

Children's experience of pain

A mixed methods study of the effect and influence of hospital clowns on hospitalized children aged 4-15 undergoing painful procedures

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A MIXED METHODS STUDY OF THE EFFECT AND
INFLUENCE OF HOSPITAL CLOWNS ON HOSPITALIZED
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DISSERTATION SUBMITTED 2019



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CV

Helle Nygård Kristensen graduated as a registered nurse from the nursing education in Viborg in 1988. Afterward, she moved to Aalborg and worked for 10 years in the pediatric oncology ward. While working in the pediatric unit, she developed an interest in leadership and started working as the head of the ward for 19 years. Through her various roles, she has systematically worked to contribute to the field by developing and evaluating targeted interventions for treatment and care for hospitalized children. She has a special interest in child perspective and collaboration with children and families with the *“child voice”* in mind. In 2004, she implemented the hospital clown program and worked closely with hospital clowns at the Pediatric Unit at Aalborg University Hospital. Her specific interest in securing best evidence-based clinical practice for children and families led to the start of a long educational career. Parallel to her job as a leader in the pediatric unit, in 2009, Helle started a one-year Healthcare Supplementary Education at Aarhus University. She obtained the Master of Clinical Nursing degree at Aarhus University in 2012 and finished a Pre-Ph.D. year at the University of Aalborg in 2014. During these years of leadership and education, Helle received funding for a Ph.D. and enrolled as a Ph.D. student in the Department of Clinical Medicine, Aalborg University in January 2016. This study provided Helle with a unique opportunity to focus on her special interest in caring for children and families in collaboration with health care professionals and hospital clowns.

ENGLISH SUMMARY

Hospitalized children around the world undergo painful procedures as an integrated part of treatment and care. Despite a continuous focus on pain management, research points to commonly under-recognized and undertreated procedural pain among hospitalized children. In general, children report that worst pain is caused by needles and invasive procedures. Unrelieved procedural pain can have psychological and emotional consequences, resulting in negative memories, distress, and fear of needles for future admissions and procedures.

Non-pharmacological strategies such as distraction interventions can help reduce pain and distress during painful procedures. Although hospital clowns are widely used at the pediatric clinics, there is limited knowledge of the effect and influence of hospital clowns on children's experience of pain and their ability to cope with common painful procedures. No studies have combined the quantitative and qualitative data to advance the knowledge of the child-hospital clown interactions during painful procedures. Thus, the aim of this mixed methods study was to expand knowledge of the effect and influence of the hospital clown on the pain experience of the hospitalized children aged 4–15 and their ability to cope during painful procedures and conditions in acute and recurrent hospitalizations.

This was sought through three individual studies. Study 1 comprised a prospective, non-blinded trial evaluation of the effect of the hospital clown on self-reported pain level compared with standard care with 111 acutely hospitalized children undergoing acute venipuncture procedures. In Study 2, a focused ethnography, including participant observations, informal interviews, and video recording, was used to explore the interactions between the hospital clown and 38 acutely hospitalized children undergoing acute venipuncture procedures in the admission unit. In study 3, a focused ethnography, including participant observations and informal interviews, was used to explore the recurrent interactions of 13 children undergoing various procedures and recurrent hospitalizations. Finally, results and findings were integrated during a mixed methods interpretation through narrative weaving and joint displays.

The results showed a positive effect on the pain intensity of the children aged 7–15 when the hospital clown was present during the acute venipuncture procedure. In contrast, a tendency for a higher pain score with

the presence of the hospital clown was found in children aged 4–6. Moreover, the results illustrated a limited effect of the hospital clown's presence when the children had previous experiences of venipunctures or were currently affected by the presence of a painful condition.

The exploration of the interactions with acutely hospitalized children undergoing venipuncture showed the importance of establishing a WE characterized by a responsive interaction between the child and hospital clown, tailored to the individual child throughout the process before, during, and after the venipuncture. Creating a familiar atmosphere and fostering a mutual understanding and a clear game plan through articulation, implementation, and evaluation with the child included helped strengthening the children's competencies in pain management and coping.

The exploration of the interactions with the recurrently hospitalized children showed that an ongoing WE based on a responsive interaction between the children and hospital clown had been established during the recurrent encounters. The hospital clown was found to be an important professional friend and common knowledge of the children's preferences, and the previously shared experiences were used to build up a trustful relationship, which positively influenced the children's expectations of managing the current situation and provided hope for managing painful situations in the future. Among the youngest children in a few cases, a hesitating attitude toward the hospital clown was observed.

The integrated mixed methods interpretation showed (1) an age-differentiated approach, (2) understanding of the child's condition, and (3) previous experiences as part of the child's history. In conclusion, a relationship with the hospital clown during a continuous responsive interaction, represented as a WE, strengthens the child's competencies in pain management and coping. The importance of supporting the child from the very first encounter and during the procedure and evaluation seems a special critical task for all health care professionals. The findings of this research advance knowledge of the psychosocial care of hospitalized children (aged 4–15) undergoing painful procedures. The research recommends initiating multidisciplinary initiatives, aimed at hospital clowns and their approaches to helping children manage pain arising from the procedures.

DANSK RESUME

På verdensplan udsættes indlagte børn for smertefulde procedurer som en integreret del af pleje og behandling. På trods af et konstant fokus på smertebehandling, peger forskning på, at der findes en udtalt grad af ikke opdaget og underbehandlet procedurerelateret smerte blandt indlagte børn. Generelt beskriver børn smerte relateret til stikke procedurer som den værst tænkelige smerte. Underbehandlet smerte kan være forbundet med psykologiske og emotionelle konsekvenser, som kan resultere i negative erindringer og stikke angst. Disse kan få betydning for fremtidige indlæggelser og smertefulde procedurer. Non-farmakologiske interventioner, som for eksempel distraktion, kan mindske oplevelsen af smerte og ubehag i forbindelse med procedurer. Selvom hospitals klovne i udbredt grad er implementeret i børneafdelinger, mangler der viden om effekten og indflydelsen af hospitals klovne på indlagte børns smerteoplevelse og evne til at klare sådanne procedurer. Ingen studier har kombineret kvantitative og kvalitative data med det formål at få viden om betydningen af en relation mellem indlagte børn og hospitals klovne relateret til almindelige smertefulde procedurer. Formålet med dette mixede metode studie var derfor at skabe viden om effekten og indflydelsen af hospitalsklovnen på 4-15 årige indlagte børns smerte oplevelse og evne til at håndtere smertefulde procedurer og tilstande i akutte og gentagne indlæggelser. Det blev undersøgt gennem 3 delstudier: en kvantitativ evaluering af effekten af hospitalsklovne sammenlignet med standard behandling, målt på selv rapporteret smerte hos 111 akut indlagte børn, der fik taget en blodprøve; et fokuseret etnografisk studie med udforskning af interaktionen mellem hospitalsklovnen og 38 akut indlagte børn, der fik taget en blodprøve, udført med deltager observationer, uformelle interviews og video optagelser; et fokuseret etnografisk studie med udforskning af interaktionen mellem hospitalsklovne og 13 børn, der gennemgik forskellige smertefulde procedurer og smertetilstande under gentagne indlæggelser, udført med deltager observationer og uformelle interviews; og endeligt en integration af resultater og fund i en mixed metode analyse.

Resultaterne af den kvantitative undersøgelse viste en positiv effekt på selv rapporteret smerte for de 7-15 årige, når hospitalsklovnen var til stede under en akut blodprøve. I modsætning hertil viste resultaterne en tendens

til en negativ effekt for de 4-6 årige. Desuden vistes en tendens til en mindre effekt, når børn havde tidligere erfaringer med blodprøver eller aktuelt havde ondt.

Udforskning af interaktionen mellem de akut indlagte børn og hospitalsklovn viste vigtigheden af at etablere et "WE", kendetegnet ved en gensidig opmærksomhed mellem barn og hospitalsklovn, skræddersyet det enkelte barn før, under og efter blodprøvetagning. Sammen med barnet blev skabt en tillidsfuld atmosfære, gensidig forståelse og specifik plan, som blev fulgt op af implementering og evaluering, hvilket så ud til at styrke børnenes kompetencer i at klare proceduren.

Udforskning af interaktionen mellem børn og hospitalsklovn i de gentagne procedurer og indlæggelser viste en kontinuerlig interaktion i et "WE". Her blev hospitalsklovn opfattet som en professionel ven, hvor fælles viden om barnet og tidligere oplevelser blev anvendt til at opbygge en tillidsfuld relation. Den tillidsfulde relation påvirkede børnene positivt i forhold til at klare den aktuelle situation og samtidig skabte den håb om at kunne klare fremtidige situationer. Blandt de yngste børn blev i få tilfælde observeret en mere tøvende adfærd i forhold til hospitalsklovn.

De integrerede fund viste (1) En alders differentieret strategi; (2) Forståelse for barnets situation; og (3) Tidligere oplevelser som en del af barnets historie. Det konkluderes i afhandlingen at en relation med hospitalsklovn gennem en kontinuerlig opmærksom interaktion, præsenteret som et "WE", styrker barnets evne til at klare en smertefuld situation både praktisk og følelsesmæssigt. Vigtigheden af at støtte barnet fra det første møde, gennem proceduren og en afsluttende evaluering understreges som særligt afgørende for alle sundhedsprofessionelle, der arbejder med syge børn. Forskningen bidrager med viden, der kan medvirke til at styrke den psykosociale pleje og behandling af 4-15 årige indlagte børn, der gennemgår smertefulde procedurer. Forskningen fremhæver ligeledes betydningen af at iværksætte multidisciplinære initiativer, der inkluderer hospitalsklovne og deres tilgang, når børn skal klare smerterelaterede procedurer.

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Helle Nygård Kristensen, February 2019

LIST OF PUBLICATIONS

1) Kristensen, H. N., Lundbye-Christensen, S., Haslund-Thomsen, H., Graven-Nielsen, T., Sørensen, E. E. (2018). Acute procedural pain in children: Intervention with the hospital clown. *The Clinical Journal of Pain*, 34(11), 1032–1038. doi:10.1097/AJP.0000000000000625

2) Kristensen, H. N., Sørensen, E. E., Stinson, J., Haslund-Thomsen, H. (2019a) "WE do it together!": An ethnographic study of the alliance between child and hospital clown during venipunctures. Resubmitted January 19, 2019 to *Journal of Pediatric Nursing*.

3) Kristensen, H. N., Sørensen, E. E., Stinson, J., Haslund-Thomsen, H. (2019b) "An ongoing WE": A focused ethnographic study of the relationship between child and hospital clown during recurrent pain-related procedures and conditions. Submitted February 5, 2019 to *Journal of Paediatric and Neonatal Pain*.

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Abbreviations

Lab tech: Biomedical laboratory technologist

HC: Hospital clown (used in joint displays)

VP: Venipuncture (used in joint displays)

FPS: Wong-Baker Faces Pain Scale

NRS: Numerical Rating Scale

CHAPTER 1. INTRODUCTION

As a registered nurse in the pediatric field throughout my career, I have always paid special attention to listening to the hospitalized child's voice. In the pediatric setting, I have experienced situations with a feeling of inadequate focus on the child's perspective and situations with children suffering from unmanaged pain. When entering the research field, I continued to have this focus. The thesis of my Master in Clinical Nursing in 2012 entitled "Is the child heard?" (Kristensen, Kronborg, & Grønkjær, 2014) was a quantitative investigation, focusing on 11–15-year-old children with psychosomatic symptoms and their perspectives in nursing documentation. The results confirmed that the child perspective on psychosomatic pain was described in less than half of the psychosocial documentation. Furthermore, the study concluded that these children are a vulnerable group, which needs to be given special attention by nurses and other health care professionals. That knowledge has continued to challenge me in my clinical practice and motivated me to focus on how we treat and care for children as a specially vulnerable group of patients, and how we maintain a focus on the child's perspective.

In addition, I was responsible for managing the hospital clowns in the pediatric unit in Aalborg in 2004 and paid special attention to their role and competencies. I began to ask myself if the hospital clown could play a role in eliciting the child's voice and perspective during treatment and care, related to pain and painful procedures. Pain is a very complex phenomenon and children suffering from acute or chronic pain, including treatment and care-related painful procedures, continue to experience unmanaged pain. Specifically, children describe pain related to needles as the worst pain possible (Birnie et al., 2014; Friedrichsdorf et al., 2015; Harrison et al., 2014; Walther-Larsen et al., 2017). Further, listening to the nurses in my clinical setting, wondering if the hospital clown might have a positive influence on a given painful situation for the child, where restraint and protest were present, made me curious about the strategies available for helping children through potential painful procedures. As a result, I asked the question if the hospital clown could have an impact on the child's experience of pain during potential painful procedures and conditions. Thus, this Ph.D. thesis will address the effect and influence of hospital clowns on 4–15-year-old

hospitalized children's experience and management of pain by using both quantitative and qualitative methods.

Conducting this research led to impressive and valuable moments with the nurses and hospital clowns, and especially children and their families during acute and long-term and/or recurrent hospitalizations, including painful procedures and conditions. The research provided a nuanced and deep insight into the interaction between the child and hospital clown and the influence on pain experience and the ability to cope with it. This will be elaborated in the thesis.

Finally, the quotation from a 7-year-old girl illustrated the core issue of giving voice to the child and a maintaining focus on improvement in managing the complexity in the field of pain. She evaluated her experience of pain on a pain scale after a venipuncture procedure: *"It doesn't hurt at all with the needle—it was zero. But, inside my head, my fear felt like a 10!!!"*

CHAPTER 2. BACKGROUND

The background and overall study is based on several literature searches conducted during the process. The rationale for the searches was to provide an overview of the existing knowledge regarding procedural pain in 4–15-year-old hospitalized children in acute and recurrent hospitalizations. In addition, the searches helped identify knowledge gaps in the use of hospital clowns as a non-pharmacological approach. This section focuses on the background of this thesis and consists of five distinct parts. First, a brief description of the search strategies during the study process is presented. Second, the field of pain concerning hospitalized children's ongoing common painful procedures is explained. Third, an overview of non-pharmacological strategies is given, and fourth, the national and international histories of hospital clown are outlined, followed by a review of research concerning the use of hospital clowns in pediatric settings. Finally, a summary and overall rationale for this research and thesis are presented.

2.1. LITERATURE REVIEW

In order to provide an overview of the existing evidence concerning hospitalized children's ongoing common pain-related procedures and how a non-pharmacological approach with hospital clowns may influence the experience of pain and ability to cope, a comprehensive literature search was conducted several times during the process. To ensure a systematic review, including peer-reviewed and gray literature, the searches were conducted in collaboration with librarians at the Medical Library in Aalborg University Hospital. The last updated search was conducted December 12, 2018 (Appendix A).

Initially, a systematic search (Table 1) was conducted in the following electronic databases: PubMed and Cinahl with MeSH and TextWord combined with AND/OR. Each search block was added a truncated free text search on specific words to strengthen the search (e.g., hospitaliz*). Based on this systematic literature review, an examination of the references lists in the relevant articles was performed. Furthermore, an Internet-based search was conducted using Google and Google Scholar especially concerning the term "hospital clowns." Initially, the search was organized following PICO in blocks with the following keywords:

Child OR adolescent OR preschool OR teen

AND

Inpatient OR hospitalized

AND

Non-pharmacological intervention OR psychological intervention OR hospital clown OR medical clown OR clown

AND

Pain OR procedural pain OR treatment related pain OR procedure OR diagnostic test OR medical procedures

The initial search was saved and repeated during the process in order to find new published studies (Table 1). During the process, more specific searches were conducted relating to specific topics or methodology used in the three papers (Table 1).

Table 1 Overview of the systematic searches during the process

Topic	Data base	Time
Initial search PICO	Pubmed, Cinahl	January 2016
Repeated PICO	Pubmed, Cinahl	March 2016
<i>Medical Clown</i>	Pubmed	July 2016
<i>Interview as a method AND children</i> (Papers 2 & 3)	Cinahl, Pubmed	July 2016
<i>Video as a method AND children</i> (Paper 2)	Cinahl, Pubmed	September 2016
Repeated <i>medical clown</i>	Pubmed	October 2016
<i>Pain measurement/ pain scales</i> (Paper 1)	Pubmed	March 2017
Repeated PICO, focus on qualitative studies	Pubmed, Cinahl,	December 2017
<i>Recurrent/repeated procedures</i> (Paper 3)	Pubmed, Cinahl	July 2018

Repeated PICO divided in 2 blocks: <i>Hospital clown</i> <i>Pain/procedures/children/hospitalized</i> (limits: 2018)*	Pubmed, Cinahl	December 2018
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**Non-pharmacological/psychological interventions* were not included in this search, based on an updated Cochrane review (Birnie, Noel, Chambers, Uman, & Parker, 2018)

2.2. PROCEDURAL PAIN

Pain due to medical procedures is a common experience during childhood. Hospitalized children of all ages suffering from acute or chronic diseases experience a variety of potentially painful procedures during examinations, treatment, and care (Birnie et al., 2018). Children often describe pain related to needles as the worst pain and the worst part of the disease (Friedrichsdorf et al., 2015; Walther-Larsen et al., 2017). In a Danish survey (Walther-Larsen et al., 2017) of the children aged 0–18 years old, procedure-related pain was cited by half of the children as the main challenge. Furthermore, 43% of children (≥ 5 years old) or parents of children (≤ 5 years old) indicated that they would have preferred a pain-relieving intervention. For children exposed to repeated and recurrent needle-related procedures, the experience can be even more painful (Bisogni et al., 2014; Plummer, McCarthy, McKenzie, Newall, & Manias, 2017; Twycross, Parker, Williams, & Gibson, 2015). Thereby, children having experiences of untreated pain are at risk of psychological negative consequences and a lower pain threshold (McMurtry et al., 2015; Noel, Chambers, Petter et al., 2012). The inadequate management of procedural pain can cause the children to run the risk of developing a fear of needles that can persist and have an impact on their future health (Birnie et al., 2018). Memory-reframing interventions are necessary to manage children’s pain and can be an asset for altering the distressing and fearful thoughts of the child, potentially resulting in reduced fear of future procedures and events (Noel, McMurtry, Pavlova, & Taddio, 2018). Specifically, assessing the memories of previous experiences and preparing the child to take these memories into consideration can form an important foundation for managing future painful procedures. In addition, the evaluation through subsequent discussion can raise awareness of the importance of the period after the end of the procedure (Noel et al., 2018). Nevertheless, research indicates that pain remains common among hospitalized children who continue to share experiences of the high frequency of undertreated pain, thus pointing to inadequate management of

pain with a need for improvement (Birnie et al., 2014; Friedrichsdorf et al., 2015; Walther-Larsen et al., 2017).

