiety in the MT group. Furthermore, trends towards statistical significance were noted as to research-assistant-rated Child Anxiety, physician-rated *Child Pain* and *Child Compliance*. Likewise, the GLM analysis of *Child Anxiety* showed trends towards statistical significance in favour of the MT group. In continuation of this, results revealed that the greatest effect of the MT intervention was in relation to this outcome measure. The remaining outcome measures were not statistically

significant but in favour of the MT group except for parent-rated *Child Pain*. However, the mean difference was close to zero and the result very far from statistically significant. Consequently, no harms of the MT intervention were noted. Besides that, the results of the inter-rater reliability tests (i.e. Pearson Correlation) varied from 6.32 to 0.993. Finally, the majority of the 21 children/families who were randomised to the MT group were satisfied with the MT intervention, whereas a minority of the families stated contrasting results. Of the 21 families, 81% wished MT under future medical procedures, 86% stated that they would recommend MT to others. 85% found the MT intervention very useful or useful.

6.24

Additional Results

In sections 6.6 to 6.23, I presented the results of the main statistical analyses related to the 16 outcome measures. In this section, I will present the following additional results that indirectly related to the outcome measures:

- Estimates regarding type of rater regarding Phase 3 Child Anxiety and Child Pain
- Distribution of participants among research-assistants in relation to randomisation and age groups
- Distribution of participants among physicians in relation to randomisation and age groups
- Distribution of physician-rated scores by physicians

6.24.1 Result of Estimates of Mean Child Anxiety and Child Pain according to Types of Rater

In the study, Child Anxiety and Child Pain related to Phase 3 were rated in each of the 41 children by a research-assistant, a physician, and the parent(s). In addition, these outcome measures were rated by the 13 enrolled children who were at the ages of five to ten. In order to compare the mean scores of these four sources/types of raters, I made two analyses based on the total sample (i.e. both groups in combination). Specifically, I used a linear mixed effects model and regarded Child Anxiety and Child Pain as the dependent variable, respectively. The type of rater was regarded as a fixed effect and the children´s randomisation number as a random effect. The first analysis included the three types of adult rater and was based on all of the 41 children. The second analysis included all four types of rater and was based on the 13 observations of the five- to ten-year-old children. As described previously in the thesis, the children gave self-report of anxiety and pain by means of the FPS-R (Hicks et al., 2001), which is a 0 to 10 point scale. On the contrary, the three adult raters used a 100mm bipolar VAS (Wewers & Lowe, 1990). In order to make the scores comparable, I multiplied the FPS-R scores with ten. This method was informed by Hicks et al. who found a strong correlation between these two scales in two studies on acute pain in children[1]. In both analyses below, the research-assistants constituted the reference group. The results of the analyses are displayed in table 6.17 in the form of means (M), confidence intervals (CI), and p-values (*p*). Please note that the mean scores reflect values on a scale from 0 to 100.

1 *One study based on 76 five- to tvelve-year-old children undergoing earpiecing (r=0.93) and another study related to surgical and other pain conditions in 45 four- to tvelve-year-old hospitalised children (r=0.92).*

Table 6.17. Results regarding comparison of Phase 3 Child Anxiety and Child Pain by type of adult rater.

Comparison of Phase 3 Child Anxiety and Child Pain by type of adult rater		
Measures	***M***	***CI***
1. Child Anxiety (*n*=41)		
Research-assistants (VAS)	49	(38 to 59)
Physicians (VAS)	43	(-14 to 2)
Parents (VAS)	51	(-5 to 11)
2. Child Pain (*n*=41)		
Research-assistants (VAS)	35	(27 to 43)
Physicians (VAS	30	(-13 to 2)
Parents (VAS)	35	(-7 to 8)

Based on table 6.17, the estimate of type of adult rater showed somewhat similar mean Child Anxiety scores, which had a range of up to 8 percentage points. Moreover, this difference (i.e. the effect of type of rater) was not statistically significant but had trends towards significance (p=0.094). Consequently, the statistical null hypothesis of no difference among raters could not be rejected. Likewise, the raters´ mean scores of Child Pain were similar and had a range of up to 5 percentage points, which was not statistically significant either (p=0.137). In addition, the lowest estimated mean score was that of the physicians.

Table 6.18 displays the result of all four types of raters´ mean Child Anxiety and Child Pain scores. The estimates of mean scores reflect values on a scale from 0 to 100. Please also note that this second analysis was based on 13 observations (i.e. the 13 five- to ten-year-old children). However, cf. the asterisk in the table 6.18, missing data points occurred in relation to child-reported Anxiety and Pain.

Table 6.18. Results regarding comparison of Phase 3 Child Anxiety and Child Pain by all four types of rater.

Comparison of Phase 3 Child Anxiety and Child Pain by all types of rater		
Measures	***M***	***CI***
1. Child Anxiety (*n*=13)		
Research-assistants (VAS)	36	(38 to 59)
Physicians (VAS)	29	(-24 to 10)
Parents (VAS)	41	(-12 to 21)
Child* (FPS-R)	28	(-26 to 9)
2. Child Pain (*n*=13)		
Research-assistants (VAS)	22	(8 to 36)
Physicians (VAS)	18	(-17 to 10)
Parents (VAS)	30	(-6 to 21)
Child** (VAS)	36	(0 to 27)
* *n*=11; ** *n*=12		

Based on table 6.18, the estimate of all four types of rater showed a somewhat similar mean Child Anxiety scores, which had a range of up to 13 percentage points. This difference (i.e. effect of type of rater) was not statistically significant (p=0.385). As to Child Pain, a larger variability among the estimated mean scores could be noted with a range of up to 18 percentage points. In addition, the lowest estimated mean score of Child Pain was that of the physicians. This was almost also the case for Child Anxiety. The result had trends towards statistical significance

(p=0.072). However, given the relatively small number of observations, one cannot take the p-value at face value. Finally, as appears from table 6.18, the lowest estimate of mean anxiety score related to the five- to ten-year-old children, who on the contrary rated the highest pain scores.

In summation, the first analysis was related to three adult raters and based on the 41 children. It showed a somewhat similar estimation of mean scores of Child Anxiety and Child Pain. On the contrary, the second analysis related to all of the four types of raters and included the 13 oldest children. In comparison with the first analysis, it showed a larger variation among the four raters´ estimated mean scores. However, this is not surprising, since it is based on fewer observations. Moreover, the five- to ten-year-old children had the lowest estimated mean anxiety score and the highest pain scores. In addition, the second lowest estimated mean score of anxiety and the lowest mean of pain were that of the physicians. In continuation of this, it should be noted that I analysed the physicians as one type of rater and did not control for the individual physician´s ratings of anxiety and pain. Finally, although two of the p-values showed a tendency towards significance and the mean scores varied more in the second analysis, an effect of type of rater could not be confirmed statistically.

6.24.2 Results of Correlations of Anxiety and Pain scores

In addition to the analysis above, I carried out a separate Pearson Correlation between the research-assistants´ and physicians´ ratings of Phase 3 Child Anxiety and Child Pain. The rationale for this is that these two types of observers have observed more children during IV-access procedures compared to most of the parents. The result of the correlation is displayed in table 6.19.

Table 6.19. Correlation of research-assistants´ and physicians´ ratings of Child Anxiety and Child Pain during the IV-access procedure (Phase 3).

Correlation between research-assistant and physician ratings of Child Anxiety & Child Pain during procedure (phase 3)			
Measure	***n***	***r***	***p***
Child Anxiety	41	0.820	0.000**
Child Pain	41	0.674	0.000**
* Sign. at the 0.05 level (2-tailed) ** Sign. at the 0.01 level (2-tailed)			

As appears from table 6.19, the correlation of *Child Anxiety* showed a strong correlation (cf. Brace et al., 2006), whereas Child Pain showed a moderate correlation. Both correlations were statistically significant.

6.24.3 Results of Distribution of Participants Among Research-Assistants

During the data collection period, I prospectively attempted to balance the distribution of the participants' randomisation status and age groups equally between the two main research-assistants (i.e. 3 and 4). This was done in order to avoid the problem that a possible distribution bias would affect their ratings etc. In table 6.20 I have summed up the results of the distribution of the four research-assistants in relation to participants.

Table 6.20. Results of distribution of randomisation and age among research-assistants.

Group and age distribution	Research-assistant 1	Research-assistant 2	Research-assistant 3	Research-assistant 4
MT group: children 1-5 years	2	1	6	4
MT group: children 5-10 years old	3	1	2	2
Control: group children 1-5 years old	1	1	6	7
Control group: children 5-10 years old	3	0	2	0

As appears from table 6.20, each research-assistant observed roughly the same number of children in the two groups. Likewise, the main research-assistants (i.e. 3 and 4) observed a somewhat equal number of children in the two groups. Furthermore, the table reflects that the majority of the children were under five years old.

6.24.4 Results of Distribution of Physicians

In the study, approximately 10 physicians performed the IV-access procedures. Then they rated four of the outcome measures (i.e. physician-rated Child Anxiety, Child Pain, Child Compliance, Parent Compliance). As opposed to the distribution of research-assistants, I had no control over the distribution of physicians in relation to randomisation and age groups. Thus, the name of the physician was registered each time an IV-access procedure was performed. This method allowed me retrospectively to examine possible bias in the distribution of physicians. Specifically, physicians who performed most of the procedures were categorised individually denoted by a separate number (i.e. physician A, B, and C). I defined these physicians as *frequently* involved in the study if they had performed at least six IV-access procedures. Besides that, remaining physicians who performed fewer than six procedures were categorised as *Other Physicians*. In addition, four IV-access procedures were performed by two different physicians, who were equally distributed between the two groups. In table 6.21 I have presented the results regarding distribution of physicians in relation to participants´ randomisation status and age.

Table 6.21. Results of distribution of physicians according to randomisation status and age group.

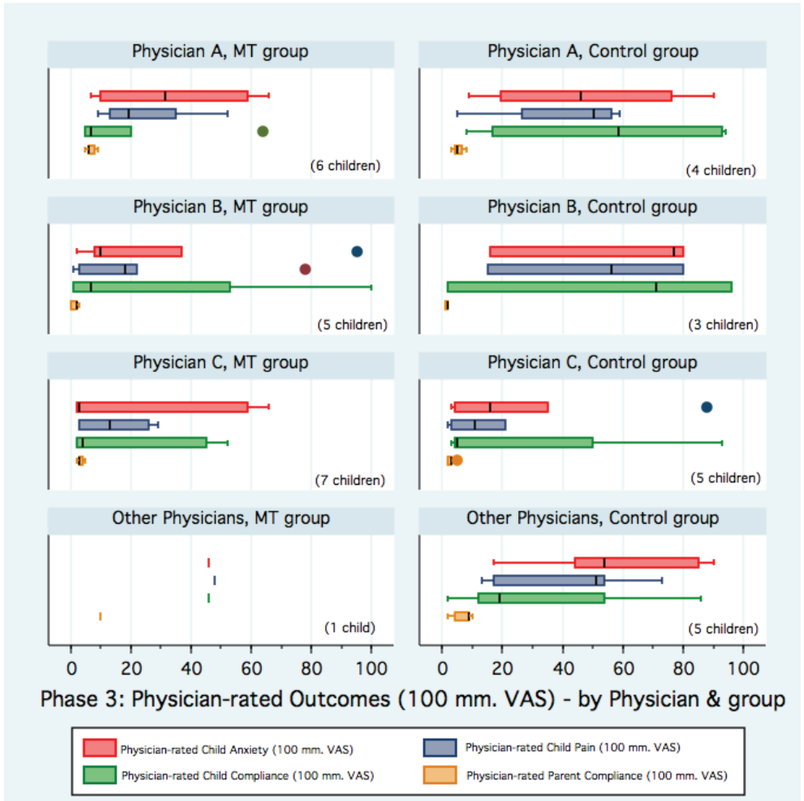
Group and age distribution	Physician A	Physician B	Physician C	Other physicians
MT group: children 1-5 years old	3	4	4	1
MT group: children 5-10 years old	3	1	3	
Control group: children 1-5 years old	3	2	3	4
Control group: children 5-10 years old	1	1	2	1

Table 6.21 shows that the physicians most frequently involved in the study (i.e. A, B, and C) performed a somewhat equal number of IV-access procedures in terms of both randomisation and age groups. It also appears from the table that each of these physicians performed two more IV-access procedures in the MT group compared to the control group. In total these three physicians performed 75% of the 41 IV-procedures. On the contrary, the six IV-procedures performed by the *Other physicians* were not equally distributed between the two groups.

6.24.5 Result of Distribution of Physician-Rated Outcome Measures by Physician

Confer section 6.24.4, the three physicians who performed 75 percent of the 41 IV-access procedures were somewhat equally distributed between the two randomisation groups as well as the age groups. However, in order to justify that the physicians can be regarded as *one* type of rater, I will now go further and examine whether the ratings of the above-mentioned three physicians are somewhat similar within the two groups. Specifically, I will address myself to the four outcome measures that were rated by the physicians (i.e. *Child Anxiety*, *Child Pain*, *Child Compliance*, and *Parent Compliance*). In addition, since the duration of the IV-access procedure proved highly statistically significant, I will also examine this outcome measure. Figure 6.29 illustrates the distribution of the four physician-rated outcome measures as rated by the three physicians. In the figure, the right columns relate to the MT group and the left columns relate the control group. The four physician-rated outcome measures are measured by means of a VAS (100mm). For general information, the box plots in the figure are based on the following number and distribution of participants in the MT group/Control group, respectively: Physician A (6/4 children), Physician B (5/3 children), Physician C (7/5 children), and Other physicians (1/5 children).

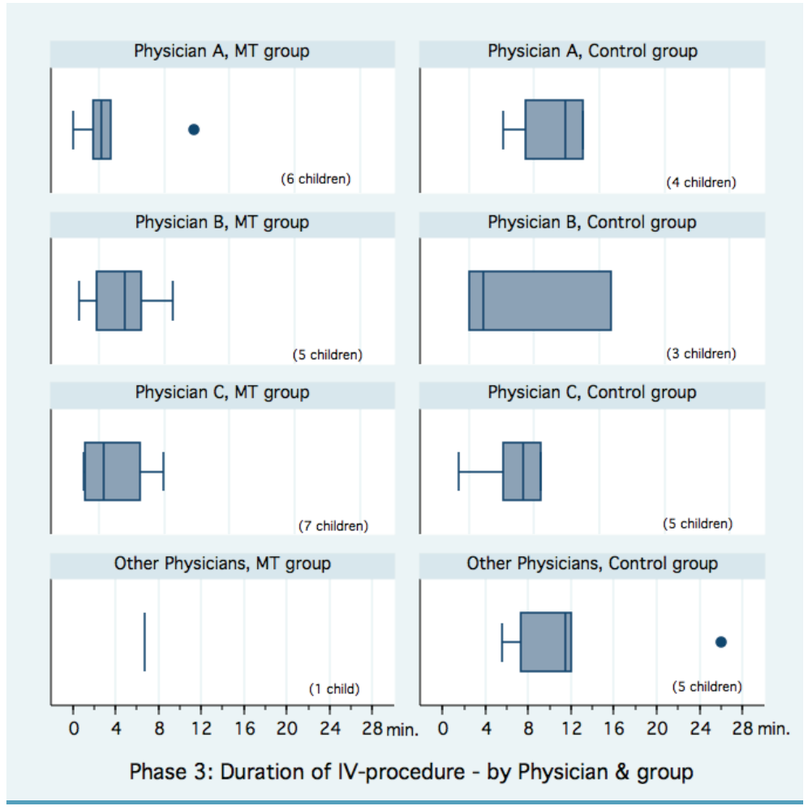
Figure 6.29. Box plots showing distribution of physician-rated outcome measures according to physician and group.



As appears from figure 6.29, the box plots related to the MT group (i.e. left side of the figure) are somewhat similarly distributed when compared across the physicians. Besides that the majority of these box plots are contained within the range of 10 to 60mm as opposed to the ones related to the Control group. As to the box plots relating to the Control group, three of the four box plots were similarly distributed across the physician, except for Physician C. In conclusion, taken into account the low number of observations, there is no clear evidence to believe that the physicians´ ratings differ notable.

In continuation of this, figure 6.30 shows the distribution of *Durations of the IV-Access Procedures* among the three physicians plus other physicians.

Figure 6.30. Box plots showing the durations of the IV-access procedure among physicians and by group.

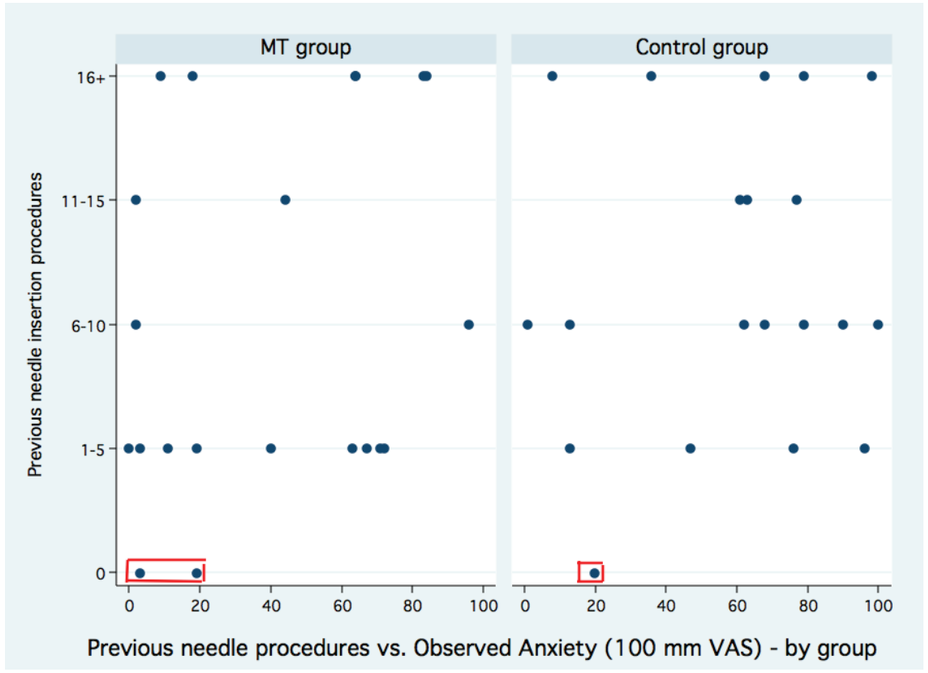


Confer figure 6.30, the distribution of boxplots by the physicians was somewhat similar within both randomisation groups. Moreover, the mean duration of the IV-access procedures in the MT group was systematically shorter regardless of the physicians.

6.24.6 Findings of Possible Tendency Towards Traumatisation

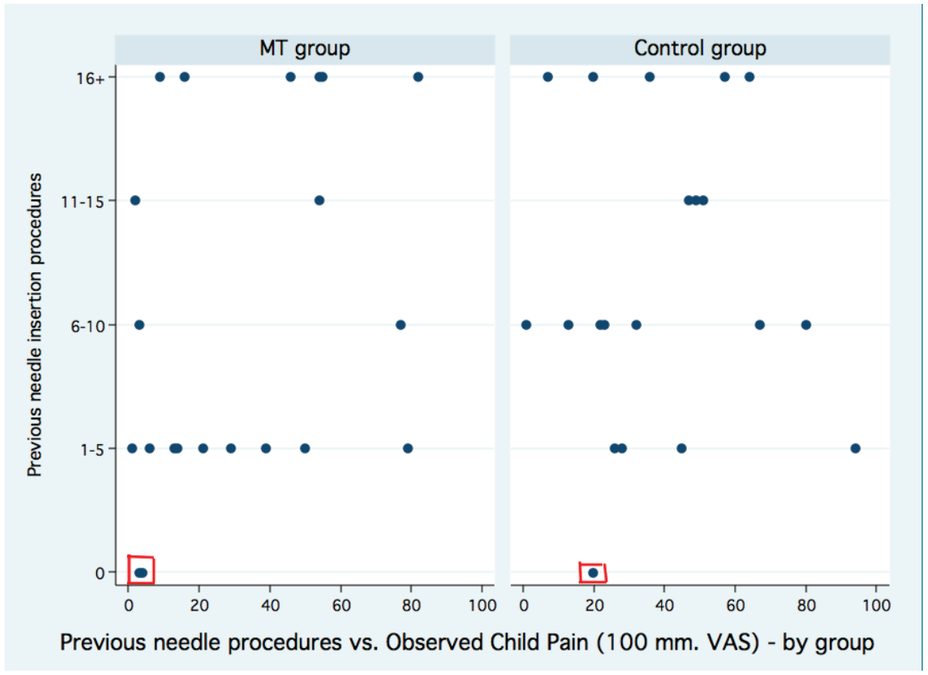
During the preparation for the main data analyses, I made various graphical plots in order to get familiar with the data set. In the following I will present two of these scatter plots that could be clinically important. These graphs relate to the research-assistants´ rating during Phase 3. In the two plots I have plotted *Number of previous needle procedures* versus *Child Anxiety* and *Child Pain*, respectively, by randomisation group. Note, that each dot represents one participant.

Figure 6.31. Scatter plot of Number of previous needle procedures versus Research-assistant-rated Child Anxiety during Phase 3 (100mm VAS) – by group.



From figure 6.31 we can see that only two children in the MT group and one in the control group had not been subjected to any previous needle procedures. I have framed these children in the red boxes. These three children had low research-assistant-rated anxiety scores compared to the remaining children, who had received 1-5 or more previous needle procedures before enrolment in the study. Likewise, the same tendency also occurred when I plotted *Number of previous needle procedures* against physician-rated as well as parent-rated *Child Anxiety*. Based on these limited observations (i.e. three children), valid conclusions cannot be made. However, the graph may reveal that traumatisation in relation to needle procedures may occur in some children after just 1-5 (or more) needle procedures. In continuation of this, I have plotted *Number of previous needle procedures* versus Research-assistant-rated *Child Pain* in figure 6.32

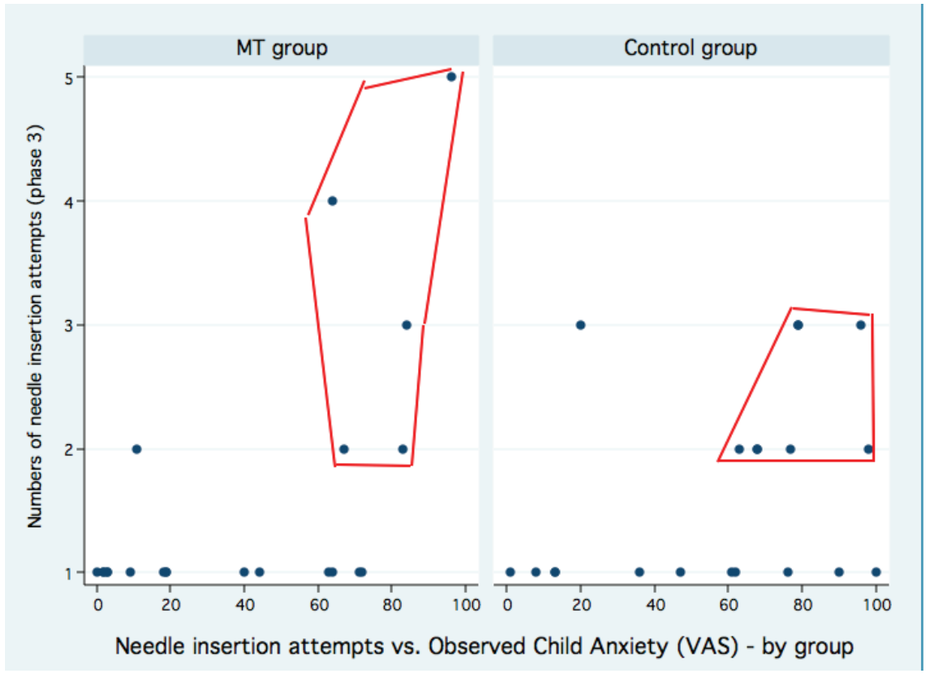
Figure 6.32. Interaction plot: Number of previous needle procedures versus Research-assistant-rated Child Pain in Phase 3 (100mm VAS) – by group.



Likewise, when inspecting figure 6.32, which relates to research-assistant-rated *Child Pain*, we find an identical tendency towards possible traumatisation. Furthermore, this tendency also appeared in the physicians´ scores, but not in those of the parents. In conclusion, no valid conclusion can be made due to the limited number of children, who had not been subjected to previous needle procedures. However, it might look as if the data could support the hypothesis that some children are traumatised already after undergoing one to five needle procedures.

I have now presented two scatter plots relating to the children´s number of previous needle procedures. In the following I will present further two more scatter plots that illuminate the relationship between the *Number of needle pricks* received during the IV-procedure in the study versus research-assistant-rated *Child Anxiety* and *Child Pain*, respectively, related to the same phase.

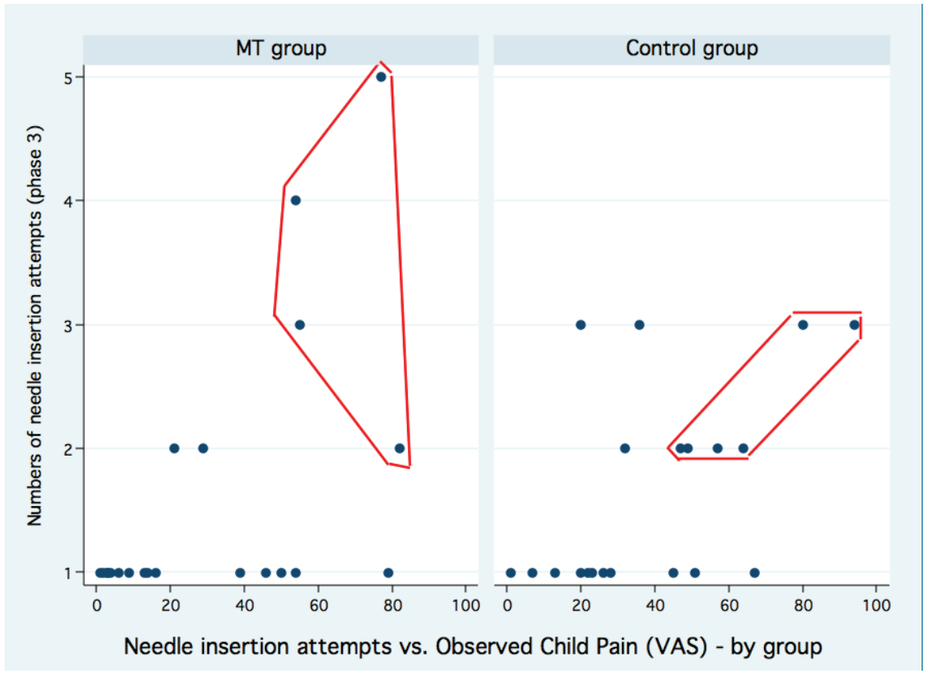
Figure 6.33. Scatter plot of Number of Needle Pricks versus Observed Child Anxiety (100mm VAS) during IV-procedure – by group.



