

**ACCEPTABILITY AND FEASIBILITY OF REIKI FOR SYMPTOM MANAGEMENT
IN CHILDREN RECEIVING PALLIATIVE CARE**

by

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Complementary therapies are chosen by parents of children receiving palliative care to augment the use of traditional medications for symptom management without the increased side effects additional medications may bring. Pain and anxiety are common symptoms for children receiving palliative care. Reiki therapy is a light touch therapy that has been examined in adults but not with children until recently. This dissertation addresses the evidence for complementary therapies for children experiencing pain and anxiety, Reiki therapy for pain and anxiety in adults, and evidence based complementary therapies for young children considering developmental stage. The main study is a quasi-experimental mixed methods pilot study design examining the acceptability and the feasibility of a Reiki therapy intervention for children ages 7 to 16 years receiving palliative care. We measured pain, anxiety, and relaxation operationalized as heart and respiratory rates pre and post Reiki therapy interventions at each of two home visits. We completed a structured interview separately with parents and children to elicit their views on the Reiki therapy experience. Paired student t-tests or Wilcoxon signed rank tests were calculated comparing the pre and post Reiki scores separately for verbal and non-verbal children for each treatment, over the entire intervention, and independent sample t-tests or Mann-Whitney tests comparing children based on demographic variables. We approached 24 child-parent dyads, 21 (87.5%) agreed to participate and signed consents while 3 (12.5%) declined to participate. Of the 21 dyads, 16 completed the study (eight verbal and eight non-verbal children). Statistical significance was obtained for verbal children for heart rate for treatment two ($t=3.550$, $p = 0.009$)^{iv}

and for nonverbal children for pain for treatment two ($Z = -2.023$, $p = 0.063$); however effect sizes using Cohen's d levels were medium to large for both verbal and non-verbal children for pain and anxiety. Children and their parents told us their experiences with Reiki therapy. Themes found in interviews augment the quantitative results. Themes included *Feeling Better*, *Hard to Judge*, and *Still Going On*, which helped clarify the quantitative results. Results support further study of Reiki therapy for symptom management in children.

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PREFACE

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1.0 INTRODUCTION/STUDY PROPOSAL

1.1 ABSTRACT

Specific Aims: Pain and anxiety are debilitating symptoms occurring in 47-75% and 32-39% of children with cancer and terminal conditions respectively that compromise quality of life (QOL) in children and increase the distress experienced by parents. Progress has been made in the recognition and management of pain in children. However there is a need for non-pharmacological therapies to augment pain medication to achieve the goal of pain relief without excess sedation that reduces the child's ability to interact with family and friends. Complementary and alternative medicine (CAM) therapies including Reiki therapy (a biofield touch therapy) are now offered to patients for relaxation and symptom management by a growing number of hospitals (e.g. Boston Children's Hospital and Yale New Haven Children's Hospital). The overall purpose of this study is to explore the feasibility and acceptability of using Reiki therapy with children ages 7 to 16 years receiving palliative care as a first step in studying the use of Reiki therapy in pediatrics through the following specific aims:

1. Assess the feasibility and acceptability of Reiki therapy as a treatment for children receiving palliative care.
 - a. Assess recruitment, retention, and data collection rates and percent completion of intervention.

- b. Explore the experience and acceptance of receiving Reiki therapy with children in relation to changes in the child's experience of pain and anxiety and the outcomes of relaxation, and QOL.
 - c. Explore the parental perception of the child's experience and acceptance of receiving Reiki therapy in relation to the child's experience of pain and anxiety, and the outcomes of relaxation and QOL.
2. Examine the effect of Reiki therapy on the symptom experience of pain and anxiety and the outcomes of relaxation, QOL, and pain and anxiety medication use in children receiving palliative care to calculate effect size for a future larger study.

Research Design: Quasi-experimental pre-post mixed-methods pilot study design. Pain, anxiety, relaxation and QOL will be measured pre and post intervention. Relaxation, measured as heart rate and respiratory rates, in addition to pain and anxiety will be measured pre and post each Reiki therapy treatment. Medications prescribed for the child and usual medication patterns will be listed during the initial visit. The parent will keep track of all pain and anxiety medications given from the initial visit until the follow up visit. Medication use data will be collected at the follow up visit to determine if medication use changed during the intervention.

Sample: Twenty children between the ages of 7 and 16 and their parents will be recruited from Supportive Care Services of Children's Hospital of Pittsburgh. Exclusion criteria: parent or child unable to communicate in English.

Variables and Measures: Aim 1: Recruited, Data Collected, Intervention Completed. Data Collected and Intervention Completed are calculated. Aim 2: Pain, anxiety, QOL, heart rate, respiratory rate, and medication use. Pain and anxiety will be measured with a visual analog

scale, anxiety and QOL will be measured with PedsQL, heart and respiratory rates will be counted manually, and medication use will be calculated based on mean daily use.

Analysis Plan: Aim 1: The analysis for Recruited, Data Collected, and Intervention Completed will use descriptive statistics only. Aims 1B and 1C will be analyzed using thematic analysis.

Aim2: Because of variation in length of time between measures for each subject, Linear Mixed Modeling (LMM) will be used to analyze pain, anxiety, heart rate, and respiratory rate. QOL will be assessed with repeated measure t-test. Mean medication use will be examined using one-way ANOVA. Spaghetti plots will be generated for all repeated variables to examine overall trends in the variables. Several co-variants will be considered during the analysis including age, gender, disease type, Intervention Completed, and pre-intervention PTES scores.

1.2 SPECIFIC AIMS

Pain and anxiety are debilitating symptoms occurring in 47-75% and 32-39% of children respectively that compromise quality of life (QOL) in children with cancer and terminal conditions and increase the distress experienced by parents (Jalmsell, Kreicbergs, Onelov, Steineck, & Henter, 2006; Kreicbergs et al., 2005; Schmidt et al., 2013; Wolfe et al., 2008). Neither clinicians nor parents want a child to suffer. A survey by Dussel et al. (2009) indicated that 34% of parents would consider *hastening their child's death rather than have them suffer with pain*.

Pain and anxiety are often related especially in children and adolescents with life-threatening illnesses. There is evidence that anxiety is associated with greater pain-related

functional disability (Simons, Sieberg, & Claar, 2012; Zernikow et al., 2012). Moreover, anxiety often accompanies pain in children in palliative care, particularly for those with cancer, respiratory conditions, or muscular dystrophy (Ho & Straatman, 2012; Pritchard et al., 2008). Yet, children's pain and anxiety do not always respond completely to traditional pharmacologic interventions. Thus many parents choose complementary (CAM) therapies for their children to augment pharmacologic interventions and to bridge the gap and achieve the goal of pain relief without excess sedation that reduces the child's ability to interact with family and friends (McCann & Newell, 2006; Samdup, Smith, & Il Song, 2006).

Many palliative care experts include CAM therapies as an essential part of palliative care for symptom management (Friedrichsdorf, 2010; Institute of Medicine, 2003; Kuttner, 2006). CAM therapies are often well received by children and are helpful with pain and anxiety (Doellman, 2003). Based on the PI's integrative literature review of CAM therapy use in pediatric oncology patients, multiple CAM therapies including hypnosis, distraction, massage, and listening to music are well-accepted by children and parents and result in decreased pain and anxiety and increased QOL both during general cancer treatments and the painful procedures that accompany cancer therapy (Thrane, 2013). The National Health Interview survey found that 11.8 percent of children had experienced some type complementary therapies within the previous year (Barnes, Bloom, & Nahin, 2008). Moreover, parents of children undergoing cancer treatments prefer either an active or collaborative role in treatment decision-making and are more likely to choose non-botanical CAM therapies for their children (Gagnon & Recklitis, 2003; Kundu, Dolan-Oves, Dimmers, Towle, & Doorenbos, 2013).

Discussing the goals of care with parents and children will help balance the desire to be pain free with the desire to be free of side effects of medications such as sedation or dizziness.

Reiki therapy, a gentle, non-invasive CAM technique has demonstrated good clinical effect in adults but has not been empirically studied in children (Thrane & Cohen, 2014). Based on adult studies, Reiki therapy is likely well suited for symptom management in children with life threatening and chronic illnesses in all phases of palliative care (Institute of Medicine, 2003; Kuttner, 2006; Mack & Wolfe, 2006; Schmidt et al., 2013; Steele et al., 2008).

To address the gap in the use of Reiki therapy in a pediatric population, **the overall purpose of this study is to** explore the feasibility and acceptability of using Reiki therapy with children ages 7 to 16 years receiving palliative care as a first step in studying the use of Reiki therapy in pediatrics. This quasi-experimental pre-post mixed-methods pilot study design will give us critical information about feasibility and acceptability and also about outcomes relating to pain, anxiety, relaxation, and QOL. Data on pain, anxiety, and relaxation will be collected at base line, pre-post each Reiki therapy session and at follow up. Short structured interviews will explore the experience of Reiki therapy with the child and their parents as part of acceptability.

1. Assess the feasibility and acceptability of Reiki therapy as a treatment for children receiving palliative care.
 - a. Assess recruitment, retention, and data collection rates and percent completion of intervention.
 - b. Explore the experience and acceptance of receiving Reiki therapy with children in relation to changes in the child's experience of pain and anxiety and the outcomes of relaxation, and QOL.
 - c. Explore the parental perception of the child's experience and acceptance of receiving Reiki therapy in relation to the child's experience of pain and anxiety, and the outcomes of relaxation and QOL.

2. Examine the effect of Reiki therapy on the symptom experience of pain and anxiety and the outcomes of relaxation, QOL, and pain and anxiety medication use in children receiving palliative care to calculate effect size for a future larger study.

The findings from this pilot study will lay the foundation for the PI's long-term program of independent nursing research in the use of Reiki therapy with children and their parents for the symptom experience of pain and anxiety and the outcomes of relaxation and QOL related to terminal or chronic illness in children.

1.3 BACKGROUND AND SIGNIFICANCE

With the advancement and success of medical science and medical care, a growing number of children are living with long term and often life-limiting chronic conditions (Bogetz, Schroeder, Bergman, Cohen, & Sourkes, 2014). Children with complex chronic conditions, a broad array of disorders which include cancer, respiratory disease (e.g., cystic fibrosis, asthma) neuromuscular diseases (e.g., muscular dystrophy, brain malformations), hematological diseases (e.g., sickle cell disease, immunodeficiencies, HIV), and congenital conditions require the use of multiple therapies and are *the main candidates for palliative care* (Feudtner et al., 2001; J. Wolfe, P. S. Hinds, & B. M. Sourkes, 2011). Out of 83 million children under the age of 19, an estimated 600,000 to 1,600,000 are living with these life-threatening/life-limiting conditions, are often technology dependent, and over 180,000 are considered “medically fragile” (Bramlett, Read, Bethell, & Blumberg, 2009; Buescher, Whitmire, Brunssen, & Klutz-Hile, 2006; Feudtner et al., 2005; United States Census, 2010). These medically fragile children require intense medical and

nursing care in the home and often-lengthy hospital stays, accounting for about 26% of hospital days and 41% of hospital charges (Simon et al., 2010). Children with life-threatening/life-limiting conditions very often experience a large number of symptoms (including pain and anxiety) requiring medical management; many of these children would benefit from palliative care, specialized symptom management, and CAM therapies such as Reiki (Henneghan & Schnyer, 2013; Moody, Siegel, Scharbach, Cunningham, & Cantor, 2011; J. Wolfe, P. S. Hinds, & B. M. Sourkes, 2011).

1.3.1 Palliative Care

The World Health Organization defines palliative care as “the active total care of the child’s body, mind and spirit . . . which begins when illness is diagnosed and continues regardless of whether or not a child receives treatment directed at the disease” (World Health Organization, 1998). More recently the American Academy of Pediatrics stated that “palliative care includes the controlling of pain and other symptoms” with the intention of reducing suffering caused by illness (American Academy of Pediatrics, 2000, p. 351). Palliative care has the potential to benefit over 1 million children living with life-threatening/life-limiting illnesses, and especially the 53,000 children who die each year (Field & Behrman, 2003; Levetown, 2000; Mathews & MacDorman, 2008). Palliative care is transdisciplinary encompassing physicians, nurses, social workers, chaplains, child life specialists, and more. Palliative care seeks to aggressively manage symptoms and improve all areas of a child’s QOL.

Palliative care is not just about physical symptom management. The goal of palliative care is quality of life not only for the child but also for the entire family. The Quality of Life

Model proposed by Padilla, Ferrell, Grant, and Rhiner (1990) encompasses physical, psychological, social, and spiritual domains of well being, emphasizing care of the whole person. The ecological model of palliative care adapted by the PI (see Figure 1) shows that the family contains or influences the child and the child contains the elements of QOL. The relationship influences of family and child are valid in both directions, i.e., not only does the family influence the child, but the child and their domains of QOL influence the family. Bereavement care, which could also be called grief care, crosses the family/child boundary to emphasize that both the family and the child should receive bereavement care from the time palliative care is initiated.

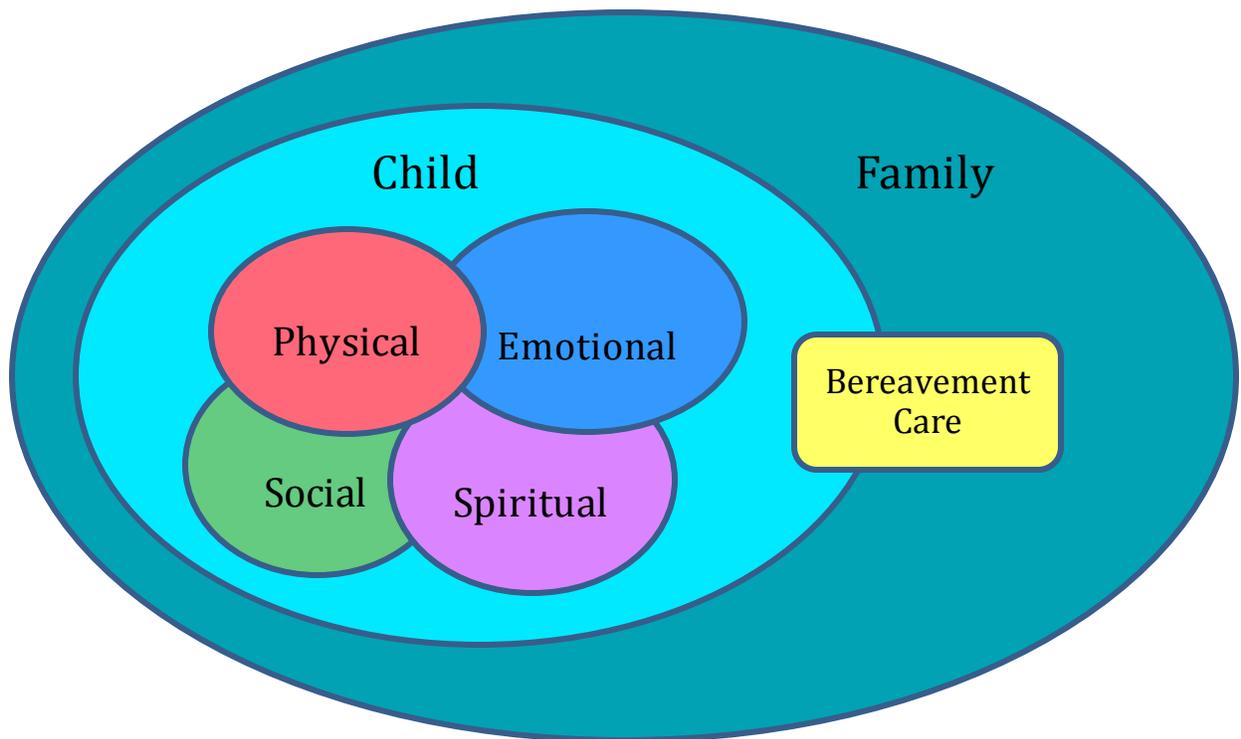


Figure 1. Ecological Model of Palliative Care

A metasummary of qualitative studies from the United States and Canada identified areas of child and family needs during palliative care including communication (general information, interaction between staff and families, psychosocial), health care accessibility, spirituality, needs of siblings, cultural, symptom management, and bereavement (Stevenson, Achille, & Lugasi, 2013). Communication is the key to good palliative care (C. May, personal communication, March 2013). Parents rated improved communication as one of the benefits of palliative care (van der Geest et al., 2014). Cultural needs may be complex especially around end of life. It is imperative that providers take culture into consideration before approaching families of a culture other than their own who may have different languages, experiences, values, religions, and ideas around healthcare and healthcare providers roles (Wiener, McConnell, Latella, & Ludi, 2013). The assistance of a palliative care team leads to better quality of life for the child and family (Groh et al., 2013).

Symptom management and the reduction of suffering is the primary goal of palliative care. The most common symptoms in children at end of life are fatigue, pain, and anxiety (Niswander, Cromwell, Chirico, Gupton, & Korones, 2014; Pritchard et al., 2008; Ullrich et al., 2010; van der Geest et al., 2014). The treatment of pain in children is particularly important and remains a challenge (Collins, Berde, & Frost, 2011; Fitzgerald & Walker, 2009; van Dijk, Peters, Bouwmeester, & Tibboel, 2002). Factors that contribute to the difficulty in assessing and treating pain and other symptoms such as anxiety include physical, emotional, and cognitive development; gender; age; culture; and previous pain experience (McGrath & Brown, 2005). Some of the barriers to pain and symptom management in children include denial of pain either by the child, family, or provider, fear of harm such as respiratory depression, or fear of addiction (Gregoire & Frager, 2006; Shaw, 2012). Although self-report remains the gold standard of

assessing pain and anxiety in children—in some cases, proxy report in the form of parent report or healthcare provider observation is the available source of assessment (Buttner & Finke, 2000; Hartrick & Kovan, 2002; Pillai Riddell & Racine, 2009; Stevens, 2007; Varni, Limbers, & Burwinkle, 2007b, 2007c). By the time an average child reaches kindergarten, they are able to report their pain, point to the painful area, and describe their pain in terms such as stabbing, burning, or the like (Hicks, von Baeyer, Spafford, van Korlaar, & Goodenough, 2001).

Palliative care not only improves symptom management and QOL, it decreases hospital admissions, hospital length of stay, and total costs (Gans et al., 2012; Keim-Malpass, Hart, & Miller, 2013; Postier, Chrastek, Nugent, Osenga, & Friedrichsdorf, 2014). Of course, cost is not a primary consideration of palliative care for families. However, hospital stays affect QOL through separation of the family, extra costs incurred while in the hospital such as parking or parent meals, and the general discomfort of being away from home for both parent and child. Palliative care promotes QOL through holistic care of the child and family by addressing all domains of QOL. Palliative care helps the family set goals of care whether the goals address treatment, comfort care, respite care, helping the child attend school, or making sure the family has the knowledge and supplies they need to successfully care for their child at home. Palliative care is the gold standard of holistic care for children with life-threatening and life-limiting illnesses.

1.3.2 Reiki Therapy

The National Center for Complementary and Integrative Health (NCCIH) classifies Reiki therapy as a biofield therapy in which the goal is to facilitate the body's own healing response

(National Center for Complementary and Integrative Health, 2012a, 2012b). Biofield energy is any electrical or magnetic field produced by a biological organism. The human body produces measurable electrical and magnetic fields (Rae, 2005; Thomas, 2012). The electrical field produced by the heart is measured through electrocardiograms (ECG) and the electrical field produced by the brain is measured with electroencephalograms (EEG). Thus the biofield is a subtle, low-energy electromagnetic field that surrounds the body as a result of normal cellular processes within the body (Movaffaghi & Farsi, 2009).

Biofields are known by many traditional healing systems as *chi*, *ki*, *qi*, and *prana* and are believed to interact with all body systems, causing changes in health (Mills & Jain, 2010). Reiki is a holistic practice that is directed toward healing the body, mind, and spirit. The Reiki practitioner seeks to infuse the recipient's biofield with Reiki energy so that the recipient's body may repair any energy disturbance found within the biofield, which in turn may affect the cells within the body. At the very least, the interaction of the energy fields of practitioner and recipient, combined with light comforting touch of the practitioner typically brings about a relaxed state.

There are three degrees or levels of Reiki therapy practice. First degree practitioners are able to treat themselves or others through light touch (Miles & True, 2003). Second degree Reiki therapy expands practice to the use of distance healing (Rand, 2005). Third degree or master level Reiki therapy expands Reiki practice to teaching others and involves extensive practice (the PI has practiced at this level for over 8 years). Children are receptive to CAM therapies: several non-Reiki CAM therapies including hypnosis, distraction, and massage have been examined and used successfully with children to manage symptoms during painful procedures and cancer treatments (Doellman, 2003; Landier & Tse, 2010; Thrane, 2013). While some of these CAM

interventions require the active participation of the child, Reiki therapy does not. Reiki therapy can be performed on anyone at any stage of life. Reiki therapy does not require participation or even consciousness: the PI has used Reiki therapy with children with severe developmental delays and children nearing death. During a Reiki therapy session, the practitioner is a conduit for energy much like a garden hose is a conduit for water. Most people leave a Reiki therapy session feeling very relaxed. A qualitative study of adults found that during a Reiki therapy session participants felt “dreamy,” “safe,” “secure,” and “more grounded” (Ring, 2009, p. 255).

Our integrative literature review of randomized clinical trials that used at least two groups (one either usual care or control) shows that Reiki therapy is effective for pain and anxiety in adults (Richeson, Spross, Lutz, & Peng, 2010; Tsang, Carlson, & Olson, 2007; Vitale & O'Connor, 2006). This review was limited to adults due to a lack of randomized control studies examining the use of Reiki therapy in children. Olson, Hanson, and Michaud (2003) examined Reiki therapy in cancer patients and found significant decreases in pain after both Reiki treatments when compared to the rest control group. Tsang et al. (2007) also found significant decreases for participants’ pain and anxiety in the intervention group when comparing pre versus post Reiki intervention. When examining Reiki as an intervention for community dwelling adults, the Reiki group had a significant decrease in both pain and anxiety while at the same time the waitlist control group had an *increase* in both pain and anxiety (Richeson et al., 2010). A recent study of 213 adult participants found that there was at least a 50 percent decrease in distress, anxiety, pain, and fatigue and that participants thought the Reiki sessions were relaxing, peaceful, and calming (Fleisher et al., 2014). Kundu et al. (2013) trained parents of hospitalized children in Reiki therapy. Seventy-six percent of parents felt that Reiki increased their child’s comfort, 88% felt their child was more relaxed, 41% had decreased pain, and *all* of

the parents felt that they had become an active part of their child's care (Kundu et al., 2013). The PI's clinical experience with the use of Reiki therapy in hospitalized children found Reiki to be frequently effective for inducing relaxation and reducing pain and anxiety.

It is not clear how Reiki therapy (or any biofield energy therapy) works. The theory of quantum physics, which studies the interactions of energy and matter, may hold promise in the future explanation of the mechanisms of Reiki therapy (Thrane & Cohen, 2014). Quantum physics has demonstrated that not only does thought alter the way a particle behaves but also that particles can and perhaps even must be in two places at the same time (Rosenblum & Kuttner, 2006). Biofield energy may be gathered and directed by the practitioner to the recipient as explained by quantum physics, i.e., *thought* produces change in how the particles move (Rosenblum & Kuttner, 2006). There is the possibility that the presence of a calm caring individual with the intention of decreasing symptoms in a child may in itself induce relaxation and decrease pain and anxiety. However, because this pilot study is focusing on feasibility and acceptability using a one-group design, we are unable to account for the cause of the relaxation. As a part of the PI's future program of research, a three-group design including a placebo or attention group will allow us to test this option. Our focus on the effect of Reiki therapy enables us to begin determination of the clinical usefulness of an intervention that is in current clinical practice with children without the benefit of a scientific approach.

1.3.3 Theoretical Framework

The Symptom Management Model (SMM) will guide this study (Dodd et al., 2001; Humphreys, Lee, Carrieri-Kohlman, Puntillo, Faucett, Janson, Aouizerat, et al., 2008). The SMM is meant to address multiple rather than single symptoms while considering research, clinical practice, home, and hospital environments. Moreover, the model acknowledges the whole person and their setting as a part of symptom management. The SMM is very flexible, using interconnected

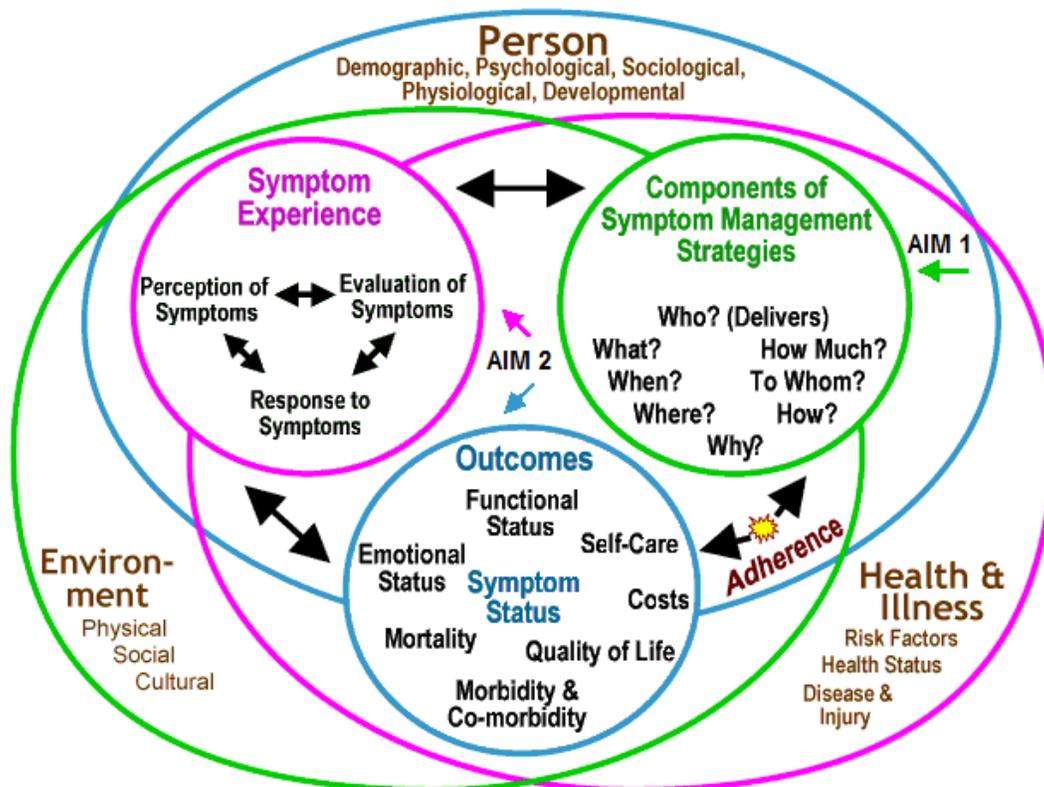


Figure 2. Symptom Management Model Including Study Aims

Used with permission from: Dodd, M., Janson, S., Facione, N., Faucett, J., Froelicher, E. S., Humphreys, J., Lee, K., Miakowski, C., Puntillo, K., Rankin S., & Taylor, D. (2001). Advancing the science of symptom management. *Journal of Advanced Nursing*, 33, 668-676. DOI 10.1046/j.1365-2648.2001.01697.x

domains and concepts clearly illustrating that symptoms and management of symptoms are a multimodal process (see Figure 2) (Dodd et al., 2001; Humphreys, Lee, Carrieri-Kohlman, Puntillo, Faucett, Janson, & Donesky-Cuenca, 2008).

The SMM considers three domains essential to nursing science: Person, Environment, and Health & Illness. The Person domain considers demographic, psychological, sociological, physiological, and development. Demographics may include age, gender, socioeconomic status, race, and ethnicity. Psychological status addresses mood and mental status. Sociological considers social interactions and behaviors. Physiological status includes how the body functions at this moment in time. Developmental status is particularly pertinent for children as their physical, psychological, sociological development is constantly changing. Generally development moves in a forward manner to an increasingly complex state but in illness there may be stagnation or even a regression while the child copes with complex illnesses (Hockenberry, 2003). The Health & Illness domain includes current health status, risk factors, disease state, and disability. Current health status may fluctuate based on disease progression, symptom status, and factors within the Person and Environmental domains. The Environment domain includes the physical, social, and cultural environment. These environments can change based on where the child is currently residing (home, hospital, or other facility). Environment plays a role in health and healing as recognized by Florence Nightingale. Physical, social, and culture interact to either help or hinder the child's health status, ability to cope with illness, and symptom management.

Connected with the three domains are the three essential concepts of Symptom Experience (perception, evaluation, and response to symptoms), Components of Symptom Management Strategies (who, what, when, where, why, how much, to whom, and how), and

Outcomes/Symptom Status (functional status, emotional status, self-care, costs, mortality, QOL, and morbidity and co-morbidity). The symptom experience is a combination of the perception, personal evaluation, and response to a symptom. How one perceives and evaluates a symptom such as pain (how much does it hurt, is the pain interfering with activity) will influence the response to the pain (asking for help, continuing with the activity). Additionally, the symptom experience changes over time altered by symptom management strategies and of course the domains of Person, Environment, and Health & Illness. The symptom management strategies are used to decrease, eliminate, or avoid a symptom. This may be accomplished through medication, another intervention such as massage, or a self-care strategy such as self-hypnosis or distraction such as watching a movie or playing a video game. Outcomes and symptom status are influenced by the symptom experience and the symptom management strategies. If a symptom is well managed then the functional status and quality of life are likely to increase, the emotional status is likely to be regulated, and morbidity may be decreased and mortality may be delayed. The interaction of the domains (Person, Environment, Health & Illness) and concepts (symptom experience, components of symptom management strategies, and outcomes/symptom status) is complex and requires a comprehensive perspective.

Guided by SMM, the aims of this pilot study are to reduce the *symptom experience* of pain and anxiety in children with the use of the *symptom management strategy* Reiki therapy while assessing the feasibility and acceptability of the Reiki therapy intervention (see Figure 2). *Outcomes* associated with reduction of pain and anxiety may include increased relaxation and improved QOL. We will also explore the child's underlying diagnosis, including primary and secondary diagnoses (Health & Illness domain); the child's age, gender, length of time on the palliative care service, use, and stage of both physical and general cognitive development, and

perceived therapeutic efficacy, the parent demographics of age, gender, education level, income, employment status, and previous CAM therapy use, and perceived therapeutic efficacy (Person domain); home and social considerations may include family, friends, visitors, or medical staff, and cultural characteristics include race, ethnicity, and religion (Environment domain). Within components of symptom management strategies a Reiki interventionist (who) will deliver two 24-minute (how much) Reiki therapy sessions (what) during a one-week time interval (when) at the child's (to whom) home (where) while the child sits or lies in a comfortable position (how) in an effort to manage noxious symptoms (why) (AIM 1). Within the symptom experience we will measure pain and anxiety (AIM 2) and within outcomes/symptom status we will measure the functional status operationalized as relaxation, pain and anxiety medication use, and QOL (AIM 2).

1.3.4 Significance and Innovation

Despite advances in assessment and treatment of unpleasant symptoms in children, parents still report that their children suffer. Although there are well-validated tools available for the assessment of children's pain and anxiety, they remain underutilized; moreover greater than half of hospitalized children experience severe unrelieved pain or anxiety in children's hospitals (Kortelnuoma, Nikkonen, & Serlo, 2008; Twycross & Collis, 2012). Pain is reported in 47-75% of children while anxiety is reported in 32-39% of children receiving palliative care (Jalmsell et al., 2006; Schmidt et al., 2013; Wolfe et al., 2008). These symptoms reduce QOL in children with cancer and terminal conditions and increase the distress experienced by parents (Kreicbergs et al., 2005). A study of 449 parents found that parents whose child suffered pain at end of life

suffered long-term emotional distress 4 to 9 years after the death (Kreicbergs et al., 2005). CAM therapies are often effective in helping children manage symptoms without additional sedation from medications thereby permitting greater alertness and allowing more interaction with family and friends (Jay, Elliott, Fitzgibbons, Woody, & Siegel, 1995; Manne et al., 1990; Nguyen, Nilsson, Hellstrom, & Bengtson, 2010; Post-White et al., 2009). Reiki therapy is a gentle non-invasive CAM therapy that promotes relaxation and has been shown effective for decreasing pain and anxiety in adults (Richeson et al., 2010; Tsang et al., 2007; Vitale & O'Connor, 2006). Reiki therapy has the potential to influence the lives of children receiving palliative care by decreasing pain and anxiety, increasing relaxation, and thereby increasing QOL without the medication side effects of excessive sedation that reduces the child's ability to interact with family and friends at very low cost.

Reiki therapy (a biofield touch therapy) has been shown to reduce pain and anxiety in various adult populations including cancer and surgical patients, resulting in clinical effect sizes (Cohen's *d*) ranging from 0.17 to 2.08 for within group comparisons and from 0.57 to 4.5 for between group comparisons (Thrane & Cohen, 2014). Anecdotal evidence indicates that Reiki therapy reduces symptom severity in children including the PI's clinical use of Reiki therapy with children in a hospital setting (Hurvitz, Leonard, Ayyangar, & Nelson, 2003; Rand, 2011). Reiki therapy has not been empirically studied in a pediatric population. This pilot study initiates the investigation of Reiki therapy for symptom management in the pediatric palliative care population.

1.4 RESEARCH DESIGN AND METHODS

1.4.1 Design

This is a quasi-experimental pre-post mixed-methods pilot study design. Pain, anxiety, relaxation and QOL will be measured pre and post intervention. Additionally pain, anxiety, and relaxation will be measured pre and post each Reiki therapy treatment. This study has two main aims:

1. Assess the feasibility and acceptability of Reiki therapy as a treatment for children receiving palliative care.
 - a. Assess recruitment, retention, and data collection rates and percent completion of intervention.
 - b. Explore the experience and acceptance of receiving Reiki therapy with children in relation to changes in the child's experience of pain and anxiety and the outcomes of relaxation, and QOL.
 - c. Explore the parental perception of the child's experience and acceptance of receiving Reiki therapy in relation to the child's experience of pain and anxiety, and the outcomes of relaxation and QOL.
2. Examine the effect of Reiki therapy on the symptom experience of pain and anxiety and the outcomes of relaxation, QOL, and pain and anxiety medication use in children receiving palliative care to calculate effect size for a future larger study.

1.4.2 Sample and Setting

A convenience sample will be recruited from the Children's Hospital of Pittsburgh of UPMC Supportive Care Services (SCS), a palliative care service that began in 2003. During 2013, SCS served 260 children from prenatal to 28 years of age (mean age 8.12 years), including 78 children that are between the ages of 7 and 16; the target population of this study. During the last five years, approximately 54% of the patients were male, 46% female, 88% white, 10% Black, and 2% other racial categories. The number of referrals to the palliative care service has increased considerably in the last year, averaging over 150 children on service at any given time. As of May 2014, SCS had 203 patients (29 inpatients and 174 outpatients) ranging from 3 weeks to 32 years of age (mean = 9.8 years, SD = 7.4 years) including 44 children ages 7 to 12, and 30 children ages 13 to 16 (74 total). We will recruit 24 children (target sample size of 20 plus 20% for potential attrition) for this pilot study.

1.4.2.1 Inclusion and Exclusion Criteria

We will recruit parent-child dyads with children between the ages of 7 and 16 who are being cared for at home by a parent or guardian. The broad age range was chosen purposefully to test the feasibility and acceptability of a Reiki therapy intervention. The minimum age of seven was chosen because by age seven, children are able to give assent and reliably self-report pain (P. S. Hinds, personal communication, October, 2013) using a visual analog scale and are able to remember things that happened in the near past (such as the Reiki therapy treatments). Parent or child unable to communicate in English is the only exclusion criteria. Because this is a pilot study testing feasibility and acceptability of Reiki therapy, the qualitative interviews are needed

to explore the perception of the Reiki therapy treatment with both the child and the parent. Therefore both parent and child must be able to communicate in English.

1.4.2.2 Sample Size Justification

Due to the exploratory nature of this study, the statistical power necessary to be generated by the small sample size is difficult to determine; we lack preliminary data with an effect size using these measures. Determining the necessary effect size (standardized mean difference of pain, anxiety, relaxation, and QOL between pre and post intervention) for each of the measures is one purpose of this pilot study. Given the feasibility of recruitment and retention in the time period of the proposed study as well as the expected precision of the effect size estimates, the sample size of 20 and a confidence coefficient of 0.95, we will have 0.47σ precision to estimate population means and 0.23 precision (conservative assuming a baseline proportion of 0.5) when estimating population proportions. In addition, we will over recruit by 20% to allow for attrition for a total of 24 participants.

1.4.3 Procedures

Aim 1a: After introduction by the palliative care team, potential subjects will be approached by the PI or other team member and introduced to the study. A confidential log will be kept of subjects contacted, their response to the study (consent or not), treatment completion, and study completion.

- If the potential subject agrees:
 - Parent will sign informed consent and the child will sign informed assent.

- The PI or other team member will set up appointments for two Reiki therapy sessions during the following week. The two sessions will be scheduled with a minimum of one day and a maximum of three days in between.
- The PI or other team member will collect the demographic data (see Appendix A), complete the pre-intervention measures, explain the Pain and Anxiety Medication Diary, and give the Diary for the parent to use during the study period.
- If the potential subject does not agree:
 - The PI or other team member will note the refusal and any explanation given in the confidential log,

Aims 1b and 1c: During the follow up visit the PI or other team member will conduct qualitative structured interviews. (see Appendix B). The PI will conduct structured interviews (5-10 minutes for children and 10-15 minutes for parents) to address the aims. Based on Hinds extensive research experience, this level of assessment should not be an undue burden on children of this age (Hinds et al., 2005; Hinds et al., 2009; Pentz et al., 2012) (personal communication, October, 2013). All interviews will be digitally recorded and transcribed verbatim. The interviews will be transcribed by a professional transcriptionist and checked for validity by the PI. Field notes will be kept.

Aim 2: Two 24-minute Reiki therapy sessions consisting of a standardized protocol of 12 hand positions held for 2 minutes each will be administered within a 5-day period at the convenience of the participant with a minimum of one and a maximum of three days between sessions. A study with adults has shown that two treatments within one week exhibited good clinical effect (Olson et al., 2003; Thrane & Cohen, 2014). While most adult studies use 30 to 60 minute Reiki treatments the PI's clinical experience with hospitalized children showed that 10 to

20 minute sessions induced a response (Richeson et al., 2010; Vitale & O'Connor, 2006). A paid Reiki therapy interventionist trained by the PI will arrive at the patient's home. The interventionist will set up a massage table (supplied by PI) or complete the session elsewhere in the home where the child feels comfortable such as the child's bed or the sofa. The child will be comfortably clothed and parent(s) may be in the room if the child or parent chooses. Sometimes when treating young children with touch therapy, the child may wish to move to a different position, a different location, or stop the session. If this occurs, the interventionist will follow the child continuing the session after the child is settled or stop the session at the child's request. If the child experiences increased pain, the session will be stopped. The interventionist will note the number of minutes for the session including any deviations from protocol or unusual occurrences in a log. The session will progress per protocol including pre- and post-intervention measures. The interventionist will leave after session. All sessions will be video recorded to track intervention fidelity unless the child or parent objects. All video recordings will be destroyed (deleted) after assessing intervention fidelity. Between 24 and 48 hours after the Reiki therapy session, the PI will re-administer the measures for pain, anxiety, relaxation, and QOL and collect the pain and anxiety medication use data.

