THE FEASIBILITY AND ACCEPTABILITY OF A BEHAVIORAL-EDUCATIONAL INTERVENTION - THE RELAX TO SLEEP PROGRAM - TO INCREASE PEDIATRIC SLEEP DURING HOSPITALIZATION: A PILOT RANDOMIZED CONTROLLED TRIAL

By

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A thesis submitted in conformity with the requirements for the degree of Doctor of Philosophy in Nursing Science

Lawrence S. Bloomberg Faculty of Nursing
University of Toronto

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The Feasibility and Acceptability of a Behavioural-Educational Intervention – the RELAX TO SLEEP Program – to Increase Pediatric Sleep During Hospitalization: A Pilot Randomized Controlled Trial

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Abstract

Background: Hospitalization can contribute to common sleep difficulties related to environmental, physiological, and psychological factors. Interventions aimed at hospitalized children need to be developed and piloted with rigorous evaluative methods. The primary purpose of this study was to examine the feasibility and acceptability of a behavioral-educational intervention – the RELAX TO SLEEP program – aimed at increasing nighttime sleep for hospitalized children. Methods: This study was a pilot randomized controlled trial. Children between the ages of 4 and 10 years, expected to stay for 3 nights in hospital, with a parent staying overnight were included. Children were excluded if they were receiving palliative care; were diagnosed with a sleep or anxiety disorder; had limited movements of extremities or had cognitive impairment; or received sedation. Forty-eight children and their caregivers consented and were randomized to either the RELAX TO SLEEP intervention group (n=24) or the Usual Care control group (n=24). The RELAX TO SLEEP program consisted of a one-on-one discussion with the researcher about sleep and sleep hygiene, a standardized educational booklet about sleep, and a relaxation breathing (RB) exercise for the child. Usual Care participants received no information about sleep or relaxation. Children wore actigraphs for 3 days and nights and
completed sleep diaries. Sleep outcomes included: total nocturnal sleep (19h30-07h29), number of nighttime awakenings, longest period of uninterrupted nocturnal sleep, and total daytime (07h30-19h29) sleep. Other outcomes measured at baseline and at 7 days post-discharge, included anxiety (Spence Pre-school/Children Anxiety Subscales), sleep habits (Children’s Sleep Habits Questionnaire [CSHQ]), and post-hospital maladaptive behaviours (Post-Hospital Behaviour Questionnaire [PHBQ]).

**Results:** Of the 68 eligible families approached, 71% (n=48) agreed to participate. Both the RELAX TO SLEEP and Usual Care group were compliant in wearing the actigraph and completing sleep diaries. Eighty-five per cent (n=19/22) of the Relax to Sleep participants reported using the RB at least once per day in hospital, and over half used it 2-3 times per day. Parental reports indicated that their child enjoyed using RB (18/22; 82%), that it was easy to use (21/22; 95%), and would use it again in the future (18/22; 82%). Parents also reported that they enjoyed the discussion about sleep and found the information helpful (21/22; 95%). Children in the RELAX TO SLEEP group obtained a mean of 50 minutes more nighttime sleep compared to the UC group (419 ± 7.84 min vs. 369.7 ± 106.4 min, group difference 49.64 min, \( t = 1.76, p=0.085 \)), despite having the same number of nighttime awakenings (14.7 [SD 5.83] and 14.7 [SD 4.7] respectively). Improved CSHQ scores at follow-up were noted for the RELAX TO SLEEP group (baseline score 44.04 [SD 7.17] to follow-up 42.38 [SD 5.41]) compared to the increase in sleep disturbance behaviour noted in the Usual Care group (baseline score 45.58 [7.82] to follow-up 47.52 [7.47]). There were no notable differences in anxiety or PHBQ scores; however, the majority of children in this sample (73%, n=32/44) scored 81 or higher on the PHBQ indicating the development of at least one new-onset maladaptive behaviour during the post-discharge period. **Conclusion:** The RELAX TO SLEEP program proposed in this study was feasible and acceptable to children and their caregivers. Further evaluation of the intervention with a large scale, multicenter RCT is needed.
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CHAPTER 1
Introduction and Background

“Early to bed, early to rise, makes a man healthy, wealthy and wise” is an old proverb coined by Benjamin Franklin on the importance of sleep. Sleep has been defined as a reversible behavioral state of decreased responsiveness and perceptual disengagement from the environment (Carskadon & Dement, 2005). Despite the common misconception that sleep is a passive state, in actuality, sleep is a period of considerable neurological and physiologic activity (Zee & Turek, 1999). Sleep is especially important for the physical and cognitive development of children, as it is believed to play a significant role in the growth and healing of body tissues, learning and processing of memory, and central nervous system repair (Zee & Turek, 1999). Sleep disturbance or lack of sufficient sleep in children has negative consequences, including impaired daytime behavior, mood, and performance and learning (Fallone, Seifer, Acebo, & Carskadon, 2002). Furthermore, inadequate sleep hinders the physiological and emotional regeneration needed to overcome illness (White, Williams, Alexander, Powell-Cope, & Conlon, 1990).

During hospitalization, sleep may be altered at a time when the benefits of sleep are needed most. It is often suggested that there is an increased need for sleep during periods of illness and stress, and that sleep aids in recovery (Southwell & Wistow, 1995). Stresses of hospitalization may exacerbate common sleep difficulties in children. As many as 20-30% of young children and adolescents in the community experience sleep problems or have some type of sleep disturbance (Dahl, 1998; Mindell & Owens, 2003a). Although the prevalence of sleep problems in hospitalized children is unknown, children may develop at least short-term problems when ill, particularly if hospitalized.
It has been noted that children have significantly later bedtimes when hospitalized compared to their usual bedtime at home. They lose 20-25% of their expected sleep time, which has been attributed to delayed sleep onset, frequent disruptions during the night, early termination of sleep, decreased nighttime sleep, and shorter periods of uninterrupted sleep (Cureton-Lane & Fontaine, 1997; Hagemann, 1981a, 1981b; White, Powell, Alexander, Williams, & Conlon, 1988; White et al., 1990). Studies conducted in the pediatric intensive care unit found decreased nighttime sleep, frequent awakenings and short periods of uninterrupted sleep (Corser, 1996; Cureton-Lane & Fontaine, 1997). A study examining the sleep quantity and sleep patterns of hospitalized children found frequent nighttime awakenings and significant decreases in sleep quantity in children between the ages of 12 months and 18 years (Stremler et al., 2009).

Hospitalization contributes to the sleep disturbance of children in a number of ways. Children who are hospitalized are attempting to sleep in a new environment, which is not conducive to their sleep needs. Loud noises from alarms and frequent interruptions from health care providers make initiating and maintaining sleep difficult. Altering or eliminating sleep routines may also affect the child’s sleep in hospital (Webster & Thompson, 1986). Moreover sleep restriction may be heightened due to the anxiety or stress that the child may experience due to hospitalization. Anxiety may influence the ability of the child to initiate and maintain sleep, as it is accompanied with other physiological activity that is counterproductive to the initiation and maintenance of sleep (Chrousos & Gold, 1992). A high level of physiological arousal from the stimulation of the sympathetic nervous system leads to increase vigilance in moments of stress, and increases in heart rate, respiratory rate, skin and core body temperature, muscle tone, and vasoconstriction of peripheral blood flow. Again, these elements are counterproductive to the onset and maintenance of sleep (Smith, 1999).
Other factors that may cause sleep disturbances in children include environmental factors related to hospitalization. The hospital environment is characterized by high levels of light and noise and frequent interruptions from health care providers (Redeker, 2000; Southwell & Wistow, 1995; Stremler et al., 2009). Often, health care providers awaken children to complete routine nursing care and procedures. Frequent awakenings during nighttime sleep may further increase physiological arousal, making it difficult for the child to fall back asleep, therefore increasing the wake-time after sleep onset (WASO). WASO is the total amount of time (in minutes) an individual is awake after initiating the first sleep episode. This is problematic on two fronts: 1) increases in WASO will hinder the child from obtaining adequate amounts of sleep since they are losing out on sleep minutes, and 2) frequent awakenings will make it difficult for the child to progress into the deeper stages of sleep necessary for recovery.

In addition to the development of sleep difficulties due to disturbances of the hospital setting, children are also likely to develop maladaptive behavioural changes during the post-hospitalization period. Maladaptive behaviours include general anxiety, apathy, withdrawal, and sleep problems related to sleep anxieties (Kain et al., 2002). Furthermore, children have increases in WASO and less efficient sleep during the post-hospitalization period compared to the pre-hospitalization period (MacLaren & Kain, 2008).

Sleep is imperative during the hospitalization period as well as upon discharge home, and interventions aimed at promoting sleep in children need to be examined. One study evaluating an audio taped storybook to promote sleep in hospitalized children has been reported, with limited applicability (White et al., 1988). Hospitalized children with parents not staying overnight were randomized to receive either a story audio taped by a parent, a story audio taped by a stranger, or no story at all. Children who received the recorded story from their parent took significantly
longer to fall asleep compared to the other groups. The authors attribute this finding to the psychological discomfort generated by remembrances of home.

Currently, the treatments that are recommended for long standing sleep problems in healthy children in the community include behavioral interventions such as systematic ignoring or graduated extinction. These techniques instruct parents to ignore bedtime crying and tantrums for specified periods. While graduated extinction has been documented to be efficacious in children with established sleep problems, the use of such behavioural interventions are inappropriate for a hospital setting (Mindell, 1999; Mindell, Kuhn, Lewin, Meltzer, & Sadeh, 2006). Such treatments should only be introduced when a child is well. Given the lack of interventions available for the promotion of sleep in hospital and the prevention of sleep disturbance in the immediate post-hospitalization period, techniques involving both the parent and child warrant further exploration.

Parental education in combination with other techniques have been reported to be efficacious treatments in infants and young children with bedtime resistance and night wakings (Mindell et al., 2006). As a component of a sleep intervention, parental education aimed at providing basic information about the importance of sleep, the development of healthy sleep hygiene practices, as well as strategies to implement during hospitalization and upon discharge may be a feasible approach to promote sleep in hospitalized children. Furthermore, child participation in a behavioural intervention such as a relaxation-based therapy may also prove to be beneficial in sleep promotion. Children who are hospitalized may feel anxious about their hospitalization, which may lead to high levels of physiological and cognitive arousal. When the arousal system is heightened, sleep is difficult to achieve. Relaxation-based interventions such as, deep breathing or abdominal breathing exercises, can be used to deactivate the arousal system.
and may offer a promising avenue to behavioral control of psychophysiological states (Morin et al., 1999; Ritz & Roth, 2003).

More research with rigorous designs and objective methods of measuring sleep patterns, such as actigraphy, need to be conducted in hospitalized children. Simple interventions such as educational strategies in combination with a relaxation technique such as controlled breathing may prove to be beneficial in promoting sleep in hospital for children, and also in the prevention of sleep disturbances in the post-hospitalization period. Given the lack of evidence-based interventions aimed at promoting child sleep during hospitalization as well as post-discharge, an important first step is to develop and pilot a sleep intervention. Therefore the primary purpose of this pilot randomized controlled trial was to determine the feasibility and acceptability of a behavioural-educational sleep intervention in hospitalized children. This pilot study also provided preliminary indicators of the effects of this intervention compared to usual care in hospitalized children.
CHAPTER 2
Review of the Literature

SLEEP PHYSIOLOGY

Sleep Stages

Normal human sleep is comprised of two states: non-rapid eye movement (NREM), and rapid eye movement (REM) sleep with five stages. The five stages are notable by polysomnography, which measures electroencephalographic (EEG) patterns, eye movement, and muscle tone (Mindell & Owens, 2003a). The two states alternate cyclically across a sleep episode. The sleep cycle begins with a NREM state and proceeds in stages of increasing depth from Stages 1 to 4, from a wakeful state, to sleep, to deep sleep and ends with REM. In adults, the cycle usually lasts about 90 minutes and repeats itself about four to five times in a night (Carskadon & Dement, 2005). Stage 1 sleep is a transition state between sleep and wakefulness and lasts for only a few minutes at the onset of sleep. This stage is characterized by a sensation of drowsiness and relaxation, slight rolling of the eyes, and a gradual decrease in vital signs (pulse, blood pressure, and respirations) (Lee, 1997). This stage is often referred to as “light sleep” (Mindell & Owens, 2003a). An individual in stage 1 can be easily awakened because it is associated with a low arousal threshold. For example, softly calling a person’s name or quietly closing a door can easily discontinue sleep. Stage 1 NREM sleep accounts for approximately 2% to 5% of total sleep (Adair & Bauchner, 1993). An increase in the amount and percentage of stage 1 sleep signifies severely disrupted sleep.

Following this brief episode of stage 1 sleep is stage 2 NREM sleep, which is considered the onset of “true” sleep (Davis, Parker, & Montgomery, 2004). In stage 2, a more intense stimulus is required to produce arousal. The same stimulus that produced arousal from stage 1
sleep often results in no awakening in stage 2 sleep. Some characteristics of stage 2 NREM sleep include: decreased eye movements; reduced muscle tone; continued deceleration of respirations, blood pressure, and heart rate; and a decline in body temperature and metabolism (Lee, 1997). The initial stage 2 period lasts from 5 to 25 minutes (Mindell & Owens, 2003a).

The third and fourth stage of NREM sleep are nearly identical and are often referred to as delta, deep, or slow-wave sleep (SWS) (Zee & Turek, 1999). The individual enters into stage 3 NREM sleep when the slow-wave activity, known as delta waves, account for more than 20% but less than 50% of the EEG activity (Carskadon & Dement, 2005). Stage 3 sleep is a transitional period to stage 4 NREM as more and more high-voltage slow wave activity occurs. Stage 4 is identified when delta or slow wave activity comprises more than 50% of the EEG record. During slow-wave sleep the highest arousal threshold occurs, therefore an incrementally larger stimulus to produce an arousal from stage 3 or 4 sleep is needed than from stage 1 or 2 sleep. Vital signs are at their lowest during this stage and body temperature is very low (Lee, 1997). During slow-wave sleep the body does most of its repair work. The release of growth hormone during SWS clearly links sleep to the regulation of somatic growth, as well as to many other neuroendocrine functions (Mindell & Owens, 2003a). Seventy percent of daily secretion of growth hormone occurs during sleep. Growth hormone enhances bone synthesis and erythropoietin formation for red blood cell formation (Robinson, Weitzel, & Henderson, 2005; Southwell & Wistow, 1995). Furthermore, the rate of healing of damaged tissue is greatest during deep sleep (Southwell & Wistow, 1995).

The final stage of the sleep cycle is REM. REM sleep is characterized by frequent bursts of rapid eye movement along with paralysis or nearly absent muscle tone. REM sleep is the stage when the most vivid and prolonged dreaming occurs. It is thought that the skeletal muscle
paralysis is to prevent the sleeping individual from acting out their dreams. The EEG activity in REM is similar to that of an awake state, thus suggesting that higher brain functioning is actively involved (Carskadon & Dement, 2005). Furthermore, irregular respirations and heart rate as well as fluctuations of other vital signs are also features of REM sleep. REM sleep is involved in vital cognitive functions such as the consolidation of memory; as well, REM sleep is integral to the growth and development of the central nervous system (Mindell & Owens, 2003a).

Non-REM and REM sleep alternate throughout the night in cycles of about 90 to 120 minutes. The relative proportion of REM and NREM sleep per cycle changes across the night such that REM sleep episodes usually become longer across the night and SWS (Stages 3 and 4 of NREM sleep) predominates at the beginning and then occupies less time in the latter cycles (Carskadon & Dement, 2005).

**Developmental Consideration of Sleep**

Age is considered to be the strongest factor affecting the pattern of sleep across the night (Carskadon & Dement, 2005). The amount of sleep necessary to feel rested decreases from birth to adulthood. During infancy, REM sleep comprises as much as 50% of an infant’s sleep and the transition from wake to sleep is often accomplished through REM sleep, called *active sleep* in newborns (Carskadon & Dement, 2005; Lee, 1997). Sleeping through the night in infancy is considered a milestone; however it is not always maintained usually because of social factors (Thiedke, 2001). The recommended amount of sleep for infants between 2 to 12 months is 9 to 12 hours of nighttime sleep, along with daytime naps ranging from 2 to 4.5 hours (Mindell & Owens, 2003a).

During toddler years and preschool years, the drive for independence may lead to increased bedtime resistance. Furthermore, the development of imagination may heighten
nighttime fears, making it difficult to initiate sleep independently. Bedtime routines are essential for parents to develop and maintain in order to help ease the transition from high levels of activity during the day to sleep onset. Toddlers require 12 to 13 hours of sleep over a 24 hour period plus usually 1 nap a day, whereas the preschooler requires 11 to 12 hours of sleep over a 24 hour period with usually no nap or one nap (Mindell & Owens, 2003a).

The sleep requirements of school-aged children are 10 to 11 hours of nighttime sleep, and adolescents require 9 to 9 ½ hours of nighttime sleep. Sleep problems associated with pre-adolescents and adolescents include increasing independence from parental supervision and increased social demands. This drive for independence often creates a shift in responsibility for health habits resulting in less parental enforcement of appropriate bedtimes. Other factors of delayed sleep onset include lifestyle demands, such as homework, after school jobs, and social activities. Furthermore, media such as television, and other electronics such as computer, video games, and the internet all compete increasingly for sleep time (Mindell & Owens, 2003a; Thiedke, 2001). A sleep phase delay during the onset of puberty in adolescents occurs, in which there is a delay in evening bedtimes and sleep onset followed with later morning awakenings. The sleep phase delay is thought to be associated with pubertal changes in the biology of the sleep/wake cycles (Oskar, Achermann, & Carskadon, 2005; Touchette, Mongrain, Petit, Tremblay, & Montplaisir, 2008).

Regulation of Sleep

Although the function of sleep is still unknown, it is generally accepted that sleep leads to some form of recuperation and is vital to life, and “rest” is not a substitute for sleep (Mindell & Owens, 2003a). The length of nocturnal sleep requirements differs among individuals and from night to night.
Two main processes regulate sleep and wakefulness: 1) The homeostatic process (referred to as Process S) which primarily regulates the length and depth of sleep and which builds during waking hours and is relieved by sleep; and 2) The circadian rhythm (referred to as Process C) which influences the internal organization of sleep and timing and duration of daily sleep-wake cycles (Davis et al., 2004). The intrinsic circadian rhythms synchronize themselves to the 24-hour-day cycle through environmental cues called “zeitgebers.” In the absence of these cues, circadian rhythms become desynchronized. The most powerful of these zeitgebers is the light-dark cycle (Mindell & Owens, 2003a). While both Process S and Process C are independent, it is important to note that there is an overlap in how each will regulate sleep and how one will directly influence the other.

The homeostatic process is the mechanism that drives the body to sleep. Process S rises during waking and declines during sleep. Furthermore, the homeostatic process interacts with process C which is independent of sleep and waking (Borbely & Achermann, 2005). The individual’s sleep propensity (level of sleepiness) or alertness is partially determined by the duration and quality of previous sleep, as well as time awake since the last sleep period (Mindell & Owens, 2003a). Over the course of the day a ‘sleep debt’ accumulates during waking hours, which increases the drive to sleep. In other words, the longer the period of wakefulness, the stronger the drive to sleep. The accumulated ‘sleep debt’ is relieved by daytime naps or nighttime sleep (Davis et al., 2004). While young children, usually toddlers, still require daytime naps, the majority of preschool-aged children stop napping between the ages of 3 and 4. Daytime naps too close to the scheduled bedtime may interfere with sleep onset and cause fragmented sleep, which will in turn cause a vicious cycle between Process C and Process S. For example, naps too close to a child’s scheduled bedtime will interfere with sleep onset, causing the child to
fall asleep much later. When the child awakens in the morning the sleep propensity is higher throughout the day because of missed out nighttime sleep. Reductions or increases of sleep time can alter the homeostatic sleep drive. The longer the sleep deprivation lasts, the stronger the sleep propensity. This can be illustrated by the fact that there is a tendency for “catching up” with both lost REM sleep and SWS the night following sleep deprivation (Roehrs, 2000). Furthermore, external factors that cue Process C such as caffeine intake, as well as not keeping up with good sleep-hygiene rules (i.e., regular sleep-wake times and bed-time routines), may not only have a significant adverse influence on the homeostatic drive, but may influence the entrainment of the circadian rhythms affecting sleep, which may have a considerable influence on sleep quality (Stanley, 2005).

During the hospitalization period, the homeostatic sleep drive may be affected by disruptions of the circadian rhythm. The child’s room is not only associated with a place to sleep, but it is used for medical procedures, socializing opportunities (e.g., visitors), for activities (e.g., play), and for entertainment (e.g., watching television). Furthermore, the unfamiliar hospital environment may lead to anxieties or worries in the child, resulting in hypervigilence and overstimulation, making sleep difficult to achieve. The ability to relax both mentally and physically affects whether or not sleep can be entered and the hospitalized environment may contribute to an altered homeostatic sleep drive. As process S builds throughout the day, so does the sleep propensity, therefore, children who are in a darkened room may be relieving the accumulated sleep debt by sleeping at inopportune times (i.e., long naps during the day), making it more difficult to initiate sleep in line with the circadian rhythm (i.e., nighttime sleep).

Process C is driven by the internal “biological clock” that dictates periods of wakefulness and sleep based largely on the light-dark cycle. The internal circadian clock is located in the
suprachiasmatic nuclei (SCN) of the anterior hypothalamus and serves as the central neural pacemaker of the circadian timing system. There is evidence to support that circadian oscillators (biological clocks) are found in tissues throughout the body requiring continuous synchronization, which is provided by the SCN in both neural and endocrine control (Moore, 2007). For example, brain circuits mediate the control of behavioral state, peripheral tissue control is mediated by circadian regulation of the autonomic nervous system, and oscillators in many tissues are controlled by circadian patterns of hormone secretion (Moore, 2007). Diurnal blood levels of cortisol, prolactin (PRL), thyroid-stimulating hormone (TSH), growth hormone (GH), and melatonin all display a circadian rhythm (Roehrs, 2000; Stanley, 2005). The secretion of GH and PRL are strongly linked to sleep as there is a marked increase of these hormones during sleep, whereas the release of cortisol and TSH is inhibited (Roehrs, 2000; Van Cauter, 2005). Conversely, delayed sleep onset or awakenings interrupting sleep, delays the release of GH and PRL and are associated with increased cortisol and TSH concentrations.

The Role of Melatonin

Melatonin is regulated by the SCN, which modulates sleep and circadian phase through the activation of the melatonin receptors (Dubocovich, 2007). Information about the lighting conditions of the external environment is conveyed to the SCN from sensory receptors in the retina via the retinohypothalamic tract (RHT) which switch the body’s production of the hormone melatonin off in the presence of light or on in the presence of darkness (Mindell & Owens, 2003a). A decrease in SCN neuron firing rate in the late day (dark) stimulates sympathetic activity resulting in melatonin production and release. Furthermore, melatonin inhibits the firing of the SCN neurons, which diminishes the circadian drive for arousal, and therefore sleep is promoted (Dubocovich, 2007).
Sleep onset may be prolonged if an individual is exposed to light prior to the onset of sleep. Examples include bright indoor lights or the lighting of a computer screen or television. Furthermore, light exposure near sleep’s end can accelerate awakening (Davis et al., 2004). This is more problematic in hospital settings, as patients report that excessive light is a source of sleep disturbance (Simpson, Lee, & Cameron, 1996). When patients are exposed to bright lights during the night, this impacts the release of melatonin causing a shift in the circadian rhythm. As a result sleep-onset insomnia and early morning awakenings may occur, as well as sleepiness at inopportune times (Stanley, 2005). Children who are hospitalized may be exposed to lights during the night for routine assessments of vital signs, or other health care procedures. Light exposure at night, when there is normally little light and when melatonin is secreted, can have a major effect on the circadian rhythms. A rapid shift in the response to light occurs around the nadir of temperature and at the time of peak melatonin secretion, usually 3:00-5:00 AM (Shneerson, 2005). Light exposure before this phase-shift transition delays the next sleep phase, making it difficult for the child to resume sleep after awakening, which leads to an increase in wake-time after sleep onset (WASO), causing fragmented sleep and a decrease in sleep efficiency. Sleep efficiency is often used as an indicator of sleep quality and is defined as the number of minutes spent in true sleep (total minutes actually in sleep during total sleep period) divided by the number of minutes of the total sleep period (between bedtime and waketime).

While exposure to bright lights during the night or close to the onset of sleep may cause a delay in sleep onset, exposure to darkness during the day may induce sleepiness; therefore hospitalized children are sleeping during inopportune times such as in the middle of the day, which also leads to fragmented sleep because their nighttime sleep onset time may be delayed. In the hospital setting, children may not have the opportunity for natural light exposure due to their illness or condition. This may lead to dark exposure during the day in their rooms. Dark exposure
during the day also causes phase shifts in the circadian rhythms, since the SCN adjusts circadian rhythms within the body to environmental light-dark cycles. In hospitalized children, exposure to bright light during wakefulness is important and should be recommended, if appropriate. During wakefulness, light exposure has several important physiological effects and includes an increase in the level of alertness, improvements in motor performance, and elevation in mood (Shneerson, 2005). Exposure to light resets the circadian rhythms each day so that they are coordinated with environmental time, which is important in the prevention of sleep restriction or disturbances not only during hospitalization but also in the post-hospitalization period.

*The Role of Social Cues in Sleep*

Although the intrinsic circadian rhythms synchronize themselves to the 24-hour-day cycle, external cues from the environment such as social zeitgebers are also necessary in the entrainment of human circadian rhythms (Elmore, Betrus, & Burr, 1994). Social zeitgebers refer to activities such as school, meals, exercise, and recreation, which often involve precise timing on the part of the individual. Such social zeitgebers in combination with the dark/light cycle will help regulate or synchronize the internal circadian rhythm with external cues. Factors such as lack of social contacts, absence of daily activities (e.g., school, sports), and irregular mealtimes often make social cues difficult to regulate during the hospitalization period.

*The Role of Body Temperature*

Sleep onset is also linked to body temperature, which varies throughout the day. As discussed previously, when light enters the eyes, melatonin levels decrease, signaling body temperature to rise and promoting wakefulness. Conversely, darkness causes melatonin levels to rise and body temperature to fall, which promotes sleep (Stanley, 2005). During sleep onset, heat loss is evoked through cutaneous vasodilation and sweating. Depending on ambient conditions, a
discrete increase in vasodilation of the hands and feet occur, which promotes sleep onset shortly thereafter (McGinty & Szymusiak, 2001). If this vasodilation has occurred somewhat before a scheduled “lights-out”, sleep latency is shorter. During the descending phase of the temperature rhythm, sleep onset normally occurs. However, it is also important to note that sleep onset evokes a further decrease in temperature, even during continuous bed rest, with the temperature nadir in the early morning (around 3AM) (McGinty & Szymusiak, 2001; Roehrs, 2000).

Sleep propensity is highest when body temperature is low and awakenings tend to occur as temperature increases, suggesting that low body temperatures directly facilitates sleep or that a mechanism that lowers body temperature also promotes sleep (McGinty & Szymusiak, 2001). Therefore moderate ambient temperatures would best facilitate sleep as higher ambient temperatures may suppress sleep because heat loss through cutaneous vasodilation and other body cooling mechanisms would be ineffective and therefore cause less efficient sleep (McGinty & Szymusiak, 2001; Webster & Thompson, 1986).

In a hospital setting, sleep patterns may be affected by changes in temperature, either environmental temperature (e.g., room temperature) or body temperature (e.g., fever). Hospital units may be kept at temperatures that the child and family are not used to, and room temperatures are difficult to control on different units. Feelings of being too hot may be further aggravated by pyrexia and restlessness. Fever is associated with a greater number of awakenings, increased total waking time and reduced amounts of SWS and REM sleep (Alexander, Fawcett, & Runciman, 2006).

**Autonomic Nervous System Balance**

The ability to fall asleep may be determined not only by the homeostatic sleep process and circadian sleep-wake rhythms, but also the level of physiological arousal. A balance of the
autonomic nervous system (ANS), in which there is a decrease in sympathetic activation and an increase in parasympathetic activity, facilitates sleep. Sympathetic activation of the ANS may be from both endogenous and exogenous origins. For example, endogenous activation of the sympathetic nervous system (SNS) can be seen in anxiety states, while caffeine is a source of exogenous stimulation. Regardless of the origin of SNS activation, sleep onset may be adversely affected (Stanley, 2005). Individuals with a high level of basal arousal would be predisposed to present with some difficulty initiating sleep and maintaining sleep (Bonnet & Arand, 1997).

The activation of the SNS, also known as the ‘fight-or-flight’ system, is thought to serve as a survival function by improving a person’s vigilance in moments of stress. Typically, the physiological changes that suggest increased SNS activity include increases in heart rate, respiratory rate, skin and core body temperature, muscle tone, and vasoconstriction of peripheral blood flow. These elements are counterproductive to the onset and maintenance of sleep. Furthermore, situational factors, such as a stressful event, cause an increase in the SNS response, which results in the release of higher than normal levels of the hormone cortisol (referred to as the ‘stress hormone’) which leads to increased wakefulness and inhibits slow-wave sleep (Stanley, 2005).

According to Benson (1975), the counterpart to the SNS response is referred to as the relaxation response, which occurs when the body no longer perceives danger, and the ANS functioning deactivates the SNS state. During this response, the body moves from a state of physiological arousal, to a state of physiological relaxation with marked decreases in blood pressure, heart rate, and respiratory rate, as well as a return of hormone levels such as cortisol to their normal states (Benson, 1975).
When the body is in a constant state of physiological arousal, therapeutic approaches can be implemented to reduce SNS activity and induce the relaxation response. Utilizing relaxation techniques such as meditation, yoga, tai chi, deep breathing exercises and other tension taming and stress-management techniques may help to achieve a good ANS balance, particularly in individuals with difficulties initiating and maintaining sleep (Bonnet & Arand, 1997; Stanley, 2005).

Relaxation therapies are based on the premise that patients, who have difficulty in initiating and maintaining sleep, as observed in insomniacs, often display high levels of arousal both at night and during daytime. According to the multi-process theory, arousals can be both physiological/somatic or cognitive in nature (Gill, Kolt, & Keating, 2004). Relaxation methods are used to disable the arousal system, and specific techniques are chosen depending on the type of arousal (Morin et al., 1999). The somatic response to a relaxation technique will have effects on physiological parameters such as respiration rate and heart rate. The cognitive effects pertain to mental activity, such that the technique helps negate intrusive thoughts or racing mind that hinder the onset of sleep (Gill et al., 2004).

Although to date there has been no evidence to determine whether relaxation techniques both somatic and cognitive in nature help promote sleep in hospitalized children, based on theory and the complex components of sleep, it is worth further exploration. It is suggested that treatments for childhood insomnia should focus on reducing excessive physiological reactivity that may be a biological feature or a response to emotional stress and anxiety, and relaxation techniques and sleep restriction are necessary to create more physiologic pressure for sleep (Tikotzky & Sadeh, 2010). In the adult literature, a review of 48 clinical trials and two meta-analyses was conducted by the American Academy of Sleep Medicine to develop practice
parameters on non-drug therapies for the clinical management of insomnia in adults (Morin et al., 1999). Based on the two meta-analyses used in this review, therapies such as relaxation techniques (i.e., meditation, progressive muscle relaxation) produced reliable and durable changes in several sleep parameters including a decrease in sleep-onset latency (effect size 0.87 and 0.88), increased reported sleep quality (effect size 0.94), decreased duration of awakenings, and an increase in total sleep time. Additional outcome research is needed to examine the effectiveness of such therapies in children with sleep disturbances especially the effectiveness of these modalities when implemented in clinical settings.

**THE ROLE OF SLEEP HYGIENE**

The term ‘sleep hygiene’ refers to behaviours, environmental conditions, and other sleep-related factors that can be adjusted to improve the quantity and quality of sleep (Stepanski & Wyatt, 2003). Common recommended sleep hygiene practices are generally aimed at having the individual avoid behaviours that interfere with a normal sleep pattern. Sleep hygiene components that are included in the development of ‘good’ sleep habits in children include avoidance of behaviours such as caffeine consumption and television viewing prior to bedtime. Other behaviours that are promoted in sleep hygiene practices for children include the maintenance of a consistent sleep schedule for both bedtimes and wake times, having a calming bedtime routine, and also, providing parental education on the development of healthy sleep hygiene practices. Each of the components of sleep hygiene practices specifically aimed at children will be discussed in the following section.

*Avoiding Television Viewing and Other Media Prior to Bedtime*

Despite the common misconception that television (TV) viewing is relaxing and aids in falling asleep, it can actually have stimulating effects rather than calming ones. Television
viewing and video game playing has been associated with sleep disturbances in children (Tazawa & Okada, 2001). In one study, TV viewing was associated with sleep difficulties, bedtime resistance, sleep-onset delay, sleep anxiety, nighttime wakings, and shortened sleep duration in children aged 4 to 10 (Owens et al., 1999). Shortened sleep duration has also been associated with children who had TVs in their bedrooms; children who had a television set in their rooms went to bed significantly later on weekdays (standardized β .097, p<0.0001) and weekend days (standardized β .092, p<0.0001) (Van den Bulck, 2004). In children aged 5 to 6, TV viewing was also related to decreased sleep length. Television viewing practices, such as watching TV alone (r=0.16, p=0.05), watching TV at bedtime (r=0.19, p=<0.01), and active viewing of adult TV (r=0.15, p=0.04) programs were also related to sleeping difficulties, especially sleep onset problems (Paavonen, Pennonen, Roine, Valkonen, & Lahidainen, 2006). Furthermore, TV viewing interferes with the development of healthy sleep habits such as having a regular sleep/wake schedule. In infants and toddlers, the number of hours of television watched per day was associated with both an irregular naptime schedule (OR: 1.09; 95% CI: 1.01-1.18) and an irregular bedtime schedule (OR: 1.13; 95% CI: 1.04-1.24) (Thompson & Christakis, 2005).

Several reasons to explain the association between TV viewing and sleep disturbances in children have been proposed. Viewing TV prior to sleep may actually delay the body’s natural mechanism of the production of melatonin because of the exposure to bright light therefore delaying the onset of sleep. TV viewing also may have a psychological impact on children in that they may watch programs with violent content or programs that are inappropriate for their ages. Violent programming prior to bedtime may inhibit the relaxation necessary for sleep induction and increase the likelihood of nightmares and nighttime anxiety (Mindell & Owens, 2003a; Owens et al., 1999). Another potential mechanism explaining the relationship between TV viewing and sleep disturbances in children include parental priorities. As children develop, there
is an increasing independence from parental supervision, which may result in less enforcement of appropriate bedtime behaviours. Parents of children who watch significant amounts of television may be poor limit-setters in general who do not enforce rules with regards to television viewing, computer use, or videogaming near bedtime (Mindell & Owens, 2003a). Decreases in sleep length may be attributed to habitually going to bed late because of engagement in television viewing activities or other activities such as computer or videogame use.

More recently, there is a growing interest in examining the impact of personal mobile phones often used for text messaging on sleep in older children and adolescents. A prospective study conducted in Belgium found that more than 50% of the participants (n=1656) used their mobile phones after lights out in their bedroom, for text messages (55.6%) and for calls (58%) (Van den Bulck, 2007). Those who used their personal mobile phones after lights out more than once a week were 5.1 times more likely to report being very tired (95% CI 2.5-10.4) during the one year follow-up period.

Avoiding Caffeine Consumption

Caffeine is the most commonly used Central Nervous System (CNS) stimulant in the world (Nehlig, 1999). The consumption of caffeine usually comes from sources such as coffee, tea, soft drinks, energy drinks, and chocolate. The most notable behavioural effects of caffeine are the promotion of wakefulness, and increased alertness and energy. More negative effects may be induced with higher doses of caffeine and include anxiety, tachycardia, restlessness, and insomnia (Nehlig, 1999). In children and adolescents, moderate to high doses of caffeine (approximately 100-400mg) led to increased reports of nervousness, jitteriness, fidgetiness, and decreased reports of sluggishness (Temple, 2009).
Caffeine consumption, is concerning for children and adolescents. A nationally representative survey conducted in the US, found that 62.7% (SEs ± 1.1) of children between the ages of 2-to 5-years-old and 74.8% (SEs ± 0.9) of children 6- to 11-years-old consumed caffeine daily (Branum, Rossen, & Schoendorf, 2014). The primary vehicle for caffeine in children is soda, which also contains a large amount of sugar. Therefore, during childhood and adolescence, exposure to repeated pairings of sugar and caffeine facilitates the development of caffeine dependence as well as enhances the preference for foods and beverages containing added sugar (Temple, 2009).

The mechanism of action of caffeine on wakefulness involves adenosine, an endogenous sleep promoting substance that builds up during the course of prolonged wakefulness and is fundamental to the homeostatic sleep mechanism. Caffeine counteracts the process of adenosine by blocking adenosine receptors found in the CNS, thereby inhibiting sleep onset and causing shortened total sleep duration (Mitler & O'Malley, 2005; Porkka-Heiskanen et al., 1997). One study demonstrated that adolescents consuming moderate to high amounts of caffeine in the form of either soda or coffee were twice as likely (OR 1.9; 95% CI 1.6-2.1) to have difficulty sleeping and were twice as likely (OR 1.8; 95% CI 1.5-2.1) to be tired in the morning than students who reported a very low or no caffeine intake (Orbeta, Overpeck, Ramcharan, Kogan, & Ledsky, 2006). Caffeine consumption has also been reported to be associated with increased WASO and more disturbed sleep. In addition, caffeine may be used to counteract the effects of poor sleep on daytime wakefulness (Pollak & Bright, 2003).

For children age 12 and under, Health Canada has made the following recommendation of maximum daily caffeine intake: children aged 4-6 should not consume more than 45 mg of caffeine daily, children aged 7-9 receive no more than 62.5 mg, and children aged 10-12
consume no more than 85mg \cite{HealthCanada2010}. To prevent sleep problems associated with the consumption of caffeinated beverages, caffeine should not be consumed 6 hours prior to the child’s bedtime. The table below provides approximations of caffeine contained in various beverages and snacks:

<table>
<thead>
<tr>
<th>Beverage Type or Food Item</th>
<th>Amount of Caffeine</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 can of caffeinated soda pop (e.g., Coke, Pepsi)</td>
<td>45 mg</td>
</tr>
<tr>
<td>8 oz. cup of coffee</td>
<td>130 mg</td>
</tr>
<tr>
<td>1 can (250mL) Energy Drink (e.g., Red Bull)</td>
<td>80-140 mg</td>
</tr>
<tr>
<td>16 oz. bottle of Snapple Iced Tea</td>
<td>48 mg</td>
</tr>
<tr>
<td>1 small Tim Horton’s Iced Cappuccino</td>
<td>90 mg</td>
</tr>
<tr>
<td>1 small Tim Horton’s Hot Chocolate</td>
<td>12 mg</td>
</tr>
<tr>
<td>1 8oz Chocolate Milk</td>
<td>4 mg</td>
</tr>
<tr>
<td>Hersey’s Special Dark Chocolate Bar (1 bar)</td>
<td>31 mg</td>
</tr>
</tbody>
</table>

Avoidance of the aforementioned behaviours is a key component in the development of ‘good’ sleep hygiene. Behaviours that are promoted in sleep hygiene practices for children include the maintenance of a consistent sleep schedule for bedtimes and wake times, having a positive, enjoyable bedtime routine, and also, providing parental education on the development of healthy sleep hygiene practices.

**Consistent Sleep Schedule**

Adherence to regular bedtimes and wake times promotes optimal sleep propensity and consolidation of sleep. The rationale is that the circadian timekeeping system is better aligned with naturally occurring sleep propensity due to regularly timed exposure to environmental and indoor light, therefore a regular waking time in the morning strengthens the circadian function and can help with sleep onset at night \cite{StepanskiWyatt2003}.

While the circadian rhythm regulates the degree of wakefulness and sleepiness, largely through light/dark cues, the timing of biologic rhythms can be modified or entrained by other
environmental cues (Herman, 2005). Therefore, regular and consistent structure provided by parents is imperative in the development of the child’s sleep-wake rhythm. Entrainment through predictable occurrences of time cues such as the timing of social and family activities, mealtime, and bedtime are required to facilitate the development of more regular rhythms in the child.

During hospitalization, children may not have the opportunity for adequate exposure to natural light during the day. Therefore the circadian rhythm may not be as strong, leading to difficulty falling asleep at the appropriate time or disturbed sleep at night. Bright light exposure during the night and frequent interruptions may lead the child to have daytime sleepiness. This sleepiness is often relieved with daytime napping which further disrupts the diurnal rhythm, increasing the likelihood of difficulty falling and staying asleep at night.

Having an irregular sleep schedule contributes to problems in the sleep-wake cycle. Even short-term delays in the circadian rhythm such as later bedtime and later rise schedules on weekends have been shown to be associated with poor academic performance, daytime sleepiness, depressive mood, and sleep/wake behaviour problems in adolescents, and lowered cognitive performance and poorer mood in young adults (Wolfson & Carskadon, 1998; Yang & Spielman, 2001). Although there are limited studies in younger children, regular sleep schedules are often recommended as part of healthy sleep hygiene practices, and have also improved sleep disturbances in children with blindness and developmental disabilities (Mindell & Goldberg, 1996; Piazza, Hagopian, Hughes, & Fisher, 1998).

**Positive Bedtime Routine**

In addition to regular bedtime and wake times, bedtime routines conducted away from bright lights may help separate sleep time from activities that may cause arousal. In children, a predictable set of bedtime activities (for example, reading a book and a warm bath) is associated
with a decrease in frequency and duration of bedtime tantrums (d=0.88; duration 1.83) and improved sleep onset latency and sleep consolidation (Mindell et al., 2006). A positive bedtime routine for the child involves the parent developing and implementing a sequence of brief, enjoyable and calming activities preceding bedtime. Having a consistent bedtime routine establishes a behavioral chain leading up to sleep onset. This treatment is based upon stimulus control techniques, and is targeted toward reducing affective and physiologic arousal at bedtime and is recommended as a practice parameter for the treatment of bedtime problems in infants and young children according to the American Academy of Sleep Medicine (Morgenthaler et al., 2006).

According to two reviews on treatment efficacy in behavioral pediatric sleep problems, positive bedtime routines produced the fastest improvement in decreasing bedtime resistance (Kuhn & Elliott, 2003; Mindell, 1999). Positive bedtime routines may also be more acceptable to parents rather than other techniques such as graduated extinction, where the child is left to ‘cry it out’. Although these reviews focused on healthy children with established behavioural sleep problems, implementing calming routines such as reading a storybook or engaging in a relaxation breathing exercise may be feasible and warranted in a hospital setting.

More recently, a randomized controlled trial was conducted to determine the impact of a consistent bedtime routine on infant and toddler sleep independent of other behavioural interventions (Mindell, Telofski, Wiegand, & Kurtz, 2009). Mothers and their infants (n=206) or toddlers (n=199) were randomly assigned to either the control group or the bedtime routine group to participate in a 3-week intervention to assess how a nighttime bedtime routine altered children’s difficult bedtime behaviours. Mothers in the routine bedtime group followed a specific 30-minute bedtime routine that included a bath, a massage or applying skin lotion, and cuddling
or another calming activity, while the mothers in the control group maintained existing bedtime habits.

The bedtime routine resulted in a significant decrease in the number of mothers who rated their child’s sleep as problematic and showed that the child fell asleep faster, awoke less often and for shorter periods during the night, and slept more regularly (p<0.001) after following the bedtime routine compared to those in the control group. Although this study did not use objective methods in measuring nighttime awakenings and duration of these awakenings such as actigraphy, utilizing a positive bedtime routine as an intervention to decrease behavioural sleep difficulties in children is promising. Attempting to provide a relaxing bedtime routine such as lowering the lights, drawing the curtains, reading a storybook, and engaging in some deep breathing exercises may be helpful in a hospital setting given its high-paced environment.

**Parent Education**

Parental education involves the process of providing parents and other primary caregivers with specific knowledge and skill set for promoting the development and competence of their child (Mahoney et al., 1999). Parent education programs have been targeted primarily towards prevention of sleep problems, largely in the post-partum period and usually include an education package containing information on sleep hygiene (Morgenthaler et al., 2006; Stremler et al., 2006; Symon, Marley, Martin, & Norman, 2005; Wolfson & Carskadon, 2002; Wolfson, Lacks, & Futterman, 1992). Parental education appears to be an effective and cost-effective treatment modality, and has been deemed as a well-established intervention for the prevention of sleep disturbance by the *American Academy of Sleep Medicine* (Morgenthaler et al., 2006).

During the hospitalization of a child, the parent often feels stressed and frightened most commonly about the uncertainty about the child’s illness and recovery, and this stress is even
greater for unplanned hospitalization or intensive care unit stay (Melnyk et al., 2004). During this stressful period, parents adopt a more supportive role and naturally try to spare their child from fear and distress by becoming more involved with their care (Meshkani & Bavarian, 2005).

Educational programs to improve both child and parental outcomes have been implemented with success. One such example, is the COPE (Creating Opportunities for Parent Empowerment) program, an intervention which has been created to improve the coping/mental health outcomes of young hospitalized/critically ill children, premature infants and their parents (Melnyk et al., 2004). The focus of the program was targeted to address the major stressors that parents experience when their child is hospitalized mainly their child’s emotions, behaviours and physical characteristics, and feelings of loss of parental role. The COPE program consists of two types of educational information. The first component consisted of child behavioral information that teaches parents about the most typical emotions and behavioral responses that young children manifest as they cope with illness or trauma and hospitalization. The second component focused on the parental role, and provided suggestions regarding how they can best help their children to cope with the hospital experience, and how they can implement the recommendations provided to them.

A review of the literature which examined prevention and intervention strategies to alleviate preoperative anxiety in children (Wright, Steward, Finley, & Buffett-Jerrott, 2007) suggests that the cost effective components of preparation programs include modeling, parental involvement, Child Life preparation, and coping skills instruction. Interventions involving parents resulted in less anxiety in both child and parent immediately following the preparation in the holding area on the day of surgery and on separation to the operating room, than children and parents who received no preparation. Wright et al. (2007) suggest that important variables to consider when designing a behavioral preparation program for a child and parent include the
child’s age, timing of the intervention relative to surgery, and the child’s history of previous hospitalization. Although to date, there have been no educational programs implemented in hospital settings to promote sleep during child hospitalization, involving parents and providing parental education has numerous potential benefits such as: eliminating separation anxiety (Kain et al., 2000), increasing child cooperation, enhancing parental satisfaction, fulfilling parents’ perceived sense of duty to be present, and enhancing parental satisfaction with the medical care (Wright et al., 2007). Furthermore, parents are in the position to enforce healthy sleep habits and therefore their participation is warranted.