When inspecting figure 6.33, we see the relationship is the following: the more needle pricks/insertion, the higher the anxiety levels. Please note that scores reflecting two to five needle pricks were much more clustered compared to those of the children who completed the IV-access procedure with only one needle prick. The same tendency was also clear when the actual *Number of needle pricks* were plotted against physician-rated *Child Anxiety* as well as parent-rated *Child Anxiety* scores.

In the next figure (figure 6.34), I have plotted the *Number of needle pricks* versus the research-assistants´ ratings of *Child Pain* (VAS) during the IV-procedure.

Figure 6.34. Scatter plot of Number of Needle Pricks versus Observed Child Pain (100mm VAS) during IV-access procedure – by group.



As appears from figure 6.34, although less clearly, we still find a similar tendency towards the more needle pricks the higher pain scores or the greater variability in pain scores. This finding applied to *Child Pain* scores rated by the research-assistants, physicians, as well as parents.

6.24.7 Section Summary

In the above-mentioned subsections I presented some additional results. In short, on the basis of estimates, I found that the ratings of the four types of raters did not differ statistically significant. Furthermore, I found that the two main research-assistants observed a somewhat equally distributed number of children in terms of randomisation and age groups. Likewise, the three physicians who performed 75% of the IV-procedures were also somewhat equally distributed in terms of randomisation and age groups. Hereafter I examined to what degree potential bias seemed to occur in terms of physician effects etc. in relation to the four physician-rated outcome measures. When comparing the scores of the three physicians who performed 75% of the IV-access procedures, I found no clear imbalance. Next,

I presented scatter plots in which I plotted *Number of previous needle procedures* versus observed *Child Anxiety* and *Child Pain*. Likewise, I plotted *Number of needle pricks* received during IV-procedure versus observed *Child Anxiety* and *Child Pain*, respectively. Based on these scatter plots, I cautiously argued that traumatisation may occur after just one to five previous needle procedures. In continuation of this I illustrated graphically that *Child Anxiety* and *Child Pain* increased with the number of received needle pricks during the IV-procedure.

6.25

Additional Results regarding the Music Therapy Intervention

In the following, I will present additional results exclusively related to the MT intervention. Initially, I will examine whether *Phases 1 & 2* lasted longer in the MT group than in the control group. In continuation of this I will present a cost-effectiveness analysis of the MT intervention. Next, I will present the results of the decision trees in the form of the most frequently used overall strategies, the children´s needs and use of musical sub-interventions etc. Finally, I will show the result of the children´s preferred songs during *Phase 1* to *5* in the MT group.

6.25.1 Results of Duration of Phases 1 & 2

In this section I will address myself to the question whether *Phases* 1 and *2* had an equal duration in the two groups. Please remember that *Phases 1* and *2* are comprised in the *Pre-Needle Period* before the actual needle procedure (i.e. *Phase 3*). Of the 41 children, who participated in the study, the research-assistants registered *Phases 1* and *2*, in 33 and 27 of the children, respectively. Consequently, as to the remaining children these phases were cancelled due to time pressure and other logistical reasons.

In the total sample, the mean and *SD* duration for *Phase 1* (*n*=33) were 19.65 and (19.05) minutes, respectively. In the MT group (*n*=18) the mean duration of *Phase 1* was 17.93 (11.78) compared to 21.72 (25.54) in the control

group (*n*=15). The mean difference was -3.79 minutes shorter in the MT group, which was not statistically significant (*p*=0.81). As to *Phase 2* the mean and *SD* for duration in the total sample (*n*=27) were 2.63 and (2.30) minutes, respectively. In the MT group (*n*=13) they were 2.72 (2.65). In the control group (*n*=14) the mean duration was 2.54 (2.02). The mean difference of plus 0.18 minutes in the MT group was not statistically significant (*p*=0.90). I have summated the above-presented results in table 6.22.

Table 6.22. Results of duration of Phases 1 and 2.

Phase	Group	Mean	S.D.
Phase 1	Total sample (*n*=33)	19.65	(19.05)
	MT group (*n*=18)	17.93	(11.78)
	Control group (*n*=15)	21.72	(25.54)
	Mean difference: -3.79 (*p*=0.81)		
Phase 2	Total sample (*n*=27)	2.63	(2.30)
	MT group (*n*=13)	2.72	(2.65)
	Control group (*n*=14)	2.54	(2.02)
	Mean difference: 0.18 (*p*=0.90)		

In conclusion, the duration of *Phases 1* and *2* was practically equal between the two groups.

6.25.2 Results of Decision Trees Used in the Music Therapy Intervention

In the method chapter (section 5.10), I described the decision trees related to the MT intervention. As clarified, I recorded my application of overall strategies and therapeutic sub-interventions immediately upon completion of the each MT procedural support session. The decision trees served several purposes in the study. First, they guided the carrying out of the MT intervention in that they functioned as a therapeutic navigation tool, which I used continuously in evaluating each child´s needs. Hence, I made systematic appraisals and choices of specific therapeutic strategies and decisions. Consequently, I hoped the decision trees would increase the effectiveness of the MT intervention. Second, the decision trees functioned as a registration tool that could illuminate possible trends related to the children´s clinical needs and wishes at the different phases of the IV-procedure as well as registration of my therapeutic decisions. In the following pages I have summated the results of the decisions trees in relation to the 21 children in the MT group (figures 6.35, 6.36, and 6.37). My intention behind the summation is to examine possible trends and needs as well as to examine the usefulness of specific sub-interventions. Please note that the results are only to be interpreted as a rough guide.

Figure 6.35. Results of applied MAE-based sub-interventions and verbal interventions during Phases 1 & 2.

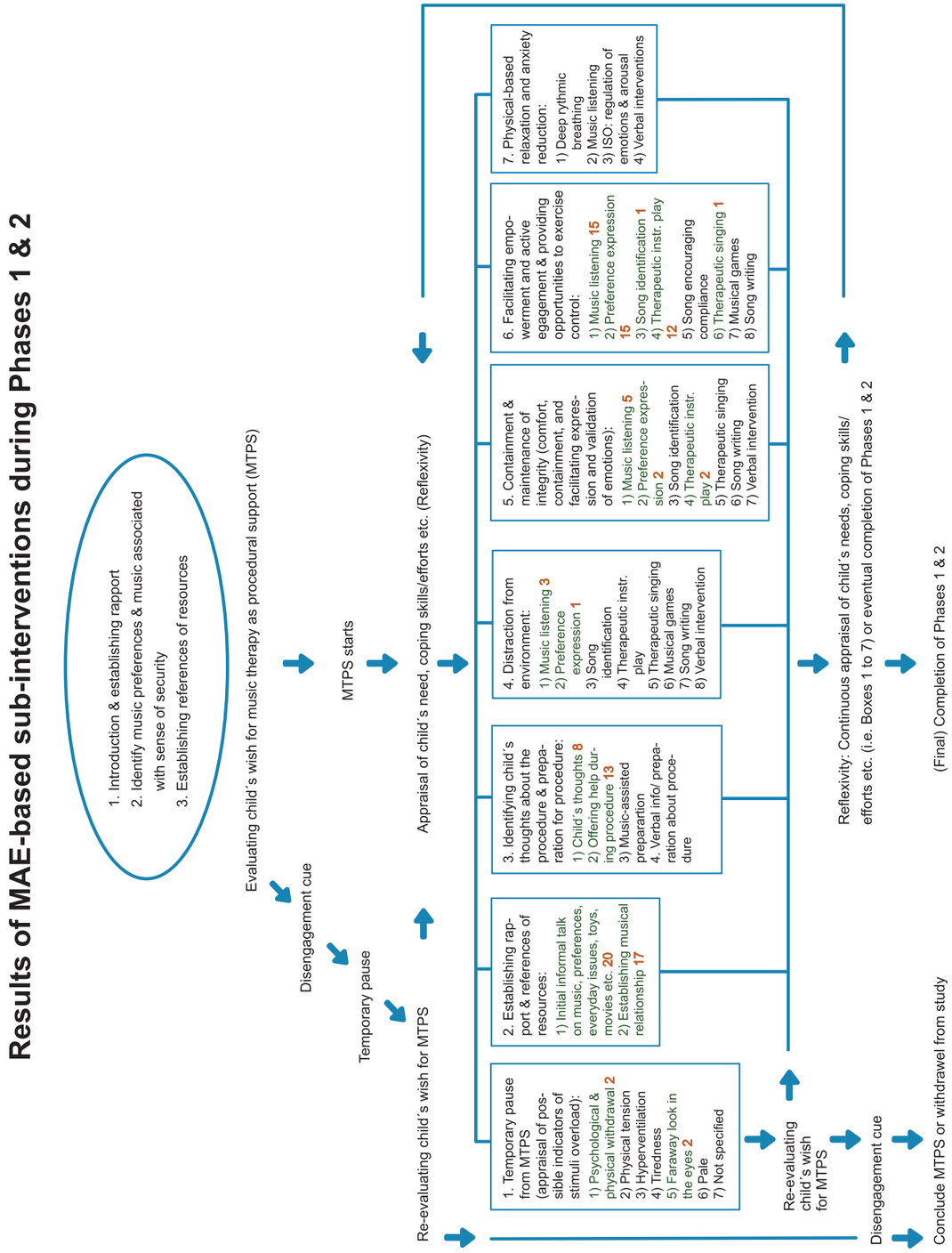


Figure 6.36. Results of applied MAE-based sub-interventions and verbal interventions during Phase 3.

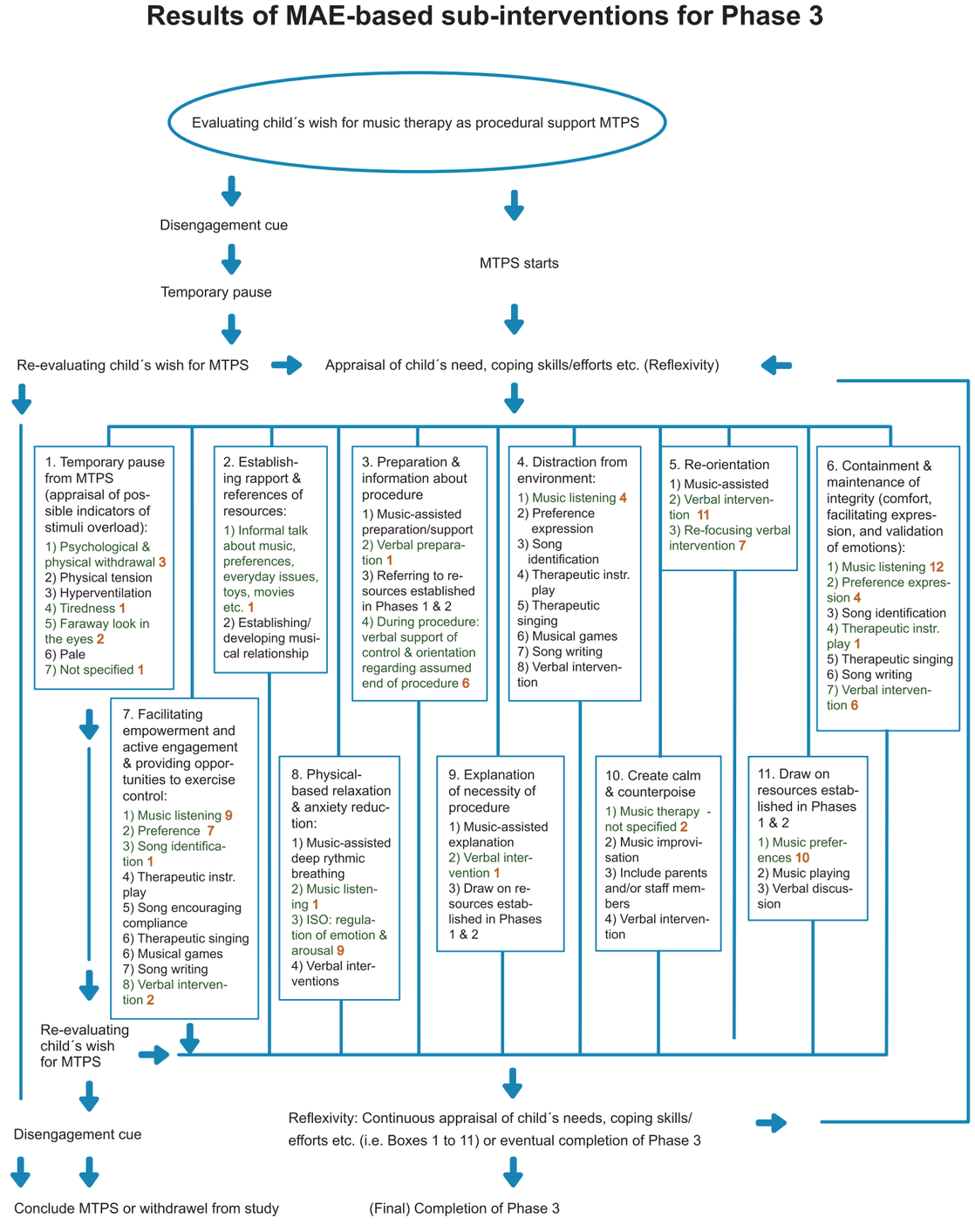
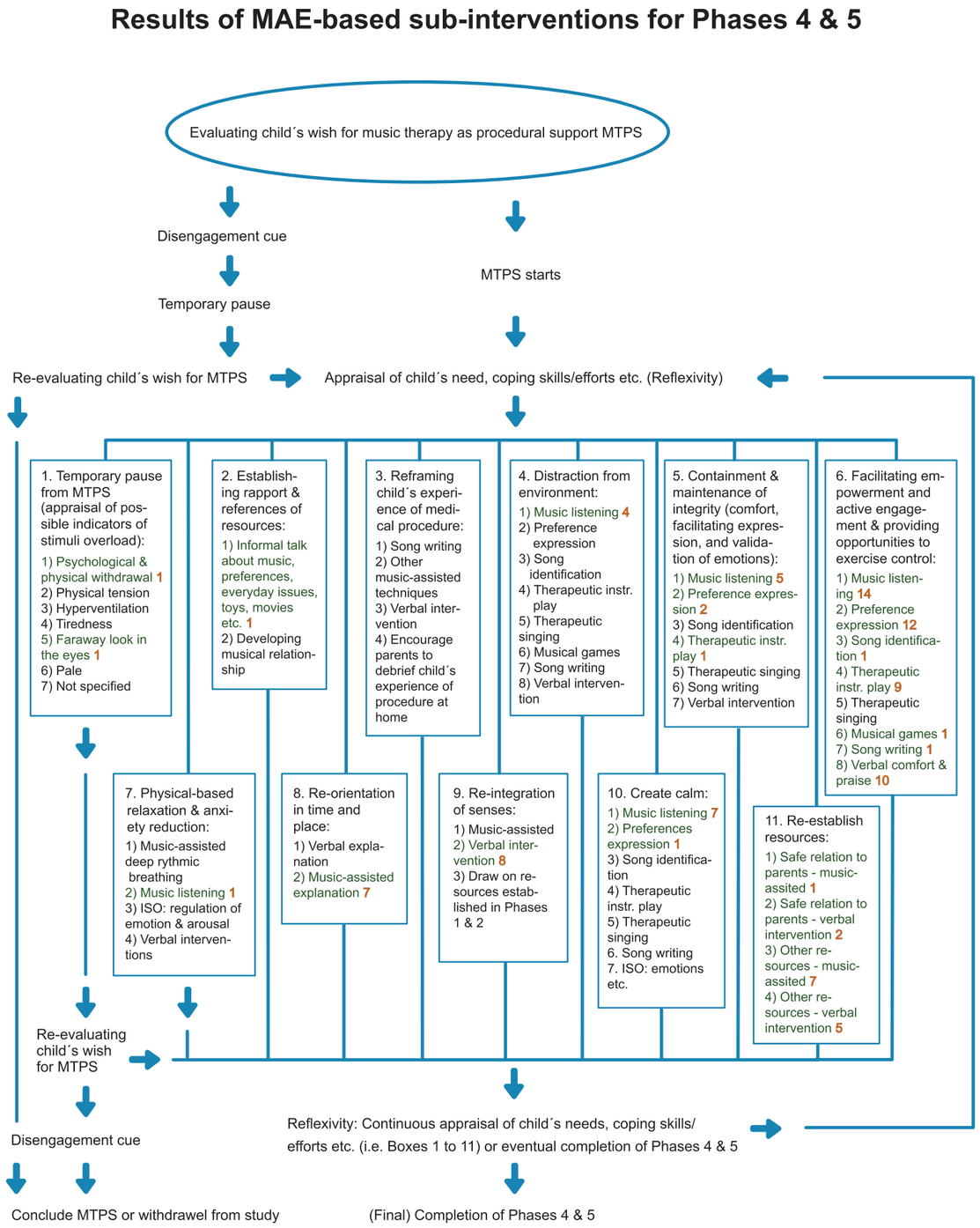


Figure 6.37. Results of applied MAE-based sub-interventions and verbal interventions during Phases 4 & 5.



Figures 6.35, 6.36, and 6.37 illustrate the frequency with which each overall strategy and sub-intervention were used. In the following I will only put forward the most frequently used overall strategies and sub-interventions. As appears from figure 6.35, *Establishing rapport* and *Resources* (box 2) were the most frequent initial strategy during Phases 1 & 2. This was done through informal talk about music preferences, other interests etc. (20 times) and by establishing a musical relationship (17 times). Subsequently, as to box 6, music listening and preference expression were applied 15 times each followed by therapeutic instrument playing (12 times) with the purpose of facilitating active engagement and support the sense of self as well as control. These musical sub-interventions were complemented 13 times by verbal interventions that stated an offer for help and support during the imminent IV-procedure (box 3).

As to Phase 3, figure 6.36 illustrates that some of the most frequent overall strategies were *Distraction from environment & procedure* (box 5), *Containment* (box 6), and *Facilitating empowerment and active engagement & providing opportunities to exercise control* (box 7), which were provided in the form of music listening. Besides that, verbal *Re-orientation* (box 4) during the IV-procedure was provided 11 times. Furthermore, referring to and playing preferred music were used 10 times as a means to *Draw on resources established in Phases 1 & 2* (box 11). Finally, the ISO principle was used 9 times with an eye to regulating emotions and arousal as support of *Physical-based relaxation and anxiety reduction* (box 8).

With regard to Phases 4 and 5, figure 6.37 shows clearly that the most frequently used overall strategy and objective of the MT intervention in these phases felt within the category of *Facilite empowerment and active engagement & providing opportunities to exercise control* (box 6). Specifically, in this category a variety of sub-interventions were used to engage and support the children, among other things music listening (14 times), music preference expressions (12 times), and therapeutic instrument play (9 times). These musical sub-interventions were complemented by verbal statements of comfort and appraisals (10 times). In addition, music-assisted *Re-orientation in time and place* (box 8) and verbal *Re-integration of senses* (box 9) were used 7 and 8 times, respectively, to improve recovery of the child. In continuation of this, music listening was used 7 times to *Create calm* (box 10). Subsequently, if there was more time left before closure of Phase 5, the last step of the recovery approach in the MT intervention consisted

of verbal and musical sub-interventions that served to *Re-establish resources* (box 11). Hence, this strategy was to refer to resources established in Phases 1 and 2. I applied sub-interventions from this category 15 times altogether.

6.25.3 **Results of Preferred Songs**

In this subsection I will present the result of the children´s preferred songs. In addition to my registration of applied strategies and sub-interventions in the decision trees, I documented all songs that were requested by child and/or parent. In the table below, I have listed the ten most frequently requested/played songs. The remaining songs appear in Appendix 9. My intention of the summation of preferred songs was to examine possible trends for preferences as well as the usefulness of specific songs with a view to informing future clinical practice and research. The results are only to be interpreted as a rough guide in that the choice of songs not only reflected the requests of the children and parents. To a less degree the list also reflects my preferences and appraisal as the music therapist. Table 6.23 illustrates how many times the specific songs were sung during all six phases. However, initially I did not systematically record if the same song was requested several times by the children. Finally, I have classified the songs according to their guiding stimulating or sedative characteristics, which relates to with what therapeutic aim I mainly performed the songs.

Table 6.23. Frequency and characteristics of music used in the music therapy group.

Frequency & Characteristics of Music Used in the Music Therapy Group				
Songs (English translation)	**Writer of lyric/composer**	**Genre**	**Guiding stimulating/ sedative characteristic**	**Frequency**
1. Lille Peter Edderkop (Itsy Bitsy Spider)	Knus Pheiffer/Unknown	Common children´s song	Sedative	19
2. Andreas sang (Andrea´s Song)	Povl Køller	Song from children´s television programme	Sedative	17
3. Mester Jakob (Brother John)	Unknown	Common children´s song	Sedative	11
4. En elefant kom marcherende (The Elephant´s song)	Unknown	Common children´s song	Moderate stimulative	11
5. Jeg er en glad lille cowboy (I am a Little Happy Cowboy)	Povl Køller	Children´s song	Stimulative	9
6. Mariehønen Evigglad (The Ever Happy Ladybird)	Halfdan Rasmussen/Henning Hansen	Common children´s song	Moderate stimulative	9
7. Hjulene på bussen (The Wheels on the Bus)	English children´s song - unknown. Danish translation by Hans-Henrik Ley.	Common children´s song	Stimulative	8
8. Bim bam busse	Hans-Henrik Ley/Jannik Hastrup	Common children´s song	Moderate stimulative	8
9. Other songs wishes by child & parents			Mixed	8
10. Improvisation			Mixed	7

From table 6.23 it appears that the ten most preferred songs comprised common children´s songs, other songs wished by child and parents as well as improvised songs/music. All songs were in Danish and had mixed stimulating and sedative characteristics.

6.25.4 Section Summary

In the final part of this chapter I have presented additional results and findings exclusively related to the MT intervention. I found that the duration of Phases 1 and 2 was practically equal in the two groups. Finally, I presented the results of the overall strategies, therapeutic decisions, and clinical needs of the children that were applied in the MT group. The results showed that the children´s clinical needs changed during the six phases, which was reflected in the applied strategies and musical and verbal sub-interventions. Finally, I presented a frequency table of the preferred songs that were requested by the children and their parents. In short, the ten most requested songs comprised well-known children´s songs, other songs wished by child and parents as well as improvised songs/music. The common children´s songs varied in terms of their stimulating and sedative quality.

6.26

Chapter Summary

In this chapter, I presented the results of the statistical analyses. Initially, I gave an overview of the contents and structure of the chapter, including definitions regarding the six phases and the measuring time points of the data collection as well as a description of the data analysis process. Next, I shortly addressed myself to the interpretation of the figures used in the chapter. Subsequently, I presented the results in relation to eligibility, randomisation, and the results of the demographical characteristics and baseline data. I found that these were not statistically significant different between the two groups, except for previous outpatient admissions. A presentation of the classification of explanatory variables was also provided. Then I presented the results of the main statistical analyses related to the 16 outcome variables, which derived from the corresponding research hypotheses. In continuation of this I went through the results of the MT satisfactory survey and the inter-rater reliability tests. After these primary analyses, I presented additional results and findings, among other things the distribution of research-assistants and physicians in terms of the participants´ randomisation status and age groups. In the final part of this chapter I presented some supplementary results and findings exclusively related to the MT intervention. Among other things, I presented the results of the decision tress plus a list of preferred song requested by the children and parents.

CHAPTER 7
DISCUSSION

THE OBJECTIVE OF THIS PHD STUDY IS TO EVALUATE THE EFFECTS OF MUSIC THERAPY AS PROCEDURAL SUPPORT (MTPS) ON 16 OUTCOME MEASURES IN RELATION TO CHILDREN UNDERGOING PERIPHERAL INTRAVENOUS ACCESS (PIVA). IN THIS CHAPTER, I WILL DISCUSS THE RESULTS OF THE STUDY.

7.1 Introduction

As outlined in the Method Chapter (chapter 5), I classified the 16 outcome measures as follows: *Child Distress*, *Child Anxiety*, *Child Pain*, *Overall Satisfaction with IV-procedure, Child Compliance* and *Parent Compliance, Number of needle pricks*, *Duration of medical procedure*, *Positive Child Behaviour*, and *Satisfaction with the music therapy intervention*. In assessing these outcome measures, I used standardised measuring tools as well as tools developed for the study. In this chapter, I will discuss the results of the study according to the overall types of outcome domains classified above, following this structure. Initially, I will discuss the main results in relation to the research hypotheses and the MT studies presented in the literature review with an eye to linking my results to the existent body of research within the field of MTPS research. In that connection, I will primarily relate to the three MT studies on *needle procedures* (Caprilli et al. 2007; Malone, 1996; Pfaff et al., 1989). Secondly, I will also relate to the results more broadly in the form of three meta-analyses in terms of the use of MT and MM under medical procedures involving paediatric patients (Klassen et al., 2008) and paediatrics (Dileo & Bradt, 2005; Standley & Whipple, 2003), respectively. To a minor extent, I will also relate the results to the remaining eight MT studies (dependent on the outcome measure in question), which relate to *other* types of medical procedures than *needle procedures*. In the Discussion Chapter, I will also refer to some aspects of the theoretical framework as well as the additional findings of the Result Chapter.

After having discussed the results in relation to each outcome domain separately, I will provide a short overall summation. Here, I will also address myself to the *additional findings* of the study and relate to different aspects of the theoretical framework which were presented in Chapters 1 to 4. Next, I will discuss the *clinical application* in terms of the clinical relevance of the results and the clinical protocol. This section is followed by a discussion of the limitations of the study. Finally, on the basis of the discussion chapter, I will state the conclusion and outline directions for future research. For general information, throughout the chapter, I will use the designation significant

in terms of statistical significance, unless otherwise specified. Moreover, I will apply the formulation MT children and control children interchangeably with the children in the MT group and the children in the control group, respectively. Likewise, I implicitly mean 'compared to the control group' when stating/commenting on the results of the MT group, unless otherwise specified. Finally, I will use the following abbreviations throughout the chapter:

- FPS-R (Faces Pain Scale –Revised)
- GLM (General Linear Model)
- LMEM (Linear Mixed Effects Model)
- MWU-T (Mann-Whitney U-test)
- OSBD-R (Observation Scale of Behavioural Distress-Revised)
- OSPCB (Observation Scale of Positive Child Behaviour)
- VAS (Visual Analogue Scale)

7.2

Discussion of Results related to the 16 Outcome Measures

As mentioned, I will now discuss the results of the analyses according to each of the hypotheses. In order to obtain clarity and a logical sequence, the discussion will follow the same order as the results were presented in the *Result Chapter*.

7.2.1 Discussion of Results regarding Child Distress (Main Outcome Measure)

In summation, *Child Distress* was rated by the research-assistant by means of the OSBD-R. Confer the descriptive summation provided in table 6.6 and figure 6.11, children in both groups exhibited practically no distress during the *Baseline Phase*. Besides that, as I expected, the distress scores of both groups increased continuously during *Phases 1* to *3* and decreased similarly continuously after the needle procedure (i.e. during *Phases 4* & *5*). This is reflected in figure 6.11 and was confirmed statistically in the LMEM analysis. However, the children in the MT group scored less mean distress during the needle procedure and the two subsequent phases (i.e. *Phase 3* and *Phases 4* & *5*, respectively). When comparing the two groups statistically, the means for *Child Distress* during the needle procedure (*Phase 3*) were not significantly different. Similarly, the result of the LMEM analysis of *Child Distress* across *Phases 1* to *5* showed no significant difference between the groups. Hence, *hypothesis 1* cannot be confirmed (cf. section 5.2.2).