It is evidenced that children as young as four years old have the ability to share their own experiences related to specific events, and mostly they have the developmental level to provide self-report of pain (Docherty & Sandelowski, 1999; Spratling, Coke, & Minick, 2012; Tomlinson, von Baeyer, Stinson, & Sung, 2010; von Baeyer, Uman, Chambers, & Gouthro, 2011). Pain is a subjective experience, consisting of sensory, emotional, and cognitive aspects (www.iasp-pain.org). Thus, children respond differently to the same set of potential distressing and painful events, with some experiencing extreme distress and pain while others are relatively unaffected. These variances are explained by Lazarus and Folkman (Biggs, Brough, & Drummond, 2017; Lazarus & Folkman, 1984) as the complexity occurring between the anticipated stressor (e.g., hospitalization, painful procedure) and the individual perception of the event. Children can provide themselves with a comforting message to reframe their thoughts (child's cognitive coping effort). On the other hand, children can practice useful activities in advance, relating to behavioral efforts of coping with potential painful procedures, for example, breathing exercises (Thompson, 2018, see Chapter 9). Thus, the child's individual temperament, experiences, preferences as well as age and developmental level may impact on his/her coping response and may, as such, be taken into consideration when managing children's painful procedures and conditions (Koller & Goldman, 2012). Moreover, social and contextual terms such as family and parents' role may influence the child's perception of acute procedural pain and his/her ability to cope (Alotaibi, Higgins, Day, & Chan, 2018; Birnie, Chambers, Chorney, Fernandez, & McGrath, 2017; Koller, 2008). An integrative review (Alotaibi et al., 2018) pointed to parental participation as a facilitator for effective pain management. Birnie et al. (2017) found that the family function influenced the child's behavior, with both child and parents coping related to child acute pain. In a study by Svendsen, Moen, Pedersen, and Bjørk (2016), the interactions between parents and health care providers were investigated in situations with preschool children who resisted to cooperate during vein cannulation. Their study provided insights into the patterns of interaction that may advance our understanding of the kind of parental participation to support the child during painful procedures.

In summary, the multidimensional character of the experience comprises the complexity and difference between individuals and within different

situations. In order to address this complexity, pain management and assessment require equal multimodal and multidisciplinary approaches, including pharmacological and non-pharmacological pain-relieving strategies (Koller & Goldman, 2012; Staehelin Jensen, Dahl, & Arendt-Nielsen, 2013, see Chapter 19; Walther-Larsen et al., 2017). Therefore, the management and assessment of procedural pain require a special focus on variables such as age, developmental levels, previous experiences, etc. (Koller & Goldman, 2012), when addressing the intensity and experience of pain. Pain assessment is essential in terms of understanding, preventing, and relieving the child's pain. Assessment comprises the interactions between several factors that form the pain experience, such as physiological, cognitive, behavioral, and contextual (Association of Paediatric Anaesthetists, 2012). Accordingly, guidelines covering pediatric pain recommend a consistent and systematic assessment of pain in children of all ages (Association of Paediatric Anaesthetists, 2012; Center of Clinical Guidelines, 2016). The measurement of pain is related to the intensity of pain, and self-reports are often considered the preferred approach used by health care professionals. Nevertheless, complexity due to context, age, developmental level, and social- and family-related issues, among others, often requires supplementary approaches to measurement and management, such as observational and behavioral techniques as well as psychological strategies (Association of Paediatric Anaesthetists, 2012; Birnie et al., 2018; von Baeyer, 2006). Further research using complementary methodological approaches is recommended to address the different psychological strategies, participation, and preferences of the child during procedural pain (Birnie et al., 2018; Koller & Goldman, 2012).

2.3. NON-PHARMACOLOGICAL APPROACH

Clinical guidelines (Association of Paediatric Anaesthetists, 2012; Center of Clinical Guidelines, 2016) recommend the use of both pharmacological and non-pharmacological strategies when managing pain related to medical procedures in children. Non-pharmacological strategies can affect how children think or how they master a painful or distressing situation before, during, or after a needle-related procedure (Birnie et al., 2018; Stinson, Yamada, Dickson, Lamba, & Stevens, 2008; Thompson, 2018). Non-pharmacological strategies can be used by children or with support from parents or health care professionals, such as nurses, doctors, psychologists, hospital clowns, or child life specialists (Birnie et al., 2018). These strategies can provide the child with a sense of predictability and feeling of control and,

thereby, enhance the child's ability to manage a distressing situation (Thompson, 2018). A review by Birnie et al. (2018) identified evidence that strategies such as distraction, hypnosis, breathing, and combined cognitive behavioral therapy can minimize pain and distress, related to medical procedures. Research concerning nurses' use of non-pharmacological strategies (Svendsen & Bjørk, 2014) found that nurses drew on non-pharmacological strategies to establish and maintain cooperation during painful and challenging procedures with hospitalized children. When personalizing and tailoring the non-pharmacological approaches to a particular child in a specific context and situation using a variety of strategies, the nurses in the study experienced better cooperation with children. The non-pharmacological approaches used among the nurses included connecting with a positive atmosphere, giving the child control, and distracting the child's attention (Svendsen & Bjørk, 2014). The act of guiding children through a painful procedure by using non-pharmacological approaches (e.g., play) need to be grounded on a trustful and secure atmosphere and specific knowledge of the child. Hence, support can facilitate the participation and involvement of the child during painful procedures (Karlsson, Dalheim Englund, Enskar, Nystrom, & Rydstrom, 2016). A trustful, respectful relationship and communication between child and nurse is further described in a review as a facilitator for effective pain care among nurses (Alotaibi et al., 2018). Hence, best practices in the choice of approach may be found through knowledge of the individual child with an identification of the individual child's previous experiences and preferences (Koller & Goldman, 2012). As such, any intervention should ideally match the individual child in a specific context (Birnie et al., 2018). To fulfill this, it seems essential to engage with the child at different points during hospitalization or during a specific distressing and painful experience (e.g., an evaluation part) (Thompson, 2018).

2.4. HOSPITAL CLOWN

2.4.1 HISTORY

Hospital clowns have a long international history. Patch Adams—a medical doctor—is considered the world's first hospital clown in 1971 in the U.S. In 1986, the Big Apple Circus Clown Care Unit, among others, was established by Michael Christensen in New York City, and was the first organized hospital

clown program with hospital clowns working in hospitals (Tan, Metsälä, & Hannula, 2014). Programs are now operating in many countries in the world (Dionigi, 2017).

In Europe, the *European Federation of Healthcare Clown Organizations* (EFHCO) was established in 2011. It was founded to protect and support professional clown work in a health care environment in a European setting, in particular, caring for hospitalized children, their families, and other vulnerable and sick people (<http://www.efhco.eu>). Inspired by the International Survey of Hospital Clown Organizations (ISHCO), a database of health care clown organizations worldwide has been developed by EFCHO. Hence, about 176 organizations are registered worldwide.

Hospital clowns started working in pediatrics in Denmark in 2001. In Denmark, the hospital clowns are organized by The Danish Hospital Clown Organization (<https://danskehospitalskllovne.dk>), established in 2003, to secure a formalized education and the drafting of professional standards for the hospital clown profession. Danish hospital clowns are educated during this one and a half year internationally recognized program and continuing training (<https://danskehospitalskllovne.dk>). Besides the formalized education, all the hospital clowns come from various backgrounds, and the role requires artistic and empathetic abilities (Tan et al., 2014).

In 2018, the Danish organization had 53 hospital clowns, covering all pediatric units in Denmark and some pediatric psychiatric units. The hospital clowns are organized and scheduled to work in specific settings in specific hospitals to secure continuity and to know each other as professionals. Mostly, the hospital clowns work in pairs.

In the Danish and European contexts, hospital clowns have a formalized education. They are trained to act as a hospital clown, combined with an understanding of medical knowledge and patient behavior (Wolyniez et al., 2013). Hospital clowns can offer individual, playful interventions and reach out to the child affected by illness. They use many techniques including theatre, clowning, improvisation, rhythm, music, and magic (<http://www.efhco.eu>). In particular the clown creates forms of play tending to invite the individual child into an imaginative and safe relationship, which can promote his/her well-being (Kingsnorth, Blain, & McKeever, 2011) and support the child in potentially stressful situations (Koller & Gryski, 2008; Linge, 2012, 2013; Kristensen, Elgaard Sorensen, Stinson, Haslund-Thomsen,

2019a, 2019b, under review). To work as a hospital clown requires professionalism in collaboration with the staff at the hospital.

2.4.2 REVIEW OF LITERATURE

To date, a number of trials with an intervention with hospital clowns using self-reported pain scales have shown conflicting results concerning the alleviative effect during hospitalization and potential painful medical procedures or conditions (Sridharan & Sivaramakrishnan, 2016), shown in the meta-analysis as a positive effect on anxiety but with no effect on pain. Nevertheless, a current study (Kristensen, Lundbye-Christensen, Haslund-Thomsen, Graven-Nielsen, & Elgaard Sorensen, 2018) found a pain relieving effect on children aged 7–15 during an acute venipuncture procedure. A review from Finlay, Baverstock, and Lenton (2014) found that the literature concerning hospital clowns is divided into three categories: (a) practical procedures (e.g., anesthesia, medical procedures, and examinations), (b) medical conditions (e.g., respiratory diseases), and (c) hospital clown within clinical teams. In conclusion, they argue that the use of clowns can have an overall positive effect and that they may be used to complement the traditional interventions in clinical practice. Based on several semi-structured interviews with parents, recent research (Bruins Slot, Hendriks, & Batenburg, 2018) managed to throw new light on the impact of hospital clowns on children, parents, and health care professionals in care settings other than hospitals. In addition, the abovementioned study focused on the actors and conditions that can influence the effect of the hospital clown and thereby added new perspectives to the previous literature. A new study on children suffering from pediatric burn injury documented how therapeutic clowning positively affected the older children's compliance with burn dressing change (Yildirim, Koroglu, Yucel, Kirlak, & Sen, 2019). As evident, research into the field of hospital clowns is growing, and many studies demonstrate different aspects of the benefits of hospital clowns and recognize hospital clowns as an integral part of the pediatric units. Nevertheless, the evaluation of the effect of hospital clowns is complex, as the performance of the hospital clown may be seen as a multi-modal intervention with combined impact on a variety of specific medical and painful conditions in different pediatric contexts (Finlay et al., 2014).

Moreover, only a few studies discuss the phenomenon *coulrophobia*—an irrational fear or dislike of clowns. A study by Bruins Slot et al. (2018) and Yildirim et al. (2019) found some cases of children feeling overwhelmed and

not enjoying the presence of the hospital clown. Nevertheless, an overall positive value of hospital clowns was reported from both children, parents, and health care providers. Meiri, Schnapp, et al. (2017) conducted a cross-sectional study on children aged 1–15 from the general pediatric hospitalized population and showed that only 14 out of 1160 children experienced a fear of clowns. Findings from Kristensen et al. (2018) registered no fear of clowns.

The hospital clowns' interactions with children in the pediatric unit are mostly cited by health care professionals as positive support that can help children adapt to various situations and further support the health care professionals' work with hospitalized children (Battrick, Glasper, Prudhoe, & Weaver, 2007; Finlay et al., 2014; Koller & Gryski, 2008). Nevertheless, further research is needed to investigate collaboration and communication between hospital clowns and health care professionals (Finlay et al., 2014; van Venrooij & Barnhoorn, 2016). Despite the growth of hospital clowns programs in the pediatric units, research concerning the impact of the systematic use of hospital clowns related to uniform painful medical procedures remains sparse (Kristensen et al., 2018).

2.5. SUMMARY AND RATIONALE FOR THIS RESEARCH

In summary, painful procedures are common during childhood, and needle-related procedures experienced by children are specifically cited as the worst pain, which also involves some of the most challenging procedures during hospitalization. The existing literature revealed that children continue experiencing undermanaged pain during hospitalization, comprising various medical procedures and conditions related to treatment and care. Moreover, children experiencing repeated painful procedures and conditions are at special risk, due to the fact that memories of previous experiences play a crucial role in coping with and response to future painful events. Hence, in managing the procedural treatment and care-related pain in hospitalized children, there still is an urgent need to reduce the experiences of pain and distress, enhancing the child's individual coping competencies.

Integrating non-pharmacological strategies is recommended to optimize and secure adequate pain management and to influence the hospitalized children's experience of pain and ability to cope during pain-related procedures and conditions. The hospital clown is characterized as a non-pharmacological strategy, operating intuitively in a professional approach,

tailored to individual child and context and by promoting the active participation of the child. Although many pediatric settings routinely use hospital clowns, there is still a lack of evidence in the complex field of assessing the effect and influence of a systematic intervention with the hospital clown in the context of hospitalized children undergoing common painful procedures and conditions.

It is hoped that the research of hospital clowns will make a significant contribution to the existing research on the use of non-pharmacological strategies in the field of procedure-related pain. The rationale for this study was therefore to expand knowledge of the effect and influence of the hospital clown on the pain experience of the hospitalized children aged 4–15 and their ability to cope during painful procedures and conditions in acute and recurrent hospitalizations. Overall, complexity characterizes this field, both regarding pain as a subjective experience, which can be moderated by various strategies and remain difficult to be assessed and evaluated. Therefore, a mixed methods design was chosen in order to draw on the strengths of both quantitative and qualitative methods.

CHAPTER 3. AIM AND OBJECTIVES

In this section, the aim of this thesis and the objectives of Studies 1, 2, and 3 are presented. This is followed by a short clarification of the choice of *age*, and use of *biomedical laboratory technologist* in this thesis.

Aim of the thesis

The aim of this mixed methods convergent study was to integrate quantitative and qualitative data to expand knowledge of the effect and influence of the hospital clown on the pain experience of the hospitalized children aged 4–15 and their ability to cope during painful procedures and conditions in acute and recurrent hospitalizations.

Study 1

The objective of this quantitative study was to evaluate the effect of an intervention with the hospital clown on self-reported pain level, compared to standard care for children receiving venipuncture in the pediatric admission unit at a hospital. The study focused on examining potential differences in intervention effect based on (a) age group [4–6 years old versus 7–15 years old], and (b) the presence of a painful condition prior to venipuncture or previous pain experiences (Paper 1).

Study 2

The objective of this qualitative study was to explore what characterizes the interaction between the acutely hospitalized child and hospital clown, and how this interaction influences the child's experience of pain and his/her ability to cope during a venipuncture procedure (Paper 2).

Study 3

The objective of this qualitative study was to explore what characterizes the interaction between the child and hospital clown during recurrent hospitalizations, comprising repeated pain-related procedures and conditions (Paper 3).

Clarification of age and biomedical laboratory technologist

Age

In this thesis, children aged 4–15 are included; young/younger refers to children aged 4–6, and old/older refers to children who are aged between 7 and 15. One criterion for this choice of age included the upper age limit in the pediatric clinics in Denmark, which is approximately 15. Another criterion included the lower age limit of four, because the participants from the age of four are old enough and have the necessary developmental abilities to be able to share their experiences and thoughts and self-report their pain (Docherty & Sandelowski, 1999; Spratling et al., 2012; Tomlinson et al., 2010; von Baeyer et al., 2011) (see Section 2.2 for procedural pain).

Biomedical laboratory technologist

In Studies 1 and 2, a biomedical laboratory technologist—known as a *lab tech*—was requested, when the child was scheduled for a venipuncture procedure. In Study 3, either the biomedical laboratory technologist or the nurses conducted the venipunctures/blood tests from port a cath.

CHAPTER 4. RESEARCH DESIGN

In this section, mixed methods approach is presented as the overall methodology used in the thesis. This is followed by a description of the philosophical assumptions, the overall research design, and the specific levels of integration.

4.1. MIXED METHODS

The rationale and justification for choosing mixed methods was the complexity in the aim of this thesis, intending to provide knowledge of the effect and influence of the hospital clown on the pain experience of the hospitalized children aged 4–15 and their ability to cope during painful procedures and conditions in acute and recurrent hospitalizations. Furthermore, this research was a response to a wish to investigate the phenomenon of pain experience based on the perspective of the child by giving voice to the child. A mixed methods research design justifies the use of multiple approaches and is an expansive, inclusive, and creative form of research to offer depth in answer to specific research questions (Johnson & Onwuegbuzie, 2004). Thus, the questions in this thesis could not be investigated in depth by quantitative or qualitative approaches alone. The adoption of the mixed methods approach in this thesis increases the chance of gaining unique insights into the multifaceted topic of hospitalized children's pain experience (Fetters, Curry, & Creswell, 2013). Viewing the term “methods” in a broader sense as *methodology* (Johnson, Onwuegbuzie, & Turner, 2007), the rationale for choosing a mixed methods approach includes strategies encompassing data collection (e.g., observations, measurement), methods of research (e.g., experiments and focused ethnography), and related philosophical assumptions.

As the three studies in this thesis were written and published in stages, a precise focus on the methodology for each study was important to secure validity and transparency, mainly because of the principles and values of each method and their subsequent integration.

Mixed methods methodology is defined as a research design that includes both philosophical assumptions and methods of inquiry (Creswell & Plano Clark, 2018), meaning that the philosophical assumptions guide the research process, and the methods guide the collection and analysis of data. A central premise in mixed methods is that a combination of both quantitative and

qualitative data provides a better understanding of the phenomenon under investigation than either approach alone, hence a sufficient breadth and depth in understanding the topic (Creswell & Plano Clark, 2018, see Chapter 1). The additional work of the integration of quantitative results and qualitative findings in this thesis sought to provide an added value and a better understanding of the research problem (Fetters & Freshwater, 2015).

4.2. PHILOSOPHICAL ASSUMPTIONS

Research begins with thoughts concerning a specific problem of interest, followed by a set of questions that attempt to provide knowledge of the specific topic (Mesel, 2013). Hence, from the beginning, thoughts and questions from nurses' in the pediatric clinic have informed the research questions in this thesis, which in turn have determined the selection of the methods.

Underlying this research are the philosophical assumptions that play an important role in defining the lens through which the topic is viewed, questions are asked, and methods are chosen (Mesel, 2013). The worldview for this convergent mixed methods study is pragmatism. Pragmatism involves flexible and practical decisions concerning the design to address the aim and the research questions of interest in the specific real world context, ensuring clinically meaningful findings (Creswell & Plano Clark, 2018).

Pragmatism is acknowledged in mixed methods research as an approach that provides multiple perspectives and enables the researcher to engage in a pluralistic position, meaning gathering both quantitative and qualitative data to answer the research question (Creswell & Plano Clark, 2018) and further guiding the merging of the two approaches into a more complete interpretation. Thus, a pragmatic approach combines deductive and inductive thinking (Creswell & Clarke, 2018). Accordingly, from an ontological perspective, pragmatism acknowledges both singular and multiple realities—the importance of both a physical world and a social and psychological world (Johnson & Onwuegbuzie, 2004). A pragmatic framework requires explicit systematic considerations of the practical and contextual responses as well as consequential criteria for making the decisions for the design (Datta, 2004). Thereby, in conducting this research, a real-world practice-oriented worldview was required. This worldview took into account questions of the practicality concerning access to the field and participants, the time needed

for the empirical data collection at different settings, “what worked” to address the questions related to the problem, the usability of the results, etc.

Finally, mixed methods research requires that the researcher be competent in several areas, due to the collective presence of quantitative, qualitative, and mixed methods approaches. Specifically, when choosing a mixed methods approach, the methodological approach requires a specific and careful choice concerning the integration of findings (Fetters et al., 2013). Accordingly, as a researcher working back and forth between different worldviews and frames captures the duality in pragmatism (Morgan, 2007). Thus, in each study included in this thesis, a mutual understanding of all the aspects of research is emphasized during continuous processes of supervision, communication, review, shared decisions of meaning and dialogue with participants (nurses, hospital clowns, parents), colleagues and supervisor team, in accordance with the pragmatic approach (Morgan, 2007).