**Consequences and Modes of Sleep Loss**

Sleep loss can result from sleep restriction or sleep disruption. Sleep restriction occurs when an individual is obtaining an insufficient amount of sleep, which can result from self-imposed sleep restriction, poor sleep hygiene, and lifestyle or school work demands that require staying awake (e.g., studying for a test or writing a term paper). In contrast to loss of sleep from sleep restriction, sleep loss can also result from sleep disruption during the night also known as sleep fragmentation. Sleep fragmentation is a result of an interruption of a sleep stage from an altered environment (e.g., noise, stress) which may be perceived as threatening (e.g., hospital monitor alarms), and leads the individual to wakefulness, which results in disrupted NREM – REM sleep cycles. Regardless of whether the sleep loss is due to restriction or fragmentation, the consequences of sleep loss on child and adolescent health outcomes are wide ranging and include impairments in learning and processing, mood and modulating emotions, daytime behaviour, and various physiological consequences.
Sleep has been known to serve several different functions including learning and memory consolidation. Although REM sleep has been noted to be an integral component of such cognitive functions (Mindell & Owens, 2003a; Smith, 2001), this idea has been challenged by a review indicating that the combined initial involvement of slow-wave sleep and the subsequent substantial contribution by REM sleep is important in the learning process (Ambrosini & Giuditta, 2001). Nonetheless, it is suggested that the progression to deeper stages of sleep (SWS and REM) are required for such cognitive functions.

Learning processes and memory consolidation play a fundamental role in school achievement, especially in academic performance. Therefore, children and adolescents obtaining inadequate or disturbed sleep will likely have problems in the academic milieu. Existing data suggest that children are likely to experience impairment in both performance and behavioral domains as a result of insufficient sleep. One study of 74 school-aged children aged 6 to 12 years old found that restricting sleep had a moderate effect on increased ratings of academic problems, was associated with increased severity of attention problems, and children were slower to process new information and more forgetful (Fallone, Acebo, Seifer, & Carskadon, 2005). These findings have important implications, since the appearance of learning difficulties in children may be due to insufficient sleep rather than a learning impediment. Consistent findings are reported in adolescents attending high school and/or college (Wolfson & Carskadon, 2002). In their review, Wolfson and Carskadon found that self-reported shortened total sleep time, erratic sleep/wake schedules, late bed and rise times, and poor sleep quality were negatively associated with academic performance for adolescents from middle school through the college years. Students with higher grades received more total sleep and had earlier bedtimes on school nights.
and reduced weekend delays of sleep schedules than students with lower grades, indicating that sleep is directly related to academic performance.

The association between sleep restriction and increased attention problems as well as slower and more difficult processing of new information may have further consequences in a hospitalized child. During the hospitalization period, children are often encouraged to participate in their healthcare. This may include having knowledge of their disease process or medication regime, or developing tactile skills such as their ability to administer an insulin injection. When education by a health care professional is being delivered it is important that the child have optimal attention to help decrease side effects of their medication, or to ensure that the medication is taken at the right time for the right reason. Therefore, optimal sleep is important during the hospitalization period.

Sleep and Impaired Mood and Modulating Emotions

There is a wealth of evidence that clearly associates mood dysfunction as a result of inadequate or disturbed sleep. Mood problems can be seen in children with sleep disturbances and are exacerbated by negative mood or a decrease in positive mood or affect (Fallone, Owens, & Deane, 2002). Furthermore, sleep quality and quantity affect the regulation of mood, or the use of cognitive strategies to modulate emotions thus sleep disturbance during critical periods of development may have long term consequences on the child’s emotional health (Owens & Witmans, 2004).

A large community study was conducted to determine the association between children’s sleep disturbance and anxiety/depression at ages 6 and 11, cross-sectionally and prospectively (Johnson, Chilcoat, & Breslau, 2000). The sample consisted of 823 children at age 6 and, of those, 717 participated again at age 11. Both mothers and teachers were asked to use the
Achenbach’s Child Behavior Checklist (CBCL) and the Teacher Report Form (TRF) respectively, to evaluate children on 110 items. The CBCL asked if the child had trouble sleeping during the past 6 months. From each checklist eight syndrome scales were derived and included: withdrawn, somatic complaints, anxious/depressed, social problems, thought problems, attention problems, delinquent behavior, and aggressive behaviour. Children with trouble sleeping had significantly increased odds of anxiety or depression based on mothers’ reports (OR 6.9, 9% CI 4.1-11.4).

Higher levels of depressed mood have also been reported in sleep restricted adolescents (Wolfson & Carskadon, 1998). Wolfson and Carskadon sought to describe the relation between adolescents’ sleep/wake habits, characteristics of students, and daytime function (mood, school performance, and behaviour) in a sample of 3,120 students at four public high schools. Adolescents who had shorter school-night sleep (on average 6h 45 min) reported increased levels of depressed mood, daytime sleepiness, and problematic sleep behaviours in comparison to longer sleepers (average 8h 15 min).

**Sleepiness and Impairment in Daytime Behaviour**

In addition to changes in mood such as irritability, children who have restricted sleep are likely to display oppositional and inattentive behaviour according to both parental and teacher reports (Bonnet & Arand, 2003; Fallone et al., 2005; Fallone, Owens, et al., 2002). Unlike adults, sleep loss in children is associated with behavioural manifestations such as increased activity, rather than the classic manifestations of sleepiness such as yawning or complaining about fatigue. These behavioural manifestations include internalizing behaviours, which range from emotional lability (excessive laughing or crying) anxiety, and low frustration tolerance and externalizing behaviours such as impulsivity and increased aggression (Owens & Witmans,
Lavigne et al. (1999) conducted a cross-sectional design examining the relationship between amount of sleep and daytime behaviour problems in preschool children. Measures assessing internalizing problems (e.g., anxiety, depression), externalizing problems (e.g., defiant, oppositional, overactive behaviours), and total behaviour problems were used in a sample of 510 children between the ages of 2 and 5 years. Significant effects were found for amount of sleep on both Total Behaviour Problems (F=6.89, 2,247; p<0.001) and Externalizing Problems (F=7.80, 2,247; p<0.0005) scales. Less night sleep (p<0.0001) and less sleep in a 24-hour period (p<0.004) were associated with increased total behaviour problems; less night sleep (p<0.0002) and less 24-hour sleep (p<0.004) were also associated with more externalizing problems on that measure.

Given the nature of the above studies, it is impossible to establish a causal relationship between sleep and behaviour problems in children; however the literature shows strong support for a relationship. Behaviour problems in children may be exacerbated due to sleep restriction from hospitalization. Children who are hospitalized are sleeping in unfamiliar surroundings, and may find it difficult to modulate emotions and cope with the various components associated with their hospital stay such as their illness, treatment regime, and procedures (i.e., lumbar puncture, or surgery) at a time when it is needed most.

*Physiological Consequences of Sleep Disruption*

Emerging research has revealed sleep to be an important regulator of many physiologic functions including autonomic, cardiovascular, neuroendocrine, and immune function. Alterations in these physiological functions may occur as a result of sleep disturbance and have health-related consequences.
Several studies evaluating autonomic activity during nighttime sleep suggest reduced sympathetic activity with predominant parasympathetic nervous system activity. Activation of the parasympathetic nervous system induces a nocturnal decline in heart rate and blood pressure (Bonnet & Arand, 1997; Meerlo, Sgoifo, & Suchecki, 2008). Given the association between sleep and decreased sympathetic activity, it is expected that sleep disruption or restriction be associated with an increase in these variables towards the levels seen during wakefulness. Several papers in a review of the physiological effects of restricted and disrupted sleep support the idea that an increase in both heart rate and blood pressure are expected as a direct result of this increased sympathetic activity (Meerlo et al., 2008). Furthermore, even brief awakenings from sleep for only a few seconds are associated with an autonomic reflex causing a temporary rise in heart rate and blood pressure towards the level seen during normal wakefulness (Sforza et al., 2004). Following a period of sleep disruption, cardiovascular activity does not rapidly return to baseline during subsequent recovery sleep. In fact heart rate and blood pressure remain elevated when recovery is insufficient (Lusardi et al., 1996). These surges in sympathetic activation and increased blood pressure may, in the long run, lead to a permanent elevation in blood pressure (Meerlo et al., 2008).

The link between sleep disruption and obesity is another negative consequence that has emerged in the literature. As the prevalence of obesity is increasing worldwide the relationship between sleep and weight has become a topic of great interest, especially in regards to children (Lumeng, Somashekar, Appugliese, Kaciroti, & Corwyn, 2007). In healthy individuals, glucose tolerance (the ability to metabolize exogenous glucose and return to baseline normoglycemia) varies across the day in that plasma glucose responses to exogenous glucose are markedly higher in the evening than in the morning and glucose tolerance is at its minimum in the middle of the night. The reduced glucose tolerance in the evening is due to a reduction in insulin sensitivity
concomitant with a reduction in the insulin secretory response to elevated glucose levels. Reduced insulin sensitivity, also known as insulin resistance, occurs when higher amounts of insulin are needed to reduce blood glucose levels following the administration of the same amount of exogenous glucose (Knutson, Spiegel, Penev, & Van Cauter, 2007).

A variety of mechanisms intervene to maintain stable glucose levels during the extended overnight fast associated with sleep. Glucose utilization is greatest during wakefulness and lowest during sleep. During the first half of the night when slow wave sleep predominates, glucose metabolism is slower. This may be attributed to the marked reduction in cerebral glucose uptake and a reduction in peripheral glucose utilization. During the second half of the night, these effects are reversed when light non-REM sleep and REM sleep are dominant and awakenings are more likely to occur (Knutson et al., 2007; Van Cauter, Polonsky, & Scheen, 1997).

In addition to the importance of sleep on endocrine function, sleep is involved in optimal immune performance. It is a common belief that individuals who have sleep disturbance are more susceptible to infections. Consistent with this, there is increasing evidence that sleep restriction has detrimental effects on the immune function (Davis et al., 2004; Everson, 1993). Studies have investigated changes in immune-cell number after sleep deprivation, however the results are inconsistent. One study showed a decrease in numbers of Natural Killer (NK) cells and other lymphocyte subsets after sleep deprivation, whereas in another study sleep deprivation led to increased numbers of NK cells and other lymphocytes (Dinges, Douglas, Hamarman, Zaugg, & Kapoor, 1995; Irwin et al., 1996). For example, a review of human studies examining total sleep deprivation and partial sleep deprivation on immune function, found that sleep deprivation increases nonspecific immune responses such as phagocyte numbers, natural killer
(NK) cell numbers, as well as NK cell activity (Dinges et al., 1995). Furthermore, the review found that sleep restriction decreases certain aspects of cellular immune function such as cytokines. In the study conducted by Irwin et al., a reduction of natural immune responses and immune cell production was associated with even a modest disturbance of sleep. After a night of sleep deprivation between 10PM and 3AM in 42 healthy male volunteers, a reduction of natural immune response as measured by NK cell activity and NK activity per number of NK cells, was found. After a night of recovery sleep, NK activity returned to baseline levels (t=2.3, df=25; P<0.03) while lymphocyte production of interleukin-2 (IL-2) production remained suppressed (t=5.3, df=36, P<0.001). These data suggest that even a modest disturbance of sleep produces a reduction of natural immune response by 50%. The conflicting results of these studies may be partly explained by the different durations of sleep deprivation used.

Nonetheless these studies have important implications for the management of patients, especially those who have diminished immune responses. NK cells mediate protection against systemic infection, and sleep may have protective effects to the child’s immune function while hospitalized (Everson, 1993). Diminished immune responses that result from sleep deprivation in hospital environments such as intensive care units might increase the risk of infections (Bryant, Trinder, & Curtis, 2004). During hospitalization, the child’s immune system needs to be functioning at optimal levels to prevent infections from occurring such as nosocomial infections, and other complications surrounding their medical condition.

**Sleep During Hospitalization**

The following literature review will discuss sleep during hospitalization and common obstacles that patients have reported to disrupt sleep while in hospital such as environmental factors, medically related factors, and psychological factors related to anxiety. Interventions that
have been utilized in various hospital settings such as behaviour modification programs as well as complementary and alternative programs to promote sleep will be summarized. Finally, a summary of the interventions geared towards hospitalized children will be provided.

**Children’s Sleep During Hospitalization**

During hospitalization, sleep may be altered at a time when the benefits of sleep are needed most. It has been reported that there is an increased need for sleep during periods of illness and stress and sleep aids in recovery (Southwell & Wistow, 1995). Stresses of hospitalization can exacerbate common sleep difficulties in children. As many as 20-30% of young children and adolescents experience sleep problems or have some type of sleep disturbance (Dahl, 1998; Mindell & Owens, 2003b). Although the prevalence of sleep problems in hospitalized children is unknown, it is expected that children are at risk for pediatric insomnia due to environmental factors related to hospitalization, physiological or medically related issues, such as pain from disease or painful procedures, and psychological issues related to anxiety (Alexander, Powell, Willams, White, & Conlon, 1988; Meltzer, Mindell, Owens, & Byars, 2007; Rose, Sanford, Thomas, & Opp, 2001). While there are several studies that have examined sources of sleep disruptions in the hospitalized setting, most have been performed in adult patients, with very few that specifically focused on the pediatric population. Nonetheless, the literature that exists suggests that children who are hospitalized have difficulty achieving proper sleep requirements (Refer to Appendix A – Summary of Research of Sleep in Hospitalized Children).

In a descriptive study of 34 hospitalized children between the ages of three and eight, children lost 20% to 25% of their usual expected sleep time (mean of 7.85 hours, range 4-10.5 hours) as a result of a prolonged time to sleep onset or early termination of sleep (Hagemann,
In a subsequent study, sleep disruptions further contributed to children’s shorter duration of sleep in time. Sleep disruptions between the times of sleep onset and sleep termination occurred frequently (mean 3.47 disruptions, range 0 -17) so that very few children were able to sleep uninterruptedly through more than half of the sleep period (Hagemann, 1981a). Internal and external causes of arousal were identified. Internal causes of arousal included: physiological needs of elimination, hunger, or thirst; physiological discomfort of pain or nausea; affective responses to anxiety or fear; and nonspecific arousal for which no cause could be identified. External causes such as environmental stimuli (e.g., noise, light, or touch not intended to awaken the child) and unnecessary hospital routines (e.g., admittance examinations late in the evening), periodic temperature taking during the night, and early arousals for preoperative bathing, further contributed to the children’s shorter duration of sleep time.

An observational study of 24 hospitalized children was undertaken to determine the extent to which factors in the hospital environment influence the sleep-wakefulness pattern during a scheduled afternoon naptime (Beardslee, 1976). The mean duration of sleep latency was 24.5 minutes (SD, not reported), and 40% of observed naptimes of children were disrupted. Sleep disruptions occurred in response to environmental stimuli such as noises by other children (e.g., crying), on-going nursing activities, as well as other noises such as the ringing of the telephone, the use of the overhead system, as well as slamming of the corridor doors.

Studies that have been conducted in an intensive care unit also suggest that children have decreased sleep duration and frequent awakenings. Cureton-Lane and Fontaine (1997), through observation, found that children slept a mean total of only 4.7 hours (SD 0.49) and the mean length of a sleep episode was only 27.6 minutes (SD 25.85). In the course of a 10-hour night, the mean number of awakenings that occurred was 9.8 (SD 2.48) suggesting frequency of
interrupted sleep. A more recent study conducted by Stremler et al. (2009) examined the sleep quantity (nocturnal and daytime), sleep patterns, and the environmental light and sound levels in a General Pediatric Unit or the Pediatric Intensive Care Unit (PICU). Actigraphy data revealed that sleep quantity (both nighttime sleep [19h30-07h29] and 24-hour sleep) across all age groups was significantly decreased in hospital with greater reductions seen in the PICU. Frequent nighttime awakenings were observed and light and sound levels were found to be above those recommended for sleep. Corser (1996), through observation, found that the mean night sleep of one to two year old children at home was 597.5 minutes (SD 107.38) (~10 hours) prior to ICU hospitalization, and 435.83 minutes (~7.5 hours) (SD=166.98, range 135-645) during the child’s ICU stay, indicating approximately 2.5 hours less than usual sleep. Children in this study also had frequent nighttime awakenings (~9 times, SD=4.4, range 3-16), with the longest sleep opportunity of 155.42 minutes (~3 hours SD=43.98, range 100-235). It took these children approximately 3.5 weeks to return to a pre-illness sleep pattern after their hospitalization.

Findings from a descriptive, longitudinal pilot study found that hospitalized children and adolescents with cancer who were receiving chemotherapy had nocturnal awakenings ranging from 0-40 (median 14) per night, as measured with actigraphy (Hinds, Hockenberry, Rai, Zhang, Razzouk, McCarthy, et al., 2007). The number of nocturnal awakenings were significantly related to fatigue over the course of hospitalization (n=26, F=5.71, p=0.027); the more awakenings experienced, the greater the fatigue reported by patients.

Due to the frequency of nighttime interruptions, it may be assumed that children are not able to reach the deeper stages of sleep that are necessary for restoration and recovery. A study that utilized polysomnography (PSG) was conducted on two children aged 3 years old, who were admitted to a PICU and managed with a neuromuscular blockade (Carno, Hoffman, Henker,
Carcillo, & Sanders, 2004). Neither child was able to progress to stage 4 sleep and time spent in the lighter stages of sleep varied. One child spent 50% of time in stage 1 sleep and 41% in stage 2, while the second child spent 11% of time in stage 1 sleep, 63% in stage 2, and 4% in stage 3. Although this study had a small sample size, and these children were very ill, these findings indicate that these children were not achieving quality sleep since they were spending more time in the early stages of NREM sleep, indicating severely disrupted sleep (Carskadon & Dement, 2005).

Children who are attempting to sleep in the hospitalized environment have significantly reduced total sleep time, frequent interruptions, and short periods of undisturbed sleep. Findings suggest that children are not able to progress to the deeper stages of sleep, which are often desired in vulnerable populations. With the exception of the studies conducted by Carno et al. (2004), Hinds et al. (2007), and Stremler et al. (2009), all of the studies discussed above determined sleep by nighttime observation and did not discuss how the observers were trained or whether inter-rater reliability was assessed, which creates potential bias. Studies using more objective methods to measure sleep are needed to determine the sleep patterns of hospitalized children. Nonetheless, there are many factors associated with the disruption or inhibition of sleep in the hospital setting as well as during the post-hospitalization period. The need for sleep tends to be greatest when an individual is subjected to stresses and anxieties related to illness and hospitalization. Yet, at a time when maximum sleep and rest are needed for recovery from the physiological and psychological effects of illness and hospitalization, children have difficulty achieving adequate sleep.
Changes in Children’s Sleep Post-Hospitalization

In addition to the development of sleep difficulties due to disruptions while in hospital, studies suggest that hospitalized children are more likely to exhibit new-onset maladaptive behavioural changes as measured by the *Post Hospitalization Behavioral Questionnaire* (PHBQ) during the post-hospitalization period (Thompson & Vernon, 1993). The PHBQ is the most commonly used measure for examining post-hospital behaviour. Behavioural changes that have been documented include: general anxiety, apathy, withdrawal, and sleep problems related to sleep anxieties. Using the PHBQ, Kotiniemie et al. (1997) reported an incidence of 18% for sleeping problems in a sample of 551 outpatient surgical children with significant decreases after 4 weeks. Similarly, Kain et al (1996) demonstrated that sleep problems occurred in up to 20.2% of children 2 weeks after surgery. In the study discussed earlier by Corser et al. (1996), the investigators note that parental perception of the child’s sleep patterns after discharged from hospital took a period of approximately 3.5 weeks to return to a pre-illness sleep pattern.

Two studies that used actigraphy to assess the sleep patterns of children before and after hospitalization were found (Refer to Appendix A – Summary of Research of Changes in Children’s Sleep Post-Hospitalization). The first study investigated the sleep characteristics of children (ages 3-9 years) before and after outpatient surgery using a sample of 92 hospitalized children and 77 community-based children (Kain et al., 2002). Approximately 47% of the children in the surgery group experienced postoperative sleep disturbances as determined by both actigraphy and the PHBQ. The actigraphy assessed sleep patterns (e.g., sleep duration, number of awakenings), whereas the PHBQ assessed other sleep problems (e.g., anxiety regarding sleep, trouble falling asleep, and nightmares). Children who developed sleep problems exhibited shorter sleep duration (502 +/- 61 min vs 568 +/- 61 min; \( p = 0.0001 \)), demonstrated a more rapid
increase in anxiety during the pre-surgical waiting area, and were reported by their parents to be in more pain on the first and second post-operative day.

The second study examined changes in sleep efficiency in 55 children (6-12 years old) undergoing tonsillectomy and adenoidectomy (MacLaren & Kain, 2008). Sleep efficiency, expressed as a percentage, is often used as an indicator of children’s sleep quality. It is defined as the number of minutes spent in true sleep (total minutes actually in sleep during total sleep period) divided by the number of minutes of the total sleep period (between bedtime and wake-time). Although true sleep time, as measured by actigraphy, before and after surgery did not differ (mean 532.16 [SD 53.22] and 532.58 [SD 81.66] respectively), nor did the number of nighttime awakenings (mean 12.03 [SD 5.48] and 13.91 [6.11] respectively), children experienced significantly more long awake episodes (>5 min) following surgery than they did prior to surgery (t=5.16, p<0.01). These longer waking episodes were also reflected in the overall sleep efficiency. The mean sleep efficiency score prior to surgery was 88.79% (SD 5.57) compared to 83.47% (SD 7.23) post-surgery. Children that were found to be less social and more anxious were more likely to experience these sleep decrements, as were children who experienced greater pain in the post-operative period. These sleep changes continued for at least 4 days after being discharged home.

It appears that children may be prone to developing sleep problems during the post-hospitalization period. Although sleep problems are generally acute, they may prolong a family’s concern about their child’s well-being, and may severely impact their own sleep. The anticipated occurrence of such changes suggests the value in preparing families for discharge, reassuring them that post-hospital behavioural changes are not uncommon yet are typically brief in duration. Postoperative sleeping patterns have been attributed to multiple factors such as the
child’s temperament, peri-operative psychological trauma the child experiences, the child’s postoperative pain, and the anxiety levels of both the parent and child. Simple interventions such as teaching the child and parent a relaxation technique may prove to be beneficial in promoting sleep in hospital, but also in the prevention of sleep disturbances in the post-hospitalization period.

Factors Contributing to Sleep Disruption During Hospitalization

There is a paucity of literature examining factors that disrupt sleep during hospitalization in the pediatric population, however, it can be expected that children are at risk for sleep disturbances because of environmental factors related to hospitalization, medically related issues, as well as psychological issues (Rose et al., 2001). Similarly these factors have contributed to reduced sleep time and sleep efficiency, as well as increased awakenings and more daytime sleep in the adult population (Redeker, 2000).

Environmental Factors

Noise and Light

High levels of light and noise characterize the hospitalized environment. Noise in hospitals has been described by patients as excessively high (Redeker, 2000). It is also likely that patients will be more prone to be awakened more easily than they would be at home given that the noises in the hospital will be new and strange and the likelihood that patients will spend most of their sleep time in lighter stages of sleep (stage 1 and 2) (Webster & Thompson, 1986).

The World Health Organization recommends that noise levels during sleep should not exceed 30 decibels (dB) for continuous background noise (www.euro.who.int/Noise). Despite these recommendations, health care professionals have limited knowledge with regard to the impact excessive noise exposure has on the hospital environment and excessive noise remains to
be a problem (Christensen, 2005). In the pediatric intensive care unit, noise levels were consistently >48 dB(A) (The A-weighted decibel scale is used because it is intended to approximate the frequency response of our hearing system) with the highest night peak reaching 103 dB(A). Polysomnography indicated that wake states occurred in over 50% of episodes in which the maximum level was ≥ 75 dB(A) for three or more consecutive minutes (Al-Samsam & Cullen, 2005). In a general pediatric unit setting, mean minutes of sound levels >80 dB ranged from 32-47 minutes (Stremler et al., 2009). One study that recorded sound in decibels (dB) found that even an empty patient room during the night averaged 45 dB and peak decibel levels, both abrupt and short in duration, were as high as 113 dB (Cmiel, Karr, Gasser, Oliphant, & Neveau, 2004).

Frequently reported sources of noise include: equipment and alarms, other patients, staff talking, and telephones or intercom systems (Closs, 1988; Cmiel et al., 2004; Kahn et al., 1998; Redeker, 2000). In one study, the mean peak sound ranged from 74.8 dBA to 84.6 dBA with the loudest noise coming from staff talking in an adult intensive care unit. Over 50% of the noises identified in this study were potentially modifiable, with television and talking being the most prominent (Kahn et al., 1998).

Excessive light is also a source of sleep disturbance (Simpson & Lee, 1996). In the pediatric population, light levels of more than 150 lux occurred from 44-99 minutes over the night (Stremler et al., 2009). Exposure to bright light at nighttime affects the circadian system, which also impacts body temperature, level of arousal, and secretion of melatonin. This affects the sleep cycle, causing sleep-onset insomnia and early morning awakenings (Badia, Boecker, & Culpepper, 1991; Crowley, Acebo, & Carskadon, 2007; Koller et al., 1994).
Temperature

Sleep is strongly linked to body temperature as it takes cues from the circadian rhythm. Feelings of being too hot or too cold can disrupt the usual circadian variation in body temperature, aggravate sleep onset and therefore cause less efficient sleep (Webster & Thompson, 1986).

Interruptions from Health Care Providers

Frequent health care interactions at night, at a time when physiological sleep propensity is highest, place patients at risk for sleep disruption and deprivation and alter sleep architecture. Patients spend more time in stages 1 and 2 NREM sleep and therefore cannot complete cycling through to the deeper stages of sleep necessary for recovery. The most frequent types of nurse-patient interactions in adult critical care units were direct monitoring of vital signs (assessment of blood pressure and body temperature), urine output, and weight; indirect monitoring such as checking intravenous catheters and providing oxygen therapy; and measures to promote oxygenation such as deep breathing and coughing exercises, suctioning, mouth care, and repositioning the patient (Tamburri, DiBrienza, Zozula, & Redeker, 2004). Given the high acuity of patients in critical care units, nursing care interactions are likely to be more frequent since the severity of illness is associated with the number of care activities. One study that reviewed the health records of 50 adult ICU patients for number of interactions with a health care professional over a 12-hour night shift, found that on average patients experienced approximately 42 interactions per night (Tamburri et al., 2004).
Physiological Factors

Pain

Physiological factors are associated with poor sleep quality, frequent awakenings, longer total wake time at night, and early morning awakenings (Closs, 1992; Raymond, Ancoli-Israel, & Choiniere, 2004; Raymond, Nielsen, Lavigne, Manzini, & Choiniere, 2001). Furthermore, sleep disturbances often exacerbate pain symptoms. Experimental studies in both animals and humans reveal that the greater the amount of sleep deprivation, the lower the pain threshold (Moldofsky, 2001; Smith & Haythronthwaite, 2004).

In hospital, pain is a major source of disturbed sleep (Celik, Oztekin, Akyolcu, & Issever, 2005). In a study conducted in patients who had undergone abdominal surgery, pain and discomfort were the main reasons for nighttime awakening (Closs, 1992). Pain was reported as affecting the sleep of 63% of patients and 49% reported that their pain was worse at night. Provision of opioid pain medications was reported by patients as the most effective means of enabling them to return to sleep. Conversely, opioids have also been known to negatively affect sleep architecture. In a study conducted with adult postoperative patients who underwent abdominal surgery, polysomnographic recordings revealed suppression of slow wave sleep and the complete elimination of REM sleep during the first and second post-operative night (Knill, Moote, Skinner, & Rose, 1990). When morphine use was highest REM sleep time was lowest, and as morphine use declined, REM sleep time increased over subsequent nights.

As pain becomes more frequent and severe it may interfere with the child’s ability to sleep and to perform daily activities. Children diagnosed with Sickle Cell Disease (SCD) are often hospitalized for management of episodes of severe recurrent pain (Jacob et al., 2006). As part of a larger study that examined pain experience, pain management, and pain outcomes
among children with sickle cell disease, Jacob et al. examined sleep, food intake, and activity levels among a convenience sample of 27 children aged between 5 and 19 years, who were experiencing pain from a vaso-occlusive episode. Using 0-10 numeric rating scales (NRSs) children were asked to rate, on a daily basis, the amount of time they slept during the night and during the day, the amount of food they ate, and the amount of their activity. The NRSs were anchored by words that younger children used and were able to understand. The Oucher Pain Scale was used to assess the child’s current pain. On the first day, the mean score on the NRSs for the amount of sleep during the night (i.e., 0= did not sleep at all to 10= slept a lot) was 4.5 +/- 1.5 (range, 2.0-8.7). More than 50% of the children reported scores lower than 5 on Day 1, which suggests disruptions in nighttime sleep. The mean score for the amount of sleep during the day was 3.3 +/- 1.5 (range, 0.9-7.6) on Day 1. Approximately 20% of the children reported that they slept during the day (scores >5), which suggests disruptions in wake patterns. Persistent unrelieved pain may lead to disrupted nighttime sleep that appears to persist throughout the entire hospitalization.

Physiologically related sleep disturbances have not been studied in hospitalized children to the same extent as they have in adults. However, research findings support a high prevalence of sleep disturbances in children in the community with chronic or recurrent pain conditions. For instance, children with asthma have been found to have increased nocturnal awakenings with increased wake time and decreased mean sleep time (Sadeh, Horowitz, & Wolach-Benodis, 1998). Children with chronic headaches had more sleep disturbances in the areas of sleep onset delay, night wakings, parasomnias, sleep anxiety, and sleep-disordered breathing compared to a normative sample (Miller, Palermo, Powers, Scher, & Hershey, 2003). Sleep abnormalities around night wakings, parasomnias, sleep anxiety, and morning wakening/daytime sleepiness were common in children diagnosed with juvenile rheumatoid arthritis (JRA) as well as children
with juvenile idiopathic arthritis (JIA) (Bloom et al., 2002; Long, Krishnamurthy, & Palermo, 2008).

Other

The paucity of literature available indicates that pain interferes with sleep onset, maintenance and quality of sleep. Sources of pain may include not only the injury itself, but also subsequent treatments such as wound cleaning, surgical procedures, skin grafts from non-burned donor sites and physical rehabilitation (Rose et al., 2001). Furthermore, sleep disturbances from other physiological related factors may include the development of a fever, or nausea and vomiting in the middle of the night. Individuals undergoing treatments for cancer often suffer the harsh side effects of chemotherapy which include nausea and vomiting (Morrow, Roscoe, Kirshner, Hynes, & Rosenbluth, 1998).

Medications Disturbing Sleep and Wakefulness

In many cases, medications have unintended effects on both sleep and wakefulness. Effects on sleep quality include alterations in the speed of sleep onset, the continuity of sleep, or the duration of sleep. Cardiovascular drugs have been associated with difficulty falling or staying asleep (Epstein & Mardon, 2006; Schweitzer, 2005). Corticosteroids, such as prednisone at high doses, have been associated with increased wakefulness and decreases in REM sleep (Mindell & Owens, 2003a). Benzodiazepines, such as midazolam, are associated with suppression of SWS with variable REM sleep suppression, and a reduction in the frequency of arousals between sleep stages (Mindell & Owens, 2003a). Opioids such as codeine or morphine are associated with improved subjective quality of sleep (Schweitzer, 2005), as well as decreases in REM sleep and SWS (Cronin, Keifer, Davies, King, & Bixler, 2001). The table below provides a snapshot of various medications and the impact on sleep.
Table 2  
Medications’ Impact on Sleep

<table>
<thead>
<tr>
<th>Medication Type and Description</th>
<th>Impact on Sleep</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cardiovascular Drugs</strong></td>
<td></td>
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<tr>
<td>• Alpha-blockers – act on nerve cells that respond to the neurotransmitter norepinephrine.</td>
<td>• Cause daytime drowsiness and fatigue as well as insomnia and nightmares.</td>
</tr>
<tr>
<td>• Beta-blockers – have vasodilating properties and are used to treat high blood pressure, arrhythmias, and angina (e.g., metoprolol and propanolol).</td>
<td>• Associated with difficulty falling or staying asleep.</td>
</tr>
<tr>
<td>• Antiarrhythmics – used to treat heart rhythm problems.</td>
<td>• Cause daytime fatigue</td>
</tr>
<tr>
<td><strong>Corticosteroids/Glucocorticoids</strong></td>
<td></td>
</tr>
<tr>
<td>• Prednisone – at high doses</td>
<td>• Associated with increased wakefulness and decreases in REM sleep.</td>
</tr>
<tr>
<td>• Bronchodilators – such as ventolin given to patients with asthma.</td>
<td>• Insomnia perhaps due to its sympathomimetic effects (e.g., increased heart rate).</td>
</tr>
<tr>
<td><strong>Benzodiazepines</strong></td>
<td></td>
</tr>
<tr>
<td>• Midazolam – commonly used in preoperative anxiety. Usually it is indicated when children are perceived to be particularly anxious and distressed.</td>
<td>• Sedation, suppression of SWS with variable REM sleep suppression, and a reduction in the frequency of arousals between sleep stages.</td>
</tr>
<tr>
<td><strong>Opioids</strong></td>
<td></td>
</tr>
<tr>
<td>• Morphine – commonly used to control pain.</td>
<td>• Associated with improved subjective quality of sleep, daytime sedation, as well as decreases in REM sleep and SWS.</td>
</tr>
<tr>
<td><strong>Other</strong></td>
<td></td>
</tr>
<tr>
<td>• Antihistamines – diphenhydramine</td>
<td>• Decreases sleep onset latency, impairs sleep quality, and causes daytime drowsiness.</td>
</tr>
<tr>
<td>• Chloral Hydrate – often used in hospitalized children as a sedative before minor medical or diagnostic procedures. Onset of action is within 30 minutes.</td>
<td>• Decreases sleep onset latency.</td>
</tr>
<tr>
<td>• Antiemetic agents – such as gravol often administered for nausea and vomiting.</td>
<td>• Causes drowsiness.</td>
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**Psychological Factors - Anxiety**

Anxiety is perhaps the main psychological factor that affects a patient’s sleep (Closs, 1988; Reid, 2001; Webster & Thompson, 1986). Symptoms of generalized anxiety in children are very similar to what an adult would experience, such as feelings of tension, apprehension, nervousness, and worry (McCann & Kain, 2001; Papay & Spielberger, 1986). Hospitalization plays a significant role in the production of anxiety in children as the child integrates into an unfamiliar environment and a new system, which gives rise to new tensions and conflicts (Lizasoain & Polaino, 1995). Sleep deprivation may be heightened due to the anxiety or stress.
that the child experiences. In addition to sleep disturbances, children may express feelings of anxiety in various other forms including new onset enuresis (bed-wetting), feeding difficulties, and apathy and withdrawal (McCann & Kain, 2001).

Hospitalized children have been reported to have many possible sources of anxiety including: fear and worry over their illness and outcome; the unfamiliar environment; surgery or other medical procedures; separation anxiety from a parent or isolation from family and friends; cultural and academic deprivation; and lack of or decreased social interaction which is imposed by the new environment (Lizasoain & Polaino, 1995; McCann & Kain, 2001; Webster & Thompson, 1986). Factors associated with how the child will respond to hospitalization have been identified and include, the child’s age and temperament, the length of hospitalization (i.e., a consolidated hospital stay vs repeated short periods of hospitalization), previous experience of hospitalization, and parental response to hospitalization given that the level of parental anxiety directly affects the child’s own anxiety (Kain et al., 2002; Kain, LC Mayes, TZ O'Connor, & Cicchetti, 1996a; Kain, Mayes, Caldwell-Andrews, Karas, & McClain, 2006; Lizasoain & Polaino, 1995).

The anticipatory response is another source of stress the child may encounter during hospitalization. The anticipatory response to stress is considered a preparatory mechanism for defense in anticipation of a perceived threat; thus the sympathetic nervous system is activated. A healthcare provider may enter the room to assess the child, the child may perceive this as a threat causing the child to anticipate the worse or associate the visit with a painful procedure like a venipuncture.

Regardless of the source, anxiety directly influences the ability of the child to achieve adequate amounts of sleep. Anxiety triggers the human stress response activating increased
serum cortisol and epinephrine activity (Chrousos & Gold, 1992). These hormones lead to an increase level of physiological arousal making it more difficult to fall asleep and stay asleep. While cortisol is released throughout sleep, a higher than normal level of cortisol leads to increased wakefulness and inhibits slow-wave sleep (Stanley, 2005). Furthermore, anxiety is accompanied with other physiological activity that is counterproductive to the initiation and maintenance of sleep including increases in heart rate, respiratory rate, skin and core body temperature, muscle tone, and vasoconstriction of peripheral blood flow (Chrousos & Gold, 1992).

**Conceptualization of Factors that Disrupt Sleep During Hospitalization**

From the above discussion, it is evident that hospitalized children are at risk for sleep disturbances because of environmental factors related to hospitalization, physiological-related issues, as well as psychological issues (Refer to Figure 1 below). These disruptions contribute to decreased total nocturnal sleep, increased frequency of night-waking, and increased difficulty initiating sleep and maintaining sleep. Consequently, the hospitalized child spends more time in stages 1 and 2 NREM sleep and cannot achieve deeper stages of sleep that are deemed necessary for recuperation and recovery. Interventions need to be developed, evaluated, and implemented to avoid the negative consequences that may occur as a result of sleep restriction. Relaxation techniques are often suggested in the literature to negate the physiological and cognitive anxiety that may occur as a result of hospitalization and may be beneficial in eliciting the relaxation response, which is needed to promote sleep onset.
INTERVENTIONS USED TO PROMOTE SLEEP IN HOSPITAL

Several studies have been conducted in various hospital units in an effort to improve sleep for patients. Hospital units include various critical care units, general medicine, medical surgical, as well as some long-term care facilities and home for the aged. The interventions used in these studies can be clustered into two categories: 1) Behaviour Modification Programs which are aimed at reducing noise levels in the environment as well as interruptions from health care providers, and to decrease pain with opioids; and 2) Complementary or Alternative Techniques which focus on various relaxation techniques such as guided imagery, music, therapeutic touch, massage, and aromatherapy. To date, two studies implemented an intervention and assessed sleep as an outcome in a hospitalized pediatric population.
Sleep Interventions for Hospitalized Children

Two studies of an intervention to promote sleep in hospitalized children have been reported (Refer to Appendix A – Summary of Research of Interventions to Promote Sleep in Hospitalized Children). The first, was a quasi-randomized controlled trial, which used story reading as an intervention to promote sleep and examine the sleep onset latency (SOL) and incidence of distress in 94 medical and surgical patients, 3 to 8 years old, on a general pediatric unit using observation methods (White et al., 1990). Children who did not have a parent staying with them overnight were randomized to receive one of the following interventions: 1) a story audio taped by a parent; 2) a story audio taped by a stranger; or 3) no story. The fourth group had parents present at bedtime and the children did not listen to a recorded story. Children who received the parent-recorded story had significantly longer SOL (mean 64.59 ± 22.05) than the other three groups of children. Children with parents present at bedtime had significantly longer SOL (mean 54.43 ± 19.90) than children who received no story (mean 36.86 ± 18.98).

Interestingly, the children who received the parent recorded story group had the highest incidence of distress (56%) in comparison to children who received the stranger-recorded story (21%) and children who received no story at all (24%). The authors attribute this finding from the psychological discomfort generated by remembrances of home. This study was the first to examine a sleep intervention in hospitalized children and is not without limitations. The randomization procedure and measures of concealment were not adequately described. Furthermore, this study has less applicability presently, since most hospitalized children have a parent staying overnight with them. A larger randomized controlled trial using more objective methods to measure sleep patterns would be necessary to evaluate the effectiveness of this intervention.
The second study was a multi-site randomized controlled pilot study examining the feasibility of an enhanced physical activity (EPA) intervention on sleep and fatigue for hospitalized children and adolescents receiving treatment for a solid tumor or for acute myeloid leukemia (AML) (Hinds, Hockenberry, Rai, Zhang, Razzouk, Cremer, et al., 2007). Twenty-nine consenting children (ages 7 to 18 years old) and their families were randomized to either the Experimental Care (EC) group (n=14) or the Standard Care (SC) group (n=15). The EC group received the EPA intervention which consisted of pedaling a stationary bicycle-style exerciser for 30 minutes twice daily for 2-4 days of hospitalization with the presence of a team member. A team member also spent an equivalent amount of time with the patients who were randomized to the SC group. The study demonstrated good compliance as the intervention was successfully implemented 85.4% of the scheduled times. When the daily differences from baseline sleep efficiency values were averaged and compared, the EC group had greater sleep efficiency than did the SC group (F=4.17, p=0.053) as determined by actigraphy. No differences in patient (F=0.19, p=0.67), parent (F=0.83, p=0.37), or nurse reports of fatigue (F=0.19, p=0.67) between the study groups were noted. Although findings from this study are encouraging, no inferences can be drawn until an adequately powered trial is conducted. Furthermore, the focus of this study was aimed at decreasing fatigue, which is often reported to be the most distressing treatment-related symptom by pediatric oncology patients. The use of a homogenous sample of hospitalized children undergoing treatment for a solid tumor or acute myeloid leukemia (AML) limits the generalizability of such an intervention to other hospitalized children. Furthermore, utilizing EPA as an intervention may not be appropriate for all children who are admitted to the hospital.

A study that assessed the effectiveness of a back massage on the behaviours and physiology of children and adolescents (n=72) who were hospitalized for depression or
adjustment disorder has been reported (Field et al., 1992). Although sleep was not the primary outcome, percentages of time in bed that sleep occurred were reported over a 5 day period. Children and adolescents between the ages of 7 and 18 years were randomly assigned to receive a 30-minute back massage from a psychology student, or to the control group, which consisted of watching a videotape of pleasant sounds and visual images. Nighttime sleep was videotaped on the first and last treatment days (days 1 and 5 respectively) using a time-lapse video camera, which enabled the researchers to code the videotapes enabling 8 hours of videotape to be coded in 2 hours. The tapes were coded for quiet sleep, active sleep, awake and lying quietly, and awake and active. The percentage of time in bed that sleep occurred significantly increased over the 5-day period (79.7% day 1, and 91.3% on day 5, p=0.01), and the percentage of time that nighttime wakefulness occurred correspondingly decreased over the same period for the massage group (15.2% day 1, and 4% day 5, p=0.05). The between group differences were not reported. The methods for scoring the videotapes, whether or not the raters were blinded to group assignment, the number of raters and their training, and other details of sleep measurement were not described, making it difficult to draw conclusions.

**Behavioural Modification Programs to Promote Sleep**

The recognition of the problem of sleep restriction in hospital settings has led to the development and implementation of sleep-promoting interventions and protocols. Behavioural modification programs that have been reported in the literature are aimed at educating members of the hospital health care teams on the importance of sleep and how behaviour modification can potentially improve sleep in patients.

Several studies have been conducted evaluating behaviour modification strategies in various types of units including intensive care units, neurological intensive care units (NICU),
medical intensive care units (MICU), acute care units, and general medical units. Behaviour modification programs that have been implemented include efforts to reduce hospital noise and light (e.g., equipment, staff noise levels, television, intercom systems), clustering patient care (e.g., providing blocked times for undisturbed sleep, having flexible medication administration times), and managing pain post-operatively (e.g., subcutaneous patient controlled analgesic [PCA] vs intravenous PCA) (Dawson, Brockbank, Carr, & Barrett, 1999; Edwards & Schuring, 1993; Jarman, Jacobs, Walter, Witney, & Zielinski, 2002; Kahn et al., 1998; McDowell, Mion, Lydon, & Inouye, 1998; Monsen & Edell-Gustafsson, 2005; Olson, Borel, Laskowitz, Moore, & McConnell, 2001; Walder, Francioli, Meyer, Lancon, & Romand, 2000).

All behaviour modification programs that have been reported have been implemented in adult hospital settings (Refer to Appendix A – Summary of Research of Behavioural Modification Programs to Promote Sleep in Hospital Settings). The lack of rigorous methods to evaluate the effectiveness of these protocols on sleep quality and quantity makes it impossible to draw conclusions. Sleep measures were conducted through nurses’ observation, which introduces various biases on sleep quantity. None of these studies used a randomized controlled trial design, therefore the effectiveness of these programs on sleep cannot be determined.

To properly assess the effectiveness of such organizational interventions, a cluster randomized controlled trial would be necessary with rigorous protocols, and objective methods to measure sleep quantity such as the use of actigraphy, which has demonstrated to be a feasible, non-invasive method in obtaining various sleep measures (e.g., total time of nocturnal sleep, number of awakenings etc.). Without such rigorous research available, it is difficult to draw conclusions on causal relationships. Furthermore, such interventions focus on organizational changes, which further necessitate the need for larger, rigorous, evaluative methods. The lack of
evidence to support the feasibility of implementing such protocols makes it a difficult undertaking.

Complementary and Alternative Techniques to Promote Sleep

Several studies have examined the use of various complementary and alternative therapies such as massage (Ejindu, 2007; Richards, 1998), music therapy or sound therapy (Brooks, 1989; Hammer, 1996; Pelletier, 2004; Summer, 1981; Zimmerman, Nieveen, Barnason, & Schmaderer, 1996), progressive relaxation (Griffin, Myers, Kopelke, & Walker, 1988) and guided imagery (Richardson, 2003) to promote sleep in hospitalized individuals. With the exception of the study conducted by Field et al. (1992) discussed earlier, all studies have been conducted on hospitalized adults and are summarized in Appendix A (Summary of Research of Complementary and Alternative Interventions to Promote Sleep in Hospital Settings).

While music therapy is thought to promote health and well-being as it decreases stress and arousal, which may be helpful in promoting sleep (Richards, Nagel, Markie, Elwell, & Barone, 2003; Zimmerman et al., 1996), most studies have focused on the effect of music on anxiety (Brooks, 1989; Hammer, 1996; Summer, 1981), and less emphasis has been placed on determining the effects of music on the promotion of sleep. The effects of other music therapy interventions (e.g., music video therapy) and sound interventions (e.g., ocean sounds) have been studied on hospitalized patients (Williamson, 1992; Zimmerman et al., 1996), however these studies did not use objective methods when assessing sleep measures, and poor random allocation methods and concealment methods (i.e., coin toss) introduce the possibility of bias to these studies.