1.4.4 Measures

1.4.4.1 Person domain

- **Demographic form** information includes child's age, gender, race, primary and secondary diagnosis, length on palliative care service, grade level, present medication use and dosages, previous CAM therapy use. Demographic information for the

parent(s) include age, gender, race, religion, educational level, income, employment status, and previous CAM therapy use (see Appendix A).

- **Treatment Expectation:** Perceived Treatment Efficacy Scale (Dunbar-Jacob et al., 1993; Engberg, Cohen, & Sereika, 2009) (PTES): Outcome expectancy can be a powerful determinate of benefit. To explore the influence of treatment outcome expectancy and determine whether Reiki therapy was perceived as credible, the PTES will be completed. PTES will be used to account for a priori beliefs of the children and parents. PTES assesses the confidence level in the ability of Reiki therapy to reduce or eliminate symptoms and improve QOL (10-point Likert scale). Parent proxy and child self-report (Dunbar-Jacob et al., 1993) measured at baseline and 24 to 48 hours after last Reiki therapy session.

1.4.4.2 Components of symptom management strategy

- **Experience of Receiving Reiki Structured Interviews:** The children will be asked three questions relating to their Reiki therapy experience with suggested follow up questions (see Appendix B). The parents will be asked three open-ended questions and four closed-ended questions about their child's Reiki therapy experience (see Appendix B).

1.4.4.3 Symptom experience

- **Pain:** Visual analog scale (VAS) a 10-cm line for pain levels 0 to 10 for children able to self-report. The VAS scale is the gold standard and is reliable for children as young as five years of age (Sanchez-Rodriguez, Miro, & Castarlenas, 2012). Children will

be given a piece of paper with a 10 centimeter line and ask to mark their pain level (Bailey, Daoust, Doyon-Trottier, Dauphin-Pierre, & Gravel, 2010; McGrath et al., 1996; Sanchez-Rodriguez et al., 2012). Pain will be measured at baseline, pre-post each Reiki therapy session, and at 24 to 48 hour follow-up.

- **Anxiety:** VAS a 10-cm line for anxiety levels 0 to 10 for children able to self-report (Sanchez-Rodriguez et al., 2012; Varni, Walco, & Katz, 1989). Children will be given a piece of paper with a 10 centimeter line and ask to mark their anxiety level (see Appendix D). Measured at baseline, pre-post each Reiki therapy session, and at 24 to 48 hour follow up. A second anxiety measure is included since the PedsQL includes an anxiety subscale.

1.4.4.4 Outcomes/symptom status

- **Relaxation:** Relaxation will be assessed objectively by measuring pulse and respiratory rate at baseline, pre-post each Reiki therapy session, and at 24 to 48 hour follow up (Kozier, Erb, Berman, & Burke, 2000). These routine non-invasive measures respect the medical fragility of these children.
- **Quality of Life:** PedsQL Short Form Generic Core Scale measures QOL. Child self-report for ages 7 and older (Gheissari et al., 2012; Varni & Limbers, 2009; Varni, Limbers, & Burwinkle, 2007a; Varni et al., 2007c; Varni, Seid, Knight, Uzark, & Szer, 2002). Measured at baseline, and at follow up. The PedsQL model has been used worldwide for over 15 years. This scale is both reliable (0.88 for child self-report and 0.90 for parent proxy report) and valid (Varni, 2014). The scale consists of 23 questions divided into four subscales (physical functioning, emotional functioning,

social functioning, and school functioning). The scale cannot be shown in the appendix due to copyright restrictions. Measured at baseline, and at 24 to 48 hour follow up.

- **Pain and Anxiety Medication Use:** Parents of participants will be given a Pain and Anxiety Medication Diary, educated to record pain and anxiety medications given to the child during the study period. Collected at 24 to 48 hour follow up.

Table 1. Timing of Measures

Measures	Specific Aim	Baseline	Pre/post Reiki	24 to 48 hours post Reiki therapy
Person:				
Child & Parent Demographic form	1	X		
Perceived Treatment Efficacy Scale (PTES)	1	X		X
Symptom Experience:				
Pain (VAS)	2	X	X	X
Anxiety (VAS & PedsQL)	2	X	X	X
Outcomes:				
Relaxation (HR & RR)	2	X	X	X
QOL (PedsQL)	2	X	X	X
Pain & Anxiety Medication use Diary	2	X		X
Structured Interviews	1B, 1C			X

To maximize participant retention and satisfaction, will be offered incentives upon completion of the two Reiki therapy sessions (\$10) and at the completion of the follow-up visit (\$40) for a total of \$50.

1.4.5 Data Analysis and Interpretation

1.4.5.1 Quantitative Analysis

The number and percentage of participants who complete each data collection time point specified in the protocol for the entire experimental period will be recorded and calculated. Rate of participant accrual will be calculated. Percentages of the following will be calculated: (1) persons eligible to participate; (2) persons who sign a consent; and (3) participants who dropped out. Reasons for attrition will be described.

The descriptive statistics of pain, anxiety, relaxation, and QOL will be reported at baseline, pre and post each Reiki therapy session and at 24 to 48 hour follow up. The differences among different time points and/or trend of change over time will be explored by using paired Student t-test or nonparametric statistics such as Wilcoxon signed rank test as appropriate. The interrelationship between demographics, pain, anxiety, relaxation, and QOL will be examined. PTES will be used to control for expectancy. Given the repeated measures structure of pain, anxiety, and relaxation longitudinal linear mixed modeling (i.e., random coefficient modeling) will be used to explore time effects as well as associations with demographics. Because this is a pilot study, the estimation of effect sizes (standardized mean difference of pain, anxiety, relaxation, and QOL between pre and post intervention) and summary statistics (means, standard deviations, etc.) will be emphasized rather than hypotheses testing. The estimates of the proportion of variance explained in the particular outcome under consideration will be computed as effect size estimates for future sample size determination of a larger prospective study.

1.4.5.2 Qualitative Analysis

Data analysis and management will be supported by the use of the qualitative software program, Atlas.ti (7, Berlin, Germany). Data will be analyzed and coded using thematic analysis. Themes and subthemes related to the child's experience and the parent's perceptions of the child's experience with Reiki therapy will be identified. The thematic analysis steps are: familiarizing ourselves with the data, generating initial codes, searching for themes, reviewing themes, defining and naming themes, and producing the report (Braun & Clarke, 2006). The PI and Dr. Danford will both participate in this process. In developing the codes and themes, interrater reliability will be calculated using percent agreement. In order to establish trustworthiness of the qualitative portion of this study, credibility of the process will be established through triangulation (Krefting, 1991). To validate the findings, 5 key informants will be contacted following thematic analysis. The data analysis and resulting themes will help guide not only the current study in terms of acceptability of the Reiki therapy, but also future studies involving Reiki therapy with children and their parents.

1.5 POTENTIAL PROBLEMS

The possibility that a child may die or become too ill to continue or families/children may choose to stop participating (we will over-recruit by 20% to compensate); broad age ranges and development levels (the aims of the study are feasibility and acceptability not efficacy and generalizability, thus broad ranges provide vital variability); Reiki therapist pre/post treatment pain and anxiety assessment administration (to reduce potential bias, the Reiki therapist will

leave the room while the paper and pencil assessments are completed pre/post Reiki responses will then be placed by the child and parent in an envelope).

1.6 IMPLICATIONS FOR FUTURE RESEARCH

This is the first step in a program of research to study the effect of Reiki therapy for symptom management with children. Further rigorous study examining the effectiveness of Reiki therapy for symptom management will broaden scientific knowledge of this non-invasive, gentle intervention to balance pharmacologic and non-pharmacologic interventions resulting in improved QOL for children in palliative and end-of-life care. Future work has three general directions: 1) to determine the effectiveness of Reiki therapy with children receiving palliative care using a larger sample size and a randomized design, 2) to examine the use of Reiki therapy for family use: future work will focus on training parents in Reiki therapy in order to examine parental use of Reiki therapy as a useful tool to help with symptom management in children who have life limiting and life threatening illnesses, and 3) to examine the use of Reiki therapy as part of bedside nurses' usual care of patients to study nursing use of Reiki therapy in hospitalized children.

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2.0 SUMMARY OF STUDY

The seeds of this study were sown in 2005 when I began doing Reiki therapy with hospitalized neurologically devastated children. Often these children become agitated and since they cannot communicate, we do not know what is bothering them. We tried the usual things, changing diaper, changing position, giving pain medication, turning on music and so on. After learning Reiki therapy I began giving these children 5-10 minute treatments after taking care of their physical needs and I observed over and over again that they became calm and relaxed. They would usually fall asleep peacefully for several hours. Until very recently (2013), no study had been published examining the use of Reiki therapy with any pediatric population although it has been used in pediatric hospitals across the country and studied in several adult populations. Therefore, the purpose of this study was to explore the feasibility and acceptability of using Reiki therapy with children ages 7 to 16 years receiving palliative care.

This study has two main aims: (1) assess the feasibility and acceptability of Reiki therapy for children receiving palliative care by: (a) assessing recruitment, retention, and data collection rates and percent completion of the intervention, (b) exploring the experience and acceptance of receiving Reiki therapy with verbal children in relation to changes in the child's experience of pain, anxiety, and relaxation, and (c) exploring the parental perception of the child's experience and acceptance of receiving Reiki therapy in relation to the child's experience of pain, anxiety,

and relaxation and (2) examine the effect of Reiki therapy on pain, anxiety, and relaxation operationalized as heart rate and respiratory rate in children receiving palliative care to calculate effect size for a future larger study.

The intervention consisted of two 24-minute Reiki therapy treatments following a standardized protocol. The Reiki therapy treatments took place in the child's home in a location where they felt comfortable, mostly the sofa or their bed. The child was fully clothed and the parents were invited to stay and watch the treatment. After the second treatment, a team member conducted structured interviews with parent and child separately.

Five manuscripts are included in this dissertation and contribute to the background of the work in some way. The first manuscript partially addressed aim #1 in that it explored the use of complementary therapies for pain and anxiety in children and was published in the *Journal of Pediatric Oncology Nursing* in 2013. This manuscript was a systematic review of complementary therapies used for pain and anxiety with children and adolescents receiving cancer treatment. It reviewed complementary therapies used with this population and included hypnosis, massage, mind-body techniques, virtual reality, creative arts therapy, and listening to music. The second manuscript addressed aim #2 and was published in the *Journal of Pain and Symptom Management* in 2014. This manuscript was an in-depth literature review examining randomized control studies that used Reiki therapy in adults with outcome variables of either pain or anxiety. The third manuscript, submitted to the *Journal of Pediatric Nursing* is a synthesis of current evidence relating to the assessment and non-pharmacologic treatment of procedural pain in young children with child development as the key guiding influence. This manuscript partially addresses aims #1 and #2 as it explores the assessment of pain in young children and the use of complementary therapies for the treatment of pain in young children. The fourth manuscript,

which is not yet submitted for publication, is a 5-year retrospective chart review describing children between the ages of 2 and 16 who received palliative care at the same hospital that we worked with for the main study. This manuscript examined time from diagnosis to referral to palliative care, time from referral to death, survival estimations, and whether pain decreased after referral to palliative care. The fifth and final manuscript addresses aims #1 and #2 in this dissertation and includes the results of the main study.

This chapter will briefly address the findings related to each study aim, changes in study design, challenges experienced, limitations, strengths, implications, and future directions will be described.

2.1 FINDINGS RELATED TO AIM #1

Aim #1: Assess the feasibility and acceptability of Reiki therapy as a treatment for children receiving palliative care.

- a. Assess recruitment, retention, and data collection rates and percent completion of intervention.*
- b. Explore the experience and acceptance of receiving Reiki therapy with verbal children in relation to changes in the child's experience of pain, anxiety, and relaxation.*
- c. Explore the parental perception of the child's experience and acceptance of receiving Reiki therapy in relation to the child's experience of pain, anxiety, and relaxation.*

Findings related to Aim #1 listed in three sub aims are reported in detail in manuscript #5 however they are listed here briefly. We approached 24 child-parent dyads between October 2014 and May 2015. Twenty-one (87.5%) dyads agreed to participate and signed the consent form. Three dyads declined to participate. For the three who did not choose to participate, one mother did not spontaneously give a reason for declining, one child did not wish to participate and one parent stated that because her child had completed treatment she did not wish to participate. Two dyads formally withdrew from the study (one child changed his mind and one mother felt that her schedule was too busy) and three mothers did not return repeated phone calls to schedule home visit appointments. The final sample included 16 dyads: 16 children and 16 parents. One nurse participated at the request of the mother due to the nurse's role as primary caregiver during the day. The final sample totaled 33 participants. Of the 16 dyads, everyone who began the intervention finished the intervention; there were no participant dropouts from the study. Structured interviews were conducted with verbal child and parents to assess study and intervention acceptability and the experience of the Reiki therapy intervention (questions related to pain, anxiety, and relaxation will be addressed in the next section). When asked if they would continue the Reiki therapy treatments if they could, six (85.7%) of the children said yes and one (14.3%) said she was unsure. Of the mothers, 14 (87.5%) of the parents said they would continue, one mother (6.3%) said she was unsure because it would be up to her child and one mother (6.3%) said no because her child was not having any symptoms currently and did not need to continue the Reiki therapy. Both the children and the mothers were asked if they would have liked the Reiki therapy treatments done differently: All seven (100%) of the children said no. Fourteen (87.5%) of the mothers said no while two (12.5%) of the mothers were unsure because they had not asked their child what they thought about the Reiki therapy treatments. We

asked the mothers if Reiki therapy was something they would like to learn so that they provide the treatment to their child themselves, 10 (62.5%) of the mothers said yes, four (25%) said no, and two (12.5%) were unsure. Finally we asked the mothers if they would participate in the study again: All 16 (100%) of the mothers said they would participate in the study again.

2.2 FINDINGS RELATED TO AIM #2

Aim #2: Examine the effect of Reiki therapy on pain, anxiety, and relaxation in children receiving palliative care.

Pain, anxiety, heart and respiratory rates were assessed pre and post each Reiki therapy treatment. Pain and anxiety were assessed via a visual analog scale (VAS) a 10-centimeter line with anchors “no pain” and “worst pain ever.” Children who did not understand the VAS could use the Wong-Baker FACES pain scale or the faces-type Children’s Fear Scale (Baker, 2009; McMurtry, Noel, Chambers, & McGrath, 2011). For non-verbal children who were unable to mark the scale, the mother or full time caregiver who knew the child well marked the VAS scale.

Pre and post assessments for pain, anxiety, heart, and respiratory rates were analyzed by paired t-test or Wilcoxon signed rank test. We calculated effect sizes using Cohen’s *d*. We analyzed verbal and non-verbal children separately. All mean scores for pain, anxiety, heart rate and respiratory rate decreased post Reiki therapy treatment. We set the significance level to $p < 0.10$ due to the sample size and the pilot nature of the study. Statistical significance was reached for respiratory rate for verbal children for treatment two ($t = 3.550$, $p = 0.009$). For non-verbal children statistical significance was reached for pain for treatment two ($Z = -2.023$, $p=0.063$) and

respiratory rate for the overall intervention ($t = 2.031$, $p = 0.082$) (see Table 18, page 200). Cohen's d scores were mainly $d > 0.50$ or a medium to large clinical effect size (see Table 19, page 200).

We used thematic analysis to identify themes and subthemes from the structured interviews. The experience of Reiki therapy as experienced by the children and perceived by the parents fell into three broad themes: *Feeling Better*, *Hard to Judge*, and *Still Going On*. There were five sub themes within *Feeling Better* including “really relaxed,” “not hurting that bad,” “calmed me down,” “happier,” and “heats me up.” For the themes *Feeling Better* and *Still Going On*, mother and child responses were very parallel even though their interviews were conducted separately. Most of the children and several parents of both verbal and non-verbal children articulated that the child just “felt better” after the Reiki therapy treatment. Nearly all the parents and several of the children described the Reiki therapy sessions as relaxing. One child said “I felt really relaxed” and her mother echoed with “she found it very relaxing.” Mothers of both verbal and non-verbal children and the children themselves described the children as having less pain after the Reiki therapy session. One mother said “she was in a lot of pain when she [the interventionist] came earlier this week and by the time she left she was almost asleep.” Several of the children and parents described the treatment as very calming. Two girls specifically said “it was calming” and another stated “it calmed me down.” One mother of a non-verbal child noticed that her child “. . . just changed. He just got really serene.” Although we did not ask about mood during the interviews, two children and several mothers mentioned that their child was happier after the treatment. One girl stated “I feel more happy like, after” and her mother said, “oh she’s been in a much better mood. Happier . . . smiling more.” Two children mentioned being warm during and after the Reiki therapy treatment. Some of the mothers felt they could not

judge the effect of the Reiki therapy treatments because their child was not experiencing pain or anxiety. One mother responded, “she was just kind of indifferent to it, she doesn’t have pain, so I don’t know that we got the full benefit of it.” Several children and parents commented that the effects of the Reiki therapy treatment lasted for the rest of the day or for one or two days after the treatment. One girl stated “For the rest of the day I feel a whole lot better than I did before.” A mother of a non-verbal child stated “maybe two hours later after the treatment he was out like a light. It was the best night ever that he slept . . . I would have to say [the effects lasted] the rest of the night and the whole next day.” The majority of the participants felt that the child received some benefit from the Reiki therapy treatments and would continue if they had the opportunity.

2.3 CHANGES TO STUDY DESIGN

Changes in study design occurred at three time points: (a) at Comprehensive Exams and Dissertation Overview, (b) when funding was received from National Institute for Nursing Research, and (c) when recruitment was slower than anticipated.

2.3.1 Changes at Comprehensive Exam and Dissertation Overview

Several changes were made to study design as a result of discussion with the dissertation committee. The baseline and 24 to 48 hour post Reiki therapy measures of pain, anxiety, and relaxation (heart rate and respiratory rate) were removed. The committee felt there was very little to be gained by these measures. We added the FACES pains scale and a faces-type fear/anxiety

scale for those children who could not understand the visual analog scales. Both the FACES pain scale and fear/anxiety scales are valid and reliable (Hockenberry, 2005; McMurtry, Noel, Chambers, & McGrath, 2011). We removed the video taping of Reiki sessions. The committee felt that video taping children might pose an ethics problem with the Institutional Review Board (IRB).

2.3.2 Changes in Order to Receive National Institute of Nursing Research Funding

Changes in study design were made to decrease the study burden to ill children and their families.

Aim 1. Remove the Perceived Treatment Efficacy Scale (PTES) measure; remove the daily pain and anxiety medication diary.

Aim 2. Remove the PedsQL quality of life measure

The third home visit was removed and the structured interviews were added to the end of the second home visit after the Reiki therapy treatment. The ongoing medication diary was removed. Child burden for measures was decreased from 33 minutes to 20 minutes. The parent burden for measures was decreased from 48 minutes to 15 minutes.

2.3.3 Changes to Address Slower than Anticipated Recruitment

Recruitment for the study began on October 17, 2014. By mid-March it was clear that at the current rate of recruitment and participant completion, we would not be able to recruit 20 participants before the end of summer. The decision was made to include non-verbal and

neurologically devastated children. IRB approval was obtained and we started recruiting from this population in early April. In order to assess pain and anxiety for non-verbal children, the parents or caregivers marked the VAS pain and anxiety scales. An additional observational pain scale was added so that the interventionist could also rate the child’s pain. The Faces Legs, Activity, Cry, and Consolability (FLACC) scale, a well-validated observational pain scale was added for this purpose (Bringuier et al., 2009; Merkel, Voepel-Lewis, & Malviya, 2002). A summary of the measures and timing of measures can be found in Table 3.

Table 2. Summary of Measures with New Study Design

<i>Measures</i>	<i>Specific</i>		<i>Pre/post</i>
	<i>Aim</i>	<i>Baseline</i>	<i>Reiki</i>
Person:			
Child & Parent Demographic form	1	X	
Symptom Experience:			
Pain (VAS or FACES)	2		X
Pain for non-verbal children (FLACC)	2		X
Anxiety (VAS or FACES)	2		X
Outcomes:			
Relaxation (HR & RR)	2		X
Pain & Anxiety Medication use Diary	2	X	
Structured Interviews	1B, 1C		

2.4 CHALLENGES EXPERIENCED

We encountered several challenges to the study related to recruitment, scheduling home visits, personnel, and planned racial and gender recruitment goals. Our main challenge for recruitment involved the number of available children that fit the inclusion criteria. During the summer of 2014, Supportive Care Services (SCS) had 71 children on their service between the ages of 7 and

16. This number appeared more than adequate to reach our final goal of recruiting 24 parent-child dyads for the study. What we did not notice was that approximately 50% of the children were neurologically devastated, or non-verbal. Our original design excluded children who could not communicate which brought the number of potential participants to approximately 35 dyads. We recruited children from the outpatient clinic when they had scheduled outpatient visits. At any given time, approximately 10-12% of the total SCS patients were in the hospital, and a large number only attended clinic visits quarterly, semi-annually, or annually. Another 10-12% of the population was managed exclusively by phone including those receiving hospice services. Finally, Children's Hospital of Pittsburgh of UPMC has a large catchment area including all of western Pennsylvania, much of northern West Virginia, southwestern New York and eastern Ohio, a radius of about 150 miles. While we knew this in advance, more children lived further out than anticipated. We originally set a distance limit of 35 miles but that quickly moved to 50 miles and most home visits included a 45 to 60 minute drive each way.

Scheduling home visits was another challenge. Our final recruitment rate at the clinic was 87.5% or 21 out of 24 dyads approached; however our final sample included only 16 dyads. Of the five who did not ultimately participate, one child decided he did not want to participate and withdrew and another mother wished to participate but her schedule would not permit and she withdrew as well. The three families who did not participate but who had signed consents simply did not return repeated phone calls over the course of several weeks. Late in the study it was discovered that people responded better to text messages than voice mails which contributed to better home visit scheduling success toward the end of the study.

Finally, scheduling personnel for the study was also a challenge. One nurse Reiki Master was unable to follow through as the interventionist due to scheduling conflicts. Another nurse

Reiki Master volunteered to be the interventionist but she did not have the child clearances required by the state of Pennsylvania. These clearances can require up to 12 weeks to complete. Finally we agreed that the PI would be the interventionist for the study. This causes some conflict, which we did our best to mitigate. Children or parents marked the pain level out of sight of the interventionist and immediately slid the paper into an envelope. The PI did not look at any of the data until after a particular child had completed the intervention. A trained research assistant came to the second home visit of each child to complete the structured interviews either in a separate room or after the PI had stepped out of the house so that the participants would feel comfortable saying how they felt. The PI scheduled the home visits at the convenience of the family but also had to work around the class and clinical schedule of the research assistant.

Based on the racial, and gender distribution of the SCS patients, we anticipated that we would recruit 62.5% females and 37.5% males (children and parents combined). We also anticipated recruiting 4% Asian, 21% African American, and 75% White individuals (children and parents combined). Of the 17 adult participants all were female and white, all but one of the child participants were white, and only five boys participated in the study. Our final enrollment is shown below in Table 4.

Table 3. Actual Study Enrollment (Children and Mothers Combined)

ETHNIC CATEGORY	FEMALES	MALES	TOTAL
Hispanic or Latino	0	0	0
Not Hispanic or Latino	28	5	33
<i>Ethnic category: Total of all subjects</i>	28	5	33
RACIAL CATEGORY			
American Indian/Alaskan Native	0	0	0
Asian	0	0	0
Native Hawaiian or other Pacific Islander	0	0	0
African American /White	1	0	1
White	27	5	32
<i>Racial categories: Total of all subjects</i>	28	5	33

2.5 LIMITATIONS AND STRENGTHS

There are several limitations to this study. When this study was first discussed and defined there were no studies examining the use of Reiki therapy with children. Because of this, we felt that a one-group design to assess the feasibility and acceptability of a Reiki therapy intervention with children and their families would be prudent. A one-group design with no control or comparison group addresses acceptability and feasibility but limits the generalizability of the pain, anxiety, and relaxation outcomes. Small sample size is a limitation but appropriate for a pilot study. The original target sample size was 20 children and 20 parents. Recruitment slowed over the course of the first six months of the study resulting in an enrollment of 10 dyads, 5 that had completed the intervention at the end of the sixth month. As a result, the criteria of the sample was reevaluated and it was determined by the team that including dyads with non-verbal children

would be acceptable. Consequently, recruitment accelerated during the last three months of the data collection phase resulting in a final sample of 16 mother-child dyads and one caregiver. Seven out of eight verbal children were oncology patients. We found that families with children in active cancer treatment were more likely to participate in the study than those who had completed treatment. The children who had completed treatment had gone back to their busy lives and were less willing to schedule the home visits. Finally, because the PI was also the interventionist results may have been compromised. In an attempt to minimize the results being compromised the data collection process was modified. The pain and anxiety scales were completed by the child or mother and concealed in an envelope before the interventionist began the treatment. In addition, an assistant completed the structured interviews in a room separate from the interventionist so that children and parents were able to speak freely.

Some of the strengths of the study include the fact that a standardized protocol was used for each Reiki treatment; 12 hand positions held for two minutes each. The interventionist kept a record of each visit including the time of each Reiki therapy treatment and whether or not the treatment followed the protocol. The mean time for treatment one over the 16 treatments was 23.88 minutes and 24.13 minutes for treatment two. The treatment followed the protocol 98.75% of the time for both treatments one and two. One interventionist completed all Reiki therapy treatments and the research assistant completed 10 out of 15 of the structured interviews.

2.6 IMPLICATIONS AND FUTURE DIRECTIONS

The positive results of this mixed-methods study support the need for future research using Reiki therapy with larger sample sizes, randomization, and other populations of children. Implications from the medium to large clinical effect sizes and the comments from the mothers and children lend credence to our supposition that Reiki therapy, a gentle, non-invasive technique was well received by both verbal and non-verbal children and their parents for increased relaxation, decreased pain and anxiety, and possible increased happiness. Reiki therapy has the potential to allow families to help children to manage pain and other symptoms without increasing their medication thereby avoiding the side effects that often occur with increased medication use.

Future directions include:

1. Determining the effectiveness of Reiki therapy with children receiving palliative care or other pediatric population such as post-operative children using a larger sample size and a randomized design. Using either a three group design including a Reiki group, a usual care group and a either a sham Reiki group or massage therapy group to account for touch and human presence in the design.
2. Examining the use of Reiki therapy for family use: future work focusing on training parents in Reiki therapy in order to examine parental use of Reiki therapy as a useful tool to help with symptom management in children who have life limiting and life threatening illnesses. Kundu, Donal-Oves, Dimmers, Towle, and Doorenbos (2013) completed a pilot study teaching parents Reiki therapy for use with their children. Reiki was well received by the parents but the study did not assess the children in any way.

3. To examine the use of Reiki therapy as part of bedside nurses' usual care of patients to study nursing use of Reiki therapy in hospitalized children. Teaching nurses to use Reiki therapy would add a technique for their use in helping manage children's symptoms either without additional medication or while waiting for medications to arrive.

2.7 REFERENCES

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3.0 LITERATURE-BASED MANUSCRIPTS

3.1 MANUSCRIPT #1: EFFECTIVENESS OF INTEGRATIVE MODALITIES FOR PAIN AND ANXIETY IN CHILDREN AND ADOLESCENTS WITH CANCER: A SYSTEMATIC REVIEW (DOI: 10.1177/1043454213511538)

3.1.1 Abstract

Throughout the trajectory of the cancer experience, children and adolescents will likely face pain and anxiety in a variety of circumstances. Integrative therapies may be used either alone or as an adjunct to standard analgesics. Children are often very receptive to integrative therapies such as music, art, guided imagery, massage, therapeutic play, distraction, and other modalities (Doellman, 2003).

The effect of integrative modalities on pain and anxiety in children with cancer has not been systematically examined across the entire cancer experience. An in-depth search of PubMed, CINAHL, MedLine, PsychInfo, and Web of Science, integrative medicine journals, and the reference lists of review articles using the search terms pain, anxiety, pediatric, child*, oncology, cancer, neoplasm, complementary, integrative, non-conventional, and unconventional yielded 164 articles. Of these, 25 warranted full-text review. Cohen's *d* calculations show medium ($d=0.70$) to extremely large (8.57) effect sizes indicating that integrative interventions

may be very effective for pain and anxiety in children undergoing cancer treatment. Integrative modalities warrant further study with larger sample sizes to better determine their effectiveness in this population.

3.1.2 Introduction

Integrative medicine is a holistic body-mind-spirit approach that combines both western medicine and complementary therapies to best serve patient and family healthcare needs. The term integrative acknowledges the blend of conventional and complementary therapies for the most comprehensive treatment for patients. . According to the National Center for Complementary and Integrative Health (NCCIH), the general categories of integrative medicine are natural products (herbs, botanicals, vitamins, and other dietary supplements), mind-body practices (prayer, meditation, yoga, acupuncture, guided imagery, hypnotherapy, tai chi), manipulative practices (massage, chiropractic), biofield therapies (Reiki, healing touch, qi gong), traditional healers (sometimes called folk healers), and whole medical systems such as Ayurvedic medicine or traditional Chinese medicine when used in addition to allopathic medicine (National Center for Complementary and Integrative Health, 2012). The purpose of this review is to determine which integrative modalities are most effective for the reduction of pain and anxiety in children and adolescents being treated for cancer.

Many cross sectional studies of the prevalence of integrative medicine use in children have been carried out around the world including Italy (Clerici, Veneroni, Giacon, Mariani, & Fossati-Bellani, 2009), Turkey (Genc, Senol, Turgay, & Kantar, 2009), Mexico (Gomez-Martinez, Tlacuilo-Parra, & Garibaldi-Covarrubias, 2007), Malaysia (Hamidah et al, 2009), and

the United States (Post-White, Fitzgerald, Hageness, & Sencer, 2009). The most common integrative therapies are natural products (herbs, vitamins, and dietary supplement), used to alleviate symptoms or improve health (Tomlinson, Hesser, Ethier, & Sung, 2011).

Very few randomized clinical trials have been conducted using integrative modalities to reduce pain or anxiety in either adults or children. Most review articles on the topic of integrative medicine use in children discuss the prevalence of integrative use (Bishop et al., 2010; Post-White, 2006), not the effectiveness of particular integrative modality for symptom relief. While there have been some reviews discussing pain or anxiety during painful procedures (Kleiber & Harper, 1999; Landier & Tse, 2010; Richardson, Smith, McCall, & Pilkington, 2006), no review has discussed integrative medicine use for pain and anxiety during the overall cancer trajectory.

Pain is a common symptom during cancer diagnosis and treatment and may come from painful procedures, disease progression, or impingement of nerves, tissues, or organs from tumors at any stage of the cancer progression (McGrath & Brown, 2005). There are many well-established tools to measure pain in children. Children as young as three years who can distinguish the concepts “less” and “more” are able to use visual analog scales such as the FACES scale developed by Wong and Baker in the 1980’s (Baker, 2009). For younger children parent proxy-report is often used to measure pain and anxiety and several well-validated rating scales have been developed for this purpose. A study of 164 children and adolescents in the United Kingdom found that 91 percent of children with end-stage cancer endured pain and 45 percent experienced anxiety (Goldman et al., 2006). This review will focus on the use of integrative medicine, i.e., practices used *together with* conventional medicine.

3.1.2.1 Study Question

Integrative modalities in general seek to alleviate suffering through a decrease in noxious symptoms. Many modalities have been studied for symptom relief in children including hypnosis, acupuncture, massage, virtual reality, folk healing, prayer, and others. The question this review seeks to answer is “Which integrative modalities are most effective for reducing pain and anxiety in children and adolescents with cancer?”

3.1.3 Criteria for Including Studies for Review

3.1.3.1 Types of Participants

Studies were considered if they were conducted with children or adolescents, aged 1 to 18 years, at any point in the cancer trajectory from new diagnosis, to on-going treatment, to long-term survivorship, or end of life.

3.1.3.2 Study Design

Studies were included that utilized any type of randomization, a control group, published in peer-reviewed journals, used any type of integrative modality except natural products (herbs, vitamins, supplements, and the like), and measured both pain and anxiety. Natural products were excluded because they are ingested and may interact with other therapies the child is receiving in unpredictable ways.

3.1.3.3 Outcome Measures

In view of the fact that the disease itself, the treatment, and long-term side effects of treatment may cause pain both acute and long-term, pain is one of the main outcomes variables of interest. Children and adolescents may feel anxious about treatments, procedures, staying in the hospital, clinic visits, or recurrence. Studies were included for review if they measured both pain and anxiety as outcomes.

3.1.3.4 Search Strategies for Identification of Studies

A systematic literature search was conducted using PubMed, PsychInfo, CINAHL, Web of Science, and MedLine via Ovid databases with no date limitation. Several journals were then searched individually including *Integrative Cancer Therapies*, *Journal of Evidence-based Complementary & Alternative Medicine*, and *Supportive Care in Cancer*. Finally, the reference lists for integrative and systematic review articles identified in the original search were examined to find relevant articles. The following key words were used: pain, anxiety, pediatric, child*, complementary, integrative, CAM, unconventional, non-conventional, cancer, oncology, and neoplasm. After removing duplicates, there were 164 articles, 74 of which reported research findings with the remainder either informational or review articles. Of the 74 research studies, 20 involved natural products (herbs, supplements, etc.), 21 measured prevalence of integrative medicine use, and 8 discussed the symptoms of pain or anxiety but did not measure them. The remaining 25 articles that reported integrative intervention findings made up the final sample for full text review.

3.1.4 Method of Review

The remaining 25 articles underwent full-text review using a systematic approach. Each article was carefully reviewed against the inclusion criteria. Thirteen studies were eliminated based on the inclusion criteria. The reasons for elimination included no randomization, no control group, or did not measure both pain and anxiety. Twelve studies met the review criteria and are included in the review (see Table 5).

3.1.5 Findings

All studies in this review had at least one statistically significant finding except for Pederson (1996) who used distraction and breathing techniques during a lumbar puncture. Effect sizes using Cohen's *d* were calculated for each study based on data reported in the study. An Excel-based program (Wilson, 2001) was used when possible (Gershon, Zimand, Pickering, Rothbaum, & Hodges, 2004; Hawkins, Lioffi, Ewart, Hatira, & Kosmidis, 1998; Jay, Elliott, Fitzgibbons, Woody, & Siegel, 1995; Lioffi, White, & Hatira, 2006, 2009; Manne et al., 1990; Nguyen, Nilsson, Hellstrom, & Bengtson, 2010; Smith, Barabasz, & Barabasz, 1996), however hand calculations using *z* scores or *p* to *z* score conversions and the formula $ES = r = Z/n^{1/2}$ if only *p* values were given (Lioffi & Hatira, 1999; Madden, Mowry, Gao, Cullen, & Foreman, 2010; Pederson, 1996; Post-White, Fitzgerald, Savik, et al., 2009).