4.3. RESEARCH DESIGN

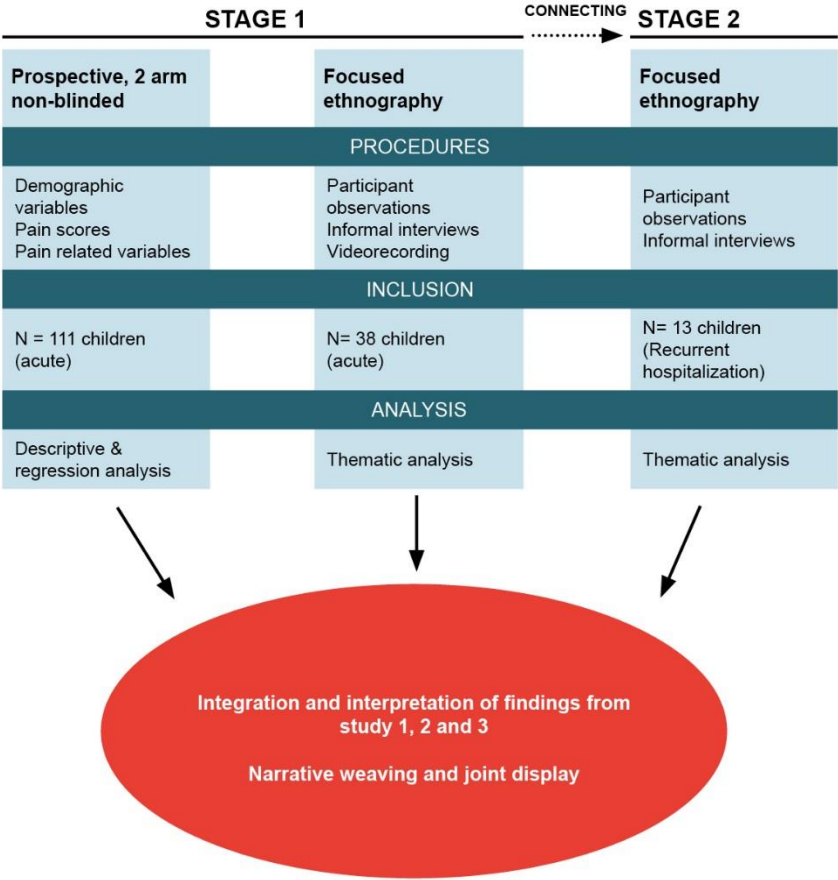
The overall program for this mixed methods study was a convergent design, consisting of three individual studies, involving two distinct stages of data collection within a sequential approach (Figure 1, p. 35). The quantitative and qualitative methods had equal priority and addressed the same concept (pain experience) (Creswell & Clarke, 2018). The thinking beyond this research is based on a dynamic approach rather than trying to fit it into an existing typology, meaning that the typology of convergent design is used as a guiding framework (Creswell & Clarke, 2018). The rationale for this will be elaborated in integration at the design level (Section 4.4).

Study 1 was a quantitative study; a prospective non-blinded study in a parallel design, investigating pain intensity in two groups of acutely hospitalized children, aged 4–15, assigned to a hospital clown intervention or standard care (Kristensen et al., 2018). Study 2 was a focused ethnography on acutely hospitalized children, aged 4–15, with field observations, informal interviews, and video recordings as data sources (Kristensen et al., 2019a, under review). Study 3 was a focused ethnography on recurrent or long-term 4–15-year-old hospitalized children with field observations and informal interviews (Kristensen et al. 2019b, under review). Thus, the sampling strategy was decided to first include a nested strategy (Creswell & Plano Clark, 2018; Fetters & Molina-Azorin, 2017) with the same individuals

(Studies 1 & 2), including quantitative data from a larger group of participants and qualitative data from a subgroup. Second, a separate strategy (Fetters & Molina-Azorin, 2017), including different individuals (Studies 1 & 2 versus Study 3), added qualitative data from recurrent hospitalizations.

In Studies 1 and 2, a concurrent timing took place in an acute pediatric admission unit by collecting both quantitative and qualitative data concurrently and analyzing them separately (Creswell & Clark, 2018). To fulfill the purpose of comparing and relating the datasets, the included children from the qualitative sample (Study 2) were a subset of the children participating in the quantitative sample (Study 1). A subsequent data collection period and analysis took place for Study 3, reasoned by the research question to include both acute and recurrent pain experiences and thereby the need for choosing different contexts. Hence, a ward treating and caring for children with cancer and rheumatological diseases was chosen in Study 3. Thereby, the different children and context in Study 3 ensured the perspectives of recurrent procedures. In the first stage, several interactions occurred at different points (Creswell & Clark, 2018); for example, the registration of pain scores (quantitative strand) was collected parallel to participant observations, informal interviews with children, and video recording (qualitative strand) concerning their words/explanations and experiences of the score. The second stage (Study 3) was linked during *connecting* (Figure 1, p. 35), due to the insights from the first stage. Thus, the thesis became an example of combining both fixed and emergent elements in the design (Creswell, 2014; Creswell & Clark, 2018), meaning that, although the study from the beginning was planned with three studies in two stages, details and nuances emerged based on the interpretation of the results from the initial Studies 1 and 2, and thereby added elements to the rationale, focus, and planning of Study 3 (e.g., focus on previous pain experiences, the structure of how to follow the hospital clowns and children over recurrent encounters).

Figure 1. A convergent mixed methods study



Integration is essential to the mixed methods methodology, which enables producing a whole that is greater than the sum of the individual quantitative and qualitative components (Fetters & Freshwater, 2015). Integration is defined as bringing the two forms of data together to “*communicate with each other*” (Fetters et al., 2013). Thus, the important questions throughout this thesis create the synergy brought about by integrating quantitative and qualitative results at multiple levels (Fetters & Freshwater, 2015). Both forms of data are necessary for understanding the research questions, and integration can occur at “*any point in a study where two or more research components are mixed or connected in some way*” (Schoonenboom & Johnson, 2017, p. 116). Thus, the mixed methods approach in this thesis was important for investigating the field of pain, expressed during the children’s perspective, aimed to achieve a more complete understanding of the effect and influence of the hospital clown on the pain experience of the hospitalized children aged 4–15 and their ability to cope during painful procedures and conditions in acute and recurrent hospitalizations. Therefore, integration in this thesis is vital to an understanding of the complexity. Integration will be elaborated in the following sections.

4.4. INTEGRATION AT DESIGN LEVEL

In this thesis, integration at the design level was accomplished by using a convergent design (see Figure 1, p. 35). The convergent design is defined as the concurrent collection of quantitative and qualitative data to implement the two strands during the same phase and with equal priority (Creswell & Clark, 2018). Specifically, in this thesis, the traditional definition of the convergent design is further developed by *connecting* Study 3 with a data collection period in a second time frame (illustrated with a dotted arrow in Figure 1). In accordance with the mixed methods literature (Creswell, 2014; Creswell & Plano Clark, 2018; Fetters et al., 2013), *connecting* is usually used as integration at methods level in sequential designs. In this thesis, the term *connecting* is used at the design level, although the data collection period takes place in a different time frame. The *connecting* occurred when linking the qualitative data concerning two identical assessments of experiences and coping during painful procedures and conditions in children, both acutely and recurrently hospitalized, in Studies 2 and 3.

4.5. INTEGRATION AT METHODS LEVEL

The integration at the methods level is conceptualized by Creswell & Clark (2018) to occur during linking the methods and the analysis. The linking can occur in four different ways: connecting, building, merging, and embedding. In this thesis, the integration involved merging the quantitative (Study 1) and the qualitative phases (Studies 2 and 3) in order to compare the results from the three strands (Fetters et al., 2013). The data collection took place through both parallel (Studies 1 and 2) and sequential strategies (Study 3), followed by separated analyses of the three studies. Specifically, the data collection procedures were carried out by asking the same questions on both the quantitative (pain intensity scores) and qualitative side (participant observations, informal interviews, and video recording concerning pain experience and ability to cope). During the process of data collection and analysis, an interactive approach was conducted, as described by Fetters et al (2013), in which remaining in the field as a researcher informed the data collection approach and nuanced the questions and the participant observations. Hence, the question of the ability to cope with pain during procedures is based on the qualitative participant observations, informal interviews, and video recording, tightly connected with the experience of pain intensity from the quantitative data. Integration by merging typically occurs after the statistical analysis of the numerical data and the qualitative analysis of the textual and visual data (Fetters et al., 2013), which is consistent with the three studies in this thesis.

4.6. INTEGRATION AT INTERPRETATION AND REPORTING LEVEL

The intent of the integration at the interpretation and reporting level is to expand the knowledge of the effect and influence of the hospital clown on the pain experience of the hospitalized children aged 4–15 and their ability to cope during painful procedures and conditions in acute and recurrent hospitalizations. Thereby, the quantitative results from Study 1 and the qualitative findings from Studies 2 and 3 are merged into an overall interpretation to fulfill the aim of this mixed methods convergent study, resulting in an added value (Fetters & Freshwater, 2015). Concerning the practical approach for merging first, a linking of the quantitative constructs and the qualitative themes was conducted by seeking common concepts (Creswell & Clark, 2018). Second, the merging is outlined via a narrative approach (Fetters et al., 2013; Fetters & Molina-Azorin, 2017), identifying similarities and differences within the three datasets. Joint displays were

applied with the purpose of directly comparing the results through a visual means (Creswell & Clark, 2018; Fetters et al., 2013). Concerning the analytical approach, a bidirectional perspective is chosen. This means a frame for the analysis at an analytical level, including the merging of the data with both quantitative and qualitative lenses simultaneously in an interactive back and forth process (Moseholm & Fetters, 2017). The quantitative and qualitative data are given equal weight during the merging. The fit of integration assessed during integration of Studies 1, 2, and 3 resulted in either *confirmation* (the findings confirmed each other), *complementarity* (the findings showed different but non-conflicting perspectives), *expansion* (the findings broadened the understanding), or *discordance* (the findings conflicted, contradicted, or disagreed with each other) (Fetters et al., 2013; Fetters & Molina-Azorin, 2017). As each of the studies was reported in separate papers, the overall integration and mixed methods interpretation were conducted during a staged approach with cross-referencing to the individual related papers (Fetters & Molina-Azorin, 2017).

CHAPTER 5. METHODS

In the following section methods and materials of Studies 1, 2, and 3 are presented. The presentation for Study 1 includes the statistical analysis and the focused ethnographic approach for Studies 2 and 3. A major issue addressed in the choice of mixed methods is the sampling strategy and the integration (see Sections 4.4., 4.5, and 4.6 for details regarding integration). Sampling in mixed methods refers to the sampling procedure for selecting both participants and settings for the quantitative and qualitative data collection due to the research design (Creswell, 2014). Thus, the sampling strategy will be elaborated in this section, including methods, data collection, and analysis. This information is based on the completed papers. Finally, an overall outline of the ethical considerations is presented.

5.1. STUDY 1

Design and materials

Study 1 (Kristensen et al., 2018) was a prospective parallel non-blinded study. Children aged 4–15 who were acutely admitted to the admission unit and scheduled a venipuncture were included. Children were assigned to either a hospital clown intervention or standard care during a venipuncture procedure. Inclusion required that the participants have the cognitive abilities to cooperate with self-reporting of pain, to be followed by at least one parent, and to speak Danish or English. In total, 116 children were enrolled in the study. Data from 111 children were included in the analysis, 49 in a hospital clown group and 62 in a standard care group (illustrated with details in a CONSORT flow diagram in Paper 1). A sample size of 52 children in each group was estimated, based on an expected deviation of pain scores of 10–20%, assuming α -level of 5% and power of 80% (Paper 1). The study is registered in www.clinicaltrials.gov (ID: NCT03366623) December 8, 2017.

Allocation

The study required a specific time frame for the hospital clown, scheduled before starting the recruitment of children, in order to secure the needed presence of the hospital clown. The hospital clown engaged with all the eligible children undergoing a venipuncture on these scheduled days and time intervals. Thereby, children were assigned to the hospital clown group

on the scheduled days and to the standard care group on days when the hospital clown was not available. A pilot study was conducted prior to the study to secure random distribution of gender, age, and diagnosis independent of the presence of the hospital clown (Paper 1).

Intervention

One male hospital clown was used for all the included children to secure minimal variation in the approach and strategies used by the hospital clown during the interaction. The child met the clown before the venipuncture procedure either in the waiting area or in the examination room.

The venipuncture procedure was performed by the biomedical laboratory technologist (referred to as *lab tech*). Often the child was added local anesthetic, which was removed by nurses before the venipuncture. The lab tech unpacked and prepared the equipment, inspected the child's arm, and placed and tightened a tourniquet. The needle (mostly a small butterfly) was inserted into the vein in the elbow. A tube holder and multiple evacuated tubes were attached to the butterfly and removed after they were filled with blood. A small patch was applied after the procedure, and the child was told to bend the arm for a short time. Lab tech left the room immediately after the venipuncture procedure.

The clown followed the child during the procedure and left when the procedure was completed and the child left the room or the admission unit. The hospital clown used different strategies before and during the procedure, such as music, songs, making temporary tattoos, holding hands, guiding, etc. The group of children allocated to the standard care group collaborated with the nurses before the procedure. The nurses verbally explained how the procedure should be, and primarily the lab tech guided through the procedure. The nurses and lab techs were randomly distributed in both groups and were not instructed to use a specific strategy, nor were the parents.

Data collection and pain assessment

Nurses or the researcher obtained baseline information (Paper 1). Self-reported pain on two age-appropriate scales (Numerical Rating Scale and Wong–Baker Faces Pain Scale) was performed by the nurse or the researcher immediately after the venipuncture procedure, during a time interval

between 0 and 5 minutes (Paper 1). Assessment of pain intensity using self-report is the recommended source in health care for children as young as 3 years of age (Tomlinson et al., 2010; von Baeyer et al., 2011). The scales are widely used in pediatric clinics (Stinson, Kavanagh, Yamada, Gill, & Stevens, 2006) and thereby well-known and usually used among the nurses in the unit. The scales were depicted on one card (Appendix F), and the child was invited to choose the scale fitting the child best, accounting for age, cognitive capacities, and developmental level (Association of Paediatric Anaesthetists, 2012; Center of Clinical Guidelines, 2016; Stinson et al., 2006).

Data analysis

Descriptive statistic was used to describe the homogeneity in general characteristics of the two groups of participants (hospital clown and standard care) (Table 1, Paper 1). Primary outcome (pain score) and other characteristics (e.g., age, gender, pain, previous venipunctures) were compared using unpaired 2-sample *t*-test. In order to capture the effect of the potential intermediate variables (e.g., local anesthetic, nitrous oxide, time per procedure, and the number of punctures), the adjusted analysis was performed using multivariable linear regression (Kirkwood & Sterne, 2003). Further analysis stratified by age (4–6 and 7–15), gender, pain, and prior venipunctures were conducted and compared by multivariable linear regression. The cut off for age groups (4–6 and 7–15) was evidenced from the literature, addressing challenges in providing self-report of pain in younger children (Kristensen et al., 2018). Bootstrapping with 1000 replications were added in all the analyses to estimate the standard error. The analysis was conducted using STATA version 14 software. Significance was found for *P*-values ≤ 0.05 .

5.2. STUDY 2

Methodology

Study 2 (Kristensen et al., 2019a, under review) was a focused ethnography. Ethnography provides knowledge of an entire culture in a process, focusing on learning about people by learning from people (Cruz & Higginbottom, 2013; Higginbottom, Pillay, & Baudu, 2013). Hence, the tradition of ethnography involves an understanding of life from the native point of view (Spradley, 1980) and is conducted in the natural setting and in real time, often staying in the field for a long period. Focused ethnography can be

delineated as complementary to ethnography to understand more specific aspects of a cultural setting and a participant's experiences of a defined element (Cruz & Higginbottom, 2013). Hence, the use of focused ethnography seemed appropriate in this study and aligned with the aim of exploring what characterized the interaction between the acutely hospitalized child and the hospital clown; focused ethnography also helped understand how this interaction influenced the children's experience of pain and their ability to cope during a venipuncture procedure in a specific context of acute hospitalization in the admission unit.

Setting and participants

The study was undertaken at two public general university hospitals (primary and secondary setting, explained in the text below and in Table 1, Paper 2). In the study, 38 children from the primary setting were included from a sample of children allocated to the non-blinded trial concurrently (Study 1, Paper 1) (Kristensen et al., 2018). The children were aged 4–15 and were acutely admitted to the admission unit at the pediatric ward and scheduled a venipuncture procedure by a pediatric doctor. The children were followed by at least one parent.

Data collection

The main data collection of the fieldwork comprised participant observation, informal interviews, and video recording, which was primarily undertaken in one pediatric admission unit during a nine-month period from April 2016 to January 2017 (despite three weeks in the second setting, December 1 to December 16, 2016). This period of data collection was extended due to a large variation in the number of the acutely admitted children for whom a venipuncture was prescribed. After having been examined by the nurse and doctor and prescribed a venipuncture, the children and their families were informed about the study by the nurse or the researcher. All the families agreed to participate. The researcher followed one hospital clown during the period. This specific hospital clown was well-known in the pediatric clinic and among the nurses but did not usually work in the admission unit before this study was undertaken. When children and their parents were introduced to the study and their consent was obtained, the children and the hospital clown were introduced to each other in the waiting area.

The participant observations were short and lasted 3–6 hours a day (Cruz & Higginbottom, 2013; Knoblauch, 2005). The researcher followed all the interactions between the children and the hospital clown for the period. Initially, grand-tour descriptive observations (Spradley, 1980) were obtained to get an overview of the typical admission of the acutely hospitalized children. These participant observations included children for whom either a venipuncture was prescribed or not as well as the situations with and without the presence of the hospital clown. These grand-tour observations were followed by focused participant observations (mini-tour) (Spradley, 1980), specifically focusing on the child-hospital clown interaction before, during, and after a venipuncture procedure, based on features such as place, actor, activities, object, goal, and feelings (Spradley, 1980).

The informal interviews were conducted both during and after the venipuncture procedure when the children collaborated with the clown as well as with the nurse and the researcher in scoring their pain and articulating their experience. The informal interviews were conducted in a creative, playful, and childlike manner (Spratling et al., 2012), with the clown typically taking the children's point of view, for example by using the children's own words, expressions, or toys in the interactions. These informal conversations during the process allowed time for the relationship to develop and drew on multiple sources (e.g., play, using temporary tattoos, and verbal and non-verbal communication) (Carnevale, Macdonald, Bluebond-Langner, & McKeever, 2008). This approach encouraged the children to describe what was important for them in the current situation, which promoted the relationship and the articulating of their experience (Roper & Shapira, 2000). Often the younger children needed more guidance on how to share their experiences (Docherty & Sandelowski, 1999) and were helped by the visual pain scale used as a kind of cue to enhance the interview.

Some of the interactions (13 children/in total 2 hours) were video-recorded during the data collection process to focus on nuances in their interactions based on auditory and visual senses (Derry et al., 2010). The video recording was primarily done to validate and distinguish the participant observations (Bazeley & Jackson, 2013). Based on a more deductive approach (Derry et al., 2010), the video segments were recorded and justified in the specific research question of capturing details in the interaction between child and clown during the specific venipuncture procedure (no video recording before and after). During the data collection period, including video recording, roles were often switched; the researcher wrote the field notes and the nurse

handled the camera or the researcher handled the camera and afterward evaluated and made notes with the nurse and the hospital clown. Children, parents, nurses, and lab techs were specifically informed in the cases that involved video.

During the final period, the researcher undertook selective observations (Spradley, 1980), following five clowns for a shorter period (December 1 to December 16, 2016) in the secondary setting (pediatric admission unit), comparable with the primary setting (outlined in Table 1, Paper 2). A move between different settings can facilitate capturing new perspectives in recurrent situations (Atkinson, 2015). Thus, to go outside the primary setting for collecting supplementary data was motivated by a desire to capture the nuances, perspectives, and diversity in the interactions between the child and hospital clown; furthermore, to explore the similarities and/or differences in the hospital clown approaches. A total of 298 hours of participant observation was conducted, equivalent to 84 pages of field notes.