Relaxation techniques such as progressive relaxation and guided imagery have also been explored as possible interventions to promote sleep in hospitalized patients. Relaxation
techniques are aimed at activating the parasympathetic nervous system, which decreases arousal levels and induces the relaxation response (Benson, 1975). Progressive muscular relaxation (PMR) is a technique described by Edmund Jacobson, which is based on the hypothesis that muscular tension accompanies anxiety therefore one, can reduce anxiety by learning how to relax the muscular tension (Scheufele, 2000). The technique involves deliberately tensing specific muscle groups then relaxing them to create awareness of tension and relaxation. It is termed progressive because it proceeds through all the major muscle groups, relaxing them one at a time, and eventually leads to total muscle relaxation. Guided imagery (GI) involves patients using their imagination to visualize a peaceful setting such as lying on a beach or watching a sunset (Richards et al., 2003). Small sample sizes and poor random allocation methods make it impossible to draw causal relationships. Furthermore, these studies were conducted on adult populations. Techniques such as PMR and imagery for relaxation may require increased concentration and time for practice, making them more challenging for the pediatric patient.

**SUMMARY OF LITERATURE AND THE NEED FOR SLEEP INTERVENTIONS**

Sleep is essential for good health and aids in the recuperation and recovery of illness. Yet, during hospitalization, a time when the benefits of sleep are needed the most, sleep is difficult to achieve. Children may be especially prone to the development of sleep issues in hospital settings and have also shown sleep anxieties during the post-hospitalization period. Despite the importance of sleep, interventions aimed at promoting sleep in hospitalized children are scant. Although there have been studies examining the effects of various behavioural modification interventions as well as complementary and alternative interventions in the promotion of sleep in hospitalized adults, the lack of quality of these studies makes it difficult to assess the effectiveness. Most of the studies recruited small sample sizes, had inadequately concealed allocation to group, or used a pre-test post-test single group design, which threaten the
validity of the findings. Most studies measured sleep quantity through observation or self-report. More objective methods of measuring sleep such as actigraphy are necessary to increase the validity of findings. Although some of the methods in promoting sleep show some promise, without rigorous methods such as controlled trials, recommendations concerning these treatments cannot be made.

While a large portion of the above noted studies aimed their intervention to focus on modifications to the environment, the feasibility and acceptability of such organizational changes is difficult to achieve. More interventions need to be developed at the individual level so that it can also be portable into the home once the patient is discharged. Utilizing various other complementary and alternative techniques such as massage require specialized training and in some cases registration to a designated college is mandatory (e.g., Registered Massage Therapist). Furthermore, the use of such techniques would increase the workload of health care clinicians and therefore they may likely dismiss the idea of incorporating massage in their patient care routine. Interventions aimed at the individual level whereby the child can have some control over their health care and parents can also participate may be more appealing.

**RELAXATION BREATHING AS A CLINICAL INTERVENTION**

*Effects of Relaxation Breathing on Anxiety*

Relaxation therapy involves a number of techniques designed to combat the stress response and elicit the relaxation response. As discussed previously, hospitalization can be the source of much stress and anxiety in children which is characterized by a variety of subjective feelings including tension, apprehension, nervousness, and worry (Kain et al., 1996a). When an individual feels anxious or appraises an event as threatening, the stress response is activated. A number of physiological events occur in response to the stressor and are mediated by the brain
through a complex network of chemical and electrical messages. The hypothalamus, which is located in the centre of the brain, integrates the autonomic nervous system (ANS) mechanisms that maintain the chemical constancy of the internal environment. The ANS is further divided into the sympathetic nervous system (SNS) and the parasympathetic nervous system (PNS). When the SNS, or commonly referred to as the “fight-or-flight” system, is triggered and activated with the release of norepinephrine this causes an increase in function of the vital organs as well as a state of body arousal (Smith, 1999).

The physiological features of the stress response include increased respiration rate, increased heart rate, and peripheral vasoconstriction that raises the blood pressure. To provide sufficient perfusion of vital organs such as the brain, heart, and skeletal muscles, blood is shunted away from the abdominal organs. The metabolic effects of the SNS include the stimulation of the adrenal cortex to produce glucocorticoids, primarily cortisol. Cortisol stimulates gluconeogenesis by the liver, which provides a readily available source of energy for the body during a stressful situation. Although the hypothalamic pituitary-adrenal axis supports and enhances the SNS response, it also suppresses the immune system and heightens susceptibility to illness, infection, and other complications such as neoplastic disease (Ader, Cohen, & Felten, 1995).

Neurobehavioral reactions when the “fight-or-flight” response is activated include increased arousal, alertness, scanning, and vigilance. This is counterintuitive for sleep onset, as the body needs to be in a relaxed state. Emotional tone is altered, with increased subjective apprehension as well as anxiety, frustration, fear, anger, and feelings of inadequacy, helplessness, or powerlessness (Schaffer & Yucha, 2004). In the presence of these emotions, the individual’s customary activities of daily living may be interrupted, for example a sleep
disturbance may be present, eating and activity patterns may be altered, and family processes or role performance may be disrupted.

While the “fight-or-flight” response is associated with the over activity of the SNS, there is another response that leads to a quieting of the same nervous system. This is known as the relaxation response which occurs when the body no longer perceives danger, and the ANS functioning returns to normal (Benson, 1975). The relaxation response has been defined as, “a set of co-coordinated physiological changes that are brought forth when a person focuses attention on a repetitive mental activity and passively ignores distracting thoughts” (Fentress, Masek, Mehegan, & Benson, 1986). During this response, the body moves from a state of physiological arousal, to a state of physiological relaxation with marked decreases in blood pressure, heart rate, respiratory rate, oxygen consumption, carbon dioxide, as well hormonal levels such as cortisol return to their normal states (Benson, 1975). In addition, the relaxation response lowers musculoskeletal tone, and altered neuroendocrine function is associated with restoration and repair of tissues. There are slight increases in the intensity of slow alpha waves on the EEG that differ from those which occur during sleep and quiet sitting and are consistent with decreased activity of the SNS (Fentress et al., 1986).

When the body is in a constant state of physiological arousal, therapeutic approaches can be implemented to reduce SNS activity and induce the relaxation response. Utilizing good sleep-hygiene measures and relaxation techniques such as meditation, yoga, tai chi, deep breathing exercises and other tension taming and stress-management techniques may help to achieve a good ANS balance, particularly in individuals with difficulties initiating and maintaining sleep (Bonnet & Arand, 1997; Stanley, 2005).
Relaxation techniques are multimodal and can include bibliotherapy, distraction techniques, massage therapy, and relaxation training. These techniques have been used in children with situational specific symptoms of anxiety, including test anxiety, anxiety relating to medical treatments, and specific children’s fears (e.g., fear of the dark) (Parslow et al., 2008). However, not all relaxation techniques are developmentally appropriate for children of all ages. Careful consideration should be given when choosing a technique for children to ensure that they are simple, easy to learn, have immediate usability, and have minimal expenditure of time and effort during use (de Jong & Gamel, 2006). Hospitalized children may be too ill to take the time and exert the attention and discipline needed to learn complex techniques. Controlled breathing is a relaxation technique that meets the aforementioned criteria, and no additional equipment costs are incurred with its use.

Relaxation breathing, or controlled breathing, can be easily taught to young children utilizing a variety of techniques, such as the use of books (e.g., bibliotherapy) or bubble blowing (Cabe, 2004; Hockenberry, 1988). Relaxation breathing is a process of reducing the experiences of anxiety symptoms (decreasing the SNS response) and eliciting the relaxation response by controlling the depth and the speed of one’s respirations (Hernandez & Kolb, 1998). Furthermore, teaching the child deep and controlled breathing can also decrease the physiological arousal system, which is needed to facilitate sleep. Not only can children overcome the physical responses of stressful situations, deep breathing exercises may ease the emotional distress and empower them to have control over emotions and behaviours (Cabe, 2004).

Relaxation Breathing in Children

Relaxation breathing or controlled breathing has been used independently or in combination with other relaxation techniques such as imagery and muscle relaxation. In children,
it has been used as a coping skill for painful medical procedures (Alvarez & Marcos, 1997; McDonnell & Bowden, 1989), as a method to reduce anxiety (Day & Sadek, 1982), and a technique used in dealing with exacerbations of medically related issues such as asthma and recurrent abdominal pain (Chiang, Ma, Huang, Tseng, & Hsueh, 2009; Weydert et al., 2006) (Refer to Appendix A – Summary of Research of Relaxation Breathing in Children).

During hospitalization, the child may undergo various procedures such as diagnostic and treatment procedures that are often invasive and painful. Breathing exercises, in which the child paces and controls breathing during stressful or painful situations, can decrease physiological responses to anxiety or fear and provide a way to focus attention elsewhere. In a review examining the therapeutic techniques used in children with cancer, distraction, imagery, and relaxation respiration exercises were the essential therapeutic methods in attempts to alleviate child discomfort evoked by invasive medical procedures (Alvarez & Marcos, 1997). Four of the nine studies described in this review used relaxation respirations in combination with other techniques in children between the ages of 3 and 15 years of age undergoing bone marrow aspiration, lumbar puncture, and/or intravenous injections. Although the studies had different outcome variables, it was noted that children had decreases in self-reported pain, observed distress, increased number of coping behaviours, and also there were decreases in parental distress and anxiety. It is difficult to draw conclusions from this review, as the authors do not discuss the details of each study, and sample sizes of these studies appear to be small. Other reports of the use of relaxation breathing techniques in the literature are also of poor quality. For example, a case study employing a simple breathing technique to reduce the stress experienced by 2 hospitalized children who were unable to cope with anxiety and pain was included (McDonnell & Bowden, 1989). No objective measures or outcome measure are discussed and therefore one cannot draw conclusions. A randomized controlled trial whose primary purpose
was to evaluate the effectiveness of the cognitive-behavioral techniques (relaxation breathing or distraction) on children’s pain experience during a bone marrow aspiration or lumbar puncture had to stop because the control group was contaminated (McCarthy, Cool, & Hanrahan, 1998).

Three randomized controlled trials that utilized relaxation breathing as an intervention have been reported. The first conducted by Day and Sadek (1982) assessed the effectiveness of Benson’s Relaxation Response on the anxiety levels of Lebanese children aged 10 to 12 years old under stress from the political warfare occurring in Lebanon. Children (n=62) were randomly assigned to receive the relaxation technique or a reading-activity with no relaxation involved. Over a 6-week period, children in the experimental group conducted relaxation breathing every morning for ten minutes prior to the start of class, while children in the control group participated in a special reading activity. Students in the experimental group reported a lower level of stress on both the situation-specific and general anxiety measures. A significant treatment effect for general stress (p<0.01) and for test anxiety was reported.

The second RCT (Chiang et al., 2009), evaluated the effectiveness of combined self-management and relaxation-breathing training for children with moderate-to-severe asthma compared to self-management-only training. Both the experimental group (n=22) and control group (n=23) participated in a self-management training, which included explanations of asthma disease, asthma medication, and monitoring with peak flow meters. Children in the experimental group also received a 30-minute relaxation breathing training, which combined some muscular tension and relaxation. During the 12-week intervention, participants practiced relaxation for 30 minutes at least three times per week. Anxiety decreased on average over the 12-week intervention for the experimental group (from a mean score of 31.73 [SD 12.27] to 26.11 [SD 11.41]), but increased for the comparison group (from a mean score of 29.96 [SD 11.96] to 32.21...
Post-intervention, children in the experimental group had significantly less total anxiety than their comparison group ($t=2.27$, $p<0.05$).

The third RCT examined the use of breathing exercises alone compared to guided imagery with progressive muscle relaxation in a group of 22 children between the ages of 5 and 18 years old with recurrent abdominal pain (Weydert et al., 2006). Both groups had four weekly sessions with a therapist and outcome measures included number of days with pain, the pain intensity, and missed activities due to abdominal pain. Children who learned guided imagery with progressive muscle relaxation had significantly greater decrease in the number of days with pain (7.5 range 2.9, 12.2) than those learning breathing exercises alone (11.3 range 4.3, 18.2) after one month ($p=0.05$) and two months (4.2 range 0.8, 7.5 vs. 7.9 range 3.7, 12; $p<0.01$), however there was no difference in the mean intensity of pain between the two treatment groups.

Due to the lack of substantial evidence regarding the use of relaxation breathing in children, it is difficult to establish efficacy of its use in the clinical setting. Therefore, it is warranted to examine its potential benefits in a clinical setting using rigorous evaluative methods. Furthermore, given that relaxation breathing appears to be an easy and cost effective method, it may also prove to be acceptable to not only children and parents, but also health care providers alike. Staff and parents demonstrated great acceptability for various relaxation techniques used in children for painful procedures (McCarthy et al., 1998). Due to the contamination of the control group, McCarthy et al. (1998) could not report on the primary purpose, but reported on acceptability issues. Parents who received a training session in each of the relaxation techniques (distraction, progressive muscle relaxation, controlled breathing, and imagery) chose distraction and controlled breathing to be used during their child’s procedures. Furthermore, the use of controlled breathing increased across time with more parents opting to
use breathing exercises during procedures. The parents also reported that controlled breathing was moderately effective in helping their child cope during the painful procedure. Imagery was thought to require more training and practice, and was not used by any of the parents. In the study conducted by Chiang, et al. (2009), many children claimed that practicing relaxation every night enabled them to feel very relaxed, calm, and to fall asleep easily. They also report that the deep breathing exercises were easy to implement, especially following the directions on the relaxation CD. These reports suggest a high acceptability of the utilization of relaxation techniques in children and further suggest that parental participation is warranted, especially in younger children.

**Parental Participation**

Hospitalization of a child may be stressful and frightening not only to the child but the parent as well. With the focus of most hospital settings being family-centered, parents often stay overnight with their hospitalized child and are also involved in their care. During the hospitalization period disruptions of parental role may occur leading to parents feeling loss of control and independence (Melnyk, Feinstein, & Fairbanks, 2006; Meshkani & Bavarian, 2005). Therefore parents may be in a unique position to participate in the delivery of the relaxation technique to their child. In an attempt to decrease the child’s anxiety through eliciting the relaxation response, parents may also experience its benefits as it provides them with a tool to assist their child in dealing with anxiety, as well as a strategy to deal with their own stress and discomfort during the hospitalization period. Other potential advantages of including the parent in this intervention is that parents have personal knowledge of the child across several domains of functioning, children usually have established trust and rapport with their parents, and parents are more broadly present during hospitalization than the health care provider (Rapee, Abbott, &
Lyneham, 2006). Furthermore, the child may respond more appropriately to the intervention if the parent is delivering it (Lamontagne, Mason, & Hepworth, 1985).

*Using Bibliotherapy*

Teaching a child to use relaxation techniques requires verbal instruction, role rehearsal, or modeling the skill to the child (Patterson & Ware, 1988). Bibliotherapy may be well received for younger children trying to learn a breathing technique. Bibliotherapy uses a book rather than a therapist to model desired behaviour, and teaches a specific strategy (Parslow et al., 2008). A small scale study with four children between the ages of 2 and 7 used story-telling and examined the efficacy of this social story on disruptive bedtime behaviors and frequent night waking (Burke, Kuhn, & Peterson, 2004). The intervention consisted of a social story (The Sleep Fairy) that clearly describes appropriate bedtime behavior. Although the study was not implemented in a hospital setting, the study found that the story produced rapid and sustained reductions in the frequency of the children’s targeted disruptive bedtime behaviors and was highly acceptable to the parents. Given the small sample size, and the descriptive nature of these findings, results cannot be generalized.

One RCT of bibliotherapy for parents of anxious children involved children aged 6-12 years (n=267). Children and their parents were randomly assigned to receive either standard group cognitive behaviour therapy (CBT) (n=90), a bibliotherapy version (n=90) of the same therapy, which instructed parents in how to administer the treatment, or a wait-list control (n=87). The bibliotherapy for parents produced significant improvement in clinically assessed anxiety compared with wait-list control ($t=2.14; p<0.05$), but not as much as those in group CBT ($t=6.95; p<0.001$) (Rapee et al., 2006). However, findings suggest that parents are in a unique position to deliver interventions to their children through the use of bibliotherapy.
While relaxation breathing has been used in children as an intervention on many different dimensions of anxiety as well as for pain management, its effect on sleep outcomes has yet to be examined. Given that hospitalization can be a source of anxiety for children and can lead to disturbed sleep, relaxation breathing may be effective in promoting sleep.

**CONCEPTUAL FRAMEWORK GUIDING THIS STUDY**

The RELAX TO SLEEP program is a behavioural-educational intervention and includes: 1) parental education on the importance of sleep and consequences of sleep restriction, as well as education on the importance of the development of healthy sleep habits in children during their hospital stay as well as upon discharge; and 2) promoting sleep by inducing the relaxation response through relaxation breathing (guided by storybook or CD) both during their hospital stay as well as in the home. Figure 2 below demonstrates the relationship and the outcomes that were hypothesized.

Figure 2 *Conceptual Framework Guiding the RELAX TO SLEEP Program*
Description of RELAX TO SLEEP Program

The RELAX TO SLEEP program consisted of an educational component as well as a behavioural component. To increase parental knowledge on sleep, the sleep education component consisted of educating the parent on the importance of sleep, the consequences of sleep restriction, common sleep problems, and child sleep during hospitalization. The term ‘sleep hygiene’ refers to behaviours, environmental conditions, and other sleep-related factors that can be adjusted to promote improved quantity and quality of sleep (Stepanski & Wyatt, 2003). Although it is difficult to modify certain behaviours and environmental conditions while hospitalized, educating the parents and child, if appropriate, on sleep hygiene practices is important. The sleep hygiene component of the intervention included information about behaviours that should be avoided and promoted while hospitalized and at home to help strengthen the circadian rhythm and the homeostatic sleep drive. Furthermore, information on strategies that parents can implement to promote sleep during their child’s hospital stay as well as upon discharge were provided. Parental participation was an essential component of the intervention since parents were in the position to enforce healthy sleep habits. A booklet containing this information was included as part of the intervention as a resource. Through a one-on-one discussion with a member of the research team, suggestions could be tailored to each child or specific sleep issue. Educating parents about sleep and sleep hygiene practices were expected to increase the quantity of the child’s nocturnal sleep. Parents need a rationale and must recognize the potential benefits of sleep hygiene and the relaxation technique if they are to encourage their child to learn and use the skill (Patterson & Ware, 1988).

The relaxation component of the conceptual framework provided a foundation and organizational structure to explain how relaxation breathing can elicit the relaxation response and counteract the physiological and psychological arousal system induced by anxiety. The
relaxation response results in a decrease of both the physiological and psychological arousal systems. This response may also decrease state anxiety which is characterized by feelings of tension, apprehension, nervousness, worry, and heightened activity of the ANS (Papay & Spielberger, 1986). Decreasing the child’s anxiety levels may lead to a decrease in the SNS arousal system, which will further increase the relaxation response. Initiating the relaxation response may then lead to the facilitation of sleep. Although components of the SNS and arousal system were not measured the relevance of including these components in the framework was deemed necessary to conceptually describe how the relaxation response could potentially lead to more sleep.

**Research Objectives**

Given the lack of evidence-based interventions aimed at promoting child sleep during hospitalization and afterward in the home, an important first step is to develop and test the feasibility and acceptability of the intervention.

**Primary Purpose**

The primary purpose of this pilot RCT was to determine the feasibility and acceptability of the RELAX TO SLEEP program in the hospital setting. Several important feasibility and acceptability questions were addressed in preparation for a larger adequately powered RCT. Below is a table of the feasibility and acceptability questions.
Table 3
Feasibility and Acceptability Objectives

<table>
<thead>
<tr>
<th>Feasibility Questions</th>
<th>Acceptability Questions</th>
</tr>
</thead>
<tbody>
<tr>
<td>What percent of families agree to participate?</td>
<td>What did the participant like about being in the RELAX TO SLEEP study?</td>
</tr>
<tr>
<td>What is the monthly recruitment rate?</td>
<td>What did the participant dislike about being in the RELAX TO SLEEP study?</td>
</tr>
<tr>
<td>What is the total amount of time required to deliver the intervention?</td>
<td>What is the likelihood the participant would choose to be in the larger study?</td>
</tr>
<tr>
<td>What numbers of families receive the one-on-one session with a member of the research team?</td>
<td>Did the actigraph cause any discomfort?</td>
</tr>
<tr>
<td>What components did people in the intervention group find useful?</td>
<td>Did the actigraph interfere with participants’ usual daily activities?</td>
</tr>
<tr>
<td>How often did they use the relaxation breathing technique in hospital? At home?</td>
<td>Did the actigraph cause the participant to worry?</td>
</tr>
<tr>
<td>How often did they use the book/CD to do the relaxation breathing technique?</td>
<td>Did the participant enjoy using relaxation breathing?</td>
</tr>
<tr>
<td>How many families are reachable at home once discharged from hospital?</td>
<td>Were the instructions of the relaxation breathing easy to follow?</td>
</tr>
<tr>
<td>How many families complete the study once discharged home?</td>
<td>Would the participant recommend relaxation breathing to others?</td>
</tr>
<tr>
<td></td>
<td>Would the participant use relaxation breathing again in the future?</td>
</tr>
</tbody>
</table>

SECONDARY PURPOSE:

For exploratory purposes only, the following research questions were posed. Note the terms primary, secondary, and other describe how the questions will be categorized for the larger trial.

Primary Research Question:

1. In hospitalized children, what is the effect of the RELAX TO SLEEP program on total nighttime (19h30-07h29) sleep compared to children receiving usual care?

Secondary Research Questions:

2. In hospitalized children, what is the effect of the RELAX TO SLEEP program on number of nighttime (19h30-07h29) awakenings compared to usual care?
3. In hospitalized children, what is the effect of the RELAX TO SLEEP program on the longest stretch of nighttime (19h30-07h29) sleep compared to usual care?
4. In hospitalized children, what is the effect of the RELAX TO SLEEP program on daytime sleep (07h30-19h29) compared to usual care?
Other Research Questions:

5. In hospitalized children, what is the effect of the RELAX TO SLEEP program on anxiety levels compared to usual care?
6. In hospitalized children, what is the effect of the RELAX TO SLEEP program on sleep disturbance behaviours post-hospitalization compared to usual care?
CHAPTER 3
Research Design and Methods

STUDY DESIGN OVERVIEW

This pilot study was a randomized controlled trial to determine the feasibility and the acceptability of a behavioural-educational sleep intervention (The RELAX TO SLEEP program), including training in use of relaxation breathing. A list of group assignments were generated by a research coordinator outside of the study team and were sequentially numbered and placed in sealed opaque envelopes which were centrally controlled at the Lawrence S. Bloomberg Faculty of Nursing at the University of Toronto. Eligible, consenting children and their families were randomly allocated to a control group or an intervention group. Participants in the control group received usual care, while those in the intervention group received usual care and the RELAX TO SLEEP program. Blinding of study participants was not possible due to the nature of the intervention. Participants in each group wore actigraphs for three days and nights. Follow-up data were collected from the parents 5-10 days post-discharge via a telephone interview conducted by a research assistant.

PARTICIPANTS AND SETTING

This study was a single center pilot trial, which was conducted at the Hospital for Sick Children (SickKids), a quaternary level pediatric hospital located in the greater Toronto area. To be approached for possible inclusion in this study, the child had to meet certain criteria.

ELIGIBILITY CRITERIA

Children anticipated to stay for 3 nights were approached for inclusion in this study. According to the practice parameters for the role of actigraphy in the study of sleep and circadian rhythms set by the American Academy of Sleep Medicine, actigraphic studies should be
conducted for a minimum of three consecutive 24-hour periods (Littner et al., 2003). Since previous sleep studies conducted at SickKids demonstrated shorter hospital stays, and due to the limited number of actigraphs, as well as not to overburden the participants with sleep diaries, we adhered to the minimum of 3 days and nights for actigraphy monitoring. Therefore, the following eligibility criteria were set for the current study:

**Inclusion Criteria**

1) Children between the ages of 4 and 10.

2) Child admitted to one of the General Pediatric Medicine (7B, 7C, 7D), Cardiology (4D), or General Surgery (5B) units.

3) Must be in a single private room.

4) Anticipated to stay for 3 nights.

5) Child must have a primary care giver (i.e., mother, father) who planned to stay overnight with the child.

6) Primary caregiver must understand English (must read English).

**Exclusion Criteria**

1) Children who are receiving palliative care only during their hospital admission.

2) Children diagnosed with a sleep disorder (e.g., restless legs syndrome) or a clinical anxiety disorder (determined by written documentation in the child’s hospital chart).

3) Children with limited or abnormal movements of both upper and lower extremities (e.g. paralysis, brain injury, cerebral palsy, use of drugs to induce paralysis, musculoskeletal impairments, use of restraints, under heavy sedation), thereby impairing sleep wake activity recording and their ability to use the relaxation breathing exercise.
4) Children who are too acutely ill to participate in the study.

5) Children who had major cognitive impairments that could affect their ability to understand and carry out the intervention.

6) Children receiving benzodiazepines or chloral hydrate.

Infants and toddlers between the ages of one and three were excluded since developmentally they would not be able to carry out the intervention. Adolescents were excluded because of their tendency to have sleep phase delay (e.g., they go to bed at a later time, and then have difficulty waking up at a desired time), which is thought to occur due to hormonal changes from puberty (Carskadon, Harvey, & Dement, 1981; Oskar et al., 2005). Although adolescence was considered a period of development based on puberty from about the age of 12 or 13 years old, it appears that children are undergoing pubertal characteristics at younger ages than previously thought. Therefore 11 to 18 year olds were also excluded from this study for the same reasons mentioned above (Herman-Giddens et al., 1997; Kaplowitz & Oberfield, 1999).

Setting

The General Pediatric Unit is the largest in-patient unit at SickKids with 50 beds and is composed of three teams (7B, 7C, 7D). Some commonly seen illnesses include: failure to thrive, feeding intolerance requiring enteral tube support, complex pneumonia requiring chest tubes, asthma, bronchiolitis, urinary tract infections, gastroenteritis, and complex care needs such as undifferentiated or undiagnosed conditions requiring multidisciplinary care (e.g., children with genetic conditions, children undergoing diagnostic investigations to establish diagnoses such as cancer, inflammatory bowel disease). Large portions of children admitted to 7B are likely to have developmental delays. The Cardiology Inpatient Unit (4D) has 29-beds and cares for children from neonates to 18 years of age with non-critical care cardiac conditions as well as pre-
and post-surgical patients, and pre- and post-transplantation patients. The General Surgery Unit (5A) is a 25-bed unit for children from neonates to 18 years of age. Various surgical procedures are conducted for children diagnosed with Chron’s disease, ulcerative colitis, imperforated anus, tumor removal, bowel obstruction, and various urological or gynecological issues.

**Procedures for the RCT**

*Recruitment and Eligibility Screening:*

Successful recruitment to the RELAX TO SLEEP study was dependent mainly on the nurses working on each of the recruitment units. The study was introduced to health care providers through a series of presentations at staff meetings, “lunch ‘n learn” sessions, and grand rounds, in which the purpose, research questions, and the use of actigraphy were presented. The emphasis of these presentations was to make the clinicians aware of the eligibility criteria of the study and the importance of active recruitment assistance. One-page handouts were provided to market the study and to remind the nurses of the eligibility criteria. Finally, snacks were provided on the recruitment units both at the launch of the study and at the end of the study period as a way to thank the staff for their assistance. Clinical Support Nurses were also provided with a coffee gift card to further demonstrate appreciation of their time and effort in screening eligible patients for possible inclusion in the study.

Clinical Support Nurses (CSN) on either the Cardiology unit, General Surgery Unit, or any of the General Pediatric units were approached to assess all in-patients’ eligibility to participate in the study (Appendix B). This was usually accomplished after morning rounds as this gave the CSN the most up-to-date information on each patient. Once potential eligible children were identified from this process, the primary nurse caring for the identified child was approached to further confirm the child’s eligibility. Eligible children and their families were
first approached by the primary nurse (staff RN) of the unit who informed the family about the study and assessed whether the family would be interested in hearing more about it. If the family was interested in hearing more about the study, the principal investigator (PI) approached children and parents to further discuss the study and re-confirm eligibility. The PI also discussed briefly how actigraphy measures sleep and wake cycles, and that the child would be required to wear it for three days and nights of their hospital stay. If both the parent and the child agreed, consent from the parent was obtained at the time assent or consent was sought from the child (Refer to Appendix C for Consent Forms). The parent of the child was asked to complete a baseline questionnaire containing: demographic data; information on current hospital stay and illness, usual sleep habits, and anxiety. The parent and/or child (if appropriate) were asked to sign an actigraphy agreement form, which outlined the care instructions of the actigraph, and instructions on when to hand in the actigraph should the researcher ask for it to be returned (Refer to Appendix D for Actigraph Care Agreement Form). Recruitment rates were monitored by keeping track of the date and number of eligible participants approached and recruited. The number of families who declined participation and reasons for refusal were tracked accordingly.

**Baseline Assessment:**

The entry form (Appendix E) had a unique identifier and included demographic variables, information on the hospital stay, reason for hospitalization, usual sleep habits and difficulty with sleep of the child (Children’s Sleep Habits Questionnaire [CSHQ]) as well as the anxiety levels of the child (The Spence Preschool Anxiety Scale [SPAS] – General Anxiety Subscale and the Separation Anxiety Subscale for children 4 and 5; and the Spence Children’s Anxiety Scale [SCAS] – General Anxiety Subscale and Separation Anxiety Subscale for children 6 and 12).
Assessing Sleep Disturbance

The CSHQ is a sleep questionnaire designed for school aged children between the ages of 4 and 12 to identify both behavioural and medically-based sleep problems (Owens, Spirito, & McGuinn, 2000). Data collected at baseline from parental report provided an estimation of the child’s normal sleep habits and difficulty with sleep prior to hospitalization. The CSHQ consists of 33 sleep-disturbance items and 3 items about usual bedtime, morning waking time, and daily total sleep duration. The 33 items are conceptually grouped into 8 subscales as follows: bedtime behaviour (bedtime resistance); sleep onset delay; sleep duration; anxiety around sleep; behaviour occurring during sleep and night wakings; sleep-disordered breathing; parasomnias (such as sleepwalking/talking, night terrors, and bedwetting); and morning waking/daytime sleepiness. Parents are asked to recall their child’s sleep behaviours over a recent typical week. A score of 41 or higher is considered to be an indicator for referral to an appropriate clinician for further assessment of sleep problems.

The CSHQ has established validity and reliability. In comparing a sample of school-age children in the community (n=469) to children who were diagnosed with sleep disorders in a pediatric sleep clinic (n=154), the internal consistency coefficients of the entire scale ranged from 0.68 to 0.78, which are considered acceptable standards. Validity was established by the ability of the CSHQ items, subscales, and total score to consistently differentiate non-sleep disordered children from those seeking an evaluation due to a suspected sleep disorder. Test-retest reliability was assessed in a volunteer sample of 60 parents from the community sample who completed a second rating of the CSHQ at a two-week interval. Correlations for the subscales ranged from 0.62 to 0.79, and t-tests between the subscales for the two administrations were all non-significant (Owens et al., 2000).
The CSHQ has been used in assessing various other domains such as the association with bed sharing and increased risk for sleep problems (Liu, Liu, & Wang, 2003), the impact of media use on sleep patterns and sleep disorders (Li et al., 2007), and to examine sleep disturbances in children with specific disorders such as Autism Spectrum Disorders (Malow et al., 2006) and Pervasive Developmental Disorder (Couturier et al., 2005).

Assessing Anxiety

Although anxiety was a secondary outcome in this study and anxiety has many dimensions, it was deemed important to have a baseline of the child’s anxiety level. Currently, the ‘gold standard’ for evaluating anxiety is the State-Trait Anxiety Inventory (STAI), a 20-item self-report for measuring anxiety in adults. The STAI differentiates between the temporary condition of “state anxiety” and the more general and long-standing quality of “trait anxiety.” The State-Trait Anxiety Inventory for Children (STAIC) is based on the same theory as the STAI only is designed to be used with upper elementary or junior high school aged children. Thus, preschool children who are particularly vulnerable to anxiety from hospitalization cannot benefit from this instrument. Finding a reliable instrument to measure state anxiety in children as young as 4 years old proved to be challenging, since most of the anxiety tools are used to diagnose children with anxiety disorders, which was not the focus of the present study.

For the present feasibility study, the Generalized and Separation Anxiety Subscales of the Spence Children’s Anxiety Scale (SCAS) and the Spence Preschool Anxiety Scale (SPAS) were completed at baseline and again at the end of the study period (5-10 days after the child had been discharged home) to determine if the intervention had an impact on certain aspects of the anxiety of the participants (Spence, Rapee, McDonald, & Ingram, 2001). The SPAS consists of 28 scored anxiety items that ask parents to report on the frequency of which an item is true for their
child. Each item is rated on a 5-point scale from 0 ‘not at all’ to 4 ‘very often true’. Item 29 is an open-ended question tapping into the child’s experience of a traumatic episode and is not scored, however is included for clinical interest only. The SCAS is a 38-item measure of anxiety symptoms in older school-aged children and contains six sub-scales, which tap into different dimensions of anxiety, including: separation anxiety, social phobia, obsessive-compulsive disorder, panic/agoraphobia, physical injury fears, and generalized anxiety. Each item is rated on a 4-point scale in terms of its frequency from “never” (0) to “always” (3). The 38 items are summed to yield a total score of anxiety, with higher scores reflecting higher levels of anxiety. The items found in the separation anxiety and generalized anxiety subscales of the SCAS and the SPAS were deemed most appropriate for the present study. Therefore, participants only completed the items from these two subscales.

The SCAS can provide an indication of whether children are showing elevated levels of anxiety, and can also be used to evaluate change over time in response to treatment or prevention programs, to identify children who are at risk of anxiety problems and who may benefit from early intervention (Spence, 1997). The SCAS has established validity and reliability. In the original paper describing the development of SCAS (Spence, 1997), the Cronbach’s alpha for the total score was reported to be 0.92; and the alphas for the six subscales ranged from 0.60 (fear of physical injury) to 0.82, which indicate acceptable values. Other studies have also demonstrated high alpha coefficients for the SCAS. One study assessed the reliability and validity of the SCAS together with the Screen for Child Anxiety Related Emotional Disorders (SCARED) in a sample of 556 primary school children (Essau, Muris, & Ederer, 2002). The SCAS demonstrated high internal consistency with an alpha level of 0.92. The internal consistency of the various subscales were also acceptable with Cronbach’s alphas ranging from 0.70 to 0.82 with the exception of the
physical injury fears subscale with an alpha of 0.57. Since the original report of the SCAS found that girls report higher levels of anxiety symptoms or anxiety disorders than do boys, gender differences were tested. Essau et al. (2002) found that girls reported significantly more anxiety symptoms than boys ($p<0.001$) further supporting the validity of the SCAS. Finally convergent validity was tested by computing correlations between SCAS and SCARED. Scores for the SCAS and SCARED were substantially interrelated. The Pearson product-moment correlations between the total scores of the SCAS and the SCARED was 0.85 ($p<0.001$) which further supports the validity of this tool. Furthermore, the psychometric properties of the parent version of the SCAS have also been established (Nauta et al., 2004).

Randomization

Randomization was centrally controlled and concealed. The opaque envelopes were kept in a locked cabinet in a locked office at the Lawrence S. Bloomberg Faculty of Nursing at the University of Toronto. The actigraphs were also kept there. Once consent had been obtained at the hospital, the PI asked the parent to complete the baseline questionnaire, while the actigraph was being set up. The opaque envelope was opened by the PI at the hospital to reveal the participant’s group allocation. The PI informed the participant of his/her allocation to either the control (Usual Care group) or experimental group (RELAX TO SLEEP group) by providing a written letter with instructions (Refer to Appendix F for Group Allocation Instruction Sheet). Once randomized, the group allocation was not altered or reassigned. Group assignment was documented on the Randomization Form, and the opaque envelope with the revealed group assignment was affixed to this form for an audit trail. The PI who performed the randomization also placed the actigraph on the child. Input from the child, parent and health care professional was sought with regards to the placement of the actigraph device based on the child’s age, the
location of the child’s intravenous or other lines, and preference. It was not always possible for the child to wear the actigraph on the non-dominant wrist since the actigraph may have interfered with IV line and/or other medically related equipment; however, all participants wore the actigraph around the wrist. In accordance with the *American Academy of Sleep Medicine Standards of Practice Committee* recommendations on the use of actigraphy for sleep studies (Littner et al., 2003), children were asked to wear the actigraph for 3 consecutive nights.

*Figure 3: Schema*

**RELAX TO SLEEP (Experimental Group)**

Immediately following randomization, and at a time convenient for the child and parent (or primary caregiver) in the RELAX TO SLEEP group, the PI delivered the RELAX TO SLEEP
program. Both the educational portion of the sleep education and sleep hygiene piece of the intervention consisted of a standardized informative package and included a discussion with the PI (Refer to Appendix G for Educational Booklet). First, a brief overview was given on normal sleep patterns, children’s sleep needs, and the signs and consequences of sleep deprivation. Second, the standardized booklet provided sleep hygiene information consisting of good sleep habits such as having a regular sleep-wake schedule, avoiding caffeine intake prior to nighttime sleep (e.g., chocolate, tea, and cola), avoiding active play or stimulating activities near nighttime sleep (e.g., watching television or the use of a computer), avoidance of naps during the day (if age appropriate), ensuring that the child is exposed to natural light or bright light during the day, providing the child with opportunities to socialize during the day such as taking them for walks (if able) or to the play area of the hospital (if able). Parents were also educated on recognizing sleepiness in their children, as the ‘classic’ manifestations of sleepiness that occur in adults (e.g., yawning) are often manifested in children in the form of mood disturbances and hyperactivity (Mindell & Owens, 2003a, 2003b). Furthermore, an explanation of how bedtime routines are involved in children’s bedtime problems and sleep disturbances in hospital were discussed. This information was tailored to a hospital setting so that suggestions made could be implemented during hospitalization. For example, parents were instructed to take their child to the playroom (located on each unit of the hospital), or to the game room, which is a hospital wide shared room, and made participants aware of areas within the hospital to obtain exposure to bright light during the day. Participants were asked to carry this information forward into the home once discharged in an attempt to avoid or reduce the development of sleep problems related to sleep anxieties in the home (MacLaren & Kain, 2008).

The relaxation technique of controlled relaxation breathing was developmentally appropriate and was delivered through a story book or an audio CD depending on the age group
and choice. For younger children (4 years to 7 years), a bedtime story book geared to take the child through a breathing technique was provided so that the parent could read to the child. Children had a choice from two storybooks. It was felt that older school-aged children (8 years to 10 years) might find storybooks infantile. Therefore an audio version of the technique was available to them, which they could also download onto an iPod (Refer to Appendix H for Relaxation Breathing Script). During this initial meeting the participants engaged in the relaxation breathing technique and practiced it with the PI. The PI used a Hoberman sphere, a geometric sphere which expands and collapses to its original shape, as a teaching tool for relaxation breathing. The participants were encouraged to practice the technique a few times prior to implementing it at bedtime. A standardized script was made available to the PI to take both the parent and the child through the technique. Implications for use of the technique were also discussed with the child and parent. For example, parents were instructed to use the relaxation technique once the child was settled in bed as part of the bedtime routine. Moreover, the technique should be used if the child awoke in the middle of the night abruptly, or if they were trying to return to sleep following a procedure or a routine assessment. A poster was posted directly across their bed to remind them to use relaxation breathing. Finally, the PI encouraged its use post-hospitalization. A checklist with all the components of the intervention was completed at the end of the discussion with participants to ensure that the intervention was delivered consistently for all participants in the RELAX TO SLEEP group (Refer to Appendix I – Intervention Fidelity Checklist).

Usual Care (Comparison Group)

Usual care at this hospital setting consisted of no information pertaining to sleep, sleep hygiene, or the use of a relaxation technique to promote sleep. Therefore, no parts of this
intervention were provided to the Usual Care group, nor did the PI spend any time to go over concerns with regards to sleep. The health care providers on the unit as well as families that had been randomized to the RELAX TO SLEEP group were asked not to share any components of the RELAX TO SLEEP program with anyone. The actigraphs were used on both the RELAX TO SLEEP and Usual Care groups, and the PI visited the child only to ensure that the actigraph device was being worn and to help fill out the sleep diaries if necessary.

**OUTCOME MEASURES**

*Primary and Secondary Outcomes:*

The primary outcome measure for this study was the total length of nocturnal sleep, defined as the number of minutes from sleep onset time to morning awakening (19h30-07h29). Secondary outcome measures included number of nighttime awakenings, longest stretch of uninterrupted sleep at night, and total daytime sleep (07h30-19h29).

*Actigraph*

All sleep outcomes were objectively measured using actigraphy. An actigraph is a non-invasive computerized device, the size of a wristwatch, which monitors and collects data generated by movements. These detected motions are sensed with a piezo-electric linear accelerometer and then translated into digital counts across 1-minute intervals and stored in internal memory. The data are later downloaded to a computer and analyzed using specific software (Action 4 software – Ambulatory Monitoring, Ardsley, NY) for actigraphy. Algorithms are used to assess the recorded activity for the previous 4 minutes and subsequent 2 minutes before making a determination of sleep or wake for each 1-minute interval. Brief movements that are made during sleep periods are recorded as sleep and brief periods of inactivity within time intervals of extensive wakefulness are recorded as wakefulness.
Although polysomnography (PSG) is considered the gold standard for the evaluation of sleep in human studies, as it can accurately measure SWS and REM sleep, it is costly and is not readily available in the hospital setting or home setting. The use of PSG requires an overnight stay in a sleep laboratory as well as the attachment of 12 electrodes to the face and scalp for continuous monitoring. This can be burdensome and intimidating to the hospitalized child.

Actigraphy has been used in a variety of settings and is a valid method that objectively measures sleep in infants, children, and adults (Kain et al., 2002; Sadeh, 1996; Sadeh, Hauri, Kripke, & Lavie, 1995). The actigraph frequently underestimates sleep onset latency; nonetheless, it is non-invasive and allows participants to remain in their natural environments while reliably quantifying periods of wakefulness and sleep.

Sleep Diary

Sleep diary data were collected during the hospital study period to support the actigraphy data (Appendix J: Sleep Diary). The sleep diary is a self-reported record of the child’s sleeping and waking times with other related information, and is used in conjunction with actigraphy. The sleep diary used in the present study was adapted for the sleep diary developed and used in a previous sleep study by one of the members of the research team. If appropriate, the child was asked to fill it out, if not, the parent was asked to complete the child’s sleep diary throughout the day and night.

In order to describe sleep in hospital and to examine potential confounders other data were recorded in the sleep diary. In addition to recording bedtimes, wake times, and nap times throughout the day, the sleep diary included questions to assess whether the child’s sleep was better or worse than their usual sleep, the frequency of nursing care activities during the night, what they did to help their child fall asleep, and any events that might have affected actigraphy
recording. For example, if the participant removed the actigraph for bathing, no motion would be detected by the device, therefore incorrectly recording it as sleep. The use of sleep diaries in conjunction with the actigraph is necessary to help with discrepancies of sleep and wakeful periods in the actigraphy data and to ensure accurate scoring of records (Sadeh & Acebo, 2002).

Pain Score and Opioid Use

As part of the sleep diary, parents were instructed to collect pain scores from their child each morning. Pain scores were collected using the Faces Pain Scale-Revised (FPS-R). Adapted originally from the Faces Pain Scale (Bieri, Reeve, Champion, Addicoat, & Ziegler, 1990), the FPS-R is a self-report measure of pain intensity which scores pain with the widely accepted 0-to-10 metric for pain scales (Hicks, von Baeyer, Spafford, van Korlaar, & Goodenough, 2001). Consisting of six drawings of faces that depict pain intensity, children are asked to rate their pain based on the drawing. Pain intensity ranges from no pain (scored 0) to very much pain (scored 10). The scores of this tool were highly correlated with scores on other validated self-report instruments in a clinical sample of 90 postoperative patients between the ages of 4 and 12, indicating that this tool is valid in measuring pain intensity in patients as young as 4 years old (Hicks et al., 2001). The validity of the FPS-R has been further documented with 623 children receiving routine immunizations (Wood et al., 2004).

Opioid use was monitored during the 3 days and nights of the hospital study period. The PI tracked this information by asking the primary nurse if the child had been on any opioids for the previous 24 hours.

Post-hospital Behaviours

To assess other outcomes such as the development of sleep disturbance behaviours during the post-hospitalization period, a research assistant (RA) made contact with the parent by
telephone within 5-10 days after the child had been discharged home asked them to complete the
*Post-Hospital Behaviour Questionnaire* (PHBQ), a self-report questionnaire for parents most
commonly used for assessing children’s post-hospital behaviour (Kain et al., 2002; Thompson &
Vernon, 1993; Vernon & Thompson, 1993). Consisting of 27 items, the PHBQ evaluates
maladaptive behavioural responses and developmental regression in children after hospitalization
and illness and includes six categories of anxiety: general anxiety, separation anxiety, sleep
anxiety, eating disturbances, aggression against authority, and apathy and withdrawal (Vernon &
Thompson, 1993). Each item requests the parent to consider the child’s post-hospital behaviour
to that prior to hospitalization. The five-point response scale ranges from the behaviour occurring
‘much less than before’ (scored -2), ‘less than before’ (scored -1), not changed (0), ‘more than
before’ (scored +1), and ‘much more than before’ (scored +2). Any response of +1 or +2
indicates new-onset negative post hospitalization behaviour. This instrument has been shown to
demonstrate acceptable test-retest reliability and to predict changes when preoperative
interventions were employed (Vernon & Thompson, 1993). The internal consistency
(Cronbach’s Alpha) varied from 0.45 to 0.73 for factors and was 0.82 for the total score, when
the PHBQ was performed on 387 children, aged from 6 months to 16 years (Vernon, Schulman,
& Foley, 1966). The validity was tested by comparing the total score from the PHBQ with
ratings done by a child psychiatrist who interviewed 20 children a week after tonsillectomies.
The total scores and ratings of change in behaviour following hospitalization were modestly
correlated (r=.45, p<0.005). A clinical psychologist’s independent ratings of tape recordings of
the interviews showed high agreement with the ratings of the psychiatrist (r=.95, P<0.001). A
comparison was made for the scores for 3 groups of children who underwent tonsillectomy
(parent interviewed, parent only filling in the questionnaire and parent both interviewed and
filling out the questionnaire) to determine whether the parental style for completing the
questionnaire introduced bias into the score. No significant differences between the 3 groups were found, which further supports the validity of the total scores of the PHBQ (Vernon et al., 1966).