Although not significant, I found less average distress in the MT group during the needle procedure. In that connection, one of the children in the MT group was stuck five times, which exceeds the clinical guidelines at AUH.

Let us call him the “Boy number 5”. Besides that, these needle pricks were given *without* EMLA. I have included this child in all the results of the statistical analyses, presented in the *Result Chapter*. However, when considered as an outlier and excluded from the analysis, which I find reasonable due to the information provided above, the result of average *Child Distress* during *Phase 3* suddenly shows trends towards significance (p=0.098). For general information, at that time, he was one year old, had undergone 6 to 10 previous needle procedures, and exhibited a great extent of obvious distress behaviour.

On the basis of this analysis, it may seem as if this tendency towards significance is due to the MT intervention. However, given that many factors influence distress, the tendency may be due to chance or several reasons other than the MT intervention. For instance, one cannot rule out that the observers were positively biased towards the MT project and consequently gave systematically more beneficial distress ratings to the children in the MT group, intentionally or un-intentionally. However, at least one can confirm that the children were distributed somewhat equally in terms of age and randomisation among all four research-assistants, as I accounted for in section. In continuation of this, the inter-rater reliability test showed a highly significant strong correlation (r=0.763) when all of the time rating intervals were analysed in combination. Furthermore, the calculation of *Phase 3* distress showed a highly significant moderate correlation (r=0.654). But that still does not rule out possible bias such as the one mentioned above. In addition, the research literature shows that the parents´ and medical staff´s behaviour may influence the child´s distress during medical procedures, including venipuncture (e.g. Dahlquist, Power, & Carlson, 1995; Mahoney et al., 2011). Due to the non-significant p-value, one cannot be certain that the group difference can be ascribed (entirely) to the effect of the MT intervention. On the other hand, in the light of the results of the remaining outcome measures discussed below, it may seem reasonable after all.

Needle-related MT studies: As mentioned above, I identified and reviewed three MT outcome studies related to *needle procedures* involving paediatric patients (Caprilli et al., 2007; Malone, 1996; Pfaff et al., 1989). All of these measured observed distress, but differ from the PhD study in some respects (e.g. type of needle procedure, p-values and effect sizes, nature of applied music interventions). As mentioned, although not significant, I found less average distress in the MT group during the needle procedure. This result is consistent with Caprilli et al., who found beneficial effects of musician-performed *musical distraction* on observed distress (as well as anxiety and

pain intensity) under blood test procedures. Specifically, Caprilli et al. found a small to moderate significant effect of in relation to distress before, during, and after the blood test procedures. On the contrary, in the PhD study, a somewhat small effect was found. The differences in terms of effect sizes and significance between these two studies may be due to the administration of EMLA and the small sample size in the PhD study. Contrary to the study by Caprilli et al., the majority of the participants in the PhD study underwent the needle procedure *with* topical anaesthetics. Furthermore, Caprilli et al. did not measure distress or pain at baseline.

Confer figure 6.11, I found ceiling effects in both groups in *Phases 1* to *5*. Hence, this may reflect that the EMLA was effective in reducing not only pain (Fetzer, 2004) but also the associated distress. As appears from the figure, approximately 50% of the children in the control group coped with the needle procedure only exhibiting minimal distress. In short, when comparing these two studies (Caprilli et al. and the PhD study), it apparently looks as if MT/musical distraction is more effective during needle procedures in which anaesthetics are *not* used. As to the difference between these studies in terms of statistical significance of results, one should bear in mind that the sample size in Caprilli et al. (n=108) was two and a half times larger than in this PhD study (n=41). This might explain that the beneficial tendency in the MT group found in the PhD study was not significant, knowing that the p-value decreases as the magnitude of the sample size increases. Likewise, the ceiling effects and small sample may similarly explain why the result of the LMEM analysis (i.e. distress analysed across *Phases 1* to *5*) was not significant either. Finally, as mentioned, Caprilli et al. did not measure distress at baseline. So given that the mean distress scores of the control group were twice as high as the one of music distraction group already *before* the needle procedures, it cannot be ruled out that the significant group difference may be due to other reasons than the music distraction. On the other hand, due to the decent sample size, substantial group differences should be washed out in principle.

Contrary to Caprilli et al., Malone (1996) found mixed results in terms of efficacy of the MT intervention in her matched controlled study (n=40). As to the 0- to 1-year-olds in the MT group, she found significant less total distress duration. On the contrary, significance was not found as to the remaining three- to seven-year old children. Specifically, overall behavioural distress duration of the three stratified age groups varied within and across the three pre-defined stages of the needle procedures (i.e. pre-needle phase, needle-phase, post-needle phase). For

instance, children at the ages one to three had almost same distress duration scores in both groups across the three needle-stages. As mentioned in the literature review, the Malone study was included in the meta-analyses Standley & Whippler (2003) and Dileo & Bradt (2005). However, in that connection, the former meta-analysis reported a small and non-significant effect contrary to the latter analysis, which reported a large effect. Anyway, besides that, the Malone study is slightly different from the PhD study as well as Caprilli et al. (2007) in that the MT intervention was not commenced prior to the onset of the needle procedures, contrary to recommendations stated in the MT literature (e.g. Turry, 1999; Whitehead-Pleaux et al., 2007). Instead, the MT intervention was started immediately upon the child entering the treatment room. This circumstance might explain the difference in terms of significance between Malone and Caprilli in that there was no time to establish rapport before commencement of the procedure. Furthermore, Malone does not state whether topical anaesthetics were provided for the children. Given that the study was undertaken in 1996, it is reasonable to assume that the procedures were performed *without* any form of topical anaesthetics. Like as Caprilli et al., the applied MT intervention is only superficially described in Malone. Consequently, this makes direct comparison among studies difficult. Finally, still in relation to the Malone study, although the three- to seven-year olds in both groups had similar pre-needle scores of distress, children in the MT group had higher distress means during the needle insertions, which, however, was not statistically significant.

Finally, as to the third needle-related MT study, Pfaff et al. (1989) examined the effects of music-assisted relaxation (MAR) on distress (as well as pain and anxiety) under bone marrow aspiration (BMA). Pfaff et al. is different from the PhD study as well as Caprilli et al. (2007) and Malone (1996) due to the nature of the needle procedure, the limited sample size, and type of disease of the participants. As to the latter, the participants in the Pfaff et al. study were children having cancer, who underwent BMA in relation to the treatment of a life-threatening disease. In short, the Pfaff et al. study comprised six children at the ages of 6 to 15 and no significance were found in terms of distress during the BMA. However, the effect of the MAR intervention was large according to Dileo & Bradt (2005). Finally, in my discussion of the study by Caprilli et al., I theorised that local anaesthetics might reduce the general level of pain and the associated distress to such a degree that the effect of MT/musical distraction becomes less statistically evident. In the study by Pfaff et al., local anaesthetics were administrated. Although not significant, the effect of MAR was large. However, on the other hand, BMA is obviously more intrusive than “simple” intravenous needle procedures. Moreover, the medical conditions of children having cancer are more critical by nature. In combination,

these factors may contribute to higher distress levels during BMA. If the MT intervention is effective, this may consequently be reflected more distinctly in the statistical results. In conclusion, the three existent needle-related MT studies show a mixed picture in terms of effects and significance. Moreover, they differ in terms of severity of disease, type of music intervention, and sample size, which does not allow for direct comparison to the present PhD study.

Meta-analyses: As reviewed and described in Chapter 4, the meta-analysis Klassen et al. (2008) estimated the effects of MT and MM on anxiety and pain in children undergoing various medical procedures. Since these outcome variables to a great degree constitute distress behaviour, I will now shortly address myself to their overall findings. As described, Klassen et al. found that MT and MM (analysed in combination) had a significant small to moderate effect on procedural-related anxiety and pain (analysed in combination) compared to control conditions. However, a subgroup analysis showed a significant effect for only MM as opposed to MT. In that connection, one should bear in mind that this subgroup analysis was based on seven MM studies versus two MT studies, which relate to surgery/ pre-operative anxiety (i.e. Kain et al, 2004; Robb et al., 1995). Consequently, the skewness in the number of MT versus MT studies constitutes a somewhat unequal frame of reference.

In continuation of this, the overall results reported by Klassen et al. (2008) conflicts with the overall findings of Standley & Whipple (2003) and Dileo & Bradt (2005), who found a significant larger effect in favour of MT (compared to MM) in paediatric patients on the basis of 29 and 11 paediatric studies, respectively. However, these studies relate to various medical conditions involving paediatric patients, not exclusively medical procedures. Consequently, this restricts the generalisability of results of the context of medical procedures. However, as to the contradictions of results among the meta-analyses, one should keep in mind that seen in a broader perspective, there is substantial evidence that MT is more effective than MM in medicine. This is consistently found in previous meta-analyses on MT and MM in medicine (Standley, 1986, 1995) as well as neonatalogy (Standley, 2002). As to the most recent one (Dileo & Bradt, 2005), this finding was based on 183 MT and MM studies involving 7.894 paediatric and adult patients distributed over 11 medical specialties. In conclusion, more research is needed to clarify whether MM really is more effective than MT in the specific context of medical procedures or whether the results of Klassen et al. are misleading due to the small number of included MT studies.

In short, Standley & Whipple (2003, p. 11) do not provide specific estimates directly related to needle procedures. Instead, they outline these overall results:

Active music participation (*d*= 0.89) was more effective than passive music listening (*d*= 0.44)

Live music was more effective (*d*= 0.82) than recorded music (*d*= 0.55)

MT & MM were more effective for major invasive procedures (*d*= 0.91) and non-invasive (*d*= 0.83) than for minor invasive procedures (*d*= 0.37)

Greatest effects were achieved for adolescents (*d*= 1.36), then infants up to 4 years (*d* = 0.74). Least effect was indicated for children aged 4-12 years (*d*= 0.43)

a) Active music participation (d= 0.89) was more effective than passive music listening (d= 0.44)
b) Live music was more effective (d= 0.82) than recorded music (d= 0.55)
c) MT & MM were more effective for major invasive procedures (d= 0.91) and non-invasive (d= 0.83) than for minor invasive procedures (d= 0.37)
d) Greatest effects were achieved for adolescents (d= 1.36), then infants up to 4 years (d = 0.74). Least effect was indicated for children aged 4-12 years (d= 0.43)
e) Observed pain and distress showed modest effect sizes in comparison to self-report and physiologic measures of the same outcome variables

On the basis of the overall results listed above, clear-cut inferences cannot be drawn as to the effects of MTPS in the context of the PhD study. As to the result of distress in the PhD study, items *a* and *b* suggest that in principle, the applied MAE-based MT intervention can be effective. On the contrary, given that PIVA is a minor invasive medical procedure and the majority of the participants were aged one to five, item *c* and *d* imply a minor effect of MT. Likewise, item e furthermore suggests a modest effect of MT. Hence, Standley & Whipple (2003, p. 11) show a mixed picture in terms of expectancy of MTPS. This relates to the fact that the meta-analysis includes 29 studies on various medical conditions and/or procedures. Consequently, direct inferences and comparisons to the results of the PhD study cannot be made and more MTPS studies are needed.

Additional related MT studies: As to the eight remaining MT studies that I reviewed, I classified Whitehead-Pleaux et al. (2006) and Whitehead-Pleaux et al. (2007) as *Other painful procedures*. Specifically, these studies examined the effects of MT on distress in relation to debridement. Although this medical procedure differs from the one in the PhD study, overlaps might exist in terms of the basic functions and mechanisms of MTPS due to the use of a MAE-based approach in these and my studies. Furthermore, the medical procedures in the present PhD study, Whitehead-Pleaux et al. (2006), and Whitehead-Pleaux et al. (2007) have the same element of infliction of pain and associated distress. In short, the beneficial tendency as to observed *Child Distress* in the PhD study contradicts the results of the explorative pilot study by Whitehead-Pleaux et al. (2006). In this study the authors found significantly higher nurse-rated child distress in the MT group compared to the control children. Furthermore, among other things, the MT children scored significantly higher anxiety before, during, and after the procedure. In the subsequent explorative mixed methods pilot study, Whitehead-Pleaux et al. (2007) examined whether higher levels of engagement reduced observed distress (as well as pain and anxiety). The results showed a significant relationship between level of engagement and nurse-rated child distress. However, due to differences of foci of studies, this finding is not comparable to the results of my study.

Summation: In conclusion, the results of *Child Distress* in the PhD study were non-significant and the MT intervention had a small effect during *Phase 3*. This might relate to the widespread use of EMLA in the participants and the small sample size, among other things. The present PhD study and the three reviewed needle-related studies share some similarities, but differences were also addressed. Among other things, the extent of contextual, clinical, and theoretical information were limited in the description of these studies, which makes direct interpretations and comparability difficult. Similarly, the results among the three meta-analyses showed conflicting results. Finally, when comparing the distress-related results of the PhD study to existent studies and meta-analyses, a mixed and conflicting picture emerged. In conclusion, more research is needed to evaluate the effects of MTPS under needle procedures involving paediatric patients.

7.7.2 Discussion of Results Regarding Child Anxiety

In short, *Child Anxiety* was rated by the child and three types of adult raters during *Phase 3* by means of an adapted version of the FPS-R and the VAS, respectively. Moreover, the research-assistant rated *Child Anxiety* in *Baseline Phase* plus *Phases 1* to *5*, which I will now shortly summarise. As appears from the descriptive summation of provided in table 6.7 and figure 6.13, the children in both groups scored practically no anxiety during the *Baseline Phase*. Besides that, as I expected, the mean anxiety scores of both groups increased gradually during *Phases 1* to *3* and decreased similarly gradually after the needle procedure (i.e. during *Phases 4* & *5*). This is reflected in figure 6.13 and was confirmed statistically in the LMEM analysis. When comparing the scores of the two groups, the MT children had less mean anxiety *during* (*Phase 3*) and *after* the needle procedure (*Phases 4* and *5*). In addition, the mean score of the control children increased slightly in *Phase 5*, contrary to the mean score of the MT group. Besides that, the LMEM analysis of *Child Anxiety* across *Phases 1* to *5*, showed no significant result.

In the following, I will refer to the results of the four types of raters, which relates exclusively to *Phase 3*. In summation, the results of the MWU-Ts analyses were as follows. As appears from table 6.16, research-ratings of *Child Anxiety* showed a mean difference of 18 percentage points in favour of the MT group. This result showed a tendency towards significance, so *hypothesis 2a* cannot be confirmed (cf. section 5.2.2). As to child-rated anxiety, a mean difference of 30 percentage points was demonstrated. Likewise, this result was not significant when analysed by means of a MWU-T. But when controlling for the four pre-defined explanatory variables, the GLM estimate showed a mean difference of 43 percentage points and trends towards significance in favour of the MT intervention. In addition, the remaining explanatory variables were not significant. Consequently, *hypothesis 2b* cannot be confirmed (cf. section 5.2.2). With regard to parent-rated *Child Anxiety*, a small mean difference of 8 percentage points was noted in favour of the MT group (i.e. MWU-T). This difference was not significant, so *hypothesis 2c* cannot be confirmed either (cf. section 5.2.2). On the contrary, physician ratings of *Child Anxiety* were 18 percentage points lower in favour of the MT group, which proved to be significant (i.e. MWU-T). Thus, *hypothesis 2d* can be confirmed (cf. section 5.2.2).

Statistical Comparison of Results of Raters: As mentioned in the previous section (i.e. the discussion on results of distress), the result of research-assistant-rated *Child Anxiety* was significant (p=0.05) after removing an outlier (i.e. Boy number 5). Moreover, the p-value of the already significant result of physician-rated *Child Anxiety* proved

to be lower (p=0.027). When the above-mentioned results of the four types of raters are seen in combination, a consistent beneficial tendency in favour of the MT intervention apparently emerges. But in order to examine this statistically, I carried out three analyses (exclusively related to *Phase 3*). The first analysis relates to the *three adult raters* (i.e. research-assistant, parents, physician) and was performed on the basis of the total sample (i.e. 41 children) by means of a LMEM. The estimate showed a somewhat similar mean score, which ranged up to 8 percentage points among these three raters (see table 6.17). As to the p-value of this estimate, the result was not significant, but had trends towards significance. This means that the null hypothesis of no difference among the raters could not be rejected, or in plain language that they scored (somewhat) similarly.

In the second analysis, I made an estimation based on *all four types* of raters on the basis of the scores of the 13 five- to ten-year-olds, who were old enough to give self-report. This estimate showed that the mean scores of *Child Anxiety* ranged up to 13 percentage points among the four types of raters, with the children rating the lowest means and the parents the highest means, respectively. Interestingly, as appears from table 6.18, the mean scores of the research-assistants and the physicians are rather close the ones of the children´s. As to the p-value, the result was far from significant, meaning that statistically there was no difference among raters (see table 6.18).

As to the third analysis, I made a Pearson Correlation of physician- and research-assistant-rated *Child Anxiety* scores. The rationale for this analysis was the assumption that these two specific types of raters would have the most equal frame of reference. The result showed a strong correlation (0.82), which was highly significant, meaning that the physician and the research-assistants scored similarly (see table 6.19). In summation, when comparing the mean scores of the two groups during *Phase 3*, all four types of raters consistently rated lower *Child Anxiety* in the MT group. When using an MWU-T, one result was significant (i.e. physician-ratings) and another had trends towards significance (i.e. ratings of research-assistant). However, after removal of an outlier, the latter also showed to be significant. When comparing the different types of raters, estimates showed somewhat equal mean scores for *Child Anxiety*, which was confirmed statistically.

Interpretation of results: So, how can these results be interpreted and to what degree can they be ascribed to the MT intervention, if at all. Well, one thing we cannot rule out is the fact that neither the participants/ families, research-assistants, physicians nor the music therapist were blinded. Consequently, the above-mentioned finding may be partly or entirely due to possible positive bias. For instance, suppose that the physicians found the MT project or the MT intervention interesting to such a degree that they (intentionally or un-intentionally) favoured the scores of the MT children. Likewise, the same could potentially be the case of the research-assistants. In continuation of this, I employed all the research-assistants for the purpose of the study. Although their payments were administrated by the hospital, it cannot be ruled out that they to some degree did feel some kind of need or unintentional pressure to please me, giving me better results than was the case. On the other hand, since the five- to ten-year olds also consistently rated substantially less anxiety, it might not be the case after all. But on the contrary, this result was based on only 13 observations, so the otherwise unambiguous distribution of scores in the MT group may be due to chance.

That said, I find it reasonable to assume that the following precautionary measures can reduce the possibility of potential methodological hazards mentioned above. First of all, the children were distributed somewhat equally in terms of age and randomisation among the four research-assistants as well as the three physicians who performed 75% of the total procedures, as accounted for in section 6.24.4. In continuation of this, as to the physicians, figure 6.29 shows that the anxiety ratings of three physicians were somewhat equally distributed according to each condition. Moreover, the results of the inter-rater reliability tests showed a highly significant strong correlation (0.712) when analysing the research-assistants´ ratings of *Child Anxiety* across *Baseline Phase* and *Phases 1* to *5* in combination (based on 48 observations). Furthermore, I found a moderate correlation (r=0.632) between the two main raters in relation to *Phase 3* (based on 9 observation). Finally, when correlating the *Child Anxiety* ratings of the research-assistants and physicians (*Phase 3*), a highly significant strong correlation was found (r=0.820). This indicates that suppose the results of the MT group were biased, it would systematically apply to the research-assistants as well as the physicians. After all, this does seem to me rather unlikely.

Perhaps the issue should be looked at from a different angle. When taking the perspective of the four assessors, we might find a more reasonable explanation accounting for the variations of the assessors in terms of significance,

tendency, and not least differences. When comparing the eyes of the observer, the child is the one who suffers most in terms of distress, pain, and emotions. Likewise, the parents obviously are also to a great degree emotionally involved during the needle procedure and may have felt responsible and sorry for their child, which may colour their experience and consequently their ratings. On the contrary, the research-assistants have no personal emotions at stake and are therefore (at least in principle) the most emotionally "objective" rater. Furthermore, due to the nature of their role, they have been trained and have rated several children undergoing the procedure. In that connection, one should also keep in mind that they are supposed to focus on their task regardless of the child´s response to the procedure, which makes it easier to keep their emotional distance. Similarly, compared to the parents, the physicians do not have personal emotions involved in conducting the procedure. Furthermore, they are trained to perform the procedure professionally regardless of the child´s reaction and whether the child is "compliant" or not. In short, as to the about 50 to 60% of the children who underwent the procedures exhibiting notable distress, pain, and anxiety, the procedure is stressing. From the perspectives of these children and parents, there is no such thing as a "good" needle procedure. In short, it seems reasonable to assume that these parents are influenced by the reaction of their child and do feel sorry for their child, which consequently may colour their ratings. On the other hand, the parents are the ones who know their child best and instinctively know how to interpret the child´s reaction, facial expression, and pain behaviour. However, this may not necessarily contradicts the above-mentioned arguments.

In conclusion, consistent significant and beneficial trends for *Child Anxiey* were found, potential bias was discussed, and a possible explanation was provided. In the following, I will change the focus of the discussion to the existent research literature to which I relate the results of the PhD study.

Needle-related studies: As to the three MT outcome studies related to needle procedures involving paediatric patients, only Pfaff et al. (1989) measured anxiety (self-reported). In her within-subjects study, she found trends towards a decrease in median anticipatory anxiety and experienced anxiety during BMA. These results are congruent with the results of *Child Anxiety* in the PhD study. However, as mentioned above, this study differs in several ways, which restricts the degree to which the results can be compared directly.

Meta-analyses: As mentioned, Standley & Whipple (2003, p. 11) do not provide specific estimates of anxiety directly related to needle procedures involving children, so direct comparison to the PhD study is not possible. But according to their overall findings, the applied MTPS intervention would be expected to have a small effect (see, table 4.3). Likewise, Dileo & Bradt (2005, pp. 55-56) do not provide such overall results exclusively related to procedural anxiety. However, on the basis of two studies including 42 paediatric research subjects, Dileo & Bradt found that MT has a very large mean effect on *mood*. In addition, the result was highly significant and homogeneity was demonstrated. However, it is not transparent to see the references of the studies in question. Likewise, based on a single study comprising 32 children, Dileo & Bradt (pp. 56-57) found a large effect of MT in relation to *feelings of control*. However, this study relates to dentistry. Although these outcome measures are not directly comparable to anxiety, these results may overlap and concur to some degree with the results of anxiety in the PhD study. Finally, when compared to control conditions, Klassen et al. (2007) found a small to medium significant effect of MT and MM (calculated in combination) on anxiety. However, this estimate was associated with a substantial heterogeneity (e.g. type of music intervention). Moreover, the estimate was made on the basis of three MM studies and two MT studies (Kain et al., 2004; Robb et al., 1995), of which the MT studies relate to pre-operative anxiety. Consequently, this estimate is not directly comparable to the results of the PhD study.

Additional related MT studies: As to the remaining MT studies, two studies measured anxiety in relation to various painful medical procedures involving paediatric burn patients (Whitehead-Pleaux et al., 2006; Whitehead-Pleaux et al., 2007) and three studies examined the effect of MT on pre-operative anxiety (Chetta, 1981; Kain et al., 2004; Robb et al., 1996). Contrary to the results of *Child Anxiety* in the PhD, when comparing the MT and control conditions, Whitehead-Pleaux et al. (2006) found a significantly higher mean anxiety score in the MT group before and during the procedure. Despite the fact that a subsequent decrease in anxiety was noted in the MT group, their mean score was still higher than the one of the control group. In their subsequent study, Whitehead-Pleaux et al. (2007) found no significant relationship between nurse-rated anxiety and level of engagement. As to the studies related to pre-operative anxiety, Chetta found no significant difference between the control and the MT conditions contrary to the PhD study. However, the children in MT group 2 scored significantly less anxiety than the children

in MT group 2. Likewise, Kain et al. (2004) neither found a significant reduction of anxiety in the MT group (n=51) compared to the Midazolam (n=34) and the control conditions (n=38). However, a (music) therapist effect was reported, which was clinically significance (see section 4.3.4).

Finally, on the contrary, the results of the PhD agree with Robb et al. (1995), in finding less anxiety as measured pre/post the MAR intervention as well as subsequently during transportation to the operating theatre. In conclusion, the above-mentioned studies measured anxiety under various medical procedures and surgery and show mixed results. Since the PhD study differs in terms of type of MT intervention as well as the medical procedure of the PhD study (i.e. needle procedure), the degree to which results can be directly compared is restricted. Consequently, more research is needed in order to provide valid comparison among studies, types of MT interventions, populations etc.

7.2.3 Discussion of Results Regarding Child Pain Intensity

In summation, *Child Pain* was rated immediately upon *Phase 3* by the child and three adult raters by means of the FPS-R and VAS, respectively. In summation, the results of the MWU-Ts analyses were as follows. Confer section 6.8, research-ratings of *Child Pain* showed a mean difference of 8 percent points in favour of the MT group. Given that the result was not significant, *hypothesis 3a* cannot be confirmed. As to child-rated anxiety (n=13), a mean difference of 19 percentage points was found in favour of the MT group. Since the result was not significant, *hypothesis 3b* cannot be confirmed. On the contrary, parent-ratings of *Child Pain* showed a mean difference of 3 percentage points in favour of the control condition, so *hypothesis 3b* cannot be confirmed. For general information, as to the 16 outcome measures, this finding constituted the only non-beneficial mean difference for the MT group. Consequently, *hypothesis 3c* cannot be confirmed. On the contrary, physician ratings of *Child Pain* were 16 percentage points lower in favour of the MT group and showed trends towards significance (p=0.06). Thus, *hypothesis 3d* can be confirmed either.

Statistical Comparison of Results of Raters: Contrary to the anxiety ratings of the above-mentioned four types of raters, their pain ratings were less consistent. Specifically, the parents´ pain ratings of the children in both groups are slightly higher pain. When comparing the figures 6.15 and 6.22, the ratings of the research-assistant and

physicians seem to concur. This was also confirmed statistically to some degree in the form of a highly significant correlation (r=0.674). Moreover, if we take a look at table 6.9, we find that two thirds of the children underwent the procedure rating no or moderate pain, which concurs to some degree with the ratings of the physician and research-assistant. On the contrary, the parents rated higher pain in both groups. So in order to examine this statistically, I carried out three analyses (exclusively related to *Phase 3*). The first analysis relates to the *three adult raters* (i.e. research-assistant, parents, and physician) and was performed on the basis of the total sample (i.e. 41 children) by means of a LMEM. The estimate showed a somewhat similar mean score, which ranged up to 5 percentage points among these raters (see table 6.17). As to the p-value of this estimate, the result was not significant (p=0.137). This means that the null hypothesis of no difference among the raters could not be rejected or in plain language that they scored similarly.