Table 4. Summary of Complementary Modalities Studies for Pain and Anxiety in Pediatric Cancer Patients

Authors/Journal /Year	Purpose of Study	Modality/ Procedure	Outcomes Measured	Study Design	Sample	Significant Results	Effect Size
Smith, J. T., Barabasz, A., Barabasz, M. <i>Journal of Counseling Psychology</i> 1996	The purpose this study was to test the neodissociation theory using hypnosis versus distraction during venipuncture or port-a-cath (PAC) access	Hypnosis & distraction for venipuncture or PAC access	Pain, Anxiety	Purposive randomized crossover (high and low hypnotizable children were randomized to groups separately for balance)	27 children ages 3-8 (mean=4.5), 63% male, 39% white, 17% African American, 31% Latino/Hispanic, 14% Haitian with a hematology/oncology diagnosis	<ul style="list-style-type: none"> Highly hypnotizable children had significantly less pain $F(2, 50) = 11.68$, $p < .001$ and anxiety $F(2,50)=13.76$, $p < .001$ during procedures Highly hypnotizable v low hypnotizable children in hypnosis arm self-report pain Highly hypnotizable v low hypnotizable children in hypnosis arm self-report anxiety 	<ul style="list-style-type: none"> $d=2.39$ $d=1.16$
Lioffi, C. Hatira, P. <i>International Journal of Clinical and Experimental Hypnosis</i> 1999	To compare the efficacy of hypnosis v mind-body coping skills	Hypnosis, mind-body during BMA	Pain, Anxiety	RCT 3 groups <ul style="list-style-type: none"> hypnosis mind-body coping skills Usual care 	30 children ages 5-15 (mean age = 8), 57% male with leukemia	<p>Hypnosis was effective for pain ($p=.005$) and anxiety ($p=.005$) in BMA after intervention</p> <p>Mind-body was effective for pain ($p=.008$) and anxiety ($p=.04$) in BMA after intervention</p>	<ul style="list-style-type: none"> Pain $d=3.87$ Anxiety $d=3.87$ Pain $d=3.07$ Anxiety $d=1.70$

<p>Liossi, C, White, P. Hatira, P. <i>Health Psychology</i> 2006</p>	<p>Compare the efficacy of EMLA cream with EMLA plus hypnosis for pain and anxiety during a lumbar puncture (LP)</p>	<p>Self-hypnosis during an LP</p>	<p>Pain, Anxiety</p>	<p>RCT 3 groups • EMLA only • EMLA+self-Hypnosis • EMLA+Attention</p>	<p>45 children, ages 6-16 (mean=8.84), 51% male diagnosed with either leukemia or non-Hodgkins lymphoma who had already experienced 5-6 LP procedures</p>	<p>Child self-report of anxiety for EMLA+hypnosis compared to EMLA+attention: T2, $t(28)=6.88$, $p<.001$, $\eta^2=.63$; And when compared to EMLA only: T2, $t(28)=10.14$, $p<.001$, $\eta^2=.79$; Child self-report pain EMLA+hypnosis group compared with: EMLA+attention group: T2, $t(28)=4.12$, $p<.001$, $\eta^2=.38$; T3, $t(28)=4.75$, $p<.001$, $\eta^2=.45$; T4, $t(28)=3.40$, $p<.002$, $\eta^2=.29$; and and when compared to the EMLA group: T2, $t(28)=6.17$, $p<.001$, $\eta^2=.58$; T3, $t(28) = 6.15$, $p<.001$, $\eta^2=.58$; T4, $t(28) = 4.88$, $p<.001$, $\eta^2=.46$</p>	<p>(EMLA+attention) (T2-T4) • $d=2.52$ • $d=2.60$ • $d=2.52$ (EMLA only) (T2-T4) • $d=3.71$ • $d=2.65$ • $d=2.49$ (EMLA+attention) • $d=1.50$ • $d=1.73$ • $d=1.24$ (EMLA only) • $d=2.24$ • $d=2.27$ • $d=1.78$</p>
<p>Liossi, C., White, P. Hatira, P. <i>Pain</i> 2009</p>	<p>Compare efficacy of EMLA cream to EMLA cream plus self-hypnosis for relief of venipuncture-induced pain and</p>	<p>Hypnosis during venipuncture</p>	<p>Pain, Anxiety</p>	<p>RCT 3 groups • EMLA only • EMLA+self-Hypnosis • EMLA+Attention</p>	<p>45 children ages 7-16 (mean=8.5), 44% male, all Greek with a diagnosis of cancer but not currently undergoing treatment</p>	<p>Significant difference between the EMLA+self-hypnosis and other groups all time points for self-report of pain $F(2,42)=42.95$, $p<.0001$, $\eta^2=.672$ and anxiety $F(2,42)=99.00$, $p<.0001$, $\eta^2=.825$ Pain: (First venipuncture)</p>	<p>Pain</p>

	anxiety					EMLA+Hyp v EMLA+Attn EMLA+Attn v EMLA Anxiety (first venipuncture) EMLA+Hyp v EMLA+Attn EMLA+Attn v EMLA	<ul style="list-style-type: none"> • $d=2.25$ • $d=1.10$ Anxiety <ul style="list-style-type: none"> • $d=4.04$ • $d=1.73$
Hawkins, P. J., Liossi, C., Ewart, B. W., et al. <i>Contemporary Hypnosis</i> 1998	The purpose of this study was to evaluate direct v indirect hypnotic suggestion to reduce pain during lumbar puncture (LP) and explore the relationship between hypnotizability and outcome	Hypnosis during LPs	Pain, Anxiety	Randomized between 2 hypnosis groups, no control	30 children ages 6-16, 40% male, all Greek with leukemia and non-Hodgkin's lymphoma who had experienced 5-6 previous LPs	<ul style="list-style-type: none"> • Lower pain ($p<.001$) and anxiety ($p<.001$) scores over time • 2 methods of hypnosis were equally effective and there was no difference in either pain ($p=.83$) or anxiety ($p=.92$) for type of suggestion. • Hypnotizability was significantly associated with results for pain ($p<.001$) and anxiety ($p<.001$) 	Pain Direct pre/post ($d=2.24$) Indirect pre/post ($d=2.40$) Anxiety Direct pre/post ($d=2.31$) Indirect pre/post ($d=2.39$)
Jay, S., Elliott, C. H., Fitzgibbons, I., et al. <i>Pain</i> 1995	To compare the efficacy of mind-body therapy versus general anesthesia in alleviating distress in pediatric cancer patients during a bone marrow aspiration (BMA)	Mind-body versus general anesthesia during BMA in an outpatient setting	Pain, Anxiety	Randomized crossover	18 children ages 3-12 (mean age 5.9) 50% male, 39% white, 44% Latino, 11% African American, 6% other with a diagnosis of leukemia.	<ul style="list-style-type: none"> • Children were more distressed in the first minute mind-body vs general anesthesia, mean 2.8, $SD=3.0$ vs mean=.13, $SD=.45$ ($t=3.71$, $df=17$, $p=.002$) • Children had more behavior-related symptoms after GA than mind-body, general anesthesia mean=.72, $SD=1.13$ v mind-body mean =.11, $SD=.47$ ($t=3.05$, $df=17$, 	<ul style="list-style-type: none"> • $d=1.24$ • $d=0.70$

						<p>p=.007)</p> <ul style="list-style-type: none"> • Parents and children preferred general anesthesia to mind-body although not statistically significant (children 58% v 42%, parents 56% v 40%) 	
<p>Pederson, C. <i>Journal of Pediatric Oncology Nursing</i> 1996</p>	<p>Measure the effect of promoting the use of selected nonpharmacologic techniques on children's pain during lumbar puncture (LP)</p>	<p>Distraction & breathing techniques during LP</p>	<p>Pain Anxiety operation alized as verbal resistance , requests for emotiona l support, muscular rigidity</p>	<p>Randomized crossover</p>	<p>8 children ages 6-14 (mean=8.4), 63% male, 100% white with a diagnosis of leukemia</p>	<ul style="list-style-type: none"> • Near-significant (p=.10) for pain • Significant for muscular rigidity (p=.04) • Near significant (p=.05) for verbal resistance • Effect sizes were corrected for small sample size 	<ul style="list-style-type: none"> • Pain $d=2.49$ • Could not calculate Verbal resistance $d=8.57$
<p>Manne, S. L., Redd, W. H., Jacobsen , P. B., et al. <i>Journal of Consulting and Clinical Psychology</i> 1990</p>	<p>To investigate a behavioral intervention incorporating parent coaching, attentional distraction, and positive reinforcement to control child distress during venipuncture</p>	<p>Behavioral during venipuncture</p>	<p>Pain, Distress</p>	<p>Randomized to either behavioral (intervention) or attention control groups (parent's attention)</p>	<p>23 children ages 3-9 (mean=4.7), 48% male, 65% white, 26% African American, 9% Hispanic with a diagnosis of some type of cancer who w restrained during previous venipuncture</p>	<ul style="list-style-type: none"> • There was significant decrease in observed distress (p<.05) from baseline for all trials combined • Non-significant decrease in child self-report of pain for all trials combined • Significant decrease in pain by parent-report (p<.01) for all trials combined 	<ul style="list-style-type: none"> • $d=1.18$ • $d=.57$ • $d=1.36$
<p>Gershon, J., Zimand, E.,</p>	<p>To determine whether an</p>	<p>Virtual reality</p>	<p>Pain, Anxiety</p>	<p>RCT 3 groups</p>	<p>59 children ages 7-19 (mean age</p>	<p>Children receiving VR</p> <ul style="list-style-type: none"> • Lower pulse rate during 	<p>Pulse rate VR</p>

Pickering, M., et al. <i>Journal of the American Academy of Child and Adolescent Psychiatry</i> 2004	immersive virtual reality (VR) technique is feasible and beneficial for children undergoing medical procedures.	program during Port-a-cath access		<ul style="list-style-type: none"> • VR • Non-VR • Distraction • Usual care 	12.7), 51% male, 64% white, 20% African American, 6% Latino, 3% Native American, 7% other with a diagnosis of cancer visting an outpatient clinic for PAC access	<p>procedure, $F=2.76$ ($p=.04$), $\eta^2=.09$ (medium effect size)</p> <ul style="list-style-type: none"> • Lower nurse pain rating during procedure ($p<.05$) for VR and nonVR over control on VAS. • No significance for anxiety 	compared to control group $d=0.74$
Madden J. R., Mowry P., Gao D., et al. <i>Journal of Pediatric Oncology Nursing</i> 2010	To evaluate the effects of a creative arts therapy (CAT) intervention on the quality of life of children receiving chemotherapy	CAT v attention during outpatient chemotherapy	Pain, Anxiety	3 Phases, (1) Randomized (2) non-randomized (3) qualitative	Ph1: 16 children ages 2-13 (median=5.3), 78% males, all diagnosed with brain tumors Ph2: 32 children ages 3-21 (median=8.3) with any type of cancer	<ul style="list-style-type: none"> • Ph1 significant per parent report effect on pain $p=.03$ • Ph2 significant on child-report of pain $p=.006$ and nervousness $p=.024$ 	<ul style="list-style-type: none"> • Pain • $d=0.54$ <ul style="list-style-type: none"> • Pain • $d=0.49$ • Nervousness • $d=0.40$
Post-White, J., Fitzgerald, M., Savik, K., et al. <i>Journal of Pediatric Oncology Nursing</i> 2009	To determine the feasibility of providing massage to children with cancer to reduce symptoms in children and anxiety in parents	Massage for general symptom management while child on chemo treatment	Pain, Anxiety	Randomized crossover (massage or quiet time)	17 children ages 1-18, 60% male, 86% white diagnosed with any type of cancer	<ul style="list-style-type: none"> • Children ages 1-13 had less anxiety ($p=.04$) and children ages 14-18 had a nearly significant decrease in anxiety ($p=.058$) • Significant for lower heart rate ($p=.02$) and nearly significant for respiratory rate ($p=.05$) • 100% of the children stated they felt better after massage physically, mentally, and emotionally 	<ul style="list-style-type: none"> • Age 1-13 $d=1.45$ • Age 14-18 $d=1.85$ • HR $d=1.37$ • RR $d=1.08$

						and the results lasted several hours up to the rest of the day	
Nguyen, T. N., Nilsson, S., Hellstrom, A. L., et al. <i>Journal of Pediatric Oncology Nursing</i> 2010	Evaluate if music medicine influences pain and anxiety in children undergoing lumbar punctures (LP)	Music Therapy during an LP	Pain, Anxiety	RCT: randomized to either music (earphone) or control	40 children ages 7-12 (mean 8.8 intervention and 9.4 control) 63% male, all Vietnamese, diagnosed with leukemia	<ul style="list-style-type: none"> • Significant child self-report for pain during (p<.001) and after (p=.003) procedure • Significant child self-report for anxiety before (p<.001) and after (p<.001) procedure • Significant vital signs include heart rate during procedure (p=.012) and respiratory rate during (p=.009) and after (p=.003) 	<ul style="list-style-type: none"> • During $d=1.49$ • After $d=1.05$ • Before $d=1.41$ • After $d=1.47$ HR (during) $d=0.98$ RR (during) $d=0.91$ RR (after) $d=1.03$

3.1.5.1 Study Design

All studies included in this review employed a form of randomization. Three studies used a randomized crossover design (Jay et al., 1995; Pederson, 1996; Post-White, Fitzgerald, Savik, et al., 2009) where the participants in the control group received attention. Two studies used randomization with the control group receiving attention of a volunteer (Madden et al., 2010; Manne et al., 1990). In one study the control group had earphones but no music in order to blind the observers (Nguyen et al., 2010). One hypnosis study randomized between two treatment types: indirect versus direct suggestion with no control (Hawkins et al., 1998) and another purposefully randomized of low- and high-hypnotizable children to achieve balanced groups (Smith et al., 1996). The remaining four studies used a three group design: the main intervention, a distraction intervention, and usual care control group (Gershon et al., 2004; Lioffi & Hatira, 1999; Lioffi et al., 2006, 2009). How subjects were randomized into groups was not detailed in seven studies (Hawkins et al., 1998; Jay et al., 1995; Lioffi & Hatira, 1999; Madden et al., 2010; Pederson, 1996; Post-White, Fitzgerald, Savik, et al., 2009; Smith et al., 1996); one study used an every other case randomization (Manne et al., 1990); one study used a table of random numbers (Lioffi et al., 2006); two studies used computer-generated random numbers (Gershon et al., 2004; Lioffi et al., 2009); and the final study used sealed, opaque envelopes (Nguyen et al., 2010).

3.1.5.2 Variables and Measures

All studies reviewed measured pain by child self-report for children ages three and over in addition to either parent proxy report or other observer report. For children less than three years old, only proxy report was used. Table 6 summarizes the measures for each study.

Table 5. Measures Used for Pain and Anxiety in Studies

Study/Purpose	Pain	Anxiety
Gershon et al. (2004) VR during PAC	Visual Analog Scale (VAS) (Varni, Walco, & Katz, 1989) Pulse-oxygen monitor	VAS
Jay et al. (1995) CBT v GA during BMA	Observational Scale of Behavioral Distress (OSBD) with established reliability and validity (Elliott, Jay, & Woody, 1987; Jay & Elliott, 1984; Jay, Ozolins, Elliott, & Caldwell, 1983)	
	5-point face/pain scale Dinamap for digital pulse readout	5-point face/anxiety scale
Madden et al. (2010) Creative arts therapy during chemotherapy	PedsQL 4.0 Cancer Module (Varni, Burwinkle, Katz, Meeske, & Dickinson, 2002) contains both a parent-proxy report and child self-report (ages 5 and older). Subscales include pain, nausea, procedural anxiety, treatment anxiety, worry, cognitive problems, perceived physical appearance, and communication. Reliability of .80 to .90 across total and individual scales.	
Nguyen et al. (2010) Music therapy for LP	Child-report Numeric Rating Scale (NRS) 0-10, validated with FACES (Jongudomkarn, Angsupakorn, & Siripul, 2008)	State-Trait Anxiety Inventory (STAI) a six-item validated scale (Marteau & Bekker, 1992)
	HR and RR were recorded before, during, and after procedure	
Post-White et al. (2009) Massage for general symptom management	PAT (pain assessment tool, parent proxy for ages 1-2), FACES (ages 3-13), VAS (ages 14-18)	State Trait Anxiety Inventory for Children (STAIC) both child self-report (ages 3-13) and parent proxy (ages 1-2) (C. Spielberger, Edwards, Lushene, Montuori, & Platzek, 1973). STAI (C. D. Spielberger, Gorsch, Lushene, Vagg, & Jacobs, 1983) for ages 14-18
Pederson (1996) Distraction & breathing techniques during LP	VAS (0-100) used by child, parent, and nurse	STAIC OSBD
Manne, et al. (1990) Behavioral intervention	Child self-report on FACES scale. Parent report using a VAS	Author developed observer scale for distress. Reliability $\alpha=.73$

to reduce distress during venipuncture		
Liossi & Hatira (1999) Hypnosis v CBT during BMA	<ul style="list-style-type: none"> • Procedure Behavior Checklist (PBCL). Trained nurse observer assessment for pain and distress behaviors (vocalizations, verbalizations, facial expressions, muscle tension and rigidity, general appearance) (LeBaron & Zeltzer, 1984) shows good reliability and validity. • FACES (Whaley & Wong, 1987) 	
Hawkins et al. (1998) Hypnosis during LP	Child self-report unspecified tool for pain and anxiety PBCL	
Liossi et al. (2006) Hypnosis for LP	PBCL FACES	
Liossi et al. (2009) Hypnosis during venipuncture	100mm VAS (Shields, Palermo, D., Grewe, & Smith, 2003)	100mm VAS (no anxiety, worst possible anxiety)
	PBCL	
Smith et al. (1996) Hypnosis or distraction for venipuncture or PAC access	Children's Global Rating Scale (CGRS) used for pain and anxiety (Carpenter, 1992) OSBD Ordinal 1-5 scale for parent proxy rating of pain and anxiety after procedure	

3.1.5.3 Participants and Sample Size

There were a total of 358 children participating in the studies ranging from 1 to 19 years old. Combined mean age from ten out of twelve studies that included data was 8.4 years old. Fifty-five percent of the participants were male. Three separate studies took place in Greece for a total of 120 Greek children (Hawkins et al., 1998; Liossi et al., 2006, 2009), and one study took place in Vietnam including 40 children (Nguyen et al., 2010). Of the studies that took place in the United States that mentioned race, a total of 160 children were 62% white, 15% African American, 14% Hispanic/Latino, 1% Native American, 2% Haitian, and 6% other (Gershon et al., 2004; Jay et al., 1995; Manne et al., 1990; Pederson, 1996; Post-White, Fitzgerald, Savik, et al., 2009; Smith et al., 1996).

Sample sizes ranged from 8 to 59 participants (mean 29.8, standard deviation 14.9). Many of the studies examined painful procedures such as lumbar punctures and bone marrow aspirations necessitating that the majority of the subjects were diagnosed with either leukemia or lymphoma (Gershon et al., 2004; Hawkins et al., 1998; Jay et al., 1995; Lioffi & Hatira, 1999; Nguyen et al., 2010; Pederson, 1996). The remaining study subjects had either brain tumors (Madden et al., 2010; Post-White, Fitzgerald, Savik, et al., 2009), rhabdomyosarcoma (Manne et al., 1990; Post-White, Fitzgerald, Savik, et al., 2009), Wilms tumor (Manne et al., 1990; Post-White, Fitzgerald, Savik, et al., 2009), Ewing sarcoma (Post-White, Fitzgerald, Savik, et al., 2009), non-specified solid tumors (Smith et al., 1996), or non-specified types of cancers (Lioffi et al., 2009).

3.1.5.4 Comparison Groups and Outcomes

With the exception of studies that used different treatment modalities for comparison (Hawkins et al., 1998; Lioffi et al., 2006, 2009; Smith et al., 1996), the remaining studies used usual care as the comparison group. All studies measured pain and some form of anxiety. Manne et al. (1990) measured distress during venipuncture while Pederson (1996) measured anxiety operationalized as verbal resistance, requests for emotional support, and muscular rigidity during a lumbar puncture (see the Measures section below for further explanation of operationalization of anxiety).

3.1.5.5 Intervention Modalities

The effectiveness of integrative modalities was primarily studied during painful procedures common throughout cancer treatment including lumbar punctures (Hawkins et al., 1998; Lioffi

et al., 2006; Nguyen et al., 2010; Pederson, 1996), bone marrow aspiration (Jay et al., 1995; Lioffi & Hatira, 1999), implanted port (or port-a-cath) access (Gershon et al., 2004; Smith et al., 1996), and venipuncture (Lioffi et al., 2009; Manne et al., 1990; Smith et al., 1996). Post-White et al. explored massage therapy for general symptom management while Madden et al. investigated creative arts therapy during chemotherapy infusions.

Hypnosis was used in five out of the twelve studies (Hawkins et al., 1998; Lioffi & Hatira, 1999; Lioffi et al., 2006, 2009; Smith et al., 1996). Mind-body methods (imagery, distraction, breathing techniques) were the primary focus of three studies (Jay et al., 1995; Manne et al., 1990; Pederson, 1996) and were used as comparison groups for two of the hypnosis studies (Lioffi & Hatira, 1999; Smith et al., 1996). Other modalities included a virtual reality program (Gershon et al., 2004), creative arts (Madden et al., 2010), massage (Post-White, Fitzgerald, Savik, et al., 2009) and music (Nguyen et al., 2010).

Hypnosis

Five studies used hypnosis to help children with pain and anxiety during procedures ranging from venipuncture to lumbar puncture and bone marrow aspiration. Hawkins et al. (2008) evaluated the effects of direct versus indirect hypnotic suggestion and the effectiveness of hypnotizability for children undergoing LPs. Thirty children ages 6 to 16 were randomly assigned to either the direct or indirect suggestion groups. Both methods of suggestion were equally effective for decreased pain ($p < .001$) and anxiety ($p < .001$) over time and there was no difference in either pain ($p = .83$) or anxiety ($p = .92$) for type of suggestion. Hypnotizability was significantly associated with results for decreased pain ($p < .001$) and anxiety ($p < .001$).

Smith et al. (1996) tested 27 children ages 3 to 8 for hypnotizability then stratified on hypnotizability to achieve a balance of low- and high-hypnotizable children in each group. Children were tested for hypnotizability by staff not participating in other areas of the study so medical personnel and observers were blind to hypnotizability. The study used a crossover design so all children participated in both the hypnosis and distraction interventions. Highly hypnotizable children had significantly less pain ($p<.001$) and anxiety ($p<.001$) during venipuncture or implantable port access than low hypnotizable children during the procedure. When highly hypnotizable children were in the hypnosis intervention effect size for child self-report of decreased pain was very large ($d=2.39$) as was child self-report of decreased anxiety ($d=1.16$).

Three studies used a three-group randomized control group design to test effectiveness of hypnosis for pain and anxiety during venipuncture (Lioffi et al., 2009), LP (Lioffi et al., 2006), and bone marrow aspiration (BMA) (Lioffi & Hatira, 1999). Lioffi and Hatira (1999) utilized three groups: hypnosis, mind-body techniques, and usual care with 30 children ages 5 to 15 with leukemia during BMA. Hypnosis was effective for decreased pain ($p=.005$, $d=3.87$) and anxiety ($p=.005$, $d=3.87$) after BMA compared to mind-body and usual care, mind-body was effective for decreased pain ($p=.008$, $d=3.07$) and anxiety ($p=.04$, $d=1.70$) after BMA compared to usual care.

Eutectic mixture of local anesthetics (EMLA) cream is a common topical anesthetic cream used with children before procedures and is often considered usual care. Lioffi et al. (2006) used three groups (EMLA only, EMLA with attention, and EMLA with hypnosis) to test the effectiveness of EMLA cream plus hypnosis on pain and anxiety in 45 children ages 6 to 16 who had already experienced at least five LP procedures compared to EMLA cream plus

attention and EMLA cream only. For the EMLA plus hypnosis group there was a significant effect for child self-report of decreased anxiety when compared to the EMLA only group (T2, $p < .001$, $d = 3.71$) and when compared to the EMLA plus attention group (T2, $p < .001$, $d = 2.52$). There was also a significant effect on child self-report of less pain in the EMLA plus hypnosis group when compared to the EMLA plus attention group at each time point (time T2, $p < .001$, $d = 1.50$) and when compared to the EMLA only group at each time point (time T2, $p < .001$, $d = 2.24$).

Lioffi et al. (2009) used the same procedure as 2006 above to explore the effect of EMLA plus hypnosis, EMLA plus attention, and EMLA only for pain and anxiety during venipuncture. Study subjects were 45 children ages 7 to 16 who had a cancer diagnosis but were not currently undergoing treatment. There was a significant effect for EMLA plus hypnosis when compared to both other groups at each time points for child self-report of decreased pain $F(2,42) = 42.95$, $p < .0001$, $\eta^2 = .672$ and child self-report of decreased anxiety $F(2,42) = 99.00$, $p < .0001$, $\eta^2 = .825$ both very large effect sizes. When comparing EMLA plus hypnosis to EMLA plus attention for child self-report of less pain the effect size was $d = 2.25$. When comparing EMLA plus attention to EMLA only for child self-report of less pain the effect size was $d = 1.10$. The same comparisons for decreased anxiety yield effect sizes of $d = 4.04$ and $d = 1.73$ respectively.

Mind-body techniques

Three studies used some type of mind-body intervention to help children cope with bone marrow aspiration (Jay et al., 1995), lumbar puncture (Pederson, 1996), and venipuncture (Manne et al., 1990). Mind-body techniques include breathing exercises, distraction (such as using a party blower or blowing bubbles), reward incentive, practicing positive coping behavior,

coaching by the parent, relaxation techniques and the like. Jay et al. (1995) used mind-body techniques compared to general anesthesia for a bone marrow aspiration in 18 children ages 3 to 12. Children experienced more distress (anxiety) during the first minute when using mind-body techniques ($p=.002$, $d=1.24$) but more negative behavior related symptoms after general anesthesia when compared to mind-body ($p=.007$, $d=0.70$). However, both children (58% v 42%) and parents (65% v 40%) preferred general anesthesia over mind-body techniques (a non-significant result).

Pederson (1996) used distraction and breathing techniques during a lumbar puncture procedure in a sample of eight children ages 6 to 14. Distraction techniques included blowing bubbles, pop-up books, plastic wands filled with sparkles, and foam puzzles. Child self-report was not significant for less pain ($p=.10$) but did have a very large effect size $d=2.49$ (corrected for small sample size). In observer report for anxiety, there was a significant result for less muscular rigidity ($p=.04$) (effect size could not be calculated due to small sample size) and a near significant result for less verbal resistance ($p=.05$) with a very large effect size $d=8.57$ (corrected for small sample size).

Manne et al. (1990) studied the use of attention distraction, paced breathing, and positive reinforcement versus parental attention (no intervention) with 23 children ages 3 to 9 who had previously been observed being physically restrained during a venipuncture. There was a significant decrease in observed distress for the intervention group ($p<.05$, $d=1.18$), a significant decrease in pain by parent report ($p<.01$, $d=1.36$), and a non-significant child self-report for decreased pain that still achieved a medium effect size ($d=0.57$).

Virtual Reality

One study (Gershon et al., 2004) explored the effect of a virtual reality (VR) program, a non-VR video game distraction, and usual care on pain and anxiety during implanted port access in 59 children ages 7 to 19. There was no significant effect for child self-report of pain or anxiety but nurses rated pain lower for VR and non-VR over control ($p < .05$) and pulse oximeter readings recorded lower pulse rate during implantable port access for VR group ($p < .05$). Effect size for pulse rate was $d = 0.74$, a large effect size.

Creative Arts Therapy

One study used creative arts therapy (CAT), which can include dance/movement therapy, music therapy, and art therapy and involves a trained therapist interaction with the child. Madden et al. (2010) used CAT to evaluate changes in quality of life including pain and anxiety for children ages two to 21 during chemotherapy treatment with a cancer diagnosis. Phase one of the study was a randomized control trial of 16 children ages 2 through 13 with brain cancer who received six one-hour CAT sessions (two sessions each of dance/movement, music, and art therapies). Phase one had a significant effect on decreased pain ($p = .03$) per parent report. Phase two was a non-randomized trial of children ages 3 to 21 receiving chemotherapy with any type of cancer diagnosis. During this phase the children received group one-hour sessions consisting of dance/movement, music, or art. This phase was significant for child self-report of decreased pain ($p = .006$).

Massage

In a study of 17 children ages 1 to 18 that were undergoing treatment for a cancer diagnosis, Post-White et al. (2009) found that all of the children felt better after the massage physically, mentally, and emotionally and the results lasted from several hours and up to the remainder of the day. Children 1 to 13 had less anxiety ($p=.04$, $d=1.45$) and children 14-18 had a nearly significant decrease in anxiety ($p=.058$) while still achieving a large effect size ($d=1.85$). For all children combined, there was a significant finding for lower heart rate ($p=.02$, $d=1.37$) and nearly significant for lower respiratory rate ($p=.05$, $d=1.08$) both of which indicate less pain and anxiety.

Music

Nguyen et al. (2010) studied the use of music on pain and anxiety for children with leukemia undergoing lumbar punctures (LP). The children aged 7 to 12 were randomized into intervention and control groups. To blind the observer to group, control group children wore identical headphones but had no music. The study found significant effects on child self-report for decreased pain during ($p<.001$, $d=1.49$) and after the LP ($p=.003$, $d=1.05$). There were significant effects on child self-report of anxiety before ($p<.001$, $d=1.41$) and after ($p<.001$, $d=1.05$) the procedure. Reduction in vital signs (an indicator of decreased pain and anxiety) during the procedure including decreased heart rate during the LP ($p=.012$, $d=0.98$) and decreased respiratory rate during ($p=.009$, $d=0.91$) and after ($p=.003$, $d=1.03$) the LP.

3.1.6 Discussion

While the heterogeneous modalities and methodologies of the included studies prohibited conducting a formal meta-analysis, collectively they provide encouraging evidence for the effectiveness of integrative approaches to managing pain and anxiety in children with cancer. With the exception of the virtual reality study, which had a medium effect size, the remaining studies in this review achieved a large to very large effect size. These results validate the effectiveness of integrative modalities for children with cancer in coping with pain and anxiety during cancer treatment and the painful procedures that are a part of treatment. In addition, the effectiveness and variety of integrative modalities highlighted in this review show that there are many ways to benefit children and decrease suffering during cancer treatment. Furthermore these studies demonstrate that individual children will respond to some but not all modalities.

The overall design quality of the studies reviewed was very good although some study designs stand out as excellent while others suffered design flaws. The recent hypnosis studies by the Lioffi team using three-group RCT design examining the effectiveness of hypnosis over attention or usual care reached the projected sample size of $N=45$ with a power of 0.9 and a large effect size (Lioffi et al., 2006, 2009) and an earlier three group RCT ($N=30$) also used standardized procedures although the authors did not mention the power of the study (Lioffi & Hatira, 1999). Pederson (1996) had difficulty recruiting subjects due to clinic changes in mid-study and personnel issues resulting in decreased power of statistical analysis but an additional design weakness included timing of assessments in relation to sedation during procedures. Measures were problematic in the massage study (Post-White, Fitzgerald, Savik, et al., 2009) as not all tools were validated for the age group (the STAI has not been validated for children

younger than eight or for proxy report) or for the outcome variable (the study used a FACES-type scale to measure nausea in children younger than nine who did not understand a VAS for this purpose); a change in inclusion criteria might have been advisable.

With the exception of massage, the remaining studies used some sort of distraction to help children cope with pain and anxiety. Distraction has many forms and is a way to focus the mind on something pleasant (or even fun) and not on the suffering at hand. Virtual reality is a way to immerse the mind more completely than just playing a video game. This modality has been studied with small samples of children since its beginning more than 20 years ago. An earlier pilot study found that using a VR program made children's chemotherapy experience "better" than receiving chemotherapy without VR (Schneider & Workman, 2000). It seems worthwhile to study VR more extensively for children and adolescents during treatment. It may be that using VR for implantable port access is too short of a time frame to be as effective as using VR for chemotherapy treatment.

By the time children are 18 to 24 months old, they have developed the cognitive ability to use symbols (e.g. using a block as a truck) resulting in the increasing use of imagination and pretend play (Lillard, 2002). By preschool age, they are able to enjoy and participate in stories because of their ability to remember and follow the story line. This ability also makes children of this age appropriate for distraction techniques such as guided imagery, hypnosis, and using imagination to participate with an adult in mutual storytelling. Children of preschool through early school age also want to please their parents so techniques such as coaching and encouragement may be helpful. Toddlers from about 18 to 36 months are able to enjoy colorful toys such as glitter wands, pinwheels, party blowers, or blowing bubbles. The studies in this review used age-appropriate distraction techniques. There was variability in the distraction

interventions that were investigated across studies. In the Jay et al. study (1995), the mind-body intervention consisted of a 45 minute film that showed the child how to do breathing exercises, modeled positive coping strategies, and talked about imagery strategies such as imagining one is at Disneyland or eating pizza. The children in this study ranged in age from 3 to 12. It is difficult to find a “one size fits all” intervention for this range of developmental levels; however it seems unlikely that a three year old would be able to stay attentive to an instructional film for this period of time; however a therapist did give guidance during the BMA on coping strategies. Pederson (1996) also used a 22-minute video tape to teach strategies to children. The child was then able to choose a distraction material for use during the next BMA. A research support person went into the BMA to help support the parent in helping their child use the coping techniques. In the Manne et al. (1990) study child-parent dyads were given personal instruction in the use of paced breathing, positive reinforcement and distraction—in this case in the use of a party blower. The child could “win” stickers by using the party blower and holding still during venipuncture. Only children who had been observed needing physical restraint during a previous venipuncture were recruited to the study. The short, personal instruction seemed to work very well for this age group (ages 3 to 9) since the effect size was very large. In the Nguyen et al. study (2010), music was used as a distraction during an LP. Children were able to choose the type of music they would like to listen to. The large and very large effect sizes for child self-report of both pain and anxiety during the music intervention shows very good evidence for the effectiveness of this simple intervention.

Culture plays a role in children’s expression of pain and anxiety. This adaptation to culture begins in infancy as children are socialized into the culture of their environment. In Western cultures that value autonomy and individualism, assertiveness in social skills and

expression of pain is normal although acceptability varies depending on age and gender (Chen & French, 2008). In collective societies such as East Asian, Latin American, or Israel, individuals are encouraged and guided from infancy to demonstrate self-control including expressions of pain or anxiety (Chen & French, 2008; Raval & Martini, 2009).

The studies reviewed here suggest that there are many integrative modalities that may be used with good effect to decrease pain and anxiety in children both during painful procedures and during general treatment for cancer. Many types of distraction techniques including hypnosis, mind-body, listening to music, and virtual reality may help decrease pain and anxiety and thereby suffering in children undergoing procedures that are part of cancer treatment. Other modalities such as massage and creative art therapy may decrease pain and anxiety associated with overall treatment while increasing mood and a feeling of well-being. Many of these techniques are easy to learn and all are within the scope of nursing practice. Nurses may use these techniques with children and teach them to parents to help support children through painful procedures and cancer treatment.

3.1.7 Limitations

While efforts were made to decrease bias as much as possible, the results of the review may be inflated by several factors. First, in order to increase the potential for significant findings, only studies that used randomization were included. This limits the studies published from other countries, which tend to conduct open, non-randomized designs. Only published peer-reviewed journal studies were included, no dissertations or conference abstracts were considered. Finally, due to the nature of research in childhood cancer in general and integrative medicine, sample

sizes of even the more rigorous studies were small (≤ 59 participants) which may inflate results despite the use of small sample size corrections in the Cohen's d statistic in the case of very small sample sizes.

3.1.8 Conclusion

There is good evidence that complementary modalities, also known as integrative medicine can help children undergoing cancer treatment in general and in painful procedures in particular. The modalities in this review including virtual reality, various mind-body techniques, creative arts therapy, listening to music, massage, and hypnosis all had good effect sizes and significant results for pain and anxiety. While these studies universally employed small sample sizes, all of the studies utilized some type of randomization and many used the gold standard randomized control design. Given that mind-body techniques and hypnosis showed good effect sizes for decreased pain and anxiety in several studies examining diverse painful procedures, there is ample evidence to recommend the use of these techniques during the painful procedures that are a part of childhood cancer treatments. They are both non-invasive and give the child a sense of control over their pain during the procedure. Creative art therapy seems like a natural modality for children with its combination of creativity and expression of feelings. However, more studies need to be done with this modality and population. Massage is another modality that has not been well studied with children in general or with cancer patients in particular. More research is needed with massage and touch therapies in order to be able to recommend their use for pain and anxiety in pediatric cancer patients.

Based on this review, further research is needed in integrative modalities. Larger sample sizes, perhaps through multisite studies are needed in order to recommend the modalities reviewed in this study and the many other possibilities such as meditation, aroma therapy, yoga, acupuncture, Reiki, and other integrative therapies that may have benefit for this population. The clinical implications of the use of integrative modalities for children undergoing cancer treatment include empowering children and their families to gain control over their pain, anxiety, and to increase well-being. Many of these modalities are within the scope of practice for nursing. While some nurses may view this as another task, many nurses will welcome adding a simple tool to their toolbox that enables them to help children in their care.

3.1.9 Acknowledgements

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3.2 MANUSCRIPT #2: EFFECT OF REIKI THERAPY ON PAIN AND ANXIETY IN ADULTS: AN IN-DEPTH LITERATURE REVIEW OF RANDOMIZED TRIALS WITH EFFECT SIZE CALCULATIONS (DOI: 10.1016/J.PMN.2013.07.008)

3.2.1 Abstract

Objective: To calculate the effect of Reiki therapy for pain and anxiety in randomized clinical trials.

Data Sources: A systematic search of PubMed, ProQuest, Cochrane, PsychInfo, CINAHL, Web of Science, Global Health, and Medline databases was conducted using the search terms pain, anxiety, and Reiki. The Center for Reiki Research was also examined for articles.

Study Selection: Studies that used randomization and a control or usual care group, used Reiki therapy in one arm of the study, published in 2000 or later in peer-reviewed journals in English, and measured pain or anxiety were included.

Results: After removing duplicates, 49 articles were examined and 12 articles received full review. Seven studies met the inclusion criteria: four articles studied cancer patients; one examined post-surgical patients; and two analyzed community dwelling older adults. Effect sizes were calculated for all studies using Cohen's d statistic. Effect sizes for within group differences ranged from $d=0.24$ for decrease in anxiety in women undergoing breast biopsy to $d=2.08$ for decreased pain in community dwelling adults. The between group differences ranged from $d=0.32$ for decrease of pain in a Reiki versus rest intervention for cancer patients to $d=4.5$ for decrease in pain in community dwelling adults.

Conclusions: While the number of studies is limited, based on the size Cohen's *d* statistics calculated in this review, there is evidence to suggest that Reiki therapy may be effective for pain and anxiety. Continued research using Reiki therapy with larger sample sizes, consistently randomized groups, and standardized treatment protocols is recommended.

3.2.2 Introduction

The use of complementary and alternative medicine (CAM) techniques is growing in popularity with the public. CAM modalities are often either lauded or debunked in the popular press and the scientific community based on the evidence of one study. Reiki therapy, a form of biofield energy has been examined with community dwelling older adults, specific disease conditions such as cancer, chronic fatigue, diabetic neuropathy, surgical patients, and others. The objective of this review is to determine if Reiki therapy is effective for pain and anxiety in adults and to calculate the effect sizes for Reiki therapy in randomized clinical trials. Moreover, this review considers the use of Reiki therapy for pain and anxiety in adults and seeks to discover if Reiki therapy is effective for these conditions based on current evidence.

There is a lot of confusion around what Reiki therapy is. From a practical standpoint, Reiki therapy is a way for the practitioner to guide energy to the recipient, to assist the innate healing energy of the recipient and facilitate self-healing (National Center for Complementary and Integrative Health, 2012a). The practitioner does not cause the healing, nor are they the source of the energy. The practitioner is a channel for the energy, much like a garden hose is a channel for water. Many call this energy universal, but some say it is from God, Buddha, or a

sacred source. A common interpretation for the word Reiki is spiritually guided life force energy (Rand, 2005).

There are several versions regarding the origins of Reiki therapy. It is generally accepted that Reiki therapy began with Dr. Mikau Usui, a spiritual seeker who undertook a 21 day penance and fast on Mount Kurama in Japan (Miles, 2008). Usui experienced the Reiki energy on the 21st day and was healed. He brought the technique to his family and subsequently opened a clinic in order to treat the public. Usui taught Reiki therapy level one to many people and taught several students the master/teacher level (Rand, 2005). Usui taught Reiki therapy as part of a spiritual practice, but not as a religion (Miles, 2008). As Reiki therapy evolved and came to the West, the hands-on healing practices came to the fore and the spirituality piece of the practice faded. There are three degrees or levels of Reiki practice. First degree practitioners are able to treat themselves or others through light touch (Miles & True, 2003). This level of Reiki is suitable for anyone from school aged children to the very old. Second degree Reiki expands practice to the use of distance healing: the practitioner may send Reiki energy to the next room or around the world (Rand, 2005). Third degree or master level Reiki expands Reiki practice to teaching and initiating others into Reiki and involves extensive practice.

A typical Reiki therapy session may last from 30 to 90 minutes. Ideally, the recipient lies comfortably on a massage table fully clothed and the practitioner places their hands lightly on the body in a set sequence of hand positions. Most people leave a Reiki therapy session feeling very relaxed. A qualitative study found that during a Reiki treatment participants felt “dreamy,” “safe,” “secure,” and “more grounded” (Ring, 2009, p. 255). A study of nurses who use Reiki therapy for self-care found that the nurses used Reiki therapy during their workday to feel more calm, centered, and more able to care for others (Vitale, 2009).

The National Center for Complementary and Integrative Health (NCCIH) places Reiki therapy in the in the category of biofield energy. Biofield energy is any electrical or magnetic field produced by a biological organism, e.g. a human. The human body produces measurable electrical and magnetic fields. The heart produces an electrical field to regulate its beat: This electrical signal is measured through an electrocardiogram (ECG or EKG), a common medical test. The brain also produces an electrical field but at a much lower level than the heart. In fact, every cell in the human body produces minute amounts of electricity, a magnetic field, has a positive charge on the outer cell wall, and a negative charge on the inner cell wall (Dale, 2009). Electrical fields produce magnetic fields with a stronger electrical field producing a stronger magnetic field (Rae, 2005; Thomas, 2012). A magnetic resonance imaging (MRI) scan uses the body's own magnetic field (along with a strong magnet and radio waves that are emitted from the machine) to produce sharp images of soft tissue within the body (Berger, 2002). Classic Newtonian physics experiments have shown how waves interact with each other: Depending on the pattern, some waves are enhanced and some are cancelled (Figure 3). The interference pattern between two human magnetic fields may explain some of the results that *any* touch therapy creates.