Children and their families were followed until the 5th to 7th post-hospitalization day, as this has been shown to be when children exhibit the most maladaptive behaviours (Kain et al., 2002). Every attempt was made to make contact on the 5th day of hospital discharge. Parents were also asked to complete a final questionnaire, which assessed many components of the acceptability of the RELAX TO SLEEP program. Questions pertaining to the participation in the study and the likelihood that they would participate again, as well as questions surrounding the educational booklet and use of the relaxation technique, and wearing the actigraph were assessed. Finally questions from the CSHQ and the SCAS were asked again at follow-up to determine any differences (Refer to Appendix K for Final Questionnaire). Once all data had been collected, a gift certificate in the amount of $10.00 to either a book store or a toy store was mailed to the family along with a thank you note to demonstrate the research team’s appreciation.

**MONITORING COMPLIANCE**

Compliance in both the RELAX TO SLEEP group and the Usual Care group was monitored by daily visits made by the PI to ensure that the sleep diaries were completed and to ensure that children did not encounter any difficulties with wearing the actigraphs. In addition, parents from the RELAX TO SLEEP group, were asked to complete a questionnaire asking them about the frequency of use of the relaxation breathing technique (Appendix K: Final Questionnaire). This was asked at the end of the hospital study period and again during the follow-up period via telephone.
PARTICIPANT SATISFACTION

Questions with regards to participant satisfaction with being in the study were asked of both the RELAX TO SLEEP group and the Usual Care group by the research assistant during the follow-up period over the telephone. Information with regards to the appeal of the RELAX TO SLEEP program was asked at the end of the 3 day hospital study period while the child was still hospitalized, and during the follow-up period at discharge via telephone to only those in the RELAX TO SLEEP group. In an attempt to decrease social desirability bias, a paper questionnaire was provided to the families during the hospital period. Parents were instructed to complete and place in an opaque envelope provided.

CONTAMINATION

Most children who are hospitalized at SickKids have their own room with a day-bed for one parent, with the exception of the emergency department, critical care units (PICU, CCU, PACU), and step-down units. Step-down units are located throughout the hospital and usually have between four and six patients and a low nurse to patient ratio. Although there are step-down units on all of the recruiting units, children in these rooms were not approached for inclusion in this study. This may have helped to reduce contamination since the RELAX TO SLEEP program was delivered in a private patient room only. Children were doing the relaxation technique in the privacy of their own room, and it is highly unlikely that other family members or patients could overhear or listen in on the educational session with the PI. To help minimize contamination the following measures were taken into account:

- The RELAX TO SLEEP group was asked not to share what they learned in the intervention with any other hospitalized families.
• The health care professionals providing care on the unit were asked not to share any of the information from the presentations conducted by the PI.

• The RELAX TO SLEEP group was asked at the end of the study period if any of the intervention was shared with another hospitalized child and/or their parent.

• Both groups were asked what they did to help their child fall asleep.

Such measures were necessary to help to determine problems with contamination to aid in planning for the larger RCT.

**CO-INTERVENTION**

The sleep diary contained a question asking participants in both groups about the use of strategies to promote sleep during their hospital stay. The question read, “What did you do to help your child fall asleep last night?” This question provided the participants an opportunity to reveal the use of any co-interventions such as medications, reading a book, using the internet as a resource for tips on sleep etc.

**LOSS TO FOLLOW-UP**

Minimal loss to follow-up was anticipated during the hospital portion of the pilot study, since data collection with the actigraph device occurred during hospitalization. If participants were discharged earlier than expected the sleep data were averaged over the two nights. Participants with only 1 night of actigraphy data were not included in the final analysis. The PI made every attempt to follow-up with families each day to facilitate completion of sleep diaries and answer any questions, as well as trouble shoot any technical issues. The purpose of these daily meetings did not only serve to increase sleep diary completion, but also helped establish rapport with participants.
Once families were discharged home, the data on the actigraphs were downloaded and saved. Between the fifth and seventh day of post-hospitalization at a convenient time for the parents, the remainder of the data were collected (anxiety levels, acceptability issues, and the PHBQ) via telephone by the RA. Additional information was sought from the parents who were randomized to the RELAX TO SLEEP group; therefore the RA was not blinded to group allocation but the RA was blinded from the protocol.

**Sample Size**

Given that the study was a pilot RCT, this study was not adequately powered to detect differences in outcome measures; therefore no inferences can be drawn from the results. Therefore a sample of 20 in each group was determined to be adequate, since the feasibility and acceptability objectives would provide important insights when preparing for the larger trial. A sample size calculation was conducted to determine how many families would be required in the trial to detect a clinical significant difference of 30-minutes with respect to mean nighttime sleep. Although there are no data to support this number in the pediatric population, a 30-minute increase in nighttime sleep in adults with insomnia showed a minimally important clinically significant difference, and patients’ self-reports of sleep quality demonstrate improvements (Morin, Culbert, & Schwartz, 1994). Using a two-sided test of hypothesis, with an alpha level of 0.05 and 80% power, 175 families would be needed for a definitive trial. To account for 20% loss to follow up a sample size of 210 would be required.

**Blinding**

Due to the nature of the intervention, it was impossible to blind the study participants or the individual who was delivering the intervention. Health care professionals associated with the recruiting units were made aware of the study, however details about the intervention were not
provided. The components of the intervention were only available to those that were randomized to the RELAX TO SLEEP group. Actigraphy, an objective outcome measure of sleep, was used in both the RELAX TO SLEEP and Usual Care groups. Parents in both groups were asked to complete sleep diaries. The RAs involved in the RELAX TO SLEEP pilot trial had no direct involvement in the care of the children, nor did they deliver the intervention. The RA performing actigraphy analysis and completing the data entry were blinded to the entire protocol. One RA, who only conducted follow-up phone calls was not blinded to group allocation since one of the questionnaires pertained only to the RELAX TO SLEEP group.

**DATA MANAGEMENT**

Data collection forms for this feasibility study contained a unique study number and a secondary identifier (i.e., the child’s birth year and month). The numeric identifications were pre-recorded prior to administering them at the site.

All personal identifiers were kept separate from the data. The master code sheet linking family contact information with numeric identification codes were stored in a locked cabinet in an office, which was also locked and separate from the data. All offices and cabinets were accessible only with keys held by the research team.

Following the third night of actigraphy data collection, the PI collected the actigraph and sleep diary data. The data from the actigraphs were downloaded to a computer that was password protected and kept in a locked office. Once the data from the actigraphs had been downloaded, the actigraphs were cleaned with antibacterial and antiviral disinfectant wipes, and the velcro straps were replaced with new straps for each child.
**Data Entry**

All data collected for the pilot trial were entered and organized into a computerized database (Microsoft Access 2007, Microsoft Corporation, Redmond, WA). This database program was developed by the researcher and contained a list of tables as well as a list of variables. These computerized files were password protected and regularly backed up on a rotating basis on the hard drive as well as an encrypted USB key. The data were entered using double-data entry to check for accuracy of data entry. Built in logic and range checks further verified the accuracy of the data.

**Data Analysis Plan**

Data were analyzed using SAS version 9.3 (SAS Institute, Cary, NC), a statistical analysis software. In keeping with the “intention-to-treat” approach, data from all participants randomized in the trial regardless of whether they received the allocated intervention or not were included in the final analysis. Baseline characteristics such as demographics were presented as frequencies. For exploratory purposes only, the student’s t-test was conducted to assess the primary outcome of nocturnal sleep time with a significance level of 0.05. Secondary actigraphic sleep data and other outcomes are presented as means (with standard deviations). Feasibility issues surrounding retention rates, withdrawal rates, refusal rates, as well as number of losses to follow-up were monitored and reported as frequencies and percentages in the data analysis.

Actigraphy data were downloaded and analyzed using autoscoring sleep-analysis software (Action4, Version 1.16, Ambulatory Monitoring, Inc, Ardsley, NY). Actigraphy data were analyzed separately by two individuals at separate times. Any discrepancies were sorted out by a third person to ensure that decisions around longest stretch of uninterrupted nocturnal sleep
and daytime sleep were correct. One third of the actigraphy data were randomly selected and assessed by a third person to ensure accuracy of the actigraphy analysis.

**Acceptability Parameters**

In preparation for an adequately powered trial, many important feasibility and acceptability questions were warranted. This pilot study sought to gain insight into how appealing the relaxation technique was to the child and their primary caregivers in order to offer justification for a larger trial in the future. Based on previous studies which assessed sleep outcomes for hospitalized children, and experts in the RCT method, the following acceptability parameters were set to determine whether a larger trial was merited:

Table 4

Acceptability Parameters

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Percentage/Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percentage of families agree to participate</td>
<td>50%</td>
</tr>
<tr>
<td>Monthly recruitment rate</td>
<td>3/week*</td>
</tr>
<tr>
<td>Total amount of time to deliver the intervention</td>
<td>30 minutes maximum</td>
</tr>
<tr>
<td>Percentage of families receive the intervention</td>
<td>80%</td>
</tr>
<tr>
<td>Percentage of families use components of the intervention</td>
<td>80%</td>
</tr>
<tr>
<td>Total number of time they do the intervention</td>
<td></td>
</tr>
<tr>
<td>a) Hospital</td>
<td></td>
</tr>
<tr>
<td>b) Home</td>
<td></td>
</tr>
<tr>
<td>Percentage of families that would choose to participate in the larger trial</td>
<td>80%</td>
</tr>
<tr>
<td>Percentage of families that found the educational booklet useful.</td>
<td>&gt;75%</td>
</tr>
<tr>
<td>Percentage of families that enjoyed using the relaxation technique</td>
<td>&gt;75%</td>
</tr>
<tr>
<td>Percentage of families that would use the technique again in the future</td>
<td>&gt;60%</td>
</tr>
</tbody>
</table>

*3/wk at a large pediatric hospital would allow recruitment of several hundred in a year with multiple hospitals.

**Ethical Considerations**

The current study was granted ethics approval by the Research Ethics Board at SickKids as well as the Human Subjects Review Committee at the University of Toronto. Once the target number of 40 was reached, an amendment was put forward to the Research Ethics Board at
SickKids to recruit and randomize an additional 8 participants to account for the four percent of the sample size that had been discharged earlier than expected.

Children and their parents were informed of the study and received verbal and written explanations of the study, including potential risks and benefits, and a copy of the consent. Signed informed consent was sought from all eligible potential participants’ caregivers (i.e., mother or father) as well as assent from the child participant. Participants were informed that they could withdraw from the study at any time without penalty and that it would not affect the care they received at SickKids. All data were kept confidential. Codes, but no names were used on questionnaires and other forms. All data were kept in a secure locked filing cabinet in a locked office. Signed consent forms were kept separately from the data, in locked cabinets at the University of Toronto. Only group data are reported.

Since the effectiveness of relaxation breathing on sleep in hospitalized children had not been established, the risks and benefits were unknown. Potential risks in using the actigraphy device, although minimal, included an allergic reaction to metal. This information was disclosed at the time consent was being obtained. It was also explained that if a child was indeed allergic to metal this could easily be overcome by wearing the device over clothing or placing a sweatband underneath the actigraph. Furthermore, if the device interfered with an IV, then the actigraph would be placed on the opposite hand.
CHAPTER 4
Results

THE SAMPLE

During the study period of November, 2011, to October 2012, 74 patients and their primary caregivers (e.g., mother, father) were approached for possible inclusion in this study. After further assessments by the PI, 6 were excluded because they did not meet the eligibility criteria (1 had Restless Legs Syndrome [RLS]; 3 patients were going to be discharged earlier than the 3 nights required for the study; 1 child had no parent or caregiver staying overnight with them; and 1 child was enrolled in another sleep study). From the 68 patients meeting eligibility criteria, 20 (29%) declined to participate. Reasons identified for refusal included: family felt too overwhelmed or felt the child was too unstable (n=9, 45%); the family was not interested in information about sleep (n=6, 30%); the family or child was highly anxious (n=4, 20%); the child was in too much pain (n=1, 5%). Thus, the acceptance rate for enrollment in the RELAX TO SLEEP pilot trial was 71% (n=48).
Figure 4 Flow Diagram

Patients Approached (n=74)

Excluded (n=26)
- Not meeting inclusion criteria (n=6)
  - Restless Legs Syndrome (n=1)
  - Early Discharge (n=3)
  - Enrolled in other sleep study (n=1)
  - No caregiver staying (n=1)
- Declined to participate (n=20)
  - Too overwhelmed/child too unstable (n=9)
  - Not interested in sleep tips (n=6)
  - Highly anxious (n=4)
  - Extreme pain (n=1)

Baseline Data Collected (n=48)

Randomized (n=48)

RELAX TO SLEEP Group (n=24)
- Received RELAX TO SLEEP (n=24)
  - Withdrawn (n=1)
    - Reason: Family emergency
  - Incomplete Actigraphy (n=3)
    - Reasons:
      - Only one night of actigraphy data
  - Incomplete Evaluation (n=1)
    - Reasons:
      - Could not track
  - Analized
    - Completed 2 or 3 nights of actigraphy data (n=20)
    - Evaluation of RELAX TO SLEEP program in hospital (n=22)

Usual Care Group (n=24)
- Received Usual care (n=24)
  - Analized
    - Completed 2 or 3 nights of actigraphy data (n=23)
  - Incomplete Actigraphy (n=1)
    - Reasons:
      - Only one night of actigraphy data

- Analysis of Post-Hospitalization Outcomes:
  - Post-Hospital Questionnaire (n=21)
  - Children’s Sleep Habits Questionnaire (n=21)
  - Spence Children’s/Preschool Anxiety Scales (n=21)
  - Evaluation of RELAX TO SLEEP program at home (n=21)
    - Reasons:
      - Unable to reach them at home (n=2)

- Analysis of Post-Hospitalization Outcomes:
  - Post-Hospital Questionnaire (n=23)
  - Children’s Sleep Habits Questionnaire (n=23)
  - Spence Children’s/Preschool Anxiety Scales (n=23)
    - Reasons:
      - Died at home (n=1)
Baseline Characteristics

Table 5 provides an overview of the study groups’ baseline characteristics. Participants ranged in age from 4 to 10 years old, with a mean of 6.5 ± 2.01 years. Twenty-one (44%) were in pre-school to senior kindergarten, while 17 (56%) were in grade school (Grades 1 through 6). Almost half of the children randomized to the RELAX TO SLEEP group were in the pre-school to SK level (n=13) as compared to only one third (n=8) in the Usual Care group. The sample was predominantly Caucasian (n=27, 56%), followed by Black (n=3), South Asian (n=3), East Asian (n=3), Hispanic (n=2), or identified themselves as more than one racial background (n=8). Over half of the participants were admitted to the hospital for an acute illness or trauma (n=33, 69%), followed by 10 (21%) for chronic illness, and 5 (10%) for planned surgery. Over half of the children recruited were from the general pediatric units (n=26, 54%), followed by the general surgery unit (n=17, 35%), and cardiac unit (n=5, 10%). At the time of randomization, most children (n=30, 63%) had not been previously hospitalized in the past year. For the 18 (37%) children that had been previously hospitalized within the past year, 10 (56%) had one previous admission, and 8 (44%) had two or three previous hospitalizations. A greater proportion in the Usual Care group had been previously hospitalized (n=12, 50%) than in the RELAX TO SLEEP experimental group (n=6, 25%). The mean number of days spent in hospital during a prior admission(s) in the last year was 11.8 days (SD 12), with a greater number of mean days in the RELAX TO SLEEP group (mean 18 days, SD 11.67) compared to the Usual Care group (mean 8.3 days, SD 11.51).
Table 5
Baseline Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>RELAX TO SLEEP</th>
<th>Usual Care</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(n=24)</td>
<td>(n=24)</td>
</tr>
<tr>
<td></td>
<td>No. (%)</td>
<td>No. (%)</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>13 (54)</td>
<td>9 (38)</td>
</tr>
<tr>
<td>Male</td>
<td>11 (46)</td>
<td>15 (62)</td>
</tr>
<tr>
<td><strong>Grade</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-school to SK</td>
<td>13 (54)</td>
<td>8 (33)</td>
</tr>
<tr>
<td>Grades 1 and 2</td>
<td>6 (25)</td>
<td>10 (42)</td>
</tr>
<tr>
<td>Grades 3 to 6</td>
<td>5 (21)</td>
<td>6 (25)</td>
</tr>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean ± SD</td>
<td>6.2 ± 1.97</td>
<td>6.8 ± 2.02</td>
</tr>
<tr>
<td><strong>Racial Background</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>South Asian</td>
<td>2 (8)</td>
<td>1 (4)</td>
</tr>
<tr>
<td>East Asian</td>
<td>1 (4)</td>
<td>2 (8)</td>
</tr>
<tr>
<td>Hispanic</td>
<td>2 (8)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>White</td>
<td>14 (58)</td>
<td>13 (54)</td>
</tr>
<tr>
<td>Black</td>
<td>2 (8)</td>
<td>1 (4)</td>
</tr>
<tr>
<td>More than one racial background</td>
<td>3 (13)</td>
<td>5 (21)</td>
</tr>
<tr>
<td>Other</td>
<td>0 (0)</td>
<td>2 (8)</td>
</tr>
<tr>
<td><strong>Type of Admission</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chronic illness</td>
<td>6 (25)</td>
<td>4 (17)</td>
</tr>
<tr>
<td>Acute Illness/trauma</td>
<td>16 (67)</td>
<td>17 (71)</td>
</tr>
<tr>
<td>Planned surgery</td>
<td>2 (8)</td>
<td>3 (12)</td>
</tr>
<tr>
<td><strong>Unit Type</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>General Pediatric Medicine</td>
<td>13 (54)</td>
<td>13 (54)</td>
</tr>
<tr>
<td>Cardiology</td>
<td>1 (4)</td>
<td>4 (17)</td>
</tr>
<tr>
<td>General Surgery</td>
<td>10 (42)</td>
<td>7 (29)</td>
</tr>
<tr>
<td><strong>Previous Hospitalization(s)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(in the last year)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>18 (75)</td>
<td>12 (50)</td>
</tr>
<tr>
<td>Yes</td>
<td>6 (25)</td>
<td>12 (50)</td>
</tr>
<tr>
<td><strong>No. of admissions in the last year</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 Admission</td>
<td>1 (6)</td>
<td>9 (50)</td>
</tr>
<tr>
<td>2 Admissions</td>
<td>2 (11)</td>
<td>2 (11)</td>
</tr>
<tr>
<td>3 Admissions</td>
<td>3 (17)</td>
<td>1 (6)</td>
</tr>
<tr>
<td>Total number of days (mean, SD)</td>
<td>18, 11.67</td>
<td>8.8, 11.51</td>
</tr>
</tbody>
</table>

*Data are presented as number (percentage), unless otherwise indicated.*

Table 6 provides the study groups’ baseline scores on the Children’s Sleep Habits Questionnaire (CSHQ). Reported weeknight and weekend sleep duration was 10.27 (SD 0.42) and 10.33 (SD 0.32) respectively. The total scores for the CSHQ ranged from 34 to 63 out of a
maximum score of 99. The mean score for the RELAX TO SLEEP group was 44.04 (SD 7.17) and 45.58 (SD 7.82) for the Usual Care comparison group. The mean score for both groups was higher than the 41 cut off score, which could indicate that this sample had behavioural sleep problems at the time of randomization. Fifteen children (63%) in the RELAX TO SLEEP group and 17 (71%) in the Usual Care group had scores of 41 or more on the CSHQ at baseline.

Table 6
Baseline Sleep on CSHQ

<table>
<thead>
<tr>
<th>Scale</th>
<th>Mean ± SD</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Relax to Sleep n=24ᵃ</td>
</tr>
<tr>
<td>Duration of Weeknight Sleep</td>
<td>10.22 ± 0.42</td>
</tr>
<tr>
<td>Duration of Weekend Sleep</td>
<td>10.29 ± 0.27</td>
</tr>
<tr>
<td>Total CSHQ Score (range 33-99)</td>
<td>44.0 ± 7.17 (min 34, max 62)</td>
</tr>
<tr>
<td>Score ≥ 41 n (%)</td>
<td>15 (63)</td>
</tr>
</tbody>
</table>

ᵃ. n=22 for duration of weeknight and weekend sleep

Table 7 provides the scores on the Spence Pre-school and Children’s Anxiety Subscales. No one scored higher than the cut off of 9 for males and/or 10 for females on the Generalized Anxiety (GA) Subscale for either group. For the Separation Anxiety (SA) Subscale, one female and two males scored higher than the cut off score of 9 for females and 7 for males. The cut off score for the pre-school GA Subscale was 6 or higher and 7 or higher for the SA Subscale. One child from the RELAX TO SLEEP group and two from the Usual Care group had scores higher than the cut off score of 6 for the generalized anxiety subscale and 7 for the separation anxiety subscale.
Table 7
Baseline Scores on SPAS/SCAS

<table>
<thead>
<tr>
<th>Anxiety</th>
<th>Relax to Sleep n=24</th>
<th>usual Care n=24</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Age 4-5</td>
<td>Age 6-10</td>
</tr>
<tr>
<td>Generalized Anxiety (GA) Mean (SD)</td>
<td>3.58 (2.15)</td>
<td>3.25 (2.09)</td>
</tr>
<tr>
<td>Separation Anxiety (SA) Mean (SD)</td>
<td>3.58 (2.23)</td>
<td>3.08 (2.46)</td>
</tr>
</tbody>
</table>

Pre-School Cut-off Scores

| GA Score ≥ 6 n (%) | 1 (0.08) | * | 2 (33.3)  | * |
| SA Score ≥ 7 n (%) | 1 (0.08) | * | 2 (33.3) | * |

Children’s Cut-off Scores

| GA Score ≥ 9 Males n (%) | * | 0 (0.0) | * | 0 (0.0) |
| GA Score ≥ 10 Females n (%) | * | 0 (0.0) | * | 0 (0.0) |
| SA Score ≥ 7 Males n (%) | * | 1 (0.08) | * | 1 (0.06) |
| SA Score ≥ 9 Females n (%) | * | 0 (0.0) | * | 1 (0.06) |

GA = Generalized Anxiety; SA = Separation Anxiety; *Note the cut-off scores for the Pre-school and Children’s Generalized and Separation Anxiety Subscales differ.

**Primary Purpose: Feasibility and Acceptability**

The primary purpose of this pilot trial was to evaluate the feasibility of the trial protocol and the acceptability of the Relax to Sleep program.

**Feasibility**

*Recruitment:* As noted in the previous chapter, estimated recruitment was set at 3 participants per week and an acceptance rate of 50%. To achieve a sample size of 48, it took 44 weeks of recruitment. This yields a recruitment rate of approximately 1 participant per week. Acceptance rate of this pilot trial was 71%. See Figure 5 below for the monthly recruitment rate.
Families who received the intervention: All 24 families who were randomized to the RELAX TO SLEEP group received the intervention and were given all the components (the educational booklet, the CD or the choice of one of two books). The majority of the children in the RELAX TO SLEEP group received the book (n=17, 71%) because it was age appropriate compared to the CD (n=5, 21%). There were some cases where the child asked for both the book and the CD (n=2, 8%). The age group of these children that asked for both was 7 to 8 years old, which is the cusp of choice for the book (4-7 years old) and the CD (8-10 years old). One family who was randomized to receive the intervention withdrew from the study just after the intervention was delivered, due to a family emergency at home.

Families present during the delivery of the intervention: All children (n=24, 100%) and their mothers (n=24, 100%) were present and received the intervention. Two fathers (8%), two
siblings (8%), two aunts (8%) and one nanny (4%) were also present when the intervention was being delivered.

**Amount of time to deliver the intervention:** An intervention fidelity checklist was developed for the PI who was delivering the RELAX TO SLEEP program to ensure that all the topics were covered consistently. The mean time for delivering the intervention was 14.58 minutes (SD 5.34) which is less than the 30 minutes maximum that was set out in the feasibility parameters.

**Components of the Educational Booklet Used in Hospital:** It was not the intention of the educational booklet that each tip be used; rather, parents would try to implement the different strategies offered in the booklet and the one-on-one discussion depending on their unique situation and abilities while their child was hospitalized and also upon discharge. Each of the suggested strategies (Table 8) was reported to be used by at least 59% of the parents of the hospitalized child (range n=13-20, 59-90%). The tips that parents implemented and rated as helpful or very helpful included tips about child sleeping in a quiet room (n=19, 86%), child sleeping in a dark room (n=18, 81%), and child exposed to bright light during the day (n=19, 86%). Some of the tips that had the lowest rates of use included advice about the child having the same bedtime each night (n=8, 36%), child having the same wake time each morning (n=9, 41%), child sleeping in a cool room (n=6, 27%), child having no caffeine after lunchtime (n=8, 36%), and avoiding stimulating activity prior to bedtime (n=8, 36%). Although a higher proportion (n=19, 86%) reported using the tip of engaging in a calming bedtime routine, only 50% (n=18) rated it as very helpful or helping a little.
Table 8  
Usefulness of Educational Booklet during Hospitalization

<table>
<thead>
<tr>
<th>TIPS from Educational Booklet</th>
<th>Usefulness in Hospital n=22</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Very helpful n (%)</td>
</tr>
<tr>
<td>Child had same bedtime each night</td>
<td>6 (27)</td>
</tr>
<tr>
<td>Child had same wake-up time each morning</td>
<td>5 (23)</td>
</tr>
<tr>
<td>Child slept in a quiet room</td>
<td>9 (41)</td>
</tr>
<tr>
<td>Child slept in a dark room</td>
<td>8 (36)</td>
</tr>
<tr>
<td>Child slept in a cool room</td>
<td>9 (41)</td>
</tr>
<tr>
<td>Child was exposed to bright light during the day</td>
<td>8 (36)</td>
</tr>
<tr>
<td>Child had no caffeine to eat or drink after lunchtime</td>
<td>4 (18)</td>
</tr>
<tr>
<td>Child avoided stimulating activity such as watching television or playing video games prior to bedtime.</td>
<td>4 (18)</td>
</tr>
<tr>
<td>Child engaged in a calming bedtime routine.</td>
<td>0 (0)</td>
</tr>
</tbody>
</table>

Compliance for Relaxation Breathing in Hospital: The acceptability parameter for number of times the relaxation breathing was done by the child was set as once per day during the hospital portion of the study period. Compliance for the relaxation breathing technique was excellent. Parental reports indicated that 86% (n=19) of children used the relaxation breathing technique at least once per day, compared to 14% (n=3) that did not use the technique at all. Of the children that used the relaxation breathing, more than half (n=12, 55%) used the technique between two to three times a day (Table 9). Eighty-two per cent (n=18) of children used the CD or book to guide the relaxation breathing technique during the hospital portion of the study, compared to 18% (n=4) who did not use it at all. In terms of frequency of use per day, 41% (n=9) used relaxation breathing once per day, 32% (n=7) used it 2 to 3 times per day, and 14% (n=3) used it more than 3 times a day.
Table 9
Participants’ Use of the Relaxation Breathing in Hospital

<table>
<thead>
<tr>
<th>Relaxation breathing (RB) in Hospital</th>
<th>Frequency of Use/Day n=22</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Often (&gt;3 times)</td>
</tr>
<tr>
<td>Child used RB during their hospital stay n (%)</td>
<td>3 (14)</td>
</tr>
<tr>
<td>Child used RB with book or CD provided n (%)</td>
<td>2 (9)</td>
</tr>
</tbody>
</table>

Reasons for Use of Relaxation Breathing in Hospital: Fifty-five percent (n=12) of the respondents reported that their child used the technique during stressful situations (e.g., needle poke, or vital signs assessments), while only 32% (n=7) reported using it if they were awakened in the middle of the night (Table 10).

Table 10
Indications for use of Relaxation Breathing in Hospital

<table>
<thead>
<tr>
<th>Uses of Relaxation Breathing (RB)</th>
<th>Frequency of Use/Day n=22</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Often (&gt;3 times)</td>
</tr>
<tr>
<td>if awakened in the night by a health care professional or a loud noise; n (%)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>during stressful situations; n (%)</td>
<td>0 (0)</td>
</tr>
</tbody>
</table>

Components of the Educational Booklet Used in the Home: At least 55% of parents implemented the tips from the educational booklet to promote their child’s sleep during the post-hospitalization period (range n=14-20, 55-91%). The tips that were used and had the highest rates of being very helpful or helpful were: child having the same bedtime every night (n=18, 82%), child had same wake-up time each morning (n=17, 81%), child slept in a quiet room (n=20, 91%), child slept in a dark room (n= 16, 73%), child slept in a cool room (n=17, 81%), child was exposed to bright light during the day (n=17, 81%), and child engaged in a calming bedtime routine (n=20, 91%). Tips that were not used as frequently included advice about the child avoiding stimulating activity such as television watching or playing video games one hour
prior to bedtime (n=10, 45%), and child avoiding consumption of caffeine after lunchtime (n=8, 36%) (Table 11).

Table 11
*Usefulness of Educational Booklet during Post-Hospitalization (Follow-up)*

<table>
<thead>
<tr>
<th>TIPS from Educational Booklet</th>
<th>Usefulness in the Home n=22</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Very helpful n (%)</td>
</tr>
<tr>
<td>Child had same bedtime each night</td>
<td>12 (55)</td>
</tr>
<tr>
<td>Child had same wake-up time each morning</td>
<td>14 (64)</td>
</tr>
<tr>
<td>Child slept in a quiet room</td>
<td>17 (77)</td>
</tr>
<tr>
<td>Child slept in a dark room</td>
<td>14 (64)</td>
</tr>
<tr>
<td>Child slept in a cool room</td>
<td>15 (68)</td>
</tr>
<tr>
<td>Child was exposed to bright light during the day</td>
<td>15 (68)</td>
</tr>
<tr>
<td>Child had no caffeine to eat or drink after lunchtime</td>
<td>11 (50)</td>
</tr>
<tr>
<td>Child avoided stimulating activity such as watching television or playing video games prior to bedtime</td>
<td>3 (14)</td>
</tr>
<tr>
<td>Child engaged in a calming bedtime routine</td>
<td>15 (68)</td>
</tr>
</tbody>
</table>

*Relaxation Breathing in the Home:* Compliance for using the relaxation breathing technique once the child was discharged home was set as once a day following hospitalization until the end of the study period (7 days after discharge). Table 12 reports on the frequency of use of the relaxation breathing technique in the home. Half of the participants (n=11, 50%) reported their child used the relaxation breathing technique once they were discharged home. Of those that used the breathing technique, 23% (n=5) used it once a day, 9% (n=2) used it two to three times a day, and 18% (n=4) used it more than three times a day. Forty percent of the children (n=9) used the technique as a part of a bedtime routine, and 45% (n=10) used either the CD or book to carry out the breathing technique.
Table 12
Post-Hospitalization use of Relaxation Breathing and Frequency of Use per Day

<table>
<thead>
<tr>
<th>Relaxation breathing (RB) Used in the home</th>
<th>Frequency of Use/Day n=22</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Often (&gt;3 times)</td>
</tr>
<tr>
<td>Child used RB once they were discharged home n (%)</td>
<td>4 (18)</td>
</tr>
<tr>
<td>Child used RB as part of a bedtime routine in the home n (%)</td>
<td>3 (14)</td>
</tr>
<tr>
<td>Child used RB with the book or CD provided in the home n (%)</td>
<td>3 (14)</td>
</tr>
</tbody>
</table>

Families reachable at home once discharged from hospital and who completed the study:

Loss to follow up after the child was discharged from hospital was minimal for this pilot study.

The final questionnaire consisted of the CSHQ, the SCAS/SPAS, the PHBQ, and finally a participant satisfaction questionnaire. Of the 23 participants in the RELAX TO SLEEP group who remained in the study at the time of hospital discharge, the RA made initial contact via telephone with all children’s parents to arrange a convenient time and date to complete the final questionnaire. After this initial contact, two participants were unreachable via telephone and therefore did not complete the final questionnaire. The evaluation of the RELAX TO SLEEP program that was completed during the follow-up period was completed by all of the remaining participants with the exception of the two families who were not reachable by telephone. In the Usual Care group, one patient died during the follow-up period; therefore, 23 remained in the study at following up and all participants were reached via telephone and completed the final questionnaire.

Compliance with measurement procedure: In addition to receiving usual care, the children randomized to the Usual Care group were required to wear the actigraphs and complete sleep diaries during the hospital study period. Children in the RELAX TO SLEEP group also wore
actigraph and completed sleep diaries as part of the participation of the study. Compliance with wearing the actigraphs and completing sleep diaries was excellent in both groups.

**Contamination:** During the follow-up period, after the child had been discharged home, parents were asked if any components of the RELAX TO SLEEP intervention were shared with another hospitalized family during their child’s hospitalization. All respondents (n=21, 100%) indicated that the information discussed during the one-on-one meeting with the PI, the contents of the educational booklet, and the relaxation breathing technique were not shared with another family while their child was hospitalized. Parental reports from the sleep diary also indicated that the Usual Care group did not use any parts of the program.

**Co-intervention:** Responses to the question, “what did you do to help your child fall asleep?” from the sleep diary (reporting on 1 to 3 nights) were examined to determine any co-interventions. The responses were clustered under the following categories and were used at least once: typical bedtime routine (this included sleep hygiene practices); parent in bed (if the parent slept with the child); reading; relaxation (this included components of the relaxation technique, deep breathing exercises with the CD, or using the hoberman sphere); the use of electronic devices (e.g., watching television, or a movie, playing on a computer or tablet); medication use (e.g., Tylenol or other meds for pain management); quiet play (e.g., colouring, doing a puzzle); doing nothing; and other. The most frequently reported activities from the RELAX TO SLEEP group included relaxation, reading, and quiet play. For the Usual Care group, medication use, having a parent in bed, and electronic activity were the most frequently reported activities used to help the child fall asleep. Other activities reported by parents from the RELAX TO SLEEP group included: “back tickles”; “rubbed back/tummy”; “warm cloth on head”; and “exhaustion.”
Activities reported from the Usual Care group included: “prayers”; “walked/rocked”; “gave positivity and reassurance”; “held hands”; and “rubbed back/tummy.”

Acceptability:

This next section reports on the acceptability of being a participant in the study, the likes and dislikes of being a participant in the study, the likelihood of participating in a larger study, and the participants’ experiences wearing the actigraph. The results reflect participants of both the RELAX TO SLEEP group and the Usual Care group. The acceptability of the RELAX TO SLEEP program is also reported.

Participant Satisfaction: Forty-four (92%) of the 48 parents and children randomized provided an evaluation of their experiences in the study; 21 (88%) of those in the RELAX TO SLEEP group and 23 (96%) of those in the Usual Care group (Table 13). The most common factor identified by participants that they liked about their study participation was their helping to answer an important research question (77%). A greater proportion of the sample (27%) indicated that their being in the study helped them feel reassured, compared to the proportion of the sample (2%) who felt it caused them to worry. Most parents in the RELAX TO SLEEP group (n=12, 57%) liked the contacts with the research team, and felt reassured (n=9, 43%).
Table 13
Participant Satisfaction with Study Participation

<table>
<thead>
<tr>
<th></th>
<th>RELAX TO SLEEP n=21</th>
<th>Usual Care n=23</th>
</tr>
</thead>
<tbody>
<tr>
<td><em><strong>Liked:</strong></em></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Contacts with the research team</td>
<td>12 (57)</td>
<td>4 (17)</td>
</tr>
<tr>
<td>Randomized to the group I wanted</td>
<td>6 (27)</td>
<td>1 (4)</td>
</tr>
<tr>
<td>Being in the RELAX TO SLEEP study helped me feel reassured</td>
<td>9 (43)</td>
<td>3 (13)</td>
</tr>
<tr>
<td>Helped to find answer to an important research question</td>
<td>14 (67)</td>
<td>20 (59)</td>
</tr>
<tr>
<td>There was nothing I liked about being a participant in the RELAX TO SLEEP study</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Other</td>
<td>4 (40)</td>
<td>6 (60)</td>
</tr>
<tr>
<td><em><strong>Disliked:</strong></em></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Contacts with the research team</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Not randomized to the group I wanted</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Participating in the RELAX TO SLEEP study caused me to feel worried</td>
<td>0 (0)</td>
<td>1 (4)</td>
</tr>
<tr>
<td>Disliked the extra demands on my time</td>
<td>0 (0)</td>
<td>3 (13)</td>
</tr>
<tr>
<td>There was nothing I disliked about being a participant in the RELAX TO SLEEP study</td>
<td>18 (86)</td>
<td>20 (87)</td>
</tr>
<tr>
<td>Other</td>
<td>3 (100)</td>
<td>0 (0)</td>
</tr>
</tbody>
</table>

*Participants could choose more than one response*

Parents in the RELAX TO SLEEP group who identified additional things they liked about their study participation noted the following: “liked the book”; “helped to improve quality of being a patient in hospital”; “enjoyed the different experience and new opportunity to learn about sleep”; “liked the information.” Parents in the Usual Care group identified these additional things they liked about their study participation: “liked that it was non-invasive”; “no extra stuff that she [child] had to do”; “doing the right thing to make sure sleep is improved”; “straight forward, well explained and easily put together”; “child enjoyed helping and participating; gave her something to talk about/think about while hospitalized. It gave her a sense of purpose.”
Most parents responded that there was nothing that they disliked about their child being in the study (n=38, 86%). Three of the 44 study respondents (7%) identified that they disliked the extra demands on their time; all were from the Usual Care group. Of the 3 parents who noted specific “other” dislikes, only one was related to the use of the relaxation breathing technique, with the statement, “Child disliked book and CD (found them boring); but I had no dislikes about being in the study.” Other noted dislikes were: “watch was uncomfortable”; “I think the study is a big challenge when there are so many noise factors – there is no control.”

Likelihood of participating in a larger study: Ninety-one per cent (n=40) of parents who responded to the participant satisfaction questionnaire indicated that they would definitely or probably participate again in a future study. Only one respondent indicated that s/he would probably not participate if given the choice to participate again in a future study, and three were unsure (Table 14).

Table 14  
Likelihood of participating in a larger study:

<table>
<thead>
<tr>
<th></th>
<th>Relax to Sleep (n=21)</th>
<th>Usual Care (n=23)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Definitely Yes</td>
<td>15 (71)</td>
<td>14 (60)</td>
</tr>
<tr>
<td>Probably Yes</td>
<td>4 (19)</td>
<td>7 (30)</td>
</tr>
<tr>
<td>Not Sure</td>
<td>2 (10)</td>
<td>1 (4)</td>
</tr>
<tr>
<td>Probably Not</td>
<td>0 (0)</td>
<td>1 (4)</td>
</tr>
<tr>
<td>Definitely Not</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
</tbody>
</table>

Experiences with the Actigraphy Device: Compliance for wearing the actigraph was high. All children who were randomized wore the actigraph on the wrist with the exception of the one child from the RELAX TO SLEEP group who withdrew shortly after the intervention was delivered. The actigraph was taken off for brief periods of time such as when changing the site of an intravenous, or for having a bath. Only one participant in the RELAX TO SLEEP group had
indicated that the velcro strap was irritating him, but then a wrist band was placed with the
actigraph over it and this solved the issue. Parents of children in the study were asked to report
about their child’s experiences with the actigraph and to rate the extent to which they agreed or
disagreed with the statement (Table 15).

Table 15
*Parental Report of their Child’s Experiences with Actigraphy Device*

<table>
<thead>
<tr>
<th>Actigraphy Device</th>
<th>RELAX TO SLEEP</th>
<th>Usual Care</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n=21 n (%)</td>
<td>n=23 n (%)</td>
</tr>
<tr>
<td>The actigraph caused child discomfort</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Strongly Disagree</td>
<td>11 (52)</td>
<td>17 (74)</td>
</tr>
<tr>
<td>Disagree</td>
<td>6 (29)</td>
<td>3 (13)</td>
</tr>
<tr>
<td>Neither Agree nor Disagree</td>
<td>1 (5)</td>
<td>1 (5)</td>
</tr>
<tr>
<td>Agree</td>
<td>3 (14)</td>
<td>2 (9)</td>
</tr>
<tr>
<td>Strongly Agree</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Wearing the actigraph interfered with child’s activities.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Strongly Disagree</td>
<td>14 (67)</td>
<td>19 (83)</td>
</tr>
<tr>
<td>Disagree</td>
<td>7 (33)</td>
<td>2 (9)</td>
</tr>
<tr>
<td>Neither Agree nor Disagree</td>
<td>0 (0)</td>
<td>1 (4)</td>
</tr>
<tr>
<td>Agree</td>
<td>0 (0)</td>
<td>1 (4)</td>
</tr>
<tr>
<td>Strongly Agree</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Wearing the actigraph caused child to worry.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Strongly Disagree</td>
<td>14 (67)</td>
<td>20 (87)</td>
</tr>
<tr>
<td>Disagree</td>
<td>7 (33)</td>
<td>3 (13)</td>
</tr>
<tr>
<td>Neither Agree nor Disagree</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Agree</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Strongly Agree</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
</tbody>
</table>

*Acceptability of the RELAX TO SLEEP Program:* Parents of participants in the RELAX TO
SLEEP group were asked about their experiences with using the RELAX TO SLEEP program. The
results indicate high acceptability of the intervention (Table 16). Almost all the participants
indicated that they strongly agreed or agreed with the following statements: Enjoyed the one-on-
one discussion with the PI (n=21, 95%); the information provided helped them to learn more
about sleep and sleep issues during hospitalization (n=21, 95%); the educational booklet was
easy to read and understand (n=22, 100%); and the tips provided in the booklet helped their child sleep during their hospital stay (n=12, 55%). Most parents felt their child enjoyed using the relaxation breathing technique and found it easy to use (n=21, 95%). Most participants indicated that they would recommend this technique to others who are hospitalized (n=18, 82%) and would use the technique again in the future (n=18, 82%).

Table 16
Participant Satisfaction of RELAX TO SLEEP Program

<table>
<thead>
<tr>
<th>RELAX TO SLEEP Program</th>
<th>Extent to whether they agree or disagree with the statement n=22</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Evaluation of one-on-one discussion</strong></td>
<td>Strongly Agree</td>
</tr>
<tr>
<td>Enjoyed the one-on-one discussion with the researcher.</td>
<td>7 (32)</td>
</tr>
<tr>
<td>Information provided helped to learn more about sleep and sleep issues during hospitalization.</td>
<td>5 (23)</td>
</tr>
<tr>
<td>Educational booklet was easy to read and understand</td>
<td>9 (41)</td>
</tr>
<tr>
<td>The tips provided in the booklet helped my child sleep during their hospital stay.</td>
<td>3 (14)</td>
</tr>
</tbody>
</table>

**Evaluation of Relaxation Breathing (RB)**

<table>
<thead>
<tr>
<th>RELAX TO SLEEP Program</th>
<th>Extent to whether they agree or disagree with the statement n=22</th>
</tr>
</thead>
<tbody>
<tr>
<td>The book or CD was easy to use</td>
<td>8 (36)</td>
</tr>
<tr>
<td>The instructions were easy to follow</td>
<td>9 (41)</td>
</tr>
<tr>
<td>Child enjoyed using RB exercise</td>
<td>4 (18)</td>
</tr>
<tr>
<td>Relaxation breathing helped child calm down in stressful situations</td>
<td>3 (14)</td>
</tr>
<tr>
<td>Relaxation breathing helped child relax and fall asleep easily</td>
<td>2 (9)</td>
</tr>
<tr>
<td>Would recommend relaxation breathing to other parents with children who are hospitalized</td>
<td>5 (23)</td>
</tr>
<tr>
<td>Would use relaxation breathing exercises with child again in the future</td>
<td>13 (59)</td>
</tr>
</tbody>
</table>

*Data are presented as no (%)
**Sleep Diary Data:** The next section reports on the data collected as part of the sleep diary. It reports on opioid administration, pain score, parental perception of nursing in the room during the night and parental perception of child’s sleep as compared to sleep at home.

**Opioid Administration:** On day two of the in-hospital period of the study, opioids had been administered within the previous 24 hours to 33% (n=14) of the children in the sample. Similarly, on the third and fourth day, 27% (n=11) and 26% (n=10) had received opioids in the past 24 hours (Table 17).

Table 17
**Opioid Administered during previous 24 hours**

<table>
<thead>
<tr>
<th>Opioid Administered (during previous 24 hours)</th>
<th>RELAX TO SLEEP n (%)</th>
<th>Usual Care n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Opioid Day 2 (n=44)</td>
<td>n=21 7 (33)</td>
<td>n=23 7 (30)</td>
</tr>
<tr>
<td>Opioid Day 3 (n=40)</td>
<td>n=18 5 (28)</td>
<td>n=22 6 (27)</td>
</tr>
<tr>
<td>Opioid Day 4 (n=38)</td>
<td>n=17 3 (18)</td>
<td>n=21 7 (33)</td>
</tr>
</tbody>
</table>

**Pain Score:** Table 18 provides the median pain scores available across days for children by group. During the in-hospital period of the study, the RELAX TO SLEEP group reported less pain (median 0, range 0-2) across all three days compared to the Usual Care group (median 2, range 1.75-4.5).

Table 18
**In hospital Pain Scores**

<table>
<thead>
<tr>
<th>Morning Pain Score (by day)</th>
<th>RELAX TO SLEEP</th>
<th>Usual Care Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain Score Day 2 (n=46)</td>
<td>n=22 0 (0, 4)</td>
<td>n=24 2 (0.5, 6)</td>
</tr>
<tr>
<td>Pain Score Day 3 (n=42)</td>
<td>n=19 0 (0, 2)</td>
<td>n=23 2 (0, 4)</td>
</tr>
<tr>
<td>Pain Score Day 4 (n=39)</td>
<td>n=18 1 (0, 2.5)</td>
<td>n=21 2 (0, 4)</td>
</tr>
</tbody>
</table>
Parental report of continuous nursing care in the room during the night: A small proportion of the sample answered yes when asked if a nurse was in the room most or all of the night (Table 19).

Table 19

Continuous nursing care during the night

<table>
<thead>
<tr>
<th>Continuous nursing care during the night</th>
<th>RELAX TO SLEEP n (%)</th>
<th>Usual Care Group n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day 2 (n=45)</td>
<td>4 (19)</td>
<td>1 (4)</td>
</tr>
<tr>
<td>Day 3 (n=43)</td>
<td>3 (15)</td>
<td>2 (9)</td>
</tr>
<tr>
<td>Day 4 (n=40)</td>
<td>5 (28)</td>
<td>1 (5)</td>
</tr>
</tbody>
</table>

*Day 2: RELAX TO SLEEP n=21, Usual Care n=24; Day 3: RELAX TO SLEEP n = 20, Usual Care n =23; Day 4 RELAX TO SLEEP n=18; Usual care n=22.

Parental perception of child’s sleep as compared to sleep at home: Parents of hospitalized children were asked to rate their child’s sleep of the previous night compared to how their child usually sleeps at home. Using a Likert where 1 is “much better” and 5 indicates “much worse”, most parents in this sample indicated that the child’s sleep was much or a little worse than how the child normally sleeps (Table 20).