Researcher role during data collection

The setting was in some way familiar to the researcher, having 28 years of working experience in the pediatrics, even though the working experiences were from another setting in the pediatric clinic. Nevertheless, a conscious awareness was present when balancing the role between familiarity and strangeness—a balance between the necessity of suspending personal preconceptions during the role as an expert and on the other hand to come to terms with the personal and emotional distance during the role as an acceptable incompetent. Thus, constant reflexivity was attempted to balance between the preconceptions and the “cultural shock” (Hammersley & Atkinson, 2013). The researcher role simultaneously alternated between the insider and outsider perspectives (Spradley, 1980). The researcher wore the nursing clothing in order not to make too much noise in the context as a participant observer. In some cases, the participant perspective was the predominant role, for example when answering questions asked by children, the hospital clown, and the parents or in situations where the nurses in the unit asked the researcher to remove the magic cream from a child’s arm. In other cases, the researcher found a distant place in the corner and quietly observed the situation from behind her notebook. Thus, the researcher followed the hospital clown during interactions with the children either as a nurse, as an invisible or as an actor in a playful and humorous way (Atkinson, 2015).

Often the researcher was present before and after the hospital clown arrived, which led to interesting discussions and, moreover, fostered a close relationship between all the professionals working in the admission unit. The researcher established a trustful rapport with all the health care professionals in the unit and especially with the specific hospital clown. Thus, an awareness of the researcher role and her potential influence on the data during the fieldwork was particularly crucial (Hammersley & Atkinson, 2013). During the short participant observations, the nurses, the hospital clown, and the researcher worked together as a team.

Data analysis

An iterative and non-linear data analysis process took place at different stages throughout the process, especially at the point where video recording was introduced and where a rethinking and analysis of current patterns led to the decision to carry out selective participant observations in the second setting (see data collection in Paper 2). The ethnographic analysis inspired by Roper and Shapira (2000) and Hammersley and Atkinson (2013) was in particular guided by the principles from the thematic analysis (Braun & Clarke, 2006, 2018). Based on the five phases, Phase one covered the transcription and familiarization with the data during a process of viewing the video files as an analytical strategy for entering the data material of field notes. A continuous back and forth process during the analysis was conducted, which involved alternating between the video recordings and the field note transcripts with noting thoughts, which, together with the coding, were followed during the process of developing patterns of the interaction (Roper & Shapira, 2000). Repeated reading of the field notes searching for initial patterns and meaning was conducted to get immersed in the material as the key to further analysis. Phase two covered the coding process of the field notes of participant observations and informal interviews. In Phase three the relationship and patterns between the codes were discussed among the research members and, thereby, an initial sorting of codes into the themes was conducted. The identification of an overarching theme, three stages categorized as three potential themes (before venipuncture, during venipuncture, after venipuncture) (Cohen, 2008), and six subthemes led to further analysis. Phases four and five involved a revision and refinement of the three potential themes by rereading the data for ascertaining if the themes fit the data material and further identify and label subthemes. The coding process was assisted by the data software tool NVivo 10 (Bazeley & Jackson, 2013).

Table 2 presents an extract from the analysis process—relationship between theme, subthemes, and codes relating to the theme: *“How do WE do this together?”* (see the related quotes in Paper 2).

Table 2 *“How do WE do this together?”* Relationship between theme, subthemes, and codes—an example.

Theme	Subthemes	Codes
“How do WE do this together?”	Familiar atmosphere	HC applying contact at a distance HC timing and giving time Mutual listening attitude by child and HC Play tailored to individual child (e.g., song, tattoos)
	Mutual understanding	HC providing procedural information HC waiting for the child to be ready Initiative of the child Child explicit worries and wishes Child express previous experiences Child feeling clarity and overview
	Clear game plan	Agreement on a specific plan for how to do (place, distraction, parent’s role) Verbal and non-verbal expression of child agreement

5.3. STUDY 3

Methodology

In Study 3 (Kristensen et al., 2019b, under review), focused ethnography was used for the methodology (see Section 5.2 for the description). The use of focused ethnography in this study was aligned with the aim of exploring what characterizes the interaction between the child and hospital clown during recurrent hospitalizations, comprising repeated painful procedures and conditions in a specific context (Paper 3).

Setting and participants

The study was undertaken at one public general university hospital (different from the hospital setting in Studies 1 and 2). The pediatric ward consisted of a 24-hour and a day section for children diagnosed with cancer and rheumatological diseases. In the study, 13 children treated for cancer or rheumatological diseases aged 4–14 were included. One criterion for inclusion required the children to have recurrent interactions during the period with the hospital clowns. These interactions involved different pain-related procedures and conditions, such as venipuncture, port a cath access, nasogastric tubes, and mobilization. In addition, the interactions included encounters without painful procedures or conditions (see Table 4, Paper 3). Another criterion required that the children should have met the hospital clown before the commencement or from the outset of the study; this was to ensure the possibility of following the children and hospital clown during their interactions over time. In total, 61 encounters between the 13 children and hospital clowns were observed.

Data collection

The data collection comprised participant observations and informal interviews with children and parents. Data were collected consecutively during a two-month period from October 30 to December 13, 2017. The researcher followed five hospital clowns, usually working in pairs in the ward. The observations were short (Roper & Shapira, 2000) and had a duration of 4–6 hours a day. Children with diseases such as rheumatological and cancer experience multiple and various types of both acute procedural pain and more chronic pain conditions (Mercadante, 2004). Typically, it was not known in advance if and when the children was admitted and prescribed a specific procedure; nor was it known if the children was suffering from more chronic pain conditions. Though the children and the hospital clown did not know if and when they would meet again. Accordingly, grand-tour participant observations alternated with mini-tour participant observations (Spradley, 1980), which enabled obtaining an overall overview of the setting and in turn concentrating on the interactions between the individual child and hospital clown during recurrent encounters. The informal interviews were not decided in advance; however, depending on the situation (Roper & Shapira, 2000), they were conducted either during or after the procedure or event. The informal interviews between the children, hospital clown, parents, and the researcher were conducted in a creative, playful, and childlike manner

(Spratling et al., 2012). The researcher asked questions about the event and interaction immediately after it had happened. Although the children were encouraged to take the lead and share their experiences, it was what was important to the children that mattered most (Spratling et al., 2012). In total, 75 hours of participant observation was conducted, equivalent to 43 pages of field notes.

Researcher role during data collection

The special conditions of children with cancer and their procedural treatment and care were somewhat familiar to the researcher after a 10-year experience of work as a nurse in a similar ward years ago, and some of the nurses were known to the researcher. Thus, the same conscious awareness of the need to balance between familiarity and strangeness, as described in Study 2, was highly relevant. The “expert” role turned out to be very important in this study, especially when contacting the parents who willingly opened up when they heard of the researcher’s working background. The familiarity and the expert role facilitated collaboration between the hospital clowns and the nurses who were somewhat skeptical from the outset about the use of hospital clowns. Having a raft of researcher roles facilitated access to different types of data (Hammersley & Atkinson, 2013) such as parents’ experiences of their children’s illness, the nurses’ attitudes toward the use of the hospital clowns in the specific painful procedures, etc. The parents’ interest and trust in the researcher encouraged their children to engage with the situation and in all the interactions. The trustful atmosphere sometimes allowed the children to be free to involve the researcher in the interaction between child and clowns. The role as an outsider was promoted by the choice of an unfamiliar pediatric ward, different from the pediatric setting in Studies 1 and 2, allowing to challenge the researcher’s taken-for-granted assumptions (Roper & Shapira, 2000).

Data analysis

The ethnographic analysis inspired by Roper and Shapira (2000) and Hammersley and Atkinson (2013) was specifically guided by the principles from the thematic analysis (Braun & Clarke, 2006, 2018), similar to Study 2. The analysis was performed in an iterative and dynamic process during and after the study period. The rereading in Phase one—searching for initial patterns and meaning—and the coding in Phase two was similar to the analysis described in Study 2. Specifically, the analysis focused on capturing

nuances and details in the evolving relationships between children and clowns during the recurrent interactions. In Phase three, the sorting of codes was discussed among the research team and was accordingly revised, resulting in a preliminary overarching theme and two preliminary themes and eight subthemes (Table 3). Within this frame, further analysis continued in Phases four and five by reviewing the entire dataset and the selected data extracts. As a result, the overarching theme and two themes were further classified; the subthemes were refined and modified and were reduced from eight subthemes to four, in accordance with the content of the themes identified. Related codes are outlined in Table 1 and 2, Paper 3.

Table 3 Illustration of analysis process—Study 3

Preliminary overarching theme: <i>Hospital clown creating continuity in an ongoing WE</i>		Final overarching theme: <i>An ongoing WE</i>	
Preliminary themes	Preliminary subthemes	Themes	Subthemes
Stronger in a WE	Step by step/small steps	Stronger in a WE	"Maybe today...?"
	Providing a seat for the hospital clown		"You are my friend"
	WE are all together		
	The importance of having a friend		
	WE give high five		
For the next time	"You did it"	Hope in a WE	"WE did it your way"
	"See you again"		"See you again"
	The way to do it		

5.4. ETHICAL CONSIDERATIONS

Any research that involves children requires a critical assessment of the associated risks and benefits to ascertain whether the study in question poses any danger to its young participants (Carnevale et al., 2008). Children are able to articulate and give voice to the quality of their own care (Carnevale et al., 2008; Koller, 2017), and the views of the children participating in this thesis are needed to gain a complete understanding of children's experiences of pain and endurance during their interactions with the hospital clown. The researcher's dual insider/outsider role (Hammersley & Atkinson, 2013) during the participant observations and informal

interviews in the two studies helped researcher blend into the settings and thereby establish a climate of trust, legitimacy, and credibility with gatekeepers, children, families, nurses, lab techs, and hospital clowns. The participative role was flexible and improvisational and drew on multiple sources, allowing the children to involve themselves in activities over time (Carnevale et al., 2008). Nevertheless, a constant awareness of the researcher's presence was needed to ensure that the children, families, nurses, and hospital clown felt comfortable with the researcher's presence during the participant observations, informal interviews, and video recording.

Prior to the start of the Ph.D. study, the research was approved by the pediatric administration at Aalborg University Hospital and Aarhus University Hospital, Skejby. Permission was given by the Danish Data Protection Agency (Journal no. 2008-58-0028; id: 2016-5). The North Denmark Region Committee on Health Ethics assessed this study and, in accordance with Danish law, it was decided that their approval was not required.

All the participating children, parents, and clowns were provided with written information (Appendix B and D) and oral explanations to assure them of the anonymity of their identities and confidentiality of their data. The Hospital Clown Organization was informed about this research during a presentation of the study, and the director was regularly updated on the progress of the study. All the children, parents, and hospital clowns agreed to participate in the study and signed the informed consent forms (Appendix C and E). The health care professionals in the pediatric wards were informed about this research via several presentations of the study. Specific meetings were conducted for different staff groups (e.g., medical doctors, lab techs, nurses). In the primary setting (Studies 1 and 2), a text description of the study was presented on a television screen in the waiting area during the nine-month period.

The data collection procedures evolved over time until they were found well aligned with the focus of the individual studies, settings, and participants. Video recording was added in Study 2 to capture possible nuances. It was not possible to keep the use of video recording anonymous (Derry et al., 2010); therefore, to assure confidentiality, the use of video was verbally elaborated to the children, parents, hospital clown, and health care professionals (i.e., nurses, lab tech); specifically, new consent was obtained by email from individual families each time a video recording was used in a specific context.

Gaining access to the field was granted via written and oral contacts with the head nurses, which followed the approval from the hospital director. Thus, the practical concerns about access were easily resolved for all the three studies. Being cognizant of the importance and the researcher's capability of creating trustful relationships, the researcher's "walk" into the fields was smooth and unproblematic. Overall, it was observed that the participating nurses, doctors, lab techs, hospital clowns, parents, and children were open-minded, interested, and willing to participate in this study. Leaving the research field was carefully planned and organized in advance (Hammersley & Atkinson, 2013).

CHAPTER 6. FINDINGS

In the following section, a summary of the results (Study 1) and findings (Studies 2 and 3) of the three individual papers is presented. These sections are followed by a report on the integrated mixed methods findings, described through narrative weaving and visually illustrated in joint displays.

6.1. STUDY 1

Characteristics of the participants. No demographic differences were found between the group of children assigned to intervention with the hospital clown or standard care (Table 4). Table 4 presents an extract of the participants' homogeneous general characteristics from Table 1 in Paper 1 (Kristensen et al., 2018).

Table 4 General characteristics of participants

n (%)			
Characteristics	Hospital clown (n = 49)	Standard care (n = 62)	P
Sex			
Boy	27 (55.1)	36 (58.1)	0.848
Girl	22 (44.9)	26 (41.9)	
Age (years)			
4-6	15 (40.5)	22 (59.5)	0.686
7-15	34 (46.0)	40 (54.0)	
Age (mean ± SD)	9.1 ± 3.4	8.6 ± 3.4	0.396
Previous VP			
Yes	27 (55.1)	29 (46.8)	0.446
No	22 (44.9)	33 (53.2)	
Pain			
Yes	18 (36.7)	31 (50.0)	0.182
No	31 (63.3)	31 (50.0)	
Pain score			
NRS	14 (28.6)	26 (41.9)	0.167
FPS	35 (71.4)	36 (58.1)	
NRS, Numerical Rating Scale; FPS, Faces Pain Scale			

The effect of intervention with the hospital clown on self-reported pain level compared to standard care. Table 5 presents an extract of Table 2 in paper 1 (Kristensen et al., 2018). Overall, results from Study 1 showed no differences in pain intensity assessed by self-reported pain scores, notwithstanding the presence of the hospital clown, even when adjusted for potentially influencing variables ($P = 0.920$). When dividing children into two age groups (4–6 and 7–15), results showed a significant difference in effect ($P = 0.018$) between the exposed and unexposed groups. Thus, the stratified analysis showed a differing effect between the age groups. Children aged 4–6 were found to have a higher pain intensity score with the presence of the hospital clown ($P = 0.054$). Whereas children aged 7–15 reported lower scores, resulting in a significant decrease in pain scores ($P = 0.025$), indicating a positive effect of the presence of the hospital clown. No differences relating to gender were found (see Paper 1). Stratified analysis showed a non-significant difference between the exposed and non-exposed groups relating to prior experiences ($P = 0.054$). The results from the group with no previous venipunctures showed an estimated positive effect of the hospital clown that was large enough to be considered of clinical importance ($P = 0.085$). In contrast, for children with previous venipuncture experiences, an estimated negative effect was registered ($P = 0.248$).

Table 5 Crude and adjusted analysis

Variables	Control group Mean \pm SD	Hospital clown group Mean \pm SD	Crude difference (SE/CI)	<i>P</i>	Adjusted difference* (SE/CI)	<i>P</i>
Total	2.7 \pm 2.8	2.5 \pm 3.2	-0.1(-1.3,1.0)	0.819	-0.1(-1.2,1.0)	0.920
Age (years)						
4-6	2.6 \pm 3.8	4.9 \pm 4.1	2.2 (-0.3,4.8)	0.087	2.6 (-0.1,5.2)	0.054
7-15	2.7 \pm 2.0	1.5 \pm 2.0	-1.2 (-2.1,-0.3)	0.010	-1.0 (-1.9,-0.1)	0.025
Diff.(4-6/7-15)			3.4 (0.6,6.8)	0.016	3.6 (0.6,6.5)	0.018
Previous VP						
Yes	1.9 \pm 2.4	2.8 \pm 3.8	1.0 (-0.7,2.6)	0.248	1.1 (-0.4,2.6)	0.163
No	3.4 \pm 2.9	2.2 \pm 2.2	-1.2 (-2.5,0.2)	0.085	-0.9 (-2.4,0.5)	0.202
Diff.(yes/no)			2.1 (-0.0,4.3)	0.054	2.0 (-0.0,4.0)	0.053
Pain condition						
Yes						
No	3.0 \pm 3.2	3.9 \pm 3.7	0.9 (-1.1,2.8)	0.389	0.8 (-1.3,2.8)	0.466
Diff.(yes/no)	2.3 \pm 2.3	1.7 \pm 2.6	-0.6 (-1.8,0.7)	0.371	-0.4 (-1.6,0.8)	0.535
			1.4 (-1.0,3.8)	0.254	1.1 (-1.1,3.4)	0.332
* Adjusted for baseline variables related to the VP procedure: local anesthetic, nitrous oxide, time per procedure, number of punctures. CI: confidence interval; Diff.: difference (Kristensen et al., 2018)						

6.2. STUDY 2

Analysis from Study 2 (Paper 2) (Kristensen et al., 2019a, under review) resulted in an overarching theme: *Hospital clown tailoring strategies to individual child creating a WE*, based on three themes labeled (a) “*How do WE do this together?*” (b) “*WE are together,*” and (c) “*I/WE did it!*” The WE represents a responsive interaction between the child and the hospital clown, characterized by a close relationship evolved during continuous focused attention between the child and hospital clown. The WE gradually grew during these three themes, and the findings from the themes summarized in this section were perceived as being tightly connected in a natural flow during the venipuncture process (before venipuncture, during venipuncture, after venipuncture). The idea of the capitalized WE was identified early in the data collection, specifically in a situation where the hospital clown expressed loudly: “*I think we can talk about, how WE manage this venipuncture.*” This articulation of a WE evolved during the researcher’s preliminary analytic reflections on the data and was further evidenced in the data during children’s expressions: “*WE can do this together.*” In that sense, the WE was explored and unfolded during the analysis as a central point of view.

“How do WE do this together?”

The theme “*How do WE do this together?*” was illustrated through three subthemes: *familiar atmosphere*, *mutual understanding*, and *clear game plan*. From the first encounter, the hospital clown tailored the approach to the individual child and started establishing a familiar atmosphere, often at a distance, by integrating the child into an interaction, explicated to the child as a WE (Section 6.2). Thereby, the child’s individual story and previous experiences were the central focus. Some children interacted spontaneously whereas others somewhat hesitated as if they needed more time. Although the children swayed between worried, crying, and relaxed emotions, the overall established rapport in a trustful atmosphere facilitated the mutual understanding of the following procedure and helped the children to put their concerns about the procedure aside. The children were allowed to express their thoughts and wishes and share them with the hospital clown in a trustful atmosphere. The understanding of the procedure was strengthened, which helped the children to collaborate in making a specific and clear game plan of “*How do WE do this together?*”

“WE are together”

The theme “*WE are together*” was illustrated from the time the lab tech entered the examination room. The theme comprised two subthemes: *the articulation of game plan* and *implementation and modifying*. The hospital clown verbally and with body language articulated loudly the mutual plan, inviting the lab tech, parents, and nurses to play their specific roles with the child as planned, hence providing the child with a feeling of not being alone but a part of a WE. During the process, the hospital clown orchestrated the situation with considerable attention on the child with respect to the child’s expression, constantly collaborating with the child and providing the child with a feeling of control. The guidance was followed by the children with mostly a conscious and relieving expression. In a few cases, the plan did not work. These situations were linked to specific situations, for example, when the children were not prepared in advance. Mainly the children managed to cooperate as planned during the interaction, irrespective of age. Otherwise, the hospital clown modified the strategies and took time out for a revised plan with the children, continuing a focus of “*WE are together.*”

“I/WE did it!”