In the second analysis, I made an estimation of *Child Pain* comprising *all four types* of raters. Data consisted of the rater scores of the 13 five- to ten-year-olds, who were old enough to give self-report. This estimate showed a greater variability of mean scores, which ranged up to 18 percentage points among the four types of raters. The results also showed that the children rated the highest mean and the physicians the lowest mean. Interestingly, as appears from table 6.18, the mean scores of the parents and children are rather close contrary to the result of the analysis regarding *Child Anxiety* in which the children had the lowest mean score and the parents had the highest. Anyway, the p-value of the estimate of *Child Pain* had trends towards significance (p=0.072). However, given that the estimate was based on few observations, the result cannot be taken at face value.

As to the third analysis, I made a Pearson Correlation of physician- and research-assistant-rated *Child Pain* scores due to the assumption that they would have the most equal frame of reference. The result showed a moderate correlation (0.674), which was highly significant, meaning that the physician and the research-assistants scored similarly (see table 6.19). In summation, when comparing the mean scores of the two groups during *Phase 3*, the ratings of the four types of raters were less consistent. Specifically, the parent ratings differed from the remaining three types of raters. When using an MWU-T, one result had trends towards significance (i.e. physician). In continuation of this, after removing an outlier (i.e. boy number 5) the result still showed trends towards significance, although the p-value was slightly higher (p=0.076). Besides that, when comparing the mean scores of the 13 oldest children, a mean difference of 19 percentage points was found in favour of the MT group. However, this difference was not

significant. And on the other hand, the parents rated 3 percentage points higher pain in the MT group. So what can we make out of this and how should these mixed results be interpreted?

Confer the theoretical framework of the study, literature show that several factors influence the perception of pain besides the "pure" neural processing of the pain stimuli (Loeser & Melzack, 2001; Melzack, 2001), including idiosyncratic, cultural, social, and environmental components (Blount et al., 2009; Cohen 2008; Young, 2005). However, in the study, I did not aim at controlling for all these factors statistically. Instead, I assumed that these factors would balance somewhat equally between the groups due to the use of randomisation. In that connection, I will not repeat my discussion on the potential systematic methodological bias addressed previously. But shortly said, a number of potential bias cannot be ruled out entirely in this study, given that neither the children, parents, assessors, nor the physicians were blinded among other things. But as put forward previously, the children were distributed somewhat equally in terms of age and randomisation among the four research-assistants as well as the three physicians who performed 75% of the total procedures, as accounted for in section 6.24.4. In continuation of this, as to the physicians, figure 6.29 shows that the pain ratings of three physicians were somewhat equally distributed according to each condition. Moreover, the results of the inter-rater reliability tests showed a significant moderate correlation (r=0.681) between the two main research-assistants. In conclusion, trends towards significance were found in relation to one rater. On the contrary, the parents rated slightly higher pain in the MT group. However, in the light of the results of the remaining outcome measures, the results may be due to the MT intervention.

Needle-related studies: As to the three needle-related MT studies, Caprilli et al. (2007) and Pfaff et al. (1989) measured *Child Pain* (self-reported). Although not significant, the MT children as wel as the physicians reported less mean pain in the PhD study. This agrees with the results of Caprilli et al., who found significantly less self-reported pain in favour of the musical distraction group (n=54) compared to the control condition (n=54). As pointed out previously, Caprilli et al. did not measure distress at baseline, so the significant group difference may be due to other reasons than the music distraction intervention, although the decent sample size in principle should wash out substantial group demographical differences etc. Likewise, Pfaff et al. found trends towards decrease in median self-reported pain. Although not self-report, these results contrast with the parent-ratings of *Child Pain* in the PhD study.

Meta-analyses: As mentioned, Standley & Whipple (2003, p. 11) do not provide specific estimates of pain directly related to needle procedures involving children. Therefore, direct comparison to the PhD study is not possible. But according to their overall results, they found observed pain to show modest effect sizes compared to physiological and self-report measures of the same outcome variable. Likewise, the effect of MT/MM under minor invasive procedures was found least effective. On the other hand, active music participation as well as live music were found to be most effective. All in all, the applied MTPS intervention may be expected to show a small effect. On the contrary, Dileo & Bradt (2005, p. 45) reported a large non-significant mean effect size of MT in relation to pain. The estimate was based on three studies including 66 paediatric patients. Unfortunately, the references of the studies do not appear clearly. Finally, the estimate regarding pain provided by Klassen et al. (2008) is calculated on the basis of four MM studies, so comparison to the results of the PhD study cannot be made.

Additional Related Studies: As to the remaining eight MT studies, Whitehead-Pleaux et al. (2006) reported higher self-reported pain scores in burn patients receiving MT before, during, and after donor site dressing change. But the result was not significant. In the context of the PhD study, this result agrees with the ratings given by the parents, but conflicts with the tendency towards significance as rated by the physician. In their subsequent study, Whitehead-Pleaux et al. (2007) examined whether the child´s level of engagement was related to self-reported pain (and anxiety). Results showed a non- significant relationship. Finally, Bradt (2010) undertook a cross-over study evaluating the effects of entrainment on post-operative pain in 32 participants and found a significant large effect on self-reported pain.

In conclusion, in the PhD study, the mean pain score rated by the parents differed from the three remaining raters, who showed less pain in the MT group plus a trend towards significance. Comparing these results to the research literature proved to be difficult due to the mixed effects reported as well as differences in terms of type of music intervention, paediatric patients, and medical procedure among other things. In conclusion, more research is needed to clarify the effect of MTPS during needle procedures. Finally, the methodological limitation of the measuring tools applied in the measuring of *Child Pain* will addressed in section 7.5.2.5.

7.2.4 Discussion of Results Regarding Child Compliance and Parent Compliance

In summary, *Child Compliance* and *Parent Compliance* were rated by the physician immediately upon completion of the needle procedure (i.e. *Phase 3*) using a 100mm bipolar VAS. As to *Child Compliance*, the result of the MWU-T showed a tendency towards statistical significance in favour of the MT group, which had a mean score 19 percentage points lower than the control group. Consequently, *hypothesis 5* cannot be confirmed. However, after removing an outlier (i.e. Boy number 5), the result was significant (p=0.047).

These results may be due to the effect of the MT. As discussed above, the children in the MT condition were significantly less anxious as rated by the physician (and research-assistant). Moreover, a trend towards significance was also found in the MT children as rated by the physicians, which also concurs with the (non-significant) mean difference reported by the research-assistant. Hence, it may be reasonable to infer that the MT was supportive in calming the MT children and reducing their reactions to the procedure, which consequently may be experienced by the physicians as better compliance. On the other hand, the tendency of significance may also or instead relate to other factors. For instance, suppose some of the physicians were positively biased towards the MT project or the MT therapist, they may intentionally or un-intentionally have given more beneficial ratings to children in the MT group. This source of bias cannot be ruled out. However, on the other hand, the children were distributed somewhat equally in terms of age and randomisation among the three main physicians who performed 75 percent of the total procedures. In continuation of this, as illustrated in figure 6.29, the physicians´ ratings were consistently lower in the MT group. This means that suppose the physicians gave biased ratings, it would involve them all.

As to *Parent Compliance*, the mean scores of the groups were identical and the result was therefore not significant, so *hypothesis 6* cannot be confirmed either. In addition, a clear ceiling effect was found in both groups (see figure 6.24). One explanation of this may be that it was left to the rater (i.e. physicians) to interpret what compliance meant to them and therefore the ceiling effect may reflect that the sparse instruction and wording provided in the VAS were insufficient. Therefore, the VAS may not be an appropriate tool for this outcome measure. However, on the other hand, as to *Child Compliance*, the distributions of scores ranged from 0mm to 100mm in both groups. Moreover, contrary to *Parent Compliance*, the VAS was apparently sensitive enough to detect group differences in relation to *Child Compliance*, even in spite of the fact that *Child Compliance* may be more complex to measure using the VAS

than *Parent Compliance*. For instance, one of the physicians raised the question and criticism whether a two-year-old can be "compliant" during a painful and/or distressing needle procedure. Another reasonable explanation could be that the ceiling effect may simply be due to the fact that most of the parents engaged constructively with the medical personnel during the needle procedure, while at the same time supporting the child as much as possible, with a view to completing the procedure as soon as possible. As pointed out by Loewy, MacGrogor, Richards, and Rodriguez (1997) "It is not useful for a child of any age to watch a parent fall apart at the moment procedural pain is experienced. This is the time a patient needs strength and ego support" (p. 50). The ceiling effect may also reflect that the parents were quite satisfied with the way the medical staff carried out the procedures, giving them no reason to be sceptical or in opposition to the medical personnel´s decisions, approach etc.

Confer the literature review (i.e. Chapter 4), none of the 11 MT outcome studies measured either forms of compliance in relation to the various medical procedures. Similarly, the three meta-analyses do not provide estimates of this outcome domain (Dileo & Bradt, 2005; Klassen et al., 2007; Standley & Whipple, 2003). Consequently, research is needed in relation to medical procedures involving paediatric patients in order to illuminate the effects of MTPS.

7.2.5 Discussion of Results Regarding Parent-Rated Overall Satisfaction with Medical Procedure

In summation, parent-rated *Overall satisfaction with medical procedure* was assessed by means of a five point Likert-type scale, which I developed for the study. The result of the MWU-T showed no significant group difference, so *hypothesis 4* cannot be confirmed. However, in the MT group the data were distributed among three of the five possible categories, with 67 percent of the ratings stated as *Very satisfied*. In the control group, data were distributed among three of the five possible categories with 55% of the ratings stated as *Very satisfied*. This percentage-wise group difference may be due to the MT intervention as the children in the MT group were found to be significantly less anxious as rated by the physician. Moreover, the trends towards significance as to child- and research-assistant-rated anxiety as well as physician-rated pain and compliance may in combination provide a reasonable explanation.

However, the percentage-wise tendency was not significant. Furthermore, when *Very satisfied* and *Satisfied* were analysed in combination, the distribution was almost identical in the groups (i.e. 86 percent in the MT group, 85 percent in the control group). So instead of immediately ascribing the above-mentioned percentage-wise tendency entirely to the MT intervention, one should keep in mind that many (other) factors may have influenced the parents´ overall experience of the procedure and consequently their appraisal of overall satisfaction with the needle procedures. For instance, the use of EMLA is significantly effective in reducing pain intensity during needle procedures (Cordoni & Cordoni, 2001; Fetzer, 2001), which influences the child´s pain perception and behaviour and consequently the parents´ perception of the needle procedure in question. Moreover, the number of needle insertions required to perform the procedure may also influenced the parents´ overall experience and consequently their degree of satisfaction with the procedure. Likewise, the clinical practice for the carrying out of the procedure may also influence satisfaction.

Another possible explanation we cannot rule out may be that the physicians or some of them were positively biased towards the MT project, so they intentionally or unintentionally behaved more friendly to the families randomised to this condition. On other hand, it may seem rather unlikely that they would change or at least exaggerate their way of relating to the MT families just for the reason of the study. In addition, in general the ratings of the control group were quite positive. Moreover, this would require a consistent bias among at least the three physicians who performed 75 percent of the procedure. In that connection, as clarified in section 6.24.4, the children were distributed somewhat equally in terms of age and randomisation among the three physicians who performed 75 percent of the total procedures.

Finally, the last consideration I will put forward in discussing possible explanations of factors influencing overall satisfaction relate to the attitudes of and interaction with the medical personnel, which I experienced in the PhD study. Contrary to the control group, one family in the MT group answered *Dissatisfied*. In addition, as mentioned above, contrary to the clinical guidelines at AUH, the child received five needle pricks after which the physician gave up completing the procedure. After *Phase 5*, the mother who is a nurse explained to me that she did not like the physician´s manner and way of relating to the child. Furthermore, during the fourth needle attempt, the physician made a banal mistake why one more needle prick was required to complete the procedure. This made the mother further upset due to the obvious and substantial distress exhibited by the child. Her emotional reaction was not least influenced by the child crying and the great extent of obvious distress behaviour, which possibly relates to the fact that the poor child was stuck 5 five *without* EMLA. After *Phase 5* she told on her own initiative that she was pleased with the MT but not the procedure, so she answered *Dissatisfied*. This statement was confirmed in her answers in the MT satisfactory survey in which she replied that she wished MT under future medical procedures, would recommend MT to others, and found the MT intervention *useful*.

As to the literature review (i.e. Chapter 4), none of the 11 MT outcome studies measured overall satisfaction with medical procedure. Likewise, the three meta-analyses do not provide data on this outcome domain (Dileo & Bradt, 2005; Klassen et al., 2007; Standley & Whipple, 2003). Unfortunately, once again, (more) research is needed to evaluate the effects of MTPS in relation to overall satisfaction with medical procedure. Finally, methodologically, the five-point Likert-type scale seems appropriately for measuring satisfaction in that no ceiling effects or central tendency bias was found in either group.

7.2.6 Discussion of Results Regarding Number of Needle Pricks

In short, the research-assistant registered each child´s number of needle pricks. When comparing the two groups, the MT group had a slightly lower mean score of needle pricks. The results of the MWU-T showed no significant difference between the groups, so *hypothesis 7* cannot be confirmed. However, when inspecting table 6.11, it appears that the percentage-wise number of needle pricks was more widely distributed among *1 to 3 needle pricks* in the control group. Specifically, 71 percent of the MT children completed the procedure receiving only *one* prick contrary to 55 percent of the children in the control group. Likewise, 14 percent of the MT children received *two* pricks contrary to 25 percent of the control children. Moreover, 5 percent completed the procedure receiving *three* pricks in the MT group as opposed to 20 percent in the control group.

However, in the MT group, one child received *four* pricks and the above-mentioned poor child received *five*, contrary to the control group. As to the "Boy number 5", one of the pricks was due to a banal mistake made by the physician, as pointed out by the child´s mother, who is a nurse. Moreover, as mentioned in section 2.2.2, the five needle pricks exceed the clinical guidelines and practice at AUH, so it is reasonable to consider this case an exception. Likewise, the child receiving four pricks borders on deviating from the clinical practice at AUH. If we include the "Boy number 5" in the analysis, the result is far from significant (p=0.387). On the contrary, if we consider the child an outlier, which I find reasonable, the MWU-T still shows no significance (p=0.212), although the p-value is now almost halved. Finally, if we consider the "Boy number 4" as an outlier for a moment and remove this observation from the analysis (MWU-T), the result suddenly shows trends towards significance (p=0.098). Although still not significant, the scores related to these two children consequently influence the result substantially. In continuation of this, it seem likely that the "Boy number 4" was randomised by chance to the MT group. Had he been randomised by chance to the control condition (and the "Boy number 5" still removed as an outlier), the result would have been in favour of the MT group. In short, four needle pricks do not radically exceed the clinical guidelines at AUH. In order to avoid accusations of manipulation of data, I will close this statistical aspect of the discussion by pointing out that as to this outcome measure, even two observations did actually influence the statistical result notably.

In conclusion, a larger sample size is important in such a study to clarify whether it is more reasonable to ascribe this apparently beneficial tendency to chance or the MTPS intervention. But as mentioned in the *Result Chapter*,

at the time I originally made the analyses, my supervisor (Søren Rittig) advised me to include these cases in the analyses. Anyway, I will now leave the p-values discussed above and address myself more descriptively to the apparently beneficial tendency displayed in the MT group. If we leave the above-mentioned two children receiving extraordinary more pricks out of account, the remaining distribution of number of needle pricks above-mentioned seems systematically lower in the MT group. Although not statistically significant, the data indicate fewer needle pricks in the MT group. A possible explanation for the apparent beneficial tendency may relate to the results discussed in section 6.24.2. Here the anxiety scores were consistently lower in the MT group, regardless of type of rater. Likewise, although less consistently, the mean scores for pain were lower in the MT group, except for the parent-ratings. In combination, this might indicate that the children in the MT group were less anxious during the procedure, needed less reassurance, felt less pain, and consequently to a greater extent lay still while focusing on the MT, which created more peace for the physician to focus and perform the procedure.

On the other hand, as mentioned in *Chapter 1*, several factors influence the degree of success in performing peripheral intravenous access, which may partly explain why the beneficial tendency of the MT was not strong enough to obtain a significant effect. In this regard, Reigart et al. (2012) point out that in the "pediatric population, obtaining PIV access may be difficult and time consuming because of multiple potential issues, including smaller, less visible veins, lack of patient co-operation, and increased adiposity in infants relative to older children and adults" (p. 1). In addition, the authors emphasise that PIV is particularly more difficult to obtain in obese patients, since the adipose tissue obscures the veins (Reigart et al., p. 2). This is also the case in babies and very young children in that they have a greater extent of subcutaneous adipose. Moreover, veins tend to be less applicable for IV-access procedures the more procedures the child has undergone, which is often the case for children having chronic diseases. Finally, the use of EMLA contracts the veins making them less visible (Fetzer, 2001; medical personnel, AUH, personal communication).

Methodologically, in the PhD study, the research-assistant registered the number of needle pricks by simple count. However, this requires that she/he can obtain free vision, which can sometimes be challenging if several adults are positioned around the hospital bed where which the procedure in performed. In the study, at least three adults were present around the bed during procedures performed in control group (i.e. parent, physician, nurse).

But occasionally, up to seven or eight adults were present in the treatment room during the procedures, more precisely two parents, the physician, one or two nurses, the research-assistant, the music therapist, one or more medical/nurse students. Hence, as a security measure, if free vision was compromised, the research-assistants were instructed to compare their result with the physician or nurse after completion of the IV-access procedure. Finally, the reliability (and validity) aspects of the count method were confirmed by the inter-rater reliability test, which showed a highly statistically significant strong correlation (r=0.972).

As to the needle-related MT studies, Malone (1996) compared the number of needle pricks and found no statistically significant difference. Unfortunately, she did not provide any information in terms of means and standard deviations. Similarly, the three meta-analyses do not provide data on this outcome domain (Dileo & Bradt, 2005; Klassen et al., 2008; Standley & Whipple, 2003). Due to the absence of data on number of needle prick required to obtain PIVA, I will refer to Linninger (2003), who registered the cumulative insertion success rates in 249 PIVA procedures performed in paediatric patients. Linninger found the following success rates: 53% at the first attempt, 67% at the second attempt, and 91% at the third attempt. Finally, the average number of attempts to successfully obtain PIVA was 2.35. In short, in the context of the PhD study, the success rate to obtain PIVA at the first attempt (55%) was to a great degree similar to the results reported by Linninger. On the contrary, the success rates related to the second and third attempts differed between these studies. This may reflect local differences in terms of clinical guidelines and practice (e.g. whether PIVA is performed by specialised PIVA personnel). Consequently, this limits the degree to which direct comparison can be made. Hence, more research and inclusion of this outcome domain (including clear contextual descriptions of the carrying out of the procedures) are needed in future MTPS studies.

7.2.7 Discussion of Results Regarding Duration of Needle Procedure

In summation, the duration of the needle procedure (i.e. *Phase 3*) was registered in minutes and seconds by the research-assistant by means of a stop watch. In total, two different stop watches were used during the data collection period. As clarified in the method chapter, I defined *Phase 3* as starting when the child has been securely positioned in the hospital bed and ending after the bandage has been placed. When inspecting figure 6.25, it appears that the

distribution of the two groups differed clearly. When comparing the two groups by means of an MWU-T, I found a highly statistically significant mean difference of 3.39 minutes in favour of the MT group. Likewise, when controlling for all the four pre-defined explanatory variables, *music therapy* proved to be the only significant explanatory variable, having a mean difference of 3.20 minutes. Hence, *hypothesis 8* cannot be confirmed. Methodologically, the use of a stop watch seems to be an appropriate method for this outcome measure. This was confirmed statistically in the form of a strong correlation (r=0.993).

Although this seems convincing, one cannot rule out that the results are due to chance or other reasons. For instance, the results could reflect that the majority of children having the most suitable veins were randomised to the MT group by chance. Similarly, perhaps the majority of less compliant children were allocated to the control condition by chance. However, due to randomisation and the fact that the magnitude of the sample size is somewhat reasonable, I consider this to be a less likely explanation. Another causal relation is of different nature. The results may be due to the fact that one or more of the physicians performed the procedure in systematically shorter time than the remaining physicians (i.e. physician effect), for instance if he/she by chance were to perform the procedure in the majority of the oldest and thereby easiest children. Or suppose that some of the physicians were positively biased towards the music therapist or the research project wishing to provide beneficial results in favour of the MT group, they would perform the procedure in shorter time. However, on the other hand, in practice it does not seem likely that they would compromise their professionalism and pose possible hazards to the children. Moreover, as accounted for in section 6.24.4, the children were distributed somewhat equally among the three physicians, who performed 75% of the total procedures, in terms of age and randomisation. In continuation of this, as to the duration of completion of procedure, no systematic *effect of physician* appears from figure 6.30.

Instead, I find it reasonable to ascribe the effect to the MT intervention in that both analyses showed significant results in favour of the MT intervention, contrary to the remaining explanatory variables. Likewise, when seen in combination with the results of the remaining outcome measures, the overall picture seems to support the interpretation that the MT actually was effective in reducing the duration of the procedure. As argued previously, consistently less *Child Anxiety* was found among all four types of rater. Specifically, significantly lesser physician-rated anxiety was found as well as trends towards significance (child- and research-assistant-ratings of this outcome

measure). Moreover, although less consistent, the mean scores for pain were lower in the MT group, except for the parent-ratings. In combination, this might indicate in practice that the children in the MT group were less anxious during the procedure, needed less time for reassurance, reacted to a lesser degree on the pain stimuli, and to a greater extent kept still while focusing on the MT, which consequently created more peace for the physician to focus on and perform the procedure.

Needle-related Studies: As to the needle-related MT studies, Malone (1996) compared the duration of needle procedures between the MT and the control groups and found no statistically significant difference. Unfortunately, she does not provide any information in terms of the specific duration in each group (i.e. means and standard deviations). Furthermore, Malone (1996) included a variety of needle procedures in her study (e.g. injections, immunizations, IV-puncture), contrary to the PhD study. In short, some of these procedures are usually performed more easily and in shorter time (e.g. injections, blood test) than others (e.g. PIVA). In conclusion, she found no statistically significance contrary to the results of the PhD study. As to the three meta-analyses, unfortunately no data on this outcome domain is provided (Dileo & Bradt, 2005; Klassen et al., 2007; Standley & Whipple, 2003). In addition, in the absence of directly comparable studies reported in the MT literature, I will refer to the study by Reigart et al. (2012) & Ellis et al. (2004), who registered the amount of time required to complete various types of needle procedures performed in paediatric patients. For general information, these studies exclusively relate to standard procedures without music/MT or other types of non-pharmacological pain management intervention. On the basis of 592 intravenous access procedures, Reigart et al. found the following median durations required to obtain PIVA:

- Infants 0-2 years old (n = 283) 11 minutes
- Young children 3-5 years old (n = 73) 8 minutes
- School-aged children 6-11 years old (n = 91) 8 minutes
- Adolescents: 12-18 years (n = 120) 7 minutes

As to the results of the PhD study, it appears that the mean duration of the control condition (10.67 minutes) cannot directly be compared to Reigart et al., who reported less time needed to complete PIVA. This may be due to differences in the working routines of the medical personnel and definitions as to when the needle procedure is considered started and ended.

An addition, Ellis et al. (2004) registered the duration of 387 commonly performed needle procedures in a paediatric hospital setting. Of these, the majority (63%) were venipunctures for blood work, while 13% were intravenous cannulisation. When the various types of needle procedures were analysed in combination, the mean duration of a procedure was 9.3 minutes (median 10 and range 2 to 90 minutes). The majority (315, 81%) of the procedures were performed *without* EMLA and had a mean duration and standard deviation of 9.5 (7.3) minutes, whereas the remaining 72 (19%) procedures were performed *with* EMLA had mean duration of 8.6 (4.2) minutes. In short, in the context of the PhD study, the mean duration of the control group (10.67 minutes) is somewhat similar to the mean duration of the combined calculation provided by Ellis et al. However, their calculation of mean duration of needle procedures performed using EMLA differs from the result of the control group in the PhD study. Consequently, since the majority of the procedures in Ellis et al. were venipunctures for blood work and procedures *without* EMLA, direct comparison to the result of the control group (or MT group) cannot be made. In conclusion, specific information on duration of procedure was insufficient in Malone (1996) and totally absent in the two remaining needle-related studies (Capprili et al, 2007; Pfaff et al., 1989). Likewise, estimates of duration of needle procedures were not comprised in the three meta-analyses (Dileo & Bradt, 2005; Klassen et al., 2008; Standley & Whipple, 2003). On the contrary, Reigart et al. and Ellis et al. illuminate some aspects of this topic. However, these studies did not allow for direct comparison. Hence, inclusion of this outcome domain is needed in future MT studies, including clear contextual descriptions of the carrying out of the procedures.

Additional Studies: Although not directly comparable, the significant results as to required time to complete the PIVA agrees with Walworth (2005), who found that MT was time- and cost-reducing as procedural support during Echocardiograms. Specifically, due to the MTPS, sedation was unnecessary and the procedures were performed in shorter time, which meant that the assistance of a nurse was obviated. Likewise, Walworth also found that for each child, the sonographer needed two thirds less time to complete the procedure. Similarly, Loewy et al. (2005) found that children receiving MTPS needed nine minutes less to fall into sleep during electroencephalogram (EEG) compared to children who underwent the procedure receiving normal pharmacological sedation. However, this difference was not significant. On the contrary, she found a statistically significant large effect in the form of a 160 minute reduction in mean length of sleep in favour of the MT group. In conclusion, these studies differ from the present PhD study in terms of type of medical procedures, infliction of pain, and study design among other things.

Although this does not allow for direct comparison, overlaps and common key mechanisms of MTPS may exist. Anyway, the results regarding duration found in the PhD study are congruent with the findings of the two above-mentioned studies.

7.2.8 Discussion of Results Regarding Positive Child Behaviour

In summation, the research-assistant registered *Positive Child Behaviour* during *Baseline Phase* and *Phases 1* to *5* by means of the Observation Scale of Positive Child Behaviour (OSPCB). As appears from the descriptive summation provided in table 6.12, the children in both groups had somewhat similar means for *Positive Child Behaviour* during the *Pre-needle Period*. As appears from table 6.12 and figure 6.26, the mean scores for this outcome measure increased from *Baseline Phase* to *Phase 1*. As I expected, the means decreased in both groups after the physician entered the treatment room (*Phase 2*) and gradually during the needle procedure. Similarly, the means increased after the needle procedure. The decrease and increase are reflected in figure 6.26 and were confirmed statistically in the LMEM analysis, which showed no significant difference between the groups. Besides that, confer the prospective plan for data analysis described in the *Method Chapter*, I compared the scores of *Phases 4* & *5* separately between the groups. As to *Phase 4*, the MT group had twice as high a mean score than did the control group. During *Phase 5*, the mean score of the MT group decreased, but was still higher than the one of the control group. When analysed with an MWU-T, results showed no significant difference regarding these two phases. All in all, *hypothesis 9* cannot be confirmed.