Table 20

Parents’ evaluations of their child’s sleep during the in-hospital study period

<table>
<thead>
<tr>
<th>Day</th>
<th>Much/A Little Worse RELAX TO SLEEP</th>
<th>Usual Care</th>
<th>About the same RELAX TO SLEEP</th>
<th>Usual Care</th>
<th>A Little/Much Better RELAX TO SLEEP</th>
<th>Usual Care</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day 2* n (%)</td>
<td>11 (50)</td>
<td>14 (58)</td>
<td>5 (23)</td>
<td>7 (29)</td>
<td>6 (27)</td>
<td>3 (13)</td>
</tr>
<tr>
<td>Day 3* n (%)</td>
<td>12 (63)</td>
<td>14 (64)</td>
<td>4 (21)</td>
<td>4 (18)</td>
<td>3 (16)</td>
<td>4 (18)</td>
</tr>
<tr>
<td>Day 4* n (%)</td>
<td>7 (41)</td>
<td>9 (41)</td>
<td>4 (24)</td>
<td>7 (32)</td>
<td>6 (35)</td>
<td>6 (27)</td>
</tr>
</tbody>
</table>

*Day 2: RELAX TO SLEEP n=22, Usual Care n=24; Day 3: RELAX TO SLEEP n = 19, Usual Care n =22; Day 4 RELAX TO SLEEP n=17; Usual care n=22.

Research Questions

Although this was a pilot randomized controlled trial and effectiveness cannot be established since this study is underpowered; for exploratory purposes only, the following
research questions were posed. Note the terms primary, secondary, and other describe how the questions would be categorized for a larger multi-site randomized controlled trial.

**Primary Research Question**

*In hospitalized children, what is the effect of the RELAX TO SLEEP program on total nighttime (19h30-07h29) sleep compared to children receiving usual care?*

Nighttime was defined as sleep between the hours of 19h30 to 07h29. The total nighttime sleep in minutes was averaged across the number of nights available for the participants. Children in RELAX TO SLEEP experimental group (n=20) had a mean of 419 (SD 71.8) minutes of sleep time during the 12 hour nighttime interval, while children in the Usual Care (n=23) comparison group had 369 (SD 71.8) minutes of sleep. A student’s t-test on the group means revealed a mean difference of 49.6 minutes (95% confidence interval [CI] -7.19, 106.5; p=0.085).

Table 21

*Primary Sleep Outcome: Comparison of Nocturnal Sleep between Treatment Groups*

<table>
<thead>
<tr>
<th>Sleep Outcome</th>
<th>Relax to Sleep Mean (SD)</th>
<th>Usual Care Mean (SD)</th>
<th>Group Difference 95% CI</th>
<th>t</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nocturnal Sleep, min</td>
<td>419.3 (71.84)</td>
<td>369.7 (106.4)</td>
<td>49.64 (-7.19, 106.5)</td>
<td>1.76</td>
<td>0.085</td>
</tr>
</tbody>
</table>

**Secondary Research Questions**

This section reports on secondary research questions as well as other sleep outcomes. Table 22 reports on the secondary sleep outcomes and Table 23 reports on other sleep outcomes.

*In hospitalized children, what is the effect of the RELAX TO SLEEP program on number of nighttime (19h30-07h29) awakenings compared to children receiving usual care?*
Both the RELAX TO SLEEP group (n=20) and the Usual Care group (n=23) had a mean of 14.7 (SD 5.8, and 4.7 respectively) awakenings during the nighttime sleep interval (19h30 to 07h29).

In hospitalized children, what is the effect of the RELAX TO SLEEP program on the longest stretch of nighttime (19h30-07h29) sleep compared to children receiving usual care?

The longest stretch of mean uninterrupted sleep for the RELAX TO SLEEP group (n=20) was 116 minutes (SD 66.9) while the Usual Care group (n=23) had a mean of 100 minutes (SD 46) of continuous sleep during the nighttime interval (19h30 to 07h29).

In hospitalized children, what is the effect of the RELAX TO SLEEP program on daytime sleep (07h30-19h29) compared to usual care?

Daytime sleep was defined as sleep occurring during the interval of 07h30 to 19h29. Children in the Usual Care group (n=23) had a mean of 113.6 minutes (SD 82.2) of daytime sleep compared to the RELAX TO SLEEP group (n=18) who had a mean of 77 minutes (SD 60.3).

Table 22
Secondary Sleep Outcomes: Nocturnal awakenings, longest period of uninterrupted nocturnal sleep, and daytime sleep between treatment groups

<table>
<thead>
<tr>
<th>Sleep Outcome</th>
<th>Relax to Sleep n=20 mean (SD)</th>
<th>Usual Care n=23 mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nocturnal awakenings, no.</td>
<td>14.7 (5.8)</td>
<td>14.7 (4.7)</td>
</tr>
<tr>
<td>Longest nocturnal sleep period, min</td>
<td>116.6 (66.9)</td>
<td>100.9 (46)</td>
</tr>
<tr>
<td>Daytime Sleep, min</td>
<td>77 (60.3)</td>
<td>113.6 (82.3)</td>
</tr>
</tbody>
</table>

**OTHER SLEEP OUTCOMES**

*Late Sleep:* Late sleep was defined as sleep that occurred between 22h00 to 06h00.

Despite having the same number of late night awakenings, children in the RELAX TO SLEEP group
had a mean of 340.2 (SD 64.7) and children in the Usual Care group had a mean 293.5 (SD 89.1).

Table 23
Other Sleep Outcomes

<table>
<thead>
<tr>
<th>Sleep Outcome</th>
<th>RELAX TO SLEEP n=20 mean (SD)</th>
<th>Usual Care n=23 mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Late nocturnal sleep period, min</td>
<td>340.2 (64.7)</td>
<td>293.5 (89.1)</td>
</tr>
<tr>
<td>Late nocturnal awakenings, no.</td>
<td>10.7 (4.3)</td>
<td>10.7 (3.6)</td>
</tr>
<tr>
<td>Wake After Sleep Onset, min</td>
<td>163.9 (93.6)</td>
<td>209.2 (121.2)</td>
</tr>
<tr>
<td>Longest daytime sleep period, min</td>
<td>36.17 (22.5)</td>
<td>46.22 (30)</td>
</tr>
</tbody>
</table>

OTHER RESEARCH QUESTIONS

In hospitalized children, what is the effect of the RELAX TO SLEEP program on anxiety levels compared to children receiving usual care?

See Table 24 for Post-hospital follow-up scores on the Children’s Generalized Anxiety (CGA) and Separation Anxiety (CSA) subscales and the Pre-school Generalized Anxiety (PGA), and Separation Anxiety (PSA) subscales.

Table 24
Post-Hospital Follow-up Scores on SPAS/SCAS

<table>
<thead>
<tr>
<th></th>
<th>RELAX TO SLEEP n = 21</th>
<th>Usual Care n = 23</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Ages 4-5 n = 10</td>
<td>Ages 6-10 n = 11</td>
</tr>
<tr>
<td>Generalized Anxiety Score, mean (SD)</td>
<td>2.45 (4.2)</td>
<td>5.18 (3.7)</td>
</tr>
<tr>
<td>Separation Anxiety Score, mean (SD)</td>
<td>1.08 (1.8)</td>
<td>2.82 (2.4)</td>
</tr>
</tbody>
</table>

*Note that n varies for each comparison due to age group difference.

There were no notable differences on the scores from baseline to follow-up between the two group on Generalized Anxiety (PGA and CGA) or Separation Anxiety (PSA and CSA) subscales (Table 25).
Table 25
Baseline and Follow-up Comparisons: Pre-school and Children’s Anxiety Subscales

<table>
<thead>
<tr>
<th></th>
<th>RELAX TO SLEEP</th>
<th>Usual Care</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline</td>
<td>Follow-up</td>
</tr>
<tr>
<td></td>
<td>n=24</td>
<td>n=21</td>
</tr>
<tr>
<td>Ages 4-5</td>
<td>Ages 6-10</td>
<td>Ages 4-5</td>
</tr>
<tr>
<td>GA Score mean (SD)</td>
<td>3.58 (2.2)</td>
<td>2.45 (4.2)</td>
</tr>
<tr>
<td>SA Score mean (SD)</td>
<td>3.58 (2.2)</td>
<td>1.08 (1.8)</td>
</tr>
</tbody>
</table>

GA = Generalized Anxiety; SA = Separation Anxiety Score

In hospitalized children, what is the effect of the RELAX TO SLEEP program on sleep disturbance behaviours and the development of maladaptive post-hospital behaviours compared to children receiving usual care?

During the follow-up period, parents of the participants were asked to fill out the Children’s Sleep Habits Questionnaire (CSHQ) and the Post Hospital Behaviour Questionnaire (PHBQ) to determine if there were any changes in sleep disturbance and to determine if the child developed any post-hospital mal-adaptive behaviour(s).

Children’s Sleep Habits Questionnaire (CSHQ): The final research question of the study sought to determine the effect of the RELAX TO SLEEP program on sleep disturbance behaviour in the post-hospitalization period and can be found in Table 26.

Table 26
Baseline and Follow-up Differences in CSHQ Scores

<table>
<thead>
<tr>
<th></th>
<th>Relax to Sleep</th>
<th>Usual Care</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline n=24</td>
<td>Follow-up n=21</td>
</tr>
<tr>
<td>CSHQ Score mean (SD)</td>
<td>44.04 (7.17)</td>
<td>42.38 (5.41)</td>
</tr>
</tbody>
</table>

Post-Hospitalization Behaviours: A score of 81 or higher on the PHBQ indicates that the child has developed a new behaviour that is regressive in nature. Of the total sample that responded (n=44), 73% (n=32) scored 81 or higher on this scale with only 27% (n=12) having no
changes to their behaviour or less maladaptive behaviour. The scores for the different subscales on the PHBQ are shown in Table 27.

Table 27

<table>
<thead>
<tr>
<th>PHBQ Subscale</th>
<th>Relax to Sleep</th>
<th>Usual Care</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n=21</td>
<td>n=23</td>
</tr>
<tr>
<td></td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
</tr>
<tr>
<td>PHBQ Total Scores</td>
<td>82.24 (4.32)</td>
<td>84.22 (4.90)</td>
</tr>
<tr>
<td>(range 27-135, no change =81)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Generalized Anxiety and Regression</td>
<td>23.81 (1.12)</td>
<td>24.13 (1.22)</td>
</tr>
<tr>
<td>(range 8-40, no change = 24)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Separation Anxiety</td>
<td>15.57 (1.36)</td>
<td>16.91 (2.13)</td>
</tr>
<tr>
<td>(range 5-25, no change=15)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anxiety about Sleep</td>
<td>9 (0.70)</td>
<td>9 (1.08)</td>
</tr>
<tr>
<td>(range 3-15, no change=15)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Eating Disturbance</td>
<td>9.38 (1.3)</td>
<td>9.43 (1.59)</td>
</tr>
<tr>
<td>(range 3-15, no change =15)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aggression towards authority</td>
<td>6.42 (1.02)</td>
<td>6.34 (0.71)</td>
</tr>
<tr>
<td>(range 2-10, no change = 6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Apathy or Withdrawal</td>
<td>18.04 (1.07)</td>
<td>18.39 (1.62)</td>
</tr>
<tr>
<td>(range 6-30, no change=18)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

SUMMARY OF RESEARCH RESULTS

The primary objective of this pilot randomized controlled trial was to determine the feasibility and the acceptability of a sleep intervention for hospitalized children. Recruitment rates were 1 patient per week for 44 weeks and acceptance rate for this pilot trial was 71%.

Compliance for both groups wearing the actigraphs and completing sleep diaries was excellent. Compliance for the RELAX TO SLEEP program was excellent for the in-hospital study period and adequate for the post-hospital follow-up period. The acceptability of both the educational booklet and the relaxation technique were high. Most parents reported children enjoyed using the relaxation breathing technique and found it easy to use and would use the technique again in the future. The tips that parents implemented and rated as helpful or very helpful during hospitalization included suggestions about: 1) the child sleeping in a quiet room; 2) child
sleeping in a dark room; and 3) child exposed to bright light during the day; and post-hospital included: 1) child slept in a quiet room; and 2) child engaged in a calming bedtime routine.

Most respondents were satisfied with their participation in the study and liked participating to help answer an important research question. Most responded that there was nothing that they disliked about their child being in the study; and they would definitely or probably participate again in a future study.

The primary research question in this feasibility study sought to determine the effect of a sleep intervention on total nocturnal sleep during hospitalization, when compared to usual care. The mean sleep for children in the RELAX TO SLEEP group was 419 minutes compared to 369 minutes of sleep for the Usual Care group. The mean difference of almost 50 minutes is suggestive of a positive effect of the RELAX TO SLEEP.

Secondary and other sleep research questions sought to determine possible influences of the effect of the RELAX TO SLEEP intervention on other sleep outcomes including: number of nighttime awakenings, total daytime sleep, longest stretch of nighttime sleep, late sleep, wake-after sleep onset, and longest period of uninterrupted daytime sleep. Upon examination of the data, there were no notable differences on any of these sleep outcomes, with the exception of late sleep.

There were no notable differences were seen on post-hospital maladaptive behaviours or anxiety levels. Children in the RELAX TO SLEEP group had a decrease in sleep disturbance from baseline to the follow-up period of the study while children in the Usual Care group had an increase in sleep disturbance from baseline to post-hospital follow-up.
CHAPTER 5
Discussion

This chapter begins with a discussion related to the primary purpose of this pilot trial which addresses the feasibility and compliance of the trial protocol, and the acceptability of the RELAX TO SLEEP intervention. Although this pilot trial was not powered to determine significant group differences, the effects of the RELAX TO SLEEP program versus Usual Care are discussed related to sleep outcomes and post-hospital maladaptive behaviours.

**PRIMARY PURPOSE: FEASIBILITY AND ACCEPTABILITY**

*Feasibility*

*Recruitment:*

One of the main reasons for conducting a feasibility study is to determine recruitment rate (Guyatt, 2006). Of the eligible participants, only 29% declined to participate in this pilot trial, suggesting that most parents and children were interested in participating in the study and potentially were receptive to the intervention. A number of strategies to facilitate recruitment were implemented prior to the launch of the pilot trial. Presentations to the unit managers, nurse educators, medical team, and clinical nursing staff were conducted to provide them with the purpose of the study and what was expected of them during the study period. In addition to the presentations and group discussions, a one page leaflet was made available to all nursing staff via e-mail from their department managers as well as hardcopies provided at the nurses’ desk as an additional resource. Once the study launched, the strategy put in place to identify eligible patients for the study was also feasible. The PI collaborated with the clinical nurse leaders at each of the recruitment units once the interdisciplinary team finished rounding on all the patients. This allowed the clinical leader to have up-to-date information on the plan of care of each patient.
and therefore was better able to identify patients that fit the eligibility criteria for the RELAX TO SLEEP study. Once patients were identified, the PI sought out the patients’ assigned bedside nurse to re-confirm eligibility.

One of the major barriers to recruitment for the current study was fewer eligible patients than expected. Aside from age, the main inclusion criterion that children did not meet was the length of stay required (3 nights of hospitalization) for actigraphy data collection, and so these children were not approached for inclusion. While decreasing the criterion of the length of stay in hospital would most likely increase recruitment rates, it would not allow sufficient time to capture the sleep patterns of the hospitalized child based on the Standards of Practice Committee Practice Parameter for the use of actigraphy data. Furthermore, the decrease in the length of stay may not give the RELAX TO SLEEP program enough time to take effect, if indeed there is one. The relaxation breathing technique was relatively easy to learn; it required brief instruction from the PI and a few demonstrations. The effects of relaxation breathing are meant to be immediate. However, sleep hygiene practices may take some time for positive changes to occur. Finally, potential eligible patients may have been missed since recruitment was based on the availability of the PI.

The participation rate for this pilot trial was higher than the initial goal of 50% acceptance rate and took less than one year to recruit the number of participants needed. The participation rate for the current study is in line with other studies. In a study conducted by Sciberras et al. (2011), to evaluate the feasibility of a behavioral sleep program for children with ADHD, out of the 43 eligible children, 27 consented and were randomized yielding an acceptance rate of 63%. A study that sought to describe the sleep quantity, sleep patterns, and environmental light and sound levels for hospitalized children had a 56% acceptance rate over a
10 month period (Stremler et al., 2009). The acceptance rate for the RELAX TO SLEEP study was 71%.

*Delivery of the Intervention:*

Pilot trials are also used to determine if the intervention can be delivered as planned (Feeley et al., 2009). As soon as the randomized assignment had been revealed the PI delivered the intervention to those randomized to the RELAX TO SLEEP group. The PI attempted to provide the intervention in the late afternoon when there were fewer interruptions from health care providers and when it was convenient to the child and care-giver.

All the components of the intervention were delivered to both the hospitalized child and their mother in all 24 cases. The mode of delivering the relaxation breathing technique varied across age groups; younger children were provided a book and older children were provided a CD. The mode of delivery was meant to accommodate developmental differences but nonetheless induce the relaxation response. Many more children received the book (n=17, 71%) compared to the CD (n=5, 21%), given the younger mean age (6.2 years) in the intervention group. The small sample size in the current study did not allow for stratification, and therefore it is difficult to examine differences in outcomes based on age and the mode of delivery (book vs CD). Stratification would ensure equal distribution in the age categories between the RELAX TO SLEEP and Usual Care groups, and should be used in future studies.

Overall the relaxation breathing exercise was acceptable to the parents and children. As mentioned previously, the intent of the *Hoberman* sphere was to be used by the PI for demonstrating how to do the relaxation breathing technique. It allowed the child to visualize how the air flows in and out of the body. Children in the RELAX TO SLEEP group demonstrated a keen interest and great enthusiasm for the sphere. This is not surprising since play is an essential part
of child development and contributes to the cognitive, physical, social, and emotional well-being of children (Ginsburg, 2007). Given that children in a hospital setting may be isolated, play may not be prioritized. The tactile nature of the *Hoberman* sphere could explain why children were so intrigued to touch and to manipulate the sphere. More spheres were made available so that the PI could leave one with the child during the hospital study period. Perhaps this type of sensory play helped the child induce the relaxation response. There is no way to know if the *Hoberman* sphere influenced the effect of the RELAX TO SLEEP program on sleep from this pilot trial, or even if the technique was used only for sleep, however in addition to visual (e.g., book) and auditory (e.g., CD) modes of doing relaxation breathing, future studies developing relaxation breathing techniques may find it helpful to include something tactile with kinesthetic movement such as the *Hoberman* sphere used in the current study.

Finally, the time to deliver the entire program took approximately 15 minutes which is less than the 30 minutes maximum time that was set out in the feasibility parameters, making this intervention feasible to deliver in a hospital setting. Non-pharmacologic therapies are often recommended as first-line therapies for sleep complaints in hospital (Young, Bourgeois, Hilty, & Hardin, 2008). However, very little evidence exists to guide clinicians on how to help hospitalized patients get restful sleep (Tamrat, Huynh-Le, & Goyal, 2013). Although the delivery of this intervention was feasible, acceptable to families, and showed some promise of benefits for sleep, given the heterogeneous and small sample size, the findings are insufficient to change practice. Further development of the RELAX TO SLEEP intervention in combination with environmental factors, such as a noise reduction protocol, should be evaluated and should assess other outcomes in addition to sleep, such as pain and anxiety.
Compliance:

In an attempt to increase compliance, the PI visited study participants daily during the hospital study period to ensure that children were wearing the actigraphs and completing the sleep diaries. Compliance for wearing the actigraph device and completing sleep diaries for both the RELAX TO SLEEP group and the Usual Care group was excellent.

The percentage of participants in the RELAX TO SLEEP group who were compliant (i.e., carried out the intervention at least once per day) decreased from when it was evaluated at the end of the hospital study period to one week post-discharge. During the hospital period of the study, the majority of children used the relaxation technique (n=19; 85%) at least once a day with more than half (n=12; 55%) using it two to three times a day. However, these rates of use declined in the post-hospitalization period as only 50% (n=11/22) reported using relaxation breathing at least once per day when they were discharged from hospital. The frequency of using the relaxation breathing technique in the hospital may be attributed to the distress and isolation associated with being hospitalized. Although it is unknown from this pilot trial, relaxation breathing may have served as a coping strategy to deal with the stress or anxiety associated with hospitalization and may have been seen as something the families could actively do. Having a child hospitalized is a stressful event for parents, and can be characterized with feelings over losing control over their child’s care (Ygge & Arnetz, 2004). Some of the major sources of parental stress during a child’s hospitalization include the uncertainty about their child’s condition and prognosis, not knowing how to care for their child’s emotional and physical needs during hospitalization, and their child’s emotional or behavioral response (Melnyk, Small, & Carno, 2004). Parental anxiety and stress negatively impact children’s outcomes (Melnyk & Feinstein, 2001). Perhaps parental involvement during the study period may have helped them obtain a measure of control over their child’s care, and provided them with a means to help
themselves and their child to generate effective coping strategies. Relaxation breathing is a coping technique that has been recommended to be used with children who are facing surgery (DeMaso & Snell, 2013). In the RELAX TO SLEEP pilot trial, the majority of parents reported that they would use the technique again in the future and that they would recommend this technique to others who are hospitalized, suggesting that they perceived it had benefited their child in some way.

The PI delivering the intervention made daily visits during the hospital study period to reinforce practice of the technique and to answer any questions about the intervention or help the family problem solve. This booster interaction may have also increased compliance with the relaxation breathing exercise during the hospital study period. Reasons for not using the relaxation breathing in the home are unknown. It is possible that caregivers and their children were not motivated to use the relaxation breathing technique since they were in familiar surroundings with familiar at-home routines and parents may not have enforced the technique due to other demands at home. Sleep may not have been perceived as a problem at home since there were no hospital context disturbances. Children in the RELAX TO SLEEP group had improved scores on the Children’s Sleep Habits Questionnaire from baseline, indicating that sleep problems improved. Finally, the current study did not include a “booster” session over the telephone. Future researchers may consider having a telephone call to provide positive reinforcement to motivate study participants to continue to practice the technique. Furthermore, with emerging interactive and communication technologies, especially the Internet and portable mobile devices, it is important to have different media for the delivery of health interventions. Perhaps the RELAX TO SLEEP program could use a more modern mode of delivery such as YouTube™ or a smartphone application. A brief video of a child using relaxation breathing could easily be made available on-line. This may have not only helped for visualization on proper use
of the technique, but perhaps increased compliance in the home. The clinical feasibility would need to be examined as this may add complexity to the intervention, and the intent of this pilot trial was to examine a behavioural-educational intervention in the context of sleep during hospitalization; post-hospital behavior was a secondary outcome and exploratory.

Strategies from the educational booklet were used by at least 59% of the parents during the hospital period, and 55% in the follow-up period. Some of the tips that had the lowest rates of use during hospitalization but much higher rates during the follow-up post-discharge period included advice about the child having the same bedtime each night and having the same wake time each morning. It is difficult to maintain the same bedtime each night and have the same wake time each morning in a hospital setting, since patients are required to adhere to the routines of the hospital unit rather than their at-home routine. Also noteworthy is although many parents (n=19, 86%) reported using the tip of engaging in a calming bedtime routine, only 50% rated it as very helpful or helping a little during their child’s hospitalization. The fast paced routine of hospital care may not coincide with at-home routines, making it difficult to establish a calming bedtime routine with the environmental stimuli, particularly excessive sound and light levels, physiological factors such as pain and painful procedures, and psychological factors such as anxiety which often characterizes the hospital setting.

Follow-up:

Minimal loss to follow-up was experienced in the current pilot study, with only 2 participants from the RELAX TO SLEEP group lost to follow-up because they were unreachable by telephone. Reported attrition rates across various categories of intervention studies range from 5% to 70% and bias is thought to be a significant concern if the attrition rate exceeds 20% (Karlson & Rapoff, 2009). The RELAX TO SLEEP study only had an attrition rate of 8% making
the attrition rate minimal. When designing the RELAX TO SLEEP pilot trial, careful consideration was taken to try to minimize the extra demands of participants. Efforts were made so that follow-up data collection occurred at a time that was convenient for the participant. The mode of follow-up data collection via telephone was also feasible. Given that our society is much more technologically savvy, it may have been helpful to provide participants with a choice between a telephone interview or to complete the final questionnaire on-line.

Acceptability

A number of parent reported findings provided indicators of the acceptability of the RELAX TO SLEEP program. The most common factor identified by parents that they liked about their study participation was helping to answer an important research question (77%). This is in line with altruism being the most commonly mentioned motivation for participation in a clinical trial (McCann, Campbell, & Entwistle, 2010; Ross et al., 1999). Most parents responded that there was nothing they disliked about their child being in the study and only a small proportion (n=3, 6.8%) said they disliked the extra demands on their time. Finally, 91% (n=40) who participated in the study said that they would definitely or probably choose to participate if they had to make the decision again, indicating high acceptability of participating in this trial.

Children who were randomized and remained in the study during the hospital portion of the study period wore actigraphs on their wrists and therefore diary substitution was not necessary. Most parents indicated that the actigraph did not cause any discomfort to their child, nor did the actigraph cause the child to worry. Any problems encountered with wearing the actigraph such as skin irritation from the Velcro strap, were easily resolved and children were excited to wear the “watch.” Perhaps the hospital environment influenced compliance of wearing the actigraph in some way. Hospitalized children are often bed bound and have a decreased level
of activity which would reduce the need to remove the actigraph (e.g., swimming, bathing). Also, children in this study often had an intravenous line, so wearing the actigraph did not seem to bother them in comparison with other medically-related equipment that they had to endure during hospitalization.

Results of parental experiences with the RELAX TO SLEEP program also indicate high acceptability of the intervention. Almost all the participants enjoyed the one-on-one discussion with the PI and found the information helped them to learn more about sleep and sleep issues. Furthermore, they found the educational booklet easy to read and understand and most parents felt their child enjoyed using the relaxation breathing technique.

**SLEEP OUTCOMES**

The conceptual framework guiding this study proposed that the RELAX TO SLEEP program would promote sleep through two avenues. The first was to promote sleep hygiene practices by educating the parents since they are in a good position to enforce and implement the information to their child’s sleep need. The second path increasing nighttime sleep was to facilitate the child’s relaxation response by using relaxation breathing as a mode to alleviate the symptoms of anxiety, which would then aid in sleep initiation and maintenance. The decision to provide a multi-faceted intervention was based on the effectiveness of sleep hygiene education combined with behavioural approaches such as relaxation training seen in insomnia patients (Morin et al., 2006; Morin et al., 1994). Furthermore, a review of behavioural treatments for bedtime problems and night wakings in young children demonstrated a high efficacy of multi-faceted interventions (Mindell et al., 2006). Although there have been no studies to date to use this combination of sleep education and relaxation breathing to improve sleep for hospitalized children, in a
systematic review of non-pharmacologic interventions to improve the sleep of hospitalized adult patients, relaxation techniques have been found to improve sleep quality (Tamrat et al., 2013).

Because the RELAX TO SLEEP intervention contained numerous strategies aimed at promoting sleep in the hospital as well as in the home and most of the participants reported using the components of the intervention, we are unable to determine which individual component of the intervention was more useful. Similarly, we do not know if the sleep hygiene information or the relaxation breathing was the more “active ingredient” of the intervention, or if the components had an additive effect. Furthermore, it is unknown if the relaxation breathing was used specifically for sleep or if it was used for other reasons (e.g., pain control). Since sleep is affected by a number of factors, it was important to include multiple strategies.

This pilot trial found a mean difference of 49.6 (95% CI -7.19, 106.5) minutes nighttime sleep between the RELAX TO SLEEP group and Usual Care group. According to the National Sleep Foundation, the recommended amount of sleep for preschoolers (ages 3-5 years) is 11 to 13 hours, and school-age children (5-10 years) should obtain between 10 to 12 hours of sleep per night. A 30-60 minute decrease in total sleep time in an 8 hour period for adults represents a decrease of 6.25% to 12.5% and is considered a clinically significant decrease in total sleep time (Carskadon & Dement, 1981). In school-age children a 6.25% to 12.5% decrease in their 10-hour sleep requirement is a loss of 37.5-75 minutes of sleep. Parental reports from the CSHQ indicate that children in this entire sample had a mean of 10 hours and 33 minutes (SD ± .31) of nighttime sleep (ages 4-6 had a mean of 10h27 minutes [SD ± .28] and ages 7-10 had a mean of 10h42 minutes [SD ± .36]) prior to hospitalization. While hospitalized, children in the RELAX TO SLEEP group obtained a mean of 419.3 minutes (SD 71.84) which is approximately 7 hours of nighttime sleep.
sleep while children in the Usual Care group obtained a mean of 369.7 minutes (SD 106.4) which is approximately 6 hours of nighttime sleep.

Compared to the recommended sleep quantity, regardless of which group these children were randomized to, these children were severely sleep restricted. This is in line with previous studies of hospitalized children that demonstrate a reduction in sleep quantity. Stremler et al. (2009) found that sleep quantity was significantly decreased in hospitalized children (ages 4-7 mean nocturnal sleep 475 minutes [95% CI 357-662]; ages 8-12 mean nocturnal sleep 436 minutes [95% CI 238-595]) with greater reductions seen in the PICU compared to the general pediatric unit. Hagemann (1981a) found that children aged 3 to 8 lost 20-25% of their usual expected sleep time. In a self-report survey of non-intensive care pediatric inpatients which explored sleep at home and in the hospital, younger children (8-12 years) reported shorter total sleep time while hospitalized (in-hospital total sleep time 501.9 [SD 102.4] vs. at-home total sleep time 558.0 [52.1], t=2.70, p=0.01) (Meltzer, Finn Davis, & Mindell, 2012). Nighttime sleep reductions, as measured by actigraphy, have also been documented in hospitalized children with cancer (Hinds, Hockenberry, Rai, Zhang, Razzouk, McCarthy, et al., 2007; Hockenberry et al., 2010; Linder & Christian, 2013). Thirty-five school-aged children receiving treatment for cancer obtained a mean of 8.5 hours of sleep (SD 1.5), with a range of 6.1-12 hours (Hockenberry et al., 2010). In a sample of 29 school-age children and adolescents receiving inpatient chemotherapy, sleep duration ranged from 4.25 hours to 14.45 hours (Hinds, Hockenberry, Rai, Zhang, Razzouk, McCarthy, et al., 2007). Finally, in a small sample of fifteen 5-12 year old children with cancer, total sleep time never reached 10 hours on any of the three nights of hospitalization (mean 8.78 hour across 3 nights) (Linder & Christian, 2013).
For hospitalized children, a mean increase of almost 50 minutes more of nocturnal sleep time represents a clinically meaningful difference. Extending children’s sleep by 30 minutes has shown improvements in children’s mood, more empathic behaviour, and decreased impulsivity and sleepiness in school (Gruber, Cassoff, Frenette, Wiebe, & Carrier, 2012). Given the links between sleep and immune functioning (Irwin et al., 1996), this 7% increase in nocturnal sleep, if it occurs in an adequately powered trial, may contribute to optimal levels of immune function necessary for the recovery of illness (Dickstein & Moldofsky, 1999; Moldofsky, 1995).

Consequences of a reduction in sleep are particularly concerning for children who are hospitalized and most need the benefits of sleep. Children who are hospitalized are attempting to recover from the effects of their illness, treatment, or surgery. Sleep disturbance can compromise the immune system which is vital in the recovery of illness. During sleep, the immune system releases cytokines which not only promote sleep, but are also needed to fight off infection or recover during a stressful situation (Krueger, 2008). Inadequate sleep may decrease the production of these protective cytokines (Krueger, 2008), and therefore prolong recovery. In adults, even acute sleep restriction (4-5 hours per night) has adverse effects and is associated with worsening of neurocognitive, mood, metabolic, and autonomic parameters (Dinges et al., 1997; Spiegel, Leproult, & Van Cauter, 1999). In children, small deficits in sleep may result in significant impairment of cognitive performance, thereby impairing the ability to stay attentive and to make balanced decisions (Sadeh, Gruber, & Raviv, 2003). Decreasing children’s sleep by one hour has also been related to increased sleepiness, and deterioration of children’s mood and behaviour at school (Gruber et al., 2012).

Despite the mean difference of 49.6 minutes (95% CI – 7.19, 106.5) between the RELAX TO SLEEP and Usual Care groups, both groups had the same mean nighttime awakenings. Upon
further exploration, children in the Usual Care group had 209.2 minutes (SD 121.2) of WASO (Wake-after sleep onset – the duration of time that the child was awake after initially falling asleep) time in the 12 hour night interval compared to 163.9 minutes (SD 93.63) in the RELAX TO SLEEP group, suggesting that the RELAX TO SLEEP group was better able to return to sleep after waking. Typically developing school-age children with no known health concerns are expected to experience 4-6 awakenings per night, although these awakenings may be very brief and might not be remembered by the child in the morning, or noticed by the parent (Mindell & Owens, 2010). This estimate of the number of awakenings is based on clinical experience and parent report rather than objective methods of measurement such as actigraphy. In a hospital setting, it would be expected that the frequency of nighttime awakenings would exceed the typical awakenings and even brief periods of wakefulness would be captured and measured by actigraphy. Hospitalized children in the current study had a mean of 14.6 awakenings (SD ± 5.3), which are consistent with other studies using actigraphy to measure sleep outcomes in hospitalized children (Hinds, Hockenberry, Rai, Zhang, Razzouk, McCarthy, et al., 2007; Linder & Christian, 2012; Stremler et al., 2009). Hinds et al. (2007) found that hospitalized children with cancer had awakenings that averaged 14 per night with the highest number of awakenings occurring on the final night of hospitalization. Linder and Christian (2012) found that awakenings ranged from 12.3 on the first night and 10.9 on the second and third night of hospitalized children with cancer. In a sample of hospitalized children in a general pediatric medicine unit and a pediatric intensive care unit, Stremler et al. (2009), found that nighttime awakenings ranged from 8 to 19 and varied by age across 3 nights with the highest number of nighttime awakenings occurring in the 4-7 year age range. Nighttime sleep is reduced and fragmented in hospital relative to expert recommendations; however there are no established norms for healthy children in the community.
Children who are hospitalized often lack the benefits of restorative nighttime sleep which may result in more daytime sleep, causing a shift in the circadian rhythm. Children in the Usual Care group had a mean of 113.6 minutes (SD 82.26) of daytime sleep compared to a mean of 77 minutes (SD 60.29) attained by children in the RELAX TO SLEEP group. This may be a result of acute sleep deprivation which has been noted for both groups earlier. The most common causes for daytime sleep in a child who typically does not nap are an inadequate duration (sleep insufficiency) or poor quality of nighttime sleep (sleep fragmentation) (Rosen & Brand, 2011). Inadequate sleep hygiene practices may interfere with daily functioning resulting in excessive daytime sleepiness (Mindell & Owens, 2003a). Perhaps the sleep hygiene information provided to the parents of children in the RELAX TO SLEEP group may have attributed to the difference observed in daytime sleep between the two groups. For example, some of the tips that were discussed during the one-on-one session with the PI included having a consistent bedtime and wake time, avoiding daytime napping close to bedtime, and exposure to bright light during the day. Hospitalized children may have inconsistencies in sleep and wake times, which may result in disruptions in both the homeostatic and circadian processes which regulate wake and sleep (Davis et al., 2004). Although it is unknown from this study, the advice given may have resulted in less daytime sleep observed in the RELAX TO SLEEP group compared to the Usual Care group.

Pain is also associated with changes in sleep continuity, sleep architecture, as well as increased sleepiness during the day (Lautenbacher, Kundermann, & Krieg, 2006). Children in the Usual Care group reported higher pain levels on the Faces Pain Scale-Revised (FPS-R) across days available during hospitalization (median 2, range 1.75-4.5) than those in the RELAX TO SLEEP group (median 0, range 0-2). Sleep difficulties in children with persistent pain are strongly predictive of function, including impaired executive dysfunction and poorer health-related quality of life (Valrie, Bromberg, Palermo, & Schanberg, 2013). Furthermore, pain disturbs sleep
as it lightens sleep, therefore diminishes the restorative benefits of slow-wave sleep (SWS) (Smith & Haythornthwaite, 2004). Despite the availability of evidence-based guidelines, a significant number of children experience moderate-to-severe pain during their hospital stay (Stevens et al., 2012). In addition to pharmacological interventions for pain management, several non-pharmacological strategies such as cognitive interventions (e.g., imagery, education) and behavioral interventions (e.g., breathing exercises) or combined are encouraged as distraction techniques to guide children’s attention away from the painful stimuli and reduce pain and anxiety (Srouji, Ratnapalan, & Scheeweiss, 2010). Anxiety and pain are also intricately interrelated. According to the biopsychosocial theory of pain, psychological and social factors also contribute to the occurrence, maintenance, and disability associated with pain (Gatchel, Peng, Peters, Fuchs, & Turk, 2007). In the current sample, the RELAX TO SLEEP group reported less pain intensity than the Usual Care group over the 3 day hospital study period. Perhaps the relaxation breathing exercise served as a distraction to pain perception and anxiety. It is unknown from the current study if the relaxation breathing technique was used only for sleep or if it was also used for pain management. Another possibility is that the RELAX TO SLEEP group slept better therefore reported less pain, or that the Usual Care group had more pain, so they slept worse; therefore a definitive trial is needed. Given the bidirectional relationship between pain and sleep (Smith & Haythornthwaite, 2004), it is important to further explore and develop an understanding of the relationship between pain, pain relief, anxiety, and sleep as it is essential to create an effective pain management regimen.

Children in the current study were severely sleep restricted. Although they attempted to make up for acute sleep restriction by sleeping during the day, daytime sleep does not fully make up for lost nighttime sleep. As discussed in previous chapters the superchiasmatic nuclei is the body’s internal ‘clock’ which: 1) promotes daytime activities and separate them from nocturnal
sleep; and 2) prepares the individual for going to sleep in the evening and waking up in the morning. For these preparations to occur, a sequence of both biochemical and physiological events must be accomplished (Waterhouse, 2010). If a lack of synchrony occurs from either the circadian or homeostatic processes, such as sleeping during the day and fragmented nighttime sleep, many aspects of the body’s physiology and biochemistry are affected. There will be increased SNS activity, increased levels of cortisol in the evening, and decreased growth hormone secretion (Waterhouse, 2010). This further impacts glucose and insulin regulation and suppresses cellular immunity (Knutson & Van Cauter, 2008). This is particularly concerning for hospitalized children as they are attempting to recover from the effects of their illness or treatment, but also need to sustain normal physiologic growth. Sleep restriction even for a few nights may also impact recovery time as inadequate sleep decrease the production of protective cytokines which are needed when the body is stressed (i.e., fighting an infection).

**POST-HOSPITALIZATION OUTCOMES**

*Anxiety*

Children are particularly vulnerable to the stress of hospitalization and anxiety and fear are among the most frequently reported emotional responses (Salmela, Aronen, & Salantera, 2011). Anxiety induces the physiological and psychological arousal system and limits the ability for the child to initiate the relaxation response needed to facilitate sleep. In the current study, no differences between the two groups on the separation or generalized anxiety subscales were found during the post-hospitalization period of this study, although this study was not adequately powered to detect any differences. It may be that anxiety experienced in this sample was not adequately captured since the Spence Children’s Anxiety Scale was developed to assess the severity of anxiety symptoms broadly in line with the dimensions of anxiety disorder proposed
by the DSM-IV (Spence, 1997). It could also mean that psychological stress and anxiety associated with hospitalization were recognized and managed. Perhaps psychometric development of a tool that measures the domains of sleep anxieties and hospital-related sleep disturbance needs to be developed.

**Sleep Disturbance**

While an improvement in children’s sleep habits was noted during the post-hospitalization period for children in the RELAX TO SLEEP group (mean score pre- 44.04 [SD 7.2] post 42.38 [SD 5.4]), children’s sleep habits worsened for children in the Usual Care group (mean score pre- 45.58 [SD 7.9] post 47.52 [SD 7.47]). Total scores on the CSHQ with one standard deviation above the mean indicate a clinically significant difference (Owens et al., 2000). The improvements seen in the RELAX TO SLEEP group may be attributed to the implementation of the sleep hygiene practices discussed during the one-on-one session once they were discharged home in a familiar environment. Sleep education around sleep hygiene practices have been shown to improve sleep difficulties in children with Attention-Deficit/Hyperactivity Disorder (ADHD) and autism spectrum disorder (ASD) (Malow et al., 2013; Sciberras, Fulton, Efron, Oberklaid, & Hiscock, 2011). In a pilot RCT using written materials about normal sleep, healthy sleep hygiene practices and standard clinical strategies for managing sleep problems (e.g., limit setting and graduated extinction) in children with ADHD, Sciberras et al. (2011) found that even a brief (1 session) sleep program improved CSHQ scores (mean change 5.09, SD 5.19) at 2 months and 5 months (mean change 6.41, SD 5.62) post-intervention. Malow et al. (2013) provided sleep education to parents of children with autism spectrum disorder (ASD) and found significant improvements in the overall CSHQ scores from baseline (mean 55.5, SD 8.1) to post-treatment (mean 49.3, SD 8.2), suggesting improvements in sleep difficulties (mean change 6.2 [SD 8.0]; p<0.001).
In our sample, the majority of children in both the RELAX TO SLEEP group (63%) and Usual Care group (71%) had sleep disturbances as indicated by the cut-off score of 41, which may reflect an overrepresentation of children with pre-existing sleep disturbance in our sample. Large portions of children with high CSHQ scores have been reported in children with juvenile rheumatoid arthritis and children with acute lymphoblastic leukemia, and since normative data have not yet been established, it may be that the CSHQ is in need of some refinement (Bloom et al., 2002; Zupanec, Jones, & Stremler, 2010).

Post-Hospitalization Behaviours

It was hypothesized that the RELAX TO SLEEP program would increase total nighttime sleep during hospitalization, and would decrease the development of post hospital maladaptive behaviours compared to usual care. There were no noted differences between the RELAX TO SLEEP group and the Usual Care group in terms of developing a maladaptive behaviour one week after being discharged from hospital. However, the majority of children in this sample (73%) developed a new-onset maladaptive behaviour during the post hospital follow-up period. Post-hospital behavioural issues are more likely to be present in younger children (Yuki & Daaboul, 2011), therefore this finding may be attributed to the younger age group (5 years or less) which represents more than half of the children in this sample.

Negative behavioural changes often include separation anxiety, sleep disturbance, aggression toward authority, temper tantrum, and eating problems (Kain, Mayes, O'Connor, & Cicchetti, 1996b). These maladaptive behaviors have been described mostly in children undergoing surgery (Fortier, Del Rosario, Rosenbaum, & Kain, 2010; Fortier et al., 2012; Kain et al., 2002; Kain et al., 1996b; MacLaren & Kain, 2008) although post-hospital behaviours have also been noted in children with a visit for a minor procedure in the emergency department.
(Brodzinski & Iyer, 2013). In the current study, there were no notable differences in sleep anxiety subscale scores between the two groups. However, there could very well have been anxieties around sleep, but they just remained unchanged post hospitalization. Children in the Usual Care group scored higher on the separation anxiety subscale compared to the RELAX TO SLEEP group (mean score of 16.91 [SD 2.13] vs 15.57 [1.36] respectively). A score above 15 on the separation anxiety subscale indicates the development of new problem behaviour on the items pertaining to anxieties around being separated by a caregiver. The difference in scores observed in the current study suggests that children in the Usual Care group had more separation anxiety one week post-hospitalization while separation anxiety remained relatively unchanged in the RELAX TO SLEEP group. Previous studies have identified younger age, less sociability, anxiety/depression, increased preoperative anxiety, and higher pain at home as significant predictors of separation anxiety (Fortier et al., 2010; Power, Howard, Wade, & Franck, 2012).

**STRENGTHS AND LIMITATIONS**

This was the first study to evaluate the feasibility and acceptability of a parental educational booklet and the use of a relaxation breathing technique by the child to promote sleep during hospitalization and post-discharge. The methods employed in this pilot trial were robust and included using an RCT design, having a single PI to deliver the intervention, developing a trial specific database to ensure data accuracy, achieving good compliance, and controlling for various sources of bias.

The randomization procedure used sealed, opaque envelopes, which were sequentially numbered and developed by a staff member who was not directly involved in the study at the Lawrence S. Bloomberg Faculty of Nursing. This ensured that each participant had the same chance of being assigned to the RELAX TO SLEEP (experimental) group or Usual Care (control)
group. Participants were randomized to the intended group and received what was intended with no violations; the envelopes with the group assignment were affixed to the randomization form for an audit pathway.

Standardized approaches for the intervention added to the strength of the study. Data suggested that participants enjoyed the intervention and most participants rated the demands on their time from study participation to be minimal.

Data were collected systematically; where available, reliable and valid tools were used to measure the outcomes and other variables of interest in this study. The use of actigraphy to measure the primary outcome was a strength of this study, as actigraphy allows participants to remain in their natural environments while reliably quantifying sleep/wake activities. In order to promote honest responses from the parents, the PI collected the completed coded instruments from parents in a sealed, opaque envelope at the end of the hospital study period. The development of a trial-specific database to enter and manage the data was a strength of this pilot trial. Data were entered into a Microsoft Access database with built in logic and range checks for accuracy of the data. The data were double entered by the PI and an RA who was blinded to the entire study protocol. All actigraphy data files were analyzed separately once by the PI and by the RA who was blinded to group assignment. Results of the two separate analyses were compared for each file and few discrepancies in decisions were found. A third party expert in actigraphy analysis randomly selected and reviewed a third of the files for accuracy of decisions.

Blinding of participants to group allocation was not possible due to the nature of the intervention. Measures were taken to prevent contamination, compliance, and co-intervention biases. Children were recruited from single patient rooms only to minimize contamination. The intervention was delivered to children randomized to receive the RELAX TO SLEEP program in
their rooms. It is highly unlikely that participants from the Usual Care group overheard or listened in during the delivery of the program. Furthermore, the RELAX TO SLEEP group was asked not to share what they learned with any other families, and were asked during follow-up if they had indeed shared this information with other hospitalized families; none had. Healthcare providers, such as nurses, were never provided with the details of the program, but rather a general description of the study. They were also asked not to share the information.

Compliance bias may occur in studies where participants are required to adhere to an intervention (Delgado-Rodriguez & Llorca, 2004). Compliance for the RELAX TO SLEEP group was defined as using the relaxation technique at least once per day during the hospital portion of the study as well as once per day once they went home until follow-up data was collected. The degree of compliance may influence the efficacy of the intervention (Delgado-Rodriguez & Llorca, 2004). Compliance with the study protocol was very good, in particular during the hospital period of the study.