The theory of quantum physics may hold promise in the future explanation of the mechanisms of Reiki. Although no verified theory exists that explains how Reiki therapy (or any biofield energy therapy) works, there may be a scientific explanation for Reiki therapy to be found in quantum physics, a branch of physics that was first discovered in the 1800's and studies extremely small particles (electrons, photons, and the like) that do not behave in a predictable way. Quantum physics studies these particles and attempts to describe the interactions of energy

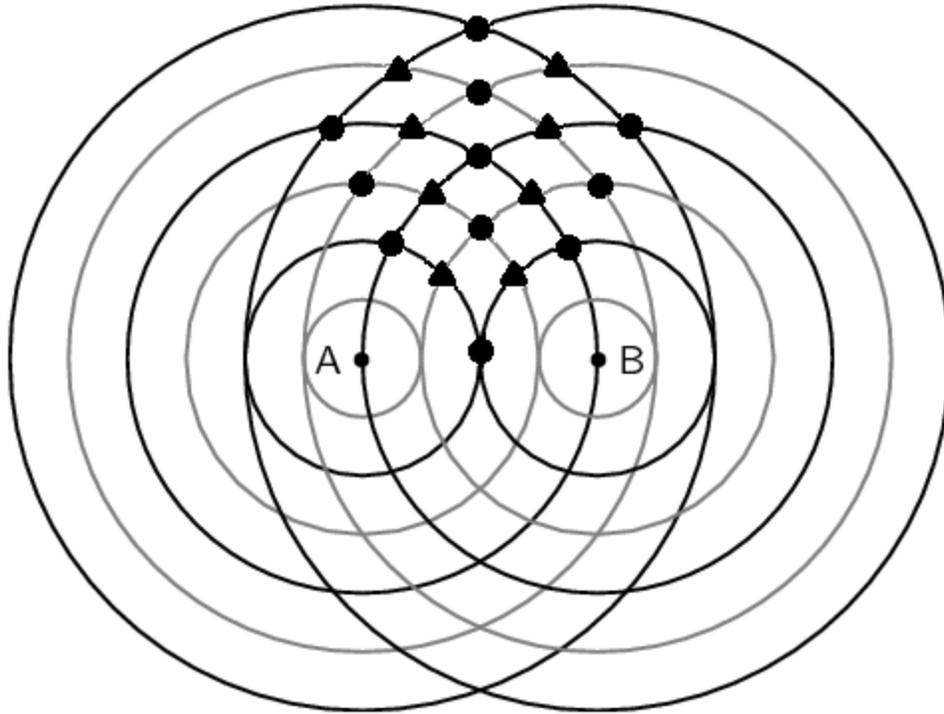


Figure 3. Wave Interference Pattern.

“A” and “B” are two people standing near each other. The black lines are peaks and the grey lines are troughs. The circles indicate areas where the two waves enhance one another (either higher peak or lower trough). The diamonds indicate areas where the two waves cancel each other.

and matter. Physicists have found that very tiny particles have some very curious properties: Not only can these tiny particles be in more than one place at once, some theorists say they *have* to be in more than one place at the same time (Rosenblum & Kuttner, 2006). The Nobel Prize in Physics for 2012 was won by two scientists who were each able to detect a particle being in two places at the same time (Nobelprize.org, 2012). Biofield energy may be gathered and directed by the practitioner to the recipient as explained by quantum physics, e.g., thought produces change in how the particles work (Rosenblum & Kuttner, 2006). Distance healing may be explained by

energy particles being simultaneously present at the location and time of the Reiki practitioner and the location and time of the recipient through the intention of the Reiki practitioner.

These particles by definition are difficult to measure but beginning in the 1960's scientists began measuring the biomagnetic field coming from the human heart that is believed to extend beyond the body (see Figure 4).

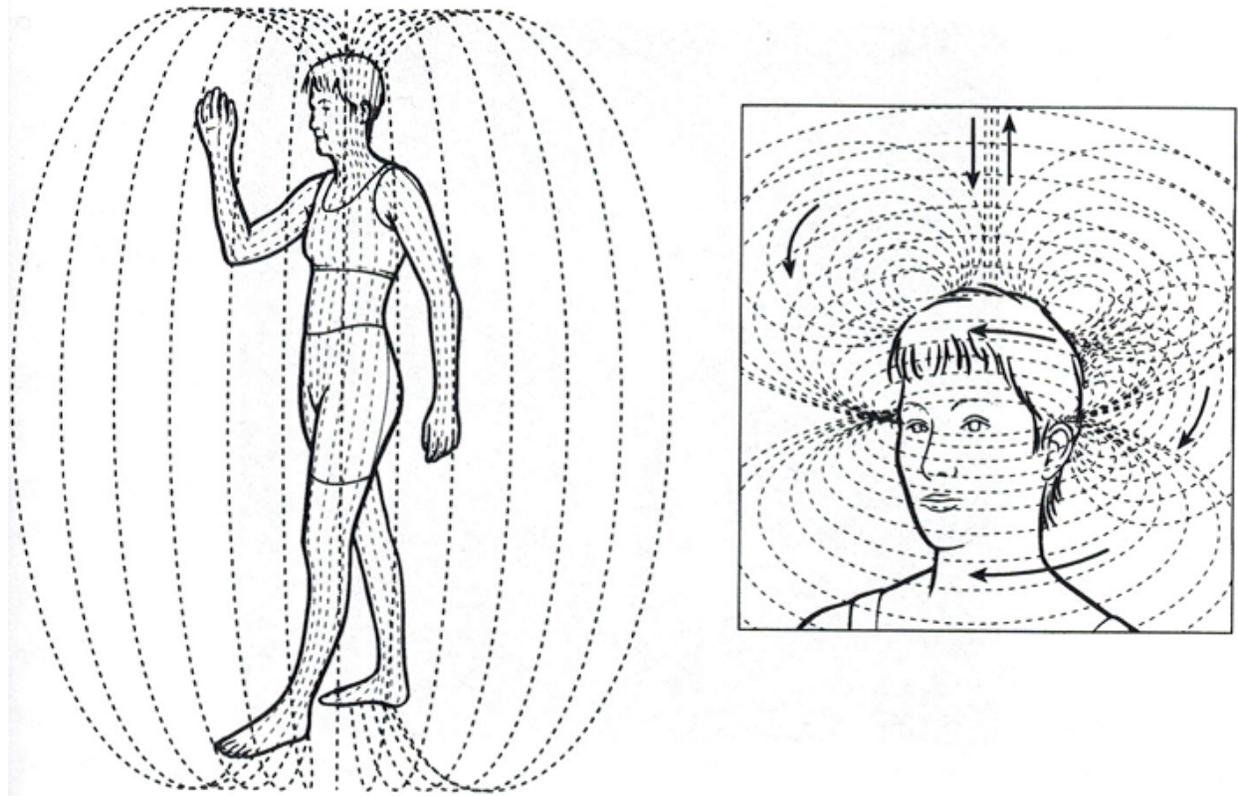


Figure 4. Human Biofield as it Extends Outside the Body

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In the 1990's Dr. John Zimmerman was able to measure a biomagnetic field coming from a healing practitioner's hands (see Figure 5) with a device called a superconducting quantum interference device (SQUID). A few years later a Japanese team measured a biomagnetic field emanating from the hands of practitioners of yoga, meditation, Qigong and similar modalities (Oschman, 2000). These electromagnetic signal pulses varied from 0.3 to 30 Hertz (cycles per second). Device-generated pulsed electromagnetic fields (PEMF) have been effective for bone stimulation, stroke rehabilitation, decreased postoperative pain, and other applications (Abo et al., 2012; Heden & Pilla, 2008; Kondo et al., 2013). Transcutaneous electrical nerve stimulation (TENS) units are a well-known example of an adjustable pulsed electromagnetic field that is used to decrease chronic pain. Although it may be difficult to imagine tiny particles that react to human thought, scientific experiments have shown this phenomenon to be true for some time now (Rae, 2005). The similarities between human-generated biomagnetic energy such as Reiki therapy and device-generated electromagnetic fields for healing seem clear. The measurement of human biofield energy demonstrates the existence of human-generated biomagnetic energy. The similarities in the behavior of quantum particles and Reiki energy require more study, however repeated physics experiments with thought-driven particles united with the measurement of human biofield energy suggests that Reiki energy may consist of quantum particles that may lead to a validated theory of Reiki therapy.

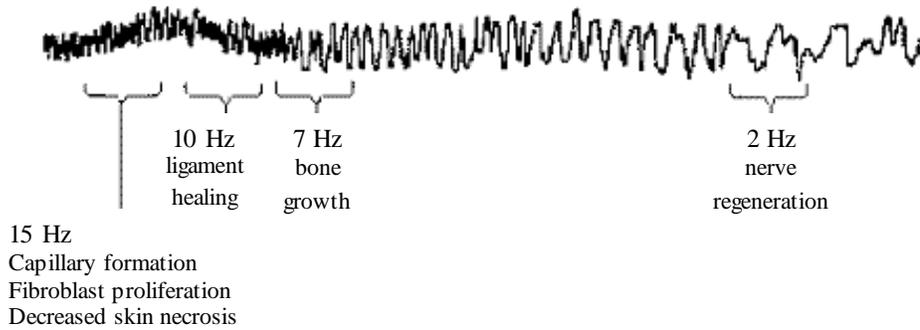


Figure 5. Signal Recorded from the Hands of a Therapeutic Touch Practitioner on the SQUID Device

Reprinted from *Energy Medicine: The Scientific Basis*, Oschman, J. L. Polarity, therapeutic touch, magnet therapy, and related methods, p. 77, Copyright Elsevier Limited (2000), with permission from Elsevier.

3.2.3 Significance

Pain is a very common symptom. Approximately 100 million Americans suffer from chronic pain (Institute of Medicine, 2011). Additionally, millions of people suffer from acute pain (pain that lasts for 6 months or less) such as people with cancer, trauma or surgical patients, and other everyday events such as a sprained ankle or a stubbed toe. Anxiety is a state that may accompany many of the conditions that cause pain such the diagnosis of a serious illness like cancer or heart disease.

Very few high-quality studies have been done exploring Reiki therapy for pain and anxiety. Despite the lack of evidence, articles are published in peer reviewed journals giving anecdotal evidence for the effectiveness of Reiki therapy citing the few studies that have been

published (Hurvitz, Leonard, Ayyangar, & Nelson, 2003; Rand, 2011). While there have been a total of four review articles published examining Reiki therapy in clinical trials (Jain & Mills, 2010; Lee, Pittler, & Ernst, 2008; vanderVaart, Gijssen, de Wildt, & Koren, 2009; Vitale, 2007), none have focused exclusively on pain and anxiety and none report effect sizes for study variables.

3.2.4 Search Strategy and Inclusion Criteria

A systematic search was conducted using PubMed, ProQuest, Cochrane, PsychInfo, CINAHL, Web of Science, Global Health, and Medline databases in addition to the Center for Reiki Research (The International Center for Reiki Training, 2012). The following keywords were used: pain, anxiety, and Reiki. The last search was run on April 4, 2012. After removing duplicates there were 49 articles: 17 review articles, 6 informational articles, 1 study that reported on the prevalence of CAM use that included Reiki, 6 qualitative studies, 1 dissertation, and 18 studies of any type, any year.

Studies that include Reiki therapy as an intervention are scarce. To present the best evidence, articles were included in the review if they (a) used Reiki therapy as one arm of the study, (b) used randomization with a control or usual care group, (c) were published in peer-reviewed journals, (d) measured either pain or anxiety, (e) published in 2000 or later, and (e) were published in English. After evaluating the 18 studies against inclusion criteria, 12 studies remained for full review (see Figure 6).

3.2.5 Method of Review and Data Extraction

Each of the 12 studies selected for full text review was carefully evaluated by both authors against the inclusion criteria. Five of the 12 did not fully meet the inclusion criteria. One article was a one-page preliminary report (Miles, 2003), a second used a convenience sample with no randomization or control (Birocco et al., 2011), a third used a semi-randomized patient preference design (Hulse, Stuart-Shor, & Russo, 2010), a fourth used a four-group design with a combination of Reiki and sham Reiki and no control (Assefi, Bogart, Goldberg, & Buchwald, 2008) and the fifth included a control group that was different from the stated design and the two experimental groups (Park, McCaffrey, Dunn, & Goodman, 2011). The remaining seven studies met the inclusion criteria for review as determined by both authors (Beard et al., 2011; Gillespie, Gillespie, & Stevens, 2007; Olson, Hanson, & Michaud, 2003; Potter, 2007; Richeson, Spross, Lutz, & Peng, 2010; Tsang, Carlson, & Olson, 2007; Vitale & O'Connor, 2006) (see Table 7).

Data were extracted from each study including: (a) sample population (disease process, gender, mean age, and race if available), (b) study design, (c) outcome measures for anxiety or pain or both and (d) statistical significance for within group and between group differences including p values, means, standard deviations, and z values for calculating Cohen's *d* statistic for effect sizes.

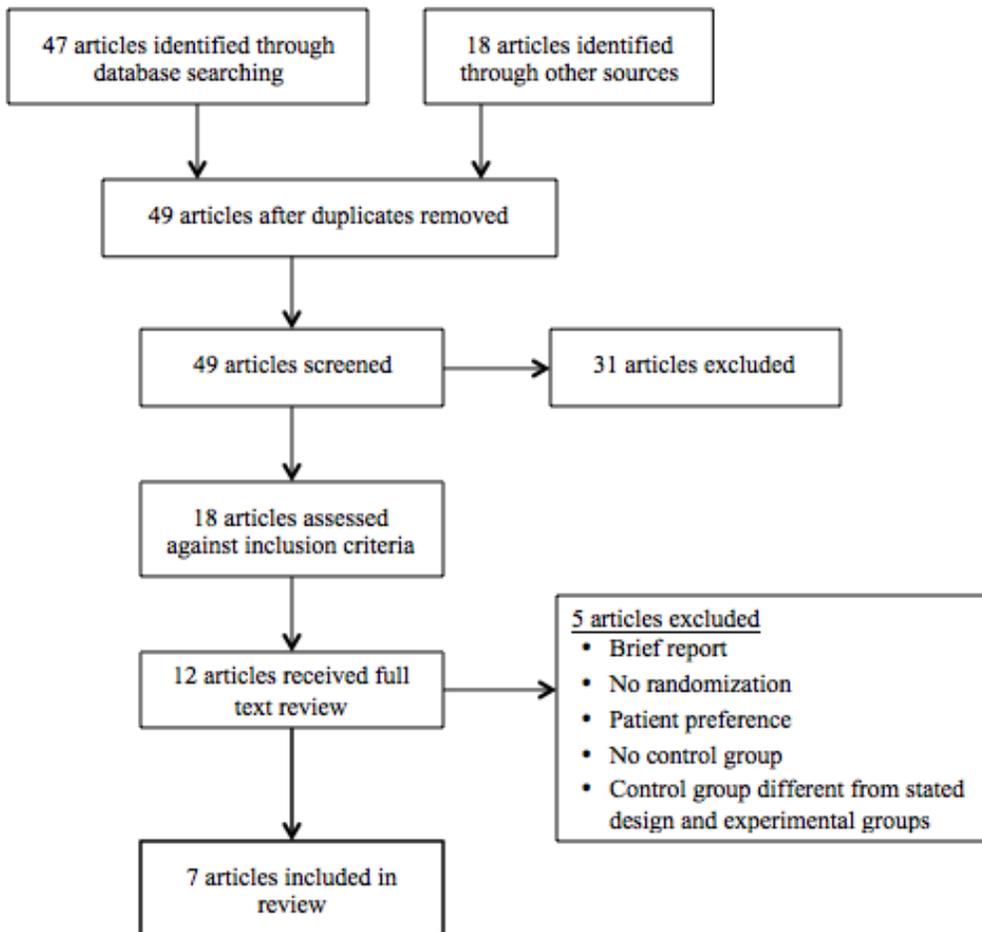


Figure 6. Reiki Article Flow Diagram

3.2.6 Findings

Sample sizes for the seven studies included in this review ranged from 16 to 160 participants (median = 24) for a total of 328 participants. There were 48% women and the mean age for the overall sample was 63 years old. Only two studies mentioned race. Beard et al. (2011) had 91% white participants but did not say how the remaining 9% of the participants identified themselves. Tsang et al. (2007) reported 75% white, 13% Asian, and 12% other participants.

The seven studies (see Table 7) included in the review examined a variety of populations: three studied cancer patients (Beard et al., 2011; Olson et al., 2003; Tsang et al., 2007), two tested Reiki therapy in a surgical setting (Potter, 2007; Vitale & O'Connor, 2006), and two looked at Reiki therapy in adults living in the community (Gillespie et al., 2007; Richeson et al., 2010). The results from each individual study may be found in Table 8.

Table 6. Summary of Reiki Studies

Authors/ Journal/Year	Purpose of Study	Outcomes Measured/ Length of Intervention	Study Design	Population/ Sample	Significant Results (Within ^{&} Between [#])	Effect Sizes: Within ^{&} Between [#]
Beard, C. Stason, W. B. Wang, Q. Manola, J. Dean-Clower, E. et al. <i>Cancer</i> , 2011	Examine the clinical effects of RRT and Reiki v. control	Anxiety <i>Reiki: twice per week for 8 weeks for 50 minutes</i>	3 group RCT • Reiki • RRT • Wait-list control	Prostate Cancer: 54 adult males, mean age 64 years (range 46-91), 91% white	↓ Anxiety for RRT (p=.02) ↓ Anxiety for Reiki (p=.10) RRT: Reiki (p=.02) RRT: Control (p=.01)	d=.55 ^{&} d=.39 ^{&} d=.57 [#] d=.62 [#]
Olson, K. Hanson, J. Michaud, M. <i>Journal of Pain and Symptom Management</i> , 2003	Determine whether Reiki + standard opioids resulted in better pain control, less analgesic use and improved QOL when compared to opioid + rest	Pain <i>Reiki treatments on days 1 and 4 of a 7 day trial for 90 minutes</i>	Randomized to either Reiki or rest group	Cancer, primarily solid tumor: 24 adults, mean age 59.5 years, 63% female	Reiki : Rest Day 1: ↓ Pain (p=.035) Day 4: ↓ Pain (p=.002)	d=.64 [#] d=.93 [#]
Tsang, K. L., Carlson, L. E., Olson, K. <i>Integrative Cancer Therapies</i> , 2007	Examine the effects of Reiki on fatigue, pain, anxiety, and overall quality of life in cancer patients who had recently completed chemotherapy treatment	Pain, Anxiety <i>Reiki tx for 5 consecutive days followed by a 1 week washout then 2 Reiki tx the following week (3 weeks total) for 45 minutes</i>	Random crossover	Cancer: 16 adults ages 33 to 84 (mean 59, SD=15.23) 81% female, 75% white, 13% Asian, 12% other with a diagnosis of colorectal (63%), breast (13%), gastric (12%), or lung (12%) cancer	Pre first Reiki session to post last Reiki session: ↓ Pain (p<.05) ↓ Anxiety (p<.005) Reiki : Rest (Day 1 → Day5) Pain Anxiety (no p values given)	d=.76 ^{&} d=.83 ^{&} d=.32 [#] d=.64 [#]
Potter, P. J.	Determine	Anxiety	Randomized	Possible breast	Reiki: HADS (Anxiety)	d=.24 ^{&}

<i>Journal of Holistic Nursing</i> , 2007	feasibility of testing Reiki for women undergoing a breast biopsy	1 Reiki tx within 7 days prior to biopsy, 1 Reiki tx within 7 days after biopsy for 50 minutes	to either Reiki or usual care	cancer: 32 women, ages 37 to 75 years	STAI Usual: HADS (Anxiety) STAI No significant differences in between group means.	d=.27& d=.24& d=.49&
Vitale, A. T., O'Connor, P. C. <i>Holist Nursing Practice</i> , 2006	Compare levels of pain and state anxiety in women after abdominal hysterectomy	Pain, Anxiety Reiki txs immediately pre-op, 24 hours and 48 hours post-op for 30 minutes	Randomized to either Reiki or usual care group	Post-hysterectomy: 22 women ages 40 to 73 years (mean=47, SD=6.5)	Reiki : Usual Care ↓ Pain at 24 hours (p=.04) ↓ Anxiety (p=.005) ↓ Pain medication ↓ Dilaudid T2 (p=.001) ↓ Dilaudid T3 (p=.007) ↓ Toradol T6 (p=.04)	d=.79# d=1.36# d=1.82# d=1.29# d=.81#
Gillespie, E. A. Gillespie, B. W. Stevens, M. J. <i>Diabetes Care</i> , 2007	Assess the effectiveness of Reiki therapy to alleviate pain and improve mobility in subjects with Type 2 diabetes and PDN	Pain 12 week intervention— 2 tx first week than once weekly for 25 minutes	3 group RCT • Reiki (93) • Sham Reiki (88) • Usual care (26)	Type 2 Diabetes 160 adults, mean age 65, 61% male	Reiki group ↓ total pain (p=.002) Sham Reiki ↓ total pain (p=.039) Usual care ↓ total pain (p=.622) No significant differences between groups for total pain.	Pre/post d=.36& d=.26& d=.17&
Richeson, M. E., Spross, J. A. Lutz, K. <i>Research in Gerontological Nursing</i> , 2010	Evaluate the effect of Reiki as an alternative and complementary approach to treating community-dwelling adults who experience pain, depression, and/or anxiety	Pain, Anxiety Reiki tx once per week for 8 weeks for 45 minutes	Randomized to either experiment or wait list control group	Community-dwelling: 20 Adults ages 57 to 76 (mean age 63.8 (SD=4.9), 60% female)	Reiki group ↓ Pain (p=.0078) ↓ Anxiety (p=.0005) Control group ↑ Pain (p=.0156) ↑ Anxiety (p=.0313) Reiki : Control Pain Anxiety	d=2.08& d=.51& d= -2.08& d= -.55& d= 4.5# d= .75#

3.2.6.1 Study Design and Comparison Groups

All studies in this review used randomization as specified in the inclusion criteria. Three studies used a two group design with the control group utilizing either usual care (Potter, 2007; Vitale & O'Connor, 2006) or wait list control (Richeson et al., 2010). Olson et al. (2003) used a rest period equal to the Reiki therapy intervention as the control group and Tsang et al. (2007) used a random crossover design. Two studies used a three group design. Beard et al. (2011) explored Reiki therapy as compared to Relaxation Response Therapy (RRT) and a wait list control while Gillespie, et al. (2007) explored Reiki and sham Reiki compared to usual care. In sham Reiki, an actor performs the same treatment sequence as the real Reiki practitioner, but with no Reiki energy.

Variables and Measures

Three of the studies examined both pain and anxiety (Richeson et al., 2010; Tsang et al., 2007; Vitale & O'Connor, 2006). Two studies considered just pain (Gillespie et al., 2007; Olson et al., 2003) and two only evaluated anxiety (Beard et al., 2011; Potter, 2007). There were a variety of validated measures used.

Anxiety.

Three studies chose the Spielberger State Anxiety Inventory (STAI) (Spielberger, Gorsch, Lushene, Vagg, & Jacobs, 1983) to measure anxiety (Beard et al., 2011; Potter, 2007; Vitale & O'Connor, 2006). The STAI scale was originally created to measure anxiety in adolescents with cancer but has been well validated in adults. Tsang et al. (2007) used the Edmonton Symptom Assessment System (ESAS) questionnaire (Chang, Hwang, & Feuerman,

Table 7. Summary of Results: Reiki therapy and control groups

Author (year)	Reiki therapy	Mean (SD)	Sham Reiki, Usual Care, Waitlist Control, or Other	Mean (SD)
Beard (2011)	N=16 Anxiety	-4,	RRT: N=16 Control: N=16	RRT: -8 Control: -1
Olson (2003)	N=11 Pain	-1.5 (Day 4)	Usual: N=13	-0.1 (Day 4)
Tsang (2007)	N=16 Crossover study Pain	Day 1 to Day 5 -1.33(1.54)	N=16 Pain	Day 1 to Day 5 -0.53(3.14)
Potter (2007)	N=17 Anxiety	T1=7.29(4.80)	N=15 Anxiety	T1=8.27(5.16)
Vitale (2006)	N=10 Pain Anxiety	24h post-surgery 3.8(2.4) At discharge 27(7.05)	N=12 Pain Anxiety	24h post-surgery 5.4(1.4) At discharge 38(9.64)
Gillespie (2007)	N=76 Pain	2.9(7.9)	Sham, N=66 Usual Care N=18	2.3(8.8) 1.8(15)
Richeson (2010)	N=12 Pain Anxiety	Pre=4.8(1.3) Post=2.2(1.2) Pre=25.2(14.4) Post=17.5(15.5)	N=8 Pain Anxiety	Pre=5.0(1.3) Post=7.6(1.2) Pre=21.2(12.9) Post=28.5(13.5)

2000) a validated nine symptom visual analog scale to measure anxiety. Potter also used the Hospital Anxiety and Depression Scale (HADS) (Zigmond & Snaith, 1983), because it recognizes anxiety in populations suffering from physical symptoms as a result of their disease. Richeson et al. (2010) used the HAM-A rating scale which exhibits high reliability and internal consistency (Cronbach's alpha = .85, r=.23, p<.05) (Diefenbach et al., 2001).

Pain.

Two studies used an 11-point Visual Analog Scale (VAS) (Olson et al., 2003; Vitale & O'Connor, 2006) to measure pain. Olson also used an unspecified "Likert" scale to measure pain. Tsang et al. also employed the ESAS questionnaire mentioned above to evaluate pain. Gillespie et al. (2007) used The McGill Pain Questionnaire (Melzack, 1975) to evaluate pain in patients with painful diabetic neuropathy. Richeson et al. utilized the faces pain scale originally developed for children but has been shown to be effective in older adults as well (A. G. S. Panel on Persistent Pain in Older Persons, 2002).

Outcomes and Effect Sizes.

All but one study included in this review achieved at least one statistically significant result on the outcome variables of interest for the Reiki therapy intervention. Effect sizes were calculated using standard equations and were measured using the Cohen's d statistic. Effect sizes for the Reiki therapy intervention ranged from small ($d=.28$) to very large (1.82).

Anxiety.

While investigating Reiki therapy and relaxation response therapy compared to wait-list control for men with prostate cancer receiving radiation therapy, Beard et al. (2011) found a within group decrease in anxiety for relaxation response therapy (RRT) with a medium effect size ($p=.02$, $d=.55$) and non-significant within group decrease in anxiety for Reiki therapy with a small effect size ($d=.39$). The between group differences of RRT compared to Reiki therapy resulted in a significant difference between RRT and Reiki therapy ($p=.02$, $d=.57$) and between RRT and control ($p=.01$, $d=.62$) both in favor of the RRT intervention. Working with cancer patients who had recently completed chemotherapy treatment, Tsang et al. (2007) found within

group differences for a decrease in anxiety ($p < .005$) and a large effect size ($d = .83$) for subjects in the Reiki therapy treatment arm when measured prior to the first Reiki therapy treatment, compared with following the last Reiki therapy treatment in a group of cancer patients on standard opioid therapy. When comparing Reiki therapy versus rest for between group differences, there was a medium effect size ($d = .64$) when calculated using means and standard deviations. Potter (2007) found a non-significant within group decrease in anxiety with a small effect size for the HADS anxiety subscale for both the Reiki therapy intervention ($d = .24$) and the usual care group ($d = .24$) and for the STAI measure for the Reiki intervention ($d = .27$) and the usual care group ($d = .49$) when exploring the use of Reiki therapy for women undergoing a breast biopsy. There were no between group differences when comparing the Reiki therapy intervention to usual care. In an investigation of women undergoing hysterectomy, Vitale et al. (2006) found a significant between group decrease in anxiety ($p = .005$) and a large effect size ($d = 1.36$) just before discharge from the hospital. Richeson et al. (2010) found a significant decrease in anxiety ($p = .0005$) and a large effect size ($d = 2.08$) within the Reiki therapy intervention and a significant *increase* in anxiety ($p = .0313$) and a large effect size ($d = -.208$) within the control group while investigating the use of Reiki therapy with community-dwelling older adults. When calculating between group differences post Reiki therapy intervention, there was a very large between group differences when comparing the Reiki therapy group to the control group ($d = -4.5$).

Pain.

A Reiki therapy intervention used with cancer patients found a significant between group decrease in pain ($p = .035$) and a medium effect size ($d = .64$) on day one of the intervention and a significant between group decrease in pain ($p = .002$) and a large effect size ($d = .93$) for opioids plus Reiki therapy when compared to opioids plus rest on day four of the intervention (Olson et

al., 2003). Cancer patients in the Tsang et al. study who had recently completed chemotherapy realized a significant decrease in pain ($p < .05$) and a medium effect size ($d = .76$) for within group measures when comparing scores from before the first Reiki treatment to after the final Reiki treatment. When comparing between group scores for Reiki therapy versus rest, the Reiki therapy group realized a small effect size ($d = .32$) when calculated using means and standard deviations (Tsang et al., 2007). When Vitale and O'Conner (2006) investigated the effect of Reiki therapy on pain in women post hysterectomy, the study found a significant between group decrease in pain at 24 hours post-surgery ($p = .04$) and a borderline large effect size ($d = .79$). Of equal interest, comparing the Reiki therapy and usual care groups, the women in the Reiki therapy intervention took less pain medication at T2 ($p = .001$, $d = 1.82$), T3 ($p = .007$, $d = 1.29$), and T6 ($p = .04$, $d = .81$) with large to very large between group effect sizes. In a study to explore the effect of Reiki and sham Reiki compared to usual care for painful diabetic neuropathy, Gillespie et al. (2007) found that Reiki and sham Reiki resulted in a within group decrease in pain ($p = .002$ and $p = .039$ respectively) and a small effect size ($d = .36$ and $d = .26$ respectively) while the usual care group had a non-significant within group decrease in pain and a very small effect size ($p = .622$, $d = .17$). There were no between group differences in total pain. Comparing a Reiki therapy intervention with a wait list control group of community dwelling older adults, there was a significant within group decrease in pain ($p = .0078$) and a large effect size ($d = 2.08$) and a significant within group increase in pain ($p = .0156$) and a large effect size ($d = -2.08$) for the wait list control group (Richeson et al., 2010). Because of the decrease in pain for the Reiki therapy group and corresponding increase in pain for the control group, the calculated effect size for the between group difference was very large ($d = 4.5$).

3.2.7 Discussion

Reiki therapy has been explored in a variety of populations including cancer patients, community dwelling adults, surgical patients and more.. The studies included in this review exhibit design flaws common to research involving complementary therapies. The most obvious difficulty is sample size. The median number of study participants was 24 (range of 16 to 160 participants). It is difficult to make generalizations to a population, even a limited one such as adults with cancer utilizing such small sample sizes. Moreover, acquiring these samples may take months to years. For example, Beard et al. took 22 months to recruit 54 subjects and Potter required 15 months to recruit 32 subjects. The length of recruitment time creates difficulties if a longitudinal design would be more appropriate. Olson et al. and another that did not meet the inclusion criteria had difficulty recruiting subjects and in fact took two years to recruit 24 adults because the subjects stated they would not participate unless they could be in the Reiki therapy group. Gillespie et al. also had to limit the control group due to high attrition.

Length of intervention may have been problematic for some study outcomes. Although Olsen et al. was able to show a significant reduction in pain and a medium effect size for the Reiki treatment group ($p=.035$, $d=.64$) on day one and significant reduction in pain and a large effect size on day four ($p=.002$, $d=.93$), the intervention consisted of only two Reiki treatments four days apart. It seems possible that if the study had lasted several weeks they may have seen the decrease in medication usage that they were looking for. Another study that may have benefitted from a longer intervention time was Gillespie et al. when they examined Reiki therapy for reduction in pain in diabetic subjects with painful diabetic neuropathy (PDN). Although this was one of the longer interventions (12 weeks total), PDN is not an easy condition to treat and

does not respond well to medications. While the intervention did achieve a statistically significant decrease in pain for the Reiki group ($p=.002$, $d=.36$), the effect sizes were not very different for the sham Reiki group ($p=.039$, $d=.26$) leading the authors to question the clinical significance. Possibly if the intervention had run 26 weeks or longer, the authors may have been able to detect a difference between the Reiki group and the sham Reiki group.

Timing of interventions can also be important to success. For example in the Reiki therapy intervention for breast biopsy, the pre-biopsy intervention was given within seven days prior to the biopsy and the post-biopsy intervention was given within seven days post biopsy. The study author admitted that the timing was for subject convenience and that an intervention “within the clinical setting might more effectively mitigate a crisis response” (Potter, 2007, p. 246). In contrast, Vitale et al. timed the Reiki therapy intervention around abdominal hysterectomy in a way that makes more sense: just prior to surgery, then 24 and 48 hours post-surgery. This timing resulted in a significant decrease in both pain and medication usage.

Most studies included in this review used a standardized protocol of timing and hand positions. However, these protocols differed significantly from study to study. Reiki treatment times varied from 25 minutes in the diabetic neuropathy study (Gillespie et al., 2007) to 90 minutes in the Reiki therapy plus opioid use in cancer patients study (Olson et al., 2003). The average treatment length was 48 minutes. All but one study used a set protocol for treatment hand positions. Richeson et al. allowed the treatments to be patient specific rather than follow a particular hand placement and timing protocol, making it difficult to compare subjects to each other much less compare between studies.

3.2.8 Suggestions for Future Research

Based on the findings of this review it may be helpful if future Reiki therapy studies consider the following design strategies. First, in order to be able to conform to scientific research standards, a three arm design which includes a Reiki intervention, a sham Reiki intervention (placebo), and a non-intervention control group seems most effective. Having a sham Reiki group allows for investigators to take into account and control for the therapeutic effect of attention and potential effect of human interaction. It has been shown that any touch therapy, even a sham intervention produces an effect on subjects as demonstrated by several of the studies in this review. Reiki interventions need to show significantly better results than the sham group in order to overcome the “placebo effect.” It is suggested that effect sizes be calculated and reported in articles so that readers may understand and compare the effect of the interventions. Second, in order to combat the reluctance of subjects to participate in complementary research, a crossover design is suggested. In this way, control subjects know that they will receive the intervention either now, or in the near future. Studies that use a crossover design seem to have fewer issues with control groups (Post-White et al., 2009; Tsang et al., 2007). Third, a standardized protocol of intervention length and hand positions seems essential. It is difficult to compare subjects who have not utilized the same treatment protocol. Fourth, researchers need to consider whether Reiki therapy is appropriate for a particular condition, and what the optimal timing of the intervention may be. For example, the timing of the Reiki treatments used in the abdominal hysterectomy study (Vitale & O'Connor, 2006) consisting of immediately before surgery then 24 and 48 hours after surgery was well considered and makes sense.

Another possible avenue of research would be to teach first degree Reiki to subjects and have them practice Reiki therapy as a self-healing strategy. This could be combined with weekly or periodic Reiki treatments by a Reiki therapy professional. The reasons for this suggestion are two-fold. First, a preliminary report using this method with an HIV population showed a decrease in pain and anxiety using self-Reiki (Miles, 2003). Second, when considering the study using Reiki versus RRT for men with prostate cancer, the RRT arm showed a larger decrease in anxiety (Beard et al., 2011). This may be because the men using RRT were encouraged to practice daily while the Reiki therapy intervention was only twice per week. It would be interesting to discover whether daily Reiki self-treatment would produce a larger decrease in pain or anxiety than a once or twice weekly session given by a Reiki therapy professional.

3.2.9 Limitations

Every effort was made to limit bias in study selection. Inclusion criteria were tight and strictly adhered to. Small sample sizes may contribute to some inflation of effect sizes. Only studies that used a reliable randomization scheme were included. There was no requirement on study use of validated measures although most studies included in this review did use validated measures. Only studies published in English were included and no gray literature such as dissertations or conference abstracts were included. Publication bias may of course account for some inflation of results.

3.2.10 Conclusion

There are very few high quality studies that explore the use of Reiki therapy for pain or anxiety. Because the number of studies is small, the interventions are dissimilar from each other, and the populations presented are so different, it is difficult to make generalizations or recommendations from these studies. Some of the dissimilarities included length of individual treatments which ranged from 30 to 90 minutes and populations varied from cancer to surgical to community dwelling adults. Design issues included small sample sizes, the timing of interventions in relation to the complaint, and the length of the intervention in relation to the issue being addressed such as painful diabetic neuropathy, which is known to be difficult to treat. While it is often difficult to recruit subjects into non-drug related studies, more than one study specifically mentioned the difficulty of recruiting or keeping subjects in the non-Reiki control groups.

On the other hand, the majority of studies in this review did achieve statistical significance or near significance on the variable of interest; either pain or anxiety or both. Effect size calculations were performed using Cohen's *d*, which allows comparison of studies in a standardized way. Effect sizes for most of the studies in this review went from small to very large. Based on statistical significance, the strength of the effect sizes (see Table 7), and public interest in Reiki therapy as a non-invasive even comforting intervention, there is enough evidence to suggest continued research using Reiki therapy. Suggestions for study design and standardization of treatment protocol were proposed in order to increase the potential for positive outcomes in future research.

3.2.10.1 Implications for Nursing Education, Practice, and Research

Reiki therapy is a non-invasive, often comforting and relaxing intervention that is within nursing scope of practice in most states. Nurses may easily learn Reiki therapy and use this intervention with patients in day-to-day practice (Whelan & Wishnia, 2003). Additionally, Reiki therapy may be a good self-care tool as suggested by more than one study (Cuneo et al., 2011; Diaz-Rodriguez et al., 2011; Vitale, 2009). Based on this review, there is enough evidence to continue researching Reiki therapy as an intervention for pain and anxiety. Certainly more research is required in order to definitively recommend Reiki therapy as an intervention for decreased pain or anxiety.

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3.3 MANUSCRIPT #3: THE ASSESSMENT AND NON-PHARMACOLOGIC TREATMENT OF PROCEDURAL PAIN FROM INFANCY TO SCHOOL AGE THROUGH A DEVELOPMENTAL LENS: A SYNTHESIS OF EVIDENCE WITH RECOMMENDATIONS

3.3.1 Abstract

Introduction: The 2011 IOM report stated that pain management in children is often lacking especially during routine medical procedures. The purpose of this review is to bring a developmental lens to the challenges in assessment and non-pharmacologic treatment of pain in young children.

Method: A synthesis of the findings from an electronic search of PubMed and University of Pittsburgh library using the keywords pain, assessment, treatment, alternative, complementary, integrative, infant, toddler, preschool, young, pediatric, and child was completed. A targeted search identified additional sources for best evidence.