In continuation of the above-mentioned summation, although not significant (p=0.13), the MT had a small effect during *Phase 4*. Confer the non-significant p-value, this result may be due to chance rather than the MT intervention. Furthermore, the mean score in the MT group during *Phase 5* decreased, contrary to the one of the control group, which makes these mixed results more difficult to interpret. But on the other hand, the mean for *Phase 5* was still higher in the MT group. As clarified previously in this chapter, the participants were distributed in terms of age group and randomisation group among the research-assistants as well as three physicians who performed 75% of the procedures. Therefore, it is reasonable to assume that no systematic error in relation to these topics influenced

the data. One possible explanation would be that seen from an overall perspective, the children in the MT group had lower anxiety, distress, and pain scores than did the control group. Moreover, percentage-wise, most of the MT children received fewer needle pricks. Finally, on average the procedures were performed in shorter time in the MT group. Consequently, the results of *Phase 4* may reflect that the MT empowered the children and supported them to recover and rebounce after the medical procedure, why they resumed playing sooner than did the control children. However, the results of *Positive Child Behaviour* do only allow for cautious interpretations.

As to the literature review (Chapter 4), none of the 11 MT outcome studies measured any form of *maintenance of positive affects* during the various medical procedures. Likewise, the three meta-analyses do not comprise data regarding this outcome domain (Dileo & Bradt, 2005; Klassen et al., 2008; Standley & Whipple, 2003). Consequently, more research is needed to examine the effects as well as illuminate the meaning of MTPS in relation to *maintenance of positive affects* under medical procedures.

As mentioned, I developed the OSPCB for the study due to lack of existing standardised tools. Given that the OSPCB is not validated, the results are subject to methodological uncertainties. However, the results of the inter-rater reliability test showed a highly significant strong correlation (r=0.794) across *Baseline Phase* plus *Phases 1* to *5* when calculated in combination (on the basis of 323 interval ratings). As to *Phases 4* and *5*, highly significant agreements were found, (r=0.810) and (r=0.645), respectively. In conclusion, validation of the OSPCB is needed in order to provide valid and reliable results. Finally, as to the existent research literature, (similar) valid tools for *maintenance of positive affects* in the context of medical procedures involving paediatric patients are warranted.

7.2.9 Discussion of Results Regarding Satisfaction of Music Therapy Intervention

Confer the results of the satisfactory survey presented in section 6.21, the majority of the participants in the MT group were satisfied with the MT intervention. In short, 81% stated that would like MT during future medical procedures, 86% answered that they would recommend MT to others, and 85% found the MT *Very useful* or *Useful* (i.e. 52% and 33%, respectively). On the contrary, five families gave more or less negative ratings in the satisfactory survey questionnaire. In total three families did not wish future MT and one answered *Don´t know*. One family

would not recommend MT to others and two replied *Don´t know*. Finally, two families found the MT useless and one answered *Neither nor*. In addition, it appeared that only one family gave consistently negative ratings (i.e. Family C). On the contrary, the answers of the remaining four families were mixed and ambiguous. In the following, I will discuss the results of these five families.

An obvious reason for dissociating themselves from the MT could be that the parents did not find the MT intervention useful or meaningful for their children or themselves. Similarly, it could be that they simply did not like the approach, manner, behaviour of the music therapist or felt they could connect with him (i.e. the therapist) on a personal level. Another interpretation could be that the families or children found it difficult to relate to the concept of MT as many people use music for pleasure and fun contrary to the context of a potentially painful and distressing needle procedure. In that connection, it could be that the parents or children misunderstood the intention of the MT intervention or that the child was not expected to "perform" or play on instruments in a "conventional" manner. Several times, I experienced that the parents interfered with the child´s musical behaviour and way of playing, suggesting "more appropriate" or conventional ways of playing.

Besides that, the MT intervention aimed at including the parents to the degree possible and implicitly accepted by them. This might explain if some of the parents found the added MT too demanding in an already potentially emotional and tense experience (i.e. needle procedure), contrary to the intention of the MT intervention. The results regarding *wish for music therapy under future medical procedures* could also reflect the fact that some children were good at coping with the procedure on their own or hardly felt any pain due to the EMLA. This was apparently reflected in the distress, anxiety, and pain scores in both groups. In addition, this was also mentioned in the qualitative written comments (case 12, Appendix 11) given by one of the families in the control group. In continuation of this, some of the children coped well with the procedure, but found the use of physical restraint more troublesome than the actual fear of needles, which I experienced in some of the children. This was mentioned by one of the families in the control group (cf. case 15, Appendix 11). Suppose that the same thing also applied to the MT group, this could explain some of the parents´ ratings. Another reasons for not wishing MT under future procedures could be that some of these five children were shy or afraid of strangers, as put forward in the written comments (cf. case 10 and 8, respectively. See Appendix 11). As to these children, the music therapist did not succeed in establishing rapport, which can be the case sometimes in clinical practice.

In conclusion, in the present study, the rating of one family was consistently negative, whereas the remaining four families gave unambiguous ratings in terms of their satisfaction with the MT intervention. That said, one of these families wished MT future medical procedures, two families stated that they would recommend MT to others, and two families answered that they found the MT *Very useful*. In order to address and illuminate the extent of satisfaction and relevance of MTPS as perceived by participants and their families, more research is needed. In continuation of this, qualitative data would be useful in combination with questionnaires in understanding and interpreting possible dissociation of families and participants.

7.3

Summative Discussion of Main Results plus Additional Findings

Above, I discussed the results of the 16 outcome measures separately more or less. In the following, I will sum up the main results and an outline an overall picture. After that, I will discuss the main findings in relation to the results of the decision trees. Likewise, I will connect to aspects of the theoretical framework of the PhD study, as presented in Chapters 2 to 4.

7.3.1 Overall Summation of Main Results

From an overall perspective, the results of the analyses were in favour of the children in the MT group, except for parent-rated *Child Pain*, which was slightly higher (i.e. 3%) in the MT group and far from significant. When compared to the control group, the children in the MT group had lower mean scores as to negatively formulated outcome measures such as distress, pain, anxiety etc. Likewise, the children in the MT group had higher mean scores as to positively formulated outcome measures (e.g. compliance). One the basis of the main analyses (MWU-T), two statistically significant results were found. These were significantly less *Child Anxiety* (i.e. physician-rated) and a highly significantly shorter mean *Duration* of the PIVA procedures. Moreover, trends towards statistical significance were found as to *Child Anxiety* (i.e. child- and research-assistant-rated) plus *Child Pain* and *Child Compliance* (i.e.

physician-rated). In addition, although not significant, when analysed descriptively, the percent-wise number of *needle pricks* required to perform the procedures were fewer in the MT group, except for two children.

Besides that, after removing one outlier from the MT group, the above-mentioned overall picture of the results was further confirmed. Specifically, I found significantly lesser *Child Anxiety* (i.e. research-assistant-rated) and *Child Compliance* (i.e. physician-rated). Trends towards significance were also found in relation to *Child Distress* (i.e. research-assistant-rated). Finally, the majority of the families and children in the MT group were satisfied with the applied MTPS intervention. That said, the study had more methodological limitations, which flaw the results. The limitations were shortly pointed out during the discussion and will be further addressed in section 7.5.

During the *Pre-needle Period* and the *Needle Period*, the mean scores for *Child Distress* and *Child Anxiety* in both groups increased gradually after which they similarly decreased gradually again. The same was the case for the mean score of *Positive Child Behaviour*, but with reversed sign. When analysed across all five phases (i.e. *Phases 1* to *5*), no significant results were found as to these three outcome measures. This may partly be due to the considerable use of EMLA, the small sample size, and ceiling effects. However, seen from an overall perspective *and* the child´s point of view, the significant results and beneficial tendencies mentioned above (i.e. *Child Distress, Child Anxiety*, *Child Pain, Child Compliance, Duration*, percentage-wise *needle pricks*) seem also *clinically significant* during the most critical phases of the needle procedure. That is first and foremost *during* the actual procedure, but not least during the *Recovery Post-Needle Period* (i.e. *Phases 4* & *5*). In continuation of this, the MT children exhibited more *Positive Child Behaviour* during the *Recovery Post-Needle Period* than did the control children, especially the first three minutes after the procedure (i.e *Phase 4*). Although not significant (p=0.13), I find the result of *Positive Child Behaviour* during *Phase 4* clinically relevant in that it seem to indicate that the MTPS intervention supported some of the MT children in re-bouncing after the medical procedure, as put forward by Ghetti (2012, p. 31). In future MTPS studies, special attention should be given to this aspect and not only what happens during medical procedure.

In its own right, the statistically significant results and tendencies mentioned above are noteworthy and clinical relevant in that the mean differences ranged from 16 to 33%. In continuation of this, I find the GLM estimate of child-rated *anxiety* especially important. This estimate showed a substantial mean difference having a moderate

effect size (d=0.55; eta squared= 0.435) with a tendency towards significance. Furthermore, this finding relates perhaps even more directly to the heart of the matter, namely meeting the *children´s needs* and reducing *their* medical fears on the basis of *their subjective experiences* of the needle procedures. However, although the distribution of the child-rated anxiety scores is unambiguous and the result of analysis encouraging, one should be cautious in making too hard or hasty inferences, given that the estimate relies on few observations. However, on the other hand, two additional results of *Child Anxiety* were significant, which therefore supports the credibility of the children´s ratings of anxiety. While the results of *Child Anxiety* showed a clear beneficial effect of the MT intervention, less consistent results among raters were found as to *Child Pain*. Moreover, the result of *Child Distress* showed a tendency toward significance after removal of an outlier. The differences among distress, anxiety and especially pain in terms of significance and magnitude of mean differences are not surprising and correspond with previous studies, as mentioned in the *Method Chapter* (Beyer, McGrath, & Berde, 1990; Chambers, Giesbrecht, Craig, Bennett, & Huntsman, 1999; van Dijk et al., 2002). As pointed out by Cohen et al. (2004) and Dijk et al. (2002), such differences may reflect different aspects of the same construct i.e. pain experience and reactions to the medical procedures rather than actual disagreements.

Likewise, as argued above, the differences among raters as to pain, may relate to their different perspective, roles, and degree of emotional "investment" etc in relation to the medical procedure. In continuation of this, from an overall perspective, the results of the PhD study indicate a consistent effect of MT on the emotional dimension and the suffering associated with the needle-related pain, which corresponds with Brown et al. (1989) and Ghetti (2012). Finally, in several of the GLM and LMEM analyses, *Age* had a significant effect, which concurs with the research literature (e.g. Blount et al., 2009; Caprilli et al., 2007; Cohen, 2008; Klassen et al., 2008; Young, 2005) and the theoretical frame for understanding trauma presented in Chapter 2 (Levine, 2006; Levine & Kline, 2007).

As to the literature review presented in *Chapter 4*, the 11 key MTPS studies showed mixed and conflicting results. Likewise, the estimates and overall findings of the three meta-analyses were not congruent. This was to great extent due to the small number of studies included as well as heterogeneity in terms of magnitude of sample size, type of music intervention, medical procedure, measuring instruments etc. Consequently, this limits the extent to which

the result of the PhD study can be compared directly to the broader research literature. Likewise, it also limits the degree to which the results of this study can be supported by the research literature in formulating clear-cut research-based clinical recommendations. Therefore, more research is needed on MTPS in paediatrics. This does not only apply to needle procedures but also to a broad range of the most frequently performed and stressing medical procedures in paediatrics. Unfortunately, in a broader perspective, small sample sizes and heterogeneity in terms of type of music intervention etc. also apply for MT research in general medicine, as emphasised by Dileo & Bradt (2005). In that connection, as addressed by Robb & Carpenter (2009) and Robb et al. (2011), the paediatric MT literature shows a considerable lack of clear and comprehensive information of the applied music interventions.

As to the small sample sizes, I made a conservative power calculation on the basis of Caprilli et al. (2007) i.e. distress during the venipuncture. According to my estimate, a total sample of 124 children was required in order to detect a significant moderate effect. In spite of that, I found two significant results plus two additional results after removal of one outlier. In addition, three other outcome measures showed a tendency towards significance. In that connection, I would appreciate to have a much larger sample. This is not for the fun of chasing significant results, but in order to reduce the statistical uncertainties of the estimates (i.e. standard errors) and to provide more precise confidence intervals. Hence, I would have been able to clarify whether the observed tendencies were likely to be due to chance, the MT intervention, or other factors. In short, quality research having large sample sizes is needed in order to produce more valid estimates, which can consequently clarify the clinical relevance and importance of the results.

Another aspect related to the *clinical significance* of the results, is of another nature. Just like the 11 reviewed MTPS studies, I evaluated the short-term effects of MTPS. Consequently, from a clinical perspective, parents, medical personnel, and others would probably like to know: "What are the long-term effects of MTPS under peripheral intravenous access?". Well, on the basis of this PhD study, I cannot make research-based inferences about this very clinically relevant question. The beneficial significant effects and tendencies found in the study may perhaps only be of short-term nature. Perhaps the results are caused by the novelty effect, since all the children only participated once. Moreover, on the basis of the results of this study, we cannot rule out that classical conditioning may occur due to the MT intervention suppose it were provided during more consecutive medical procedures. Similarly, in a

broader perspective, the majority of the 11 reviewed studies examined the short-term effects of MTPS. Furthermore, mixed and conflicting results were found. Consequently, this does not allow to infer that the provision of MTPS under consecutive medical procedures will automatically result in improved coping, less distress, anxiety etc.

That said, on the other hand, the clinical MT literature as well as my clinical experience tell me that MT is supportive and indicated as procedural support in the paediatric population. In short, future research should also examine the possible long-term effects. In that connection, inspired by Gold, Solli, Krüger, and Lie (2009), possible dose-response relationships are similarly important to examine in future research with an eye to informing and improving clinical practice. This is particularly important to examine due to the nature of the clinical context of MTPS. We know that establishing rapport is essential in all therapy and influences the outcome of the therapy, but MTPS is often of a short-term nature, especially when supporting outpatients under medical procedures. Consequently, this poses clinical challenges to the music therapist in terms of establishing rapport in very short time. As mentioned above, although mixed results are found in the literature review, some studies actually reported statistical and clinical significant short-term results. But future research is particularly needed in relation to children having chronic and life-threatening diseases, since they are subject to long-term treatment regimes, which implies repeatedly medical procedures.

7.3.2 Discussion of Main Findings in Relation to Results of Decision Trees

In short, the research protocol was fixed, whereas the clinical protocol was flexible and based on a client-centered approach to therapy. This pragmatic *Real World* approach (Robson, 2011), influenced the PhD study in several ways and contradicts with the traditional post-/positivistic paradigm in which quantitative research is rooted. Instead of a manualised approach, which is normally used in RCT studies/fixed designs, I applied flexible approach in order to meet the individual needs of the children. Although flexible and complex, the MT intervention was partly structured and informed by the decision trees (i.e. figures 5.9, 5.10, and 5.11) and the outline of clinical needs (figure 5.8) plus the process of reflexivity (Ghetti, 2012), intuition etc. During the preparation of the study, I developed the decision trees as a means of documentation and clarification of possible patterns in my clinical work. Besides the clinical

use-value, the decision tress also aimed at generating data that can illuminate the possible relationship among significant results and the applied therapeutic techniques. In the following, I will shortly discuss the main results of the therapeutic choices and techniques applied during the MTPS intervention in relation to the some of the main statistical results. In the discussion, I will connect to aspects of the theoretical framework of the PhD study as well as two additional articles hat were not included in Chapters 2 to 4 (i.e. the meta-analyses Kleiber & Harper, 1999; Uman, Chambers, McGrath, and Kisely, 2008).

Although significant results were "only" found in relation to *Phase 3*, I find it important also to shortly outline the therapeutic decisions and efforts related to the *Pre-needle Period* (i.e. *Phases 1 & 2*). Figure 6.35 sums up all of the MAE-based sub-interventions and verbal techniques that were applied during *Phases 1 & 2*. Below I have outlined the categories that were used ten or more times. As appears clearly from this figure, the majority of the applied techniques relate to these three main categories of therapeutic objectives:

- Facilitating empowerment and active engagement & providing opportunities to exercise control (box 6, applied 44 times)
- Establishing rapport & references of resources (box 2, applied 37 times)
- Identifying child´s thoughts about the procedure & preparation for the procedure (box 3, applied 21 times)

As argued previously, *establishment of rapport* is crucial and especially challenging in MTPS due to the short time available during the pre-procedural period (in this study called *Pre-needle Period*) and the short-term relationship between therapist and child. As appears, the result suggests that *establishment of rapport and resources* were widely practiced. Likewise, the MTPS facilitated musical experiences that engaged and empowered the child. Besides that, the MTPS also addressed the child´s thoughts about the needle procedure, which agrees with Cohen (2008), who emphasises the importance of appropriate preparation of the child prior to medical procedures. It seems likely that the musical process and the supportive role of the therapist used (cf. Nguyen et al., 2005) in meeting these three main objectives have constituted a resource for the child, which played an important role during the subsequent needle procedure. Similarly, when looking at the research literature, it seems likely *the establishment of rapport* and *a musical relationship* may have played an important role for the significant result found in Caprilli et al. (2007) contrary to Malone (1996), who did not start the MT intervention prior to the needle procedures.

As to *Phase 3*, figure 6.36 sums up the MAE-based sub-interventions and verbal techniques applied during this phase. Specifically, the most frequently applied sub-interventions aimed at supporting the following overall clinical needs/therapeutic objectives:

- Distraction from environment and procedure (box 5, applied 25 times)
- Containment & maintenance of integrity (box 6, applied 22 times)
- Facilitating empowerment & active engagement (box 7, applied 19 times)
- Re-orientation (box 4, applied 19 times)
- Physical-based relaxation & anxiety reduction (box 8, applied 10 times)
- Draw on resources established in Phases 1 & 2 (box 11, applied 10 times)

What comes to mind here is the variety of therapeutic objectives as well as techniques. As advocated by Fratianne et al. (2001) and Ghetti (2012), the MAE enables facilitation of a variety of musical experiences and levels of engagement. However, in the PhD study, most of the sub-interventions applied during *Phase 3* required *low levels* of engagement (i.e. music listening, preference expression). The provision of various types of music experience may have supported a broad range of coping strategies similar to Siegel (1983), who found that *successful copers* applied a greater extent of coping strategies, contrary to *unsuccessful copers* (cf. Chapter 2, section 2.5.2). As appears above, *Distraction from environment and procedure* was the clinical need met to the greatest extent as appraised by the music therapist. This corresponds with the meta-analysis, Kleiber & Harper (1999), who illuminate the importance and beneficial effects of *distraction*. On the basis of 16 studies comprising 491 paediatric patients, Kleiber & Harper found distraction to be an effective intervention in reducing distress behaviour under various medical procedures. Moreover, their finding corresponds with the results of a more recent and larger abbreviated Cochrane Review (Uman et al., 2008). Uman et al. include 28 RCT studies on needle-related procedures comprising 1.039 children undergoing various types of non-pharmacological interventions and 951 children randomised to comparable control conditions. On the basis of their meta-analysis, Uman et al. found *distraction* and effective in reducing self-reported pain. Due to the overlaps and fundamental functions of distraction, these results may be generalised to some degree to the context of the PhD.

During *Phase 3*, the MTPS intervention aimed at meeting and supporting a variety of therapeutic objectives. Besides *distraction*, as mentioned above, the remaining objectives that were among the most frequently addressed comprised: *Containment & maintenance of integrity*, *Facilitating empowerment & active engagement*, and verbal *re-orientation*.

As to *Containment & maintenance of integrity* and *Physical-based relaxation & anxiety reduction*, I used the musical parameters of anxiolytic and sedative music proposed Wigram (2004) and Wigram et al. (2002, p. 114) to a wide extent in order to reduce anxiety and to comfort the child. The wide use of these musical parameters is reflected in table 6.23, which summarises the ten most frequently applied songs. In addition, the ISO-principle was also used to some extent to reduce anxiety and regulate emotions plus arousal. The extensive use of these musical parameters might also partly account for the effects of the MT intervention. Moreover, as outlined in the bullets above, a large number of the applied techniques during the needle procedure were classified as *Re-orientation*, which partly relates to box 3 in figure 6.36 (i.e. *Preparation & information about procedure*). In discussing the possible relationships for the effects of the MT intervention, Cohen (2008) comes to mind. My verbal interventions were inspired by the research-based recommendations proposed by him. As to the result of frequency related to *Facilitating empowerment and active engagement*, Fratianne et al. (2001) and Ghetti (2008) illuminate the clinical benefits of the applied MTPS approach (MAE) in meeting childrens´ needs under medical procedures. Specifically, the applied sub-interventions allowed me to shift back and forth among sub-interventions that required varying levels of engagement in spite of the children´s level of anxiety. The MT intervention also aimed at providing the child experiences of empowerment and metaphoric opportunities to exercise control in the form of preference expression and music listening among other things (cf. Sheridan & McFerran, 2004). In continuation of this, *Draw on resources established in Phases 1 & 2* in the form of *music preferences* was also frequently used with an view to recalling positive emotions during the painful event, as described by Brown et al. (1989), as well as counteracting negative emotions and possible traumatisation, which were highlighted by Young (2005) and Levine & Kline (2007).

7.4

Clinical Applicability

In *Chapters 2* to *4*, I described the theoretical framework of the MT intervention. Subsequently, I defined and described the MTPS intervention (*Chapter 5*). Furthermore, I discussed the results of the decision trees in the section above. In this section, I will shortly address myself to the important aspects required as a music therapist in using the MT method and the clinical relevance of the results. Moreover, possible contraindications will also be described.

7.4.1 Therapeutic Requirements in Using the Music Therapy Method

Previously in this chapter, I discussed the main results of the study. Significant results were found as well as trends towards significance. In the following, I will address important aspects required in using the MT method in clinical practice.

MTPS is a complex and interdisciplinary enterprise. On the basis of my clinical experience as the music therapist in the study, I found several things to be clinically important in performing the applied MT intervention. In order to meet the individual and rapidly changing needs of the children, the applied MAE-based intervention requires that the music therapist masters a broad range of musical and verbal skills, techniques, personal, and professional competences. In that regard, three keywords come to mind: reflexivity, flexibility, and co-operation. The fact that the intervention is rooted in a person-centered approach to therapy requires a great degree of reflexibility and flexibility from a professional and personal perspective. In using the applied intervention, one needs to be receptive and adaptable to the dynamics and responses of the child, parents, and medical personnel. Furthermore, as a music therapist, one is very exposed due to the presence of the involved persons. Finally, the music therapist also needs to

know and use the proposed tools (i.e. decision trees and overview of clinical objectives) by heart. These tools provide clear clinical guidelines, which also at the same time allows for a great degree of flexibility. The tools can be used to document and clarify aspects of clinical practice in a structured and easy way. The tools and the intervention may also be used under related medical procedures.

7.4.2 Clinical Relevance of Results

As discussed previously in this chapter, the overall picture of the results of the study proved beneficial for the children receiving MT under PIVA. As discussed, the children in the MT group were rated less anxious and more compliant, among other things, which allowed the physician to obtain PIVA in shorter 33% time. As to *Duration*, this finding is not only primarily clinically beneficial for the child. This finding proved to be time reducing for the physician. Originally, I wanted to include a cost-effectiveness analysis as suggested by McGrath et al., (2008). However, this was not possible, since the paediatric department includes time spent on PIVA as a part of their overall treatment. Hence, I could not use a pre-defined fixed economic estimate in calculating the economical aspect. However, according to the record of the paediatric nephro-urological unit, PIVA were performed 458 times during 12 months in potentially eligible children at the out-patient unit. If MT can effectively reduce the duration of the procedure in average, there may be a considerable potential. Besides that, according to Søren Rittig, this number only reflects a minor part of the total number of PIVAs performed in the in- and outpatient nephro-urological unit. Furthermore, when applied to the entire paediatric department, the reduction of time required to obtain PIVA are enormous. Besides that, as discussed previously, the significant results also proved to be of emotional importance to the children. In the following, I will let the parents express their experience of the MT intervention.

7.4.3 Qualitative Written Comments regarding the Music Therapy Intervention

As described previously in this chapter, the MTPS intervention was significantly effective in reducing the *duration* of the needle procedure as well as physician-rated *Child Anxiety*. Similarly, physician-rated *Child Pain*, *Child Compliance*,

and child-rated *anxiety* showed trends towards significance. Furthermore, the majority of the families found the MT intervention helpful and supportive in relation to PIVA. But what does a significant difference of 18 percentage points *Child Anxiety* actually means in practice for the children and parents? In illuminating this type of questions, I will now present some of the qualitative comments written by the parents, who´s children were randomised to the MT group. Please note, as I accounted for in the Method Chapter (section 5.4.5), I included a separate sheet for optional comments for the parents. However, these data were not validated and by providing the comments below, I do *not* attempt to suggest that the study is a mixed methods study. That would be a misrepresentation. Instead, I regard this as a *non-validated "bonus mateial"* that may qualify and illuminate some important issues in terms of clinical applications and clinical relevance of the MPS intervention.

Case 2 (MT group):

In addition to the questionnaires the mother wrote this letter on her own initiative: *"Dear Ilan, thank you for making our girl´s first examination* (Ilan: intravenous access procedure & kidney scanning) *and meeting with the "needle" a pleasant experience. Although she did not say much she was well and had a nice time. You were good at catching her attention with your singing, your calm, and pleasant manner. Yours sincerely".*

Case 4 (MT group):

The parent of the child wrote: *"Fantastically good effect – my daughter very pleasantly occupied by the music before the procedure. Much sooner relaxed after the procedure. Last time she about to faint – this was not at all the case this time! The musician had very good intuition towards the child – good at inspiring".*

Case 13 (MT group):

The parent of the child wrote: *"Music therapy is a good thing in relation to the stressing things that is about to happen, since it can sometimes divert the attention from the stressing tings.*

7.4.4 Additional Video Recorded Interview with Family X

As a further addition non-valid bonus, I have provided a short video excerpt in which parents of a three-year-old is interviewed by the research-assistant after the PIVA procedure. In the interview, the parents state their experience of the role of the MT intervention in relation to PIVA. The video excerpt is contained in the enclosed DVD (Appendix 12, at the end of track 1 & Appendix 13) on the basis of the written consent of the parents.

7.4.5 Contraindications

On the basis of the written comments presented above plus my clinical experience from being the music therapist in the study, I found that the MTPS intervention my not be suitable, or at least less beneficial, for children who are shy or private by person. In addition, on the basis of the statistical analyses, it appeared that seven children received needle pricks exclusively *without* EMLA. Of these, three were randomised to the MT group and four to the control group. When comparing scatter plots of these seven children, I found that the three children in the MT group had the highest scores of anxiety, pain, and distress. Whether this distribution of scores between the groups was due to chance is unknown due to this limited number of observations. I made a dichotomous category in order to control for needle pricks *without* EMLA and attempted to include this dichotomous variable into the GLM and the LMEM. However, this lead to very conflicting estimates and results, which do not make sense when compared to the overall picture of the effects of the MT intervention. Unfortunately, the sample size was too small to allow me to perform any sub-group analysis. In the light of the literature, these results conflict with the preliminary assumption stated previously that MTPS is more effective under needle procedure *without* any anaesthetics (Caprilli et al., 2007; Malone, 1996).

7.5

Limitations of the Study

In this section, I will account for the limitations of the study according to the applied clinical method, research protocol, statistical analyses, generalisability of the results, and the results of the PhD study in relation to the MTPS research literature.