Co-intervention bias occurs when participants receive other (unaccounted for) interventions at the same time as that of the study (Krishna, Maithereyi, & Surapaneni, 2010). Opioid administration for the previous 24 hours was assessed daily during the hospital study period, and no notable differences were found in the administration of opioids between groups. An open-ended question was asked to all participants to elicit information of co-intervention during the hospital portion of the study; however, a potential limitation of this study is that they were not asked this during the follow-up period. There was no control over participants using other sources of co-intervention once discharged home; however, randomization should ensure that participants using co-intervention in the home would be equally distributed between the RELAX TO SLEEP group and the Usual Care group.
Children in the RELAX TO SLEEP group received the intervention and daily visits, while children in the Usual Care group did not receive any information about sleep or a relaxation breathing technique, however still received daily visits. Perhaps the additional time spent with the RELAX TO SLEEP group introduced attention bias and contributed to the difference noted in nighttime sleep. However, it is unlikely that attention bias would have any effect on sleep outcomes as they were measured objectively using actigraphy.

This study was conducted from a single hospital site with a small, heterogeneous sample of children. Using multiple units for recruitment such as the general medical unit, the cardiac unit, and surgical unit may have confounded the outcomes and therefore threatened the internal validity of the study. Children recruited from each of these units were admitted with different diagnoses and had varying lengths of hospital stay, which may have influenced the primary outcome of total nighttime sleep. Patients with varying reasons for admission (e.g., surgical vs. chronic disease) will have differences in pain intensity (Kavanagh, Watt-Watson, & Stevens, 2007; Taylor, Boyer, & Campbell, 2008), may have different rates of recovery, risk of complications (e.g., infection), which may lead to longer hospitalization and unplanned readmissions. Regardless of diagnosis, children with longer hospital stays may have adapted to sleep in a hospitalized environment. The sample size in this study was too small to statistically control for confounding variables. Also, it may be possible that a higher proportion of parents who were concerned that their child might develop or have an existing sleep problem during hospital chose to participate, however this study used random allocation which would give each participant equal chance of receiving the intervention. This pilot trial was not powered to prevent the risk of Type I or Type II errors. However, the purpose of this study was to determine feasibility, compliance, and acceptability rather than significant differences between groups.
CHAPTER 6
Summary, Implications, and Conclusion

SUMMARY

Sleep is a biological process essential for health and well-being and serves both restorative and reparative roles within the body. As many as 20-30% of young children and adolescents in the community experience sleep problems or have some type of sleep disturbance (Mindell & Owens, 2003b). Being hospitalized can exacerbate common sleep difficulties in children. Hospitalized children lose 20-25% of their expected sleep time attributed to delayed sleep onset, frequent disruptions during the night, early termination of sleep, decreased nighttime sleep, and shorter periods of uninterrupted sleep (Hagemann, 1981a). Sleep disturbances in hospital may be clustered into three main categories and include: environmental factors related to noise and frequent interruptions from health care providers; physiologically related issues, such as symptoms both of a result of the disease condition and the treatment for it; and psychological issues related to anxiety. Although sleep interventions exist for healthy children in the community, interventions aimed at hospitalized children need to be developed and piloted with rigorous evaluative methods.

Interventions such as educational strategies in combination with a relaxation technique such as controlled breathing may prove to be beneficial in promoting sleep both during hospitalization and once the child is discharged home. The primary purpose of this study was to examine the feasibility and acceptability of a behavioral-educational intervention – the RELAX TO SLEEP program – aimed at increasing nighttime sleep for hospitalized children. In this single centered pilot trial, 48 children meeting the eligibility criteria were randomized to either the RELAX TO SLEEP experimental group or the Usual Care control group. The RELAX TO SLEEP
program consisted of a discussion about sleep with the PI along with a standardized educational booklet about sleep and a breathing relaxation technique for the child. Usual Care participants received no information about sleep or relaxation. Participants ranged in age from 4 to 10 years old, with a mean of 6.5 ± 2.01 years. The majority of children in this sample were in grade school, predominantly Caucasian, and admitted to the hospital for an acute illness or trauma.

The RELAX TO SLEEP pilot trial was feasible and acceptable. Children in both groups were compliant with wearing the actigraph and completing sleep diaries. In addition, compliance for the RELAX TO SLEEP group was excellent with 86% of participants reporting using the relaxation technique >1 per day in hospital. Parental reports indicated that their child enjoyed using the relaxation breathing technique, that it was easy to use, and would use it again in the future. Parents also reported that they enjoyed the discussion about sleep and found the information helpful. Minimal loss to follow-up was experienced and making contact with parents to collect follow-up data was feasible.

All sleep outcomes were measured during the hospital study period for 3 days and nights using actigraphy; an objective measure for sleep/wake patterns. Given that this study was underpowered to draw inferences, sleep outcomes were compared between the RELAX TO SLEEP and Usual Care groups for exploratory purposes only. The RELAX TO SLEEP group had a mean of 419.3 minutes (SD 71.84) of nighttime sleep in a 12 hour interval over the hospital study period compared to the Usual Care group who had a mean of 369.7 minutes (SD 106.4) yielding a mean difference of 49.6 minutes (95% CI -7.19, 106.5, p=0.085). The mean daytime sleep was 76.94 (SD 60.29) for the RELAX TO SLEEP group compared to a mean of 113.6 minutes (SD 82.26) for the Usual Care group. There were no other notable differences between the two groups on any of the other actigraphy sleep outcomes. During the post-hospitalization period, children in the
RELAX TO SLEEP group had a reduction in CSHQ scores from baseline to follow-up indicating an improvement in sleep problems compared to the Usual Care group who had higher scores from baseline to follow-up indicating worsening of sleep problems. No differences were found in anxiety and post-hospital maladaptive behaviors between the two groups at follow-up; however the majority of the children in the entire sample (n=32/44, 73%) developed at least one new-onset maladaptive behaviour during the post-hospital study period.

**IMPLICATIONS**

Sleep is a complex process with multiple interacting components. Several studies aiming to determine the major sources of sleep disturbance among hospitalized patients have implicated both personal and external factors (Jarman et al., 2002; Southwell & Wistow, 1995; Tranmer, Minard, Fox, & Rebelo, 2003). Several implications for research have been identified and relate to a larger more definitive trial with modifications, and an examination of the relationship between sleep, anxiety, and pain. Clinical implications include more education around sleep and its importance in the hospital environment, as well as development of a standardized protocol to assess sleep disturbance hospital wide.

*Implications for Future Research*

Given that the findings from the current pilot trial identified good feasibility, compliance and acceptability of the trial protocol of the RELAX TO SLEEP program, the primary implication is to conduct a larger trial with some modifications. Recruitment for this pilot trial took 44 weeks to recruit a sample size of 48. Recruitment of considerably larger number of children for a future trial would require a multisite study and sufficient funding to support such a trial. Based on detecting a 30-minute difference with respect to mean nighttime sleep, which is considered clinically significant and a moderate effect size (Morin et al., 1994), using a two sided test of
hypothesis, with an alpha level of 0.05 and 80% power and accounting for loss to follow-up, a total of 208 participants would be needed. A Bonferonni adjustment to account for multiple comparisons of secondary and other outcomes would be needed (0.05/X comparisons).

The data from this pilot trial demonstrated that the timing and duration of the intervention were appropriate. Parents were receptive to the one-on-one discussion with the researcher, and the intervention took an average of 15 minutes to deliver. The current study sought to develop an intervention geared at the individual level, to make parents aware of sleep during hospitalization, to improve sleep hygiene in hospital and at home, and a breathing technique for the child, which could be portable and implemented at any time. The standardized booklet allowed for the information to be structured and consistent, so parents could use it as a resource. Because the RELAX TO SLEEP intervention contained numerous strategies aimed at promoting sleep in the hospital as well as in the home and most of the participants reported using the components of the intervention, we are unable to determine if certain components had more of an effect than others. One way this can be determined is with the addition of a third “arm” which would receive just the educational component of the RELAX TO SLEEP program. However, sleep in hospital is complex and sleep disturbances are multifactorial, therefore an intervention with a multi-pronged approach is clinically relevant and necessary.

The unequal attention between the two groups may also introduce attention bias. To control for the effect of group interactions future studies may consider using an attention-control group. If an attention-control group is used, similar elements as the intervention group should be provided such as equal face-to-face time. The discussion should be unrelated to the topic discussed in the intervention group. In the current study it is unlikely that the sleep outcomes data were prone to the effects of attention bias since objective measures for sleep were used.
The researcher was the only person delivering the intervention, which is associated with several advantages. In particular, the researcher was the developer of the intervention and was highly committed to delivering the intervention in a consistent manner, with attention to the quality of each interaction with the child and the parent. In a larger trial more than one person would be required to deliver the intervention. In addition to the intervention fidelity checklist that has been developed in the current study to ensure the reliability of the intervention being delivered, training of the individuals delivering the intervention, further development of the RELAX TO SLEEP intervention manual, and documentation logs to monitor the intervention would also be required. Resnick et al. (2005) suggest that the intervention be supervised to ensure treatment fidelity and preserve the internal validity of the study. Furthermore, because the RELAX TO SLEEP program takes between 15 to 30 minutes to deliver depending upon the needs of the family, ideally, nurses employed on site would be hired and trained to deliver the sleep intervention. RELAX TO SLEEP intervention (RTSI) nurses with experience working on the pediatric unit should be sought. Given that health care professionals receive little training in the area of sleep (Mindell, Moline, Zendell, Brown, & Fry, 1994), training would include education on the basic neurobiology of sleep and circadian rhythms, developmental sleep norms for children, consequences of sleep restriction of daytime function and physical well-being, children’s sleep in hospital, and in the home, and finally strategies focused on sleep hygiene and relaxation strategies. To ensure consistency, each sleep intervention nurse should practice the delivery of the in-hospital session with 5 hospitalized patients (not actively in the study).

Hospitalized children are admitted for various medical conditions and procedures and length of stay varies based on the child’s status. Furthermore, the sleep needs in the pediatric population are developmental in nature, so a child that is 4 years old will require more sleep than a child who is 10. Therefore, a future trial should consider stratification by age group (ages 4-6
and 7-10) and reason for admission – acute (including non-planned surgery i.e., appendectomy) or chronic (e.g., cystic fibrosis admitted for treatment). It may also be beneficial to include children with one particular medical condition who have already been reported to have poorer subjective sleep quality and spend more time awake during the night, such as children with asthma (Diette et al., 2000) who are admitted for treatment of exacerbated symptoms.

Nonetheless, other outcomes that influence sleep should also be examined such as environmental factors such as noise and light levels, pain and pain management, and anxiety. Psychometric development of a tool to measure anxiety as it relates to sleep and hospitalization should be developed. Finally, the sleep patterns of hospitalized children should also be examined once they have been discharged home. Actigraphy is an objective method for measuring sleep-wake patterns and can be worn comfortably around the wrist, and allows children to remain in their natural environments. Actigraphy data can be collected for 5-7 days post discharge and can be compared with several other outcomes including sleep habits as well as post-hospital behaviour.

The majority of children in this sample developed a new onset maladaptive behaviour one week post-discharge. These changes are of particular concern if they persist for an extended period of time and can negatively affect the child’s responses to subsequent medical care or interfere with children’s emotional and cognitive development (Fortier et al., 2010). More research needs to be conducted to explore the relationship between sleep, anxiety, and pain in hospital and how these interrelate during the post-discharge period. Most studies conducted in the pediatric population suggest that the recovery process in the post-discharge period is more painful, slower, and more complicated in patients with high levels of anxiety (Caldwell-Andrews & Kain, 2006; Kain et al., 2002; Kain, Mayes, Caldwell-Andrews, Karas, & McClain, 2005). These studies have focused only on surgical patients that have undergone elective surgery. More
research on pediatric inpatients with various reasons for admission need to be explored for sleep disturbances.

Although the RELAX TO SLEEP pilot trial did not assess parents’ sleep, future studies should also examine the primary caregiver’s sleep in addition to their child’s sleep. Parents of children who are hospitalized are at risk for disturbed sleep as well. These disturbances are not just from the environmental stimuli of the hospital setting, but may include increased caregiving demands and high levels of stress and worry due to their child’s medical condition. Sleep disturbance in caregivers of ill (e.g., cancer, asthma) children, have been associated with fatigue, which may negatively impact their psychological and physical health and put them at risk for depression and anxiety, and perceived lower quality of life (Fagnano, Bayer, Isensee, Hernandez, & Halterman, 2011; Klassen et al., 2008; Meltzer & Moore, 2008; Zupanec et al., 2010). This may impact the parent’s ability to make important decisions about the treatment and health care of their child. Parents of hospitalized children may benefit from sleep interventions which include sleep hygiene and relaxation techniques such as the RELAX TO SLEEP program, however more research is needed to examine their sleep disturbances first, and examine other interrelated factors such as fatigue, anxiety and depression before interventions can be developed and evaluated.

The RELAX TO SLEEP study forms a basis for future investigation to improve not just sleep outcomes, but potentially other child outcomes related to pain (and opioid use) and anxiety, which interrelate (Noel, McMurtry, Chambers, & McGrath, 2010; Valrie et al., 2013). However, an important first step is to investigate the mechanisms associating sleep, anxiety, and pain on functional outcomes of poor sleep in pediatric populations. Understanding the relationships amongst this triad may lead to improved symptom management strategies. This is especially
important in the context of hospitalized children as the clinical management of their condition may be complicated by sleep disturbance, anxiety, and pain. Such a study will inform knowledge about the trajectories, risk factors and the impact of sleep disturbance in hospitalized children (with various medical conditions) which are highly clinically relevant.

**Implications for Practice**

Sleep is critically important to children’s health and well-being. Children with acute and chronic medical conditions are at increased risk of sleep disruptions (Passarelli et al., 2006; Yuksel et al., 2007). Sleep should be given important consideration in the management of common medical conditions in children. Understanding the consequences of disturbed sleep is important for all health care providers, especially for nurses who spend a significant amount of time delivering care and interacting with children and their family members while in the hospital setting.

While the results of the RELAX TO SLEEP pilot trial are suggestive of some benefit toward sleep in hospitalized children, more interventional studies using a multipronged approach to address both individual and external factors affecting sleep need to be developed and evaluated with rigorous evaluative methods. Hospital environmental stimuli, particularly sound levels continue to be problematic, and likely contribute to frequent awakenings in hospital. While the RELAX TO SLEEP study did not measure sound, parents in this study expressed concerns to the PI about the high levels of noise disrupting their child’s sleep. Nighttime sound levels frequently exceed the WHO’s recommended average sound levels of 35 dB for hospital rooms in which patients are being actively treated (Berglund, Lindvall, & Schwela, 1999). In a general pediatric unit, Stremler et al. (2009) found sound levels reached >80 dB for as many as 20 minutes over the course of a night. In a study among school-age children with cancer receiving inpatient
chemotherapy, Linder and Christian (2012) found nighttime sound levels at 40 dB with abrupt increases in excess of 80 dB, which is equivalent to the level of noise a chainsaw would make. Frequent interruptions in children’s nighttime sleep results in insufficient sleep and limits the opportunity to achieve adequate SWS and REM sleep, thereby reducing the restorative function of sleep. It takes children about 90 minutes to achieve one full sleep cycle. The longest period of uninterrupted nighttime sleep across the nights available for the RELAX TO SLEEP group was 116.6 minutes and 100.9 minutes for the Usual Care group, suggesting that these children may have been able to gain the restorative benefits of sleep for at least one sleep cycle.

Implications for practice include modifying the hospital care environment, including maintaining usual bedtimes and minimizing disruption. Changes could include things like dimming the hallway lights after certain hours, ensuring that health care personnel are not having loud conversations outside patient rooms, ensuring that IVs are well maintained so that they are not beeping and interrupting the sleep of children and their families. Behavioral modifications in a hospital environment are important in the effort to reduce noise and promote sleep (Cmiel et al., 2004). Organizational interventions such as staff education or establishing quiet hours have shown to reduce noise in the hospital setting, however are difficult to sustain (Moore et al., 1998; Walder et al., 2000). Organizational efforts to reduce noise and other environmental factors (e.g., bright lights) are important for practice implications. To better study this, an optimal standardized inpatient sleep protocol that minimizes interruptions to sleep and assesses the sleep patterns of hospitalized children is needed. Circadian rhythms and homeostatic sleep drive are important regulators of sleep, and are heavily influenced by exposure to light. Understanding the degree to which external factors disturb sleep and rhythms in the inpatient setting through modifications to the unit environments can assist with designing appropriate interventions that facilitate sleep. Finally, various relaxation therapies which have been explored individually
and/or in combination with others need to be further explored to assess to what degree it helps sleep, and which patients it is most likely to help (e.g., acute, planned surgical, or chronic).

Nurses are in a unique position to screen children and their families for potential sleep disturbance and educate family members about healthy sleep habits. However, health care providers receive little content on sleep during their academic education (Mindell et al., 2013; Mindell & Owens, 2003b) and the lack of effective strategies to improve sleep is sparse. Nurses and other health care providers (HCP) can be educated to provide support and assessments around sleep issues during hospitalization. Education around basic neurobiology of sleep and circadian rhythms, the importance of sleep, the consequences of sleep restriction would help to increase knowledge base and recognition that sleep is an important contributor to child health. From there, the development of evidenced-based interventions to promote sleep can be established. At the organizational level, guidelines can then be developed to include important information about sleep, a clear direction for assessment and management of sleep disturbance in hospital, and evidenced-based interventions to promote sleep. Policies for sleep education for staff, patients, and families should also be included.

**CONCLUSION**

This is the first study to test the feasibility and acceptability of a behavioural-educational sleep program: the RELAX TO SLEEP program on hospitalized children. Consistent with the conceptual framework that parental education about the importance of sleep and sleep hygiene combined with a relaxation technique for the child, may increase total nighttime sleep, this study demonstrates that a simple sleep intervention has the potential to increase total nighttime sleep. Although findings from this pilot study are encouraging, a more definitive trial to estimate the effect of such a program on various sleep outcomes in hospitalized children is warranted.
References


Van den Bulck, J. (2007). Adolescent use of mobile phones for calling and for sending text messages after lights out: Results from a prospective cohort study with a one-year follow up. Sleep, 30(9), 1220-1223.


Zee, P., & Turek, F. (1999). Introduction to sleep and circadian rhythms. In F. Turek & P. Zee (Eds.), *Regulation of sleep and circadian rhythms* (pp. 1-17). New York: Marcel Dekker, INC.


Appendix A

SUMMARY OF LITERATURE REVIEW
<table>
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<tr>
<th>Authors</th>
<th>Design &amp; Purpose</th>
<th>Sample</th>
<th>Description</th>
<th>Outcomes</th>
<th>Findings</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beardslee, (1976)</td>
<td>Observational study</td>
<td>n= 24</td>
<td>Hospitalized children between the ages of 2 and 5 years of age.</td>
<td>Wakefulness</td>
<td>Mean duration of the scheduled nap time was 76 minutes (range 54 to 94 min).</td>
<td>No description of how many observers they used and what the inter-rater reliability was.</td>
</tr>
<tr>
<td></td>
<td>Purpose: To identify the nature of the children’s experiences, environment and sleep –wake patterns</td>
<td></td>
<td>Twenty-four children were observed for a total of 125 days. Each child was observed for a minimum of 4 days; most were observed for either 5 or 6 days. During naptime, the investigator remained seated in the room of the child under observation.</td>
<td>Sleep</td>
<td>Mean SOL was 24.5 min</td>
<td>No description of observation tool used to make assessments of sleep and wakefulness</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Sleep Disruption</td>
<td>40% of observed naptimes of children were disrupted.</td>
<td>Study findings suggest that environmental stimuli cause sleep disturbance in hospital setting.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Sleep disruptions occurred in response to stimuli such as: noises by other children (e.g., crying), nurses, noise from telephone, overhead system, and slamming of doors.</td>
<td></td>
</tr>
<tr>
<td>Carno et al. (2004)</td>
<td>Case study</td>
<td>n= 2</td>
<td>Hospitalized children age 3 years old.</td>
<td>Total time spent in NREM sleep (stages 1 to 4) over the 4 days.</td>
<td>Total sleep time by stage: Subject 1 spent 50% time in Stage 1 sleep and 41% in stage 2.</td>
<td>Small sample size</td>
</tr>
<tr>
<td></td>
<td>Purpose: To determine the feasibility of using PSG to assess sleep patterns in children who were admitted to a PICU on a neuromuscular blockade.</td>
<td></td>
<td>Data collected continuously in 12 hr periods beginning at 7 pm and ending after a total of 96 hours of data collection. Medication administration and ENT suction times were recorded. No attempt to alter nursing care or environmental conditions during data collection. Data corrupted on first 24 hours for Subject 1.</td>
<td></td>
<td>Subject 2 spent 11% of time in stage 1 sleep 63% in stage 2 and 4% in stage 3. Neither subject progressed to stage 4 sleep. Greater proportion of sleep occurred during the day.</td>
<td>Variability between medications used for sedation and neuromuscular blockade. Subject 1 received no benzodiazepines (exhibited no SWS sleep) while subject 2 received lorazepam (exhibited a small amount of SWS sleep). Findings indicate that these children were not achieving quality sleep since they were spending more time in the early stages of NREM sleep indicating severely disrupted sleep.</td>
</tr>
<tr>
<td>Corser (1996)</td>
<td>Exploratory Descriptive Study</td>
<td>n= 12</td>
<td>Hospitalized children between the ages of 13 and 35 months in PICU setting.</td>
<td>Sleep (PSBOT) and Sleep Hx Interview Guide. Pain (CHEOPS) Noise (Sound Level)</td>
<td>Mean night sleep of the sample at home was 597.5 minutes (~10 hour sleep). Mean sleep time for children in the ICU was 435.83 min (~7.5 hrs). Children awoke after the onset of sleep a mean of 9.03 times during the 12 hour night. The longest sleep opportunity was 155.42 minutes, with the longest sustained sleep period being 128.74 minutes.</td>
<td>Described the instruments used as well as the validity and reliability of the instruments that were developed for the purposes of this study.</td>
</tr>
<tr>
<td></td>
<td>Purpose: To examine the sleep of 1- and 2-year-old children during and after hospitalization in an ICU setting.</td>
<td></td>
<td>A 12-hour observation period beginning at 7:00 PM and ending at 7:00 AM the next morning was established. Observations were recorded every 5 minutes and included pain, light, noise, caregiver activity, and sleep state.</td>
<td></td>
<td></td>
<td>Potential for recall bias. Small sample size.</td>
</tr>
</tbody>
</table>
Cureton-Lane & Fontaine (1997)  
Descriptive Study  
Purpose: To evaluate the sleep patterns of PICU patients and the relationship of noise, light, contact with caregivers, parental presence, and severity of illness to the sleep obtained by children during a night in the PICU.  
n= 9  
Convenience sample of children who were in PICU for at least 24 hours between the ages of 3 and 10 years old.  
Observations occurred at 5-min intervals from 8PM until 6AM.  
The nurse-researcher quietly approached the subject’s bed and observed the following: the level of cortical vigilance, noise I decibels, light in foot-candles, whether any healthcare worker was touching the child, and whether the parent was at the bedside.  
Sound level meters and light level meters were placed close to the child.  
Cureton-Lane & Fontaine (1997)  
Sleep (PSBOT)  
Noise (Sekonic Studio Deluxe)  
Contact with caregivers  
Parental presence  
Severity of illness  
Light, noise, caregiver activity were negatively correlated with sleep.  
Pain and treatment with benzodiazepines were associated with sleep acquisition.  
Sleep pattern disturbance that developed during an intensive care hospitalization persisted after discharge from the ICU and the hospital. Child’s return to a pre-illness sleep pattern revealed a period of 3.5 weeks.  
At home, children slept a mean of 9.6 hours and awoke a mean of 0.4 times during the night.  
Children in the PICU slept a mean total of only 4.7 hours in the 10 hour observation period. The mean length of a sleep episode was only 27.6 minutes. The number of awakenings ranged from 6 to 14, with a mean of 9.8 awakenings in the course of a 10-hour night.  
Mean noise level in this PICU was 55.1 dB(A) (range 40 to 95 dB(A)  
Light levels varied from 5 to 14 ft-c, with a mean of 23.4 ft-c.  
Significant predictors of sleep were: noise (P<.001), light (P=.02); and contact with staff (P<0.001).  
Continuous actigraphy monitoring or observation would establish whether the shortened nighttime sleep reported in this study is associated with increased levels of daytime sleep.  
Small sample size.  
Potential for recall bias.

Hagemann, V. (1981a)  
Descriptive Observational study  
Purpose: To determine the sleep duration and sleep disruption in hospitalized children.  
n= 34  
Ages 3 to 8 years old admitted to the hospital.  
Observations of 3-4 children each night were made for approximately 15-30 seconds every 5 minutes from 8:00 PM to 8:30AM. The children were observed in sequence, each cycle of observations beginning with the same child. Initial observations were made from the hallway  
Typical sleep behaviour at home & previous experiences in a hospital at night (research nurse conducted an interview)  
Normal sleep duration: Ranged from 4 to 10.5 hours with a mean of 7.85 hours.  
The greatest mean difference was the 0.77 hours more sleep obtained by the children who had a hax of a previous hospital admission when compared with those children who had not been in the hospital previous to this admission.  
Described the observation method used, however did not describe who developed it, whether the validity or reliability has been assessed. Did not describe how many observers were used in the study and what the inter-rater reliability was.
until the children appeared asleep. Observations thereafter were made at the bedsides until the termination of the sleep period. made for sleep, wakefulness, and arousal.

Sleep onset times ranged from 8:00PM to 1:45 AM. The median time of sleep onset was shortly before 10:00PM.

Sleep termination occurred between 4:30AM and 8:30 AM for 33 children (only one child slept until 8:30AM). The majority of children (~30) were awake substantially earlier than 8:30AM. The early sleep termination time contributed to a reduction of total sleep duration.

Duration of sleep disruptions: ranged from 0 to 195 min. the mean of total duration of disrupted sleep was 43 minutes. Disruptions of 30 min or less during the night occurred among 59% of the children. A total of one or more hours of sleep disruption occurred among 29% of the children.

One-third of the children had disruptions, which reduced their sleep duration by one or more hours.

Children lost 20-25% of their usual amount of sleep.

| Hagemann, V. (1981b) | Descriptive Observational study | n= 34 Ages 3 to 8 years old admitted to the hospital. | Causes of arousal resulting in sleep disruption were of an internal or external nature:
Internal causes included: physiological needs of elimination, hunger, or thirst; physiological discomfort of pain or nausea; affective responses to anxiety or fear; and nonspecific arousals for which no cause could be identified.
External causes of arousal included: environmental stimuli such as noise, light, | Sleep disruptions between the times of sleep onset and sleep termination occurred frequently (total number among all children was 118, mean 3.47 disruptions per child, range 0 to 17) so that very few children were able to sleep uninterrupted through more than half of the sleep period.
Findings suggest that these children may not be achieving deep sleep and REM stage sleep due to the frequent interruptions, which make it difficult to progress to these deeper stages of sleep.
No objective measures used. Poorly described methodology |
or touch not intended to awaken the children, and caretaking measures which occurred when the staff intentionally awakened the children to obtain their temperature, pulse or respiration readings, to carry out tests or treatments, or to bathe the children.

| Hinds et al. (2007) | Descriptive, Longitudinal pilot study. Purpose: to document the number of nocturnal awakenings, and sleep environment interruptions experienced by children and adolescents. To determine whether sleep duration and fatigue are correlated of nocturnal awakenings and sleep environment interruptions. To assess the acceptability of wrist actigraphy. | n= 29 Children and adolescents between the ages of 7 and 18 years old who were hospitalized to receive chemotherapy for solid tumors or acute myeloid leukemia Two pediatric cancer centers | Actigraphs were placed on patients’ wrists on the day of admission for 2 to 4 days and nights of hospitalization. Parents completed a daily sleep diary. Fatigue was measured at baseline and daily thereafter. | Sleep and Nocturnal interruptions: Actigraphy Sleep diary Room entry and exit checklist Fatigue Fatigue Scale – Child Fatigue Scale – Adolescent Fatigue Scale – Parent Fatigue Scale – Staff Physiologic factors: Hemoglobin level Hematocrit Transfusion record Concurrent medications | Nocturnal Awakenings: Ranged from 0-40 (median = 14) per night; the highest number of awakenings occurred on the final night of hospitalization. Only one patient had no sleep awakenings, and that was noted on only one night. 11% of patients experienced 1-3 awakenings during the first 30 minutes of the nocturnal sleep period. The longest nocturnal sleep period without awakenings for patients: 70% (n=19) was one hour on one to two nights; 22% (n=6) was two hours on one to two nights; 7% (n=2) was four hours on one night. The number of nocturnal awakenings during the first night was significantly lower than that experienced during the second night (t=2.95, p=0.017). Room entry and exit checklists revealed that parents and staff members entered and exited pt.’s rooms 3-22 times per night; The number of nocturnal awakenings was: - significantly related to fatigue over the course of hospitalization (n=26, F=5.71, p=0.027) indicating the more awakenings experienced, the greater the fatigue reported by patients). - Significantly related to sleep-use during subsequent nights of hospitalization. | Used actigraphy. Pediatric patients with cancer hospitalized to receive chemotherapy are very likely to experience repeated nocturnal awakenings and sleep environment interruptions caused by a number of adverse sources. They are likely to experience longer sleep duration periods and hospital-related fatigue. These children sleep longer but not necessarily better, and longer sleep periods may, in fact, interfere with daytime activity, which, in turn, may adversely affect quality sleep during subsequent nights of hospitalization. |
Stremler et al. (2009) - Prospective, observational design.  
**Purpose:** To describe, for hospitalized children: 1) sleep quantity (nocturnal and daytime); 2) sleep patterns (awakening, longest stretches); and 3) environmental light and sound levels.  
**n=69** Children between the ages of 12 months and 18 years in a general pediatric unit or the PICU.  
For 3 days and nights children who met the inclusion criteria wore an Actigraph and completed a sleep diary. Light and sound meters were placed at the bedside.  
Children or parents completed a sleep diary.  
**Sleep (actigraphy, sleep diaries, CSHQ)**  
**Light (Light meter)**  
**Sound (Sound meter)**  
Mean nocturnal sleep time (19h30-07h29) was:  
Ages 1-3: 444 minutes (95% CI 137-600);  
Ages 4-7: 475 minutes (95% CI 357-662);  
Ages 8-12: 436 minutes (95% CI 238-595);  
Ages 13-18: 384 minutes (95% CI 217-512).  
Mean number of night awakenings was:  
Ages 1-3: 14 (95% CI 8-21)  
Ages 4-7: 18 (95% CI 12-23)  
Ages 8-12: 14 (95% CI 5-24)  
Ages 13-18: 12 (95% CI 1-18).  
Light and sound levels were high at night.  
Mean minutes of light >150 lux ranged from 44-99 minutes, mean minutes of sound >46 dB ranged from 84-116, mean minutes >80 dB ranged from 32 47 across the four age groups.  
**Duration over the course of hospitalization by patient report and by parent report.** Thus the higher the number of nocturnal awakenings, the longer patients slept.  
Hematocrit and Hemoglobin level were not related to changes in fatigue level.  
**Used actigraph to collect sleep data.**  
Sleep quantity across all age groups was significantly decreased in hospital with greater reductions seen in the PICU.  
Frequent nighttime awakenings were observed and were highest in the 4-7 year old age group, indicating poor sleep quality during hospitalization.  
Light and sound levels were found to be above those recommended for sleep.
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<tr>
<td>Kain et al. (2002)</td>
<td>Longitudinal Cohort Controlled Study</td>
<td>Total of 169 Children aged 3-9 years.  n= 92 in the study group undergoing outpatient surgery.  n= 77 children in the control group who were recruited from the community.</td>
<td>Children underwent actigraphy sleep monitoring for at least 3 nights before surgery and 5 postoperative days (POD).  Factor analysis of the PHBQ was conducted and the researchers only administered the items related to sleep anxiety which included questions related to: bad dreams, waking up and crying, bedtime resistance, fear of the dark, and difficulty initiating sleep.  Postoperative sleep disturbances were determined by either a change of more than 1 SD in percentage sleep by actigraphy, or a negative change on the PHBQ (sleep-related items).</td>
<td>Sleep: Actigraphy and the PHBQ (items related to sleep anxiety).  Baseline and other measures: Coping, Temperament Anxiety Surgical procedures Postoperative pain</td>
<td>Approximately 47% of the children in the surgery group experienced postoperative sleeping disturbances as determined by actigraphy and the PHBQ.  Children who developed PHBQ-based sleep problems exhibited shorter sleep duration (502 +/- 61 min vs 568 +/- 61 min; p = 0.0001), and those with actigraph-based sleep problems were reported by their parents to be in more pain on the first and second post-operative day.  Children with lower sociability (temperament) had more sleep problems as measured by actigraphy.</td>
<td>Children in this study only stayed in the hospital for one night – difficult to conclude the magnitude of Post-hospital behaviours in longer hospital stays.  All children in this study underwent T&amp;A. Cannot generalize to all hospitalized children.</td>
</tr>
<tr>
<td>MacLaren &amp; Kain (2008)</td>
<td>Before-and-after study</td>
<td>n=55 children Ages 6 to 12 years old undergoing</td>
<td>Children’s sleep was recorded using actigraphy for 5 nights prior to surgery, the night of surgery, and four additional nights following surgery with</td>
<td>Sleep Efficiency: Actigraphy</td>
<td>Children spent the same number of minutes asleep before and after surgery (True sleep time).  Total number of night awakenings did not differ from pre- to postsurgery.</td>
<td>Children in this study only stayed in the hospital for one night – difficult to assess if there would be higher magnitude in decrease sleep efficiency the longer the hospital stay.</td>
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following surgery. T&A. accompanying sleep diaries. Significant sleep decrement was defined as a negative change in sleep efficiency that is greater than 1 SD of presurgery sleep efficiency. That is, children’s sleep efficiency after surgery is >1 SD less than their sleep efficiency before surgery. Poor sleep was defined as 10% less than perfect sleep efficiency (>90%).

Children experienced significantly more long awake episodes (>5 min) following surgery than they did prior to surgery. These longer waking episodes are also reflected in the overall sleep efficiency. The mean sleep efficiency score prior to surgery was 88.79% (SD, 5.57) compared to 83.47% (SD 7.23) post surgery. Approximately 30% of children demonstrated clinically significant decrements in sleep efficiency. Children that were found to be less social and more anxious were more likely to experience these sleep decrements as were children who experienced greater pain in the postoperative period. The most notable decrement in sleep efficiency was on the night of surgery while hospitalized. Sleep changes continued for at least 4 days after being discharged home. Limited generalizability as all children in this study underwent T&A.
### SUMMARY OF RESEARCH – INTERVENTIONS TO PROMOTE SLEEP IN HOSPITALIZED CHILDREN

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<tr>
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<tr>
<td>White et al. (1990)</td>
<td>Quasi-RCT</td>
<td>n=94</td>
<td>Children who did not have a parent staying overnight with them were randomized to receive one of the following: 1) A story audio taped by a parent (n=19) – (PRS). 2) A story audio taped by a stranger (n=14) – (SRS). 3) No story (n=17) – (NoS). 4) Convenience sample of children who had parents present at bedtime and child did not listen to a recorder story (n=47) – (PPB). Four observers were randomly assigned to observations, that were made in the darkened room, with the observer seated about 2 feet from the foot of the child’s bed, and directly facing the child. Observations ceased 15 minutes after the final eyes closed and body still were noted. Observation procedures were carried out for 2 nights.</td>
<td>SOL – observed using the Sleep Onset Latency Behavior Catalog. (This catalog was developed and included a list of 54 behaviours of children and others in the child’s hospital environment). There were 8 conceptual categories making up the behaviour catalog: distress, self-soothing, communication, pleasure, neutral, sleep, active, and inactive. Sleep was defined as continuous eye closure and lack of observable activity for a period of 15 minutes.</td>
<td>Mean SOL in minutes: PPB – 54.43 (SD=19.90) PRS – 64.59 (SD=22.05) SRS – 37.64 (SD=12.28) NoS – 36.86 (SD=18.98)</td>
<td>Children in the PBR group had significantly longer SOL than the other three groups. Children in the PPB group had significantly longer SOL than children in the NoS group, which was not statistically significantly different from the children in the SRS group. Incidence of Behavioral Distress: PPB – 51% PRS – 56% SRS – 21% NoS – 24%</td>
</tr>
</tbody>
</table>
Hinds et al. (2007)  
**RCT**  
**Purpose:** To determine the feasibility of an EPA intervention in children and adolescents receiving tx for a solid tumor or AML and to assess the sleep and fatigue outcomes of the intervention.  

- **n=29**  
- Hospitalized children receiving tx for solid tumor or for acute myeloid leukemia (AML); ages 7-18 years  

After consent was obtained, the patient was randomly assigned to a study arm by a computer-generated program. Participants randomized to the intervention group (n=14) engaged in an enhanced activity intervention which consisted of pedaling a stationary bicycle-style exerciser for 30 minutes twice daily for 2-4 days of hospitalization. Those who were randomized to the standard care arm (n=15) received standard care and a team member also spent an equivalent amount of time with patients who were randomized to the standard care arm.  

- **Wrist actigraphy with daily sleep diary (parent recorded)**  
- **Fatigue:**  
  - Fatigue Scale for 7-12 year old (FS-C).  
  - Fatigue Scale for 13-18 year old (FS-A).  
  - Fatigue Scale – parent version (FS-P).  
  - Fatigue Scale – staff version (FS-S).  

The intervention was successfully implemented 85.4% of the scheduled times. Sleep was significantly more efficient in the experimental arm than in the control arm when daily differences from baseline sleep efficiency values were averages and compared (F=4.17, p=0.053). In a mixed model analysis, sleep duration (F=0.54, p=0.47) and sleep efficiency (F=0.04, p=0.85) were not seen to differ between study arms. No significant differences in patient reports, in parent reports, or in nurse reports of fatigue between the study arms or over time.  

Field et al. (1992)  
**RCT**  
**Purpose:** To examine the independent effects of massage on the behaviours and physiology of children and adolescents who were hospitalized for depression or adjustment.  

- **n=72**  
- Ages 7 to 18 years  

Children and adolescents were randomly assigned to the intervention group or control group.  

- **Intervention Group:** A 30-minute back massage from a psychology student.  
- **Control Group:** Watching a videotape of pleasant sounds and visual images.  

State Anxiety: State-Trait Anxiety Inventory for Children (STAI-C)  
Mood: Profile of Mood States (POMS)  
Nighttime sleep: Videotaped  

Massage group had immediate effects such as significant decrease in STAIC scores and POMS, and increased ratings of affect, which remained elevated at follow-up, indicating that the patients were showing more positive affect after the massage.  

The percentage of time in bed that sleep occurred increased over the 5-day period (79.7% day 1, and 91.3% on day 5, p=0.01), and the percentage of time that nighttime wakefulness occurred correspondingly decreased.  

The methods for scoring the videotapes, whether or not the raters were blinded to group assignment, the number of raters and their training, and other details of sleep measurement were not described making it difficult to draw conclusions.  

Limited generalizability to hospitalized children.
disorder.

| | Nighttime sleep was videotaped on the first and last treatment days (days 1 and 5 respectively) using a time-lapse video camera, which enabled the researchers to code the videotapes enabling 8 hours of videotape to be coded in 2 hours.
The tapes were coded for: quiet sleep, active sleep, awake and lying quietly, and awake and active. | Behaviour: Behavior observation ratings and activity level (7-bheavior rating scale)
Physiological and biochemical measures: Pulse rate, cortisol samples | over the same period for the massage group (15.2% day 1, and 4% day 5, p=0.05). |
## Summary of Research – Behavioural Modification Programs to Promote Sleep in Hospital Settings

<table>
<thead>
<tr>
<th>Authors</th>
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</thead>
<tbody>
<tr>
<td>Dawson et al. (1999)</td>
<td>RCT</td>
<td>n=100 Female patients undergoing major reconstructive plastic or gynecological surgery.</td>
<td>Randomized to either: 1) Receive subcutaneous (PCA) (bolus dose 0.5 mg diamorphine in 1 ml with a 5-minute lockout) (n=39); or 2) Receive intravenous PCA (bolus dose 0.5 mg diamorphine in 1 ml with a 5-minute lockout) post-operatively (n=42).</td>
<td>Pain: (NRS 0-10) Sleep disturbance (Subjective – none, occasionally, a lot and constantly) Nausea (NRS – 0-3)</td>
<td>The intravenous group experienced significantly higher pain scores than the subcutaneous group (P&lt;0.01). Sleep was significantly less affected by pain in the subcutaneous group compared to those with intravenous PCA (P&lt;0.001). The authors attribute this finding to the slower absorption of the analgesia delivered subcutaneously resulting in a slower peak plasma concentration which is sustained over a longer period of time resulting in less break-through pain.</td>
<td>Due to the small sample size, findings cannot be generalized, but it is possible that these issues are relevant for the postoperative patient and the nurse providing care. If post-operative patients have adequate pain control they are less likely to experience sleep disturbances from pain. However, sleep disturbance was not measured objectively.</td>
</tr>
<tr>
<td>Edwards &amp; Schuring (1993)</td>
<td>Retrospective and Interventional Study</td>
<td>n=21 adult patients with multisystem diagnoses in a 10-bed medical intensive care unit (MICU)</td>
<td>Using retrospective chart review, a convenience sample was obtained of the records for the first 40 patients who spent at least 7 days in the unit starting from a specific date. The staff personnel along with the consultation with the MICU medical director, the MICU staff pharmacist and the respiratory therapy</td>
<td>Number of blocks of at least 60 minutes of undisturbed time per patient per day – measured with chart review.</td>
<td>Descriptive analysis showed that the average number of blocks was 2.2 (SD=1.4), with only one of these falling during conventional sleeping hours. Forty-eight percent of the interrupted blocks of time only one procedure was performed</td>
<td>More descriptive results of the effectiveness of this sleep protocol. No outcome measures reported and no other statistical analysis were done. A subsequent study validates nurses’ observations of sleep/wake states using polysomnography.</td>
</tr>
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</table>
Kahn et al. (1998)  
Two phase descriptive.  
Purpose: To determine the causes of noise pollution in the hospital setting and to determine if behaviour modification could have an impact on noise in the ICU

| Setting: Medical Intensive Care Unit (MICU) | During the noise identification phase of the study sound peaks were recorded simultaneously with the loudest noise heard subjectively by one observer. The behaviour modification program was implemented for 3 weeks and consisted of a comprehensive education program directed at all of the staff. The objective was to attempt to reduce the number of sound peaks greater than 80 dBA. This educational program included: |
| Noise: Sound levels were measured in dBA using a sound level meter with internal storage capabilities. 12 individual noises contributed to the high peak sound levels of which the mean peak sound levels ranged from 74.8 to 84.6 dBA. The most frequent occurrence of noise was from the monitor alarms, television, and staff talking. A significant reduction in the 24-hour mean peak noise level was demonstrated (p=0.0001), as well as the mean peak noise level (p=0.0001). With the exception of the midnight to 6AM period, each of the other 6-hour time periods (6AM to 12AM; 12PM to 6 PM; 6 PM to 12 AM) demonstrated a statistically significant decrease in mean peak sound level (p=0.0001). |
| Sound levels are extremely high. Causes of noises: Equipment – cannot be modifiable because of the importance of alerting staff when there is a problem. Human behaviour – modifiable Noise identification portion of the study was subjective (had an observer). |
discussions about noise pollution and the impact of noise on patients and on the work environment. In addition, it highlighted the types of noise that can be modified by staff such as turning off the television in patient rooms, placing beepers in the vibrate mode, decreasing the use of the intercom, turning down the volume on the overhead speakers, and decreasing or eliminating any loud or unnecessary conversation from the patient bedside.

Jarman et al. (2002)

<table>
<thead>
<tr>
<th>Description</th>
<th>Purposes: 1) to compare patient’s “at home” sleeping patterns with “in hospital” sleep patterns; 2) to examine patients’ levels of satisfaction with the changed medication times; and 3) to examine the implications of a change of medication times for clinical nursing practice.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nurses (n=25) and patients (n=52)</td>
<td>A change in the administration of routine medications so that evening medications can be given between 20:00 hours and 22:00 hours and morning medication could be given between 0600 hours and 0800 hours. Do not describe the outcome data collected or the method used to collect the data.</td>
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<tr>
<td>Patients were able to sleep longer. Although they tended to wake earlier, their ‘in hospital’ and ‘at home’ sleeping patterns were more closely aligned. There was agreement among the nurse participants that the change to flexible medication times allowed patients to sleep longer.</td>
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<tr>
<td><strong>McDowell et al. (1998)</strong></td>
<td><strong>Prospective Cohort Study</strong></td>
</tr>
<tr>
<td>Monsen &amp; Edell-Gustafsson</td>
<td><strong>Pre-post design.</strong></td>
</tr>
</tbody>
</table>
personnel and recorded noise level during two weeks before and after implementation of a behavioural modification programme (which included non-disturbance periods on a NICU).

- n= 9 patients pre-intervention phase (M1)
- n=14 patients during implementation phase (M2)
- documentation of sleep disturbance factors was carried out during fourteen 24-h period by healthcare personnel.

The personnel for a total of 71 completed record forms. Objective registration of noise level was performed simultaneously for twelve 24-h periods.

During M2 the same documentation and objective registration of noise level were repeated on the NICU during fourteen 24 h periods for a total of 68 completed record forms.

The Behavioural modification programme included changing nursing and medical routines, education about sleep, sleep disturbances, neuro-physiological recovery, and noise effects on humans. It also consisted of two non-disturbance periods: 13.00h and 15.00h during the day and between 24.00 h and 05.00 h during the night.

Sleep hygiene factors including general nursing care, specific nursing care, and medical treatment; and 3) technical equipment such as infusion pump and ventilator.

Noise: Sound meter (dBA)

Significant find for eliminating student teaching and cleaning services during the blocked times (p=0.002)

Noise level and peak noise levels had significantly decreased after the program. However the peak sounds still remained high.

| Olson, et al. (2001) | Pretest-posttest design. | n=843 patients with a total of 5727 | Data collection was divided into 2 phases. Phase 1, the pre- | Light: Light Meter (in lux). | Decreased mean sound and light levels during the 2 blocked quiet times. | Trained nurse observers were also staff nurses on the unit – therefore study did not |
hypothesis that patients in the neurocritical care unit will be more likely to sleep if light and sound stimuli are decreased. To determine the overall feasibility of providing a structured "quiet time" in a critical care setting.

Measurement obtained. During the control phase: 2839 observations were made for 379 patients; for the intervention phase 2888 observations were made for 464 patients.