Results: Assessment of developmental cues is essential. For example, crying, facial expression, and body posture are behaviors in infancy that indicate pain: However in toddlers these same behaviors are not necessarily indicative of pain. Preschoolers need observation scales in combination with self-report while for older children self-report is the gold standard. Pain

management in infants includes swaddling and sucking. However for toddlers, preschoolers and older children, increasingly sophisticated distraction techniques such as easily implemented non-pharmacologic pain management strategies include reading stories, watching cartoons, or listening to music.

Discussion: A developmental approach to assessing and treating pain is critical. Swaddling, picture books, or blowing bubbles are easy and effective when used at the appropriate developmental stage and relieve both physical and emotional pain. Untreated pain in infants and young children may lead to increased pain perception and chronic pain in adolescents and adults. Continued research in the non-pharmacological treatment of pain is an important part of the national agenda.

3.3.2 Introduction

Despite decades of research in the assessment and treatment of pain in pediatrics, infants and young children still suffer unnecessary pain. Moreover, despite intense research and education over the last decade, the assessment and treatment of pain in infants and young children remain challenging with potential long-term consequences (Fitzgerald & Walker, 2009; van Dijk, Peters, Bouwmeester, & Tibboel, 2002). Pain experiences in infancy and childhood may result in long-term changes in physiological and behavioral responses to pain (Anand & International Evidence-Based Group for Neonatal, 2001; Institute of Medicine, 2011). In fact, children who suffered traumatic pain were 1.5 times more likely to suffer chronic pain in adulthood while children who experienced frequent headaches were 2.2 times more likely to experience frequent headaches in adulthood (Fearon & Hotopf, 2001; Jones, Power, & Macfarlane, 2009).

Unrelieved pain during infancy and childhood leads to a hypersensitivity to pain through a “rewiring” of the peripheral as well as central nervous system leading to life-long changes in pain perception (Fitzgerald & Walker, 2009; Woolf, 2007). One study of male infants circumcised within two days of birth indicated that they had higher pain scores when receiving two-month immunizations than male babies who had not been circumcised (Stevens, 2007). Relatedly, failure to control pain in infants with sickle cell disease has lifelong implications including poor coping strategies (Benjamin, 2008). Chronic pain in adults and children is a national and international challenge and results in suffering and increase healthcare costs. By improving the assessment and treatment of pain in early childhood, we may be able to address this challenge.

For children and infants, the pain experience often occurs during routine medical procedures such as heel sticks and vaccinations or during more severe instances of post-operative pain or pain from traumatic injuries. According to the International Association for the Study of Pain (IASP), the definition of pain is “an unpleasant sensory and emotional experience associated with actual or potential tissue damage...” (2012, p. para. 5). IASP explains that the lack of ability to communicate using language does not mean that a child is not experiencing pain. In order to end unnecessary pain in childhood, and its long-term consequences, we must interpret infant and child communication including verbalizations such as crying, body movements such as kicking, and facial expressions such as a furrowed brow with our knowledge of child development.

The Institute of Medicine (IOM) states that pain is a national challenge and pain management in children is often lacking even in pediatric emergency departments (Institute of Medicine, 2011). Despite the fact that there are well-validated tools available for the assessment

of children's pain, more than half of hospitalized children experience severe unrelieved pain (Kortessluoma, Nikkonen, & Serlo, 2008; Twycross & Collis, 2012). This implies that either the tools are not being used to assess the pain or the pain is not being adequately treated. Hospitals in the United States are mandated to assess pain on a routine basis and hospital policies reflect that mandate. Studies conducted in Europe show that nurses may not be consistently assessing pain, may not always believe children when they report pain, and may not treat pain adequately (Kortessluoma et al., 2008; Twycross & Collis, 2012). Although we did not find a similar study from the United States, clinical experience of pain management specialists and the IOM report demonstrate that pediatric nurses in the United States have many of the same issues.

Similar issues also arise in the treatment of pain. A study in Canada examined whether pain was addressed during routine childhood vaccinations and found that although both pharmacological and non-pharmacological interventions are available and easy to use, these interventions were not done mainly due to lack of knowledge (Taddio et al., 2009). Non-pharmacological interventions such as music, hypnosis, distraction, and massage are often successful in decreasing pain during procedures such as venipuncture and lumbar puncture as well as general pain in pre-adolescent children (Nguyen, Nilsson, Hellstrom, & Bengtson, 2010; Post-White et al., 2009; Smith, Barabasz, & Barabasz, 1996). Simple techniques are very helpful for children during medical procedures but healthcare providers are often not introduced to these techniques during their formal education.

Factors that contribute to the difficulty in assessing and treating pain include a variety of dynamics from the child, their parents, and the health care providers. A child's physical, emotional, and cognitive development modifies their response to pain. Other aspects include the child's fear, anxiety, anger, lack of control or choice, underlying illness causing the pain,

situational factors, and previous experiences with pain (McGrath & Brown, 2005). Parent and staff response to the child's fear, anxiety, or anger can also alter the child's response to pain (McGrath & Brown, 2005). Self-report remains the gold standard of assessing pain in adults, however infants, toddlers, preschool children, and non-verbal children are unable to report pain or are unable to do so reliably (Hunter, McDowell, Hennessy, & Cassey, 2000; von Baeyer, Forsyth, Stanford, Watson, & Chambers, 2009). Particularly in infants, proxy report in the form of parent report or healthcare provider observation are the common available sources of pain assessment (Buttner & Finke, 2000; Hartrick & Kovan, 2002; Pillai Riddell & Racine, 2009; Stevens, 2007). Given the large number of signs and symptoms presented by children related to their pain experience, the purpose of this article is to bring a developmental lens to the challenges of assessing and treating pain in young children.

3.3.3 Methods

A synthesis of the findings from an electronic search of PubMed and University of Pittsburgh general non-medical library electronic resources using the keywords pain, assessment, treatment, alternative, complementary, integrative, infant, toddler, preschool, young, pediatric, and child in combination with a targeted search to identify additional sources for best evidence was completed. After removing duplicates, the initial search resulted in 118 articles including 92 research studies, 5 informational articles, and 21 review articles. Articles that addressed the main purpose of this topic were used in this synthesis. Articles were excluded if they did not directly relate to the specific age groups of this synthesis (infant, toddler, preschooler, or early elementary schooler), or were not non-pharmacologic interventions. Additional supporting

sources included those related to developmental issues, assessment tool validation, and position statements from experts and organizations such as the World Health Organization and the International Association for the Study of Pain (see Figure 7). The original search provided the direction of the article and main evidence for the synthesis. The first author (ST) conducted the initial search; all authors informally evaluated the studies and came to agreement about their inclusion, and contributed to the data synthesis. From the original search, 18 articles were used

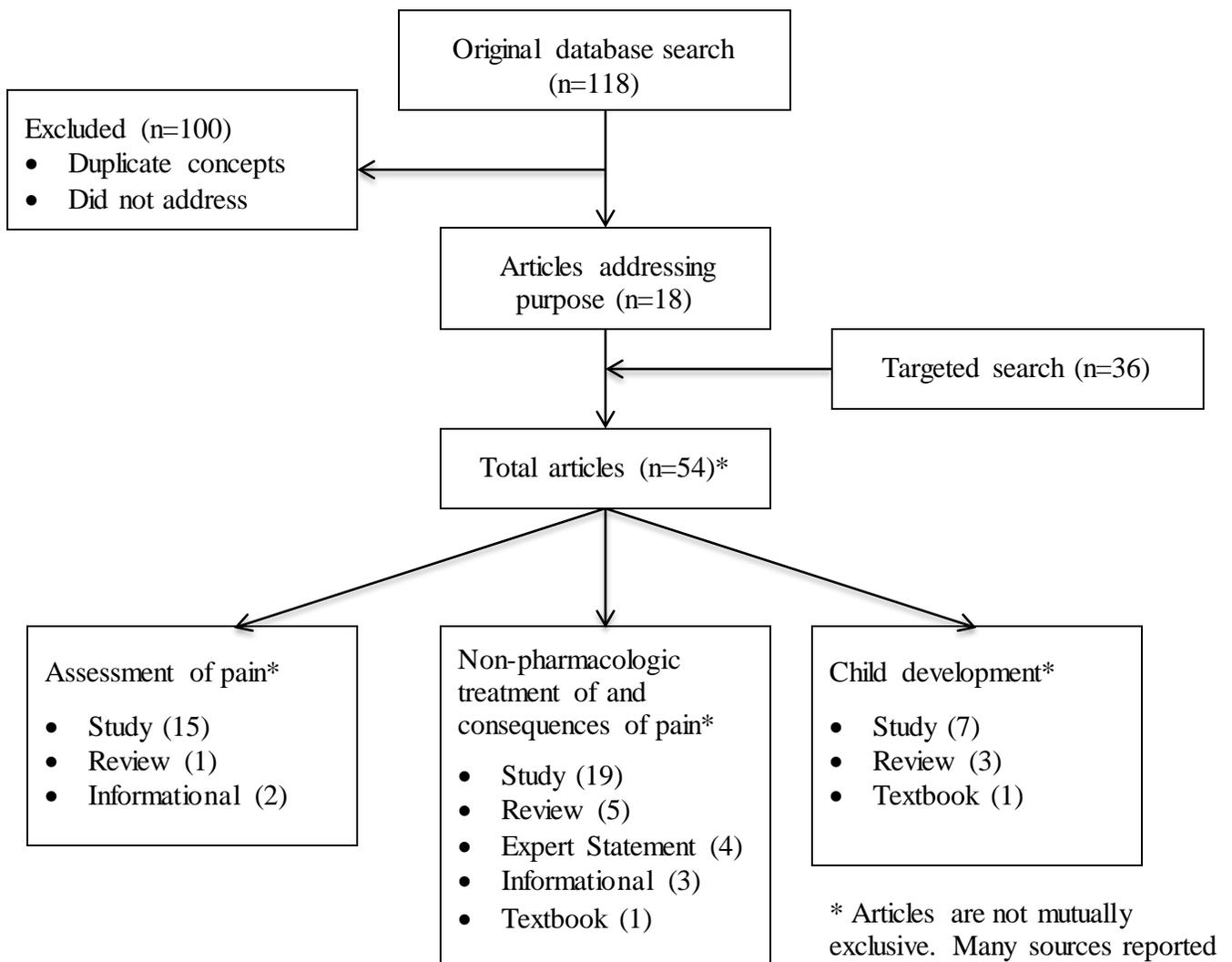


Figure 7. Pain in Young Children Article Flow Diagram

including 12 research studies, 5 reviews, and 1 informational survey. In addition, 36 research studies and review articles were found through a targeted search. In total, in-depth review of 154 articles was conducted.

3.3.4 Infants

3.3.4.1 Pain Assessment: Considering the Role of Attachment

There are a variety of pain tools available for the assessment of pain in infants. These tools rely mainly on observer report and consider a variety of infant behaviors including facial expression, cry, movement, tone, body posture, and consolability (Buttner & Finke, 2000; van Dijk et al., 2002). Some assessment tools also take into account physiologic signs such as respiratory and heart rate, oxygenation, or blood pressure (van Dijk et al., 2002). In an analysis of the most specific and reliable behaviors used by health care providers for the assessment of pain in infants, Buttner and Finke (2000) found that crying, facial expression, and body posture were the most sensitive cues to identifying pain.

The CRIES observational assessment tool is often used by hospitals during the neonatal period. This tool assesses the following attributes of the infant: Cry described as none, crying but consolable, high-pitched and inconsolable, Requires oxygen to maintain a saturation above 95%, Increased vital signs, facial Expression described as no grimace, grimace, or grimace and grunting, and Sleepless described as continuously asleep, frequently awake, constantly awake (Krechel & Bildner, 1995). An example of a popular observational assessment tool used by many hospitals for older infants is the FLACC (Face, Legs, Activity, Cry, and Consolability) measurement tool (Merkel, Voepel-Lewis, & Malviya, 2002). For both measures, each category

is scored and then totaled and compared to established criteria such as the two-step approach recommended by World Health Organization (2012) for mild, moderate or severe pain.

Although both of these measures provide useful and observable information, neither takes into account the child's attachment with an important adult in their lives the most salient developmental process in infancy (hereafter referred to as the parent although the adult may not be the biological parent). Infant reaction to painful stimuli is a bidirectional process between parent and infant (Pillai Riddell & Racine, 2009). Specifically, a parent who is sensitive to the infant's pain cues will be more likely to provide soothing behaviors such as rocking, touching, or swaddling, to calm the infant more quickly (Jahromi, Putnam, & Stifter, 2004; Schechter et al., 2007). These parental soothing behaviors in turn result in the infant being more attentive to the parent, which strengthens the parent-child attachment. Understanding the degree of parent-child attachment may not change the amount of pain the child is experiencing, but it will provide important information for determining how to proceed with treatment. For example, if a child is experiencing pain but has a close attachment with a parent, then the child will likely receive relief from comforting by the parent, and may not need the same treatment as a child with the same amount of pain but no parent support.

3.3.4.2 Pain Treatment: Attachment, Swaddling, & the Sucking Response

Several non-pharmacologic methods have been shown to be effective in reducing pain in infants undergoing painful procedures. These methods may be effective in part because of their responsiveness to the developmental characteristics of infancy. For example, building on the infant's need for attachment, Kangaroo Care (skin to skin contact with a parent) for 30 minutes prior to and during the painful procedure has been shown to decrease infant pain and distress

(Stevens, 2007). In addition, studies on swaddling, which mimic the feeling of being held, suggest that infants' vital signs recover more quickly when swaddled during a painful procedure (Fernandes, Campbell-Yeo, & Johnston, 2011; Spence et al., 2009). Other treatment methods capitalize on infants' natural sucking response. Offering infants pacifiers, both with and without sucrose, and breastfeeding, have been shown to decrease pain during painful procedures including vaccinations and heel lancing (Marin Gabriel et al., 2013; Stevens, Yamada, & Ohlsson, 2010). A Cochrane review found that breastfeeding infants during painful procedures resulted in statistically lower heart rates and decreased total crying time when compared to swaddling, holding, and pacifier interventions (Shah, Herbozo, Aliwalas, & Shah, 2012). Bembich et al. (2013) used functional MRI to evaluate brain activity in infants during painful procedures using both sucrose solutions and breastfeeding: Breastfeeding stimulated cortical activation leading the authors to posit that breastfeeding is a multisensory experience leading to decreased pain perception.

Although these developmentally-informed non-pharmacologic pain treatment strategies show promise individually, recent research suggests that a combination of techniques such as breastfeeding, pacifiers, swaddling, and rocking may be more effective than one technique used alone (Harrington et al., 2012). As evidenced in this research on infancy, taking advantage of developmental characteristics may be an effective approach to decreasing the pain and suffering attached to common medical procedures.

3.3.5 Toddlers

3.3.5.1 Pain Assessment: Beyond Physiology

The assessment of pain in toddlers presents similar issues as infants. Toddlers are venturing toward autonomy, but still look to their parents for security in new situations and when things are frightening or painful. Toddlers cannot conceptualize pain in terms of location or intensity. Most hospitals and providers use the same tools to measure pain in toddlers as they do in infants (e.g., FLACC mentioned above). Other pain scales used with toddlers includes **Children's and Infants' Postoperative Pain Scale (CHIPPS)** and **Children's Hospital of Eastern Ontario Pain Scale (CHEOPS)**. The CHIPPS scale assesses crying (none, moaning, screaming), facial expression (relaxed, wry mouth, grimacing), posture of the trunk (neutral, variable, rear up), posture of the legs (neutral, kicking, tightened), and motor restlessness (none, moderate, restless). The CHEOPS scale tested on children ages one to five is more complex: This scale assesses cry (no cry, moaning, crying), facial expression (smiling, composed, grimace), child verbalizations (positive, none, complaints other than pain, pain complaints, both pain and non-pain complaints), torso (neutral, shifting, tense), touch (not touching, reach, touch, grab, restrained), legs (neutral, squirming kicking, drawn up tensed, standing, restrained). Although some of these such as FLACC are still useful, research suggests that those that have a physical measure such as heart rate are not effective for this developmental stage. For example, Buttner and Finke (2000) found that for toddlers, physiological indicators such as heart rate, respiratory rate, and blood pressure were not good indicators for pain. Instead, observational assessments such as those used in FLACC or CHIPPS were both specific and sensitive measures of pain in toddlers. In a prospective study involving 150 children and four observers, both FLACC and

CHIPPS were found to be homogeneous, have good face and construct validity, sensitivity, and specificity to pain whereas the psychometric properties of CHEOPS was not as consistent because the category “touch” has a low score for reliability and internal validity (Bringuer et al., 2009). This suggests that behavioral indicators may need more careful consideration. Stressful situations may result in variable pain scores depending on parental attachment, parental stress, experience level of the observer, and temperament of the child (Frank, Blount, Smith, Manimala, & Martin, 1995; Hartrick & Kovan, 2002; Schechter et al., 2007).

3.3.5.2 Pain Treatment: The Emergence of Cognitive Skills

Toddlerhood can be a demanding age group for parents and nurses who are attempting to soothe these young children during and after painful procedures. This is in part because their cognitive abilities are still emerging and, as such, non-painful situations such as taking a temperature may seem just as distressing as receiving an injection. Moreover, at this stage parental empathetic attention may cause the toddler to react in an especially distressed way (McMurtry, Chambers, McGrath, & Asp, 2010).

One positive outcome of toddlers’ cognitive advances is that distraction is now more effective than before, and is more effective than common techniques such as parental empathetic attention (Schechter et al., 2007). Thus, treating toddler pain can be easier than in infancy as toddlers are increasingly inclined to take their behavioral cues from parents and other adults. Specifically, techniques such as playing peek-a-boo, blowing bubbles, or looking at books are easily implemented distractions for toddlers when parents or other adults join in the game (Jay, Elliott, Fitzgibbons, Woody, & Siegel, 1995; Manne et al., 1990).

3.3.6 Preschoolers

3.3.6.1 Pain Assessment: Emerging Self-Awareness and Language Skills

Beginning in preschool, children are developing the ability to use self-report tools such as a the Wong-Baker FACES pain scale (see Figure 8) with varying degrees of precision (Hunter et al., 2000; von Baeyer et al., 2009). Children in this age group often lack the ability to describe their pain although often they are at the very least able to point to the area that hurts (von Baeyer et al., 2009). In a study of healthy children ages three to five years old, von Bayer et al. found that three year old children show a response bias by choosing either the high or low end of the scale consistently and are not always able to put a faces-type of pain scale in the correct order, from low to high pain level. By the age of five, however, the children had developed a higher level of self-awareness and language that translated into more nuanced and useful responses (von Baeyer et al., 2009). Based on this study, von Bayer et al. recommend using a proxy pain assessment, such as the FLACC scale mentioned above, *in conjunction* with self-report for children younger than five years of age.

Because preschoolers are just beginning to development sufficient self-awareness and language skills to effectively use self-report assessments, observational pain assessment tools are still used for this age group in situations such as trauma or post-surgically. Hesselgard, Larsson, Romner, Stromblad, and Reinstrup (2007) felt that most observational scales were too complicated for fast and accurate pain measurement, especially in the post-surgical setting. Thus the Behavioral Observational Pain Scale (BOPS) was created to be a fast and accurate observational measure of pain for children ages one to seven, assessing facial expression, verbalization, and body position separately on a scale of zero to two for a total possible pain

score of zero to six (Hesselgard et al., 2007). In psychometric testing, the scale achieved a high inter-rater reliability (0.93), a high correlation with the CHEOPS pain scale ($r=0.87$), and a high construct validity and sensitivity to measuring pain and pain relief with preschool children (Hesselgard et al., 2007). When testing the FLACC pain scale in post-operative children, Malviya, Voepel-Lewis, Burke, Merkel, and Tait (2006) found a high intra-class correlation coefficient (ICC) for total pain scores ($ICC=0.90$). In sum, observational pain assessment such as the BOPS and FLACC may be valid and useful at this stage, but self-report may also be effective as self-awareness and language skills emerge.



Figure 8. Wong-Baker FACES Pain Scale.

3.3.6.2 Pain Treatment: Increases in Cognition and the Complexity of Distractions

Like toddlerhood, the use of distraction techniques is a way to help preschoolers decrease the perception of pain and cope with painful procedures (Weiss, Dahlquist, & Wohlheiter, 2011). One example of the effectiveness of distraction is seen in a study with 120 healthy three to five year old children who kept their non-dominant hands in a cooler filled with water maintained at 50°F and experienced either an active or passive distraction (Weiss et al., 2011). Interactive distraction consisted of playing a video game with a joystick. Passive distraction involved

watching the game output without actually playing it. Results indicated that both passive and interactive distraction conditions worked equally well to increase pain tolerance in the experimental groups when compared to the control group (Weiss et al., 2011). In another study on distraction, Yoo, Kim, Hur, and Kim (2011) used a three-minute animated cartoon intervention shown on a laptop computer for three to five year olds during a blood draw procedure. In this quasi-experimental intervention, (Yoo et al., 2011) found that when comparing the intervention group with the control group, the intervention group had significantly lower cortisol and glucose levels indicating lower stress levels, and a lower self-reported pain score. These results suggest that distractions may be effective at this stage, although the form of distractions is notably more complex than in toddlerhood (peek-a-boo, bubble blowing, etc.). Since preschoolers are now mastering increasingly complex cognitive skills such as using symbols, manipulating whole numbers, and engaging in more elaborate pretend play scenarios; it is understandable that their need for more complex distractions increases as well.

It is also important to note that the timing of the distraction is an important consideration. In contrast to the above interventions, Dixey, Seiler, Woodie, Grantham, and Carmon (2008) studied the child's response after a procedure using stickers, which are sometimes given to children as a reward following a procedure. They found that giving a child a cartoon sticker following a finger stick blood test procedure did not decrease child self-report of pain when compared to children who did not receive a sticker. This suggests that interventions *during* a procedure work better to decrease pain than those interventions completed after a procedure.

3.3.7 Early Elementary Schoolers

3.3.7.1 Pain Assessment: Burst in Vocabulary Development Aids Self-Report

By the time a typically developing child reaches kindergarten, they are not only able to report their pain but also point to the painful area and describe their pain using descriptive terms such as stabbing or burning, (Hicks, von Baeyer, Spafford, van Korlaar, & Goodenough, 2001). Specifically, a substantial burst in vocabulary at this stage increases early elementary schoolers' ability to express themselves and communicate nuanced aspects of pain. The FACES Pain Scale has been validated over time and found highly correlated with a visual analog scale (VAS) for this age group (Garra et al., 2010; Hicks et al., 2001). The FACES Pain Scale or a visual numerical scale is appropriate for assessing pain in this age group. In addition to pointing to the face associated with their pain level, early elementary schoolers may be able to describe their pain to a nurse with more nuance and detail.

Simultaneously, cultural and social norms have been observed by the child and reinforced by the parents and the community. The end result becomes the child's ability to control their expression making proxy pain report difficult and self-report of pain the only reliable measure (Chen & French, 2008; Huguet, Stinson, & McGrath, 2010). Western societies, for example, often value autonomy and individual decision-making relatively more than self-regulation and control (MacCoby & Martin, 1983). On the other hand, for cultures that value group orientation and group harmony (e.g., many East Asian and Latin American families), self-control is more highly valued and lack of self-regulation may be considered a significant problem (Zhou, Eisenberg, Wang, & Reiser, 2004). As a result, it may be easier to assess pain cues of children from Western cultures, because they show their pain relatively more freely without being trained

to enact as much restraint as their peers. Understanding cultural norms may increase nurse's attunement to variation in self-report responses and make this a more valid approach to pain assessment.

3.3.7.2 Pain Treatment: Reading Relational Cues

As in earlier stages, studies have shown that distractions provided by caregivers, not verbal reassurance, can be useful for treating pain in early elementary schoolers, but their effectiveness is dependent on the type of relational cues the child gets from the adult. For example, in one study by Frank et al. (1995), 77 children receiving routine vaccinations were examined and researchers found that children's coping behaviors were accounted for mainly as a result of parents and staff promoting coping behavior. Furthermore, parental distress-promoting behaviors, such as *punishment, criticism, empathic comments, apologies, and reassurance* were significant predictors of child distress. Children at this stage are often quite skilled at observing and interpreting adult behavior, and these cues influence their experience of pain (Blount et al., 1989). This is exemplified in McMurtry et al. (2010) study examining parental facial expression and tone of voice and found that children rated parents as more fearful when giving reassurances in general but particularly when either fearful facial expression or falling tone of voice accompanied the words of reassurance. These children were picking up nuances in relational cues.

Distractions that are perceived as more authentically calm and positive, however, convey to children that it is acceptable to lower their reaction to the pain. This type of distraction technique may include talking to the child about something other than the procedure or the child's illness. Furthermore, when children perceived a happy expression and a rising tone of

voice as parental happiness, they believed that the parent was neither fearful nor distressed (McMurtry et al., 2010). In sum, children's heightened ability to read the intentions behind adult cues during distractions make it increasingly important for adults to manage their own concerns and express genuine calmness.

3.3.8 Discussion

Pain assessment and treatment in young children presents special challenges to healthcare providers and parents. Based on current research, pain assessment is not an exact science in any age group. While health care providers understand that self-report is the gold standard for older children, adolescents, and adults; toddlers and preschoolers and even early elementary schoolers benefit from the addition of observational assessment tools such as FLACC, CHIPPS, CHEOPS, or BOPS depending on the situation (Bringuier et al., 2009; Frank et al., 1995; Hartrick & Kovan, 2002; Malviya et al., 2006; von Baeyer et al., 2009). Full term infants express their pain through cry, facial expression, and body movements and are not influenced by culture or social norms. Physiological signs may be reasonable indicators of pain in infancy when combined with observation of cry, facial expression and body movements. However, even at this age, pain expression is a bidirectional process between infant and parent or caregiver (Pillai Riddell & Racine, 2009). Assessment and treatment of pain during infancy should include the important influence of parents and their role in the child's pain management. Sensitive caregivers who have well-attached infants are better able and more likely to provide appropriate soothing behaviors allowing infants to cope with stressful or painful situations (Jahromi et al., 2004; Schechter et al., 2007). Toddlers continue to rely on their parents and other important adults, and considering this

while treating pain may mean consciously incorporating adults for distraction and connection. Suggesting appropriate distractions for caregivers to employ during painful procedures such as playing peek-a-boo or blowing bubbles not only helps the child cope but gives the caregiver something positive to help their child and avoids empathetic behaviors such as parental apology or exaggerated reassurance (Jay et al., 1995; Schechter et al., 2007). Additionally, toddlers have a growing sense of self yet still emerging cognitive abilities, thus rendering temperature taking as upsetting as receiving a vaccination. Because of this quandary, physiological signs are not a good indicator of pain in this age group. Preschoolers are able to begin reliably telling practitioners that they have pain. However some observation is still necessary as this age group may still be developing the language skills needed to express nuances especially regarding moderate pain levels. Allowing preschoolers to self-report pain will give them practice in using these tools although their ratings may not always reflect the child's perceived pain; for this reason using an observational tool *in addition to* self report will yield a more reliable pain report (Hunter et al., 2000; von Baeyer et al., 2009). It is important for young children through elementary school to use a visual scale such as either a FACES-type of pain scale or other visual scale: Visual tools are helpful for young children who may not be able to visualize numbers and rate their pain accordingly (Garra et al., 2010; Hicks et al., 2001). By school age, self-report is the most reliable method of pain assessment for typically developing children. School-age children have learned to self-regulate not only their actions but also their facial expressions based on cultural norms. Therefore, health care providers *cannot* use only observation to determine a child's pain level validly or reliably.

Poor assessments and under treatment of infant and child pain remains a challenge for health care providers and caregivers (Kortessluoma et al., 2008; Twycross & Collis, 2012). The

biggest asset in the assessment and treatment of pain in young children is parents: Children who have a relationship with parents or caregivers may be much more amenable to being assessed and are able to benefit from non-pharmacologic treatments. The use of non-pharmacological methods for procedures such as heel lancing, vaccinations, and even more painful procedures such as lumbar punctures have demonstrated effectiveness in decreasing infant and child pain and increasing coping (Harrington et al., 2012; Marin Gabriel et al., 2013; Smith et al., 1996; Taddio et al., 2009; Yoo et al., 2011). The consideration of developmental stage for the selection of assessment tools and non-pharmacologic treatment of pain will decrease children's suffering during painful procedures. Educational awareness coupled with institutional changes resulting in system-wide cultural transformations could lead to a significant reduction in childhood suffering from pain.

3.3.9 Limitations

This narrative was not meant to be an exhaustive review of the literature. While every effort was made to include only well-designed studies and reviews, no formal rating of the quality of the studies or study design was carried out. While this review considered peer-reviewed studies and textbook sources, we did not consider grey literature, which may have given us additional, updated information. We only considered sources published in English. This exclusion may have eliminated a rich source of child development studies and non-pharmacologic interventions. However, cultural norms including child self-regulation can vary significantly and would deserve separate treatment beyond the scope of this synthesis. Use of cultural awareness when using interventions mentioned in this synthesis is important.

3.3.10 Recommendations for Health Care Providers

Use of an evidence-based approach is the key recommendation for practitioners. Research has created reliable and valid measurement tools for assessing pain in infants and young children. Practitioners and the institutions they work in must make it a priority to choose an appropriate tool for each age group, educate practitioners in its use, and learn to assess according to evidence and institutional policy. Studies have shown that when measurement tools are used as intended within institutional guidelines, infant and child pain and suffering can be well managed. Commitment to pain management is crucial and an institutional culture shift to the regular assessment, documentation, and management of pain must happen. With the growing number of studies showing solid evidence for both assessment and treatment of pain at each child developmental level, practitioners need an evidence-based approach and institutional commitment to make the practice changes necessary to treat children's pain.

3.3.11 Recommendations for Researchers

A heartening number of studies have been performed in relation to the assessment and treatment of infant and child pain management strategies. A plethora of studies have examined various assessment tools for each age group. Future efforts to develop infant pain assessments may consider including observations of the strength of the parent-child attachment, or the apparent sensitivity of the parent to the infant as a way to ensure a more contextualized, and ecologically valid approach (Olds, 2008). One possible direction for researchers is to study nurses' and other health care providers during pain assessment to identify barriers in using the assessment as it was

intended. Moreover, it is essential to educate nurses regarding developmentally informed pain management both pharmacologic and especially non-pharmacologic. Simple non-pharmacologic methods are unknown to many healthcare providers thus their use is typically limited.

3.3.12 Recommendations for Policy-Makers

Recommendations for policy-makers are clear: (a) support research exploring the best treatment options for each developmental level, including non-pharmacological options, (b) support research investigating healthcare providers skill when implementing pain assessment and treatment practices, (c) mandate education programs for providers on the best practice for both assessment and treatment of pain, and (d) mandate the use of evidence-based practices in the assessment and treatment of pain in infants and children. Research has shown that untreated and undertreated pain in infancy leads to increased pain perception in children and an increased risk of chronic pain in adulthood. From a monetary perspective, chronic pain conditions are expensive not only in healthcare dollars spent in treatment but also in lost work productivity. In adolescents alone, chronic pain is estimated to cost \$19.5 billion yearly, taking into account direct and indirect patients costs including hospital admissions, emergency and primary care visits, diagnostic costs, and lost parental work productivity (Groenewald, Essner, Wright, Fesinmeyer, & Palermo, 2014). For adults, Gaskin and Richard (2012) calculated that the total cost for pain including lost work productivity is between \$560 to \$635 billion dollars and is more than heart disease (\$309 billion) and cancer (\$243 billion) combined. Research and education are vital to decrease pain and suffering in infants, young children, and ultimately in adulthood resulting in decreased healthcare costs.

3.3.13 Conclusion

Assessment and treatment of pain in infants and young children is challenging. While it is now recognized that infants feel pain from the moment they are born, healthcare has not yet completely come to terms with that fact in either the assessment or treatment of newborn pain. Traditional medical approaches often result in unnecessary pain when non-pharmacologic interventions such as swaddling or breastfeeding may soothe infants more quickly with fewer side effects. Toddlers may be the most challenging developmental stage for assessment although simple distraction techniques work well for treatment as increased awareness of self leads to indiscriminate distress from strange people and benign procedures as well as legitimately painful events. Preschool and early school age children are very open to non-pharmacological interventions such as video games, cartoons, stories, or counting which serve to focus the mind on something other than the painful event, thus decreasing the perception of pain and decreasing stress. Previous research on implementation suggests that institutional commitment and support is necessary for change to take place (Struder, 2003). Using a developmental approach to assessment and non-pharmacological treatment can lead to better outcomes. Cooperation between policy makers, institutions, and healthcare providers can result in less pain and suffering in infants and children.

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4.0 MANUSCRIPT #4: PEDIATRIC PALLIATIVE CARE: A 5-YEAR RETROSPECTIVE CHART REVIEW STUDY

4.1 ABSTRACT

Objective: To describe a cohort of pediatric patients receiving palliative care and examine the relationships between selected patient sociodemographic and clinical characteristics (disease type, age, gender, race, and religion), the outcome of the time elapsed from diagnosis to death and whether pain decreased after referral when compared to before referral.

Methods: A retrospective cohort of 256 children who received a referral to palliative care during the 5-year study period (1/1/2009 through 12/31/2013) was examined. The main outcomes were patient survival measured from referral to palliative care to death based on disease types. Kaplan-Meier survival estimates were used to show patient survival and Cox proportional hazards regression were used to build predictive models based on the covariates of gender, age, race, religion, and disease categories, and pain assessment.

Results: Patient survival experience did not differ significantly based on patient gender, age, race, or religion; however, patient survival experience did vary based on referring diagnosis ($\chi^2=40.3_{df=4}$, $p<.001$), specifically cancer. Pain did decrease post-referral.

Conclusion: This cohort provides important information on the complexity of disease processes for children referred to palliative care, types of illnesses referred, survival, hazard ratios for several illness processes, and pain. Four adjusted models were derived using hazard model.

Keywords: pediatric, child, palliative, life-limiting, life-threatening, survival curve

4.2 INTRODUCTION

With the advancement and success of medical science and medical care, a growing number of children are living with long-term and often life-limiting chronic conditions (Bogetz, Schroeder, Bergman, Cohen, & Sourkes, 2014). Children with complex chronic conditions, a broad array of disorders including cancer, respiratory diseases (e.g., cystic fibrosis, asthma), neuromuscular diseases (e.g., muscular dystrophy, brain malformations), hematological diseases (e.g., sickle cell disease, immunodeficiencies, HIV), and congenital conditions (e.g., hypoplastic left heart syndrome, Trisomy 13) require the use of multiple therapies and represent the main pediatric candidates for palliative care (Feudtner et al., 2001; Wolfe, Hinds, & Sourkes, 2011). Of the 83 million children under the age of 19 years in the United States, an estimated 600,000 to 1,600,000 are living with these life-threatening/life-limiting conditions; many are technology dependent, and over 180,000 are considered “medically fragile” (Bramlett, Read, Bethell, & Blumberg, 2009; Buescher, Whitmire, Brunssen, & Klutz-Hile, 2006; Feudtner et al., 2005; United States Census, 2010). These medically fragile children require intense medical and nursing care in the home and often-lengthy hospital stays; their care accounts for about 26% of all hospital days and 41% of all hospital charges (Simon et al., 2010). Approximately 53,000

children die each year with about half within the first year of life (Field & Behrman, 2003; Mathews & MacDorman, 2008). Of the remaining deaths, about half (12,000) result from complex and chronic conditions (Mathews & MacDorman, 2008).

Pediatric palliative care is an approach informed by a philosophy of care that aims to manage and prevent symptoms and suffering in the ill child as well as his or her family (Wolfe, J., Hinds, P. S., & Sourkes, B. M., 2011). According to the Center to Advance Palliative Care (CAPC) pediatric palliative care involves specialized medical care to relieve pain and distressing symptoms, helps patients and families make difficult decisions, assists patients to complete life-prolonging or curative treatments, and increases patient and family satisfaction. Above all, palliative care is family-centered care (Center to Advance Palliative Care, 2012).

The American Academy of Pediatrics issued a statement recommending palliative care for all children living with a life-threatening illness in the year 2000, yet only 58% of pediatric specialty hospitals providing oncology care had at least a minimal palliative care service seven years later (American Academy of Pediatrics, 2000; Johnston et al., 2008). Earlier studies found that palliative care results in higher healthcare provider and parent satisfaction, better symptom management, higher quality of life, and often longer life; however, the current literature lacks an adequate description of the pediatric population receiving this care or an exploration of sociodemographic or illness characteristics that may be relevant (Austin, Luker, Caress, & Hallett, 2000; Davies et al., 2005; Good, Cavenagh, & Ravenscroft, 2004; Johnston et al., 2008; Temel et al., 2010).

In this longitudinal retrospective chart review study, we examined data from all children referred to palliative care between the ages of 2 and 16 years during the five-year period 1/1/2009 through 12/31/2013 at one children's hospital in southwestern Pennsylvania. The

palliative care program at this hospital was started in 2003 and has experienced a steady increase in census since its inception. Currently the service has over 200 patients, including about 10 perinatal patients. Patients, families, and hospital staff report being very satisfied with the palliative care service, which provides 24/7 in-hospital care as well as outpatient consultation. The purpose of this study is to describe this cohort of pediatric patients receiving palliative care and to examine the relationships between the outcomes of patient survival following palliative care referral. Additionally, we examined relationships between patient survival following referral to palliative care and key clinical and sociodemographic variables. The research questions were as follows: (a) What are the characteristics of the sample? (b) Are there types of illnesses that tend to co-occur? (c) What are the associations between patient survival and gender, age, religion, race, referring diagnoses, and diagnostic categories? and (d) did pain scores decrease after referral to palliative care?

4.3 METHODS

4.3.1 Research Design and Sample Selection

This retrospective chart review study examined patients served by the palliative care team at a southwestern Pennsylvania children's hospital during a five-year period. A cohort was created by examining records of all patients referred to palliative care during the study period of 1/1/2009 through 12/31/2013. Children were included in the cohort if they were between the ages of 2 and 16 years when they received the referral to palliative care. The minimum age of 2 years was

selected in order to exclude infant-specific conditions related to short gestation, low birth weight, and lethal congenital conditions. The maximum age of 16 was chosen to stay within childhood from a developmental perspective.

4.3.2 Procedures

Inpatient and outpatient data were retrieved from the electronic medical record (EMR) and the weekly lists of current patients maintained by the manager of the palliative care service through a combination of programmatic data retrieval and hand data collection. The Institutional Review Board of the University of Pittsburgh and the Steering Committee of Children's Hospital of Pittsburgh of UPMC approved this study.

4.3.3 Data Analysis

All data analyses were conducted using IBM SPSS Statistics v22 for Macintosh (IBM Corp., 2013) with $p < .05$ as the significance level. All data were screened for missing data, outliers, and violations of statistical assumptions. Descriptive statistics were computed to describe the sample characteristics including gender and age distribution, disposition at the end of the study period (alive or deceased), race, religion, mutually exclusive distribution of five referring illness categories (cancer, congenital/genetic, transplant, trauma and other), and non-exclusive distribution for 15 illness categories (see Table 10). Average daily pain scores were calculated.