7.5.1 Clinical Method

Ad described previously in the thesis, the clinical method was flexible and aimed at meeting the individual needs of the participants. From a clinical perspective, this flexibility seems beneficial for the children in principle. However, this meant that the MTPS intervention relied heavily on the skills, sensitivity, and reflexivity of the music therapist nevertheless because all MTPS sessions were performed by one and the same music therapist (i.e. the researcher/me). If the sessions were provided by a more experienced music therapist clinician, the clinical intervention may have been better and consequently the effects of the intervention. In continuation of this, it is possible that the statistically significant results found reflect an “Ilan Sanfi”-effect rather than an estimation of the effect of MTPS in general. Therefore, future studies should include more clinicians just like Robb et al. (2007) and evaluate possible therapist effects just like Kain et al. (2004).

7.5.2 Research Protocol

According to Robson (2011), the use of an RCT design is appropriate in examining effects among two or more groups. However, as put forward by Craig et al. (2006) parallel group RCTs aim at estimating: “the average effect

of an intervention in a population, and provide little's information about within or between person variability in response to interventions, or about the mechanisms by which effective interventions achieve change" (p. 25). In the previous section, I cautiously discussed possible relationship and aspects among the applied techniques, the statistical results, and theoretical aspects. But in order to do this on a more reliable manner, a mixed methods design would be appropriate (Clark & Creswell, 2011).

7.5.2.1 Randomisation

In the study, I used the SNOSE method (Doig & Simpson, 2005) to generate the randomisation sequence and as a means to obtain allocation concealment, which was carried out by me. The co-operating nurse enrolled the majority of the participants and opened the majority of the envelopes, while I administrated these tasks in relation to a minority of the children. It is a limitation of the study that the concealment of the randomisation sequence was violated in that it was communicated in advance to the research-assistants and the music therapist/researcher. However, on the other hand, in practice none of the involved persons were blinded (i.e. participants, research-assistants, the music therapist, medical personnel). Furthermore, while the randomisation sequence was fixed, the order on the list of admitted outpatients on the day in question was often changed and only finally known 15-30 minutes prior to enrolment of the participants due to the working routines of the medical personnel.

7.5.2.2. Blinding

It is a limitation that none of the participants, raters, or clinicians were blind. Therefore it is possible that some degree of assessor bias and social desirability influenced the data and consequently the results of the statistical analyses.

7.5.2.3. Sample Size and Recruitment

During the course of data collection, it turned out that fewer eligible children were admitted for kidney scanning, which limited the recruitment. Consequently, the MT working party evaluated whether other paediatric units could be involved in the study, which, however, was not possible. Therefore this circumstance limited the number of participants. In that connection, an additional restriction of the recruitment was that 17 children were not enrolled in the study although they either met the study criteria or gave written consent (see section 6.2.1). In future studies, more paediatric units or hospitals should be involved to obtain a larger sample. Consequently, the total sample comprised 41 children who were enrolled and completed participation in the study. Although all participants were included in the statistical analyses, a larger sample size would have reduced the standard errors of the estimates and consequently generated more reliable results. Although the overall picture of the results indicate that the MT intervention is beneficial, it is possible that Type 1 errors occurred due to the relatively small sample (Kirkwood & Sterne, 2003). In continuation of this, as to the results showing a tendency towards significance, larger sample would have reduced the statistical uncertainty and clarify whether these results could reasonably be ascribed the MT intervention other factors.

7.5.2.4 Protocol for Data Collection

As mentioned above, it is a limitation that none of the outcome assessors were blinded in the study, why assessor bias may have influenced the results. Moreover, in observing each child, the research-assistants were to register numerous data continuously. The sheets for the data registration were highly structured and use-friendly. However, occasionally the assistants felt slightly overloaded during *Phase 3*, during which most data were obtained (see figure 6.2). The role of the research-assistants was clarified during the course of trained and furthermore outlined on the front page of each sheet of the data collection document (cf. section 5.6.2). Moreover, they were trained how to manage the administration of questionnaires using manualised instructions and wordings (i.e. child, parents, physicians). However, it cannot be ruled out that the manualised approach was deviated to some degree. Moreover, the five- to ten-year-old children rated their perceived levels of anxiety and pain intensity using the FPS-R. As discussed previously, it is possible that these children embellished their ratings in order to please the research-assistant or tone down their ratings to reassure their parents (i.e. social desirability).

7.5.2.5 Measuring Instruments

In the study, I applied a triangulation of outcome measures and raters in relation to *Child Anxiety* and *Child Pain* on the basis of the research literature (Beyer et al., 1990, Cohen et al., 2004; Manne, Jacobsen, & Redd, 1992; MacGrath et al., 2009; van Dijk et al., 2001). In addition, I used partly validated measuring instruments (e.g. VAS, FPS-R, OSBD-R) and partly tools developed for the study (e.g OSPCB, Likert-type Scale), which I will address below.

Inter-rater reliability: I calculated inter-rater reliability between the two main research-assistants who observed 70% of the children. The calculations were made on the basis of nine children using Pearson Correlations. However, the calculation was only made at the end of the data collection period and the inter-rater agreement ranged from 0.632 to 0.997 (se table 6.15).

Observation Scales: In the study, I applied the Observation Scale of Behavioural Distress – Revised (OSBD-R), which is valid for measuring observed distress. However, I did not make a back translation of the descriptions of categories and wording of the scale before it was applied by the research-assistants in the study. Moreover, I applied live rating, which was administered by non-blinded assessors. Therefore, assessor bias may have influenced the data. In addition, during *Phases 1* and *2*, ceiling effect was found. Finally, as to the inter-rater reliability, results showed a moderate correlation (0.65) in relation to *Phase 3* and a strong correlation (0.76) when analysed across all six phases. As mentioned above, another limitation was that the inter-rater reliability test was only made at the final part of the data collection. Better inter-rater agreement as to *Phase 3* could have been obtained by means of more training and establishment of better agreement during the course of training.

On the basis of the recommendation proposed by the pedIMMPACT group (McGrath et al., 2008, p. 777), I measured *maintenance of positive affects*. But due to lack of standardised measuring instruments, I developed the Observation Scale of Positive Child Behaviour (OSPCB). Since it was beyond the scope of the study to validate the scale, the results of this scale can be called into question. However, I calculated inter-rater reliabiliy and found a strong correlation (r=0.81) for *Phase 4* and a moderate correlation (r=0.65) for *Phase 5*. In future research, observation scales of child coping could be used as an alternative such as the Behavioural Approach-Avoidance and Distress Scale (Hubert et al., 1988).

In continuation of this, I applied the VAS was to assess *Child Anxiety* and *Child Pain* (i.e. research-assistants, parents, physicians) and *Child Compliance* and *Parent Compliance* (physician). The choice of using the VAS was a trade-off. On the one hand, this tool enabled triangulating of data of the three adult raters plus the child. Furthermore, the VAS is feasible in the context of the medical procedure. On the other hand, when used as an one-item global observation scale, the validity of the scale can be called into question. Specifically, as pointed out by van Dijk et al. (2002), there is not sufficient evidence to support the use of the VAS as an observational scale for anxiety and pain due to lack of satisfying results in the research literature as to concurrent validity (at least at the time of their study). The same applies for *Child Compliance* as well as *Parent Compliance*, which were also rated using the VAS. In the study, it was left to the rater to appraise and define to what degree the child was anxious and felt pain. In that connection, I only calculated inter-rated agreement between the two research-assistants at the end of the data collection period. Although, the four research-assistants were trained in using the VAS, the inter-rated test should have been calculated before they started collecting data. If so, this would have improved the validity of the VAS as an observation scale.

Self-report: As recommended by the pedIMMPACT group (McGrath et al., 2009), I used the Faces Pain Scale - Revised (Hicks et al., 2001), which is valid for children´s self-report of pain intensity. However, it is a limitation of the study that the FPS-R was only used upon completion of the needle procedure, not at baseline. In their study, Bond et al. (2005) found that pain scales (self-report) were more correctly filled in post-operatively if the participants either had previous experience with the specific scale or received instruction before surgery. The use of such a precautionary measure could improve the validity of the FPS-R. But due to feasibility aspects and in order to reduce the research burdens, I did not employ such measures.

As to child-rated anxiety, I used an adapted version of the FPS-R. Although the wordings were tested during a pilot study, the validity of the scale was flawed. Specifically, the facial expression of pain reflected in the scale differs from the facial expression of anxiety (i.e. closed eyes and open mouth versus open eyes and closed mouth). It is possible that the use of precautionary measures such as the one described by Bond et al. (2005) would have generated more reliable data.

Questionnaires: *Overall satisfaction with the needle procedure* was rated by the parents using a five-point Likert-type scale, which I developed for the study. Likewise, I developed the questionnaires of the satisfactory survey in the MT group. Therefore, it is a limitation of the study that these tools were not subject to traditional validation.

7.5.2.6 Statistical Analyses

Except for the data on the satisfactory survey in the MT group, all outcome measures were analysed by means of a Mann-Whitney U-test (MWU-T). In order to control for the four pre-defined explanatory variables, the same outcome measures were also analysed using a General Linear Model (GLM). Furthermore, *Child Distress*, *Child Anxiety*, and *Positive Child Behaviour* were analysed across *Phases 1* to *5* using a Linear Mixed Effects Model (LMEM). It is reasonable to assume that the results of the MWU-T analyses are reliable in that this model is robust and the children were randomised (Kirkewood & Sterne, 2003). On the contrary, as emphasised in the presentation of the results, I violated the statistical assumptions of the GLMs and LMEMs (i.e. normality and homogeneity) due to lack of non-parametric alternatives, in order to control for the pre-defined explanatory variables. This meant that the results of these analyses could not strictly be taken at face value. Finally, it is a limitation of the study that incongruences were found among the results of the MWU-T, GLM, and LMEM analyses in terms of significance ascribed to the MT intervention. On the other hand, given that these models differ by nature (e.g. statistical assumptions) and due to the small sample, one cannot expect all models to provide identical results.

Explanatory Variables: Confer the prospective plan for the data analyses, four explanatory variables were controlled for (i.e. *randomisation*, *age*, *previous number of needle procedures*, *needle pricks with/without EMLA*). The small number of participants (i.e. seven children) receiving needle pricks *without* EMLA limited the validity of this explanatory variable in the analyses. As to the number of *in-* and *outpatient admissions* plus *previous needle procedures*, these data were registered in categories, not as exact numbers. In continuation of this, I only recorded the extent of *previous number of needle procedures* and not to what degree the children were traumatised.

Confounding Variables: According to Young (2005) and Blount et al. (2009), high trait and state anxiety are associated

with greater pain responses. As mentioned above, the self-report of pain were only measured upon completion of the needle procedure, not at baseline. In that connection, the study is limited in that no assessments of these factors were made or controlled for in the statistical analyses. Likewise, no data on parents´ state anxiety were assessed as well as to what extent the participants were traumatised due to medical procedures. These factors were therefore not controlled for in the analyses. Similarly, no assessment was made regarding the children´s relation to music, music training etc. Besides that, in my statistical analyses, I did not control for gender differences as described in the research literature (e.g. Blount et al., 2009; Cohen, 2008; Young, 2005) or the behaviour of the parents and medical personnel (Mahoney et al., 2010), which are found to be predictive for coping and distress. Finally, it is possible that some of the physicians were positively biased towards the MT project and therefore rated the MT children more beneficially than the children in the control group. On the contrary, during the pilot studies and main studies, respectively, I actually felt some degree of resistance from two staff-members.

7.5.3 Generalisability of Results

In spite of the relatively small sample, this study provides evidence that MTPS is effective under PIVA in reducing the *Duration* of the procedure and *Child Anxiety* (i.e. physician-rated). Moreover, trends towards significance were found as to child-rated *Anxiety* (GLM) and research-assistant-rated *Child Anxiety* plus physician-rated *Child Pain* and *Compliance*. Besides that, after removal of an outlier from the MT group, these results became more distinct in terms of the beneficial effects of the MT intervention i.e. a total of four significant results and three results showing trends towards significance). However, except for the measuring of *Duration*, the tools used for the remaining significant outcome measures were not validated, why the validity of the results were flawed.

In the study, three physicians performed 75% of the PIVA procedures, which were somewhat equally distributed between the two groups. Therefore it is reasonable to infer that the results of the study are not subject to individual physician effects. On the contrary, all MTPS sessions were performed by one and the same music therapist, why the results are dependent on the specific music therapist in question. Hence, the study does not clarify whether the MTPS intervention is to cause a similar effect when performed by different music therapists.

Since PIVA is one of the most frequently performed medical procedures in paediatrics and the procedure is performed in a somewhat standardised manner, it seem reasonable that the results may be generalised to the whole population (i.e. children having nephro-urological diseases). The same may apply to some degree for in- and outpatients having other diseases, who undergo PIVA. However, this study do not illuminate whether the effects of MTPS also applies to children having life-threatening, chronic diseases, or chronic pains who are therefore subject to repeatedly PIVA and other medical procedures.

As to the geographical aspect, the results may to some extent be generalised to more regional contexts in Denmark other than Central Region Denmark (and Jutland), where the participants live. Given that the PIVA procedure is performed in a standardised to a great extent, the results may also be extrapolated to other cultural contexts in which a family-centered approach to paediatrics is practice and where the use of EMLA is an integral part of standard treatment (e.g. Scandinavia).

A factor not controlled for in the study was gender. Given that girls were overrepresented in the MT group (15/21) as well as the control group (8/12), it is unknown whether this factor influenced the results. As to age, the inclusion criterion was children at the ages of one to ten. However, the majority of the participants were one to five years old. Although controlling for age and significant effects were found, I did not make specific sub-group analyses to clarify potential differences among specific age groups (e.g. preschooler versus schoolchildren). Therefore, the study does not illuminate whether the significant effects apply in infants or 11- to 18-year-olds.

The study took place at a paediatric unit of a Danish hospital, which has no tradition for MT as an integrated part of the overall treatment strategy and interdisciplinary clinical practice. It is therefore uncertain whether or to what degree the results were influenced by this circumstance. In continuing this aspect, the study does not clarify whether similar results can be expected if the study is to be replicated in a similar context at a different hospital.

7.6

Conclusion and Directions for Future Research

In the following, I will present the conclusion of the study and outline recommendations for future research.

7.6.1 Conclusion

In this section, I will link the results of the study to the research hypotheses (section 5.2.2) and state the conclusion.

The participants of this randomised controlled trial (RCT) were 41 children at the ages of one to ten having various nephro-urological diseases, who underwent a single peripheral intravenous access procedure (standard treatment) either with or without music therapy procedural support (MTPS). Confer the research question/hypotheses, I hypothesised that a single MTPS session would reduce *Child Distress*, *Child Anxiety*, *Child Pain*, *Number of needle pricks* required to perform the procedure, and the *Duration* of the procedure as well as improve *Child* and *Parent Compliance*, *Overall satisfaction with the PIVA procedure*, and *Positive Child Behaviour*. Finally, I also hypothesised that the majority of families randomised to the MT group would find the MTPS intervention supportive and helpful in relation to PIVA.

The 16 outcome measures were assessed by valid tools as well as non-validated measuring instruments developed for the study. Of the 16 outcome measures, four relate to *Child Anxiety* (hypotheses 2a-d) and four relate to *Child Pain* (hypotheses 3a-d), which were rated by the research-assistant (a), children (d) at the ages of five to ten, parents (c), physician (d), respectively.

From an overall perspective, the results of the study were in favour of the MT group, except for parent-rated *Child Pain* (hypothesis 3c), which was slightly higher in the MT group. In addition, similar mean scores were found in the two groups for *Parent Compliance* (hypothesis 6). The results of the study showed that a single MTPS session was highly significantly effective in reducing the *Duration* (hypothesis 8) of the PIVA procedure. The MT intervention was also significantly effective in reducing *Child Anxiety* (hypothesis 2d), which moreover concurred with the three remaining raters´ scores of MT group. Besides that, trends towards significance were found in relation to *Child Anxiety* (hypotheses 2a and 2b), *Child Pain* (hypothesis 3d), and *Child Compliance* (hypothesis 5). Furthermore, the results of *Number of needle pricks* (hypothesis 7) suggest that MTPS may cause an effective reduction of this outcome measure. On the contrary, it is uncertain whether MTPS intervention can improve the already high level of *Overall satisfaction with medical procedure* (hypothesis 4).

Moreover, after removing an outlier (from the MT group), the overall picture became more distinct showing two additional statistically significant results in favour of the MT group. These are *Child Anxiety* (hypothesis 2a) and *Child Compliance* (hypothesis 5). A trend towards significance was also found for *Child Distress* (hypothesis 1). All the above-mentioned significant results had mean differences ranging from 16 to 33 percentage points. Finally, the majority of the families randomised to the MT group found the MT intervention supportive and helpful in relation to PIVA.

In conclusion, when combining these results as discussed in section 7.3, the overall picture may be interpreted as follows. The study showed that the MT intervention supported the children in reducing their anxiety and distress. The intervention calmed down the children, who became more compliant and kept still during the procedure. This allowed the physician to focus to a greater extent on the procedure, which was therefore completed sooner.

From a clinical perspective, the MTPS intervention was feasible and fit the working routines of the medical personnel. In fact, the MT intervention released time for the physician and the assisting nurse, which furthermore may constitute an economic benefit. The PhD study also illuminates important practical aspects of MTPS and provides two research-based clinical tools that informed the clinical process of the MT intervention. These tools

can be used directly by paediatric music therapist in clinical practice as well as for research purposes in relation to PIVA. In continuation of this, the clinical tools may also be applied to related medical procedures.

The main methodological limitations count a relatively small sample, lack of blinding of assessor, and the fact that most of the significant results were measured by means of non-valid tools. Clinically, the study does not illuminate the aspect whether the effect were due to the applied MTPS intervention or idiosyncratic skills and personality of the music therapist in that all MTPS sessions were performed by one and the same clinician. Furthermore, the study does not account for the potential long-term effects of the MTPS intervention. In conclusion, the study merits further research and recommendations are provided in the following.

7.6.2 Recommendations for Future Research

On the basis of the findings and limitations of the PhD study, I will now outline my recommendations for future research within the field of MTPS under PIVA and other related medical procedures. As appears below, the results and findings of the present study raised more questions that were answered.

This study shows that MTPS was significantly effective in reducing *Child anxiety*, among other things, in young children undergoing PIVA. As young children are found to be more vulnerable than older children (Blount et al., 2009; Cohen, 2004; Young, 2005), future studies should address this age group. Moreover, although the MT intervention proved effective in reducing anxiety, a substantial percentage of the children in both groups coped well with the procedure, at least according to the ratings of the research-assistant, physicians, and their parents. From a clinical and economical perspective, resources should be better allocated to the children having the greatest needs for MTPS under medical procedures. On the basis of scatter plots presented in section 6.24.6, it seems as if *Previous number of needle procedures* is associated with the child´s actual scores of *Child Anxiety* and *Child Pain* (i.e. the more previous procedures the higher anxiety). Future studies should therefore focus on new-diagnosed children, who have no previous or notable experience with distressing medical procedures and/or children who exhibit/score high levels of anxiety, distress, and pain. Instead of generating *average* estimates of successful and un-successful copers,

the most vulnerable children should be given the clinical and research resources. Hence, screening tools should be developed for clinical and research purposes.

Just as the majority of existent MTPS studies, this PhD study examined the short-term effects of MTPS. Due to substantial lack of evidence for the potential long-term effects of MTPS, this should be evaluated in future studies. Following this topic, evaluation of possible dose-response relationships should also be illuminated (cf. Gold et al. 2009). In that connection, as put forward by McGrath et al. (2009), possible *adverse events*, maintenance of *positive affect*, and the economical aspects of the intervention in question should also be examined. Just like the majority of the existent MT studies, I did not use blinded assessors, which should be avoided to the extent possible in future studies. In that connection, the use of video recording/excerpts can to some degree counteract this limitation, contrary to life observation. Moreover, the video recording approach offers several additional advantages. For instance, video excerpts are more convenient for initial training purposes as well as in establishing inter-rater agreement, since the recordings can be played back endless times. In addition, several measuring instruments can be applied. Consequently, this allows the measuring of negatively as well positively formulated outcome measures, including distress and child coping (e.g. the Child Adult Medical Procedure Interaction Scale – Revised, Blount et al., 1997).

Besides that, lack of large or sufficient sample sizes is widespread in the MT research literature, just as in the PhD study. Inclusion of more paediatric units, hospitals, and consequently music therapist may be of great importance in obtaining a secure recruitment outcome (e.g. Robb et al., 2007). In addition, the involvement of more clinicians also enables evaluation of possible therapist effects (cf. Kain et a., 2004). Besides that, future studies applying blinded outcome assessors should follow the guidelines outline in the CONSORT statement in terms of randomisation and allocation concealment. Furthermore, in the PhD study, the effects of an MAE-based intervention were examined. As outlined and argued by Ghetti (2012), there are three main approaches to MTPS (i.e. MAE, Integration, MAR). In that connection, a key focus in future studies is to identify to whom and under which medical procedures these approaches are most effective and in what way.

In addition to the above-mentioned recommendations, future studies should also contrast the effects of MTPS interventions to pharmacological and/or other non-pharmacological interventions (e.g. Kain et al., 2004). Moreover, as emphasised by Ghetti (2012, pp. 30-32), the MTPS research literature does not provide much information to which degree the effect is caused by the impact of the music therapist or the applied MT intervention. This is also an important topic in future research.

Besides that, not only the effects of MTPS need to be examined. Similarly, the children´s perception of the provided interventions as well as the therapeutic process also need to be illuminated in future research, which implies utilisation of a variety of research paradigms as advocated by Dileo & Bradt (2005, p. 84). As mentioned introductory to this section, I found that the results of study raised more questions than were answered. In that connection, some of these questions relate to a more qualitative nature, which calls for application of qualitative of mixed method approaches (Clark & Creswell, 2011). In that connection, as argued by Craig et al. (2006): “Parallel group RCTs aim to estimate the average effect of an intervention in a population, and provide little’s information about within or between person variability in response to interventions, or about the mechanisms by which effective interventions achieve change”. Finally, the reviewed studies in the literature review (i.e. *Chapter 4*) showed substantial lack of contextual information regarding the applied music interventions. As advocated by Robb & Carpenter (2009), appropriate information should be provided.

7.7

Danish Abstract

Baggrund

Perifer intravenøs adgang (PIVA) er en fællesbetegnelse for alle invasive procedurer, som indebærer indsættelse af nåle i en vene (f.eks. venflon og blodprøver). PIVA er den oftest udførte medicinske procedure på en børneafdeling. Trods brug af lokalbedøvelse kan PIVA forårsage ofte smerte samt øget angst og ubehag. Endvidere kan fysisk tvang ofte nødvendigt under proceduren hos især små børn. Ifølge forskningslitteraturen kan smertefulde og for barnet stressende medicinske procedurer forårsage negative langtidseffekter. Indtil nu har tre studier undersøgt effekten af musikterapi som støtte ved medicinske procedurer (MSMP) i forbindelse med nålestiksprocedurer. På baggrund af den begrænsede viden, ønsker jeg med denne undersøgelse at undersøge effekten af MSMP i en randomiseret kontrolleret undersøgelse. Derudover har undersøgelsen til hensigt at belyse kliniske aspekter af MSMP af den anvendte musikterapi (MT) intervention og tilvejebringe forskningsbaserede redskaber, som er brugervenlige og kan bruges direkte af klinikere.

Metode

I undersøgelsen deltog 41 børn i alderen 1-10 år under en enkelt anlæggelse af venflon. Børnene blev randomiseret til enten en musikterapi- eller en kontrolgruppe og den eneste forskel mellem grupperne bestod i, at den førstnævnte gruppe fik individuel musikterapi (*music alternate engagement*) før, under og efter venflon/nålesiksproceduren. Musikterapien blev udført af en uddannet musikterapeut og bestod af sange og musik, improviseret musik og spil på instrumenter, ønsket af barnet eller af barnets forældre. Undersøgelse blev udført i overensstemmelse med gældende regler for forskning og kliniske arbejde.

I studiet undersøgtes effekten af musikterapi på 16 effektmål, som kan sammenfattes således: ubehag, angst, smerte, overordnet tilfredshed med den medicinske procedure, samarbejdsvillighed, antal nålestiks, varighed af proceduren, positiv adfærd og leg, og tilfredshed med musikterapiinterventionen. Kort fortalt, blev effekten målt via selvrapportering, observation og tællelige data.

Resultater

Overordnet set faldt undersøgelsens resultater ud til musikterapigruppens fordel på nær forældrenes vurdering af barnets smerte, som var en smule højere i musikterapigruppen. Derudover var lægens vurdering af forældrenes samarbejdsvillighed ens i de to grupper. Hvad angår effekterne af musikterapien, viste undersøgelsen, at en enkel musikterapisession under anlæggelse af venflon medførte en højsignifikant forskel på 33% mellem de to grupper i forhold til procedurens varighed. Musikterapien reducerede også lægens vurdering af børnenes angst signifikant. Endvidere viste resultaterne tendens til signifikans i forhold til angst vurderet af børnene selv og observatøren samt lægens vurdering af barnets smerte og samarbejdsvillighed. Undersøgelsens resultater viser endvidere, at musikterapien måske kan reducere antallet af nålestik. Derimod viste resultatet af *Overordnet tilfredshed med proceduren* sig ikke at være signifikant forskelligt grupperne imellem.

Endvidere svarede størstedelen af deltagerne i musikterapigruppen, at de fandt musikterapien nyttig og hjælpsom. Da datamaterialet blev analyseret uden en ”outlier” fra musikterapigruppen, tegnede det overordnede billede af musikterapiens effekt sig endnu tydeligere. I disse analyser viste yderligere to resultater sig signifikante.

Konklusion

Undersøgelsen viser, at musikterapi som støtte ved medicinske procedurer givet i forbindelse med en enkelt procedure kunne reducere børnenes angst og varigheden af proceduren. Undersøgelsens signifikante resultater og det overordnede billede berettiger videre forskning indenfor dette felt.

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Appendices

Appendix 1: Summation of Bruscia´s Classification of Medical Music Therapy
(Bruscia, 1998, pp. 193-199)

Auxiliary level	• *Therapeutic music*: the use of music e.g. for relaxation, manage pain and reduce stress in intensive care units and patient rooms. (Does not require a music therapist). • *Music therapy consultations*: short-term services which are consultative in nature e.g. MT assessment of clients, consultation with other professionals on how to use music therapeutically.
Augmentative practices	• *Music in medicine*: the use of music as distraction and to reduce anxiety, stress and discomfort before, during and after surgery and other medical procedures. (The music takes precedence over the therapeutic relationship, which is supportive and has a short-term duration). • *Music in palliative care*: the use of music to provide comfort, diversion, managing pain, anxiety and stress. (Supportive client-therapist relation).
Intensive practices	• *Music as therapy*: addressing significant needs of the client throughout over an extended period of time. (The music takes precedence over the client-therapist relationship, which is supportive and has a long-term duration). • *Music therapy and medicine*: (MT&M) addressing significant needs of the client throughout over an extended period of time. In addition to *music in/as therapy*, MT&M may also include among other things supportive music psychotherapy, music activity therapy and other augmentative practices that might enhance the treatment or quality of life of the medical patient. (The role of the music and the client-therapist relationship are equal, supportive and has a long-term duration). • *Arts therapy and medicine*: same goals as *music therapy and medicine* and differs only in the additional inclusion of related arts experiences. • *Rehabilitative music therapy*: goals are restorative (speech, occupational, and physical therapy, and has a greater scope and depth than activity therapy because it addresses emotional as well as adaptational needs, incl. feeling that arise out of the recovery process itself. Music may be used *in* or *as* therapy, and the client-therapist relationship is often used as a vehicle for therapeutic change (Bruscia, 1998, pp. 198-199). • In *Palliative music therapy*: the use of music therapy to work *together over a period of time, using musical experiences and the relationship…as a means of examining and working through the final stage of the dying process"* (Bruscia, 1998, p. 199)
Primary level	• (No term stated): *"…a process of intervention and change characterised by both depth and breadth"* (Bruscia, 1998, p. 199).