Intervention phase, served as the control condition. During this time no changes in milieu were incorporated. Phase 2 began 1 month after the initiation of a unit-based quiet-time policy. Staff members were instructed to make efforts to decrease light and sound between 2AM and 4AM and between 2PM and 4PM. During this time, lights were dimmed, blinds were closed, and televisions were turned off. Visits by patients’ family members, CCU staff were minimized.

All patients were assigned a randomized identification number.

Six RNs were trained observers. Patients were observed for a minimum of 5 seconds, and marked each patient as asleep, not asleep, or unable to determine.

Sound: Sound Meter (in dB)

Sleep status: Observations using a modified version of the Nurses Observation Check List.

No significant differences of patients asleep in the intervention and control group at 2:45AM (P=.49).

Percentage of patients asleep at 3:30AM tended to be higher in the intervention group than in the control group. At 2:45PM and 3:30PM the percentage of patients asleep was significantly higher in the intervention group than in the control group (P=.008 and .04, respectively).

The likelihood of sleep was higher in the intervention group than in the control group: Patients in the intervention group were 1.6 times more likely than patients in the control group to be asleep (95% CI, 1.03, 2.57; P<0.001).

Obtain blinded observations of sleep.

Did not use more objective methods to measure sleep patterns.

Compliance with the policy varied.


Setting: Surgical Intensive Care Unit (ICU).

Light and noise were measured during two night periods before and after the

Light Monitoring: light levels were obtained

No difference in light levels was found between baseline levels and post guideline implementation, as baseline levels were already less
The purpose of this study was two-fold: 1) to evaluate the environmental factors related to sleep disturbance in a surgical ICU; and 2) to observe the effect of guidelines implementing simple behaviours such as closing all doors leading to patient rooms, reducing the level of sound on equipment, limiting and clustering nursing care activities between 23:00 – 05:00, decreasing and lowering voices when speaking; limiting the use of telephone or intercom except in emergency situations, turning the television or radio off, and no direct light or flashlight use between 23:00 – 5:00.

Nine patient rooms were observed before and 8 patient rooms after the guidelines were implemented.

The modification program with simple behavior rules for the ICU personnel during the night shift were developed.

Between the two observation periods, the following guidelines were implemented in the surveyed patient’s room:
1. Systematic closure of all doors.
2. Maximal reduction of the intensity of the alarm sound of the hemodynamic surveillance monitor.
3. Coordination and limitation of nursing interventions between 11 pm and 5 am.
4. Conversation only with a low voice; no use of phone, interphone, television, or radio.
5. No direct light or use of electric torch in the room surveyed between 11 pm and 5 am.

Using a luxmeter (Minolta T-1) Sound monitoring: Sound levels in a weighted decibels (dB) were obtained using a sound level meter.

Clinical Evaluation of the Patient’s sleep: the nurses filled out a multi choice questionnaire. They estimated the sleep duration (answer possibilities: <30 mins, 30 min – 1 hour, 1-2 hrs, 2-4 hrs, 4-6 hrs) and the number of awakenings.

A significant reduction was noted in maximal noise, peak noise, as well as the number of identified alarms per night for noise level during the second phase of the study.

No differences were found for background noise indicating that noise levels were still high in the MICU.

Sleep disturbances for patients including length of uninterrupted sleep and number of awakenings did not differ after implementation of the guidelines.
### SUMMARY OF RESEARCH – COMPLEMENTARY AND ALTERNATIVE INTERVENTIONS TO PROMOTE SLEEP IN HOSPITAL SETTINGS

<table>
<thead>
<tr>
<th>Authors</th>
<th>Design &amp; Purpose</th>
<th>Sample</th>
<th>Description</th>
<th>Outcomes</th>
<th>Findings</th>
<th>Comments</th>
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</table>
| Ejindu (2007) | Randomized within group crossover pilot study  
Purpose: To compare the effects of facial massage with that of foot massage on sleep induction and vital signs. | n=6 female volunteers | The first subject was randomly assigned to begin the treatment with either the foot or the facial massage and others that followed were consecutively assigned to the opposite treatment. The group acted as its own control group.  
The interventions were a 20-minute foot massage (10-minutes per foot) and a 20-minute facial massage.  
Measures of sleep were obtained prior, during, and after the intervention. The ESS  
Vital signs were measured after an initial rest period of a minimum of 5 min with the subject lying on a massage couch in the supine position. | Sleep: Subjective levels of sleepiness using the Epworth Sleepiness Scale (ESS); subjective levels of current sleepiness immediately before the massage as measured by the Stanford Sleepiness Scale (SSS) and the Alert-Doze Visual Analogue Scale (10cm line with the words “alert” and “dozing”).  
Vital Signs: Blood pressure and pulse (electronic vital signs monitor), resp rate per minute by the researcher. | Before and After Foot Massage: No differences in the means of subject’s vital signs before and after foot massage were observed.  
Mean sleep scores before the foot massage was 1.8 and during was 6.5 indicating higher degree of sleepiness (P=.00011)  
Before and After Facial Massage: A clinically significant drop of 8.5 mmHg in the mean SBP value (p=0.092) was recorded before and after facial massage.  
Mean sleep before facial massage was 2.3 and during was 7.2 (p=0.00107) indicating a higher degree of sleepiness. | Selection bias, small sample size, underpowered.  
Desirability bias – a desire to please may also cause subjects to give answer they perceive desirable to the researcher.  
Cannot detect statistically significant differences due to small sample size. |
<table>
<thead>
<tr>
<th>Griffin et al. (1988)</th>
<th>RCT</th>
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<tbody>
<tr>
<td><strong>Purpose:</strong> to test the relationship between the effects of PMR relaxation and disturbance due to hospital noise among acutely ill hospitalized patients.</td>
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<tr>
<td>n=100 Patients were recruited from either a CCU or a telemetry unit.</td>
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<td>Randomly assigned to the control group (n=50) or the experimental group (n=50).</td>
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<td><strong>Intervention:</strong> PMR was taught in a 1-hr session. Evaluation of the technique was performed by the researcher at the end of the training session using different parameters (subjective reports of feeling relaxed; a relaxed deep breathing pattern; relaxed body position with feet at 45degree angles to one another). Subjects needed to achieve at least two of the parameters. Post PMR data was collected on the third evening after admission to the assigned unit. Data for the control group were collected at the same time interval.</td>
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<td><strong>Noise sensitivity:</strong> Weinstein Noise Sensitivity Scale</td>
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<td><strong>Top Disturbance Due to Hospital Noise Scale</strong></td>
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<tr>
<td><strong>Demographic Data</strong></td>
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<tr>
<td>A majority of the subjects in all groups rated their sleep as poor or said they were unable to sleep. All reported frequent awakenings by the staff. In the post-intervention data, subjects in the experimental group demonstrated significantly lower levels of disturbance after receiving relaxation training.</td>
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<tr>
<td>Did not disclose randomization procedure. Did not report how sleep was measured. Most likely an item on one of the outcome measurements used.</td>
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<tr>
<td>Author</td>
<td>Design Type</td>
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<tr>
<td>Richards (1998)</td>
<td>RCT – posttest-only design</td>
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<td></td>
<td>n=69 older men</td>
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<tr>
<td>Richardson (2003)</td>
<td>RCT Pre and post-treatment observations.</td>
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<td>n= 36 Critical Care patients</td>
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were obtained at pretest and following each of the two treatments of relaxation and imagery.  

gender, and time, with males’ scores improving rapidly, and females’ scores first dropping, then improving rapidly. This suggests that women take more time to respond to the intervention. 

Williamson (1992)  
**RCT** Before and after trial.  
**Purpose:** to investigate the influence of ocean sounds (white noise) on the night sleep pattern of postoperative CABG patients after transfer from an ICU.  

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<td></td>
<td><strong>RCT</strong></td>
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<td>Before and after trial.</td>
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<td><strong>Purpose:</strong> to investigate the influence of ocean sounds (white noise) on the night sleep pattern of postoperative CABG patients after transfer from an ICU.</td>
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<td>n=60</td>
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<td>Adult patients between the ages of 35 and 69 undergoing a CABG for the first time.</td>
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<td>A coin toss determined that the first patient was to be assigned to the control group after transfer to the progressive care area. Thereafter, every other post-transfer patient was systematically assigned to either the experimental or control group.</td>
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<td>Sleep: The Richards-Campbell Sleep Questionnaire (RCSQ) – a VAS self-reported sleep scores on sleep depth, latency to sleep onset, awakening, return to sleep, quality of sleep and a total sleep score.</td>
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<tr>
<td>The Sleep Depth scores reported by patients in the ocean sounds group were significantly higher than those in the control group, indicating a perception of deeper sleep (F=12.05, P=0.001).</td>
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<td>The group receiving the ocean sounds reported being awake less during the night (F=5.19, P=.026) compared to the control group.</td>
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<td>The group that listened to ocean sounds reported that they returned to sleep quicker than the control group (F=7.24, P=0.009).</td>
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<td>The group that heard ocean sounds scored higher scores on quality of sleep (F=9.50, P=0.003).</td>
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<td>The group receiving the ocean sounds reported higher total sleep score (F=10.98, P=0.002) compared to the control group.</td>
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<td>Did not use objective method to determine sleep patterns.</td>
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<td>Potential bias - poor random allocation methods and concealment methods (i.e., used coin toss for group allocation).</td>
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Zimmerman et al. (1996)  
**RCT**  
**Purpose:** To determine the effects of second and third day  

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<td><strong>RCT</strong></td>
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<td>n=96 postoperative patients having CABG surgery.</td>
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<td>Patients were randomly assigned to one of the following groups: 1) music therapy where participants were given Pain: Verbal Rating Scale and the McGill pain Questionnaire</td>
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<td>For the evaluative component of pain, those in the music group had significantly (F[2,93] = 4.74, p=.05) lower scores on postoperative Day 2 than the rest</td>
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<td>The intervention was delivered during the daytime, so the strategies were not always used a time when the patient might be</td>
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<tr>
<td>postoperative music intervention (music, music video) on pain and sleep.</td>
<td>Male: n=65 Female: n=31</td>
<td>a choice of five audio tapes of soothing music that facilitates relaxation which they could listen to on headphones (n=32); 2) music video therapy where patients viewed a 30-minute videocassette of soft instrumental music combined with visual images of different scenes (n=32); or 3) scheduled rest period group (the comparison group) where patients had an undisturbed 30-minute rest period (n=32). Patients were randomly allocated to listen to music audio tapes via headphone, watch a music video with relaxing, nature scenes, or have a rest period.</td>
<td>Sleep: The Richards-Campbell Sleep Questionnaire period control group. Effects of the intervention on sleep indicated that the video group had significantly (F[2,93] = 3.18, p&lt;0.05) better sleep scores than the control group on the third morning. The sleep scores of the recipients of the music intervention also indicated an improvement in sleep when compared with the control group, with the difference between the two groups approaching statistical significance (p=0.6).</td>
<td>sleepy or attempting to sleep.</td>
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</table>
**SUMMARY OF RESEARCH – RELAXATION BREATHING IN CHILDREN**

<table>
<thead>
<tr>
<th>Authors</th>
<th>Design &amp; Purpose</th>
<th>Sample</th>
<th>Description</th>
<th>Outcomes</th>
<th>Findings</th>
<th>Comments</th>
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<tbody>
<tr>
<td>Alvarez &amp; Marcos (1997)</td>
<td>Review</td>
<td>Provided an overview of techniques used in children with cancer.</td>
<td>No discussion of how literature was found, inclusion or exclusion criteria of literature. Authors just give an overview or snapshot into the available therapeutic techniques used in children with cancer to alleviate discomfort evoked by invasive medical procedures</td>
<td>N/A</td>
<td>Four of the nine studies described in this review used relaxation respirations in combination with other techniques in children between the ages of 3 and 15 years of age undergoing bone marrow aspiration, lumbar puncture, and/or intravenous injections. Although the studies had different outcome variables, it was noted that children had decreases in self-reported pain, observed distress, increased number of coping behaviours, and also there were decreases in parental distress and anxiety.</td>
<td>It is difficult to draw conclusions from this review, as the authors do not discuss the method used, nor do they discuss the details of each study, and sample sizes of these studies appear to be small.</td>
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<tr>
<td>Chiang et al. (2009)</td>
<td>RCT</td>
<td>Chinese Children between the ages of 6 and 14 years with moderate-to-severe asthma.</td>
<td>Children and their parents were randomly assigned to either the experimental or comparison group and matched by gender, age, and asthma severity. Intervention Group: Asthma self-management and a 30 min of training in a relaxation-breathing technique and a CD for home practice. Parents and children were</td>
<td>Anxiety Chinese Children’s Anxiety Scale and the Chinese Children’s Manifest Anxiety Scale and the General Anxiety Scale for Chinese Children. Self-perceived health status: Perceived Health Status Scale</td>
<td>Physiological indicators improved for both groups over the 12-week intervention. Total anxiety and general tendency to anxiety scores changed significantly more from pre-to post-intervention in the experimental group (31.73, SD 12.27 and 26.11, SD 11.41) compared to the control group (29.96, SD 11.96 and 32.21, SD 17.76). Tendency to anxiety (CCAS scores) in the experimental group was decreased on average.</td>
<td>Although not part of the analysis, some of the qualitative data from interviews with parents and asthmatic children were discussed. Many children claimed that practicing relaxation every night enabled them to feel very relaxed, calm, and to fall asleep easily. Furthermore, children reported that the deep breathing exercises were very comfortable, especially following the directions on the relaxation CD. These reports suggest a</td>
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<tr>
<td>Study</td>
<td>Study Design</td>
<td>Purpose</td>
<td>Participants</td>
<td>Procedures</td>
<td>Outcomes</td>
<td>Comments</td>
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<tr>
<td>Day &amp; Sadek (1982)</td>
<td>RCT</td>
<td>To assess the effectiveness of Benson's Relaxation Response on the anxiety levels of Lebanese children under stress from the political warfare occurring in Lebanon</td>
<td>n=62 Children between the ages of 10 and 12 years</td>
<td>Children were randomly assigned to one of the following groups: Intervention Group: children in this group received a relaxation technique. Control Group: Children received a reading-activity with no relaxation involved.</td>
<td>Test Anxiety: Test Anxiety Scale for Children (TASC). General Anxiety: General Anxiety Scale for Children (GASC).</td>
<td>A significant treatment effect for general stress (p&lt;0.01) and for test anxiety (p&lt;0.01). Students in the experimental group reported a lower level of stress on both the situation-specific and general anxiety measures. Girls reported a significantly higher stress level than did the boys (on the general anxiety measure). Treatment differences after 3 weeks of not practicing intervention the relaxation response had disappeared for both the GASC and the TASC.</td>
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</table>

Contacted once per week by telephone to encourage regular practice.

Comparison Group: Asthma self-management with no training in the relaxation technique.

During the 12-week intervention, participants practiced relaxation for 30 minutes at least three times per week.

Asthma (Signs and symptoms): Signs/symptoms checklist
Peak expiratory flow rate: Astech peak flow meters.

(16.64-12.67), but increased in the comparison group (14.74-15.77).
| Weydert et al. (2006) | RCT | Purpose: To evaluate the efficacy of guided imagery compared to breathing exercises alone for the treatment of recurrent abdominal pain in children. | n=22 Children between the ages of 5 to 18 years with recurrent abdominal pain. | Children were randomized to receive either breathing techniques alone or guided imagery (GI) with PMR. GI with PMR: 4 sessions were done on a weekly basis. Audiotape of the relaxation and imagery was sent with the child to practice at home twice daily. Three follow up sessions, which lasted 20-30 minutes, were done to assess competence, to assess compliance with daily practice, and for reinstruction and Abdominal pain and disability: Daily pain diaries (included pain intensity, missed activities days such as school or sports). Symptom and Psychological Factors: Bowel Symptom Questionnaire (BSQ), Child Depression Inventory (CDI), Multidimensional Anxiety Scale for Children (MASC), EAS Temperament | Compared to children learning breathing exercises alone, those who learned GI and PMR had significantly greater decrease in days with pain during the initial month (67% vs. 21%, P=0.05) and 2 months of follow up (82% vs. 45%, p=0.01). Children in the GI and PMR group had a significantly greater decrease in days with missed activities than children learning breathing exercises alone during the first months (85% vs. 15%, P=0.02) and in the second month of follow up (95% vs. 77%, P=0.05). There was no significant difference in the mean intensity of pain between the two | Cannot tell if the treatment effects are due to Guided Imagery alone, PMR alone or a combination of both. |
reinforcement.

The control group was designed to mimic the intervention. During the first session children were instructed on 3 breathing techniques that facilitate relaxation: abdominal breathing, “breathing in fives” and “bubble breathing.” Audiotape was made for children to take with them to practice at home twice daily, repeating each of the three exercises 5 times a piece. At each of the 4 sessions, subjects were evaluated for their competence in performing these exercises to achieve relaxation.
Appendix B

ELIGIBILITY SCREENING FORM
Eligibility Screening Form

Please Screen the child you are caring for today for eligibility for the RELAX TO SLEEP Study.
*(MUST BE “YES” TO BE ELIGIBLE)*

<table>
<thead>
<tr>
<th>Question</th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Is this child between the ages of 4 and 10 years old?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Do you anticipate this child staying in hospital for 3 nights?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Do the child and parent understand English? (parent must read English)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*(ALL ANSWERS IN THIS SECTION MUST BE “NO” TO BE ELIGIBLE)*

<table>
<thead>
<tr>
<th>Question</th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>4. Is this child undergoing palliative care or expected to die during this hospital stay?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Does this child have limited or abnormal movements of both upper and lower extremities?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Is this child diagnosed with a sleep disorder or a clinical anxiety disorder?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Does this child have developmental delays that would impede his/her ability to participate in the RELAX TO SLEEP Study?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. Is this child receiving sedation that limits their verbal response and/or normal movements to verbal stimuli?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

On the basis of the above criteria, is this child eligible for the RELAX TO SLEEP Study?

NO ☐

YES ☐...if yes, please now assess his/her willingness to have someone from the study tell him/her about it.

Is the family interested in hearing more about the RELAX TO SLEEP Study?

YES ☐

NO ☐...if no, why not?

After hearing about the RELAX TO SLEEP Study did the family consent to participate?

YES ☐

NO ☐...if no, why not?
Appendix C

CONSENT FORMS
The RELAX TO SLEEP Study: The feasibility, acceptability, and effectiveness of a psycho-educational intervention on sleep in hospitalized pediatric patients.

Investigators:
Robyn Stremler, RN, PhD, Assistant Professor Lawrence S. Bloomberg Faculty of Nursing, University of Toronto and Adjunct Scientist, the Hospital for Sick Children, Toronto, ON.
Efrosini A. Papaconstantinou, RN, BScN, MSc, and PhD Candidate, Lawrence S. Bloomberg Faculty of Nursing, University of Toronto, Toronto, ON.

Why are we doing this study?
Sleep is important to keep us healthy. Sometimes children find it hard to fall asleep and stay asleep while they are in the hospital because of loud noises, interruptions from nurses coming into the room, and feeling worried about being in the hospital. We are trying to find out if a simple discussion on sleep and doing a relaxation exercise are helpful in getting to sleep during your hospital stay and when you go home. This information will help us find things to help children who are in the hospital sleep better in the future.

What will happen during the study?
1. If you say yes to being in the study, you and your parent will fill out a short questionnaire. It will ask background information, like your age, how well you usually sleep, and how you are feeling. The questionnaire takes about 15 minutes to complete. The researcher will take some information about the medicines you are taking and who went into your room each night from your medical chart each day that you are in the study.
2. Once you have completed the short questionnaire you will begin wearing an actigraph. It is the size of a watch. The actigraph measures when you are sleeping and when you are awake by measuring how often you move. We ask that you wear the actigraph when we give it to you and for the next 3 nights and days. You will wear the actigraph around your wrist, just like a wristwatch or around your ankle if you can’t wear it around your wrist.
3. While you are wearing the actigraph you and your mom or dad will fill out a “Sleep Diary.” The Sleep Diary asks you to record when you are sleeping, when your mom and dad are in the room and things that interrupt your sleep. In the Sleep Diary there are also some questions for you to answer. The questions ask you about how well you think you slept, when you had to take the actigraph off, what kinds of things you did that helped you fall asleep, and your pain level. The
Sleep Diary will take about 15 minutes each day to complete. Over the 3 days that you are wearing the actigraph a researcher will visit you each day to help you complete the Sleep Diary.

4. After the actigraph is in place you will be ‘randomly assigned’ to either Group A (intervention group) or Group B (usual care group). Randomization means that the group is chosen for you by chance, as if by tossing a coin. This means that if you agree to be in the study you will have an equal chance of being in Group A or Group B.

5. If you are in Group B you will continue to wear the actigraph and a researcher will visit you for three days to help you fill out the Sleep Diary. If you are in Group A, the researcher will talk to you and your mom or dad about sleep and teach you how to relax. We want you to do the relaxation exercise at least one time a day at night just before bedtime. We want you to do this when you go home as well.

6. When we visit you on the final day we will pick up the actigraph and the Sleep Diary. This visit will be arranged at a time that is good for you. Between the 5th and 10th day after you have gone home, a researcher will call your mom or dad and ask them to complete a final questionnaire. The questions ask about your sleep, your experience of hospitalization, what things you think helped you to get to sleep or stopped you from getting to sleep, and your feelings about being in the study. This questionnaire takes about 30 minutes to complete.

Are there good things and bad things about the study?
If you have an allergy to metal, you might get a rash from the actigraph. If this happens you can wear it over your clothes or over an armband. Having to wear the actigraph and fill out the Sleep Diary might bother you because it is something extra you need to do for the day. The good thing about this study is that the information we get from you might help children sleep better in the future in hospital and when they go home.

Who will know about what I did in the study?
No one will know about your information unless you say it is okay. If we feel your health may be in danger, we may have to report your results to your doctor. Your information will be locked away safely and only the people on the research team can see your information.

Can I decide if I want to be in the study?
It is your choice to be in the study. Nobody will be angry or upset if you do not want to be in the study. We are talking to your parent/legal guardians about the study and you should talk to them about it too.

I was present when ______________________ read this form and said that he or she agreed, or assented, to take part in this study.

_________________________  ____________________
Printed Name of person who obtained assent     Signature & Date
The RELAX TO SLEEP Study: The feasibility, acceptability, and effectiveness of a psycho-educational intervention on sleep in hospitalized pediatric patients.

Investigators:
Robyn Stremler, RN, PhD, Assistant Professor Lawrence S. Bloomberg Faculty of Nursing, University of Toronto and Adjunct Scientist, the Hospital for Sick Children, Toronto, ON.
Efrosini A. Papaconstantinou, RN, BScN, MSc, and PhD Candidate, Lawrence S. Bloomberg Faculty of Nursing, University of Toronto, Toronto, ON.

Purpose of the Research:
Sleep is important for good health. Sleep problems such as difficulty falling asleep and staying asleep are common in children. During hospitalization, these sleep problems may get worse. Even after discharged home, children may develop sleep problems that they never had before their hospital stay. Some factors that add to sleep problems during hospitalization include: loud noise, interruptions from health care providers, pain, and stress or anxiety related to hospital stay. We are interested in knowing if a simple discussion on sleep and things you can do to get to sleep in hospital, as well as a relaxation technique are helpful in getting to sleep both in hospital and at home. This information will help us plan a bigger study on ways to improve sleep for children who are in the hospital in the future.

Description of the Research:
In order to answer the study questions, children 4 to 12 years old from pediatric medicine and cardiology units will be asked to participate in the study. This study will include 40 children. Participation in the study involves the following:
1. If you consent to participate in this study you will be asked to fill in a short questionnaire. The questionnaire asks you for some background information about yourself and your sleep. The questionnaire takes about 15 minutes to complete.
2. Some information about your medications and the number of times people went into your room at night will be taken from your medical chart. This information will be collected each of the 3 days that you will be involved in the study.
3. Once you have completed the short questionnaire you will begin wearing an actigraph. The actigraph is similar in size to a watch. This device measures when
you are at rest and when you are being active. This will help us know when you are sleeping. We ask that you wear the actigraph for the remainder of the day when we give it to you and for the next 3 nights and days. You will wear the actigraph around your wrist or ankle, just like a wristwatch. At this time we ask you to sign an actigraph care agreement form. This form discusses your agreement to return the actigraph device to the researchers when requested.

4. During the time you are wearing the actigraph we also ask that you fill out a “Sleep Diary.” This diary asks you to record when you are sleeping, when your parent is in the room and any interruptions during your sleep. In the Sleep Diary there are also some questions about how well you think you slept and when you had to take the actigraph off. Other questions include things that you did that helped you fall asleep. The Sleep Diary will take about 15 minutes each day to complete. There will also be a question that asks about your pain. Over the three days that you are wearing the actigraph a member of the research team will visit you each day to help you complete the pain scores and, if needed, the sleep diary.

5. After the actigraph is in place you will be ‘randomly assigned’ to either Group A (intervention group) or Group B (usual care group). Randomization means that neither you nor your caregivers choose the group you are in; rather the group is chosen for you, by chance, as if by tossing a coin. This means that if you agree to be in the study you will have a 50-50 chance of being randomized to either Group A or Group B.

6. If you are in Group B you will continue to wear the actigraph and be visited daily for three days by a member of the research team to help you fill out the sleep diary. If you are assigned to Group A a member from the research team will go over some information on sleep and teach you how to relax, and will ask you to use the relaxation exercise at least once per day at night just before bedtime. We will ask that you continue this when you go home as well.

7. When we visit you on the final day we will pick up the actigraph and the Sleep Diary. This visit will be arranged at a time that is convenient for you. Between the 5th and 10th day after you have been discharged home, you will receive a phone call from a member of the research team and will be asked to complete a questionnaire over the telephone. The questions ask about your sleep and experiences of hospitalization as well as what you liked and disliked about being in the study and what things you think helped you to get sleep or stopped you from getting sleep. This questionnaire will take about 30 minutes to complete.

Potential Harms:
If you have an allergy to metal, wearing the actigraph may give you a rash. If this happens and you still want to participate, you can wear the actigraph over your clothing or a sweatband that we will provide. There are no other potential harms associated with participation in this study. There are no consequences if you should choose not to participate in this research study.

Potential Discomforts or Inconvenience:
As part of the study a member of the research team will meet with you in person
on each of the three days that you wear the actigraph. Every attempt will be made to
ensure minimal disruption to your schedule. It may be inconvenient for you to wear the
actigraph and for you to fill out the sleep diary over a three-day period. Also, once you
have left the hospital and gone home a telephone call will be made in an attempt to
gather a final questionnaire. You may find this to be inconvenient but every attempt will
be made to schedule a time that is acceptable to you.

**Potential Benefits to individual subjects and to society:**

You may not benefit from taking part in this study. Your sleep might improve, but
this cannot be predicted for you. We hope that the information gained from the study will
help us learn more about improving sleep for children staying in hospitals. This
information will also help us plan a bigger study in the future. If you are interested in the
outcome of the study, please let the researcher know by filling out the attached sheet
and you will be sent a summary of the results after the study is completed.

**Confidentiality:**

We will respect your privacy. No information about who you are will be given to
anyone or be published without your permission, unless required by law. For example,
the law could make us give information about you, if a child has been abused, if you
have an illness that could spread to others, if you or someone else talks about suicide
(killing themselves), or if the court orders us to give them the study papers.

SickKids Clinical Research Monitors, or the regulator of the study may see your
health record to check on the study. By signing this consent form you agree to let these
people look at your records. We will put a copy of this research consent form in your
patient health record and give you a copy as well.

The data produced from this study will be stored in a secure, locked location. Only
members of the research team (and maybe those individuals described above) will have
access to the data. This could include external research team members. Following
completion of the research study the data will be kept as long as required by SickKids
policy. Published study results will not reveal your identity.

**Compensation:**

We will provide you with some compensation, a $10 gift card to a bookstore and
a storybook, in recognition of your time and effort.

**Participation:**

It is your choice to take part in this study. You can stop at any time. The care you
receive at SickKids will not be affected in any way by whether you take part in this
study.

New information that we get while we are doing this study may affect your
decision to take part in this study. If this happens, we will tell you about this new
information and we will ask you again if you still want to be in the study.

During this study we may create new tests, new medicines or other things that
may be worth some money. Although we may make money from these findings, we
cannot give you any of this money now or in the future because you took part in this
study. We will give you a copy of this consent form for your records. In some situations,
the study doctor or the company paying for the study may decide to stop the study. This could happen even if the study is helping you. If this happens the study doctor will talk to you about what will happen next. If you become ill or become harmed because you took part in this study, we will treat you for free. Your signing this consent form does not interfere with your legal rights in any way. The staff of the study, any people who gave money for the study, or the hospital are still responsible, legally and professionally, for what they do.

**Sponsorship:**
None

**Conflict of Interest:**
I, and the other research team members have no conflict of interest to declare.
The RELAX TO SLEEP Study: The feasibility, acceptability, and effectiveness of a psycho-educational intervention on sleep in hospitalized pediatric patients.

Investigators:
Robyn Stremler, RN, PhD, Assistant Professor Lawrence S. Bloomberg Faculty of Nursing, University of Toronto and Adjunct Scientist, the Hospital for Sick Children, Toronto, ON.
Efrosini A. Papaconstantinou, RN, BScN, MSc, and PhD Candidate, Lawrence S. Bloomberg Faculty of Nursing, University of Toronto, Toronto, ON.

Consent
By signing this form, I agree that:

1. You have explained this study to me. You have answered all my questions.
2. You have explained the possible harms and benefits (if any) of this study.
3. I understand that I have the right not to take part in the study and the right to stop at any time. My decision about me taking part in the study will not affect my health care at SickKids.
4. I am free now, and in the future, to ask questions about the study.
5. I have been told that my medical records will be kept private. You will give no one information about me, unless the law requires you to.
6. I understand that no information about who I am will be given to anyone or be published without first asking my permission.
7. I have read and understood pages 1 to 6 of this consent form. I agree, or consent, to take part in this study.

I hereby consent to participate.

Printed Name of Participant: ___________________________  Participant’s Signature & Date: ___________________________

Printed Name of Person who explained consent: ___________________________  Signature & Date: ___________________________

We will keep a signed copy of this Consent Form for our records and we will give you a signed copy as well.

If you have any questions about this study, please contact Efrosini Papaconstantinou at 416-768-6966 or e-mail: efrosini.papaconstantinou@utoronto.ca

If you have questions about your rights as a subject in a study, or injuries during a study, please call the Research Ethics Manager at 416-813-5718.
The RELAX TO SLEEP Study: The feasibility, acceptability, and effectiveness of a psycho-educational intervention on sleep in hospitalized pediatric patients.

If you would like to receive a summary of the study results, please print your name and address where we can send the summary to below:

Name: ________________________________

Address: ________________________________

_____________________________________

_____________________________________

E-mail: ________________________________
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Description of the Research:
In order to answer the study questions, children 4 to 12 years old from pediatric medicine and cardiology units will be asked to participate in the study. This study will include 40 children. Participation in the study involves the following:
1. If you consent for your child to participate in this study you will be asked to fill in a short questionnaire. The questionnaire asks you for some background information about your child and his or her sleep. The questionnaire takes about 15 minutes to complete.
2. Some information about your child’s medications and the number of times people went into your child’s room at night will be taken from your child’s medical chart. This information will be collected each of the 3 days that your child will be involved in the study.
3. Once you have completed the short questionnaire your child will begin wearing
an actigraph. The actigraph is similar in size to a watch. This device measures when your child is at rest and when your child is being active. This will help us know when he or she is sleeping. We ask that your child wear the actigraph for the remainder of the day when we give it to him or her and for the next 3 nights and days. Your child will wear the actigraph around his or her wrist or ankle, just like a wristwatch. We will help you decide if the ankle or wrist is best for you child based on your child’s age, and where your child has IV lines in place. At this time we ask you to sign an actigraph care agreement form. This form discusses your agreement to return the actigraph device to the researchers when requested.

4. During the time your child is wearing the actigraph we also ask that you fill out a “Sleep Diary.” This diary asks you to record when your child is sleeping, when you are in the room and any interruptions during your child’s sleep. In the Sleep Diary there are also some questions about how well you think your child slept and when your child had to take the actigraph off. Other questions include things that you did that helped you fall asleep. The Sleep Diary will take about 15 minutes each day to complete. There will also be a question that asks about your child’s pain. Over the three days that your child is wearing the actigraph a member of the research team will visit you and your child each day to help you complete the pain score and, if needed, the sleep diary.

5. After the actigraph is in place your child will be ‘randomly assigned’ to either Group A (intervention group) or Group B (usual care group). Randomization means that neither you nor your caregivers choose the group you are in; rather the group is chosen for you, by chance, as if by tossing a coin. This means that if you agree to allow your child to participate in the study, he or she will have a 50-50 chance of being randomized to either Group A or Group B.

6. If your child is assigned to Group B he or she will continue to wear the actigraph and be visited daily for three days by a member of the research team to help you and your child fill out the sleep diary. If your child has been assigned to Group A a member from the research team will go over some information on sleep and teach you and your child how to relax, and will ask your child to use the relaxation exercise at least once per day at night just before bedtime. We will ask that your child continue this when you go home.

7. When we visit you on the final day we will pick up the actigraph and the Sleep Diary. This visit will be arranged at a time that is convenient for you. Between the 5th and 10th day after you have been discharged home, you will receive a phone call from a member of the research team and will be asked to complete a questionnaire over the telephone. The questions ask about your child’s sleep and experiences of hospitalization as well as what you liked and disliked about being in the study and what things you think helped your child to get sleep or stopped your child from getting sleep. This questionnaire will take about 30 minutes to complete.

Potential Harms:
If your child has an allergy to metal, wearing the actigraph may give him or her a rash. If this happens and you and your child still want to participate, your child can wear the actigraph over clothing or a sweatband that we will provide. There are no other
potential harms associated with participation in this study. There are no consequences if you or your child should choose not to participate in this research study.

**Potential Discomforts or Inconvenience:**

As part of the study a member of the research team will meet with you in person on each of the three days that your child wears the actigraph. Every attempt will be made to ensure minimal disruption to your schedule. It may be inconvenient for your child to wear the actigraph and for you to fill out the sleep diary over a three-day period. Also, once you have left the hospital and gone home a telephone call will be made in an attempt to gather a final questionnaire. You may find this to be inconvenient but every attempt will be made to schedule a time that is acceptable to you and your child.

**Potential Benefits to individual subjects and to society:**

Your child may not benefit from taking part in this study. Your child’s sleep might improve, but this cannot be predicted for you. We hope that the information gained from the study will help us learn more about improving sleep for children staying in hospitals. This information will also help us plan a bigger study in the future. If you are interested in the outcome of the study, please let the researcher know by filling out the attached sheet and you will be sent a summary of the results after the study is completed.

**Confidentiality:**

We will respect your and your child’s privacy. No information about who you or your child are will be given to anyone or be published without your permission, unless required by law. For example, the law could make us give information about you or your child, if a child has been abused, if you or your child have an illness that could spread to others, if you or someone else talks about suicide (killing themselves), or if the court orders us to give them the study papers.

SickKids Clinical Research Monitors, or the regulator of the study may see your child’s health record to check on the study. By signing this consent form you agree to let these people look at your child’s records. We will put a copy of this research consent form in your child’s health record and give you and your child a copy as well.

The data produced from this study will be stored in a secure, locked location. Only members of the research team (and maybe those individuals described above) will have access to the data. This could include external research team members. Following completion of the research study the data will be kept as long as required by SickKids policy. Published study results will not reveal your or your child’s identity.

**Compensation:**

We will provide your child with some compensation, a $10 gift card to a bookstore and a storybook, in recognition of your child’s time and effort.

**Participation:**

It is you and your child’s choice to take part in this study. You and your child can stop at any time. The care you and your child receive at SickKids will not be affected in any way by whether your child takes part in this study.
New information that we get while we are doing this study may affect your decision to take part in this study. If this happens, we will tell you about this new information and we will ask you again if you still want to be in the study.

During this study we may create new tests, new medicines or other things that may be worth some money. Although we may make money from these findings, we cannot give you or your child any of this money now or in the future because you took part in this study. We will give you a copy of this consent form for your records. In some situations, the study doctor or the company paying for the study may decide to stop the study. This could happen even if the study is helping you and your child. If this happens the study doctor will talk to you about what will happen next. If you or your child become ill or become harmed because you took part in this study, we will treat you and your child for free. Your signing this consent form does not interfere with your legal rights or your child’s legal rights in any way. The staff of the study, any people who gave money for the study, or the hospital are still responsible, legally and professionally, for what they do.

**Sponsorship:**
None

**Conflict of Interest:**
I, and the other research team members have no conflict of interest to declare.
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Efrosini A. Papaconstantinou, RN, BScN, MSc, and PhD Candidate, Lawrence S. Bloomberg Faculty of Nursing, University of Toronto, Toronto, ON.

Consent
By signing this form, I agree that:
1. You have explained this study to me. You have answered all my questions.
2. You have explained the possible harms and benefits (if any) of this study.
3. I understand that my child and I have the right not to take part in the study and the right to stop at any time. My decision about me and my child taking part in the study will not affect my child’s health care at SickKids.
4. I am free now, and in the future, to ask questions about the study.
5. I have been told that my child’s medical records will be kept private. You will give no one information about me or my child, unless the law requires you to.
6. I understand that no information about who I am or who my child is will be given to anyone or be published without first asking my permission.
7. I have read and understood pages 1 to 6 of this consent form. I agree, or consent, to take part in this study and that my child, ________________, may take part in this study.

I hereby consent to participate.

Printed Name of Parent/Legal Guardian

Parent/Legal Guardian’s signature & Date

Printed Name of Person who explained consent

Signature & Date

We will keep a signed copy of this Consent Form for our records and we will give you and your child a signed copy as well.

If you have any questions about this study, please contact Efrosini Papaconstantinou at 416-768-6966 or e-mail: efrosini.papaconstantinou@utoronto.ca

If you have questions about your rights as a subject in a study, or injuries during a study, please call the Research Ethics Manager at 416-813-5718.
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If you would like to receive a summary of the study results, please print your name and address where we can send the summary to below:

Name: 

Address: 

E-mail: 

Appendix D

ACTIGRAF CARE AGREEMENT FORM
The RELAX TO SLEEP Study

Actigraph Care Agreement

As part of my child’s participation in the study, he/she will be asked to wear an actigraph (a special watch used to measure sleep). Actigraphs are expensive equipment and therefore it is critical that parents and children take good care of this equipment. In signed below I agree to take good care of the actigraph. I also agree to return the actigraph promptly to the researchers when requested.

If you have any questions about this form, please contact the principle investigator, Efrosini Papaconstantinou at XXX-XXX-XXXX or efrosini.papaconstantinou@utoronto.ca

Participant (Print Name)  Signature    Date
(if appropriate)

Parent (Print Name)      Signature     Date
Appendix E

ENTRY FORM
1. Today's Date: □□□□ / □□ / □□
   year   month   day

2. Child’s Gender: ☐ male ☐ female

3. Child’s last grade level completed:
   ☐ N/A, pre-school/toddler age ☐ JK  ☐ SK  ☐ Grade 1  ☐ Grade 2  ☐ Grade 3
   ☐ Grade 4  ☐ Grade 5  ☐ Grade 6  ☐ Grade 7  ☐ Grade 8  ☐ Other (specify) _________

4. How old is the Child: _____ (in years)

5. Child’s racial background:
   ☐ South Asian  ☐ Black
   ☐ East Asian  ☐ First Nations/Aboriginal
   ☐ West Asian  ☐ More than one racial background
   ☐ Hispanic  ☐ Other (specify) ____________________
   ☐ White  ☐ Arab
### The Children’s Sleep Habits Questionnaire (CSHQ)

The following statements are about your child’s sleep habits and possible difficulties with sleep before coming to stay in the hospital. Think about the most recent typical week in your child’s life when answering these questions. Answer **USUALLY** if something occurs 5 or more times in a week; answer **SOMETIMES** if it occurs 2 – 4 times in a week; answer **RARELY** if something occurs never or 1 time during a week.

### Bedtime

**Write in child’s USUAL bedtime:**

<table>
<thead>
<tr>
<th></th>
<th>Weeknights</th>
<th></th>
<th>Weekends</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Hours</td>
<td>Minutes</td>
<td>Hours</td>
</tr>
</tbody>
</table>

- **Child goes to sleep at the same time at night**
  - Usually (5-7)
  - Sometimes (2-4)
  - Rarely (0-1)

- **Child falls asleep within 20 minutes after going to bed**
  - Usually (5-7)
  - Sometimes (2-4)
  - Rarely (0-1)

- **Child falls asleep alone in own bed**
  - Usually (5-7)
  - Sometimes (2-4)
  - Rarely (0-1)

- **Child falls asleep in parent’s or sibling’s bed**
  - Usually (5-7)
  - Sometimes (2-4)
  - Rarely (0-1)

- **Child needs parent in the room to fall asleep**
  - Usually (5-7)
  - Sometimes (2-4)
  - Rarely (0-1)

- **Child struggles at bedtime (cries, refuses to stay in bed, etc.)**
  - Usually (5-7)
  - Sometimes (2-4)
  - Rarely (0-1)

- **Child is afraid of sleeping in the dark**
  - Usually (5-7)
  - Sometimes (2-4)
  - Rarely (0-1)

- **Child is afraid of sleeping alone**
  - Usually (5-7)
  - Sometimes (2-4)
  - Rarely (0-1)

### Sleep Behavior

**Child’s usual amount of sleep each day:**

(Combining nighttime sleep and naps)

<table>
<thead>
<tr>
<th></th>
<th>Weekdays</th>
<th></th>
<th>Weekends</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Hours</td>
<td>Minutes</td>
<td>Hours</td>
</tr>
</tbody>
</table>

**Usually (5-7)**
**Sometimes (2-4)**
**Rarely (0-1)**

- **Child sleeps too little**
  - Usually (5-7)
  - Sometimes (2-4)
  - Rarely (0-1)

- **Child sleeps the right amount**
  - Usually (5-7)
  - Sometimes (2-4)
  - Rarely (0-1)

- **Child sleeps about the same amount each day**
  - Usually (5-7)
  - Sometimes (2-4)
  - Rarely (0-1)

- **Child wets the bed at night**
  - Usually (5-7)
  - Sometimes (2-4)
  - Rarely (0-1)

- **Child talks during sleep**
  - Usually (5-7)
  - Sometimes (2-4)
  - Rarely (0-1)

- **Child is restless and moves a lot during sleep**
  - Usually (5-7)
  - Sometimes (2-4)
  - Rarely (0-1)

- **Child sleepwalks during the night**
  - Usually (5-7)
  - Sometimes (2-4)
  - Rarely (0-1)

- **Child moves to someone else’s bed during the night (parent, brother, sister, etc)**
  - Usually (5-7)
  - Sometimes (2-4)
  - Rarely (0-1)

- **Child grinds teeth during sleep (your dentist may have told you this)**
  - Usually (5-7)
  - Sometimes (2-4)
  - Rarely (0-1)

- **Child snores loudly**
  - Usually (5-7)
  - Sometimes (2-4)
  - Rarely (0-1)

- **Child seems to stop breathing during sleep**
  - Usually (5-7)
  - Sometimes (2-4)
  - Rarely (0-1)

- **Child snorts and/or gasps during sleep**
  - Usually (5-7)
  - Sometimes (2-4)
  - Rarely (0-1)

- **Child has trouble sleeping away from home (visiting relatives, vacation)**
  - Usually (5-7)
  - Sometimes (2-4)
  - Rarely (0-1)
### Waking During the Night

<table>
<thead>
<tr>
<th>Event</th>
<th>Usually (5-7)</th>
<th>Sometimes (2-4)</th>
<th>Rarely (0-1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Child awakens during night screaming, sweating, and inconsolable</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>Child awakens alarmed by a frightening dream</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
</tbody>
</table>

### Morning Waking

Write in the time of day child usually wakes in the morning:
- **Weekdays**: [ ] [ ][ ] [ ]
- **Weekends**: [ ] [ ][ ] [ ]

### Daytime Sleepiness

<table>
<thead>
<tr>
<th>Event</th>
<th>Usually (5-7)</th>
<th>Sometimes (2-4)</th>
<th>Rarely (0-1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Child seems tired</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
</tbody>
</table>

During a usual week has your child appeared sleepy or fallen asleep during the following (check all that apply):

<table>
<thead>
<tr>
<th>Activity</th>
<th>Very Sleepy</th>
<th>Falls Asleep</th>
<th>Not Applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Watching TV</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>Riding in a car</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
</tbody>
</table>
Below is a list of items that describe children. For each item please circle the response that best describes your child. Please circle 4 if the item is **very often true**, 3 if the item is **quite often true**, 2 if the item is **sometimes true**, 1 if the item is **seldom true** or if it is **not true at all** circle the 0. Please answer all the items as well as you can, even if some do not seem to apply to your child.

<table>
<thead>
<tr>
<th></th>
<th>NOT True at All</th>
<th>Seldom True</th>
<th>Sometimes True</th>
<th>Quite Often True</th>
<th>Very Often True</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>1.</td>
<td>Has difficulty stopping him/herself from worrying....</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>2.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>2.</td>
<td>Is tense, restless or irritable due to worrying</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>3.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>3.</td>
<td>Is reluctant to go to sleep without you or to sleep away from home</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>4.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>4.</td>
<td>Has trouble sleeping due to worrying</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>5.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>5.</td>
<td>Worries that something bad will happen to his/her parents</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>6.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>6.</td>
<td>Spends a large part of each day worrying about various things</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>7.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>7.</td>
<td>Worries that something bad might happen to him/her (e.g., getting lost or kidnapped), so he/she won't be able to see you again</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>8.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>8.</td>
<td>Becomes distressed about your leaving him/her at preschool/school or with a babysitter</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>9.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>9.</td>
<td>Has nightmares about being apart from you</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>10.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>10.</td>
<td>Asks for reassurance when it doesn't seem necessary</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>11.</td>
<td><strong>Has your child ever experienced anything really bad or traumatic</strong> (e.g., severe accident, death of a family member/friend, assault, robbery, disaster)</td>
<td>YES</td>
<td>NO</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11.</td>
<td>Please briefly describe the event that your child experienced</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
If you answered **NO** to question 11, please **do not** answer questions 12-16. **If you answered YES, please DO** answer the following questions.