Kaplan-Meier (KM) survival estimates and Cox proportional hazards regression were used to find survival curves and build predictive models of survival based on the covariates of

gender, age, race, religion, and disease categories. Univariate analyses considering each predictor one at a time were conducted with KM estimation and Cox regression using the predictors of patient's gender, age, race, religion, and each disease category separately followed by two-way interactions. Hazard ratios (HR) are reported for each grouping. Hazard ratios are ratios of subsequent groups compared to the first, or reference group. Hazard ratios represent the instantaneous death rate: in other words the risk of dying in the next instant after living x days. The entire set of significant disease covariates was used to fit an overall model with and without interactions. Principle axis factoring (PAF) was used to identify classes of diagnoses that grouped together in a clinically meaningful way (e.g. Cancer and pain, or congenital/genetic conditions and ostomies). Using the factors identified using PAF, we ran Cox regression modeling entering factors as blocks both with and without significant interactions. Finally we targeted specific conditions including cancer, congenital/genetic, and trauma to fit models for each of these disorders.

4.3.4 Measurement

Data were cleaned and de-identified. Exhaustive hand data gathering to reduce missing data from the computer generated files was carried out. Data collected include gender, race, religion, date of birth, date of death (if applicable), last date mentioned in the EMR, date of referral to palliative care, referring diagnosis, all diagnoses and International Classification of Disease, 9th or 10th revision (ICD-9, ICD-10) codes found in the medical record. Children were grouped based on age into Preschool (ages 2 to 4), Early Elementary (ages 5 to 8), Late Elementary (ages 9 to 12), and Adolescents (ages 12 to 16) to make meaningful comparisons based on

developmental stage. Race was collapsed into White and Other. Religion was categorized as Catholic, Protestant, None, Other, and Unknown. Types of illnesses were grouped per ICD-9 and ICD-10 codes. Categories of illnesses were collapsed so that at each category contained at least 20% of the total number of illness codes. Two exceptions were Mood Disorders (any type of anxiety or depression) and Technology Dependence as these two categories are frequently found in the literature. The dependent variable was length of service (LOS) with the palliative care team as the time measure and death as the event of interest (factor for KM or status for Cox). Right censoring occurred if a child was lost to follow up or reached the end of the study period.

4.4 RESULTS

A total of 256 children were in the cohort (see Table 8). The mean age of the cohort was 9.5 years (SD = 4.5 years). The mean age at diagnosis for the referring illness was 5.27 years (SD = 5.41, median = 3.45) with a range of -13 days (prenatal) to 16.9 years. The mean time from diagnosis to referral to palliative care was 4.36 years (SD = 4.99) with a range of 0 to 16.97 years and a median of 2.3 years. The mean time from diagnosis to death was 3.26 years (SD = 3.53) ranging from 14 days to 15.25 years and a median of 1.76 years. The time from referral to death was a mean value of 203 days (SD = 232) and a median time of 134 days ranging from 4 to 1364 days (3.73 years). Most children had more than one concurrent illness condition (see Table 9), ranging from 1 to 13 of the 15 defined illness categories considered (mean = 5.29, SD = 2.75, median = 5.0).

Based on Kaplan-Meier estimation, the time from diagnosis to death did not significantly differ based on gender, age, race, or religion, but were significant for referring diagnosis (see Figures 9 and 10) and illness categories cancer, congenital/genetic conditions, ostomies, pain and painful conditions, psychiatric disorders not including mood, and trauma (see Table 10). Cox regression models were not significant for gender, age, or race but there were differences for religion, cancer, congenital/genetic conditions, ostomies, pain and painful conditions, psychiatric disorders not including mood, and trauma (see Table 11). The groupings discovered during PAF did not result in any significant models. For gender, male is the reference group; the unadjusted HR for females is 1.357 (95% CI, 0.913-2.018). For age, preschool is the reference group giving an unadjusted HR for early elementary of .942 (95% CI, 0.528-1.680), 1.036 (95% CI, 0.608- 1.766) for late elementary, and 0.750 (0.417-1.348) for adolescents. For religion, families that declared their religion as “other” are about 3.144 (95% CI, 1.877-5.360) times to die at any given time point compared with those that declared their religion to be “none.” Catholics are about 1.348 (95% CI, 0.727-2.498) times more likely to die at any given time point, whereas Protestants have about 90 percent the hazard HR=0.903 (95% CI, 0.471-1.731). Races other than white have a HR of 1.355 (95% CI, 0.769-2.388) compared to whites. The most common referring diagnosis was cancer. Congenital/genetic conditions have a HR of 0.297 (95% CI, 0.184-0.478) compared to cancer, transplant patients have a HR of 0.517 (95% CI, 0.248-1.077) compared to cancer and trauma has a HR of 0.173 (95% CI, 0.042-0.709) when compared to cancer. Of the 15 illness categories used in this analysis, cancer congenital/genetic, ostomies, pain and painful conditions, psychiatric not including mood disorders, and trauma all had significant results. The unadjusted HR given in Table 11 is comparing having the condition versus not having the condition.

When examining all diagnosis categories as covariates together, the best fitting model includes cancer, pain, and trauma (see Table 12). In this model cancer has a HR of 5.239 (95% CI, 3.241-8.468), pain and painful conditions has a HR of 0.510 (95% CI, 0.340-0.764) and trauma has a HR of 0.502 (95% CI, 0.259-0.970). A model was fit for cancer diagnosis specifically. This model consists of the diagnoses cancer, neurological conditions, pain, and transplant and transplant complications. The transplant condition includes 22 (34% of all transplants) bone marrow transplants. The HR of 7.281 (95% CI, 4.262-12.441) for cancer is higher in this model than the general adjusted model previously discussed. The remaining components for this model include neurological conditions (HR=1.580, 95% CI, 1.009-2.475), pain (HR=0.409, 95% CI, 0.268-0.623), and transplant (HR=1.794, 95% CI, 1.089-2.955). The model fit for congenital/genetic conditions (HR=0.618, 95% CI, 0.412-0.926) includes psychiatric conditions (HR=0.427, 95% CI, 0.302-0.754). Finally the best-fit model for trauma (HR=0.427, 95% CI, 0.221-0.825) includes ostomies (HR=0.477, 95% CI, 0.302-0.754).

All pain data were cleaned. In order to compare pre-referral pain scores to post referral pain scores only children who had pain assessments for three days pre-referral and three days post-referral were considered. This resulted in an N of 48 for this analysis. Many of the children in the sample were either admitted, diagnosed and referred on the same day (thus eliminating pre-referral pain scores) or referred and discharge that same day (thus eliminating post-referral pain scores) thereby decreasing our sample size for this analysis. We calculated a daily mean pain score and hypothesized that pain would decrease after referral. Pain scores were significantly different post-referral when compared to pre-referral $t(47) = 1.816$, $p < .05$ using a one tailed test, supporting our hypothesis.

4.5 DISCUSSION

This retrospective, descriptive study examined the demographics, survival curves, and hazard ratios of this large (N=256) cohort of children receiving palliative care. Relatively little quantitative research or review articles have been completed in a pediatric palliative care population: most studies are qualitative (Kumar, 2011). This indicates that research in pediatric palliative care is still in the early stage. In fact a search of PubMed using the terms quantitative, research, pediatric, and palliative resulted in only 3 research studies directly exploring pediatric palliative care in children: The remaining 16 results included studies reporting on healthcare provider knowledge or attitudes, research with parents of children in palliative care, and instrument development.

One other study reported on ages at diagnosis and time to referral, although they considered only children with cancer. Johnston and Vadeboncoeur (2012) reported a mean age at diagnosis of 7.7 years compared to our mean age of 6.3 years. The mean time from diagnosis to referral in the Johnston study was 1.26 years (SD=1.53 years) compared to our 5.2 years (SD=5.4 years). The time from diagnosis to death in the Johnston study was 1.76 years (SD=1.5 years) and from referral to death was 4.4 months (SD=6 months) compared to our 5.2 years (SD=5.4 years) and 6.8 months (SD=7.7 months) respectively. The shorter time frames reported in the Johnston study are likely due to the fact that all the children had cancer while the children in this study had a wide variety of diagnoses.

Many believe that palliative care is mainly for oncology patients at end of life: This cohort tells a different story. Two of the larger reported studies in pediatric palliative care included one descriptive study examining 50 oncology patients while another described 98

severely impaired children enrolled in a publically funded pediatric palliative care program (Johnston & Vadeboncoeur, 2012; Knapp et al., 2012). While cancer was the largest referring diagnosis in this study (42%), the percentage of children with congenital or genetic conditions was a close second (38%). Six of the 14 transplants were bone marrow although not all of those were for a cancer diagnosis. Trauma represented 5.5% of the cohort. These are the children we do not often think of as receiving palliative care but traumatic brain injuries, near drowning, and non-accidental traumas (injuries intentionally caused by an adult) may result in neurological devastation or injuries that require complex medical management.

The number and complexity of medical conditions is considerable. Out of 256 children, only 17 (6.6%) had just one illness category. With a mean of 5.29 illness categories each this cohort requires complex medical management of an interdisciplinary team. These results are echoed in the Knapp et al. (2012) study which examined quality of life in children enrolled in a publically funded palliative care program. While the study did not list the illnesses found in the children, it did mention that 1/3 of the children were non-verbal and another 1/3 had severe cognitive impairment (Knapp et al., 2012). Knapp's results are similar to the results of this study.

The racial mix of the cohort reflects the racial mix of the area, as does the number of religions named by the parents. It would be interesting to be able to explore the beliefs of those who named Other as their religion as those children had a significantly steeper survival function with a mean survival after referral of 2.83 years, as compared to Protestants who had the longest mean survival time after referral of 6.59 years. While spiritual support is one of the cornerstones of palliative care, research examining spirituality during pediatric palliative care is sparse and mainly focused on parental spirituality as a coping mechanism (Davies, Brenner, Orloff, Sumner, & Worden, 2002; Hexem, Mollen, Carroll, Lanctot, & Feudtner, 2011; Knapp et al., 2011).

Wiener, McConnell, Latella, and Ludi (2013) in a review of the literature found that culture and religion had a significant impact on decision making for families with children in palliative care and recommended further research in this area.

We found certain disease conditions that tended to occur together through principle axis factoring (PAF). These were (a) ostomies, technology dependence, vision and hearing problems, psychiatric disorders not including mood, pulmonary disorders, respiratory failure, and cardiac conditions; (b) neurological conditions including epilepsy and congenital and genetic conditions; (c) mood disorders, cancer treatment side effects, pain and painful conditions, and trauma; (d) transplant and liver/kidney/GI conditions. Cancer was a factor by itself in the PAF result. The category of ostomies included any man-made opening in the body with tracheostomy and gastrostomy being the most common. These groupings make clinical sense and this is a unique and interesting finding.

While gender and age were not statistically significant when calculating Cox regression hazard ratios, they still displayed interesting results. Girls were more likely to die more quickly compared to boys (HR=1.357). Late elementary aged children were more likely to die slightly sooner than preschool children (HR=1.036) but early elementary children lived longer (HR=0.942) and adolescents much longer (HR=0.750) when compared to preschool children. The analysis revealed that about 42% of children referred to this palliative care service had a cancer diagnosis and these children had a very steep survival curve (see Figure 10) compared to other diagnoses and shorter mean survival time (3.29 years) compared to psychiatric disorders who had a mean survival time of 7.31 years after referral to palliative care. No other studies addressed survival or hazard ratios.

4.6 LIMITATIONS

There are several limitations to this study. This was a retrospective chart review so only the data contained in the chart could be used. There were 23 children listed as alive that were lost to follow up who may or may not be alive. Based on clinical notes in the system, most of these children moved away from the area but for some, it may be that they are alive but their last clinic visit was toward the end of the year. This leads to an uncertain right censoring date so both the KM survival models and the Cox regression may be slightly different. The date of death was difficult to find. If no actual date of death was found, the weekly patient lists kept by the manager of the palliative care team were consulted. The date of death was entered as the last week the child appeared on the list (so the child died between one and six days later). The date of the referring diagnosis was difficult to find. Physician notes, operative notes, lab results, and other clinical notes were searched for a date of diagnosis. In some cases, only a month and year were found. In this case the last day of the month was entered for the diagnosis date giving a more conservative time to referral and/or time to death. The uncertainty of these two dates (date of diagnosis and date of death) and the conservative approach used to quantify them may have resulted in a shorter mean time from diagnosis to referral, from referral to death, and from diagnosis to death than actually occurred resulting in potentially steeper survival curves.

4.7 CONCLUSION

Describing this large (N=256) cohort provides important information on the complexity of disease processes for children referred to palliative care, types of illnesses referred, survival curves for demographic and illness variables, and hazard ratios for six of the 15 illness processes: cancer; congenital and genetic conditions; ostomies; pain; psychiatric disorders not including mood; and trauma. We derived four adjusted models using Cox regression modeling: an overall model based on all significant illness categories and specific models for cancer, congenital/genetic conditions, and trauma. Future prospective research will provide valuable insight into whether and how palliative care is helpful for children and their families for symptom management, quality of life, and length of life when comparing those who do and do not receive palliative care. Important research has been done but our understanding of the needs of children in palliative care is in the early stages. Research examining the needs of both children and their families with life-threatening illnesses (such as cancer) and life-limiting illnesses (such as the many congenital/genetic conditions listed earlier) is important for the quality of life of these children and their families.

4.8 TABLES AND FIGURES

Table 8. Demographics of the Cohort

<i>Variable</i>	<i>Frequency</i>	<i>Percentage</i>
Gender		
Male	13	53.5%
Female	7	46.5%
	11	
	9	
Age Groups (at referral)		
Preschool Ages 2 to 4	57	22.3%
Early Elementary Ages 5 to 8	59	23.0%
Late Elementary Ages 9 to 12	73	28.5%
Adolescents Ages 13 to 16	67	26.2%
Disposition at the end of the study period		
Alive	15	61.7%
Deceased	8	38.3%
	98	
Race		
White	22	87.5%
Black	4	10.2%
Hispanic	26	1.2%
Asian	3	0.4%
Middle Eastern	1	0.4%
Not Specified	1	0.4%
	1	
Religion		
Amish	5	2.0%
Baptist	7	2.7%
Catholic	49	19.1%
Christian	21	8.2%
Church of Christ	1	0.4%
Evangelical	1	0.4%
Islamic	3	1.2%
Jehovah's Witness	1	0.4%
Jewish	1	0.4%
Lutheran	7	2.7%
Methodist	7	2.7%
None	85	33.2%
Other	46	18.0%
Presbyterian	4	1.6%
Protestant	7	2.7%
Unknown	11	4.3%

Table 9. Diagnoses Statistics

<i>Variable</i>	<i>Frequency</i>	<i>Percentage</i>
Referring Diagnosis		
Cancer	107	41.8%
Congenital/Genetic	97	37.9%
Transplant	23	9.0%
Trauma	14	5.5%
Other	14	5.5%
Diagnosis Categories in Cohort (not mutually exclusive)		
Cancer	122	47.7%
Cancer Treatment Side Effects	64	25.0%
Cardiac	88	34.4%
Congenital & Genetic Conditions	137	53.5%
Liver, Kidney, or GI	108	42.2%
Mood Disorders	44	17.2%
Neurological Including Epilepsy	138	53.9%
Ostomies (tracheostomy, gastrostomy, colostomy, ileostomy)	100	39.1%
Pain and Painful Conditions	155	60.5%
Psychiatric Not Including Mood	52	20.3%
Pulmonary	131	51.2%
Technology Dependent	49	19.1%
Trauma	52	20.3%
Transplant & Transplant Complications	65	25.4%
Vision & Hearing Disorders	59	23.0%
Number of Illness Conditions in Cohort		
1 Condition	17	6.6%
2 Conditions	19	7.4%
3 Conditions	42	16.4%
4 Conditions	35	13.7%
5 Conditions	35	13.7%
6 Conditions	31	12.1%
7 Conditions	23	9.0%
8 Conditions	18	7.0%
9 Conditions	14	5.5%
10 Conditions	9	3.5%
11 Conditions	6	2.3%
12 Conditions	6	2.3%
13 Conditions	1	0.4%

Table 10. Kaplan-Meier Survival Estimates for Children Receiving Palliative Care

<i>Covariate</i>	<i>N</i> <i>Deaths</i>	<i>Mean</i> <i>Survival Time</i> <i>(years)</i>	<i>95% CI</i>		<i>Chi-Square</i> <i>(Breslow)</i>	<i>Sig.</i>
			Lower	Upper		
Gender	98	5.40	4.82	5.99	2.503	.114
Male	46	5.83	5.04	6.61		
Female	52	4.82	3.98	5.67		
Age	98	5.40	4.82	5.99	.455	.500
Preschool	24	5.08	3.86	6.31		
Early Elementary	22	5.31	4.18	6.43		
Late Elementary	31	5.00	3.90	6.11		
Adolescent	21	5.84	4.74	6.94		
Religion ^a	89	5.58	4.98	6.18	.340	.560
None	23	6.34	5.37	7.30		
Other	33	2.83	1.73	3.93		
Catholic	18	5.69	4.41	6.97		
Protestant	15	6.59	5.54	7.64		
Race ^b	97	5.43	4.84	6.02	1.934	.164
White	83	5.49	4.86	6.12		
Other	14	4.81	3.24	6.38		
Referring Diagnosis ^c	98				24.076	.000
Cancer	65					
Cong/Gen	23					
Transplant	8					
Trauma	2					
Other	0					
<hr/>						
Diagnosis Categories						
Cancer	76	3.29	2.52	4.06	50.564	.000
Congenital/Genetic	42	6.13	5.36	6.91	10.232	.001
Ostomies	25	6.75	5.91	7.59	12.801	.000
Pain	50	5.88	5.18	5.59	6.204	.013
Psychiatric	11	7.31	6.30	8.32	7.367	.007
Trauma	10	7.22	6.23	8.21	7.664	.006

^a There were 11 children with “unknown” religion

^b There was one child with “unknown” race

^c No statistics were generated for this group as category “Other” had no deaths

Table 11. Cox Regression Hazard Ratios for Children Receiving Palliative Care

Covariate	Wald	Sig.	Hazard Ratio	95% CI for Exp(B)	
			Exp(B)	Lower	Upper
Gender	2.276	.131	1.357	.913	2.018
Age					
Preschool	1.454	.693			
Early Elementary	.042	.838	.942	.528	1.680
Late Elementary	.017	.896	1.036	.608	1.766
Adolescent	.926	.336	.750	.417	1.348
Religion					
None	25.407	.000			
Other	17.704	.000	3.144	1.877	5.360
Catholic	.900	.343	1.348	.727	2.498
Protestant	.094	.759	.903	.471	1.731
Race	1.102	.294	1.355	.769	2.388
Referring Diagnosis					
Cancer	25.599	.000			
Cong/Gen	24.886	.000	.297	.184	.478
Transplant	3.101	.078	.517	.248	1.077
Trauma	5.952	.015	.173	.042	.709
Other	.004	.947	.000	.000	5.2E+157
Cancer	43.795	.000	4.989	3.100	8.031
Congenital/Genetic	8.536	.003	.550	.369	.822
Ostomies	12.601	.000	.439	.278	.691
Pain	7.515	.006	.573	.385	.853
Psychiatric	9.064	.003	.381	.203	.714
Trauma	8.484	.004	.378	.197	.728

Table 12. Cox Regression Model Fitting

Covariate	Wald	Sig.	Hazard Ratio Exp(B)	95% CI for Exp(B)	
				Lower	Upper
Model Based on All Significant Diagnosis Categories ^a					
Cancer	45.678	.000	5.239	3.241	8.468
Pain	10.667	.001	.510	.340	.764
Trauma	4.200	.040	.502	.259	.970
Model: Cancer ^a					
Cancer	52.777	.000	7.281	4.262	12.441
Neurological	4.004	.045	1.580	1.009	2.475
Pain	17.336	.000	.409	.268	.623
Transplant & Complications	5.272	.022	1.794	1.089	2.955
Model: Congenital/Genetic ^a					
Congenital/Genetic	5.427	.020	.618	.412	.926
Psychiatric	6.861	.009	.427	.226	.804
Model: Trauma ^a					
Trauma	6.422	.011	.427	.221	.825
Ostomies	10.069	.002	.477	.302	.754

^a Forward stepped entry method. No interaction terms were significant in the model.

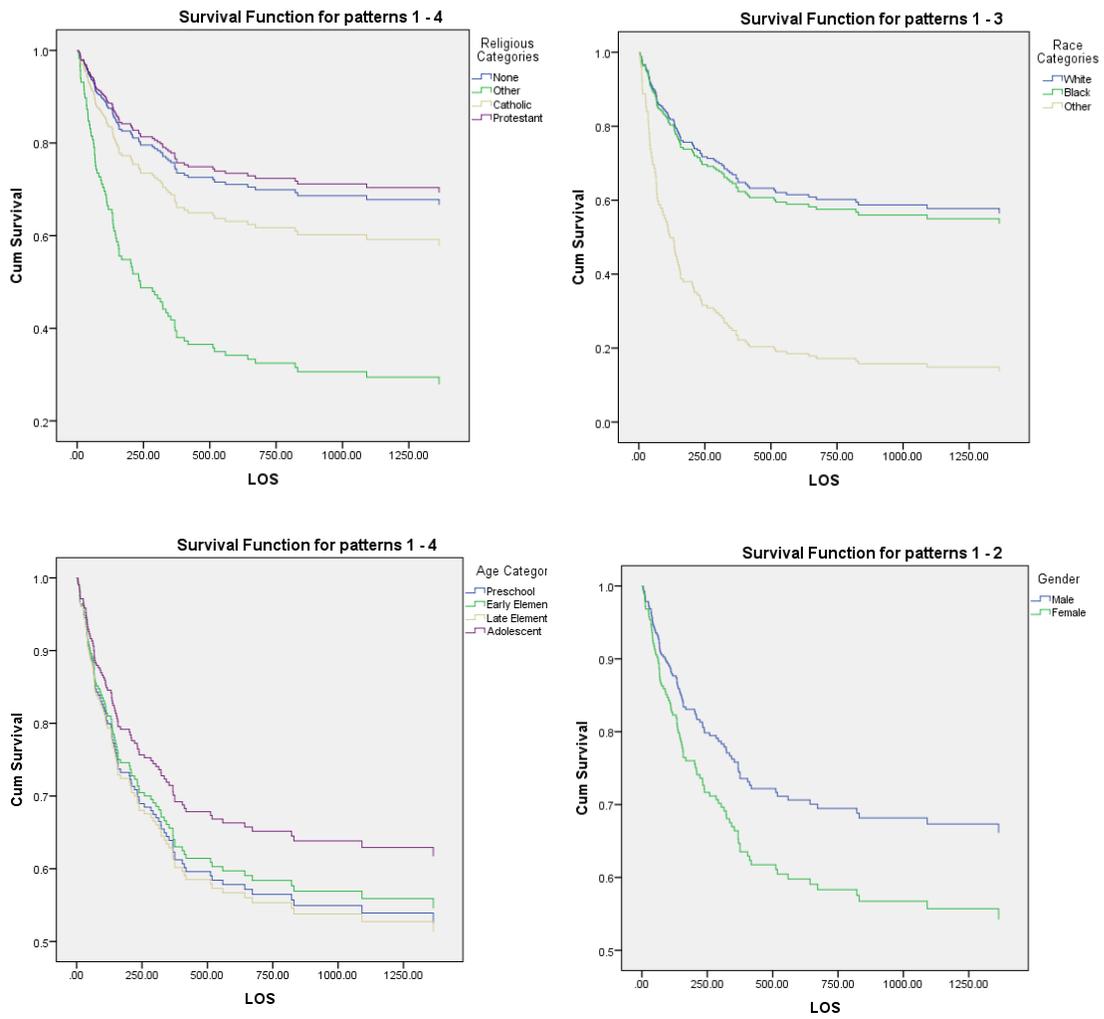


Figure 9. Survival Curves for Religion, Race, Age, and Gender

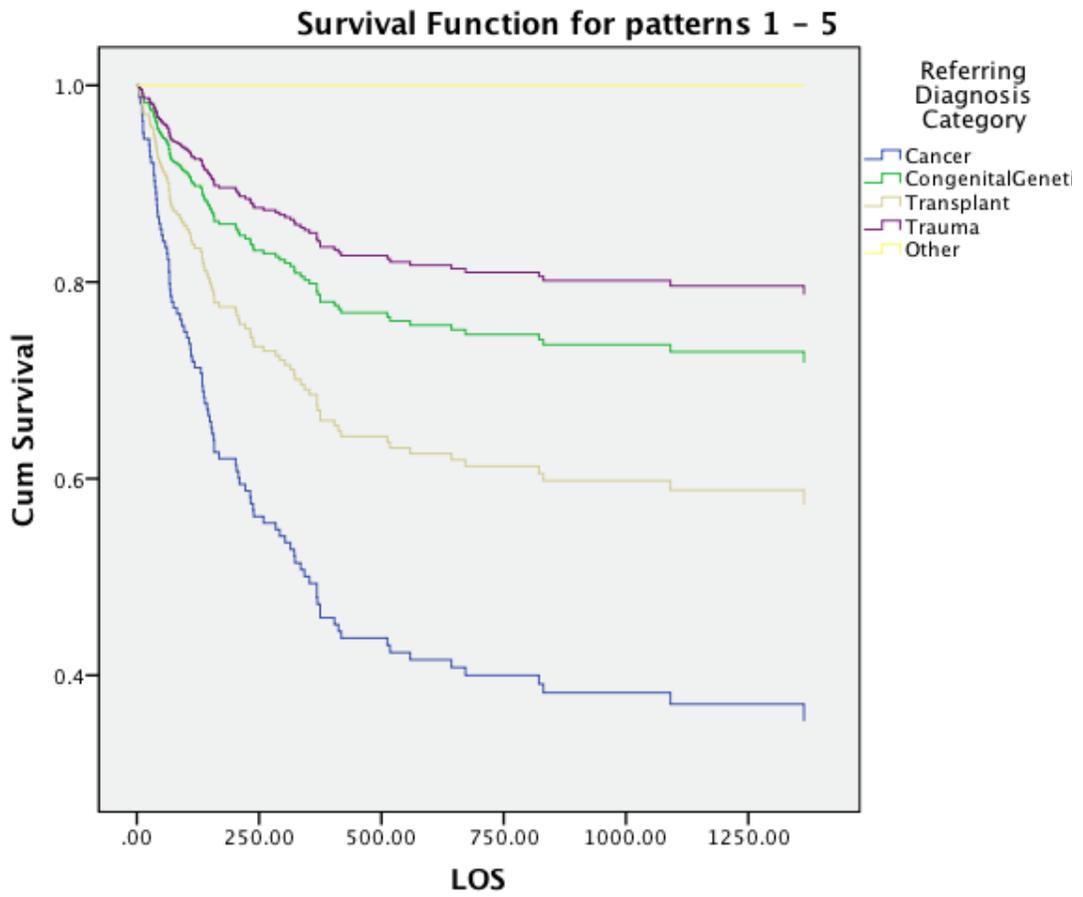


Figure 10. Survival Curve for Referring Diagnosis

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**5.0 MANUSCRIPT #5: FEASIBILITY AND ACCEPTABILITY OF REIKI
THERAPY FOR SYMPTOM MANAGEMENT IN CHILDREN RECEIVING
PALLIATIVE CARE**

5.1 ABSTRACT

Introduction: Reiki therapy is a complementary energy therapy this is generally relaxing. Children are receptive to complementary therapies for symptom management. Reiki is appropriate for children receiving palliative care because it is a gentle, light touch therapy that promotes relaxation. This quasi-experimental pre-post mixed-methods one group pilot study examined the feasibility and acceptability of Reiki therapy as a treatment for children ages 7 to 16 receiving palliative care.

Methods: We assessed recruitment, retention, data collection rates, and percent completion of the intervention. Pain, anxiety, heart rate, and respiratory rates were measured pre and post each of two Reiki sessions. We conducted structured interviews with the mothers and verbal children to elicit their experience. Statistics included sample description, paired t-tests or Wilcoxon signed-rank test for pre and post measures and independent t-tests or Mann-Whitney tests comparing children based on verbal versus non-verbal, age, and gender. Cohen's *d* statistics were calculated. Qualitative data were analyzed using thematic analysis.

Results: We approached 24 child-parent dyads, 21 (87.5%) agreed to participate and signed consents while 3 (12.5%) declined to participate. Of the 21 dyads, 16 completed the study (eight verbal and eight non-verbal children). Statistical significance was obtained for verbal children for heart rate for treatment two ($t=3.550$, $p = 0.009$) and for nonverbal children for pain for treatment two ($Z = 02.023$, $p = 0.063$); effect sizes using Cohen's d levels were medium to large for both verbal and non-verbal children for pain and anxiety. Themes included *Feeling Better*, *Hard to Judge*, and *Still Going On*.

Discussion: The results of this pilot study are encouraging for future study of Reiki therapy for symptom management in children receiving palliative care. Mothers and children were generally positive regarding the experience of receiving Reiki therapy with children reporting they “felt really relaxed,” while mothers stated, “it was a good experience” and “she was relaxed afterward.” The qualitative results clarified the quantitative results offering evidence that Reiki therapy may be a useful adjunct to the traditional medical management of symptoms in children receiving palliative care.

5.2 BACKGROUND/SIGNIFICANCE

5.2.1 Reiki Therapy

Reiki therapy is a generally relaxing energy therapy wherein the practitioner uses light touch or positions hands slightly above the body. The National Center for Complementary and Integrative Health (NCCIH) classifies Reiki therapy as a biofield therapy in which the goal is to facilitate the

body's own healing response (National Center for Complementary and Integrative Health, 2006). Biofield energy is any electrical or magnetic field produced by a biological organism. The human body produces measurable electrical and magnetic fields as a result of normal cellular processes (Movaffaghi & Farsi, 2009; Rae, 2005; Thomas, 2012).

Biofields or energy fields within the body are known by many traditional healing systems. For example *chi* in China, *ki* or *qi* in Japan, and *prana* in India and are believed to interact with all body systems, causing changes in health (Mills & Jain, 2010). Reiki is a holistic practice that is directed toward healing the body, mind, and spirit. The Reiki practitioner seeks to infuse the recipient's biofield with Reiki energy so that the body may repair any energy disturbance found within the biofield, which in turn may affect the cells within the body. At the very least, the interaction of the energy fields of practitioner and recipient, combined with light comforting touch of the practitioner typically brings about a relaxed state.

There are three degrees or levels of Reiki therapy practice. First degree practitioners are able to treat themselves or others through light touch (Miles & True, 2003). Second degree Reiki therapy expands practice to the use of distance healing (Rand, 2005). Third degree or master level Reiki therapy expands Reiki practice to teaching others and involves extensive practice.

Children are receptive to complementary therapies: several non-Reiki therapies including hypnosis, distraction, and massage have been examined and used successfully with children to manage symptoms during painful procedures and cancer treatments (Doellman, 2003; Landier & Tse, 2010; Thrane, 2013). While some of these interventions require the active participation of the child, Reiki therapy does not. Reiki therapy can be performed on anyone at any stage of life. Reiki therapy does not require participation or even consciousness. Most people leave a Reiki therapy session feeling very relaxed. A qualitative study of adults found that during a Reiki

therapy session participants felt “dreamy,” “safe,” “secure,” and “more grounded” (Ring, 2009, p. 255).

Our integrative literature review of randomized clinical trials that used at least two groups (one either usual care or control) shows that Reiki therapy is effective for pain and anxiety in adults (Thrane & Cohen, 2014). This review was limited to adults due to a lack of randomized control studies examining the use of Reiki therapy in children at the time of the review. Olson, Hanson, and Michaud (2003) examined Reiki therapy in adult cancer patients and found significant decreases in pain after two Reiki treatments when compared to the rest control group. Tsang, Carlson, and Olson (2007) also found significant decreases for participants’ pain and anxiety in the intervention group when comparing pre versus post Reiki intervention. When examining Reiki as an intervention for community dwelling adults, the Reiki treatment group had a significant decrease in both pain and anxiety while at the same time the waitlist control group had an *increase* in both pain and anxiety (Richeson, Spross, Lutz, & Peng, 2010). A recent study of 213 adult participants found that there was at least a 50 percent decrease in distress, anxiety, pain, and fatigue and that participants thought the Reiki sessions were relaxing, peaceful, and calming (Fleisher et al., 2014).

Since early 2013, two empirical studies and one case report have been published examining the use of Reiki with children. Kundu, Dolan-Oves, Dimmers, Towle, and Doorenbos (2013) trained parents of hospitalized children in Reiki therapy. Seventy-six percent of parents felt that Reiki increased their child’s comfort, 88% felt their child was more relaxed, 41% had decreased pain, and *all* of the parents felt that they had become an active part of their child’s care (Kundu et al., 2013). In a double blind randomized controlled trial, 38 children received either Reiki or sham (pretend) Reiki treatments before dental surgery: There were no differences found

between the groups on the outcomes of pain or medication use (Kundu, Lin, Oron, & Doorenbos, 2014). Bukowski and Berardi (2014) completed a case study of a nine-year-old girl with a history of seizures. The girl received six weeks of Reiki therapy. The authors reported a positive change in sleep, an increase in relaxation, no seizures during the study period but no changes in the child's report of well being (Bukowski & Berardi, 2014).

It is not clear how Reiki therapy (or any biofield energy therapy) works. The theory of quantum physics, which studies the interactions of energy and matter, may hold promise in the future explanation of the mechanisms of Reiki therapy (Thrane & Cohen, 2014). Quantum physics has demonstrated that not only does thought alter the way a particle behaves but also that particles can and perhaps even must be in two places at the same time (Rosenblum & Kuttner, 2006). Biofield energy may be gathered and directed by the practitioner to the recipient as explained by quantum physics, i.e., *thought* produces change in how the particles move (Rosenblum & Kuttner, 2006). There is the possibility that the presence of a calm caring individual with the intention of decreasing symptoms in a child may itself induce relaxation and decrease pain and anxiety.

5.2.2 Palliative Care

Palliative care is “the active total care of the child’s body, mind and spirit . . . which begins when illness is diagnosed and continues regardless of whether or not a child receives treatment directed at the disease” (World Health Organization, 1998). More recently the American Academy of Pediatrics stated that “palliative care includes the controlling of pain and other symptoms” with the intention of reducing suffering caused by illness and has the potential to benefit over 1

million children living with life-threatening or life-limiting illnesses (American Academy of Pediatrics, 2000, p. 351; Field & Behrman, 2003). Palliative care is transdisciplinary encompassing physicians, nurses, social workers, chaplains, child life specialists, and more. Palliative care seeks to aggressively manage symptoms and improve all areas of a child and family's quality of life.

Many palliative care experts include complementary therapies as an essential part of palliative care for symptom management (Friedrichsdorf, 2010; Institute of Medicine, 2003; Kuttner, 2006). Complementary therapies are often well received by children and are helpful with pain and anxiety (Doellman, 2003). Multiple complementary therapies including hypnosis, distraction, massage, and listening to music are well-accepted by children and parents and result in decreased pain and anxiety and increased quality of life both during general cancer treatments and the painful procedures that accompany cancer therapy (Thrane, 2013). The National Health Interview survey found that 11.8 percent of children had experienced some type complementary therapies within the previous year (Barnes, Bloom, & Nahin, 2008). Moreover, parents of children undergoing cancer treatments prefer either an active or collaborative role in treatment decision-making and are more likely to choose non-botanical complementary therapies for their children (Gagnon & Recklitis, 2003; Kundu et al., 2013)

The goal of palliative care is quality of life not only for the child but also for the entire family. The Quality of Life Model proposed by Padilla, Ferrell, Grant, and Rhiner (1990) encompasses physical, psychological, social, and spiritual domains of well being, emphasizing care of the whole person. The ecological model of palliative care adapted from the Quality of Life Model by the first author (ST) (see Figure 1) shows that the family contains or influences the child and the child contains the elements of quality of life. The relationship influences of

family and child are valid in both directions, i.e., not only does the family influence the child, but also the child and their domains of quality of life influence the family. Bereavement care, which

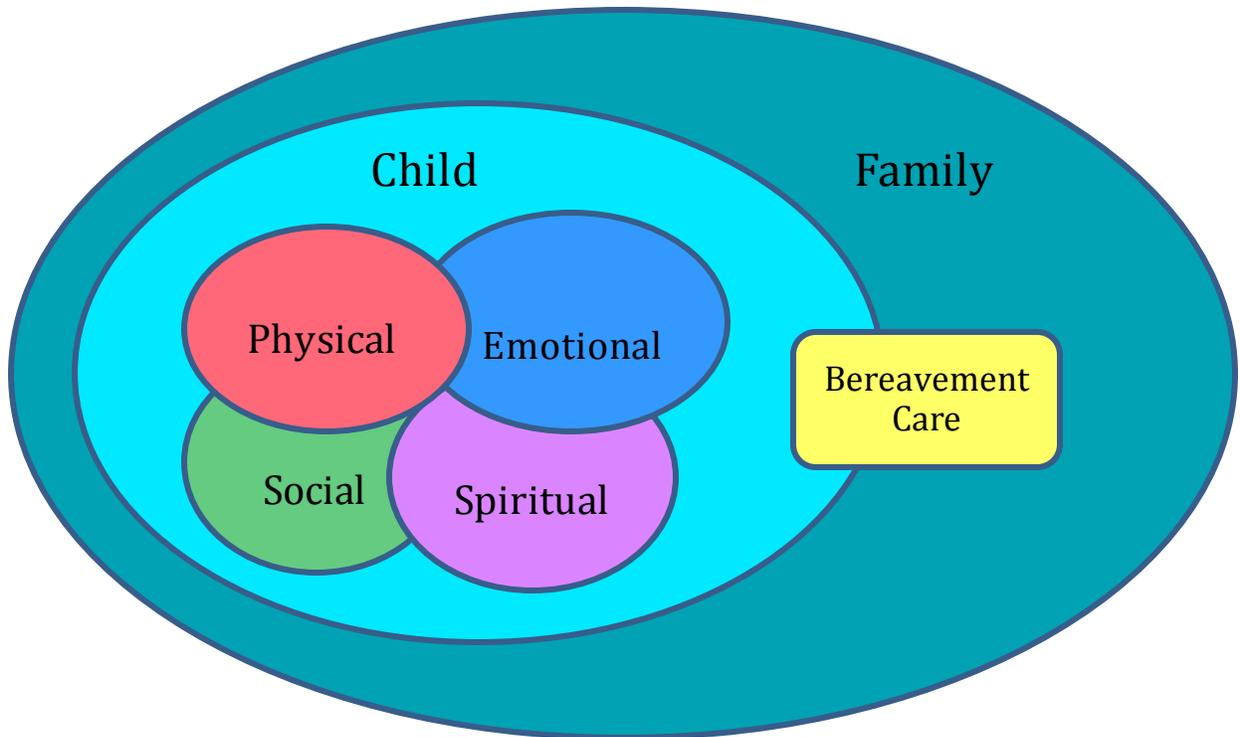


Figure 11. Ecological Model of Palliative Care

could also be called grief care, crosses the family/child boundary to emphasize that both the family and the child should receive bereavement care from the time palliative care is initiated. A metasummary of qualitative studies from the United States and Canada identified areas of child and family needs during palliative care including communication (general information, interaction between staff and families, psychosocial), health care accessibility, spirituality, needs of siblings, cultural, symptom management, and bereavement (Stevenson, Achille, & Lugasi, 2013). Communication is the key to good palliative care (C. May, personal communication, March 2013). Parents rated improved communication as one of the benefits of palliative care (van der Geest et al., 2014). Cultural needs may be complex especially around end of life. It is

imperative that providers take culture into consideration before approaching families of a culture other than their own who may have different languages, experiences, values, religions, and ideas around healthcare and healthcare providers roles (Wiener, McConnell, Latella, & Ludi, 2013). Studies have shown that palliative care leads to higher satisfaction for patients, families, and healthcare providers (Austin, Luker, Caress, & Hallett, 2000; Davies et al., 2005). The assistance of a palliative care team leads to better quality of life for the child and family (Groh et al., 2013).