Appendix 2: Strategy of the Literature Search

Appendix 2. Detailed Description of Strategy for the Literature Search

The strategy for the literature search was as follows. A main comprehensive literature search was conducted between January 1 and May 20, 2008 during the 1st semester of the course of the PhD project, in relation to the obligatory *elaborated proposal*. Subsequently, during February 2010 and May 2012, respectively, two additional minor/less comprehensive literature searches were conducted. The latter searches aimed especially at identifying newer outcome studies on music therapy studies and medical procedures involving paediatric patients with a view to updating the actual literature review (i.e. Chapter 4).

STRATEGY FOR THE MAIN LITERATURE SEARCH

On the basis of the focus, dependent, and independent variable of the PhD study, relevant search words and combinations hereof were used in systematically exhaustive searches as described in items 1 to 6:

1. Public Internet Databases

Following the recommendation proposed by Bonde (2006) and the advice of the librarian at Aalborg University Library who administer the music therapy area (i.e. Tove Lohsien), systematically search in these databases was conducted: Music Therapy World, Google Scholar, PsycInfo, Rilm, Medline, Cairss, Auboline (the database of Aalborg University Library), PubMed, CHINHAL, Cochrane, Academic Research, and Academic Search.

Following the advice from the librarian (Tove Lohsien), Ingenta was not included. Furthermore some searches in Music Therapy World were not succeeded, since the database was out of order. The specific search words applied in these databases are listed in the following (i.e. items 1a to 1c).

1a. Combination of Search Words Used in Google Scholar

I conducted ordinary searches in Google Scholar (not advanced search) using the combinations listed below. For each word combination I briefly screened the text excerpts of the first 200 hits/results:

1. “Music therapy", pediatrics, hospitalized children, coping
2. "music therapy" "procedural pain" "hospitalized children"
3. “music intervention" "procedural pain" "hospitalized children"
4. "music therapy" "needle stick" "hospitalized children"
5. “music intervention" "needle stick" "hospitalized children"
6. "music therapy" "needle stick" pediatrics
7. "music intervention" "needle stick" pediatrics
8. "music therapy" "anxiety management" "hospitalized children"
9. "music intervention" "anxiety management" "hospitalized children
10. "music therapy" "pain management" "hospitalized children”
11. "music intervention" "pain management" "hospitalized children"
12. "anxiety management" "hospitalized children" music

1b. Combination of Search Words Used in CINAHL (advanced search)

I conducted an advanced search in CINAHL (i.e. Select Field optional) using these word combinations:

1. Music therapy + pediatric* + paediatric*
2. Music therapy + pediatric*
3. Music therapy + pediatric
4. Music therapy + hospitalized children
5. Music intervention + hospitalized children
6. Music intervention + pediatrics + paediatrics
7. Music intervention + pediatric + paediatric
8. Music intervention + pediatric* + paediatric*
9. Interactive music + hospitalized children
10. Interactive music + pediatrics + paediatrics
11. Interactive music + pediatric + paediatric
12. Interactive music + pediatric* + paediatric*

1c. Combination of Search Words Used in the 10 Remaining Databases

The following 10 databases were searched using the listed word combinations, and a brief review of abstract and title was made. I appraised the relevance of the hits/results by quickly reading the title, abstract, or text excerpts: 1. Academic Research, 2. Academic Search Premier, 3. Auboline, 4. Cairss, 5. Cochrane, 6. Medline, 7. MT World*) , 8. Psychinfo, 9. PubMed and 10. Rilm:

1. ”Music therapy” + hospitalized children
2. ”Music therapy” + pediatrics + paediatrics
3. ”Music intervention” + hospitalized children
4. ”Music intervention” + pediatrics + paediatrics
5. ”Interactive music” + hospitalized children
6. ”Interactive music” + pediatrics + paediatrics

*) MT-world under Structured Review Databases: Archive (Collected Papers + Conference Rapports) + Dissertations. The following word combination was used: pediatric, paediatric, hospitalized children. The following searches under Structured Review Databases (with the word combination listed above) failed: Bibliography + In-house + Research register + Practice register + Commentaries.

2. Published Databases

I also screened the CD-ROM (2nd edition) *Music Therapy Research Quantitative and Qualitative Foundations* published by the American Music Therapy Association (AMTA).

3. Internet Search and/or Hand Search in Specific Music Therapy Journals

I conducted an internet-based search and/or hand search in the tables of contents in all issues of the following music therapy journals: Journal of Music Therapy, Music Therapy Perspectives, The Australian Journal of Music Therapy, and Nordic Journal of Music Therapy. In addition, a search in the Canadian Journal of Music Therapy was also attempted, which turned out not to be possible.

4. Meta-Analyses Reviewed

As appears from Chapter 4, I reviewed the meta-analyses on medical music therapy and music medicine Dileo & Bradt (2005) and Standley & Whipple (2003).

5. Consult Colleagues and Leading Music Therapy Researchers

In addition to discussions with my supervisors, I consulted with Cheryl Dileo and Joanne Loewy.

6. Manual Search in Reference Lists in Books on Medical Music Therapy

I made systematic manual searches in the reference lists in the following books: Dileo (1999), Loewy (1997), Myskja (2005), Nöcker-Ribaupierre (2004), Robb (2003), Standley & Whipple (2003), and Standley (2005)[1].

STRATEGY FOR THE TWO SUBSEQUENT LITERATURE SEARCHES

The strategy for the two subsequent "follow-up" searches was as follows.

A. Literature Search February 2010

1. Advanced Search in Google Scholar

The first 30 hits/results were appraised using the combination of these search words in the Google Scholar categories marked with ():

(published from) 2007 + "music therapy" + (at least one of the following words): "music intervention" "procedural distress" "procedural anxiety" "procedural pain" "hospitalized children" pediatrics coping" "needle stick"

2. Journal of Pediatric Psychology

Same procedure as used in the revised searches in Google Scholar (mentioned above, item 1.).

[1] For general information, Standley (2005) also contains abstracts of unpublished master´s theses on medical music therapy research undertaken by staff and students at Florida State University.

3. Music Therapy Journals

Manual search and/or internet-based search in tables of contents and/or abstracts in: Nordic Journal of Music Therapy, Music Therapy Perspectives, Australian Journal of Music Therapy, Journal of Music Therapy, and the British Journal of Music Therapy.

B. Literature Search May 2012

1. Music Therapy Journals

Manual search and/or internet-based search in tables of contents and/or abstracts in: Nordic Journal of Music Therapy, Music Therapy Perspectives, Australian Journal of Music Therapy, Journal of Music Therapy, and the British Journal of Music Therapy.

Appendix 3: Reasons for Deselecting Music Therapy Outcome Studies

In her article Micci (1984) described a MT technique for children with heart diseases undergoing cardiac catheterisation. The article also contained an evaluation of the MT technique in the form of comments given by the participating children and their parents along with questionnaires filled in by medical staff. Due to the informal evaluation of the clinical intervention the reference did not meet the inclusion criteria of the present review (i.e. outcome study).

The study by Ryan (1989) could not be accessed, and was therefore not appraised during the literature assessment process.

Aldridge (1993) examined the effect of MT on preoperative anxiety. Likewise, it was not possible to get access to the article via neither Aalborg University Library nor the Danish National Public Library.

Fratianne et al. (2001) examined the effect of MT in the form of music-based imagery and music alternate engagement on pain and anxiety during debridement in 25 burn patients. But since the participants were both children and adults the study did not meet the inclusion criteria of the literature review (i.e. paediatric patients only).

In their article Prensner and colleges (2001) describe different MT protocols used for burn patients. The article also comprises preliminary results of a pilot study with 63 burn patients. However, the article primarily relates to clinical aspects of MT with this population. Moreover, the participants were both children and adults and the nature of the data could not meet the inclusion criteria of this review. Thus, this research article was deselected.

In a pilot study Barrera et al. (2002) trialled the effect of active MT on anxiety and comfort in children with cancer. The study was not about medical procedures, and did therefore not meet the predefined inclusion criteria of the literature review.

Sahler et al. (2003) evaluated the effect of a combined receptive MT and relaxation imagery intervention on pain, nausea, and determination of time-to-engraftment. 42 cancer patients participated in the study. Since the age span of the participants was 5 to 65 years the study was not included in the literature review.

Robb (2003a) examined the effects of MT on depression and anxiety. However, the study is not about MTPS.

Robb et al. (2007) examined the effect of Active Music Engagement on coping-related behaviours, positive facial affects, and initiation in 83 young children with cancer. The study was not about medical procedures, and was therefore not included in the literature review.

Longhi & Pickett (2008) studied the effect of live music (performed by a musician) on physiological measures (i.e. pulse, heart rate, and oxygen saturation) in 21 long-term hospitalised children with cardiac and/or respiratory problems. The study was not about specific medical procedures, and was therefore not included in the literature review.

In her article O´Callaghan (2009) described the use of MT as a non-pharmacological anxiolytic for children receiving radiotherapy. The article addressed clinical perspectives, meaning and benefits of music therapy, which was illustrated through three short case studies. Due to the qualitative nature of the article it did not meet the inclusion criterion of the literature review.

Hendon & Bohon (2007) compared the effect of MT and play therapy in 60 hospitalised children. The outcome measure was happiness operationally defined as the frequency of smiles during. The study related to general wellbeing during admission, and not medical procedures. Therefore, the study was deselected in the literature review.

Walworth´s (2010) study on the effect of live music therapy for patients undergoing magnetic resonance imagine, was deselected, since it included both paediatric and adult participants.

Appendix 4: The Applied Version of FPS-R for Child-reported Pain (Danish)

Intro: Jeg vil gerne vide, om det gjorde ondt, da lægen stak dig, og om du var bange.

- Derfor har jeg taget nogle tegninger med, som du (barnet) kan pege på.
- Jeg vil læse det op, der står på sedlen - for det er vigtigt, at alle børn hører mine spørgsmål på samme måde.

(1) Ansigterne her viser, hvor meget noget kan gøre ondt – altså ikke hvordan man ser ud, men om det gør ondt!

(2) Det her ansigt (peg på ansigtet længst til venstre) viser, at det ikke gør ondt.

(3) Ansigterne viser at det gør mere og mere ondt (peg på hvert ansigt fra venstre mod højre) til det her ansigt (peg på ansigtet længst til højre) – som viser, det gør allermest ondt.

(4) Hvis de her ansigter var dig - hvor ondt gjorde det så, da lægen stak dig? Altså ikke hvordan du så ud, men hvor ondt det gjorde!

Appendix 5: The Applied Version of FPS-R for Child-rated Anxiety (Danish).

Modification of the FPS-R for the use of child-rated Anxiety.

Intro: Nu vil jeg vise dig det samme skema igen.

- Derfor har jeg taget nogle tegninger med, som du (barnet) kan pege på.
- Jeg vil læse det op, der står på sedlen - for det er vigtigt, at alle børn hører mine spørgsmål på samme måde.

(1) Nu viser ansigterne, hvor bange man kan være – **altså ikke hvordan man ser ud, men hvordan man føler sig indeni!**

(2) Det her ansigt (peg på ansigtet længst til venstre) viser, at man slet ikke er bange.

(3) Ansigterne viser, at man er mere og mere bange (peg på hvert ansigt fra venstre mod højre) til det her ansigt (peg på ansigtet længst til højre) – som viser, at man er allermest bange.

(4) Hvis de her ansigter var dig - hvor bange var du, da lægen stak dig? **Altså ikke hvordan du så ud, men hvor bange følte du dig indeni?**

Appendix 6: Translation and Back-translation of the FPS-R

1. Original English version of the FPS-R (5th version - August 2007, www.painsourcebook.ca)

In the following instructions, say "hurt" or "pain," whichever seems right for a particular child.

"**These faces show how much something can hurt. This face** [point to left-most face] **shows no pain. The faces show more and more pain** [point to each from left to right] **up to this one** [point to right-most face] **- it shows very much pain. Point to the face that shows how much you hurt** [right now]."

Score the chosen face **0, 2, 4, 6, 8,** or **10**, counting left to right, so '0' = 'no pain' and '10' = 'very much pain.' Do not use words like 'happy' and 'sad'. This scale is intended to measure how children feel inside, not how their face looks.

2. Danish translation of the FPS-R, translated by the researcher and used in the study

Intro: Jeg vil gerne vide, om det gjorde ondt, da lægen stak dig, og om du var bange.

- Derfor har jeg taget nogle tegninger med, som du (barnet) kan pege på.
- Jeg vil læse det op, der står på sedlen - for det er vigtigt, at alle børn hører mine spørgsmål på samme måde.

a) Ansigterne her viser, hvor meget noget kan gøre ondt – **altså ikke hvordan man ser ud, men om det gør ondt!**

b) **Det her ansigt** (peg på ansigtet længst til venstre) **viser, at det ikke gør ondt.**

c) **Ansigterne viser at det gør mere og mere ondt** (peg på hvert ansigt fra venstre mod højre) **til det her ansigt** (peg på ansigtet længst til højre) **– som viser, det gør allermest ondt.**

d) Hvis de her ansigter var dig - hvor ondt gjorde det så, da lægen stak dig? **Altså ikke hvordan du så ud, men hvor ondt det gjorde!**

3. Back-translation by skilled bilingual person (i.e. professor Lars Ole Bonde)

Say "hurts" or "pain" in the following instruction depending on what seems right for each child.

"**These faces show how much something can hurt** [how much pain there can be].

This face (point to the face to the far left) **shows, that it does not hurt at all** [that there is no pain].

The faces show that it hurts more and more (point at each face from the left to the right) **to this face** (point to the face to the far right), **which shows that it hurts very much** [that there is a lot of pain]

Point to the face that shows how much you hurt [right now]."

The selected face is scored **0, 2, 4, 6, 8**, or **10**, by counting from the left to the right, so that "0" = "no pain" and "10" = "a lot of pain". Avoid using words like "happy" or "sad". The purpose of this scale is to measure children´s inner feeling, not how their face actually looks.

Appendix 7: Procedure of Testing out the FPS-R during Pilot Study

In the process of translating the FPS-R into Danish, I carried out a separate pilot study validating the suitability and comprehensibility following this progression:

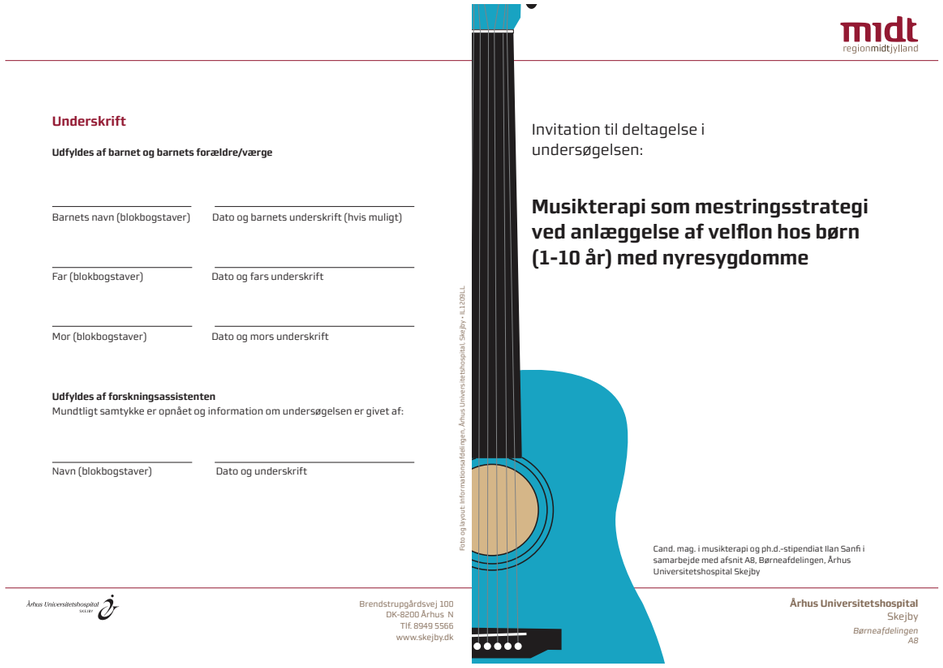
(1) I explained the purpose of conversation in these words: “I am the music man who plays for and with the children in the hospital. I am in the process of planning a study. In that connection, I would like to review this questionnaire that I have translated and intend to use in the study of other children than you

(2) Next, I then asked the child and parents to focus on the wording and give feedback (e.g. whether the translation was too complicated, long etc.) I asked the children to imagine or recall a situation at the hospital in which they experienced pain.

(3) Then I read out the FPS-R instruction and wording in its whole and pointed at the faces according to the instructions

(4) 4. Finally, I asked them to pay attention to the wordings and read out again each sentence – this time separately followed by additional questions addressing the comprehensibility aspect

Appendix 8: Information Brochure to Participants



midt
regionmidtjylland

Underskrift

Udfyldes af barnet og barnets forældre/værge

Barnets navn (blokbogstaver) _____ Dato og barnets underskrift (hvis muligt) _____

Far (blokbogstaver) _____ Dato og fars underskrift _____

Mor (blokbogstaver) _____ Dato og mors underskrift _____

Udfyldes af forskningsassistenten
Mundtligt samtykke er opnået og information om undersøgelsen er givet af:

Navn (blokbogstaver) _____ Dato og underskrift _____

Invitation til deltagelse i undersøgelsen:

Musikterapi som mestringsstrategi ved anlæggelse af velflon hos børn (1-10 år) med nyresygdomme

Foto og layout: Informationsafdelingen, Århus Universitetshospital, Skejby • IL 12981L

Cand. mag. i musikterapi og ph.d.-stipendiat Ilan Sanfi i samarbejde med afsnit A8, Børneafdelingen, Århus Universitetshospital Skejby

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www.skejby.dk

Århus Universitetshospital
Skejby
Børneafdelingen
A8

Kære familien

D. / 2010 skal _____ til nyreundersøgelse på Århus Universitetshospital Skejby. Nyreundersøgelsen indebærer anlæggelse af venflon (en nålestiksprocedure) på afsnit A8. I den forbindelse tillader vi os at spørge, hvorvidt I vil deltage i et forskningsprojekt. Forskningsprojektet har til formål at afdække, om musikterapi kan have en positiv virkning på barnets velbefindende og evne til at mestre nålestikproceduren.
I evt. tilfælde af aflysning af nyreundersøgelsen, bedes I venligst se bort fra denne informationspjece.

Informationspjecen beskriver, hvad undersøgelsen går ud på og indebærer for jer. Først når I har læst denne information, kan I afgøre, om I ønsker at deltage. I har mulighed for min. 2 dages betænkningstid, før I beslutter jer for at deltage eller ej, og skal derfor ikke føle jer presset til at svare med det samme.

Det er frivilligt, om I ønsker at deltage i undersøgelsen. Uanset jeres beslutning vil jeres barn få den samme behandling. Hvad enten I ønsker at deltage i undersøgelsen eller ej, bedes I venligst returnere nedenstående dokument (Erklæring om informeret samtykke) i den vedlagte svarkuvert senest d. / af hensyn til undersøgelsens og personalets planlægning.

Hvis I har en e-mailadresse, bedes I samtidig sende svar på mail: ilan@sanfi.dk.
Dette vil have stor betydning for planlægning og gennemførelse af undersøgelsen. På forhånd mange tak.

Hvad er musikterapi?

Målet med musikterapien i undersøgelsen er at støtte barnet i at mestre proceduren og reducere barnets oplevelse af især angst og smerte.
Den form for musikterapi som vil blive anvendt i undersøgelsen, vil bestå af kendte børnesange, spontant improviserede sange samt de sange, som jeres barn evt. måtte ønske. Barnet vil således i høj grad få mulighed for at foreslå de sange, som vil blive sunget, og være velkommen til at synge med (uden at der dog ligger en forventning eller et krav herom). Sangene og musikken vil blive sunget og spillet af Ilan Sanfi, som er cand.mag. i musikterapi. Musikterapien vil begynde i venteværelset og derefter fortsætte i behandlingsrummet under anlæggelse af venflon samt et stykke tid efter, at proceduren er færdig.

Forventet udbytte og risici ved musikterapi under anlæggelse af venflon

Musikterapien i undersøgelsen har til formål at støtte barnet (og forældrene) følelsesmæssigt og mentalt i forbindelse med anlæggelse af venflon. Musikterapien forventes at kunne hjælpe barnet med at reducere

dets oplevelse af angst og smerte. For at få udbytte af musikterapien, behøver barnet/I ikke at have tidligere erfaring med hverken at spille eller synge. Dog er det vigtigt, at især barnet ikke er negativt indstillet over for det eller udsættes for musik, det ikke bryder sig om. Skulle det imidlertid være tilfældet, har I på et hvert tidspunkt ret til uden varsel og forbehold enten at afbryde musikken, eller helt at trække jeres samtykke tilbage, og dermed træde ud af undersøgelsen

Hvad indebærer deltagelse i undersøgelsen?

Deltagelse i undersøgelsen vedrører én anlæggelse af venflon, og indebærer:

- at alle deltagere fordeles via lodtrækningsprincip i to grupper, hvoraf kun den ene (musikterapigruppen) vil få musikterapi. Der er således kun 50 % sandsynlighed for, at jeres barn vil få musikterapi under anlæggelse af venflon.
- at I skal afkrydse 4 korte spørgeskemaer efter anlæggelse af venflon.
- at en forskningsassistent observerer proceduren og udfylder et par skemaer

Vi gør opmærksom på, at uanset udfaldet af denne lodtrækning, indebærer deltagelse i undersøgelsen udfyldelse af spørgeskemaerne, hvilket vi anslår vil vare max. 5 min.

Oplysninger fra journalen og publikation

Såfremt I ønsker at deltage i undersøgelsen, vil følgende oplysninger blive indhentet fra barnets journal af Ilan Sanfi, som har journalindsigt og tavshedspligt: navn, alder, fødselsdato, køn og aktuel samt evt. tidligere diagnose. Oplysningerne vil blive behandlet fortroligt og opbevaret utilgængeligt og aflåst på Børneafdelingen, Århus Universitetshospital Skejby.
Undersøgelsen vil give anledning til mindst én efterfølgende artikel i et internationalt fagtidsskrift. Herudover forventes publikation i nationale fagtidsskrifter samt populærvidenskabelige artikler og omtale i dagspressen. Information om deltagernes identitet og journaloplysninger vil blive fremstillet i anonymiseret form.

Økonomisk støtte

Ilan Sanfis ph.d.-stipendium er finansieret af Forskningsrådet for Kultur og Kommunikation, som hører under Videnskabsministeriet. Endvidere har Det Obelske Familiefond støttet projektet.

Fortrydelsesret

Selvom I har givet tilsagn om at deltage, kan I dog stadig til enhver tid og uden begrundelse trække jeres samtykke tilbage og trække jer ud af undersøgelsen uden konsekvenser for jeres barns nuværende eller evt. fremtidige behandling.
Forud for deltagelse i en sådan undersøgelse kræver dansk lov, at begge forældre (ved fælles forældremyndighed) bekræfter dette ved at skrive under på nedenstående dokument (Erklæringen om informeret samtykke). Såfremt det er muligt, ønskes endvidere barnets underskrift og mundtlige accept herpå. Kort tid inden selve proceduren vil en forskningsassistent kontakte jer i dagsafsnittets venteværelse. Her vil I have mulighed for at stille evt. spørgsmål vedr. undersøgelsen. Endvidere vil han/hun vejlede jer i udfyldelse af spørgeskemaerne.

Hvis I ikke ønsker at deltage i undersøgelsen

Hvis I ikke ønsker at deltage i undersøgelsen, bedes I venligst bekræfte dette skriftligt ved at returnere nedenstående dokument i den vedlagte frankerede svarkuvert.

Har I yderligere spørgsmål til undersøgelsen, er I altid velkomne til at kontakte overlæge Søren Rittig (89496726), oversygeplejerske Inge Pia Christensen (89496701) eller musikterapeut Ilan Sanfi (22973661 & ilan@sanfi.dk).

På forhånd tak.

Med venlig hilsen
Søren Rittig, Inge Pia Christensen og Ilan Sanfi
Afsnit A8, Børneafdelingen
Århus Universitetshospital Skejby

Erklæring om informeret samtykke

(skal returneres)

Hvad enten I ønsker at deltage i undersøgelsen eller ej, bedes I venligst udfylde og returnere dette dokument i den vedlagte frankerede svarkuvert og samtidigt maile jeres svar til: ilan@sanfi.dk senest d. / .
På forhånd mange tak for hjælpen

Udfyldes af barnet og barnets forældre/værge

NEJ tak____ vi ønsker ikke at deltage i undersøgelsen.
JA tak____ vi ønsker at deltage i undersøgelsen.

Med vores underskrift (forældre/værge) giver vi hermed informeret samtykke til, at vores barn/vi ønsker at deltage i den beskrevne videnskabelige undersøgelse:
Musikterapi som mestringsstrategi ved anlæggelse af venflon hos børn (1-10 år) med nyresygdomme.