The theme “*I/WE did it!*” was outlined at the time when the lab tech left the room and until the child or the hospital clown finished the encounter. The theme comprised one sub-theme: *the mutual evaluation*. The hospital clown stayed in the room with the child, often remaining seated side by side. The hospital clown showed the child that the encounter was not over yet. The child responded by continuing playing, chattering, or holding hands, looking with an intense focus at the hospital clown. The WE was particularly intense and strong at the moment they maintained sitting side by side, having managed the procedure together. The hospital clown acknowledged the children’s experience by showing a genuine interest in sharing and understanding their experience. Thereby, the hospital clown encouraged the children to memorize and undertook a conscious evaluation with the children, providing them with an awareness of their individual strategies and the way they coped in the situation. The children often reflected loudly and had a clear answer or sense of how they managed. This point in that the WE was a culmination, maintaining the children’s feeling of “*I did it,*” often underlined by a mutual high five. On this basis, the hospital clown initiated and guided the dialogue with the children concerning a strategy for the future. The hospital clown insisted on a dialogue with the children, aiming to

reduce the anticipatory fear for future procedures and providing the children with competencies for managing in the future. The hospital clown clearly expressed the individual strategy in words on a level adequate for the children. Even when the children were in some cases mostly listening, the hospital clown encouraged them to share and give consent to the plan. Most of the time, the children actively participated, otherwise when accompanied by their parents. The importance of remaining in a WE after the venipuncture procedure was stressed in the feeling of “I/WE did it.”

6.3. STUDY 3

Analysis from Study 3 (Paper 3)(Kristensen et al., 2019b, under review) resulted in an overarching theme, *An ongoing WE*, based on two themes: *Stronger in a WE* and *Hope in the WE*. Overall, the findings showed a strong and close relationship build-up between the child and hospital clown over time during recurrent encounters. This relationship assisted the child in managing the situation and resulted in a mutual expectation and hope for support from the hospital clown in an ongoing relationship.

Stronger in a WE

The theme *Stronger in a WE* comprised two subthemes: “*Maybe today...?*” and “*You are my friend.*” Initially, the hospital clown took small steps in the contact, waiting for consent and response from the child. Acknowledgement of the current state/condition of the individual child in some cases postponed the encounter to another time. The hospital clown demonstrated an expectation that there would always be a new chance of meeting by asking “*Maybe today..?*” The hospital clown let the door open to new opportunities, which encouraged the children to share and express their thoughts and feelings in the current situation or the next time. The building of a trustful atmosphere showed that they could count on the hospital clown as a friend being present in the current challenging situations and in the future. The contact established over time had the character of a professional friendship with closeness and interest, expressed physically and verbally by the children, hospital clown, and parents. A strong supportive relationship was established, based on the shared experiences and deep insights into the children’s situation. With the hospital clown present in an interaction, they achieved a feeling of sharing the pain and challenges with someone (the hospital clown), hence easier management, as clearly expressed by a 12-year-old boy before a procedure: “*And you [hospital clown] you can manage*

*a part of it [the pain],” and after the procedure: “You [hospital clown] you managed [the pain] with me and took a part of it—thanks! It was OK with the venipuncture!” (ID 12) (Paper 3). As such, the children alternated between different emotional states in a responsive interaction with the hospital clown, providing a feeling of *stronger in a WE*.*

Hope in the WE

The theme *Hope in the WE* was expressed in two subthemes: “*WE did it your way*” and “*See you again*.” The needs and expressions of the children were handled by the hospital clown in a responsive interaction, based on a deep insight into the individual child’s history. The child’s expressions at the same time exhibited worry and open-mindedness. The recurrent feature of the relationship was that the child and the hospital clown cared about each other, which gave the child a feeling of not being alone during the painful events. A mutual evaluation initiated by the hospital clown underlined *WE did it your way*, and strengthened the child’s feeling of being able to manage the current situation. At the same time, this process of evaluation created awareness of the individual coping strategies, which seemed important for the children and were implemented in the following pain-related events. The children and the hospital clown expressed hope that the interactions could continue. Additionally, they felt assured during the interactions that the hospital clown could be present and support them in the future as a friend. Overall, the children did not directly talk much about the pain itself; they rather shared their feelings about the ways how to manage it. Therefore, the interactions with the hospital clown focused on the hope for managing pain both during specific procedures and more general painful conditions and hospitalization. Hence, the interaction between the children and hospital clown maintained a mutual *Hope in the WE*.

6.4. INTEGRATED MIXED METHODS FINDINGS

The mixed methods integration of quantitative results (Study 1) and qualitative findings (Studies 2 and 3) in this thesis helped expand knowledge of the effect and influence of the hospital clown on the pain experience of the hospitalized children aged 4–15 and their ability to cope during painful procedures and conditions in acute and recurrent hospitalizations.

The process of linking quantitative and qualitative data (initially by searching for common concepts) into an overall mixed methods interpretation occurs

through narrative discussion and joint display (Creswell, 2014; Creswell & Plano Clark, 2018). The analytical approach for integration at the interpretation level is described in detail in Section 4.6. The fit of integration describes in what way the quantitative and qualitative findings cohere by means of either confirmation, complementarity, discordance, or expanding (Creswell, 2014; Creswell & Plano Clark, 2018; Fetters et al., 2013; Fetters & Molina-Azorin, 2017). The identification of the themes appeared through an interactive back and forth process by a simultaneous frame for merging the quantitative results (Study 1) and the qualitative findings (Studies 2 and 3) (Moseholm & Fetters, 2017). Accordingly, three integrated findings were identified and selected for merging. The integrated findings were labeled (1) *An age-differentiated approach*, (2) *Understanding the child's condition*, and (3) *Previous experiences as a part of the child's history*. The integrated mixed methods findings will be presented in the following sections during narrative weaving, followed by joint displays to evaluate and structure the inferences of the findings (Guetterman, Fetters, & Creswell, 2015).

6.4.1 MIXED METHODS FINDING 1

An age-differentiated approach

The perspective of age relating to an interaction with the hospital clown was initially presented during the quantitative findings in Study 1. Thus, the integrated finding covers the perspective of age as an important factor in the child-hospital clown interaction. The stratified analysis (see Section 6.1) in Study 1 showed significant differences in pain scores, varying between specified age groups (Table 6). An increase in pain scores was found in the group of children aged 4–6 with the hospital clown intervention [2.6 (-0.1, 5.2), $P = 0.054$]. In contrast, a decrease in pain scores was found in the group of children aged 7–15 with the hospital clown intervention [-1.0 (-1.9, -0.1), $P = 0.025$]. The difference in effect between the two age groups were statistically significant ($P = 0.018$), meaning a significant difference between the exposed and the non-exposed group of children.

Concerning the children aged 4–6, Studies 2 and 3 confirmed each other as describing an established WE, influencing the children's ability to manage a painful procedure or condition in both the current acute situation and recurrent procedures and hospitalizations. Therefore, contrasts and

knowledge were added from Studies 2 and 3 relative to Study 1 for this age group. Although the pain scores among the children aged 4–6 were somewhat inconsistent with Study 2, the participant observations were also somewhat consistent, as some of the youngest children more than the older group of children were hesitating, sniffing, or crying during the procedures (Study 2). However, the hospital clown tailored and modified the strategies to the children's various expressions. The hospital clown kept an intense focus with the children, stressing *WE are together* and the children (aged 4–6) mostly cooperated keeping their arms straight without moving, even when a worried facial expression was observed (Study 2). Study 3 revealed in a few cases how interactions represented by "*Maybe today...*" and "*You are my friend*" (e.g., waiting attitude, contact at a distance, knowing the individual child's preferences) and especially time devoted by the hospital clown to establishing and maintaining a relationship would probably influence the pain experience in the future encounters (Table 6).

The findings confirmed how closely the children (aged 4–6) paid attention to the interactions, while the hospital clown guided them through the procedure. These findings suggested a positive outcome of the specific painful procedure based on strategies that were tailored to the age of the children. Nevertheless, these contradictory findings illustrate an expanded understanding of the assessment of pain experience of younger children by using pain scales, pointing at a positive influence of the hospital clown, although the pain score was higher with the hospital clown.

Studies 2 and 3 confirmed the positive outcome of pain intensity for the children aged 7–15 in Study 1 ($P = 0.025$) (Table 6), meaning that the hospital clown during specific strategies supported the children during a responsive interaction, which provided them with a feeling of *WE are together* and *Stronger in a WE* (Table 6). A feeling of not being alone allowed the children a feeling of control. The redirecting of the focus of attention during the venipuncture, often through tattoos (Study 2), suggested that the older children were able to push the procedure aside, resulting in a lower pain score (Study 1).

Studies 1 and 2 were further confirmed and deepened knowledge during exploration of the recurrent hospitalized children in study 3. A responsive interaction in a WE between children of all ages and hospital clown that evolved over time mostly led to a strong and close relationship ("*You are my friend,*") which expanded the knowledge of strategies that were key to the

individual children's ability to manage a painful procedure or condition. Nevertheless, from Study 3, it is not possible to draw a conclusion from the pain scores. However, based on the participant observations and interviews, a possible positive outcome of the specific pain assessment may be suggested, otherwise, the pain intensity was high while the children thought that they could cope with it.

Table 6: Joint display of mixed methods, Finding 1

<i>An age-differentiated approach</i>					
Study 1 Stratified analysis by multivariable linear regression	Variables	Control Group (Mean ± SD)	Hospital clown group (Mean ± SD)	Adjusted difference (SE/CI)	P
	Age (y)				
	4–6	2.6 ± 3.8	4.9 ± 4.1	2.6 (-0.1,5.2)	0.054
	7–15	2.7 ± 2.0	1.5 ± 2.0	-1.0 (-1.9,-0.1)	0.025
	Diff. Yes/no			3.6 (0.6,6.5)	0.018
Study 2 Description of qualitative themes with subthemes	<p>“WE are together!” HC guided the children through the procedure, redirected the focus of attention, allowed the children a feeling of control, and placed the painful procedures in the background. Hesitating, crying, or sniffing were common for the children aged 4–6. HC tailored and orchestrated, based on an intense focus on the children's various expressions, confirming the responsive interaction in a WE as strengthening ability to manage despite age.</p> <ul style="list-style-type: none"> • Articulation of game plan • Implementing and modifying 				
Study 3 Description of qualitative themes with subthemes	<p>Stronger in a WE Building an ongoing WE, based on the children's age, preferences, and shared experiences led to an individual strategy for managing, taking into account the children's age. A sometimes hesitating expression was handled during attentive responsiveness and closeness, evolved over time by giving time according to the children's terms.</p> <ul style="list-style-type: none"> • “Maybe today...” • “You are my friend” 				

6.4.2 MIXED METHODS FINDING 2

Understanding the child's condition

This integrated finding covers the perspective of having an attentive focus on listening to the children's voice and understanding their condition. Some of the children were suffering from pain besides scheduled various acute medical procedures. When suffering from pain due to the disease, treatment, or care, the children complained about a double painful and challenging situation, as they had to deal with both an overall feeling of pain and an insecure situation, relating to the painful procedure.

Study 1 suggests that children, to a limited extent, benefit from the hospital clown intervention, as a remedy to suffering from pain during the acute admission [0.8 (-1.3, 2.8)], although the result is not statistically significant ($P = 0.466$). Compared to the group of children with no pain, there were no differences in effect ($P = 0.332$) (Table 7).

Study 3 revealed how the hospital clown appreciated the current state of the children, which sometimes caused the encounter to be postponed to another day ("*Maybe today*") (Table 7). Hence, these findings complemented Study 1 by confirming that, among different aspects, a painful current condition could affect the children in a way that they would not have the mental capacity to invite/accommodate the hospital clown in the current situation. However, the recurrent hospitalized children were certain that the hospital clown would be there in future situations—"*See you again*"—in contrast to the acute short-term hospitalized children. Thus, Study 3, to some degree, expanded Study 1; for example, the hospital clown asked for permission and acknowledged the current painful condition or the related mental challenges by giving time, possibly withdrawing and promising the children to come again ("*Maybe today*") to share the joy and challenges as friends ("*You are my friend*") (Table 7). On the other hand, the clown's cautious approach in Study 3 led the children to push pain, bad mood, etc. to the background, with a feeling of being *Stronger in a WE*. This suggests a positive influence on the children's ability to manage and alleviate pain, which was contradictory to Study 1. Moreover, the evaluation ("*WE did it your way*") involved in the interaction a focus on *Hope in the WE*, expressed as an expectation from the children for the hospital clown to help despite the status quo (Study 3).

The importance of giving time to foster a relationship, based on the children's terms in their current state, was observed in Study 2 during the acute venipuncture situations. These findings contrasted with those of Study 1. Hence, Study 2 suggests how the hospital clown used a conscious-focused approach when integrating the children in "*How do WE do this together?*" (Table 7), taking small steps in the initial meeting to provide a *familiar atmosphere* and the following preparation of the children, which led to an intuitively uncovering of their condition (e.g., pain). Building a *mutual understanding* of the condition formed the basis for a *clear game plan*. Thus, the *articulation, implementation, and modification* of this game plan in the second phase ("*WE do/are together*") suggests contradictory findings, compared to Study 1 by suggesting a positive influence of the hospital clown, even when they were suffering from a painful condition; for example, the children acted and collaborated with relief, smile, and intense gazes in their responsive interactions with the hospital clown (Study 2). Supplementary Study 2 added knowledge to Study 3 and highlighted the importance of maintaining the child-hospital clown alliance by showing how the hospital clown created continuity during the three phases (before, during, and after venipuncture) in the acute short-term encounter. Thus, continuity during recurrent encounters ("*See you again*") (Table 7) in Study 3 were complemented by Study 2, revealing how the children challenged their current pain, given the benefits of the hospital clown strategy (creating a WE during steps) throughout the acute procedure, when the interaction was maintained entirely according to the children's terms.

Table 7: Joint display of mixed methods, Finding 2

<i>Understanding the child's condition</i>					
Study 1 Stratified analysis by multivariable linear regression	Variables	Control Group (Mean ± SD)	Hospital clown group (Mean ± SD)	Adjusted difference (SE/CI)	P
	Pain				
	Yes	3.0 ± 3.2	3.9 ± 3.7	0.8 (-1.3,2.8)	0.466
	No	2.3 ± 2.3	1.7 ± 2.6	-0.4 (-1.6,0.8)	0.535
	Diff. Yes/no			1.1 (-1.1,3.4)	0.332
Study 2 Description of qualitative themes with subthemes	"How do WE do this together?"				
	<p>A consciously tailored and focused HC approach, including the current condition of the children, initially established a responsive interaction in a WE. Despite pain or worried expressions, the children managed to share and push these thoughts to the background, when interacting according to the children's terms.</p> <ul style="list-style-type: none"> • Familiar atmosphere • Mutual understanding • Clear game plan <p>"WE do/are together"</p> <p>Maintaining the ongoing WE, HC articulated the plan based on the children's condition. The children expressed relief, an intense focus on HC, and managed to collaborate with HC, which was tailored and modified accordingly.</p> <ul style="list-style-type: none"> • Articulation of game plan • Implementation and modifying 				
Study 3: Description of qualitative themes with subthemes	Stronger in a WE				
	<p>Small steps and time based on the children's expression led to a strong relationship and a mutual expectation of meeting again, allowing all feelings to be shared, which either postponed the encounter or pushed the painful condition to the background</p> <ul style="list-style-type: none"> • "Maybe today...?" • "You are my friend" <p>Hope in the WE</p> <p>Maintaining a focus on the needs and expression of the children, facilitated hope as relating to an expectation of help from the HC in the current and future situations. The evaluation provided hope for managing pain regardless of the current condition</p> <ul style="list-style-type: none"> • "WE did it your way" • "See you again" 				

6.4.3 MIXED METHODS FINDING 3

Previous experiences as a part of the child's history

When previous experiences were a part of the children's histories, they were forced to navigate the multiple and diverse feelings (e.g., worries, anxiety, fear of restraint, pain, relaxation, relief) of an uncertain situation. The findings suggest that this happened irrespective of the hospital clowns' presence. In Studies 2 and 3, previous experiences and related feelings seemed to either strengthen or diminish the children's expectations of ability to cope with a current situation. Although the hospital clown was present, the children managed the pain differently during the procedure with either a relieving attitude or a hesitating and anxious one.

Study 1 to some degree complemented the impact of previous experiences by affecting the pain intensity. This was in particular expressed by a tendency to increase the pain intensity scores with the presence of the hospital clown [SE/CI 1.1 (-0.4, 2.6)] (Table 8). Even Study 2 showed how the hospital clown used a conscious strategy for verbalizing the previous experiences and building up the current situation based on these experiences and related needs (*Familiar atmosphere* and *Mutual understanding*). In contrast, the findings from the children with no previous venipunctures showed the benefit of the intervention with the hospital clown given the lower pain intensity scores [SE/CI -0.9 (-2.4, 0.5)]. The findings (Study 1) thereby illustrated that the children felt more challenged by the previous experiences in mind and thereby to a minor degree benefited from the hospital clown intervention. This is further confirmed in comparison with the group of children with no previous experiences, showing an insignificant difference in the effect of the presence of the hospital clown [SE/CI 2.0 (-0.0, 4.0), $P = 0.053$] (Table 8).

However, Study 2 revealed how worries connected to both the acute current situation and previous experiences were positively managed during the interaction with the hospital clown by a conscious verbalizing of "*How do WE do this together*" (Table 8). Sharing and creating a *mutual understanding* during responsive interaction, based on an individual unique approach, seemed to help the children manage the stressful situation independent of pain intensity assessment. In addition, a mutual evaluation ("*WE did it*") supported the children in identifying and being aware of the individual strategies for the future, as indicated in the informal interviews with the

children managing to share the strategies for the next procedure with the hospital clown based on the current situation ("*WE did it*") (Table 8). Thus, the children expressed an expectation for the hospital clown to help as a way to manage pain in the current acute situation. Study 3 confirmed these findings, describing how the visualization and repetition of the children's individual coping strategies in the responsive interaction were present during the recurrent encounters. This suggests how an ongoing interaction with the hospital clown strengthened their hope for a less painful experience in the future ("*Hope in the WE*"). However, a few cases from Study 2 revealed that previous experiences based on restraining and threats affected the children in a way that the *mutual game plan* was not effective. Thus, the interaction with the hospital clown did not help the children in managing the procedure, pointing at a probably negative effect on pain, as shown in Study 1.

Study 3 further expanded the findings ("*WE did it*") from Study 2. "*WE did it your way*" illustrated how the hospital clown continuously helped the children navigate their contrasting feelings, building together a strategy, specifically based on their common previous experiences. At the same time this continuity provided hope for a subsequent time together ("*See you again*") (Table 8). Study 2 suggests the importance of conducting an evaluation (mutual evaluation) as a part of the procedure to modify memories, reduce the anticipatory fear for subsequent procedures, and providing the children with competencies in pain management. However, expanding on this, the exploration of the recurrent encounters in Study 3 showed that the individually tailored approach included perspectives of the recurrent interactions and the histories of the children. This provided the children with the unique feeling of being remembered and received as a well-known individual, which facilitated a feeling of safety and hope. The feeling of *Hope in the WE* provided during the responsive interaction in the individually tailored approach was translated and fulfilled in the concrete subsequent situations and thereby supported the children in their navigation of the different feelings, such as pain, worries, and "*See you again*" (Table 8).

In addition, the feeling of *Hope in a WE*, established during the ongoing encounters (Study 3), to some degree both contrasted and expand the pain intensity scores in Study 1. It was contrasting because the children expressed less pain and more hope for managing the situation when interacting with the hospital clown; it was expanding because they expressed fear and pain about the scheduled procedure, even when the hospital clown was present

but simultaneously experienced control and opportunities for coping despite pain and fear.