Palliative care not only improves symptom management and quality of life, it decreases hospital admissions, hospital length of stay, and total costs (Gans et al., 2012; Keim-Malpass, Hart, & Miller, 2013; Postier, Chrastek, Nugent, Osenga, & Friedrichsdorf, 2014). Of course, cost is not a primary consideration of palliative care for families. However, hospital stays affect quality of life through separation of the family, extra costs incurred while in the hospital such as parking or parent meals, and the general discomfort of being away from home for both parent and child. Palliative care promotes quality of life through holistic care of the child and family by addressing all domains of quality of life. Palliative care helps the family set goals of care whether the goals address treatment, comfort care, respite care, helping the child attend school, or making sure the family has the knowledge and supplies they need to successfully care for their child at home. Palliative care is the gold standard of holistic care for children with life-threatening and life-limiting illnesses.

5.2.3 Pain and Anxiety

Pain and anxiety are debilitating symptoms occurring in 47-75% and 32-39% of children respectively in children with cancer and terminal conditions, compromise quality of life, and

increase the distress experienced by parents (Jalmsell, Kreicbergs, Onelov, Steineck, & Henter, 2006; Kreicbergs et al., 2005; Schmidt et al., 2013; J. Wolfe et al., 2008). Neither clinicians nor parents want a child to suffer. A survey by Dussel et al. (2009) indicated that 34% of parents would consider *hastening their child's death rather than have them suffer with pain*.

Symptom management and the reduction of suffering is the primary goal of palliative care. The most common symptoms in children at end of life are fatigue, pain, and anxiety (Niswander, Cromwell, Chirico, Gupton, & Korones, 2014; Pritchard et al., 2008; Ullrich et al., 2010; van der Geest et al., 2014). The treatment of pain in children is particularly important and remains a challenge (Collins, Berde, & Frost, 2011; Fitzgerald & Walker, 2009; van Dijk, Peters, Bouwmeester, & Tibboel, 2002). Factors that contribute to the difficulty in assessing and treating pain and other symptoms such as anxiety include physical, emotional, and cognitive development; gender; age; culture; and previous pain experience (McGrath & Brown, 2005). Some of the barriers to pain and symptom management in children include denial of pain either by the child, family, or provider, fear of harm such as respiratory depression, or fear of addiction (Gregoire & Frager, 2006; Shaw, 2012). Although self-report remains the gold standard of assessing pain and anxiety in children—in some cases, proxy report in the form of parent report or healthcare provider observation is the available source of assessment (Buttner & Finke, 2000; Hartrick & Kovan, 2002; Pillai Riddell & Racine, 2009; Stevens, 2007; Varni, Limbers, & Burwinkle, 2007a, 2007b). By the time an average child reaches kindergarten, they are able to report their pain, point to the painful area, and describe their pain in terms such as stabbing, burning, or the like (Hicks, von Baeyer, Spafford, van Korlaar, & Goodenough, 2001).

Pain and anxiety are often related especially in children and adolescents with life-threatening illnesses. There is evidence that anxiety is associated with greater pain-related

functional disability (Simons, Sieberg, & Claar, 2012; Zernikow et al., 2012). Moreover, anxiety often accompanies pain in children in palliative care, particularly for those with cancer, respiratory conditions, or muscular dystrophy (Ho & Straatman, 2012; Pritchard et al., 2008). Yet, children's pain and anxiety do not always respond completely to traditional pharmacologic interventions. Thus many parents choose complementary therapies for their children to augment pharmacologic interventions and to bridge the gap and achieve the goal of pain relief without excess sedation that reduces the child's ability to interact with family and friends (McCann & Newell, 2006; Samdup, Smith, & Il Song, 2006).

Discussing the goals of care with parents and children will help balance the desire to be pain free with the desire to be free of side effects of medications such as sedation or dizziness. Reiki therapy, a gentle, non-invasive complementary technique has demonstrated good clinical effect in adults that has only recently been empirically studied in children but has not been studied with children receiving palliative care (Thrane & Cohen, 2014). Moreover, no study has asked children or their parents about the child's experience with Reiki therapy. Based on adult studies, Reiki therapy is likely well suited for symptom management in children with life threatening and chronic illnesses in all phases of palliative care (Institute of Medicine, 2003; Kuttner, 2006; Mack & Wolfe, 2006; Schmidt et al., 2013; Steele et al., 2008). To address the gap in the use of Reiki therapy in a pediatric population, the overall purpose of this study is to explore the feasibility and acceptability of using Reiki therapy with children ages 7 to 16 years receiving palliative care.

5.3 METHODS

5.3.1 Research Design

This was a quasi-experimental pre-post mixed-methods one-group pilot study design. Pain and anxiety, measured using a Visual Analog Scale (VAS) and relaxation operationalized as heart rate and respiratory rate were measured pre and post each Reiki therapy treatment. Structured interviews were conducted with parents and verbal children after the second Reiki therapy treatment. This study has two main aims:

1. Assess the feasibility and acceptability of Reiki therapy as a treatment for children receiving palliative care.
 - a. Assess recruitment, retention, and data collection rates and percent completion of intervention.
 - b. Explore the experience and acceptance of receiving Reiki therapy with verbal children in relation to changes in the child's experience of pain, anxiety, and relaxation.
 - c. Explore the parental perception of the child's experience and acceptance of receiving Reiki therapy in relation to the child's experience of pain, anxiety, and relaxation.
2. Examine the effect of Reiki therapy on pain, anxiety, and relaxation operationalized as heart rate and respiratory rate in children receiving palliative care to calculate effect size for a future larger study.

5.3.2 Sample and Setting

A convenience sample was recruited from the Children's Hospital of Pittsburgh of UPMC Supportive Care Services (SCS), a palliative care service that began in 2003. During 2013, SCS served 260 children from prenatal to 28 years of age (mean age 8.12 years), including 78

children that are between the ages of 7 and 16; the target population of this study. During the last five years, approximately 54% of the patients were male, 46% female, 88% White, 10% Black, and 2% other racial categories. The number of referrals to the palliative care service has increased considerably in the last two years, averaging over 200 children on service at any given time. Thus our target sample size was 20 child-parent dyads.

5.3.2.1 Inclusion and Exclusion Criteria.

We recruited child-parent dyads with children between the ages of 7 and 16 who were being cared for at home by a parent or guardian. The broad age range was chosen purposefully to test the feasibility and acceptability of a Reiki therapy intervention. The minimum age of seven was chosen because by age seven, children are able to give assent and reliably self-report pain (P. S. Hinds, personal communication, October, 2013) using a visual analog scale and are able to remember events that happened in the near past (such as the Reiki therapy treatments). Parents and verbal children were excluded if they were unable to communicate in English.

5.3.3 Procedures

University of Pittsburgh IRB approval was obtained. Recruitment was completed in the outpatient clinics of Children's Hospital of Pittsburgh of UPMC when participants had regularly scheduled appointments. We approached families who were being cared for by SCS who fit the inclusion criteria based on the SCS patient roster. A team member from SCS introduced the first author (ST) who then described the study, and obtained consent from the parent and assent from the child when applicable. Demographic data were collected and appointments for the Reiki therapy

treatments were made either at the time of recruitment or via phone at a time of the family's convenience. If the child or parent declined to participate, any spontaneous explanation for declining was noted.

The intervention consisted of two 24-minute Reiki therapy sessions utilizing a standardized protocol of 12 hand positions held for two minutes each with a minimum of one and a maximum of three days between sessions. A study with adults demonstrated that two treatments within one week resulted in a statistically significant decrease in pain (Olson et al., 2003). While most adult studies use 30 to 60 minute Reiki treatments, anecdotal evidence from the first author's (ST) clinical experience with hospitalized children found 10 to 20 minute sessions induced a response (Richeson et al., 2010; Vitale & O'Connor, 2006). The Reiki sessions were completed wherever the child was comfortable. The child was comfortably clothed and parents were invited to watch the session. The interventionist noted the number of minutes for the session including any deviations from protocol or unusual occurrences in a log. Data on pain, anxiety, heart rate and respiratory rate were collected pre and post each Reiki therapy session. An assistant conducted brief structured interviews to explore the experience of Reiki therapy with the child and their parents as part of acceptability. All interviews were digitally recorded and transcribed verbatim.

5.3.4 Measures

5.3.4.1 Demographics

All data were collected and recorded using code numbers for each child using a single code for each child-parent dyad. Measures included demographic data for the child (age, gender, race,

primary diagnosis, length of time on supportive care service, grade level, current medications for pain or anxiety, and previous complementary therapy use if any) and the parent (age, gender, race, educational level, income, employment status, and previous complementary therapy use if any).

5.3.4.2 Pain

For children able to self-report a visual analog scale (VAS) and a FACES scale were used. The VAS scale, a 10-cm line for pain levels 0 to 10 is the gold standard and is reliable for children as young as five years of age (Sanchez-Rodriguez, Miro, & Castarlenas, 2012). The FACES Pain Scale has been validated over time and found highly correlated with a visual analog scale (VAS) for children age five and over (Garra et al., 2010; Hicks et al., 2001). Children were given a piece of paper with a 10 centimeter line and a FACES scale and asked to mark their pain level on one of the scales (Bailey, Daoust, Doyon-Trottier, Dauphin-Pierre, & Gravel, 2010; McGrath et al., 1996; Sanchez-Rodriguez et al., 2012). For children unable to mark their pain level, the parents were asked to mark their child's perceived pain level on the scale. In this case the interventionist also used the Faces, Legs, Activity, Cry, Consolability (FLACC) observational scale to rate the child's pain. Bringuier et al. (2009) found the FLACC scale to have good face and construct validity, sensitivity, and specificity to pain in a prospective study of 150 children.

5.3.4.3 Anxiety

We also used a 10-cm VAS scale for anxiety and The Children's Fear Scale, a faces-type scale for children able to self-report (Sanchez-Rodriguez et al., 2012; Varni, Walco, & Katz, 1989). The Children's Fear Scale has been tested for both fear and anxiety and shows good convergent

validity with a previously validated scale (Children's Anxiety and Pain Scale) $r= 0.73$ and for test-retest reliability $r=0.76$ (McMurtry, Noel, Chambers, & McGrath, 2011). Children were given a piece of paper with a 10 centimeter line and the anxiety faces-type scale and asked to mark their anxiety level on one of the scales. For children unable to mark their anxiety level, the parents were asked to mark their child's perceived anxiety level on the scale.

5.3.4.4 Relaxation

Relaxation was assessed objectively by measuring heart rate and respiratory rate. The combination of these two measures are a valid measure of relaxation (Kozier, Erb, Berman, & Burke, 2000). These routine non-invasive measures respect the medical fragility of these children.

5.3.5 Data Analysis

5.3.5.1 Quantitative Analysis

The number and percentage of participants who completed each data collection time point specified in the protocol for the entire experimental period were recorded and calculated. Rate of participant accrual were calculated. Percentages of the following were calculated: (1) persons eligible to participate; (2) persons who sign a consent; and (3) participants who dropped out. Reasons for attrition were described.

The descriptive statistics of pain, anxiety, heart rate, and respiratory rate, were reported pre and post each Reiki therapy session. The differences among different time points and/or trend of change over time were explored by using paired Student t-tests or Wilcoxon signed-rank

tests. Because this is a pilot study, the estimation of effect sizes (standardized mean difference of pain, anxiety, relaxation, between pre and post intervention) and summary statistics (means, standard deviations, etc.) were emphasized rather than hypothesis testing. The estimates of the proportion of variance explained in the particular outcome under consideration will be computed as effect size estimates for future sample size determination of a larger prospective study. All quantitative data analyses were conducted using IBM SPSS Statistics v22 for Macintosh (IBM Corp., 2013) with $p < .10$ as the significance level due to small sample size.

5.3.5.2 Qualitative analysis

Parent and child interview data were analyzed using thematic analysis. Themes and subthemes related to the child's experience and the parent's perceptions of the child's experience with Reiki therapy were identified. The thematic analysis steps included: familiarizing ourselves with the data, searching for themes, naming and defining themes, reviewing themes, and producing the report (Braun & Clarke, 2006). The first and second authors (ST and CD) participated in this process. In order to establish trustworthiness of the qualitative portion of this study, credibility of the process was established through triangulation by comparing the child and corresponding parent interviews in combination with field notes and the quantitative results (Krefting, 1991).

5.4 RESULTS

We approached families served by SCS based on the inclusion criteria of children ages 7 to 16 years old. At the beginning of the recruitment period, October 2014, there were 73 children ages

7 to 16. Some of these children were being actively treated with regular hospital and clinic visits while others were followed with once yearly visits or via phone with SCS team members. The original study design aimed to recruit only verbal children in order to explore their experience with Reiki therapy. However, between October and February, only 10 dyads were recruited and only 5 had completed the intervention. Consequently, the decision was made to include non-verbal children in order to increase recruitment. We obtained IRB approval for the modification to include non-verbal children and their parents.

5.4.1 Sample

We approached 24 child-parent dyads between October 2014 and May 2015. From those dyads approached, the mean age of the children was 11.6 years ($SD=3.1$), 15 (62.5%) were girls, 22 (91.7%) were White, one (4.2%) was African American, and one (4.2%) was of mixed African-American/White race. The median time with SCS was 1.54 years (range 1 day to 9.8 years); the parents were 100% female with 23 (95.8%) white and one (4.2%) African American.

The final sample included 16 children (8 verbal and 8 non-verbal), their parents, and one nurse for a total of 33 participants. The children had a mean age of 12.6 years, 11 were girls, 15 were White, one was of mixed African-American/White race, and the median time with SCS was 1.58 years (range 48 days to 9.8 years). The parents were 100% female and 100% White with a mean age of 43.7 years. Since 100% of the parents were mothers, therefore hereafter the term mother will be used to describe the parent. All of the mothers had at least a high school education and 87.5% had some college. Most mothers were employed at least part time (see Table 14). Six of the children (37.5%) and five (31.3%) of the mothers had experienced a variety

of complementary therapies prior to recruitment (see Table 15). Illness conditions were categorized into cancer (all types), congenital conditions (microcephaly, cerebral palsy, seizures), and genetic conditions (Cystic Fibrosis, Muscular Dystrophy). Seven (43.8%) had cancer, four (25%) had a congenital condition, and five (31.3%) had a genetic condition. When comparing the verbal and non-verbal children the groups differed on age ($p=0.047$) with the verbal children being older and gender ($p=0.11$) as all the boys were in the non-verbal group. No other demographic variable was significantly different (race, mother's age, education, income, or employment status). We asked mothers about the medications their child takes either on a regular or occasional basis for pain or anxiety. Some of the children took daily medications but most needed medications such as lorazepam or ibuprofen for occasional anxiety episodes or minor pain (see Table 16).

5.4.2 Feasibility and Acceptability

From the 24 children and their mothers, 21 (87.5%) agreed to participate and signed consent forms, while three (12.5%) declined to participate. Of the three who declined, one mother did not spontaneously give a reason for refusal, one child did not wish to participate, and one mother felt that because her child had completed treatment she did not wish to participate. Of the 21 families who consented, two families formally withdrew from the study (one child decided he did not wish to participate and another mother decided her schedule was just too busy) and three mothers did not return phone calls to set up appointments, leaving 16 child-parent dyads (see Table 17).

After both Reiki therapy treatments had been completed, we asked verbal children ($n=7$, 1 child refused the interview) two acceptability questions and their mothers' four acceptability

questions relating to the Reiki therapy treatments. When asked if they would continue the Reiki therapy treatments if they could, six (85.7%) of the children said yes and one (14.3%) said she was unsure. Of the mothers, 14 (87.5%) of the mothers said they would continue, one (6.3%) said she was unsure because it would be up to her child and one (6.3%) said no because her child was not having any symptoms currently and did not need to continue the Reiki therapy. Both the children and the mothers were asked if they would have liked the Reiki therapy treatments done differently: All seven (100%) of the children said no. Fourteen (87.5%) of the mothers said no while two (12.5%) of the mothers were unsure because they had not asked their child what they thought about the Reiki therapy treatments. We asked the mothers if Reiki therapy was something they would like to learn so that they could use it on a regular basis, 10 (62.5%) of the mothers said yes, four (25%) said no, and two (12.5%) were unsure. Finally we asked the mothers if they would participate in the study again: All 16 (100%) of the mothers said they would participate in the study again. Moreover, all children that started the intervention finished both sessions. No one dropped out once they had experienced one of the Reiki therapy treatments.

5.4.3 Pain, Anxiety, and Relaxation

Pain, anxiety, heart and respiratory rates were assessed pre and post each Reiki therapy treatment. Heart rate and respiratory rate met the tests of normality and homogeneity of variance. Pain and anxiety scores were non-normally distributed. We used paired t-tests for heart rate and respiratory rates and Wilcoxon signed-rank test for pain and anxiety. While verbal children completed self-report measures for pain and anxiety, mothers completed pain and anxiety

measures for the non-verbal children. Because of this difference verbal and non-verbal children results are reported separately. Due to the pilot nature of the study and small sample sizes, significance was set to $p < 0.10$.

For both Reiki therapy treatments one and two, there was a decrease in all mean scores for all outcome variables for both verbal and non-verbal children (see Table 18). Significance was found for heart rate for treatment two for verbal children ($t = 3.550$, $p = 0.009$) while for non-verbal children pain for treatment two ($Z = -2.023$, $p = 0.63$) and heart rate for the overall intervention ($t = 2.031$, $p = 0.082$) were significant. We calculated effect size using the Cohen's d statistic for each outcome. Many outcome variables for treatments one and two achieved a medium effect size ($d > 0.50$) or large effect size ($d > 0.80$) (see Table 19 for effect sizes).

Because lack of pain or anxiety was not an exclusion criterion for the study, we conducted a sub analysis considering only children who had either pain or anxiety before Reiki therapy treatments one and two reported as four conditions separately for verbal and non-verbal children (see Table 20). For verbal children only respiratory rate was significant for anxiety before treatment two ($t = 5.745$, $p = 0.010$). For non-verbal children pain was significant for those having pain before treatment one ($Z = -2.023$, $p = 0.063$), heart rate was significant ($t = 3.053$, $p = 0.093$) for those with anxiety before treatment one and respiratory rate was significant ($t = 3.000$, $p = 0.095$) for those with anxiety before treatment two. Effect sizes for all conditions for both verbal and non-verbal children were medium or large with the exception of pain for verbal children with anxiety before treatment two (see Table 21). These large effect sizes suggest that Reiki therapy was effective for pain and anxiety for both verbal and non-verbal children who had either pain or anxiety before the Reiki treatment.

The sample was split into two groups and compared based on three demographic characteristics: verbal compared to non-verbal children, older compared to younger children, and girls compared to boys. Pre and post measures were analyzed for each grouping using an independent sample t-tests for heart and respiratory rates and Mann-Whitney test for pain and anxiety. When comparing verbal (n=8) and non-verbal (n=8) children, the mean values for pre and post heart rate, respiratory rate and anxiety were higher in the non-verbal group for both treatments. For the non-verbal children, the mother or the full-time caregiver rated both pain and anxiety as perceived pain and anxiety. The only significant difference was for post treatment heart rate for treatment one ($p=0.083$). When comparing older (ages 13-16, n=7) and younger children (ages 8-12, n=9), the younger children experienced higher pre and post heart and respiratory rates for the first treatment while the older children experienced higher pre and post pain scores for both treatments. The only significant difference was for post treatment one heart rate ($p=0.042$) and pain ($p=0.091$). In the comparison between girls (n=11) and boys (n=5) there were no trends and no significant differences.

5.4.4 The Reiki Experience According to Parents and Children

Brief structured interviews were conducted separately with seven of the eight verbal children and with all mothers of the verbal and non-verbal children (n=16). One nurse, as a primary caregiver of a non-verbal child, was also included in the interview process following receipt of the mother's permission. Thus the final sample size of parents or primary caregivers was 17. All participants provided appropriate consent. The questions for the child included: (a) tell me about your Reiki therapy treatment and (b) tell me about how the Reiki treatments made you feel. The

questions for the mother included: (a) tell me about your child's experience with the Reiki therapy treatment, (b) tell me about your child's response to the Reiki therapy treatment, (c) tell me about any changes in your child's medication use or activity levels since the Reiki treatment, and (d) if you noticed a change in your child, how long did the change last. The Reiki therapy experience described by the children and mothers resulted in three themes: "Feeling Better," "Hard to Judge," and "Still Going On."

5.4.4.1 Feeling better

The theme Feeling Better was generally articulated by most of the children and several mothers of both verbal and non-verbal children at the completion of the Reiki therapy intervention. One mother stated, "she [child] said um, 'I feel a lot better, I feel different.'" Another mother of a non-verbal child referred to the child's mobility when walking in her statement "she had a great day on her feet yesterday." Many of the comments related to the theme Feeling Better were detailed and specific. Therefore, this theme was further divided into five subthemes including "really relaxed," "not hurting that bad," "calmed me down," "happier," and "heats me up."

Really relaxed

Several of the children and nearly all the mothers described the Reiki therapy sessions as relaxing when asked about the treatment session. One child said "I felt really relaxed" and her mother also commented "she found it very relaxing." Another mother said, "she was like, movin' like she was more relaxed." The mothers of non-verbal children also characterized their child as very relaxed when describing their child's response to the Reiki intervention. One mother said "she was um, you know breathing harder, but as the therapy went on, her heart rate went down

so you could tell she was relaxing.” Another mother commented, “her heart rate definitely went down, you know from what it was. It kept going down from when the therapy went on . . . that had to show me that she was, you know, relaxed during it.” As documented in the field notes, one non-verbal child had been agitated at the beginning of the treatment, flailing her arms and legs, but as the treatment went on, the child calmed and fell asleep. This child’s mother stated “she fell asleep the other day afterwards, so maybe it did relax her.” Another non-verbal child was described by her mother as typically being anxious with new people as indicated by an increased heart rate and decreased oxygen saturation. This child relaxed and fell asleep during the first treatment and her oxygen saturation was at 100% by the end of the treatment. A third non-verbal child who tended to be in constant motion, stopped moving, quieted, and put her head on the interventionist’s arm. She was awake with her eyes open; she appeared relaxed and content as documented in the field notes. Her full time nurse caregiver stated, “she just leaned on, on [interventionist’s] arm, and just really relaxed.” Field note documentation reflected that most of the non-verbal children and three of the verbal children fell asleep during part or all of the treatments.

Not hurting that bad

The mothers of both the verbal and non-verbal children as well as the children themselves reported less pain after the Reiki session. One mother said “she was in a lot of pain when she [the interventionist] came earlier this week and by the time she left she [child] was almost asleep.” Her daughter stated that “it’s still hurting but it’s not hurting that bad.” Another mother commented that her child “. . . has been using a lot less pain medicine the last couple days.”

Calmed me down

Several of the children and mothers described the treatment as very calming. Two children specifically said “it was calming” and another stated, “it calmed me down.” One mother of a non-verbal child noticed that her child “. . . just changed. He just got really serene.” Another mentioned, “. . . after the treatment he was really calm.” Unlike the first treatment, shortly into the second treatment one non-verbal child leaned back into the interventionist and remained in that position throughout the treatment. Another non-verbal child who had appeared a bit worried during the first treatment, settled quickly during the second treatment and was documented to appear calm and content.

Happier

Two children and several mothers mentioned that their child was happier after the treatment. One girl stated “I feel more happy like, after” and her mother confirmed this by stating, “oh she’s been in a much better mood. Happier . . . smiling more.” When asked how she could tell her child felt better, a mother of one teenaged girl commented, “she talked more.” A mother of a non-verbal child said “he would lean in towards her [the interventionist], or um, just kinda be happy about it” and another stated, “he was just kinda like looking down and smiling.”

Heats me up

Two children mentioned being warm during and after the Reiki therapy treatment. One child said “It’s warm . . . if I’m cold, it kind of heats me up.” This child’s comment was reinforced when her mother reiterated a conversation with her daughter following the first Reiki therapy treatment, “. . . she said that it was neat that she felt really warm . . . and that the therapist’s hands felt really warm.”

5.4.4.2 Hard to judge

Some of the mothers felt they could not judge the effect of the Reiki therapy treatments because their child was not experiencing pain or anxiety. One mother responded, “she was just kind of indifferent to it, she doesn’t have pain, so I don’t know that we got the full benefit of it.” Another mother stated “I really didn’t see much of a response, but at the same time she wasn’t in pain or anxiety at the time.” A third mother echoed these thoughts and provided further explanation by saying,

I think that if it were in the hospital when she was in for like, transplant her pain was so bad, her anxiety, I think she would have benefited from it then, um, but with her not having pain right now I think it’s hard for me to judge the effectiveness of it.

5.4.4.3 Still going on

Several children and mothers commented that the effects of the Reiki therapy treatment lasted the rest of the day or for one or two days after the treatment. One girl stated “For the rest of the day I feel a whole lot better than I did before.” When her mother was asked how long the effects lasted she said the effects were “still going on.” A second girl said that the effects lasted “for the next couple days.” A mother of a non-verbal child stated “maybe two hours later after the treatment he was out like a light. It was the best night ever that he slept . . . I would have to say [the effects lasted] the rest of the night and the whole next day.” Another mother of a child with chronic seizures said that her child’s heart rate “. . . lowered probably about half way through [the Reiki treatment] and it just stayed, just stayed lowered after she [the interventionist] left and everything.” One mother of a non-verbal child stated her child “had a very bad day yesterday . . . [with] seizures, . . . increased oxygen needs . . . then today when he was awake he was having

more seizures.” The nurse mentioned he had been given medication for seizures during the previous 18 hours with little to no effect. The interventionist noted at the beginning of the treatment that the child had two 10-15 second seizures in the first five minutes of treatment and was breathing over his vent at a rate of 20 to 24 breaths per minute. As the Reiki therapy treatment continued, his breathing slowed to the vent setting of 12 breaths per minute, his oxygen saturations increased, his heart rate slowed, and he did not experience further seizures during the intervention.

With few exceptions, children seemed to receive benefit from the Reiki therapy treatments. Mothers of most verbal and non-verbal children felt that their children had a positive experience and derived some benefit from the Reiki therapy. The children’s experiences ranged from feeling “just not so tense and stuff” to “It makes me feel like, warm” and “I felt really relaxed” and finally “well, it’s like different!” The mother’s comments were also encouraging and ranged from “after the treatment he was really calm” to “he seems to enjoy it” and “it was a good experience.” The intervention field notes documented that mothers stayed to watch one or both treatments and often seemed fascinated watching the changes in their children. One mother was heard whispering, “look at his face!” One mother identified that the Reiki therapy treatment would likely offer more benefit if their child was in the hospital or was experiencing symptoms. Reiki therapy was well received by all the children and their mothers even when they were not sure of the response. Most dyads expressed they would have liked to continue the treatments.

5.5 LIMITATIONS

There are several limitations to this study. A one-group design with a small sample size and with no control or comparison group addresses acceptability and feasibility but limits the generalizability of the pain, anxiety, and relaxation outcomes. The original target sample size was 20 children and 20 parents. However, slow recruitment in the early part of the study necessitated including non-verbal children in order to bring our total numbers to 16 children and 16 mothers within a nine-month period. Having only eight verbal children (and one refusal to participate in the interview) limited our qualitative results in relation to what the children had to tell us. Finally, because the first author and PI (ST) was also the interventionist may have resulted in some compromise of the results. Every effort was made to have the children and mothers assess the child's pain and anxiety out of sight of the interventionist and objective measures of heart rate and respiratory rates were added. In addition, an assistant completed the structured interviews in a room separate from the interventionist so that children and mothers were able to speak freely.

5.6 DISCUSSION

Until recently, Reiki therapy had not been studied in children although it has been used clinically for many years without benefit of scientific evidence in major children's hospitals, hospices, and other care areas. Complementary therapies such as massage or Reiki therapy are often included in palliative care for symptom management because they help children manage symptoms

without the additional side effects that are often the result of increased medications (Friedrichsdorf, 2010). The main goal of palliative care is the aggressive management of symptoms in order to decrease suffering and to promote comfort and quality of life for children and families (Center to Advance Palliative Care, 2012; J. Wolfe, Hinds, & Sourkes, 2011). The main goal of this pilot study was to explore the feasibility and acceptability of using Reiki therapy with children ages 7 to 16 years receiving palliative care. Our secondary goal was to measure pain, anxiety, and relaxation (operationalized as heart rate and respiratory rates) pre and post each of two Reiki therapy treatment sessions in order to examine the clinical effect of Reiki therapy with these children.

Our findings demonstrate that using Reiki therapy is feasible with children and their families and an acceptable complementary therapy for children receiving palliative care. Our initial recruitment rate of 21 dyads (87.5%) was encouraging, however with two dyads formally withdrawing and three not returning calls, our sample size decreased to 16 children and their mothers. We added non-verbal, neurologically devastated children to the study when it became clear that we were not meeting recruitment rates with verbal children. One mother who withdrew from the study after several weeks of actively trying to schedule the intervention said, “My schedule is just too busy!” Most of the children who participated were either receiving active cancer treatment or were non-verbal, requiring full time care. The fact that no one failed to complete the study once they began, that all of the mothers stated they would participate again, and that not one child or mother thought the treatment should be done differently speaks to the acceptability of Reiki therapy as an intervention for children receiving palliative care.

One mother who did participate in the study stated “I think that if it were in the hospital when she was in for like, transplant her pain was so bad, her anxiety, I think she would have

benefitted from it then” leads us to believe that offering Reiki therapy in the hospital during active treatment may be well-received. Olson et al. (2003) found that so many adults on a palliative care inpatient unit wanted Reiki therapy and not the control group that they had to stop recruitment on their study examining Reiki therapy for pain and quality of life. Vitale and O'Connor (2006) successfully completed a randomized control trial examining pain using Reiki therapy for hospitalized adult women receiving abdominal hysterectomies. These studies show acceptability with adults: Now we need to explore Reiki therapy with hospitalized children.

Statistical significance was reached for a few outcomes, but perhaps more importantly for a pilot study was the trends of the pre and post Reiki treatment mean values. For both verbal and non-verbal children pain, anxiety, heart rate and respiratory rate all had a mean value decrease for pre to post Reiki therapy. The sub analysis that considered only children who had either pain or anxiety before the Reiki treatment, the means for pain, anxiety, and respiratory rates decreased for both verbal and non-verbal children; heart rate decreased for non-verbal children. For verbal children there was an increase in heart rate for treatment two whether the children had pain or anxiety prior to the Reiki treatment. Effect sizes for treatments one and two the effect sizes for pain and anxiety were medium to large for both verbal and non-verbal children. These effect sizes echo the mother who mentioned “she was in a lot of pain when she [the interventionist] came earlier this week and by the time she left she [child] was almost asleep” and the child who said “I feel a whole lot better than I did before.” The comments of the children: “it was calming,” “I felt really relaxed,” “it makes me feel like, warm” and “just not so tense and stuff” establish the human side of decreased heart rate for the first treatment (verbal: $d=1.30$, non-verbal: $d=1.23$) and decreased respiratory rate for the second treatment (verbal: $d=2.68$, non-verbal: $d=1.11$). The interviews with the children provided valuable insight regarding how they felt after

the Reiki therapy treatments and strengthened the quantitative evidence as shown through their words. The interviews with the mothers aid us in understanding the child's reaction to the Reiki therapy.

The reactions of the non-verbal children who lack social constructs and whose reactions are purely their own without cultural restrictions may tell the story best. The non-verbal children showed their anxiety for a new person and situation by increased mean heart rate, increased mean respiratory rate, and the mother's perception of increased general anxiety. Statistically this difference was illustrated by a significant difference from the verbal children in heart rate for treatment one ($p=0.083$) and in decreased heart rate for the overall intervention ($p = 0.082$). These children did not experience increased anxiety for treatment two. The mothers of the non-verbal children were often fascinated by their child's reaction to the Reiki therapy treatment. We heard comments including "he would lean into her," "she didn't show any signs of, of, rejection I'll call it, or dislike" which was a common reaction to other new people according to the child's nurse. Other comments included "she was very calm, and um, content," "he seemed to enjoy it," and "he just got really, serene." These observations support further research into Reiki therapy for children with neurological challenges.

While several children and mothers commented that the treatment effects lasted either the rest of the day or several days, we did not see that in the data. To see if there was a lasting effect for the Reiki therapy we looked at the difference for the intervention as a whole (pre treatment one to post treatment two). There was a decrease in mean scores for all variables but only heart rate was statistically significant for non-verbal children ($p=0.082$). The effect sizes for pain and anxiety for this time span were also very small for pain (verbal: $d = 0$, nonverbal: $d=0.27$) and small for anxiety (verbal: $d=0.49$, non-verbal: $d=0.37$). There could be several reasons for this

but an obvious one is that three children (two children with osteosarcoma who were post limb salvage surgery, and one non-verbal child) had increased pain scores prior to the second Reiki treatment compared to the first Reiki treatment. We suggest that a longer intervention, for example two treatments per week for four to six weeks may be necessary to see an overall effect of the Reiki treatment for particularly painful conditions.

One unexpected result, in that we did not measure it nor ask about it, is that two children reported feeling happier and two separate mothers reported that their child was happier. The adult literature has explored the use of Reiki therapy for people with depression with good results. Richeson et al. (2010) completed eight weeks of once weekly 30-minute Reiki therapy treatments with community dwelling older adults: The Reiki group showed significant improvement in depression using the Geriatric Depression Scale. Shore (2004) examined stress and mild depression in adults with once weekly Reiki treatments for six weeks: At the end of the study and at the one year follow up, the Reiki group was significantly improved using the Beck Depression Inventory when compared to the control group. One mother in our study said about her child, “she’s been in a way better mood, happier . . . smiling more” while another mentioned that her teenaged daughter “talked more” and one of the children said “I feel more happy . . . for the next couple days.” These results need further exploration with children and adolescents.

Some of the experiences of the interventionist from the field notes included a new puppy that promptly lay on the child’s lap and fell asleep while at another session, a protective cat sat on the back of the sofa and watched much of the treatment. One profound moment was the non-verbal child who was in constant motion due to a neurological condition who suddenly stopped all movement and laid her head on the interventionist’s arm for a full 10 minutes during the second treatment and seemed to just be soaking in the moment. And finally when the

interventionist walked into his room to complete the second treatment one boy with muscular dystrophy's entire face lit up when he saw her. These experiences speak to the receptiveness of the children and families and even their pets to Reiki therapy.

Pilot studies fulfill a number of functions in research: to test the feasibility of an intervention, to test a research protocol, to collect preliminary data, to train a new researcher in the process of research and more (van Teijlingen & Hundley, 2002). Overall, the results of this study are very encouraging for the future study and use of Reiki therapy with children and adolescents. All the children and most of the mothers (the two that were unsure had not discussed the treatments with their children) would not have changed the way the Reiki treatments were done. While we did not reach statistical significance on most outcome variables, the majority of variables for each Reiki sessions had a medium to large effect size. The PI for the study gained experience in study design, grant writing, working with an internal review board (IRB), recruitment, retention, study management, and quantitative and qualitative data analysis. Most importantly, virtually all the children liked the Reiki treatment and received some positive benefit according to their own and their mother's comments. Further study of Reiki therapy with children receiving palliative care and other pediatric populations is worthwhile and necessary in order to provide scientific evidence of the benefit (or lack thereof) of Reiki therapy.

5.7 FUTURE DIRECTIONS

The data analysis and resulting themes helped guide not only the current study in terms of acceptability of the Reiki therapy, but also future studies involving Reiki therapy with children and their parents.

Future directions include:

1. To determine the effectiveness of Reiki therapy with children receiving palliative care or other pediatric population using a larger sample size and a randomized design. Using either a three group design including a Reiki group, a usual care group and a either a sham Reiki group or massage therapy group to account for touch and human presence in the design.
2. To examine the use of Reiki therapy for family use: future work focusing on training parents in Reiki therapy in order to examine parental use of Reiki therapy as a useful tool to help with symptom management in children who have life limiting and life threatening illnesses. Kundu et al. (2013) completed a pilot study teaching parents Reiki therapy for use with their children. Reiki was well received by the parents but the study did not assess the children in any way.
3. To examine the use of Reiki therapy as part of bedside nurses' usual care of patients to study nursing use of Reiki therapy in hospitalized children. Teaching nurses to use Reiki therapy would add a technique for their use in helping manage children's symptoms either without additional medication or while waiting for medications to arrive.