Med vores underskrifter bekræfter vi endvidere:

- at have læst ovenstående informationspjece
- at vi er informeret om, at deltagelse i undersøgelsen er frivillig
- at vi er informeret om, at vores samtykke når som helst uden forbehold kan trækkes tilbage uden at det vil få konsekvenser for vores barns nuværende eller evt. fremtidige behandling
- at vi er informeret om, at der ved deltagelse i undersøgelsen kun vil være 50% sandsynlighed for at modtage musikterapi i forbindelse med anlæggelse af venflon

Appendix 9: Result of Repertoire Applied in the Music Therapy Group

Frequency & Characteristics of songs used in the study				
Songs (English translation)	**Writer of lyric/Composer**	**Genre**	**Guiding stimulating/ sedative characteristic**	**Frequency**
1. Lille Peter Edderkop (Itsy Bitsy Spider)	Knus Pheiffer/Unknown	Common children´s song	Sedative	19
2. Andreas sang (Andrea´s Song)	Povl Køller	Song from children´s television programme	Sedative	17
3. Mester Jakob (Brother John)	Unknown	Common children´s song	Sedative	11
4. En elefant kom marcherende (The Elephant´s Song)	Unknown	Common children´s song	Moderate stimulative	11
5. Jeg er en glad lille cowboy (I am a Little Happy Cowboy)	Povl Køller	Children´s song	Stimulative	9
6. Mariehønen Evigglad (The Ever Happy Ladybird)	Halfdan Rasmussen/Henning Hansen	Common children´s song	Moderate stimulative	9
7. Hjulene på bussen (The Wheels on the Bus)	English children´s song - unknown. Danish translation by Hans-Henrik Ley.	Common children´s song	Stimulative	8
8. Bim bam busse	Hans-Henrik Ley/Jannik Hastrup	Common children´s song	Moderate stimulative	8
9. Other song wishes by child & parents			Mixed	8
10. Improvisation			Mixed	7
11. Se min kjole (The Dress Song)	Gunnar Nyborg-Jensen	Common children´s song	Sedative	7
12. Puff´ den magiske drage (Puff the Magic Dragon)	Leonard Lipton/Peter Yarrow. Danish translation: Per Borgsten	Pop song	Stimulating	6

13. Jeg vil ha en stor ballon (The Balloon Song)	Billy Mure. Danish translation: Peter Mynte		Moderate stimulative	6
14. I en skov en hytte lå (The song about the Rabbit and the Hunter)	Unknown	Common children´s song	Moderate stimulative	5
15. Jamaica	Jørgen Wedege	Common children´s song	Stimulative	5
16. Bjørnen sover (The Sleeping Bear)	Unknown	Common children´s song	Sedative	4
17. Kajs sang (Kaj´s Song)	Povl Køller	Song from children´s television programme	Stimulative	4
18. Postmand Per (Postman Pat)	Bryan Daly.	Song from children´s television programme	Moderate stimulative	4
19. Jeg har en rokketand (The Loose Tooth Song)	Povl Køller	Song from children´s television programme	Stimulative	4
20. Blæksprutten Olsen (Olsen the Octopus)	Halfdan Rasmussen/Tage Mortensen	Common children´s song	Sedative	3
21. Godmorgen sol (Good Morning Sun)	Halfdan Rasmussen/Benny Andersen	Common children´s song	Stimulative	3
22. Vil du, vil du (Do You Want to Follow Me?)	Unknown	Common children´s song	Sedative	3
23. Bondemanden (The Farmer song)	Gunvor Bjerre/Povl Køller	Song from children´s television programme	Stimulative	2
24. Buster (Buster the Kid)	Nanna Lüders	Song from children´s movie	Moderate stimulative	2
25. Jutlandia	Kim Larsen	(Ordinary) Pop song	Stimulative	2
26. Se den lille kattekilling (See the Little Kitten)	Wagner Baunvig/Hakon Andersen	Common children´s song	Sedative	2
27. Susan Himmelblå (Susan the Wonderful)	Kim Larsen	(Ordinary) Pop song	Stimulative	2
28. Tangokat (The Tango Cat Song)		Common children´s song	Stimulative	2
29. Æblemand (The Apple Man Song)		Common children´s song	Moderate stimulative	2

30. Cirkelines fødselsdagssang (Cirkeline´s Birthday Song)	Hanne Hastrup/Hans-Henrik Ley	Song from children´s television programme	Stimulative	1
31. Fætter Mikkel (Mikkel the Musical Fox)		Common children´s song	Stimulative	1
32. Hvis du ser en krokodille (If You See a Crocodile in Your Bath Tub)	Jørgen Sørensen	Common children´s song	Stimulative	1
33. I en lille båd der ginger (In a Small Rocking Boat)	Flemming "Bamse" Jørgensen	(Ordinary) Pop song	Stimulative	1
34. Imagine	John Lennon	(Ordinary) Pop song	Sedative	1
35. Jeg ved en lærkerede (I Know Where to Find a Lark´s Nest)	Harald Bergstedt/Carl Nielsen	Traditional folksong	Sedative	1
36. Joanna	Kim Larsen	(Ordinary) Pop song	Moderate stimulative	1
37. Køb bananer (Buy my Bananas Song)	Kim Larsen	(Ordinary) Pop song	Stimulative	1
38. Lille Lise (Little Lise)	C.M. Bellmann	Common children´s song	Sedative	1
39. Om lidt (In a second We´re Gone)	Kim Larsen	(Ordinary) Pop song	Sedative	1
40. Papirsklip	Kim Larsen	(Ordinary) Pop song	Moderate stimulative	1
41. Pjerrot og månen (Pierrot and the Moon)	French song	Common children´s song	Sedative	1
42. Rapanden Rasmus (Rasmus the Funny Duck)	Halfdan Rasmussen	Common children´s song	Moderate stimulative	1
43. Solen er så rød mor (The Sun is Burning Mother)	Harald Bergstedt/Carl Nielsen	Traditional children´s song	Sedative	1
44. Tornerose (The Sleeping Beauty)	Unknown	Common children´s song	Stimulative	1
45. Vimmersvej (Vimmers Street)	Flemming "Bamse" Jørgensen	(Ordinary) Pop song	Stimulative	1

Appendix 10: Ethical Approvals

Fra Marie Bartholdy [Marie.Bartholdy@STAB.RM.DK]
Sendt 28-10-2008 15:22:49
Til Ilan Sanfi [ilan@sanfi.dk]
Kopi til
Vedrørende SV: Vurdering af krav om anmeldelsespligt

Forespørgsel 112/2008

Kære Ilan Sanfi.

Du har spurgt De videnskabsetiske Komiteer for Region Midtjylland om nedenfor beskrevne studier skal anmeldes til komiteen.

Komiteen har vurderet, at således som projekterne er beskrevet, er de ikke omfattet af begrebet "biomedicinsk forskning" således som dette er beskrevet i komitéloven § 7, nr. 1. Projektet skal derfor ikke anmeldes, jfr. komitéloven § 8, stk. 1.

Du kan således iværksætte dit projekt uden yderligere tilbagemelding fra komiteen.

Den omtalte lov er lov nr. 402 af 28. maj 2003 om et videnskabsetisk komitésystem og behandling af biomedicinske forskningsprojekter.

Venlig hilsen

Marie Bartholdy
Fuldmægtig
Tlf. 8728 4409

Fra: Ilan Sanfi [ilan@sanfi.dk]
Sendt: 10-10-2008 14:22
Til: Marie Bartholdy [marie.bartholdy@stab.rm.dk]
Emne: Vurdering af krav om anmeldelsespligt
Kære Marie
Med henvisning til behagelig telefonsamtale i går sender jeg hermed som aftalt et kort resumé af de to kliniske undersøgelser i fm. mit ph.d.-projekt. På baggrund af mailen ønskes vurderet, om undersøgelserne falder indenfor eller udenfor krav om anmeldelsespligten.

1. BAGGRUND
Jeg er musikterapeut og ph.d.-stipendiat indskrevet på Forskerskolen i Musikterapi på Aalborg Universitet (AAU). Som led i mit ph.d.-projekt skal jeg lave to (uafhængige) klinisk kontrollerede effektundersøgelser, som gennemføres på henholdsvis børneafsnit A4 og A8 på Århus Universitetshospital, Skejby (AUH).
Ph.d.-projekt sker i samarbejde mellem mig, AAU og AUH. Jeg er forskningsansvarlig, og overlæge Henrik Hasle fra afsnit A4 og Søren Rittig afsnit A8 er kontaktpersoner.

2. Kort om undersøgelse 1
Undersøgelse 1 har til formål at afdække effekten af musikterapi under lægning af venflon hos børn med nyresygdomme i alderen 1-10 år - på oplevelse af angst, smerte, kontrol og samarbejde samt tidforbrug. Til orientering skal børnene have foretaget anlægning af venflon uafhængigt af min undersøgelse.
* Jeg forventer 80 børn/deltagere, som randomiseres til to eksperimental- og to kontrolgrupper.
* Interventionen/musikterapien består af sange med akkompagnement, som tilbydes før, under og efter anlægning af venflon.
* Musikterapien udføres af en uddannet musikterapeut - cand.mag. i musikterapi (alias undertegnede).
Undersøgelsen udføres i overensstemmelse med Helsinki dekleration II samt Musikterapeuternes Landsklubs etiske regelsæt (http://www.musikterapi.org/index.php?MTL:etiske_principper).
* I undersøgelsen forventes følgende måleredskaber anvendt: observationsskala til måling af adfærd, selvrapportering af oplevet angst, smerte, samarbejde og tilfredshed med proceduren (præ/post eller post). Herudover registreres relevante person- og journaldata.
3. Kort om undersøgelse 2
Delundersøgelse 2 har til formål at undersøge effekten af designede musik-fortællinger på kvalme, opkast, stemningsleje, kropslig anspændthed og skøn af fødeindtag.
Til orientering skal børnene have kemoterapi uafhængigt af min undersøgelse.

* Alle deltagere som opfylder inklusionskriterierne vil blive inviteret til deltagelse i undersøgelsen. Vi forventer ml. 14-18 børn.
* Interventionen vil bestå af 3 musik-fortællinger, som skal bruges/høres systematisk (min. én gang dagligt) under 2 af 4 kemoterapikure. Jeg vil forestå komposition og produktion af musik-fortællingerne, som er designet med henblik på at virke beroligende og mentalt stimulerende.
* Undersøgelsen udføres i overensstemmelse med Helsinki dekleration II samt Musikterapeuternes Landsklubs etiske regelsæt (http://www.musikterapi.org/index.php?MTL:etiske_principper).
* I undersøgelsen forventes følgende måleredskaber anvendt: a) selvrapportering til måling af stemningsleje, smerte og kropslig anspændthed. Dagbog til systematisk egenregistrering af kvalme, opkast og skøn af fødeindtag. Herudover registreres relevante person- og journaldata.

4. Forberedende pilotundersøgelser & samlet tidsplan
Forud for hver hovedundersøgelse gennemføres en pilotundersøgelse. Formålet hermed er at forberede hovedundersøgelserne, herunder afprøve måleredskaber, evaluere gennemførlighed, få mulighed for at ændre og tilpasse interventionen samt at indsamle kvalitative data vedr. deltagernes oplevelse af interventionen.
Den samlede tidsplan ser således ud:
* Pilotundersøgelse 1 (musikterapi under anlægning af venflon): marts - april 2009.
* Hovedundersøgelse 1 (musikterapi under anlægning af venflon): maj til december 2009.
* Pilotundersøgelse 2 (musik-fortællinger til børn med kræft): december 2008 til januar 2009.
* Hovedundersøgelse 2 (musik-fortællinger til børn med kræft): marts 2009 til juni 2010.
Skriv endelig, hvis du skulle have brug for yderligere information om undersøgelserne.
Skulle det vise sig, at de to hoved- og de to pilotundersøgelser falder udenfor anmeldelsespligten, vil jeg venligst bede om et skriftligt dokument/bekræftelse herpå (på engelsk), da jeg skal lave ph.d. via publikation i internationale tidsskrifter.
Jeg glæder mig til at høre fra dig.
På forhånd tak - og rigtig god weekend.
Med venlig hilsen ilan

Ilan Sanfi - music therapist and musician.
PhD student, The Doctoral Programme in Music Therapy. Department of Communication, Aalborg University, Denmark (http://www.musikterapi.aau.dk/forskerskolen_index.htm).
BA & MA in music therapy, Aalborg University, Denmark (www.musikterapi.aau.dk).
BA in music education, The Royal Academy of Music, Århus, Denmark (www.musik-kons.dk).
Phone: + 45 - 22973661
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DATATILSYNET

Ph.d.-studerende Ilan Sanfi
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9220 Aalborg Ø

Sendt til: ilan@sanfi.dk

26. juni 2009

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E-post
dt@datatilsynet.dk
www.datatilsynet.dk

J.nr. 2009-41-3619

Sagsbehandler
Frederik Rechenback Enelund
Direkte 3319 3245

Vedrørende anmeldelse af: Musikterapi som mestringsstrategi ved anlægning af venflon hos børn med nyresygdomme: En kontrolleret undersøgelse med fokus på observeret angst og ubehag samt selvrapporteret angst, smerte, patienttilfredshed, samarbejdsvillighed & varighed og antal stik

Ovennævnte projekt er den 17. juni 2009 anmeldt til Datatilsynet efter persondatalovens[1] § 48, stk. 1. Der er samtidigt søgt om Datatilsynets tilladelse.

Det fremgår af anmeldelsen, at De er dataansvarlig for projektets oplysninger. Behandlingen af oplysningerne ønskes påbegyndt snarest og forventes at ophøre 30. juli 2011.

Oplysningerne vil blive behandlet på følgende adresse: Børneafdeling A, Århus Universitetshospital, Skejby, Brendstrupgårdsvej 100, 8200 Århus Nord.

TILLADELSE

Datatilsynet meddeler hermed tilladelse til projektets gennemførelse, jf. persondatalovens § 50, stk. 1, nr. 1. Datatilsynet fastsætter i den forbindelse nedenstående vilkår:

Generelle vilkår

Tilladelsen gælder indtil: 30. juli 2011

Ved tilladelsens udløb skal De særligt være opmærksom på følgende:

Hvis De ikke inden denne dato har fået tilladelsen forlænget, går Datatilsynet ud fra, at projektet er afsluttet, og at personoplysningerne er slettet, anonymiseret, tilintetgjort eller overført til arkiv, jf. nedenstående vilkår vedrørende projektets afslutning. Anmeldelsen af Deres projekt fjernes derfor fra fortegnelsen over anmeldte behandlinger på Datatilsynets hjemmeside.

[1] Lov nr. 429 af 31. maj 2000 om behandling af personoplysninger med senere ændringer.

Datatilsynet gør samtidig opmærksom på, at al behandling (herunder også opbevaring) af personoplysninger efter tilladelsens udløb er en overtrædelse af persondataloven, jf. § 70.

1. Ph.d.-studerende Ilan Sanfi er ansvarlig for overholdelsen af de fastsatte vilkår.

2. Oplysningerne må kun anvendes til brug for projektets gennemførelse.

3. Behandling af personoplysninger må kun foretages af den dataansvarlige eller på foranledning af den dataansvarlige og på dennes ansvar.

4. Enhver, der foretager behandling af projektets oplysninger, skal være bekendt med de fastsatte vilkår.

5. De fastsatte vilkår skal tillige iagttages ved behandling, der foretages af databehandler.

6. Lokaler, der benyttes til opbevaring og behandling af projektets oplysninger, skal være indrettet med henblik på at forhindre uvedkommende adgang.

7. Behandling af oplysninger skal tilrettelægges således, at oplysningerne ikke hændeligt eller ulovligt tilintetgøres, fortabes eller forringes. Der skal endvidere foretages den fornødne kontrol for at sikre, at der ikke behandles urigtige eller vildledende oplysninger. Urigtige eller vildledende oplysninger eller oplysninger, som er behandlet i strid med loven eller disse vilkår, skal berigtiges eller slettes.

8. Oplysninger må ikke opbevares på en måde, der giver mulighed for at identificere de registrerede i et længere tidsrum end det, der er nødvendigt af hensyn til projektets gennemførelse.

9. En eventuel offentliggørelse af undersøgelsens resultater må ikke ske på en sådan måde, at det er muligt at identificere enkeltpersoner.

10. Eventuelle vilkår, der fastsættes efter anden lovgivning, forudsættes overholdt.

Elektroniske oplysninger

11. Identifikationsoplysninger skal krypteres eller erstattes af et kodenummer el. lign. Alternativt kan alle oplysninger lagres krypteret**.** Krypteringsnøgle, kodenøgle m.v. skal opbevares forsvarligt og adskilt fra personoplysningerne.

12. Adgangen til projektdata må kun finde sted ved benyttelse af et fortroligt password. Password skal udskiftes mindst én gang om året, og når forholdene tilsiger det.

13. Ved overførsel af personhenførbare oplysninger via Internet eller andet eksternt netværk skal der træffes de fornødne sikkerhedsforanstaltninger mod, at oplysningerne kommer til uvedkommendes kendskab. Oplysningerne skal som minimum være forsvarligt krypteret under hele transmissionen. Ved anvendelse af interne net skal det sikres, at uvedkommende ikke kan få adgang til oplysningerne.

14. Udtagelige lagringsmedier, sikkerhedskopier af data m.v. skal opbevares forsvarligt aflåst og således, at uvedkommende ikke kan få adgang til oplysningerne.

Manuelle oplysninger

15. Manuelt projektmateriale, udskrifter, fejl- og kontrollister, m.v., der direkte eller indirekte kan henføres til bestemte personer, skal opbevares forsvarligt aflåst og på en sådan måde, at uvedkommende ikke kan gøre sig bekendt med indholdet.

Oplysningspligt over for den registrerede

16. Hvis der skal indsamles oplysninger hos den registrerede (ved interview, spørgeskema, klinisk eller paraklinisk undersøgelse, behandling, observation m.v.) skal der uddeles/fremsendes nærmere information om projektet. Den registrerede skal heri oplyses om den dataansvarliges navn, formålet med projektet, at det er frivilligt at deltage, og at et samtykke til deltagelse til enhver tid kan trækkes tilbage. Hvis oplysningerne skal videregives til brug i anden videnskabelig eller statistisk sammenhæng, skal der også oplyses om formålet med videregivelsen samt modtagerens identitet.

17. Den registrerede skal endvidere oplyses om, at projektet er anmeldt til Datatilsynet efter persondataloven, samt at Datatilsynet har fastsat nærmere vilkår for projektet til beskyttelse af den registreredes privatliv.

Indsigtsret

18. Den registrerede har ikke krav på indsigt i de oplysninger, der behandles om den pågældende.

Videregivelse

19. Videregivelse af personhenførbare oplysninger til tredjepart må kun ske til brug i andet statistisk eller videnskabeligt øjemed.

20. Videregivelse må kun ske efter forudgående tilladelse fra Datatilsynet. Datatilsynet kan stille nærmere vilkår for videregivelsen samt for modtagerens behandling af oplysningerne.

Ændringer i projektet

21. Væsentlige ændringer i projektet skal anmeldes til Datatilsynet (som ændring af eksisterende anmeldelse). Ændringer af mindre væsentlig betydning kan meddeles Datatilsynet.

22. *Ændring af tidspunktet for projektets afslutning skal altid anmeldes.*

Ved projektets afslutning

23. *Senest ved projektets afslutning skal oplysningerne slettes, anonymiseres eller tilintetgøres, således at det efterfølgende ikke er muligt at identificere enkeltpersoner, der indgår i undersøgelsen.*

24. Alternativt kan oplysningerne overføres til videre opbevaring i Statens Arkiver (herunder Dansk Dataarkiv) efter arkivlovens regler.

25. Sletning af oplysninger fra elektroniske medier skal ske på en sådan måde, at oplysningerne ikke kan genetableres.

Ovenstående vilkår er gældende indtil videre. Datatilsynet forbeholder sig senere at tage vilkårene op til revision, hvis der skulle vise sig behov for det.

Datatilsynet gør opmærksom på, at denne tilladelse alene er en tilladelse til at behandle personoplysninger i forbindelse med projektets gennemførelse. Tilladelsen indebærer således ikke en forpligtelse for myndigheder, virksomheder m.v. til at udlevere eventuelle oplysninger til Dem til brug for projektet.

En videregivelse af oplysninger *fra* statistiske registre, videnskabelige projekter m.v. kræver dog, at den dataansvarlige har indhentet særlig tilladelse hertil fra Datatilsynet, jf. persondatalovens § 10, stk. 3.

Anmeldelsen offentliggøres i fortegnelsen over anmeldte behandlinger på Datatilsynets hjemmeside **www.datatilsynet.dk**.

Persondataloven kan læses/hentes på Datatilsynets hjemmeside under punktet "Lovgivning".

Advarsel – ved brug af Excel, PowerPoint m.v.
Den dataansvarlige skal til enhver tid sikre sig, at dokumenter og andre præsentationer, som publiceres eller på anden måde gøres tilgængelig for andre på internettet, usb-nøgle eller på andet elektronisk medie, ikke indeholder personoplysninger.

Der skal vises særlig agtpågivenhed i forbindelse med brug af grafiske præsentationer i Excel og PowerPoint, da de uforvarende kan indeholde indlejrede persondata i form af regneark, tabeller mv.

Præsentationer, der gøres tilgængelig på internettet, bør derfor omformateres til Portable Digital Format (PDF), da dette fjerner eventuelle indlejrede Excel-tabeller.

Med venlig hilsen

Frederik Rechenback Enelund

Appendix 11: Summation of Non-validated Qualitative Comments Written by the Parents

Summation of Non-validated Qualitative Comments Written by the Parents

Case 1 (MT group):

On the satisfaction questionnaire the mother wrote this additional comment on her own initiative: "*Really good initially before the actual needle procedure. There was too much confusion with many different people, who talked at the same time – the quiet background music was really good.* (Ilan: It was) *really good after the needle prick with the singing and music*".

On the questionnaire regarding usefulness the mother wrote this additional comment on her own initiative: "*Incredibly good idea to distract the child and to focus on a good thing namely music. Relaxing*".

Case 2 (MT group):

In addition to the questionnaires the mother wrote this letter on her own initiative: "*Dear Ilan, thank you for making our girl's first examination* (Ilan: intravenous access procedure & kidney scanning) *and meeting with the "needle" a pleasant experience. Although she did not say much she was well and had a nice time. You were good at catching her attention with your singing, your calm, and pleasant manner. Yours sincerely*".

Case 3 (MT group):

The child's mother wrote: "*Our girl was afraid of needles due to a previous similar needle procedure. Here numbing plaster* (Ilan: EMLA) *was used, but in another place than where she was actually stuck*".

Case 4 (MT group):

The parent of the child wrote: "*Fantastically good effect – my daughter very pleasantly occupied by the music before the procedure. Much sooner relaxed after the procedure. Last time she about to faint – this was not at all the case this time! The musician had very good intuition towards the child – good at inspiring*".

Case 5 (MT group):

The parent(s) of the child wrote: "*The music took the focus off the somewhat unpleasant thing that was about to happen. He thought it was cosy to be allowed to play along. The music is a really good initiative!*".

Case 6 (MT group):

The parent(s) of the child wrote: "*The music calmed her at the first needle prick.* (Ilan: At the) *second needle prick it did not help*".

Case 7 (MT group):

The parent(s) of the child wrote: "*It worked well for our boy that the music continued subsequently. He calmed down quickly. Due to time pressure we did not have time to music before* (Ilan: the needle procedure). *For young children well-known songs are not particularly necessary, just as long as there is music*".

Case 8 (MT group):

The parent(s) of the child wrote: "*Our girl is quite afraid of strangers right now, that is why she did not really fall for the music*".

Case 9 (MT group):

The parent(s) of the child wrote: *"Very good, it has a soothing effect and makes the child think of something else so that they do not have time to feel fear. So we are very positively surprised by the course of the procedure".*

Case 10 (MT group):

The parent(s) of the child wrote: *"The music itself was ok, but for my daughter there were too many people involved. She is a very private person. Maybe we should have rejected* (Ilan: consent to) *the video recording".*

Case 11 (MT group):

The parent(s) of the child wrote: *"Your calm appearance, calm talking during the course , and the instruments* (Ilan: bongos, xylophone, metalophone, and guitar) *were distracting and relaxing for both our son and us as parents!!".*

Case 12 (MT group):

The parent of the child wrote: *"I think music therapy is really good. But in our case it has probably not had a big effect with regard to the pick line insertion since our daughter normally deals with such things quite calmly".*

Case 13 (MT group):

The parent of the child wrote: *"Music therapy is a good thing in relation to the stressing things that is about to happen, since it can sometimes divert the attention from the stressing tings.*

Case 14 (Control group):

The parent of the child wrote: *"Our son was calm just until the needle prick. When he was stuck, he was surprisingly calm. He did actually not react to the needle prick".*

Case 15 (Control group):

The parent of the child wrote: *"Our son is not specifically afraid of needles, but more of being restrained".*

Appendix 13: Transcription and Translation of Interview with Family X in the MT Group

1. Transcription of Interview (Danish)

Mother: Jamen, de andre gange vores barn er blevet stukket, har han været meget meget meget ked af det. Og vi har skullet fiksere ham, flere voksne skulle simpelthen holde ham fast i sengen, hvor han har grædt og vredet sig rundt i sengen…hvor det har været rigtig svært at skulle fiksere den lille arm, der skulle holdes stille der hvor stikket skulle komme…Det startede da vores dreng var ét år, hvor han blev stukket første gang. Og det har været helt derfra, at han været så panisk, når han skulle stikkes…

Research-assistant: Hm…og hvordan har I oplevet denne gang? Hvordan har det været anderledes fra de andre gange?

Mother: Jamen, forskellen har været kæmpe stor. Jeg har aldrig oplevet det så smertefrit, som det har været denne gang og så hurtigt. Nu var det så også heldigt, at det lykkes i første forsøg at lægge nålen ind. Det er det ikke gjort de andre gange…og det kan være så mange ting…Men det gør det selvfølgelig ikke lettere, når han ikke har ligget stille, hvilket han gjorde i dag…Så det var jo…kæmpe success.

Research-assistant: Så der er både sådan selve proceduren med nålestikket og musik terapien, der har været…

Mother: Jeg tror det har været en kombination, for han var da tydeligvis fanget af det musik inden allerede inden lægen kom ind. Og jeg havde faktisk ikke troet at han bare ville sætte sig ned og begynde at spille, det havde jeg ikke lige forventet…at han ville fordi, han var trykket af det her i forvejen…Altså det har afledt ham helt tydeligvis.

Research-assistant: Ja.

Mother: Og så tænker jeg også at det der med at der en anden voksen end lige forældrene, der går igen hele tiden og snakker med lægen, fortæller "Nu kommer lægen ind, og nu skal han prikke der"… Altså, jeg har en fornemmelsen, at når jeg har sagt det, så hører han ikke efter på samme vis at…end når der kommer en anden og fortæller det, så det har været fint…at forbedere ham det.

2. Translation of Interview (English)

Mother: Well, during the previous times our child was stuck he was very very very upset. And he was restrained in the hospital bed by more adults, he cried and wrenched himself in the bed…it was really difficult to strap down the little arm, which needed to lay still during the needle pricks…It originated when he was one year old and was stuck for the very first time. And since that time he has been so panic during needle pricks…

Research-assistant: Hm…and what is your experience this time? How has it been different from the previous times?

Mother: Well, the difference has been gigantic. I have never experienced the needle procedure in such a painless way as today and also so quickly. We were lucky that the needle was placed successfully during the very first attempt. This never happened during the previous procedures…and it could be due to many reasons…But of course the circumstance is not easier when he is not laying still, which he did today…So it has been…an enormous success.

Research-assistant: So it is both the (needle) procedure itself including the needle prick and the music therapy that have been…

Mother: I think it was a combination, because he was clearly caught by the music already before the physician entered the treatment room. And I did actually not expect him to sit down starting to play, I did not expect that… that he would, because he was already influenced by this (Ilan: the situation)…Well, it has clearly diverted his attention.

Research-assistant: Yes.

Mother: And I also think that the concept of an additional adult (other than the parents) recurring during the course of the needle procedure…who talks with the physician, explaining "Now, the physician enters, and now he is about to give you a needle prick here"… Well, I sense that when I say such things our child does not pay attention/comprehends in the same way…compared to if another person is present and explains these things, so it has been very good…to prepare him for this (Ilan: the imminent procedure).