Table 8: Joint display of mixed methods, Finding 3

<i>Previous experiences as a part of the child's history</i>					
Study 1 Stratified analysis by multivariable linear regression	Variables	Control Group (Mean \pm SD)	Hospital clown group Mean \pm SD)	Adjusted difference (SE/CI)	P
	Previous venipunctures				
	Yes	1.9 \pm 2.4	2.8 \pm 3.8	1.1 (-0.4,2.6)	0.163
	No	3.4 \pm 2.9	2.2 \pm 2.2	-0.9 (-2.4,0.5)	0.202
	Diff. Yes/no			2.0 (-0.0,4.0)	0.053
Study 2 Description of qualitative themes with subthemes	<p>"How do WE do this together"</p> <p>Prior experiences were expressed as diverse feelings. Invited to be a part of the WE, encouraged the children to tell the previous individual story. A feeling of being met and potentiality to share in a mutual understanding and plan, enhanced the children's feeling of control and ability to manage painful procedures. Prior experiences also caused no positive influence of HC.</p> <ul style="list-style-type: none"> • Familiar atmosphere • Mutual understanding • Clear game plan <p>"WE did it!"</p> <p>By maintaining the WE in an evaluation, sharing the expression and identifying individual strategies for the future, caused an awareness and reflection on individual competencies. The dialogue provided a modifying of memories for the VP to be less distressing and to reduce anticipatory fear for future procedures.</p> <ul style="list-style-type: none"> • Mutual evaluation 				
Study 3: Description of qualitative themes with subthemes	<p>Hope in the WE</p> <p>Children shared contradictory feelings, expressing hope for the HC to help. The ongoing relationship allowed building on previous experiences and assured the children in the wishes for a strategy, including presence and support from the HC. The evaluation focusing on individual strategies used by the children strengthened hope for better managing of pain and for continuous encounters with the HC.</p> <ul style="list-style-type: none"> • "WE did it your way" • "See you again" 				

CHAPTER 7. DISCUSSION

In this section, the integrated mixed methods interpretations are discussed, structured according to the three integrated mixed methods findings. Additionally, a discussion of the methodological considerations follows, which is organized as a discussion of the mixed methods process and a discussion of the design and methods chosen for the three individual studies.

7.1. DISCUSSION OF MIXED METHODS FINDINGS

In response to expand knowledge, the new insights about the influence of the hospital clown on hospitalized children's pain experience and ability to cope during painful procedures and conditions in acute and recurrent hospitalizations, the findings revealed a relationship in a WE, illustrating that a responsive interaction between the child and hospital clown is essential. The WE was established from the very beginning and maintained throughout the process of an acute or recurrent painful procedure or condition. A uniquely tailored and modified hospital clown approach, responding to the individual child's expression and needs, was found essential for strengthening the children's competencies for managing procedure-related pain. The interpretation uncovered three integrated findings: (1) an age-differentiated approach, (2) understanding the child's condition, and 3) previous experiences as a part of the child's history.

An age-differentiated approach

The findings showed the importance of age for establishing a relationship between child and hospital clown, tailored to the age of the child. Providing an age-specific approach suggested a positive influence on pain experience and ability to manage the specific procedures or conditions either in acute or recurrent procedures. Nevertheless, findings also revealed specific attention on the young children, as findings showed how this age group, despite cooperating, was more likely to express a hesitating, crying, and worried expression during the encounters; and also had a tendency for a higher pain score during hospital clown encounters. In the comprehensive child life literature (Thompson, 2018), age is mentioned as one of the most critical variables to affect a child's emotional response to hospitalization and medical procedures. The present findings reflect this and are in line with Linge's (2012) results who also reported that age played a pivotal role in the

child-hospital clown interactions, based on interviews with nine hospitalized children aged 2–18 in the context of hospitalization. Contrary to Linge (2012), the present findings covered specific procedures. Nevertheless, there are also some similarities, in that a hesitating and cautious attitude, expressed by younger children also described by Linge, suggests that more time is needed to be devoted to establishing the relationship. According to Linge (2012), younger children were more indulged in the magic relationship, whereas older children were more adapted to reality and switched between roles. The present findings expand the findings from Linge (2012), as presenting children of all ages to collaborate, accommodating an age-appropriate and individually tailored and modified approach during the process. Hence, the present findings implied that children of all ages were offered a feeling of not being alone, as established by the WE, which strengthened their competencies in managing the painful procedure. The tailored approach to the children's age in the findings stresses the need for further research, addressing strategies for children at various ages (Birnie et al., 2018; Chambers, Taddio, Uman, & McMurtry, 2009; Koller & Goldman, 2012).

The present findings emphasize the importance of a conscious focus on an age-differentiated approach in a WE, which may help children of different ages manage a painful procedure. Changes and development of cognition, emotion, and psychosocial relationship during childhood (Sommer, Samuelsen, Hundeide, 2010) underline the importance of an age-tailored hospital clown strategy. Evidence of the group of children aged 4–6 indicates that this period is most vulnerable in terms of procedures and hospitalization (Thompson, 2018). Related to the present findings, explanations can be found for the differences in age from cognitive and psychosocial development. Children aged 4–6 master the imagination and magical thinking; however, they have limited abilities due to abstract thinking, whereas children aged 6–12 master more complex thinking, including a more systematic approach with concepts, time, space, and quantity attached to a concrete situation. From 12 years of age onward, the child masters theoretical and hypothetical thinking. They reach a higher degree that enables them to apply the concepts they have learned in one situation to another and to evaluate their own logic and thinking (Kaakinen, Coehlo, Steele, Tabacco, & Hanson, 2015, Chapter 13; Thompson, 2018, see Chapter 2). Accordingly, the present findings imply how strategies based on guiding the children in a relationship increased feelings of control and assessed understandings of the situation for the younger children by using more

concrete terms (e.g., tattoos, toys, etc.), which seemed vital to this age group (Linge, 2012; Thompson, 2018). The strategies for older children, however, include interactions more associated with a reality that involves choices, self-expression, and support connected with other relations at home or school.

The hospital clown strategies found in the present study did not focus on the children as separate from the context of their parents and social surroundings. The hospital clown included parents and health care professionals, taking into account the children's age. Accordingly, the children collaborated during the pain-related experiences, founded in a trustful WE with the hospital clown, influenced by both a familiar, cultural, and social context (Birnie et al., 2017). Hence, the pain experience and ability to manage were reflected by the individual child's age and developmental level related to both the concrete procedure and the contextual challenges. Explanations of the findings regarding age may as such be considered in accordance to parents' role, family functioning, anxiety, and previous experiences (Thompson, 2018), associated with a potentially painful procedure, which might influence the children's coping with pain-related events and behaviors (Birnie et al., 2017). Given the parents' presence during the painful procedures, additional research concerning parents' role is required (Birnie et al., 2018).

Understanding the child's condition

Maintaining a special focus on the individual child's condition by listening to the child's voice from the first encounter was found essential. Accordingly, the hospital clown took small conscious steps in the initial contacts with the child. The children affected by pain, bad mood, etc. arising from the disease treatment or care had to experience a double challenging situation. In some cases, such a condition resulted in the suspension of the encounter or the tendency for a minor effect on pain experience in acute situations. Nevertheless, most of the time, the children expressed a wish for interaction with the hospital clown, as they received relief and an intense focus from the hospital clown. Specifically, the children, either verbally or through gestures, asked with certainty that the hospital clown stays with them during admission or recurrent encounters. Thus, continuity during the process represented a key aspect in the managing of the specific scheduled procedure besides the condition of pain or related challenges. The use of psychological support and preparations for double challenging situations may require the inclusion of the hospital clown interactions in all phases of

an event (before, during, and after) (Thompson, 2018). Furthermore, different circumstances and sometimes lack of time can affect the interaction, thus implying that the presented strategies of establishing a familiar atmosphere, mutual understanding, and game plan in a close and friendly approach might be tailored to the individual child to enhance the children's coping with pain related procedures. According to Lazarus (Biggs et al., 2017; Lazarus & Folkman, 1984; Thompson, 2018), a child's effort to cope with a stressful event may be considered either emotion-focused (e.g., regulation of the emotional response) or problem-focused (e.g., managing the situation). Thus, the individually tailored approach in the present findings was linked to an understanding of WE to both accommodating the children's emotional feelings (*mutual understanding*, "*You are my friend*") and the more specific plan for managing (*game plan*). Understanding and respecting the children's condition completely and conducting a proper appraisal of the situation ("*WE did it your way*") might form the basis for enhancing the children's feeling of managing. This was specifically expressed during a unique close and familiar atmosphere during the interaction with the hospital clown as a friend. It can thus be suggested that WE is essential in supporting the children, based on the entire history of the individual child.

The responsive interaction between children and hospital clown as friends build on the trust established from the first encounter. A strong and trustful relationship was represented in a feeling of being met with an understanding of the current condition, further facilitated by enrolment in a WE during the preparation with a mutual understanding, game plan, and certainty for the hospital clown to stay during the procedure or for next time. This relationship was initially facilitated by the hospital clown and further maintained during a responsive interaction as WE in the specific context. Five relation aspects of the Fundamentals of Care Framework (FoC) are described as fundamental for nurse's to establish a relationship (Feo & Kitson, 2016; Alison Kitson, Conroy, Kuluski, Lolock, & Lyons, 2013). The relational aspects of trust, focus, anticipate, know, and evaluate are necessary to establish a relationship that can support the individually tailored care (Kitson et al., 2013). Thus, the present findings expand on this framework, indicating that the hospital clown (as the professional) established this relationship and expressed as an ongoing WE. *Trust* occurred during the establishment of an initial familiar atmosphere; *focus* was provided by the hospital clown's undivided attention on the child and the child's condition; *anticipate* was stressed by a preparation and mutual game plan; *know* was verbalized by seeing the child's condition from the first encounter and build-up in the WE, and finally

evaluate was founded in the conscious focus after the procedures to help the child be aware of how the child managed pain. Therefore, the hospital clown mediated the psychosocial dimensions as enhancing the children's understanding and facilitating their coping with pain during the current painful situations. It can, therefore, be assumed that these findings of the responsive interaction in a WE during procedures and related conditions implicate that support for a child's coping with pain might be handled as a special task in the room. Incorporating hospital clowns as integral part of the team around the children undergoing painful procedures during the whole and/or recurrent encounters might provide the children with the power and belief of managing pain (Meiri, Ankri, et al., 2017; Ofir, Tener, Lev-Wiesel, On, & Lang-Franco, 2016; Tener, Ofir, Lev-Wiesel, Franco, & On, 2016). Thus, an important point for further research and discussion is the fact that the need for supporting the children in coping before, during, and after a painful procedure by a strong relation might require an extra person in the room beside the health care professionals handling the procedures. The establishing of a relationship and integrating the physical, psychosocial, and relational perspectives may constitute the foundation for a whole child-centered care, moderated by a nurse as being responsible during the encounters (Feo & Kitson, 2016; Kitson, Conroy, Wengstrom, Profetto-McGrath, & Robertson-Malt, 2010; Kitson & Soerensen, 2017). The present findings have raised important questions about how the focus on the psychosocial dimensions, shown in a WE, can be perceived as important as the physical and practical issues and thereby provide the children with an integrated experience of care in painful procedures and related conditions.

Previous experiences as a part of the child's history

Findings showed that the child's previous experiences implied multiple and diverse feelings, affecting the pain experience and the pain intensity during painful procedures. Thus, previous experiences seemed to either strengthen or diminish the child's expectation of ability to manage. Specifically, a tendency to increased pain intensity and worried expressions and attitudes were found for children with previous experiences, even when the hospital clown was present. Consequently, the hospital clown tailored the strategy to the individual child, aiming to provide a mutual understanding and game plan for strengthening the children's ability to cope with a pain related event. As children often report needle-related procedures as the worst pain (Friedrichsdorf et al., 2015; Walther-Larsen et al., 2017), these findings confirm the association that negative previous needle-related experiences

may follow the children and thus have an influence on the children's expectations of pain and the efficacy of strategies for pain management (Kristensen et al., 2018). In reviewing the literature, data has shown that previous experiences considered negative may affect the appraisal of the child and following the child's response of pain in the current situation (Chen, Zeltzer, Craske, & Katz, 2000; McMurtry et al., 2015; Noel, Chambers, Petter, et al., 2012; Noel, Chambers, McGrath, et al., 2012; Noel et al., 2018; Thompson, 2018). The hospital clown verbalized this issue of the children's previous experiences by directly asking the children from the very beginning about how they felt during previous experiences, hence promoting the expression of the children, who responded either with relief or more hesitating/worried attitude. Subsequently, the hospital clown embraced the children's expression and derived emotions in preparing the children. However, it is possible that negative previous experiences based on threat and restraint require special attention and approaches, including a longer process of preparation. Comprehensive research on the risk of negative pain memories concerning vaccinations and their influence on children's experience of pain during recurrent procedures accounts for the importance of drawing attention to unmanaged pain (McMurtry et al., 2015; Noel, Chambers, McGrath, et al., 2012). The work of McMurtry et al. (2015) provide a conceptual foundation for understanding the development and maintenance of pain and fear based on painful procedures. They outlined different treatment strategies for preventing or alleviating the experience of pain and fear based on previous experiences. Accordingly, the strategies provided in the present findings, encompassing the previous experiences, explain how the hospital clown established an evaluation, which supported the children in a feeling of *"I/WE did it"* or *"WE did it your way."* As such, the evaluation worked as a kind of framing a memory that may serve as a foundation for the subsequent procedure (Kennedy, Luhmann, & Zempsky, 2008). Despite a paucity of research on memory-reframing interventions (Noel et al., 2018), findings from Noel et al. (2018) provide some evidence that interventions of reframing may modify a child's memory of needle-related procedures and thereby positively influence the child's anticipatory fear of pain related to future procedures. The present findings identified the evaluation after the procedure to be an integrated part of managing the painful procedure. Thus, the present findings expanded previous research on language-based memory reframing (Noel et al., 2018) by illustrating how an interaction with a hospital clown can offer an accurate and positive reframing of children's memories by maintaining a close alliance during an evaluation following the needle-related procedure.

The present findings showed that combining multiple strategies, used in a tailored and trustful interaction (WE), enhanced the children's competencies of pain management and provided the children with a renewed interpretation of the procedure. Children clearly expressed previous experiences and expectations of pain and fear with a wish for the hospital clown to be present as an opportunity for managing the situation. In addition, the mutual evaluation facilitated an awareness for the children of individual strategies, which were specifically verbalized as important for the future. Usually, the physical feeling of pain may be gone in a short while after this kind of procedures. Nevertheless, the emotional and psychological feeling may maintain over time (McMurtry et al., 2015) and may increase pain for future procedures. The present findings are consistent with the updated Cochrane review on psychological strategies for reducing pain and distress of children and teens getting a needle (Birnie et al., 2018), recommending various strategies. The present findings have identified various approaches, provided by the hospital clown, in an individually tailored interaction. These findings complemented the findings from Svendsen and Bjørk (2014) who found that nurses concerned with establishing relationship and cooperation with a child during medical procedures used them as a goal for making informed decisions on the adoption of an appropriate strategy. Nurses in the study indicated that the use of non-pharmacological strategies, despite their pain relief, also promoted the interaction, founded in an evaluation of the individual child's needs. Hence, the present findings provided subtle perspectives on how to manage the expectancy of pain and fear, evolved from previous experiences by conducting a conscious evaluation as an integrated part of a procedure. Tener et al (2016), in their interviews with nine children aged 5–16 undergoing invasive examinations and their accompanying parents, found that the effect of a child-hospital clown alliance during medical procedures at the hospital can continue and increase after returning home. Thus, the present findings suggest a positive influence on ongoing encounters. Further research should follow up on children undergoing continuous encounters over a longer period of time with similar procedures.

7.2. METHODOLOGICAL CONSIDERATIONS

In this section, the methodological considerations are discussed in terms of strengths and limitations of the mixed methods approach and of the

methods used in each individual study, including aspects of validity, reliability, and generalizability/transferability. Methods chosen in Studies 2 and 3 were similar and hence will be discussed jointly.

7.2.1 MIXED METHODS APPROACH

The mixed methods design chosen in this thesis revealed new integrated findings described through narrative weaving and joint displays. No studies have combined quantitative and qualitative data to expand the knowledge of the child-hospital clown interactions during painful procedures, although new knowledge of interactions between the hospitalized children and the hospital clown during different painful procedures and conditions were found. The use of mixed methods is founded on the research questions in which several data sources are required for the purpose of comparing, expanding, or contrasting the results and findings (Creswell & Plano Clark, 2018). In addition, the mixed methods approach provides knowledge that cannot be captured by either a quantitative or qualitative approach alone. Therefore, the research questions benefited from the use of the mixed methods design (Creswell, 2014; Creswell & Plano Clark, 2018; Fetters & Molina-Azorin, 2017) and were further validated through the identification of three mixed methods findings, which were based on the combined strengths of the quantitative pain assessments and the focused ethnographic explorations. Nevertheless, the mixed methods design also poses some important questions to be discussed either as limitations or specific strengths.

The validity issue in mixed methods research is discussed by Onwuegbuzie and Johnson (2006), recommending the term *legitimation* as a bilingual nomenclature comprising both quantitative and qualitative approaches. As such, the terms validity (in the quantitative approach) and the terms trustworthiness and credibility (qualitative approach) are covered by legitimation when assessing the mixed methods study. However, validity covers an understandable term, accepted by both quantitative and qualitative researchers (Creswell & Plano Clark, 2018) and, as such, are used as equivalent to legitimation in this discussion.

The **convergent design** involves separate collection and analysis of quantitative and qualitative data. The design is useful when gathering both types of data in the field concurrently, with the intent to merge the quantitative results and qualitative findings (Creswell, 2014; Creswell &

Plano Clark, 2018). The convergent design in this thesis is both sequential and concurrent. It was concurrent in Studies 1 and 2 as data collection and analysis almost occurred simultaneously; it was sequential in Study 3 as data collection and analysis took place after Studies 1 and 2, allowing the focus of observations to emerge and thus provided nuances to the observations (Creswell, 2014; Creswell & Plano Clark, 2018; Schoonenboom & Johnson, 2017). Keeping the analysis separately for the three studies may be considered a strength in this thesis and is handled by interpretation by narrative weaving and visual joint displays (Creswell & Plano Clark, 2018).

Validity threats vary among the designs within mixed methods approaches (Creswell & Plano Clark, 2018). To minimize these threats and improve the quality, the convergent design requires parallel questions addressing the same concept (Creswell & Plano Clark, 2018). As such, the quantitative variables (pain intensity) and the qualitative phenomena (experience of pain and ability to cope) were parallel. Nevertheless, some quantitative constructs and qualitative themes cannot be linked (Creswell & Plano Clark, 2018; Fetters et al., 2013) (e.g., duration of procedures, gender, parents' role) and may be unveiled in future papers.

The **point of integration** is the most important part of the design of a mixed methods study (Schoonenboom & Johnson, 2017). The mixed methods integration can integrate the results and findings from separate studies and yield synergy that would not be possible by simply adding the results and findings from each study (Fetters et al., 2013; Fetters & Freshwater, 2015). The integration in this thesis occurred at different levels, as mentioned in the design section (Chapter 4). The convergent core design was appropriate as a frame for the concurrent collection of data in Studies 1 and 2 and connecting of Study 3 in a subsequent data collection. The label *connecting* of Study 3 was revised several times during reflections in a team of mixed methods researchers. Finally, the label *connecting* was decided based on referring to two assessments of the hospital clown interactions (in two stages). Ideally, a plan developed for data collection is conducive to merging different datasets by choosing similar instruments (pain score, similar questions concerning pain experience) and thereby looking for common concepts (Creswell & Plano Clark, 2018; Fetters et al., 2013). However, the integration at the methods level represent some limitations, such as the use of self-reported pain, which was not chosen as a data collection method in Study 3, due to the type of interactions. The aim in study 3 was to follow the individual child during recurrent interactions during participant observations and informal

interviews. Thus, sometimes no procedure was included in the interaction (see Table 4, Paper 3), resulting in no systematic use of assessment scales for pain scores. Similar procedures with pain assessment scales during a uniform procedure in both acute and recurrent hospitalized children might have constituted a stronger argument. This might be considered a limitation for the merging of the results and call for future investigations to compare self-reported pain during acute and recurrent pain-related procedures.