5.8 TABLES

Table 13. Family Demographics, N=16 dyads

	Completed Intervention
Child Age, Mean(SD)	12.6 years (2.4)
Child Gender, Female (%)	11 (68.8%)
Child Race	
White, n(%)	15 (93.8%)
Mixed race, n(%)	1 (6.3%)
Time Supportive Care Services, median (range)	1.58 years (48 days – 9.8 years)
Child previous complementary therapies? (Yes), n(%)	6 (37.5%)
Parent Age, mean (SD)	43.7 years (11.3)
Parent Gender, Female	16 (100%)
Parent Race, n(%)	
White	16 (100%)
Parent Education, n(%)	
High School,	2 (12.5%)
Some College	6 (37.5%)
Associate Degree	2 (12.5%)
Bachelor Degree	6 (37.5%)
Family Income, n(%)	
< \$10,000	1 (6.3%)
\$10-20,000	4 (25.0%)
\$20-40,000	4 (25.0%)
\$40-80,000	2 (12.5%)
> \$80,000	5 (31.3%)
Employment, n(%)	
Employed at least part time	11 (68.9%)
Homemaker	2 (12.5%)
Medical leave	2 (12.5%)
Unemployed	1 (6.3%)
Parent previous complementary therapies? (Yes), n(%)	5 (31.3%)

Table 14. Complementary Therapy use Prior to Study

Complementary Therapies	Child	Parent
Cranial Sacral Therapy	1	--
Low sugar diet	1	--
Massage	2	3
Meditation	--	1
Prayer	2	1
Reflexology	1	--
Reiki	1	1
Stretching	1	--
Vitamins	1	1
Yoga	1	2

Table 15. Medications Used Prior to Study by Children for Pain or Anxiety

Pain Medications	N(%)
Acetaminophen	8 (50.0%)
Fentanyl	1 (6.3%)
Gabapentin	1 (6.3%)
Ibuprofen	7 (43.8%)
Midol	1 (6.3%)
Morphine	2 (12.5%)
Oxycodone	4 (25.0%)
Oxymorphone	1 (6.3%)
Anxiety Medications	
Lorazepam	5 (31.3%)
Diphenhydramine	1 (6.3%)
Clonazepam	3 (18.8%)

Table 16. Recruitment and Retention

	N(%)
Families Approached	24 (100%)
Consent	21 (87.5%)
Refused	3 (12.5%)
Withdrew	2 (8.3%)
Non-response after consent	3 (12.5%)
Completed Intervention	16 (66.7%)

Table 17. Outcomes for Pain, Anxiety, Heart Rate, and Respiratory Rate (**p < .05, *p < .10)

<i>Verbal (n=8)</i>	<i>Pain^a</i>	<i>Anxiety^a</i>	<i>Heart Rate^b</i>	<i>Respiratory Rate^b</i>
Treatment 1	1.16 (2.04)	0.53 (0.89)	87.75 (16.71)	19.25 (5.12)
Pre/Post	0.80 (1.69)	0.03 (0.07)	78.75 (14.10)	17.75 (2.49)
Mean (SD)	Z = -1.841 p = 0.125	Z = -1.826 p = 0.125	t = 1.723 p = 0.129	t = 0.767 p = 0.468
Treatment 2	1.37 (2.13)	0.49 (0.99)	86.29 (11.80)	20.25 (3.11)
Pre/Post	1.07 (2.03)	0.26 (0.65)	85.63 (14.46)	17.25 (2.38)
Mean (SD)	Z = -1.069 p = 0.500	Z = -1.604 p = 0.250	t = 0.308 p = 0.768	t = 3.550 p = 0.009**
Pre Tx1 to Post Tx 2	1.16 (2.04)	0.53 (0.89)	87.75 (16.71)	19.25 (5.12)
Mean (SD)	1.07 (2.03) Z = .000 p = 1.00	0.26 (0.65) Z = -0.944 p = 0.438	85.63 (14.46) t = 0.438 p = 0.675	17.25 (2.38) t = 0.882 p = 0.407
<i>Non-verbal (n=8)</i>	<i>Pain^a</i>	<i>Anxiety^a</i>	<i>Heart Rate^b</i>	<i>Respiratory Rate^b</i>
Treatment 1	0.79 (2.00)	0.77 (1.56)	99.50 (14.00)	22.63 (6.95)
Pre/Post	0.21 (0.60)	0.12 (0.30)	93.13 (16.55)	19.13 (6.45)
Mean (SD)	Z = -1.342 p = 0.500	Z = -1.604 p = 0.250	t = 1.631 p = 0.147	t = 1.594 p = 0.155
Treatment 2	1.09 (1.17)	1.05 (1.80)	88.50 (8.88)	20.50 (5.32)
Pre/Post	0.37 (0.72)	0.31 (0.70)	88.25 (15.98)	18.25 (6.36)
Mean (SD)	Z = -2.023 p = 0.063*	Z = -1.604 p = 0.250	t = 0.076 p = 0.941	t = 1.468 p = 0.185
Pre Tx1 to Post Tx 2	0.79 (2.00)	0.77 (1.56)	99.50 (14.00)	22.63 (6.95)
Mean (SD)	0.37 (0.72) Z = -0.535 p = 0.750	0.31 (0.70) Z = -0.730 p = 0.625	88.25 (15.98) t = 1.690 p = 0.135	18.25 (6.36) t = 2.031 p = 0.082*

^a Wincoxon Signed Rank Text (non-normal distributions)

^b Paired t-test (normal distributions)

Table 18. Cohen's d Effect Sizes on Outcomes (**= large effect, *= medium effect)

	<i>Pain^a</i>		<i>Anxiety^a</i>		<i>Heart Rate^b</i>		<i>Respiratory Rate^b</i>	
	Verb	N-Verb	Verb	N-Verb	Verb	N-Verb	Verb	N-Verb
Treatment 1	1.04**	0.71*	1.03**	0.88**	1.30**	1.23**	0.35	1.21**
Treatment 2	0.60*	1.17**	0.95**	0.88**	0.25	0.06	2.68**	1.11**
Pre Tx1 to Post Tx2	0	0.27	0.49	0.37	0.33	1.28**	0.67*	1.54**

^a Calculated using Z scores

^b Calculated using t scores

Table 19. Sub Analysis with Children with Pain or Anxiety Before Each Reiki Therapy

Treatment (**p < .05, *p < .10)

<i>Verbal</i>	<i>Pain^a</i>	<i>Anxiety^a</i>	<i>Heart Rate^b</i>	<i>Respiratory Rate^b</i>
Pain Prior to Treatment 1 (n=4)	2.31 (2.48)	0.44 (0.53)	85.50 (24.73)	20.50 (5.51)
Mean (SD)	1.60 (2.22)	0.05 (0.10)	81.50 (18.14)	16.50 (2.52)
	Z = -1.841	Z = -1.604	t = 0.478	t = 1.852
	p=0.125	p=0.250	p=0.665	p=0.161
Pain Prior to Treatment 2 (n=3)	3.20 (2.21)	0.98 (1.49)	85.33 (6.11)	21.33 (2.31)
Mean (SD)	2.48 (3.02)	0.68 (1.02)	98.33 (8.96)	18.00 (3.46)
	Z = -1.069	Z = -1.342	t = -1.508	t = 1.890
	p=0.500	p=0.500	p=0.271	p=0.199
Anxiety Prior to Treatment 1 (n=4)	1.04 (1.78)	1.06 (1.05)	89.50 (23.06)	22.00 (3.65)
Mean (SD)	0.39 (0.56)	0.05 (0.10)	84.50 (16.52)	16.50 (2.52)
	Z = -1.633	Z = -1.826	t = 0.599	t = 5.745
	p=0.250	p=0.125	p=0.591	p=0.010**
Anxiety Prior to Treatment 2 (n=3)	2.53 (2.94)	1.15 (1.35)	80.67 (13.32)	18.00 (3.46)
Mean (SD)	2.48 (3.02)	0.68 (1.02)	85.00 (19.67)	16.00 (3.46)
	Z = -0.447	Z = -1.604	t = -0.589	t = 1.000
	p=1.000	p=0.250	p=0.615	p=0.423
<i>Non-Verbal</i>	<i>Pain^a</i>	<i>Anxiety^a</i>	<i>Heart Rate^a</i>	<i>Respiratory Rate^a</i>
Pain Prior to Treatment 1 (n=2)	3.15 (3.61)	2.25 (3.18)	110.00 (8.49)	22.50 (2.12)
Mean (SD)	0.85 (1.20)	0.05 (0.07)	94.00 (8.49)	18.50 (3.54)
	Z = -1.342	Z = -1.000	Z = -1.414	Z = -1.000
	p=0.500	p=1.000	p=0.500	p=1.000
Pain Prior to Treatment 2 (n=5)	1.74 (0.98)	1.68 (2.09)	88.00 (5.48)	23.20 (1.10)
Mean (SD)	0.59 (0.86)	0.50 (0.87)	84.80 (15.79)	19.20 (4.38)
	Z = -2.023	Z = -1.604	t = 0.673	t = 2.108
	p=0.063*	p=0.250	p=0.538	p=0.103
Anxiety Prior to Treatment 1 (n=3)	0.20 (0.35)	2.05 (2.13)	99.33 (17.01)	25.67 (4.04)
Mean (SD)	0.00 (0.00)	0.32 (0.46)	88.00 (17.44)	19.00 (6.25)
	Z = -1.000	Z = -1.604	t = 3.053	t = 1.387
	p=1.000	p=0.250	p=0.093*	p=0.300
Anxiety Prior to Treatment 2 (n=3)	1.55 (1.31)	2.80 (2.01)	87.33 (3.06)	23.33 (1.16)
Mean (SD)	0.70 (1.13)	0.83 (1.04)	86.00 (7.21)	17.33 (4.62)
	Z = -1.604	Z = -1.604	t = 0.555	t = 3.000
	p=0.250	p=0.250	p=0.635	p=0.095*

^a Wincoxon Signed Rank Text (non-normal distributions)

^b Paired t-test (normal distributions)

Table 20. Sub Analysis for Children in Pain or Anxiety Before Each Reiki Therapy Treatment

(**= large effect, *= medium effect)

	<i>Pain^a</i>		<i>Anxiety^a</i>		<i>Heart Rate^b</i>		<i>Respiratory Rate^b</i>	
	Verb	N-Verb	Verb	N-Verb	Verb	N-Verb	Verb	N-Verb
Pain Tx1	1.71**	1.81**	1.38**	1.15**	0.55*	1.00**	2.14**	2.00**
Pain Tx2	0.97**	1.66**	1.31**	1.18**	2.13**	0.67*	2.67**	2.11**
Anxiety Tx1	1.41**	0.89**	1.69**	1.73**	0.69*	4.32**	6.63**	1.96**
Anxiety Tx2	0.37	1.73**	1.73**	1.73**	0.83**	0.79*	1.41**	4.24**

^a Calculated using Z scores

^b Calculated using t scores

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APPENDIX A

PARTICIPANT DEMOGRAPHIC FORM

Demographic Data Form

Subject ID _____

Child:

Age _____

Gender _____

Race _____

Diagnosis _____

Length on palliative care service _____ months

Educational level (grade in school) _____

Present medication use and dosages

Medication	Dose	Frequency

Previous CAM therapy use _____ yes, _____ no

List CAM therapy if applicable _____

Parent(s):

Age _____

Gender _____

Race _____

Educational level:

_____ less than high school, _____ high school, _____ some college,

_____ Associates Degree, _____ Bachelor's Degree _____ Master's Degree, _____ PhD

Income (yearly):

_____ < 10,000, _____ 10,001 to 20,000, _____ 20,001 to 40,000, _____ 40,001 to 80,000,
_____ > 80,000

Employment status _____

Previous CAM therapy use _____ yes, _____ no

List CAM therapy if applicable _____

APPENDIX B

STRUCTURED INTERVIEW GUIDE

Children

1. Tell me about your Reiki therapy treatment?
(What you liked? What you did not like? What you would have liked done differently?)
2. Tell me (a story) about how the Reiki treatment made you feel?
(Did it make you feel better or worse or the same? Tell me why?)
3. If you could, would you like to continue the Reiki therapy treatments? Why or why not?

Parents

1. Tell me about your child's experience with the Reiki therapy treatment?
(What do you think your child liked? What did they not like? What do you think they would have liked done differently?)
2. Tell me about your child's response to the Reiki therapy treatment
(Did their pain or anxiety change?)
3. Tell me about any changes in your child's medication use or activity levels since the Reiki treatment? (Changes in participation in activities they enjoy, or are important to your child and to your family)
4. If you noticed a change in your child, how long did the change last?
(A few hours, the rest of the day, more than 1 day)
5. If you had the opportunity, would you continue the Reiki therapy treatments? (yes or no)
6. If you were able to go back in time, would you participate in the study again? (yes or no)
7. Is Reiki therapy something you would like to learn how to do so that you could use it on a regular basis? (yes or no).

APPENDIX C

PERMISSIONS TO REPRINT FIGURE 2: SYMPTOM MANAGEMENT MODEL

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APPENDIX F

PERMISSION TO REPRINT FACES PAIN SCALE (FIGURE 8)



Our Foundation Exists to Provide Global Access to our Scale and to Promote Optimal Pain Assessment, Pain Management, and Atraumatic Care.

Dear Susan,

Thank you for completing our web form.

We would be happy for you to use the scale in your dissertation with no licensing fee required.

Here are links to the digital formats of the scale, including all the necessary copyright and trademark information for publication, for your use: [JPEG-Blue](#), [JPEG-Black](#).

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Please let me know if you have any questions. I was happy to see your topic and I would love to read your dissertation. I am finishing my certification in Healing Touch and I find it to be a great tool for people in cancer treatment.

Kind regards,

Connie

Connie M. Baker, MS
Executive Director
Wong-Baker FACES® Foundation
www.WongBakerFACES.org
(405) 608-8083

(405)608-8084 fax

APPENDIX G

INSTITUTIONAL REVIEW BOARD APPROVALS AND MODIFICATIONS

G.1 INITIAL APPROVAL



University of Pittsburgh
Institutional Review Board

3500 Fifth Avenue
Pittsburgh, PA 15213
(412) 383-1480
(412) 383-1508 (fax)
<http://www.ibr.pitt.edu>

Memorandum

To: Susan Thrane MSN RN
From: IRB Office
Date: 8/27/2014
IRB#: [PRO14060613](#)
Subject: Acceptability and Feasibility of Reiki for Symptom Management in Children Receiving Palliative Care

The University of Pittsburgh Institutional Review Board reviewed and approved the above referenced study by the expedited review procedure authorized under 45 CFR 46.110 and 21 CFR 56.110. Your research study was approved under:

45 CFR 46.110.(4)

45 CFR 46.110.(7)

This study has been approved under 45 CFR 46.404 for the inclusion of children. The IRB has determined that the written permission of one parent is sufficient.

The risk level designation is Minimal Risk.

Approval Date: 8/27/2014

Expiration Date: 8/26/2015

For studies being conducted in UPMC facilities, no clinical activities can be undertaken by investigators until they have received approval from the UPMC Fiscal Review Office.

Please note that it is the investigator's responsibility to report to the IRB any unanticipated problems involving risks to subjects or others [see 45 CFR 46.103(b)(5) and 21 CFR 56.108(b)]. Refer to the IRB Policy and Procedure Manual regarding the reporting requirements for unanticipated problems which include, but are not limited to, adverse events. If you have any questions about this process, please contact the Adverse Events Coordinator at 412-383-1480.

The protocol and consent forms, along with a brief progress report must be resubmitted at least one month prior to the renewal date noted above as required by FWA00006790 (University of Pittsburgh), FWA00006735 (University of Pittsburgh Medical Center), FWA00000600 (Children's Hospital of Pittsburgh), FWA00003567 (Magee-Womens Health Corporation), FWA00003338 (University of Pittsburgh)

Medical Center Cancer Institute).

Please be advised that your research study may be audited periodically by the University of Pittsburgh Research Conduct and Compliance Office.

G.2 MODIFICATION FOR NINR CHANGES



University of Pittsburgh
Institutional Review Board

3500 Fifth Avenue
Ground Level
Pittsburgh, PA 15213
(412) 383-1480
(412) 383-1508 (fax)
<http://www.irb.pitt.edu>

Memorandum

To: Susan Thrane
From: IRB Office
Date: 11/4/2014
IRB#: [MOD14060613-03](#) / PRO14060613
Subject: Acceptability and Feasibility of Reiki for Symptom Management in Children Receiving Palliative Care

The University of Pittsburgh Institutional Review Board reviewed and approved the requested modifications by expedited review procedure authorized under 45 CFR 46.110 and 21 CFR 56.110.

Modification Approval Date: 11/4/2014
Expiration Date: 8/26/2015

For studies being conducted in UPMC facilities, no clinical activities that are impacted by the modifications can be undertaken by investigators until they have received approval from the UPMC Fiscal Review Office.

Please note that it is the investigator's responsibility to report to the IRB any unanticipated problems involving risks to subjects or others [see 45 CFR 46.103(b)(5) and 21 CFR 56.108(b)]. Refer to the IRB Policy and Procedure Manual regarding the reporting requirements for unanticipated problems which include, but are not limited to, adverse events. If you have any questions about this process, please contact the Adverse Events Coordinator at 412-383-1480.

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Please be advised that your research study may be audited periodically by the University of Pittsburgh Research Conduct and Compliance Office.

G.3 MODIFICATION TO INCLUDE NON-VERBAL CHILDREN



University of Pittsburgh
Institutional Review Board

3500 Fifth Avenue
Ground Level
Pittsburgh, PA 15213
(412) 383-1480
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<http://www.irb.pitt.edu>

Memorandum

To: Susan Thrane
From: IRB Office
Date: 3/30/2015
IRB#: [MOD14060613-04](#) / PRO14060613
Subject: Acceptability and Feasibility of Reiki for Symptom Management in Children Receiving Palliative Care

The University of Pittsburgh Institutional Review Board reviewed and approved the requested modifications by expedited review procedure authorized under 45 CFR 46.110 and 21 CFR 56.110.

Modification Approval Date: 3/30/2015
Expiration Date: 8/26/2015

For studies being conducted in UPMC facilities, no clinical activities that are impacted by the modifications can be undertaken by investigators until they have received approval from the UPMC Fiscal Review Office.

Please note that it is the investigator's responsibility to report to the IRB any unanticipated problems involving risks to subjects or others [see 45 CFR 46.103(b)(5) and 21 CFR 56.108(b)]. Refer to the IRB Policy and Procedure Manual regarding the reporting requirements for unanticipated problems which include, but are not limited to, adverse events. If you have any questions about this process, please contact the Adverse Events Coordinator at 412-383-1480.

The protocol and consent forms, along with a brief progress report must be resubmitted at least one month prior to the renewal date noted above as required by FWA00006790 (University of Pittsburgh), FWA00006735 (University of Pittsburgh Medical Center), FWA00000600 (Children's Hospital of Pittsburgh), FWA00003567 (Magee-Womens Health Corporation), FWA00003338 (University of Pittsburgh Medical Center Cancer Institute).

Please be advised that your research study may be audited periodically by the University of Pittsburgh Research Conduct and Compliance Office.

APPENDIX H

CONSENT FORMS

H.1 INITIAL CONSENT FORM

Consent to Act as a Participant in a Research Study

Acceptability and Feasibility of Reiki for Symptom Management in Children Receiving Palliative Care

Principle Investigator:

Susan Thrane, PhD(c), MSN, RN
University of Pittsburgh, School of Nursing
3500 Victoria Street, Victoria Building
Pittsburgh, PA 15261
Email: sut11@pitt.edu

Co-Investigators:

Dr. Scott Maurer, MD
4401 Penn Avenue, Floor 9
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Office: 412-692-5055
scott.maurer@chp.edu

Dr. Cynthia Danford, PhD, RN, PNP-BC, CPNP-PC
School of Nursing
458 Victoria Building, 3500 Victoria Street
Pittsburgh, PA 15261
danfordc@pitt.edu

Source of Support: Sigma Theta Tau International Eta Chapter Corrine Barnes Scholarship and University of Pittsburgh School of Nursing Jayne F. Wiggins Memorial Scholarship/Research Award.

There is no cost to participate in this study.

Why is this research being done?

This research study is being conducted to see if Reiki therapy (a complementary non-medical therapy that includes light touch) is acceptable to children and their parents/guardians. We would like to see if children and their parents/guardians like Reiki therapy and to see if it helps them with symptom management while they are getting palliative care.

Who is being asked to take part in this research study?

Children who are between the ages of 7 and 16 who are receiving palliative care with Supportive Care Services through Children's Hospital of Pittsburgh of UPMC are eligible to participate.

We will enroll 20 to 24 children and their parents/guardians in this study. The study will take 5 to 8 days from the first Reiki therapy visit if you decide to participate and sign the consent form.

Your physician is involved as a co-investigator in this research study. Before agreeing to participate, or at any time during your study participation, you may discuss your care with another doctor who is not associated with this research study. You are not under any obligation to participate in any research study offered by your physician or the Supportive Care Services team.

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University Of Pittsburgh
Institutional Review Board

Approval Date: 8/27/2014
Renewal Date: 8/26/2015

IRB #: PRO14060613

What procedures will be performed for research purposes?

Recruitment Visit:

We will ask you to fill out a form with personal information to be used in the study. This information is confidential and only the study team may see it. It will not be shown to anyone not on the study team. When the results of the study are published, all participating family's information will be reported as one number (an average of all information) or in such a way that it is impossible to tell who gave the information.

We will ask the parent to fill in a questionnaire called the Perceived Therapeutic Efficacy Scale (PTES), which has 5 questions. We will also explain and help you fill in a medication diary to list all medications your child takes for pain or anxiety. You will write on the diary each time you give these medications from today until the follow up visit. We will also have your child answer a paper and pencil quality of life questionnaire called the PedsQL.

Finally, we will set up appointments for the Reiki therapy treatments and follow up visit. The Reiki treatments visits must be 1 to 3 days apart and the follow up visit will be 1 to 2 days after the last Reiki treatment visit. Today's visit including reading this form, asking questions, completing all forms and questionnaires, and making the appointments will take about 40 to 70 minutes. The total time for this study from the first Reiki treatment to the follow up visit will be between 5 and 8 days.

Reiki Therapy Visits:

There will be 2 Reiki therapy treatments 1 to 3 days apart that will take place in your home. Each treatment will last about 24 minutes. Your child will be fully clothed throughout the treatment and you may be in the room if you or your child chooses. The treatments will take place either on a massage table that we will bring or any place your child is comfortable (such as a bed or sofa). During the treatment, the Reiki therapist will place their hands lightly on 12 different locations on your child's body and hold each position for 2 minutes. Six of the hand positions are on the front of the body and 6 are on the child's back. If the child can not lay on their stomach or back, we can do the treatments while the child is lying on their side or sitting up in a chair. We will ask your child to rate his or her pain and anxiety using paper and pencil forms. We will also count her or her heart rate and respiratory rate before and after each Reiki therapy treatment. These assessments will take about 5 minutes before and after the Reiki therapy treatment. The total time for the two Reiki treatment visits is about 45 minutes each including the symptom rating.

Follow Up Visit:

The PI will conduct a follow up visit at your home 1 to 2 days after the second Reiki treatment. At the follow up visit, we will ask you and your child a few questions about the child's experience with the Reiki therapy treatment. The questions for your child will take about 5 to 10 minutes and the questions for the parent will take about 10 to 15 minutes. We will also have your child complete the paper and pencil quality of life questionnaire that he or she completed at the recruitment visit and the paper and pencil pain and anxiety measures in addition to counting his or her heart and respiratory rates. The follow up visit will take between 30 and 45 minutes.



What are the possible risks, side effects, and discomforts of this research study?

There is a risk for becoming tired during while filling out the paper and pencil questions and while answering questions in the follow up visit. If this happens we will stop and rest or stop completely if you or your child asks.

There is a risk for becoming tired or having pain due to the child's illness during the Reiki therapy treatment. If either of these happens, we will take a break or stop completely if the you or your child asks.

What are the possible benefits from taking part in this study?

The child may experience feelings of relaxation.

What are the risks to my privacy if I take part in this study?

There is a slight risk that someone may find out you participated in this study. We will take care to make sure that your information is not seen by anyone that is not a member of the study team. We will assign a code number to your information and keep the list that shows names in a separate locked cabinet. No information will be put in your medical record. Data will be kept for a minimum of 7 years following completion of this study.

In addition to the investigators listed on the first page of this authorization (consent) form and their research staff, authorized representatives of the University of Pittsburgh Research Conduct and Compliance Office may review your identifiable research information for the purpose of monitoring the appropriate conduct of this research study. In unusual cases, the investigators may be required to release identifiable information related to your participation in this research study in response to an order from a court of law. If the investigators learn that you or someone with whom you are involved is in serious danger or potential harm, they will need to inform, as required by Pennsylvania law, the appropriate agencies.

Is my participation in this research study voluntary?

Your participation in this research study is entirely voluntary. You may want to discuss this study with your family and friends and your personal physician before agreeing to participate. If there are any words you do not understand, feel free to ask us. The investigators will be available to answer your current and future questions.

Whether or not you provide your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh. Whether or not you provide your consent for participation in this research study will have no effect on your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

May I withdraw, at a future date, my consent for participation in this research study?

You can, at any time withdraw from this research study. This means that you will also be withdrawn from further participation in this research study. Any identifiable research or medical information obtained as part of this study prior to the date that you withdrew your consent will continue to be used and disclosed by the investigators for the purposes described above.



To formally withdraw from this research study, you should provide a written and dated notice of this decision to the principal investigator of this research study at the address listed on the first page of this form. Your decision to withdraw from this study will have no effect on your current or future relationship with the University of Pittsburgh.

Your decision to withdraw your consent for participation in this research study will have no effect on your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

It is possible that you may be removed from the research study by the researchers if, for example you do not complete the follow up appointment.

Will I be paid if I take part in this research study?

The parent will be given one \$10 gift card at the end of the follow up visit.

VOLUNTARY CONSENT

The above information has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions, voice concerns or complaints about any aspect of this research study during the course of this study, and that such future questions, concerns or complaints will be answered by a qualified individual or by the investigator(s) listed on the first page of this consent document at the telephone number(s) given.

I understand that I may always request that my questions, concerns or complaints be addressed by a listed investigator. I understand that I may contact the Human Subjects Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations that occurred during my participation. By signing this form I agree to participate in this research study. A copy of this consent form will be given to me.

I understand that, as a minor (age less than 18 years), the below-named child is not permitted to participate in this research study without my consent. Therefore, by signing this form, I give my consent for his/her participation in this research study.

Legal Guardian's Name (Print)

Relationship to Participant (Child)

Legal Guardian Signature

Date

CHILD ASSENT (to be used with children who are developmentally able to sign)
This research has been explained to me, and I agree to participate.

Signature of Child-Subject

Date

Printed Name of Child-Subject

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University Of Pittsburgh
Institutional Review Board

Approval Date: 8/27/2014
Renewal Date: 8/26/2015

IRB #: PRO14060613

INVESTIGATOR CERTIFICATION:

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions, concerns or complaints as they arise.

I further certify that no research component of this protocol was begun until after this consent form was signed.

Printed Name of Person Obtaining Consent

Role in Research Study

Signature of Person Obtaining Consent

Date (Time if placed in medical record)

If you have any questions about your rights as a research subject or wish to talk to someone other the research team, please call the University of Pittsburgh Human Subjects Protection Advocate toll-free at 866-212-2668.



H.2 NINR MODIFICATION REVISED CONSENT

Consent to Act as a Participant in a Research Study

Acceptability and Feasibility of Reiki for Symptom Management in Children Receiving Palliative Care

Principle Investigator:

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Source of Support: Sigma Theta Tau International Eta Chapter Corrine Barnes Scholarship, University of Pittsburgh School of Nursing Jayne F. Wiggins Memorial Scholarship/Research Award, and the National Institute of Nursing Research (1F31NR014762-01A1)

There is no cost to participate in this study.

Why is this research being done?

This research study is being conducted to see if Reiki therapy (a complementary non-medical therapy that includes light touch) is acceptable to children and their parents/guardians. We would like to see if children and their parents/guardians like Reiki therapy and to see if it helps them with symptom management while they are getting palliative care.

Who is being asked to take part in this research study?

Children who are between the ages of 7 and 16 who are receiving palliative care with Supportive Care Services through Children's Hospital of Pittsburgh of UPMC are eligible to participate.

We will enroll 20 to 24 children and their parents/guardians in this study. The study will take 2 to 3 days from the first Reiki therapy visit if you decide to participate and sign the consent form.

Your physician is involved as a co-investigator in this research study. Before agreeing to participate, or at any time during your study participation, you may discuss your care with another doctor who is not associated with this research study. You are not under any obligation to participate in any research study offered by your physician or the Supportive Care Services team.

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University Of Pittsburgh
Institutional Review Board

Approval Date: 10/3/2014
Renewal Date: 8/26/2015

IRB #: PRO14060613

What procedures will be performed for research purposes?

Recruitment Visit:

We will ask you to fill out a form with personal information to be used in the study. This information is confidential and only the study team may see it. It will not be shown to anyone not on the study team. When the results of the study are published, all participating family's information will be reported as one number (an average of all information) or in such a way that it is impossible to tell who gave the information.

We will set up appointments for the Reiki therapy treatments. The Reiki treatments visits must be 1 to 3 days apart. Today's visit including reading this form, asking questions, completing all forms and making the appointments will take about 25 to 35 minutes. The total time for this study from the first Reiki treatment will be between 3 and 5 days.

Reiki Therapy Visits:

There will be 2 Reiki therapy treatments 1 to 3 days apart that will take place in your home. Each treatment will last about 24 minutes. Your child will be fully clothed throughout the treatment and you may be in the room if you or your child chooses. The treatments will take place either on a massage table that we will bring or any place your child is comfortable (such as a bed or sofa). During the treatment, the Reiki therapist will place their hands lightly on 12 different locations on your child's body and hold each position for 2 minutes. Six of the hand positions are on the front of the body and 6 are on the child's back. If the child can not lay on their stomach or back, we can do the treatments while the child is lying on their side or sitting up in a chair. We will ask your child to rate his or her pain and anxiety using paper and pencil forms. We will also count her or her heart rate and respiratory rate before and after each Reiki therapy treatment. These assessments will take about 5 minutes before and after the Reiki therapy treatment. The total time for first Reiki treatment visit is about 45 minutes including the symptom rating. Right after the second Reiki therapy treatment, we will ask you and your child a few questions about the child's experience with the Reiki therapy treatment. The questions for your child will take about 5 minutes and the questions for the parent will take about 10 minutes. The total time for the second Reiki treatment visit and interview will be about 1 hour.

What are the possible risks, side effects, and discomforts of this research study?

There is a risk for becoming tired during while filling out the paper and pencil questions and while answering questions in the follow up visit. If this happens we will stop and rest or stop completely if you or your child asks.

There is a risk for becoming tired or having pain due to the child's illness during the Reiki therapy treatment. If either of these happens, we will take a break or stop completely if the you or your child asks.

What are the possible benefits from taking part in this study?

The child may experience feelings of relaxation.



What are the risks to my privacy if I take part in this study?

There is a slight risk that someone may find out you participated in this study. We will take care to make sure that your information is not seen by anyone that is not a member of the study team. We will assign a code number to your information and keep the list that shows names in a separate locked cabinet. No information will be put in your medical record. Data will be kept for a minimum of 7 years following completion of this study.

In addition to the investigators listed on the first page of this authorization (consent) form and their research staff, authorized representatives of the University of Pittsburgh Research Conduct and Compliance Office may review your identifiable research information for the purpose of monitoring the appropriate conduct of this research study. In unusual cases, the investigators may be required to release identifiable information related to your participation in this research study in response to an order from a court of law. If the investigators learn that you or someone with whom you are involved is in serious danger or potential harm, they will need to inform, as required by Pennsylvania law, the appropriate agencies.

Is my participation in this research study voluntary?

Your participation in this research study is entirely voluntary. You may want to discuss this study with your family and friends and your personal physician before agreeing to participate. If there are any words you do not understand, feel free to ask us. The investigators will be available to answer your current and future questions.

Whether or not you provide your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh. Whether or not you provide your consent for participation in this research study will have no effect on your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

May I withdraw, at a future date, my consent for participation in this research study?

You can, at any time withdraw from this research study. This means that you will also be withdrawn from further participation in this research study. Any identifiable research or medical information obtained as part of this study prior to the date that you withdrew your consent will continue to be used and disclosed by the investigators for the purposes described above.

To formally withdraw from this research study, you should provide a written and dated notice of this decision to the principal investigator of this research study at the address listed on the first page of this form. Your decision to withdraw from this study will have no effect on your current or future relationship with the University of Pittsburgh.

Your decision to withdraw your consent for participation in this research study will have no effect on your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

It is possible that you may be removed from the research study by the researchers if, for example you do not complete the follow up appointment.



Will I be paid if I take part in this research study?

The parent will be given one \$40 gift card at the end of second visit.

VOLUNTARY CONSENT

The above information has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions, voice concerns or complaints about any aspect of this research study during the course of this study, and that such future questions, concerns or complaints will be answered by a qualified individual or by the investigator(s) listed on the first page of this consent document at the telephone number(s) given.

I understand that I may always request that my questions, concerns or complaints be addressed by a listed investigator. I understand that I may contact the Human Subjects Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations that occurred during my participation. By signing this form I agree to participate in this research study. A copy of this consent form will be given to me.

I understand that, as a minor (age less than 18 years), the below-named child is not permitted to participate in this research study without my consent. Therefore, by signing this form, I give my consent for his/her participation in this research study.

Legal Guardian's Name (Print) Relationship to Participant (Child)

Legal Guardian Signature Date

CHILD ASSENT (to be used with children who are developmentally able to sign)
This research has been explained to me, and I agree to participate.

Signature of Child-Subject Date

Printed Name of Child-Subject

INVESTIGATOR CERTIFICATION:

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions, concerns or complaints as they arise.

I further certify that no research component of this protocol was begun until after this consent form was signed.

Printed Name of Person Obtaining Consent

Role in Research Study

Signature of Person Obtaining Consent

Date (Time if placed in medical record)

If you have any questions about your rights as a research subject or wish to talk to someone other than the research team, please call the University of Pittsburgh Human Subjects Protection Advocate toll-free at 866-212-2668.



H.3 CONSENT ADDING NON-VERBAL CHILDREN

Consent to Act as a Participant in a Research Study

Acceptability and Feasibility of Reiki for Symptom Management in Children Receiving Palliative Care

Principle Investigator:

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Source of Support: Sigma Theta Tau International Eta Chapter Corrine Barnes Scholarship, University of Pittsburgh School of Nursing Jayne F. Wiggins Memorial Scholarship/Research Award, and the National Institute of Nursing Research (1F31NR014762-01A1)

There is no cost to participate in this study.

Why is this research being done?

This research study is being conducted to see if Reiki therapy (a complementary non-medical therapy that includes light touch) is acceptable to children and their parents/guardians. We would like to see if children and their parents/guardians like Reiki therapy and to see if it helps them with symptom management while they are getting palliative care.

Who is being asked to take part in this research study?

Children who are between the ages of 7 and 16 who are receiving palliative care with Supportive Care Services through Children's Hospital of Pittsburgh of UPMC are eligible to participate.

We will enroll 20 to 24 children and their parents/guardians in this study. The study will take 2 to 3 days from the first Reiki therapy visit if you decide to participate and sign the consent form.

Your physician is involved as a co-investigator in this research study. Before agreeing to participate, or at any time during your study participation, you may discuss your care with another doctor who is not associated with this research study. You are not under any obligation to participate in any research study offered by your physician or the Supportive Care Services team.

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University Of Pittsburgh
Institutional Review Board

Approval Date: 3/30/2015
Renewal Date: 8/26/2015

IRB #: PRO14060613

What procedures will be performed for research purposes?

Recruitment Visit:

We will ask you to fill out a form with personal information to be used in the study. This information is confidential and only the study team may see it. It will not be shown to anyone not on the study team. When the results of the study are published, all participating family's information will be reported as one number (an average of all information) or in such a way that it is impossible to tell who gave the information.

We will set up appointments for the Reiki therapy treatments. The Reiki treatments visits must be 1 to 3 days apart. Today's visit including reading this form, asking questions, completing all forms and making the appointments will take about 25 to 35 minutes. The total time for this study from the first Reiki treatment will be between 3 and 5 days.

Reiki Therapy Visits:

There will be 2 Reiki therapy treatments 1 to 3 days apart that will take place in your home. Each treatment will last about 24 minutes. Your child will be fully clothed throughout the treatment and you may be in the room if you or your child chooses. The treatments will take place either on a massage table that we will bring or any place your child is comfortable (such as a bed or sofa). During the treatment, the Reiki therapist will place their hands lightly on 12 different locations on your child's body and hold each position for 2 minutes. Six of the hand positions are on the front of the body and 6 are on the child's back. If the child can not lay on their stomach or back, we can do the treatments while the child is lying on their side or sitting up in a chair. We will ask your child to rate his or her pain and anxiety using paper and pencil forms. We will also count her or her heart rate and respiratory rate before and after each Reiki therapy treatment. These assessments will take about 3 minutes before and after the Reiki therapy treatment. The total time for first Reiki treatment visit is about 35 minutes including the symptom rating. Right after the second Reiki therapy treatment, we will ask you and your child (if they are able) a few questions about the child's experience with the Reiki therapy treatment. The questions for your child will take less than 5 minutes and the questions for the parent will take less than 10 minutes. The total time for the second Reiki treatment visit and interview will be about 50 minutes.

What are the possible risks, side effects, and discomforts of this research study?

There is a risk for becoming tired during while filling out the paper and pencil questions and while answering questions in the follow up visit. If this happens we will stop and rest or stop completely if you or your child asks.

There is a risk for becoming tired or having pain due to the child's illness during the Reiki therapy treatment. If either of these happens, we will take a break or stop completely if the you or your child asks.

What are the possible benefits from taking part in this study?

The child may experience feelings of relaxation.



What are the risks to my privacy if I take part in this study?

There is a slight risk that someone may find out you participated in this study. We will take care to make sure that your information is not seen by anyone that is not a member of the study team. We will assign a code number to your information and keep the list that shows names in a separate locked cabinet. No information will be put in your medical record. Data will be kept for a minimum of 7 years following completion of this study.

In addition to the investigators listed on the first page of this authorization (consent) form and their research staff, authorized representatives of the University of Pittsburgh Research Conduct and Compliance Office may review your identifiable research information for the purpose of monitoring the appropriate conduct of this research study. In unusual cases, the investigators may be required to release identifiable information related to your participation in this research study in response to an order from a court of law. If the investigators learn that you or someone with whom you are involved is in serious danger or potential harm, they will need to inform, as required by Pennsylvania law, the appropriate agencies.

Is my participation in this research study voluntary?

Your participation in this research study is entirely voluntary. You may want to discuss this study with your family and friends and your personal physician before agreeing to participate. If there are any words you do not understand, feel free to ask us. The investigators will be available to answer your current and future questions.

Whether or not you provide your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh. Whether or not you provide your consent for participation in this research study will have no effect on your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

May I withdraw, at a future date, my consent for participation in this research study?

You can, at any time withdraw from this research study. This means that you will also be withdrawn from further participation in this research study. Any identifiable research or medical information obtained as part of this study prior to the date that you withdrew your consent will continue to be used and disclosed by the investigators for the purposes described above.

To formally withdraw from this research study, you should provide a written and dated notice of this decision to the principal investigator of this research study at the address listed on the first page of this form. Your decision to withdraw from this study will have no effect on your current or future relationship with the University of Pittsburgh.

Your decision to withdraw your consent for participation in this research study will have no effect on your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

It is possible that you may be removed from the research study by the researchers if, for example you do not complete the follow up appointment.



_____ If the child is non-verbal and is unable to understand the research study and unable to provide assent, the legal guardian shall initial this paragraph.

This child is unable to provide assent to participate in this study. The legal guardian has consented for their child to participate in this study and understands that if there is any sign from the child of unwillingness to participate during a Reiki therapy treatment, the treatment will be stopped and the parent consulted.

Printed Name of Person from
Research Team

Signature of Person from
Research Team

INVESTIGATOR CERTIFICATION:

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions, concerns or complaints as they arise.

I further certify that no research component of this protocol was begun until after this consent form was signed.

Printed Name of Person from Research
Team Obtaining Consent

Role in Research Study

Signature of Person from Research
Team Obtaining Consent

Date

If you have any questions about your rights as a research subject or wish to talk to someone other than the research team, please call the University of Pittsburgh Human Subjects Protection Advocate toll-free at 866-212-2668.



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