The complexity in conducting a mixed methods study is an important point for discussion. The methodology requires researcher skills in both quantitative, qualitative, and mixed methods research in one single study. As such, the mixed methods design needs a research team with various backgrounds and research competencies (Creswell, 2014; Fetters & Molina-Azorin, 2017). To adopt this potential disadvantage, the research team in this study was represented by quantitative (e.g., statistical) and qualitative (e.g., ethnographic) competencies. In addition, competencies in specific areas were sought, such as video ethnography, mixed methods, pain, and pediatrics. The key components of both quantitative and qualitative research have to be fulfilled within the research team with a focus on the individual research traditions to be discussed in collaboration with the team members (Creswell, 2014). Thus, this thesis was conducted in two stages with three individual studies, outlined in three individual papers. During the process, team members contributed to various degrees, dependent on the specific research skills and a specific point of focus.

Time and resources needed may be considered a challenge when conducting a three year Ph.D. study (Ministerial order of the Ph.D. programme in Denmark) within a mixed methods design (Creswell & Plano Clark, 2018). Thus, time for collecting data in Studies 1 and 2 was prolonged due to a small number of acutely hospitalized children scheduled a venipuncture during the period. Therefore, the researcher experienced challenges to cover each tradition and/or method in depth (e.g., video-recording, discussed in this section and in Study 2). Furthermore, the data collection period for Study 3 may be considered limited, due to the unpredictable planning of treatment and care-related procedures for the participating children. Thus, it was not known beforehand if the child was going to have a procedure. In addition, the hospital clowns have set schedules with limited working hours. Nevertheless, the process of fieldwork is never complete; it is rather cyclical and interactive (Atkinson, 2015, see Chapter 3), and, as such, preliminary ideas from the first stage (Studies 1 and 2) strengthened the focus for the

second stage of data collection. Thus, the findings of 13 children during 61 interactions were considered to constitute the focus of the recurrent interactions. A longer period of fieldwork could have contributed to more nuances concerning interactions in specific procedures.

The selection of different participants is considered necessary for the legitimacy of making meta inferences in the mixed methods study (Creswell & Plano Clark, 2018; Onwuegbuzie & Johnson, 2006). In this thesis, no same individuals were selected for the three studies in regard to the purpose of expanding insights in both acute short-term and recurrent long-term hospitalized children. Nevertheless, the participants in Study 2 represented a subsample of participants from Study 1 and were hence considered similar. To minimize the threats of sampling validity regarding Study 3, hospitalized children at the same age were included. In addition, unequal quantitative and qualitative sample sizes were acknowledged by means of comparing group data instead of data for each individual (Creswell, 2014; Creswell & Plano Clark, 2018; Onwuegbuzie & Johnson, 2006).

The potential of conflicting findings, as observed in the mixed methods findings of age-related differences, raises the question of legitimacy (Fetters et al., 2013; Onwuegbuzie & Johnson, 2006). Nevertheless, the purpose of this thesis was not to validate findings; it was rather to show complementary findings by combining quantitative and qualitative methods and approaches (Onwuegbuzie & Johnson, 2006) and thereby expand and provide a subtle form of knowledge of the field of procedural pain within an interaction with hospital clowns. Thus, the disconfirming results concerning children aged 4–6 can lead to further exploration of pain assessment for this age group.

7.2.2 STUDY 1

Study 1 was designed as a prospective non-blinded trial. A parallel design was used to allocate children who were admitted to the admission unit consecutively. The results of the study may be considered valid due to the following strengths and limitations.

The main limitation concerning the allocation of children to either the experimental (hospital clown present) or the control group (standard care) was attributed to the availability of the hospital clown. The hospital clown

was only available on scheduled days and time intervals on weekdays and in the evening, planned by clown and researcher for the study before starting the recruitment of children (Kristensen et al., 2018). Thus, this study is not categorized as a Randomized Controlled Trial. Accordingly, children were assigned to the hospital clown if they were admitted on days when the hospital clown was present and to the standard care group on days when the hospital clown was absent. To secure a random distribution, a pilot study was conducted prior to the recruitment. The pilot study investigated the distribution of 173 diagnoses on gender and age and showed a random distribution of all days of the week, thus strengthening the allocation of children (Kristensen et al., 2018).

A limitation of this study is its small sample size, especially when dividing the age groups for the stratified analysis; therefore, some of the outcome variables only demonstrated a tendency for an increase or a decrease in pain intensity. Nevertheless, an estimation for clinical relevance (Powell, Kelly, & Williams, 2001; von Baeyer, 2006) of 10–20% of deviations of pain scores was conducted, estimating a sample size of 52 children in each group, which was reached by a total of 116 children and a total of 111 participants who were included in the analysis (Figure 1, Paper 1).

A strength of this study was the assessment of one homogeneous procedure (venipuncture) for all the participating children, conducted by a team of lab techs, usually working with children. Another strength in the design of the study was the use of only one and the same hospital clown, ensuring a similar intervention. Nevertheless, the intervention cannot be considered identical, as the human expression and character of the hospital clown were changed and tailored, depending on the situation of the individual child. The individually tailored approach may be considered a limitation, due to the strength of the statistical analysis, or strength due to the individual interaction with the children.

In this study, self-report of pain intensity was the only pain intensity measurement chosen. The reason for this choice was balancing the risks (distressing supplementary measures as pulse, blood pressure), considering children as an especially vulnerable group, and the benefits of the research results. The children's agreement to participate is essential (Carnevale et al., 2008). The self-report of pain is considered a part of the standard measurement, included in the treatment and care for hospitalized children, and therefore does not pose additional challenges to the children. Moreover,

the specific time frame and task for the nurses and other professional staff facilitated the choice. However, from the beginning, it was decided that the study should be integrated into a mixed methods approach, collecting observational data concurrently, and, as such, this was expected to compensate and validate the choice of only one pain measurement.

Children's self-report of pain is recommended as a reliable measurement of pain (Association of Paediatric Anaesthetists, 2012; Center of Clinical Guidelines, 2016; von Baeyer, 2006), commonly used among health care professionals in pediatrics in Denmark. As such, self-reporting provides valuable information on pain intensity and is often the preferred approach during clinical practice and research contexts (Association of Paediatric Anaesthetists, 2012). Nevertheless, self-reporting has limitations, such as bias due to the interpretation and differences in age and developmental level (Stinson et al., 2006). Given the aspects of the younger children's ability to handle self-reporting, other sources of information are required for a complete picture of the pain experience, such as observations of behavior, parents' descriptions, clinical data, information of previous experiences, and other contextual aspects (Stinson et al., 2006; von Baeyer, 2006).

Due to this discussion of pain measurement, the strength of this mixed methods study design is the use of different data sources (participant observation, informal interviews, video recording) to understand the pain experience; thus, the results of the self-reported pain may be interpreted in the light of these data, as discussed in the mixed methods findings. The use of two assessment scales (FPS and NRS) may be discussed as a potential for response bias, as younger children tend to choose the FPS and the extreme ends of the scale (Stinson et al., 2006). Nevertheless, results showed a random distribution of the scales in both the hospital clown group and the standard care group (Table 4). Furthermore, the results did not show a significantly higher score in children aged 4-6 (standard care group) compared with children aged 7-15 (standard care group), which indicated no favoring of the high end of pain scales among the youngest age group (Table 5) (see paper 1 for details).

7.2.3 STUDY 2

Study 2 is conducted as a focused ethnographic study. In this respect, the study was restricted to provide insight in the specific context (Cruz &

Higginbottom, 2013; Higginbottom et al., 2013; Knoblauch, 2005) by exploring the interaction between child and hospital clown during the data sources: participant observation, informal interviews, and video recording.

In the ethnographic approach, the researcher role is related to the relationships established with the informants during the period in the field and is therefore situated, positioned, and partial (Koch & Vallgård, 2008, see Chapter 4). The participant observations influence the researcher and the participants through the fieldwork. Hence, reflexivity during the research process is critical and must be explicated as a criterion for ethnographic validity along the way (Koch & Vallgård, 2008, see Chapter 4). The role of an insider or outsider is widely discussed in ethnographic research (Hammersley & Atkinson, 2013; Higginbottom et al., 2013; J. Spradley, 1980) with divergent views. Focused ethnography often tends to be conducted in a familiar setting (Higginbottom et al., 2013). In this respect, the preconceptions of the researcher as a pediatric nurse shaped the researcher's preconceptions in the field and are therefore central in the discussion of the validity of the research (Atkinson, 2015; Hammersley & Atkinson, 2013; Higginbottom et al., 2013). The primary setting was familiar to the researcher. In a familiar setting, the suspending of the researcher's preconceptions can be more difficult than in an unfamiliar setting (Hammersley & Atkinson, 2013). Reflexivity during the process was secured by sharing and explicating the field notes with two researchers from the research team, thus providing transparency of the effect of the researcher and the analysis of the data. (Cruz & Higginbottom, 2013; Hammersley & Atkinson, 2013). However, the focus of research was child-hospital clown interactions and as such the researcher did not follow the hospital clowns before this study was undertaken.

Moreover, reflexivity attempts to make transparent the effect of choices of methodology, the researcher role, and data collection (Cruz & Higginbottom, 2013; Higginbottom et al., 2013). Reflections among the research team led to exploring of the research question by examining a different context and five different hospital clowns. Hence, the choice of moving to a secondary setting in this study emerged during the primary fieldwork period, as questions of comparing and validating the participant observations and informal interviews from primary setting with a secondary setting. Moving between different contexts can further facilitate the observing of different perspectives of the empirical and analytical object (the research question) across settings (Atkinson, 2015; Koch & Vallgård, 2008, see Chapter 4) and

facilitate a shift in the role of the researcher. This reflexivity established the validity of the results of the child-hospital clown interactions in the primary setting. As such, the researcher role shifted to a more novice role in the secondary setting, which strengthened the alternating between the insider and outsider perspectives (Spradley, 1980), and thereby allowed naïve questions and doubts to be presented. The fieldwork is developmental and not linear (Atkinson, 2015). Hence, it is worth mentioning a note of caution due to the choices of the time period for conducting fieldwork in the secondary setting, suggesting the possibility for other nuances to be captured if a reverse ordering was planned.

The reliability is strengthened during the long period of data collection (Roper & Shapira, 2000), giving the opportunity to include many children and observe the hospital clown in many interactions from several angles with children at different ages and acute conditions. The systematic and repeated participant observations and informal interviews provided the researcher with transparency during the data collection period and thereby strengthened the reliability (Koch & Vallgård, 2008; Roper & Shapira, 2000). Nevertheless, ethnography is a translation (Spradley, 1979), considered in this study as trying to represent both the native (child and clown) and the ethnographer's meaning during the descriptions.

Fieldwork is multimodal and dependent on more than one form of data collection (Atkinson, 2015; Hammersley & Atkinson, 2013). Different data collection methods were used in this study (e.g., participant observation, informal interviews, and video recording) and made different contributions, complemented each other, and thereby strengthened the reality and the meaning of the children's experience during painful acute venipunctures. The triangulation with multiple data collection as participant observation, informal interview, and video recording thereby strengthened the rigor during the comparison and validation of the findings (Higginbottom et al., 2013; Roper & Shapira, 2000). This might be considered a strength that enhanced the validity in Study 2. Fully addressing the context with parents, nurses, and other health care staff was outside the aim of this thesis. Nevertheless, the inclusion of these perspectives might have yielded more perspectives, suggesting further analysis of the data in future research.

An important point of discussion is the use of video recording. The video recording in this study alongside the participant observations and informal interviews was chosen as supplementary in the way of hearing, seeing, and

feeling information, that cannot be captured or can be unconsciously modified during the transcription. Focused ethnography concerns specific interactions and social events. For that reason, the use of video recording can supplement the observations, providing aspects to the understanding of the observations (Knoblauch, 2005). Thereby the video recording supported the understanding of the characteristics of the child-hospital clown interactions during the venipuncture procedures. However, the use of video cannot capture senses such as smell, touch, taste, or emotions; moreover, the representation is partial and framed by decisions concerning the placing of the camera, etc. (Hammersley & Atkinson, 2013). The video recordings represent specific events and are selected and removed from a larger context (Derry et al, 2010). Hence, the transcribed participant observations and informal interviews might provide a broader context of the situation. Nevertheless, as argued by (Pink, 2015, see Chapter 6), video recording can stimulate and invite the researchers' memories of multiple senses experienced during the field work. When seeing and hearing the video data several times, the researcher can capture a more conscious view and nuances of the physical and emotional reactions of the participants (Pink, 2015, see Chapter 6; Bazeley & Jackson, 2013). The video recording in this study is used as an adjunct to the textual data. A more comprehensive analysis of the video data in its own right could have been interesting and may have captured even more nuances. The extent of this thesis has been critical for the decision of representing the video data as a supplement.

7.2.4 STUDY 3

Study 3 is conducted as a focused ethnographic study. As such, the study was restricted to exploring the specific contexts of recurrent interactions (Cruz & Higginbottom, 2013; Higginbottom et al., 2013; Knoblauch, 2005). The data sources were participant observations and informal interviews. The choice of an ethnographic approach as a method is discussed in Study 2. The results of Study 3 should be considered in light of the following limitations.

The sampling was consecutive (Polit & Beck, 2017), with a total of 13 participating children who were divided into age groups: 4–6 ($n = 5$) and 7–15 ($n = 8$), respectively. Despite the number of the participants, the reliability in this study is strengthened, mainly because the researcher was able to follow each child during recurrent encounters (from 2–12 encounters with

the clown; Table 4, Paper 3). The choice of setting is critical for gathering rich data (Hammersley & Atkinson, 2013; Polit & Beck, 2017) and as such an often named limitation of ethnography is the small number of cases. However, the continuity in the cases, obtained through triangulation of participant observations and informal interviews, increased the validity (Roper & Shapira, 2000). The choice of children with diagnoses of cancer enhanced the possibility of capturing the focus of the research question regarding following each individual child and the hospital clown during recurrent interactions.

The use of video recording, as chosen in Study 2, might capture more details and thereby contribute as a powerful data resource (Derry et al., 2010). However, hospitalized children considered vulnerable and especially children suffering from long-term diseases such as cancer in recurrent hospitalizations are challenged in managing repeated treatment and care-related painful procedures and conditions (Hedstrøm et al, 2003). Thus, research with children as participants should carefully consider how the research questions can be answered with minimum risks and tailored to the specific sample of participants (Carnevale et al., 2008). In addition, it was not always known in advance if a specific child was scheduled a painful procedure. Thus, the video was not included in Study 3.

With respect to the credibility and trustworthiness of the interpretations of the findings, member checking (Braun & Clarke, 2018, see Chapter 12) was performed in a dialogue with parents, hospital clowns, some of the children, and nurses who were asked to express their thoughts concerning their interactions with the hospital clown after a specific encounter. The credibility was further enhanced during continuous discussions among the research team, addressing the specific analysis and interpretations of the themes.

CHAPTER 8. CONCLUSION

This thesis aimed to integrate quantitative and qualitative data to expand knowledge of the effect and influence of the hospital clown on the pain experiences of the hospitalized children aged 4–15 and their ability to cope during painful procedures and conditions in acute and recurrent hospitalizations. This was sought through an evaluation of the effect of the hospital clown on self-reported pain level compared with standard care in acute venipuncture procedures, an exploration of the characteristic of the interaction between the hospital clown and the acutely hospitalized child undergoing venipuncture procedures, an exploration of the characteristic of the interaction during recurrent hospitalizations, and finally through an integrated mixed methods interpretation.

In conclusion,

- The use of hospital clowns in acute venipunctures had a positive effect on the children older than 6 years. The children with previous experiences of venipunctures or affected by pain had a slight tendency to benefit from the hospital clown.
- A WE, characterized by a responsive interaction established from the first encounter with the children and maintained during three stages (*before venipuncture, during venipuncture, and after venipuncture*) strengthened the children's competencies in pain management and coping in the acute venipuncture procedure. The continuous WE specifically allowed the interactions to be tailored to the individual child. An evaluation emphasized the importance of creating awareness of the individual child's strategies for managing in the future.
- Recurrent hospitalizations comprised an ongoing WE, with an understanding of the hospital clown as a close professional friend. This WE was built up based on specific knowledge of the children's preferences, situation, and earlier shared experiences and provided the children with hope for a continuous relationship and for managing pain related procedures and conditions in the future.

The integrated conclusions were as follows:

- An age-differentiated approach was important and strengthened pain management and coping in various ages. Children aged 4–6 expressed more worries and pain but had the ability to positively manage during a modified and tailored approach, based on guiding on more concrete terms. Children aged 7–15, however, managed the reality by a feeling of more control.
- The children's physical and psychological condition affected their interactions with the hospital clown, connected with a feeling of more pain or less mental capacity to interact. The hospital clown had a conscious focus on establishing, maintaining, and modifying a tailored, trustful, and responsive interaction in a WE in order to support the children as a special task during the procedures. The children adopted this WE as hope for managing and for a new chance.
- Previous experiences were a part of the children's histories, which either enhanced or diminished the children's feeling of ability to manage. An evaluation manifested the children's individual strategies for how to manage future procedures and framed a memory for the children, which might strengthen the children's competencies for managing pain related procedures and conditions in the future. Thus, taking the memory into account for the next situation was critical.

In summary, the identification of a WE, characterized by a responsive interaction between child and hospital clown was important for the children's pain experience and ability to cope. The WE was initially established by the hospital clown and further tailored during the process in a mutual close and trustful individual relationship with the children, which illustrate the importance of getting to know the individual child from the very first encounter. The continuity in this WE was understood both as continuity during a single specific situation and as continuity over recurrent hospitalizations, painful procedures, and conditions.

CHAPTER 9. PERSPECTIVES AND IMPLICATIONS

This thesis highlights the clinical importance of establishing a responsive interaction concerning managing pain and the ability to cope during common acute and recurrent painful procedures and conditions, assuring that the hospitalized child's voice and perspective are included and explicated. Specifically, this thesis demonstrates how a WE established between a child and hospital clown can strengthen the child's competencies in pain management and coping. Thus this thesis adds to the body of knowledge on how hospitalized children (aged 4–15) deal with pain during common painful procedures and conditions. Moreover, the thesis illustrates the importance of a continued focus on the development of eligible pain management approaches for hospitalized children.

The importance of supporting the children in an individually tailored relational approach from the very first encounter, during the procedure, and at the end of the evaluation seems essential to the treatment and care of every hospitalized child. This thesis provides useful knowledge into psychosocial care of hospitalized children undergoing painful procedures and advocates initiating multidisciplinary initiatives such as hospital clowns who work in the pediatric units to ensure best clinical practice.

9.1. IMPLICATIONS FOR CLINICAL PRACTICE

The important implications for health care professionals who work with hospitalized children and their families involve:

- Establishing a trustful relationship in a WE atmosphere, tailored to the individual child from the first encounter; this continued and evolving relationship throughout the entire encounter or hospitalization should reflect the uniqueness of the child's history, based on characteristics such as age, cognitive abilities, previous experiences, levels of distress and pain, etc.;
- Recognizing the importance of WE as a special psychosocial and relational caring practice to be taken into consideration during painful procedures and conditions during hospitalization. It is imperative to ascertain from the outset the person or group that is responsible for

establishing and maintaining this relationship during potentially painful care or treatment procedures;

- Considering the active involvement of the child and the integration of the child's preferences in the identification and selection of the individual strategies for coping with pain;
- Considering evaluation an integral part of the procedure related to coping with pain to raise the child's awareness of his/her personal coping strategies and to strengthen the child's self-confidence and judgment of the situation. It is also recommended to acknowledge evaluation as an integrated part of the treatment procedure to enhance the preparation of future procedures and save time;
- Recognizing the age of the child as the key to understanding which strategies work best in planning and ensuring best health care for the individual child and his/her family;
- Establishing a responsive interaction in an ongoing process during care and treatment related to painful procedures and conditions to be extended to the other stages of the child's admission, treatment, and care in the context of hospitalization;
- Advocating and increasing the possibility of further contribution to and integration of hospital clowns when scheduling pain-related procedures in hospital contexts;
- Improving dialogue and collaboration with the hospital clowns to address mutual inspiration, aimed at specific hospital clown approaches, which might complement the traditional clinical interventions during a multidisciplinary collaboration.

9.2. IMPLICATIONS FOR FURTHER RESEARCH

This thesis underlines the complexity in the field of pain management among hospitalized children aged 4–15. The findings provide the following insights for further research in the related areas:

Children were accompanied by their parents when admitted to the hospital and therefore parents were an integral part of the context. The existing literature suggests that social and contextual terms such as family and parents may influence the child's behavior. Thus parents' cognitive, behavioral, and emotional function might affect the child's experience and ability to cope with painful procedures and conditions either as a resource or a stressor (Birnie et al., 2017; Kaakinen et al., 2015, Chapter 1). In this thesis, these perspectives of parents were not analyzed during the presence of a

hospital clown and thus require further research investigating the parents' role during painful procedures when the hospital clowns are present.

The findings of this thesis provide knowledge of the children's experience of pain and their ability to cope during both acute and recurrent hospitalizations. The recurrent interactions between the children and hospital clowns investigated in Study 3 only identified the characteristics from a limited period of time. To follow up on these results, it may be relevant to explore the potential long-term influence of systematic interactions between the child and hospital clown (see Tener et al., 2016).

In light of the growing number of hospital clowns working in the health care system, attention must be paid to the administrative planning, economic resources, and collaboration between hospital clowns and health care professionals (see Finlay et al., 2014; van Venrooij & Barnhoorn, 2017). Moreover, the involvement of hospital clowns during care-related practice raises the questions about how the communication and arrangement of a person-oriented or "whole-person" care (Kitson & Soerensen, 2017; Uhrenfeldt, Sørensen, Bahnsen, & Pedersen, 2018) can be incorporated into the collaboration between hospital clowns and health care professionals in particular nurses. Further work needs to be done in order to provide insights into the barriers and benefits involved in the collaboration with hospitalized children.

Finally, several questions remain to be answered concerning parents', nurses', and other health care professionals' views on the presence of hospital clowns during care-related practice (e.g., pain and pain-related procedures). For example, how can the hospital clown, if possible at all, promote the interaction between the child and the child's parents or between the child and the nurses? Further research on this question and similar ones can be useful to illuminate the cooperation between hospital clowns, hospital clown organizations, and health care professionals in pediatric clinics in hospitals, which aim for the best individually tailored-care for the hospitalized children.

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APPENDICES

Appendix A. Search strategy

Appendix B. Participant information, Study 2

Appendix C. Informed consent, Study 2

Appendix D. Participant information, Study 3

Appendix E. Informed consent, hospital clowns, Studies 2 & 3

Appendix F. Pain scale

Appendix A. Literature search

Example of systematic literature search

Database: Ovid MEDLINE(R) ALL <1946 to December 06, 2018>

Search Strategy: 12122018 (Table 1)

-
- 1 pain/ or acute pain/ (128279)
 - 2 Pain Management/ (29117)
 - 3 Pain Measurement/ (79075)
 - 4 1 or 2 or 3 (197950)
 - 5 Diagnostic Tests, Routine/ (10308)
 - 6 (procedur* or acute or measure* or assessment' or management* or diagnostic test*).mp. (6728728)
 - 7 5 or 6 (6728728)
 - 8 4 and 7 (133294)
 - 9 (pain adj3 (procedur* or acute or measure* or assessment' or management* or diagnostic test*)).mp. (148625)
 - 10 8 or 9 (170407)
 - 11 exp child/ (1797817)
 - 12 adolescent/ (1897585)
 - 13 (child* or adolescent* or teen*).mp. (3283793)
 - 14 11 or 12 or 13 (3283793)
 - 15 inpatients/ (18762)
 - 16 exp hospitalization/ (213765)
 - 17 (inpatient* or hospitaliz*).mp. (327735)
 - 18 15 or 16 or 17 (419816)
 - 19 14 and 18 (109179)
 - 20 child, hospitalized/ (6358)
 - 21 adolescent, hospitalized/ (424)
 - 22 19 or 20 or 21 (109179)
 - 23 10 and 22 (1820)
 - 24 limit 23 to yr="2017 - 2018" (167)
 - 25 ((medical or hospital*) adj3 clown*).mp. (64)

Appendix B. Participant information

Information til børn og forældre i Børnemodtagelsen

Denne information omhandler et sundhedsvidenskabeligt forskningsprojekt:

"Hospitalsindlagte børns smerteoplevelse"

Undersøgelsen foregår i børneafdelingens børnemodtagelse på Aalborg Universitetshospital i perioden april – december 2016, og er en undersøgelse af hvilken betydning hospitalsklovnens tilstedeværelse har på børns oplevelse af smerter i forbindelse med undersøgelse og behandling.

Målgruppen for undersøgelsen er alle børn i alderen 4-15 år og deres forældre, der kommer akut til børnemodtagelsen. Undersøgelsen vil indbefatte børn, der taler dansk /engelsk, og som har én eller begge forældre med. Der forventes omkring 100 deltagende børn og deres forældre. Alle børn og forældre vil modtage mundtlig

og skriftlig information, og forældre skal give skriftlig samtykke til deltagelse. Alle oplysninger anonymiseres.

Ansvarlig for projektet er sygeplejerske og ph.d. studerende Helle Nygård Kristensen. Projektets udføres i samarbejde med sygeplejersker, læger og bioanalytikere tilknyttet børneafdelingen og hospitalsklovn Theodor.



Kontakt:

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Baggrund:

Smertefulde undersøgelser – det at skulle stikkes – ved vi, som personale, fylder allermest hos indlagte børn og forældre. Børn beskriver det som "det værst tænkelige".

Da mange børn indlægges akut, er der oftest kun kort tid til at forberede børnene på de undersøgelser, der skal foretages i det akutte forløb. Derfor ved vi, at oplevelsen kan være stressende og kaotisk for både jeres barn og jer, som forældre. Vi ved også, at mange børn kommer til at opleve flere smertefulde undersøgelser og behandlinger, og at tidligere negative oplevelser kan komme til at påvirke barnet med psykiske konsekvenser ved fremtidige indlæggelser. Derfor er der stort behov at få viden om børns oplevelse af smerter i forbindelse med smertefulde undersøgelser og behandlinger, og derved kunne udvikle mulighederne for at hjælpe børn, så de oplever mindst mulig smerte under indlæggelse.

Vi har her i børneafdelingen samarbejdet med hospitalsklovnen siden 2004, og vi har derfor lang erfaring med, at de bidrager til at skabe en stemning af smil, glæde og lettelse for alle. Men vi ved ikke, om det vil kunne mindske barnets smerte og hjælpe barnet til bedre at kunne klare situationen, hvis hospitalsklovnen er til stede, når barnet skal gennemgå smertefulde undersøgelser og behandlinger.

Projektets første del foregår her i børneafdelingen, hvor alle akutte børn kommer. Næste fase af projektet vil foregå i børneafdelingens sengeafsnit, hvor børn er indlagt i længerevarende forløb.

Metode:

Vi sammenligner 2 grupper af børn. Den ene gruppe oplever, at hospitalsklovnen Theodor er til stede både i ventrum-

met og i undersøgelsesrummet, hvor undersøgelse af lunge og sygeplejerske og eventuelt blodprøve foregår. Den anden gruppe har ikke hospitalsklovnen Theodor til stede. At hospitalsklovnen kun er tilstede hos den ene gruppe børn svarer til det tilbud, vi har i øjeblikket, fordi vi ikke har mulighed for at have en hospitalsklov til stede altid. Vi måler derfor på det, som er vores praksis nu. Forældre vil i ventrummet blive spurgt om deltagelse, og sygeplejersken vil efterfølgende på et skema afkrydse: barnets alder, tidligere indlæggelser, møde med hospitalsklovnen og smerter ved ankomst. Efter blodprøvetagning vil alle børn blive bedt om at fortælle, hvor ondt det gjorde på en smerteskala.

I ventrummet og i undersøgelsesrummet vil hospitalsklovnen Theodor på nogle tidspunkter blive fulgt af Helle, som er projektansvarlig. Hun vil observere, hvad der er på spil, når hospitalsklovnen Theodor er til stede eller ikke er der, ligesom hun vil observere situationer, hvor børnene får taget blodprøver. Der vil i perioder forekomme videooptagelse i ventrummet. Enkelte børn over 10 år vil blive stillet spørgsmål om oplevelsen.

Resultater:

Vi forventer, at undersøgelsen vil give os en viden om børns oplevelse af smerter, når de skal gennemgå smertefulde procedurer, som f.eks. blodprøver, og samtidig give indblik i betydning og effekt af hospitalsklovnens tilstedeværelse, som derved kan være med til at optimere fremtidige smertelindrende muligheder og initiativer for hospitalsindlagte børn og deres smertebehandling.



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– i gode hænder

Appendix C. Declaration of consent

SAMTYKKE ERKLÆRING



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– i gode hænder

Samtykke fra forældremyndighedsindehaveren til mit/vores barns deltagelse i et sundhedsvidenskabeligt forskningsprojekt.

Forskningsprojektets titel:

Hospitalsindlagte børns smerteoplevelse. En undersøgelse af effekten og betydningen af hospitalsklovnens tilstedeværelse på hospitalsindlagte børns oplevelse og mestring af smerter i relation til smertefulde procedurer i korte og længerevarende forløb.

Erklæring fra indehaveren af forældremyndigheden:

Jeg/vi har fået skriftlig og mundtlig information og jeg/vi ved nok om formål, metode, fordele og ulemper til at give mit/vores samtykke.

Jeg/vi ved, at det er **frivilligt at deltage**, og at jeg/vi altid kan trække mit/vores samtykke tilbage uden, at min/vores datter/søn mister sine nuværende eller fremtidige rettigheder til behandling og pleje.

Jeg/vi giver samtykke til, at _____ (barnets navn) deltager i forskningsprojektet. Jeg/vi har fået en kopi af dette samtykkeark samt en kopi af den skriftlige information om projektet til eget brug.

Navnet eller navnene på forældremyndighedens indehaver(e):

Dato: _____ Underskrift: _____

Dato: _____ Underskrift: _____

Ønsker du/I at blive informeret om forskningsprojektets resultat?

Ja ☐ (sæt kryds) Hvis ja: E-mail: _____

Nej ☐ (sæt kryds)

Erklæring fra den, der afgiver information:

Jeg erklærer, at forældrene/barnet har modtaget mundtlig og skriftlig information om projektet. Efter min overbevisning er der givet tilstrækkelig information til, at forældrene kan træffe beslutning om barnets deltagelse i projektet.

Navnet på den sygeplejerske, der har afgivet information: _____

Dato: _____ Underskrift: _____

Appendix D. Participant information

Deltagerinformation

Denne information omhandler et sundhedsvidenskabeligt forskningsprojekt, som aktuelt udføres her i børneafdelingen BU2, Aarhus Universitetshospital, Skejby, i samarbejde med børneafdelingen, Aalborg Universitetshospital, i perioden November - December 2017.

Projektet omhandler:

Hospitalsindlagte børns smerteoplevelse. Studiet er en undersøgelse af hvilken betydning hospitalsklovnens tilstedeværelse har på børns oplevelse af smerter i forbindelse med undersøgelser og behandlinger.

Projektet udføres i et samarbejde mellem Børneafdelingen, Skejby, Børneafdelingen og Forskningsenhed for Klinisk Sygepleje, Aalborg Universitetshospital.

Projektansvarlig:

Sygeplejerske og ph.d. studerende, Helle Nygård Kristensen, som er ansat i børneafdelingen, Aalborg Universitetshospital, og indskrevet ved Aalborg Universitet.

Baggrund:

For hele tiden at kunne udvikle nye måder at håndtere børns smerter på, er det vigtigt at få viden om, hvordan børn oplever smerter i forbindelse med smertefulde undersøgelser og behandlinger.

Jeg vil derfor gerne spørge dig som forældre, om du og dit barn vil deltage i dette sundhedsvidenskabelige forskningsprojekt, hvor jeg undersøger om hospitalsklovnens tilstedeværelse har en betydning for syge børns oplevelse af smerter og deres evne til at klare situationer, hvor de udsættes for smertefulde undersøgelser eller behandlinger, som f.eks. stikke procedurer.



Du har som forældre mulighed for at afslå at deltage og kan til hver en tid trække dig ud af undersøgelsen, hvilket naturligvis ikke vil påvirke dit barns fremtidige pleje og behandling.

Formål

Vores erfaringer som personale i børneafdelingen og studier fra andre lande viser, at "det at skulle stikkes", fylder allermost for børn, der kommer på hospitalet – og for jer forældre. Mange børn bliver indlagt akut, og der er ikke altid tid nok til at forberede tilstrækkeligt på det, der skal ske. Derfor ved vi også, at det kan opleves både kaotisk og stressende for jer og jeres barn. Mange børn, ligesom jeres barn, oplever gentagne indlæggelser og flere forskellige smertefulde undersøgelser og behandlinger under en indlæggelse. Vi ved, at tidligere dårlige oplevelser kan få betydning for jeres barn ved fremtidige kontakter med sundhedsvæsenet. Selvom vi anvender "tryllecreme", lattergas og lignende, hvis det er muligt, er det ikke altid tilstrækkeligt.

Vi har lang erfaring med samarbejde med hospitalsklovne. De bidrager med smil og glæde. Men vi ved ikke, om det vil kunne mindske jeres barns smerte og hjælpe jeres barn til bedre at kunne klare situationen, hvis hospitalsklovn er til stede, når jeres barn kommer her i afdelingen og er med, når jeres barn skal gennemgå forskellige smertefulde procedurer. Vi er interesseret i at undersøge om en kendt relation med hospitalsklovn har betydning for jeres barns smerteoplevelse og måde at klare gentagne undersøgelser og behandlinger på.

Plan

Jeg er ansvarlig for projektet, og jeg vil samarbejde med de læger og sygeplejersker, I kender her i BU2, og de hospitalsklovne, der kommer her. Jeg vil i en periode fra 30. oktober 2017 være til stede i BU2 sammen med hospitalsklovnene. Jeg vil følge klovnene på deres vej rundt i afdelingen – i ventrum, opholdsrum og på jeres sengestuer – for

at se på, hvad der sker, når jeres barn skal gennemgå forskellige undersøgelser og behandlinger, som kan forvolde smerte.

Der er planlagt deltagelse af børn, som kommer gentagne gange her i BU2. Derfor vil I også opleve, at jeg er med flere gange sammen med hospitalsklovnene og sammen med jer. Hospitalsklovn vil sammen med mig følge med ind på stuen og være til stede ved den undersøgelse eller procedure, som jeres barn skal gennemgå. Efterfølgende vil jeres barn blive bedt om at fortælle hvor ondt, det gjorde på en skala fra 1-10 eller på en ansigtsskala. Sygeplejersken eller jeg vil fortælle dig og dit barn om denne smerte skala.

Jeg vil desuden tale med jer og jeres barn om oplevelsen. Alle informationer vil blive anonymiseret.

Resultater

Projektet som helhed vil strække sig over 3 år og resultaterne kan forventes at blive gjort op i løbet af 2018.

Vi forventer, at undersøgelsen vil give os en viden om børns oplevelse af smerter, når de skal gennemgå smertefulde procedurer, og samtidig give indblik i betydning og effekt af hospitalsklovnens tilstedeværelse. Denne viden ønsker vi, kan være med til at optimere fremtidige smertelindrende muligheder og initiativer for hospitalsindlagte børn og deres smertebehandling.

Med denne information håber jeg, at du/I har fået tilstrækkelig indblik i, hvad det vil sige at deltage i dette projekt for jer og jeres barn, og at du/I føler dig/ jer tilstrækkelig informeret til at tage beslutning om evt. deltagelse.

Venlige hilsner
Helle Nygård Kristensen
23305158
hnk@rn.dk

Appendix E. Declaration of consent

SAMTYKKE ERKLÆRING



Samtykke fra hospitalsklovne's deltagelse i et sundhedsvidenskabeligt forskningsprojekt.

Forskningsprojektets titel:

Hospitalsindlagte børns smerteoplevelse. En undersøgelse af effekten og betydningen af hospitalsklovnens tilstedeværelse på hospitalsindlagte børns oplevelse og mestring af smerter i relation til smertefulde procedurer i korte og længerevarende forløb.

Erklæring:

Jeg har fået skriftlig og mundtlig information, og jeg ved nok om formål, metode, fordele og ulemper til at give mit samtykke.

Jeg ved, at det er frivilligt at deltage, og at jeg altid kan trække mit samtykke tilbage uden, at det ændrer på mine nuværende eller fremtidige arbejdsforhold i funktionen som hospitalsklovn i børneafdelingen.

Jeg giver samtykke til at deltage i forskningsprojektet. Jeg har fået en kopi af dette samtykkeark samt en kopi af den skriftlige information om projektet til eget brug.

Navnet på deltager:

Dato: _____ Underskrift: _____

Ønsker du at blive informeret om forskningsprojektets resultat?

Ja ☐ (sæt kryds) Hvis ja: E-mail: _____

Nej ☐ (sæt kryds)

Erklæring fra den, der afgiver information:

Jeg erklærer, at ovennævnte hospitalsklovn har modtaget mundtlig og skriftlig information om projektet.

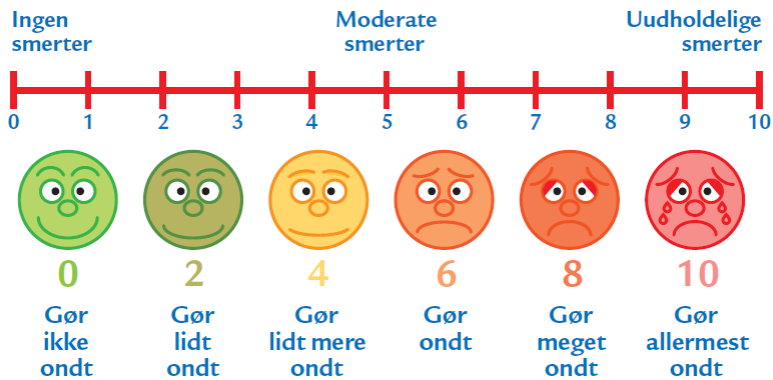
Efter min overbevisning er der givet tilstrækkelig information til at træffe beslutning om deltagelse i projektet.

Navnet på forskningsansvarlig, der har afgivet information:

Dato: _____ Underskrift: _____

Appendix F. Pain scale

Pain scale combining Numerical rating Scale (NRS) and Wong-Baker Faces Pain Scale (FPS) used in study 1 for self-reported pain.



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