<table>
<thead>
<tr>
<th>Do the following statements describe your child’s behaviour since the event?</th>
</tr>
</thead>
<tbody>
<tr>
<td>12. Has bad dreams or nightmares about the event</td>
</tr>
<tr>
<td>13. Remembers the event and becomes distressed</td>
</tr>
<tr>
<td>14. Becomes distressed when reminded of the event</td>
</tr>
<tr>
<td>15. Suddenly behaves as if he/she is reliving the bad experience</td>
</tr>
<tr>
<td>16. Shows bodily signs of fear (e.g., sweating, shaking or racing heart) when reminded of the event</td>
</tr>
</tbody>
</table>
Spence Children’s Anxiety Scale  
(Parent Report)

Below is a list of items that describe children. For each item please circle the response that best describes your child. Please answer all the items.

<p>| | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. My child worries about things.</td>
<td>Never</td>
<td>Sometimes</td>
<td>Often</td>
<td>Always</td>
</tr>
<tr>
<td>2. When my child has a problem, she/he complains of having a funny feeling in his/her stomach.</td>
<td>Never</td>
<td>Sometimes</td>
<td>Often</td>
<td>Always</td>
</tr>
<tr>
<td>3. My child complains of feeling afraid.</td>
<td>Never</td>
<td>Sometimes</td>
<td>Often</td>
<td>Always</td>
</tr>
<tr>
<td>4. My child would feel afraid of being on his/her own at home.</td>
<td>Never</td>
<td>Sometimes</td>
<td>Often</td>
<td>Always</td>
</tr>
<tr>
<td>5. My child worries about being away from us/me.</td>
<td>Never</td>
<td>Sometimes</td>
<td>Often</td>
<td>Always</td>
</tr>
<tr>
<td>6. My child worries that something awful will happen to someone in our family.</td>
<td>Never</td>
<td>Sometimes</td>
<td>Often</td>
<td>Always</td>
</tr>
<tr>
<td>7. My child is scared if she/he has to sleep on his/her own.</td>
<td>Never</td>
<td>Sometimes</td>
<td>Often</td>
<td>Always</td>
</tr>
<tr>
<td>8. My child has trouble going to school in the mornings because she/he feels nervous or afraid.</td>
<td>Never</td>
<td>Sometimes</td>
<td>Often</td>
<td>Always</td>
</tr>
<tr>
<td>9. When my child has a problem, she/he complains of his/her heart beating really fast.</td>
<td>Never</td>
<td>Sometimes</td>
<td>Often</td>
<td>Always</td>
</tr>
<tr>
<td>10. My child worries that something bad will happen to him/her.</td>
<td>Never</td>
<td>Sometimes</td>
<td>Often</td>
<td>Always</td>
</tr>
<tr>
<td>11. When my child has a problem, she/he feels shaky.</td>
<td>Never</td>
<td>Sometimes</td>
<td>Often</td>
<td>Always</td>
</tr>
<tr>
<td>12. My child would feel scared if she/he had to stay away from home overnight.</td>
<td>Never</td>
<td>Sometimes</td>
<td>Often</td>
<td>Always</td>
</tr>
<tr>
<td>13. Is there anything else that your child is really afraid of?</td>
<td>YES</td>
<td>NO</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Please write down what it is, and fill out how often she/he is afraid of this thing:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Never</td>
<td>Sometimes</td>
<td>Often</td>
<td>Always</td>
</tr>
<tr>
<td></td>
<td>Never</td>
<td>Sometimes</td>
<td>Often</td>
<td>Always</td>
</tr>
<tr>
<td></td>
<td>Never</td>
<td>Sometimes</td>
<td>Often</td>
<td>Always</td>
</tr>
</tbody>
</table>
For Researcher Only

1. Type of Admission
   - Chronic illness
   - Acute illness/trauma
   - Planned surgery
   - Other: ______________________

2. When was this child admitted to SickKids? ☐ ☐ ☐ / ☐ ☐ ☐
   - year
   - month
   - day

3. What unit has this child been admitted to? ________________

4. When was this child admitted to this unit? ☐ ☐ ☐ / ☐ ☐ ☐
   - year
   - month
   - day

5. Not including the child’s current hospital stay, has the child been in the hospital in the past 12 months?
   - ☐ No  ☐ Yes ➔ If yes, list the admission dates and number of days in the hospital below.

<table>
<thead>
<tr>
<th>Admission Date:</th>
<th># of days in the hospital</th>
</tr>
</thead>
<tbody>
<tr>
<td>Year/month/day</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Randomization Procedure:
Once the Entry Form has been completed please take the next sequentially numbered opaque envelope and fill out the following information:

1. Study Code Number: Study Number ☐-☐☐
2. Child’s Date of Birth: Child’s Date of Birth ☐ ☐ ☐ ☐
   - year
   - month

Open the envelope to reveal allocated study group then affix envelope to this form for an audit trail.

Allocated Study Group:

☐ Group A – RELAX TO SLEEP Program
☐ Group B – Usual Care

Date and Time of Randomization:

☐☐☐☐ ☐☐☐☐ ☐☐☐☐ ☐☐☐☐ ☐☐☐☐ ☐☐☐☐ ☐☐☐☐ ☐☐☐☐ 24-hour clock
Appendix F

GROUP ALLOCATION LETTER
Instructions for Group A – Sleep Intervention in the RELAX TO SLEEP Study

Dear Participant,

You have been randomly assigned to Group A, the sleep intervention group. In a few moments or at a time when is convenient for you, a member from the research team will come in to provide you information on sleep and consequences of sleep disturbance, sleep hygiene practices, and teach you and your child how to use relaxation breathing.

While you are taking part in this study please keep the following in mind:

- We ask that your child continue to wear the actigraph for the duration of the study. Please note that the device cannot be immersed in water, therefore should be removed when bathing or showering.
- We ask that you try and practice the relaxation breathing exercise with your child at least once a day, every day, over the next 3 days while you are in hospital.
- We ask that you continue to use the relaxation breathing exercise when you are discharged home.
- The book or compact disc (CD) you have been given is designed to help you and your child use the deep breathing exercise to relax. Ideally, this should be used at bedtime as part of a relaxing bedtime routine. Practicing the exercise on the CD or reading the book may help you and your child get better at relaxing, so if it helps you to listen or read more frequently than just at bedtime, feel free to do that.
- We ask that you do not share any parts of this information with any other families during your hospital stay. We also ask you to practice the technique together with your child.
- We ask that you or your child (if appropriate) fill out the sleep diary in the morning as well as the questions related to the breathing relaxation exercise.
- Every morning a member of the research team will come to help fill out the sleep diary.
- If you are discharged home prior to the 3 days of the study please return the actigraph device at the front with the unit administrator. Once you are at home, a member of the research team will contact you by telephone to complete a final questionnaire.
- To thank you and your child for your time and effort in participating in the RELAX TO SLEEP study a small gift will be provided at the completion of the study.

If you have any questions or problems with the actigraph device, using the CD, or doing the relaxation exercise, you can contact me at XXX-XXX-XXXX. Thank you,

Efrosini Papaconstantinou, RN, BScN, MSc, PhD Candidate
Instructions for Group B – Usual Care Group in the RELAX TO SLEEP Study

Dear Participant,

You have been randomly assigned to receive usual care. While you are taking part in this study please keep the following in mind:

- We ask that your child continue to wear the actigraph for the duration of the study. Please note that the device cannot be immersed in water, therefore should be removed when bathing or showering.
- We ask that you or your child (if appropriate) fill out the sleep diary in the morning.
- Every morning a member of the research team will come to help fill out the sleep diary.
- If you are discharged home prior to the 3 days of the study please return the actigraph device at the front with the unit administrator. Once you are at home, a member of the research team will contact you by telephone to complete a final questionnaire.
- To thank you and your child for your time and effort in participating in the RELAX to SLEEP study a small gift will be provided at the completion of the study.

If you have any questions or problems with the actigraph device, or you have questions about the study, you can contact me at XXX-XXX-XXXX.

Thank you,

Efrosini Papaconstantinou, RN, BScN, MSc, PhD Candidate
Appendix G

EDUCATIONAL BOOKLET
For more information on the RELAX TO SLEEP Study please contact:

Efrosini Papaconstantinou

Cell Number: XXX-XXX-XXXX
Sleep is essential for good health! Regardless of age, sleep is what all humans need for general wellbeing, and this is especially true for children. Sleep problems are one of the most common concerns that parents have. During hospitalization, common sleep problems may worsen. Even after you are discharged home, your child may have problems with sleep, which he/she never had prior to hospitalization.

These books involve colorful pictures and imagery. The colorful imagery in the stories quiets the mind and relaxes the body.

Older children (6-7 years old) may also choose this method of learning the relaxation technique.

For the older child (8-10 years old) relaxation breathing can be provided through the use of a CD or can be available through an iPod.

A member from the RELAX TO SLEEP study research team will provide you with your choice.

This relaxation technique is a basic exercise and does not take long to learn. In fact, everyone can learn to relax with practice and through the use of breathing.

This booklet will provide you with information on:

- The importance of sleep
- How sleep works
- What drives us to sleep
- How much sleep is recommended for children
- How to tell if your child is NOT getting enough sleep
- Common sleep problems
- Sleep during hospitalization
- Strategies that can help your child get the best sleep possible during your hospital stay as well as when you go home.
- Relaxation techniques to use during your hospital stay and at home.
During your bedtime routine, you can initiate and have the child practice the relaxation technique through the same breathing technique to encourage a relaxation state. Using a story book is helpful. For preschool age children and younger school-aged children the following storybooks can help take your child through relaxation breathing:

A Boy and a Bear

Sea Otter Cove

The Importance of Sleep

Sleep is essential for your child’s health. Kids today have busy days. Between school, homework, running around with friends, and going to sports practice or music lessons, by the end of the day your child’s brain and body needs a break. Sleep serves many purposes to our health and helps children grow and develop, learn better, and heal from illness and injury.

Sleep Helps You Grow and Develop

- Your child needs healthy sleep so that muscles, bones, and skin can grow. Most of your child’s bone growth occurs during the night while your child is snoozing.
- Growth hormones are released during sleep, which results in physical growth.
- While asleep, your child’s body is also developing a stronger immune system, which is important for fighting off infection or illness.

Sleep Helps to Repair Your Body

- Our bodies produce extra protein molecules while we are sleeping.
- These protein molecules help to repair our body from injuries at the cellular level, deep inside our bodies.
- Damage to your child’s body from things like stress, infection, and cuts and scrapes are repaired while your child is fast asleep.

Sleep Helps with Learning, Memory, and Brain Functioning

- Not only is sleep necessary for your child’s body, it’s important for their developing brains!
- Sleep helps your child remember what he/she learned, pay attention and concentrate, and solve problems and think of new ideas.
- While your child is sleeping, his/her brain is busy organizing and processing new knowledge. This helps your child increase their ability to remember!
How sleep works

There are two different types of sleep called:

- NREM (non-rapid eye movement)
- REM (rapid eye movement)

As your child drifts off to sleep, they look so peaceful, and it doesn’t seem like much is happening.

In actuality, your child begins to enter the 4 stages of NREM sleep and REM sleep.

Stage 1 and 2 are the lighter stages of sleep and help us transition to the much needed deeper stages of sleep (stage 3 and 4), also known as Slow Wave Sleep (SWS).

Stage 4 NREM is important for growth and healing of injury. REM sleep is known as the “dreaming” stage of sleep and is important for things like memory and learning new ideas.

Everybody, regardless of age, needs both types of sleep to be healthy and well rested each day.

We cycle through NREM and REM about every 90 minutes from bedtime to morning. For most kids that’s about 5 times a night. Being able to move into and stay in the deeper stages of sleep allows your child to gain the benefits that sleep has to offer!

How to teach your child relaxation breathing:

During your participation in the RELAX TO SLEEP study you will be asked to encourage your child to use relaxation breathing. It is a simple technique and there are various methods of teaching this form of breathing to children as young as 4 years of age.

Children can be taught to relax quickly when faced with stressful situations. Begin by doing this exercise with your child. At first it’s best to have your child lying down to learn the proper way to breathe. Then you can expand this exercise having your child sitting upright in a chair or bed.

- Have your child lay on his/her back and put his/her hand on his/her belly. You may choose a favourite small toy to put on his/her belly instead.
- Ask your child to take a slow deep breath in through their nose and then have them let out the breath through their mouth with a gentle ah-h-h-h-h sound. (With his/her hand point out that the child should feel his/her belly rise and fall, or watch the toy rise and fall).
- Have the child breathe in slowly through his/her nose and out through his/her mouth like they are trying to move a feather up in the air.
- Breathe in slowly to the count of 2, 3, 4 and out 2, 3, 4. Count with the child “In 2, 3, 4 and out 2, 3, 4."

This technique can be used when your child is anxious about a procedure such as having a needle or having a blood sample taken or even if the child is frightened by a medical team clinician.
Relaxation
The next section of this booklet discusses a breathing exercise to help your child achieve a state of relaxation.

What is relaxation breathing?
Relaxation breathing, sometimes referred to as belly breathing, or diaphragmatic breathing is a technique that teaches your child how to slow down and deepen his or her breathing when feeling stressed or anxious. Proper breathing is very important for creating a state of relaxation.

Why is relaxation breathing important for sleep?
During your hospital stay, your child may feel anxious or worried and may not be able to sleep properly. When this happens, your child may feel more awake and have difficulty relaxing during bedtime.

When your child is worried or anxious his or her breathing will change. For example, a child’s breath may become shorter, quick, and more shallow and your child may even hyperventilate. This type of breathing can actually cause the feeling of anxiety to feel worse making it even more difficult to sleep.

Relaxation breathing may decrease feelings of anxiety and worry and bring about the relaxation response. Teaching your child deep and controlled breathing can make them feel more relaxed so that they can fall asleep easier. The more you practice this technique with your child, the more likely they will feel confident in using relaxation breathing and they will be able to use this technique not only for sleep but to help them when other challenging things happen to them.

Doing relaxed breathing can help lower your child’s anxiety, and give him/her a sense of control. Relaxed breathing is a great tool that your child can use as part of a bedtime routine, or when awakened in the night, and when feeling anxious, especially during his/her hospital stay. The relaxation technique can be used anywhere, at anytime; your child can use relaxation breathing at home when you leave the hospital, and in situations when you are not there to help him or her through it.

What Drives us to Sleep
There are two things that drive the body to sleep.

Homeostatic Process
• Just like a full tank of gas in a car, your child’s energy eventually runs out! After your child goes to school, plays outside for recess, goes to soccer practice, then comes home to do their homework, by the end of the day their tank is running on empty. They need to be refueled! In this case, sleep is the fuel to get them through another day! After a full night of sleep, they wake up ready for a new day!

• In younger children, a mid-day nap often offsets the drive to sleep allowing them to refuel to continue their day after their nap.

Circadian Rhythm
• Deep inside our brains is a tiny internal clock that tells us when to sleep and when to be awake. Our clock is affected by the light-dark cycle or whether we are in a light or a dark place.

• When day turns to night, a chemical called melatonin is released which makes us sleepy. Melatonin is then ‘turned off’ as the sun rises and shines into our bedroom.

• Exposure to natural and bright light during the day helps to keep this rhythm strong.

• Our brain also takes cues from what is around us when it’s time to sleep. For instance, having a consistent routine such as specific times for dinner, homework time, and bedtimes, trains your brain to be in tune with the light-dark cycle making falling asleep more predictable.
How much sleep is enough?
Children need sufficient sleep to grow, develop, and function at their best. Remember, that children are unique and different and so are their sleep needs! Expect your child to sleep for about the same amount each day. Below you will find the recommended hours of sleep per day.

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Recommended Hours of Sleep Per Day</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toddlers (aged 1-3 years)</td>
<td>Between 12 and 14 hours of sleep</td>
</tr>
<tr>
<td></td>
<td>(including nap time)</td>
</tr>
<tr>
<td>Preschoolers (aged 3-5 years)</td>
<td>Between 11 and 13 hours of sleep</td>
</tr>
<tr>
<td></td>
<td>(including nap time)</td>
</tr>
<tr>
<td>School-aged Children (1st through to 5th grade)</td>
<td>Between 10 and 11 hours</td>
</tr>
<tr>
<td></td>
<td>(usually do not need a nap)</td>
</tr>
</tbody>
</table>

How can I tell my child is NOT getting enough sleep?
If your child seems sleepy during the day, they are likely not getting enough sleep. Even if they are sleeping the recommended hours for their age group, your child may not be getting good quality sleep. This means that they are not reaching the deeper stages of sleep such as stage 4 and REM.

Signs that your child is overtired may be the opposite of what you might expect. Besides yawning or rubbing sleepy eyes, your child may show different signs of sleepiness such as ‘acting out’ or becoming ‘hyper’ around bedtime. Other signs that your child may not be getting enough sleep may include:

- Drowsiness or falling asleep every time they get in the car
- Being cranky and irritable during the day, or has behavioral problems such as getting into arguments.
- Mood swings or is irritable.
- Difficulties with concentration.
- Difficulties falling asleep, and staying asleep during the night.
- Needs to be woken up by you every morning.
- Often falls asleep at school during class time.
- Performing poorly at school.

Avoid Caffeine Intake
Coffee and tea are drinks most people know contain caffeine, but drinks such as colas, energy drinks and many other soft drinks also contain caffeine. Also, other treats such as chocolate or chocolate chip cookies contain caffeine. Caffeine acts as a stimulant and makes it very difficult for your child or even an adult to fall asleep and stay asleep.

Health Canada has made the following recommendation of maximum daily caffeine intake for children age 12 and under; children aged 4-6 should not consume more than 45 mg of caffeine daily, children aged 7-9 receive no more than 62.5 mg, and children aged 10-12 consume no more than 85mg (Health Canada, 2010). The table below provides some examples of caffeine contained in various beverages:

<table>
<thead>
<tr>
<th>Beverage Type or Food Item</th>
<th>Amount of Caffeine</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 can of caffeinated soda pop (e.g., coke, sprite, mountain dew)</td>
<td>45 mg</td>
</tr>
<tr>
<td>8oz cup of coffee</td>
<td>130 mg</td>
</tr>
<tr>
<td>1 can (250mL) Energy Drink (e.g., Red Bull)</td>
<td>80-140 mg</td>
</tr>
<tr>
<td>16 oz grande coffee at Starbucks</td>
<td>330 mg</td>
</tr>
<tr>
<td>16oz bottle of Snapple Iced Tea</td>
<td>48 mg</td>
</tr>
<tr>
<td>Hersey’s Special Dark Chocolate Bar (1.5 oz or 1 bar)</td>
<td>31 mg</td>
</tr>
</tbody>
</table>

While in hospital it may be difficult to set limits for your child. This is normal. If you are using treats that contain caffeine as a reward, such as chocolate milk, try to consume 6 hours prior to your child’s bedtime. A glass of milk or a cup of warm milk may be a better substitute.
Avoid Exposure to Bright Lights and Engaging in Stimulating Activity Just Before Bedtime

Each of us has an “internal clock” that takes in information about the lighting conditions around us. The amount of light that we are exposed to signals our brains to associate daytime with being awake and alert, and nighttime with being sleepy.

The exposure of bright light from playing a video game or watching an exciting program on television or a movie stimulates your child and causes arousal, which makes them sleep less. Research has shown that children who have a computer or television in their room sleep less on average than children who don’t.

While in hospital it is important to expose your child to natural light or bright light during the day. This signals to your child that it is daytime.

If your child is unable to go outside, provide him/her with other opportunities to socialize during the day such as taking him/her for a walk (if able) or to the play area of the hospital (if able).

Although each room at SickKids is equipped with a television and DVD/VCR player, try to avoid this type of stimulating activity at least 1 hour before your child’s bedtime.

Common Sleep Problems:

All children and adults wake briefly throughout the night, but so briefly that we don’t usually remember. These brief awakenings are just our brain’s way of making sure everything is safe around us and then we can quickly go back to sleep again.

Preschoolers

* A child who has not learned how to fall asleep on his own at bedtime may not be able to return to sleep when he/she wakes in the middle of the night without help from his parents because his brain has identified that something is different and he/she needs his/her parents to recreate the way in which he fell asleep at the beginning of the night.
* Preschoolers have expanded language and cognitive skills, which may lead to increased bedtime resistance. If your preschooler stalls at bedtime, be sure to set clear limits, such as how many books you will read.
* Anticipate hearing “Just ONE more, PLEASE!!” The key is to be consistent whether it’s a story or song or glass of water!
* Preschoolers have a wild imagination, which may heighten nighttime fears. Nighttime fears and nightmares are a normal part of your child’s development. Children may complain of a fear of robbers, monsters, unexplained sounds, and darkness. These fears may then turn into frightening dreams or nightmares.

- During hospitalization your child is exposed to a new environment.
- Hospitals can be a scary place for children because of the unknown.
- Fears of separation from parents for a procedure or fear of pain can make children anxious therefore making falling asleep a difficult task.

*See Sleep During Hospitalization for some tips on how to make bedtime easier while you’re in hospital or when you go home.
School-Aged Children

* School-aged children may have social anxiety, which may lead them to worry at night, interfering with their ability to fall asleep.
* In older school-aged children, concerns about schoolwork may keep them from sleeping. Grade school children strive for independence from their parents and rely more on their friends. This may result in less enforcement of appropriate bedtimes and inadequate sleep duration.
* Involvement in academic social, athletic, and family activities, as well as parent work schedules, may conflict with time for sleep and cause irregularity of sleep-wake schedules.

Relaxing Bedtime Routine

- Start the night with a relaxing bedtime routine.
- Keeping a familiar routine is comforting for children.
- Never cancel this ritual because of misbehavior earlier in the day.
- Before leaving your child’s bedroom, ask, “Do you need anything else?”

Set Clear Limits

- Setting clear limits and enforcing them will help your child know you are not kidding around.
- Tell your child how many stories you will read upfront. Expect that your child will ask you for “Just ONE more PLEASE!” If you decide that there is only time for 2 stories then stick to it.

Establish Rules

- Enforce the rule that once the bedtime routine is over your child is placed in the bed.

Praise Appropriate Sleeping Behaviour

- Following the bedtime sequence and praising your child for completing each activity, including going to bed may teach a child bedtime cooperation.
- Praise your child in the morning if he stayed in his bedroom all night.
- Tell your child that people are happier when they get a good night’s sleep.
- If your child fought bedtime and fell asleep late, wake him/her up at the regular time in the morning to help keep his regulate sleep/wake schedule.

Bedtime Routine in Hospital

While in hospital you may find it difficult to establish a bedtime routine or you may find that your usual bedtime routine is disrupted being in a new environment. Try to encourage as much of your bedtime routine from home as possible. For instance, after your nurse has assessed your child and has administered his/her medications, try to engage in some relaxing activities such as a bedtime story, songs, or cuddles. Your child may also benefit from a familiar object from home such as a “blankie” while hospitalized.
Establish a Relaxing Bedtime Routine
It is helpful to establish a bedtime routine that is the same every night and includes calm and enjoyable activities.

- Pre-bedtime routines help prepare your child physiologically and behaviorally to wind down before bed and signal to him/her that bedtime is approaching.
- Always doing things in the same order trains your child's brain to start shutting down.
- Activities that can help with your child's normal daily rhythm and signals to your child that it is “sleepy time” may include:
  - Having a warm bath
  - Brushing teeth
  - Putting on pajamas
  - Reading bedtime stories

Once you determine your child's natural bedtime, develop a 20-minute or so fixed sequence of calming pre-bed activities. The activities occurring closest to 'lights out' should occur in the room where your child sleeps.

Bedtime Resistance
Remember, your child may show signs of bedtime resistance such as:

- Coming out of their bedroom.
- Asking ongoing questions.
- Repeated requests such as, “I need to go to the bathroom” or “Can I have some water?”
- Protesting, crying, or temper tantrums when you leave the room.

Sleep During Hospitalization and Beyond
Optimal sleep is especially important during times of illness but is sometimes hard to achieve. Getting good quality sleep helps the body repair itself and recover from injury. During your hospital stay it may be hard for your child to fall asleep and stay asleep. Here are some reasons why:

Noise and Interruptions
Hospitals can be quite noisy. Sources of noise can include:

- Hospital equipment
- Alarms
- Telephones and the intercom systems
- Interruptions from health care professionals coming to assess your child.

Pain or Discomfort

- Pain from a procedure may disturb your child’s sleep. If your child has pain it is important that it is managed properly with pain medication. Talk to your nurse if you have concerns.
- Other factors may include the development of a fever, or vomiting.
- These things may be unpredictable and cause frequent awakenings in your child during the night, as well as increase the time it takes your child to fall back asleep.

Fear and Anxiety

- Whether planned or on an emergency basis, it is normal for a child to experience certain fears when they are hospitalized.
- A common source of fear is being separated from their parents.
- Parents may also have fears about the hospital experience making it difficult to reassure the child. Children can easily pick up parental anxiety as well making the child more fearful.
- The hospital can be a frightening place full of unfamiliar things, sounds, and people. This can make sleeping difficult since the child may be tense with their unfamiliar surrounding. Frequent interruptions from health care professionals may also add to the anxiety of a child making it more difficult to fall asleep and stay asleep.
- Even after hospitalization you may notice that your child has developed new behaviours that never existed. In addition to sleep problems, these new behaviours may include bed-wetting, poor eating, and tantrums.

Dealing with Bedtime Resistance
Attempts to resist bedtime are not unusual, but can be exhausting for parents and caregivers. If you find that your child is resisting bedtime here are some tips:

- Relaxing Bedtime Routine
- Set Clear Limits
- Establish Bedtime Rules
- Praise Appropriate Sleeping Behaviour
Developing Good Sleep Habits
Getting enough sleep is crucial to the development of your child. Whether a sleep problem existed prior to hospitalization, developed during hospitalization, or developed after your hospital stay, there are things that you can do to help your child get the sleep they need.

Developing good sleep hygiene practices is an important key in helping your child get the sleep they need. Sleep hygiene are habits or simple guidelines meant to promote a good night’s sleep.

Sleep hygiene practices include:
* Developing a regular sleep schedule
* Establishing a relaxing bedtime routine
* Avoiding bright lights or stimulating activity just before bed.
* Avoiding caffeine drinks or substances that contain caffeine.

Develop a Regular Sleep Schedule
To help your child become a good sleeper try to encourage the same wake up time and the same bedtime every day. Given the hustle and bustle of every day life, parents struggle to maintain a sleep schedule, however children who have a predictable bedtime and waketime have less difficulty falling asleep than children who don’t have a regular sleep schedule.

Sleeping and Waking Up at the Same Time
- A regular waketime is important even on the weekend as it sets the ‘start’ button for the day.
- Remember, our brain has a timekeeping system that picks up cues from the environment.
- Our brain associates daylight with being awake and darkness with sleepiness.
- Getting up at the same time helps to keep your body clock synchronized with what is going on outside.
- If your child sticks to a fairly regular waking and sleep time their body will become accustomed to it.
- If your child’s schedule is all over the place, the brain gets confused. This results in more difficulty falling asleep at bedtime, or falling asleep at inappropriate times like the classroom.

Predictable Activities
- Predictable timing of social and family activities, mealtimes, and bedtimes will help your child develop more regular rhythms.
- This will also help cue the brain that it’s time to start winding down.

Watch for Signs of Sleepiness
- Try and keep an eye out for your child’s tired signs.
- Remember, children may not always show the “classic” sleepy signs such as yawning or stretching.
- You may see changes in their mood when they are tired such as increased irritability, they may get frustrated more easily, or become aggressive or hyperactive.
- Encourage a bedtime based on these signs.
- Missing the “window of opportunity” when your child falls asleep most easily, makes for greater difficulties getting him/her to bed.

Sleep Schedule while Hospitalized
- While your child is in hospital it may be difficult to establish a regular sleep schedule or you may find it impossible to keep your at-home routine.
- The hospital environment may not be conducive to your child’s sleep needs because of loud noises, interruptions from your child’s health care providers, or your child may have pain, feel anxious, or worried.

TIPS to help your child sleep better while in hospital:
* IF your child is able, take your child out for a walk, even just to the playroom. Exposure to bright light during the day can help regulate the brain’s natural sleep/wake rhythm.
* If your child is NOT able to leave their room, try opening the lights and the blinds to the windows to let in some natural light during the day. In the evening time, draw the blinds and curtains to prevent the bright lights in the hallway from getting in the way of sleep. If the blinds are drawn and the lights are off during the day, sleeping during the day might be more likely and might make it harder to sleep at night.
* Talk to your nurse to see if you can come up with a bedtime for your child that works for everyone. Your nurse may be able to conduct routine assessments and provide your child’s medications early in the night to allow for your child to get to bed at the same time every night.
* Bring a transitional object like a favourite blanket or a teddy bear that your child enjoys sleeping with.
Appendix H

RELAXATION BREATHING SCRIPT
Relaxation Script

One way to relax your body is by breathing deeply. Let's get ready to relax. I will now lead you through a breathing exercise to help you relax. Close your eyes, and take a deep breathe in….now breathe out.

Breathe in (count 1, 2, 3,...) ...and breathe out (count, 1, 2, 3)...

Keep breathing slowly like this. Feel how it relaxes you to breathe deeply.

Now place both hands on your belly and notice your belly as you breathe in and out…. Notice how your belly moves up and down…. Imagine that your body is like a balloon. When you breathe in, feel your chest and sides expanding, like a balloon filling with air. Now, when you breathe out, imagine your body is like a balloon shrinking with the air being let out. (Parent…to breathe….out….allowing the sound of the air….coming out of your lung….to coincide with the air coming out of the child’s belly (balloon).

Breathe in like a balloon being blown up…(count here, 1,2,3,…using sounds of air coming into lungs)…Now breathe out, (count 1,2,3) allowing the feeling of air to be like air coming out of a balloon. Let the air out by blowing the air through your mouth.

Breathe in through your nose; (1,2,3) imagining your body expanding like a balloon….and now imagine letting the end of the balloon go, and the air rushing out as you breathe out through your mouth.

Now imagine that you are filling up, like the air in a balloon. Imagine that you breathe air into your lungs, and then when you breathe out through your mouth, imagine that you are filling up ….like the balloon. Each breath you blow makes the balloon feel like it is getting even bigger….with your bigger breathes….feel that …growing….your lungs, like the balloon are getting bigger with the air...

As you breathe in and out…..imagine filling the balloon as it gets bigger and bigger with each breath out. Breathe in... and then blow
up the balloon even more….allowing it to become
bigger….bigger….bigger.

Now, imagine letting go of the balloon, so it flies around the room as
the air escapes.

Watch it floating around the room…and notice how your body feels
now….Feel your body relaxing just like a light…empty balloon.
Continue the relaxation breathing.

Continue breathing slowly and deeply. Let your whole body become
relaxed. See how relaxed you can make your body….allow yourself to
feel more and more relaxed…and quiet…and feeling
good…very…very…calm…notice how calm you feel now…

Now your body feels heavy and relaxed.

Relax even more by noticing your breathing again. See how calm
your breathing is. In…and out….in…and out…..

Keep breathing and simply relax. There is nothing you need to do
right now except relax quietly…and enjoy the calmness that you feel

Your body feels heavy and relaxed.

Relax even more by noticing your breathing again. See how calm
your breathing is. In…and out…..in….and out…..

Keep breathing and simply relax. There is nothing you need to do
right now except relax quietly…and enjoy the calmness that you feel…you allowed yourself to become more calm and relaxed…your
are in control…

See how calm and relaxed you feel. It feels good to relax.

Your relaxation time is finished now. Keep your eyes closed for a little
longer. Enjoy this calm feeling.

You can do this on your own…or with the story/or CD…just on your
own…any time you need to feel that calmed state, feeling of
relaxation….or help you rest or prepare to go to bed and sleep….
Appendix I

INTERVENTION FIDELITY CHECKLIST
INTERVENTION FIDELITY CHECKLIST

Please check to indicate that you feel the topic was well-covered or that the relaxation technique was effectively used. Please explain any boxes left unchecked in the “Comments” section.

<table>
<thead>
<tr>
<th>Things to know about the importance of sleep in children:</th>
<th>Things to know about sleep hygiene:</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Growth and Development</td>
<td>☐ Develop a regular sleep schedule</td>
</tr>
<tr>
<td>☐ Reparative Roles</td>
<td>☐ Establish a relaxing bedtime routine</td>
</tr>
<tr>
<td>☐ Learning &amp; Memory</td>
<td>☐ Avoiding bright lights or stimulating activity just before bed</td>
</tr>
<tr>
<td>Things to know about how sleep works and driving forces of sleep:</td>
<td>☐ Limit or avoid caffeine</td>
</tr>
<tr>
<td>☐ Sleep Stages</td>
<td>Tips for sleep hygiene practices in during hospital stay:</td>
</tr>
<tr>
<td>☐ Homeostatic Process</td>
<td>☐ Exposure to bright light during the day.</td>
</tr>
<tr>
<td>☐ Circadian Rhythm</td>
<td>☐ Limit exposure to bright light during the night.</td>
</tr>
<tr>
<td>Things to know about sleepiness:</td>
<td>☐ Talk to nurse for a mutually agreed upon bedtime</td>
</tr>
<tr>
<td>☐ Recommended amount of sleep by age group</td>
<td>☐ Bring a transitional object (i.e., blanket or teddy bear).</td>
</tr>
<tr>
<td>☐ Signs of sleepiness</td>
<td>Tips about dealing with bedtime resistance:</td>
</tr>
<tr>
<td>☐ Common sleep problems</td>
<td>☐ Set clear limits</td>
</tr>
<tr>
<td>Things to know about sleep during hospitalization:</td>
<td>☐ Establish rules</td>
</tr>
<tr>
<td>☐ Environmental Factors - Noise</td>
<td>☐ Praise appropriate sleep behaviour</td>
</tr>
<tr>
<td>• Hospital equipment/alarms</td>
<td>Things to know about Relaxation Breathing:</td>
</tr>
<tr>
<td>• Telephones/intercom systems</td>
<td>☐ Describe relaxation breathing</td>
</tr>
<tr>
<td>• Clinicians coming in to assess child.</td>
<td>☐ Importance of relaxation breathing for sleep.</td>
</tr>
<tr>
<td>☐ Pain or Discomfort</td>
<td>☐ Teaching relaxation breathing to children.</td>
</tr>
<tr>
<td>• Pain from procedure</td>
<td></td>
</tr>
<tr>
<td>• Fever, N&amp;V</td>
<td></td>
</tr>
<tr>
<td>☐ Fear and Anxiety</td>
<td></td>
</tr>
<tr>
<td>• Separation anxiety</td>
<td></td>
</tr>
<tr>
<td>• Parental anxiety</td>
<td></td>
</tr>
<tr>
<td>• Anxieties post-hospitalization</td>
<td></td>
</tr>
</tbody>
</table>

Comments (use back of page if needed):
INTERVENTION FORM

1. Who was present for the intervention (tick all that apply)?
   
   Child:  □ present for **some** of the intervention  
           □ present for **all** of the intervention  
   
   Mother: □ present for **some** of the intervention  
           □ present for **all** of the intervention  
   
   Father: □ present for **some** of the intervention  
           □ present for **all** of the intervention  
   
   Other: □ present for **some** of the intervention  
           □ present for **all** of the intervention  
   
   Please specify: ____________________________

2. Who gave the intervention?

   □ PI (EP)  □ RA ____ (initial here)

3. Date intervention given: □□□□ □□ □□
   year      month    day

4. What parts of the intervention were given:

   □ ALL PARTS (in-person, booklet, and book OR CD)

   If all parts were not given, tick all that were done/given.  
   □ Booklet  
   □ Book OR CD  
   □ Nothing
Appendix J

Sleep Diary
RELAX TO SLEEP STUDY

SLEEP DIARY
CHILDREN 4 TO 10 YEARS OLD

Contact Information:

Efrosini Papaconstantinou, RN, BScN, MSc, PhD Candidate
Cell: XXX-XXX-XXXX

The Hospital for Sick Children (SickKids)
Cardiology (4D), General Surgery (5B), and General Pediatrics (7B, 7C and 7D)
555 University Ave
Toronto, Ontario M5G 1X8

Note: If at anytime you are no longer able to be in the study, please call the contact above and return this sleep diary and your actigraph to the front desk.
Thank you.
EXAMPLE: _______________

INSTRUCTIONS: Fill in the times your child is asleep with shaded boxes.
Leave blank the times your child is awake.
Fill in the times when you (the parent) are in the room with shaded boxes.
Leave blank the times you are not present in the room.

For example: Your child fell asleep at 9pm. Your child was woken up by the nurse for medications at 10pm. You were in the room from 8 to 10pm and 10:30pm to 7am. Your child fell back to sleep at 10:30pm and woke up at 6am when a nurse arrived to take blood.

Night-time:

<table>
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<th>Time</th>
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<th>8P</th>
<th>8:30</th>
<th>9P</th>
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<th>10P</th>
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<th>11P</th>
<th>12A</th>
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<th>5:30</th>
<th>6A</th>
<th>6:30</th>
<th>7A</th>
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<tbody>
<tr>
<td>Child’s sleep:</td>
<td></td>
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<td></td>
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<td>Parent in the room:</td>
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</table>
INSTRUCTIONS: Fill in the times your child is asleep with shaded boxes. Leave blank the times your child is awake. Fill in the times when you (the parent) are in the room with shaded boxes. Leave blank the times you are not in the room.

Day-time:

| Time  | 7:30 | 8A  | 8:30 | 9A  | 9:30 | 10A | 10:30 | 11A | 11:30 | 12P | 12:30 | 1P  | 1:30 | 2P  | 2:30 | 3P  | 3:30 | 4P  | 4:30 | 5P  | 5:30 | 6P  | 6:30 | 7P  | 7:30 |
|-------|------|-----|------|-----|------|-----|--------|-----|-------|-----|--------|-----|------|-----|------|-----|------|-----|------|-----|------|-----|------|-----|
| Sleep |      |     |      |     |      |     |        |     |       |     |        |     |      |     |      |     |      |     |      |     |      |     |      |     |
| Room  |      |     |      |     |      |     |        |     |       |     |        |     |      |     |      |     |      |     |      |     |      |     |      |     |

Night-time:

| Time  | 7:30 | 8P  | 8:30 | 9P  | 9:30 | 10P | 10:30 | 11P | 11:30 | 12A | 12:30 | 1A  | 1:30 | 2A  | 2:30 | 3A  | 3:30 | 4A  | 4:30 | 5A  | 5:30 | 6A  | 6:30 | 7A  | 7:30 |
|-------|------|-----|------|-----|------|-----|--------|-----|-------|-----|--------|-----|------|-----|------|-----|------|-----|------|-----|------|-----|------|-----|
| Sleep |      |     |      |     |      |     |        |     |       |     |        |     |      |     |      |     |      |     |      |     |      |     |      |     |
| Room  |      |     |      |     |      |     |        |     |       |     |        |     |      |     |      |     |      |     |      |     |      |     |      |     |

Did your child take the actigraph off in the last 24-hours (7:30 AM yesterday to 7:29AM today)?

☐ No ☐ Yes ➔ If yes, please note the time and how long the actigraph was off below:
DAY 2: ____________ MORNING
(DAY OF THE WEEK)

1. Which unit did your child sleep in last night? ○ Cardiology Unit (4D) ○ 5B ○ 7B/C/D ○ Other (Please specify): _____

2. Was a nurse in the room with your child most or all of the night? ○ Yes ○ No

3. How was your child’s sleep last night compared to how your child usually sleeps?
   ○ Much worse ○ A little worse ○ About the same ○ A little better ○ Much better

4. Did anyone else stay in the same room as your child last night?
   ○ No ○ Yes
   ➔ If yes, please indicate. (Check ALL that apply)
   ○ Mother ○ Sibling ○ Other Patient’s family members
   ○ Father ○ Other Patient ○ Other: _____________

5. During the last 24-hours (7:30 AM yesterday to 7:29 AM today) what did you do to help your child fall asleep?
   Please describe here:
6. Child's Pain: The research nurse will help you fill out your child's pain score each morning.

Instructions: These faces show how much something can hurt. The face on far left shows no pain. The faces show more and more pain up to the one on the far right, which shows very much pain. Point to the face that shows how much you hurt.

Time completed: \(\square\square:\square\square\) AM/PM
INSTRUCTIONS: Fill in the times your child is asleep with shaded boxes. Leave blank the times your child is awake. Fill in the times when you (the parent) are in the room with shaded boxes. Leave blank the times you are not in the room.

Day-time:

<table>
<thead>
<tr>
<th>Time</th>
<th>7:30</th>
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<td>Child’s sleep:</td>
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Night-time:

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<tr>
<th>Time</th>
<th>7:30</th>
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<td>Parent in the room</td>
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</table>

Did your child take the actigraph off in the last 24-hours (7:30 AM yesterday to 7:29AM today)?

☐ No  ☐ Yes ➔ If yes, please note the time and how long the actigraph was off below:


DAY 3: ____________ MORNING

1. Which unit did your child sleep in last night? ○ Cardiology Unit (4D) ○ 5B ○ 7B/C/D ○ Other (Please specify):_____
2. Was a nurse in the room with your child most or all of the night? ○ Yes ○ No
3. How was your child’s sleep last night compared to how your child usually sleeps?
   ○ Much worse ○ A little worse ○ About the same ○ A little better ○ Much better
4. Did anyone else stay in the same room as your child last night?
   ○ No ○ Yes
   ⇒ If yes, please indicate. (Check ALL that apply)
   ○ Mother ○ Sibling ○ Other Patient’s family members
   ○ Father ○ Other Patient ○ Other: ______________
5. During the last 24-hours (7:30 AM yesterday to 7:29 AM today) what did you do to help your child fall asleep?
   Please describe here:
DAY 3: __________ MORNING con’t

(DAY OF THE WEEK)

6. Child’s Pain: The research nurse will help you fill out your child’s pain score each morning.

Instructions: These faces show how much something can hurt. The face on far left shows no pain. The faces show more and more pain up to the one on the far right, which shows very much pain. Point to the face that shows how much you hurt.

Time completed: □□□□ AM/PM
INSTRUCTIONS: Fill in the times your child is asleep with shaded boxes. Leave blank the times your child is awake.
Fill in the times when you (the parent) are in the room with shaded boxes. Leave blank the times you are not in the room.

Day-time:

| 7:30   | S| S| S| S| S| S| S| S| S| S| S| S| S| S| S| S| S| S| S| S| S| S| S| S| S| S| S| S| S| S| S| S| S| S| S| S|
| 8:00   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| 9:00   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| 10:00  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| 11:00  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| 12:00  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| 1:00   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| 2:00   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| 3:00   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| 4:00   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| 5:00   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| 6:00   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| 7:00   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

Night-time:

| 7:30   | S| S| S| S| S| S| S| S| S| S| S| S| S| S| S| S| S| S| S| S| S| S| S| S| S| S| S| S| S| S| S| S| S| S| S| S|
| 8:00   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| 9:00   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| 10:00  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| 11:00  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| 12:00  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| 1:00   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| 2:00   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| 3:00   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| 4:00   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| 5:00   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| 6:00   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| 7:00   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

Did your child take the actigraph off in the last 24-hours (7:30 AM yesterday to 7:29AM today)?

☐ No  ☐ Yes ➔ If yes, please note the time and how long the actigraph was off below:

[Blank space]
DAY 4: __________ MORNING
(DAY OF THE WEEK)

1. Which unit did your child sleep in last night?  
   ☒ Cardiology Unit (4D)  ☒ 5B  ☒ 7B/C/D  ☒ Other (Please specify): _____

2. Was a nurse in the room with your child most or all of the night?  
   ☒ Yes  ☒ No

3. How was your child’s sleep last night compared to how your child usually sleeps?  
   ☒ Much worse  ☒ A little worse  ☒ About the same  ☒ A little better  ☒ Much better

4. Did anyone else stay in the same room as your child last night?  
   ☒ No  ☒ Yes  
   ➔ If yes, please indicate. (Check ALL that apply)  
   ☒ Mother  ☒ Sibling  ☒ Other Patient’s family members  
   ☒ Father  ☒ Other Patient  ☒ Other: ______________

5. During the last 24-hours (7:30 AM yesterday to 7:29 AM today) what did you do to help your child fall asleep?  
   Please describe here:
DAY 4: __________ MORNING con’t

(DAY OF THE WEEK)

6. Child’s Pain: The research nurse will help you fill out your child’s pain score each morning.

Instructions: These faces show how much something can hurt. The face on far left shows no pain. The faces show more and more pain up to the one on the far right, which shows very much pain. Point to the face that shows how much you hurt.

Time completed: □□:□□ AM/PM
INSTRUCTIONS: Fill in the times your child is asleep with shaded boxes. Leave blank the times your child is awake.
Fill in the times when you (the parent) are in the room with shaded boxes. Leave blank the times you are not in the room.

Day-time:

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<tr>
<th>Time</th>
<th>7:30</th>
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<td>Child's sleep:</td>
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Appendix K

**Final Questionnaire**
### The Children’s Sleep Habits Questionnaire

The following statements are about your child’s sleep habits and possible difficulties with sleep after your hospital stay. Think about the week after your child was discharged from hospital when answering these questions. Answer **USUALLY** if something occurs **5 or more times** in a week; answer **SOMETIMES** if it occurs **2 – 4 times** in a week; answer **RARELY** if something occurs **never or 1 time** during a week.

#### Bedtime

Write in child’s USUAL bedtime:  

<table>
<thead>
<tr>
<th></th>
<th>Weeknights</th>
<th>Weekends</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hours</td>
<td>Minutes</td>
<td>Hours</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Statement</th>
<th>Usually (5-7)</th>
<th>Sometimes (2-4)</th>
<th>Rarely (0-1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Child goes to sleep at the same time at night</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Child falls asleep within 20 minutes after going to bed</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td>Child falls asleep alone in own bed</td>
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<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Child falls asleep in parent’s or sibling’s bed</td>
<td>☐</td>
<td>☐</td>
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</tr>
<tr>
<td>Child needs parent in the room to fall asleep</td>
<td>☐</td>
<td>☐</td>
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</tr>
<tr>
<td>Child struggles at bedtime (cries, refuses to stay in bed, etc.)</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Child is afraid of sleeping in the dark</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Child is afraid of sleeping alone</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

#### Sleep Behavior

Child’s usual amount of sleep each day:  

(Combining nighttime sleep and naps)  

<table>
<thead>
<tr>
<th></th>
<th>Weekdays</th>
<th>Weekends</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hours</td>
<td>Minutes</td>
<td>Hours</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Statement</th>
<th>Usually (5-7)</th>
<th>Sometimes (2-4)</th>
<th>Rarely (0-1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Child sleeps too little</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Child sleeps the right amount</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Child sleeps about the same amount each day</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Child wets the bed at night</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Child talks during sleep</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Child is restless and moves a lot during sleep</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Child sleepwalks during the night</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Child moves to someone else’s bed during the night (parent, brother, sister, etc)</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Child grinds teeth during sleep (your dentist may have told you this)</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td>Child snores loudly</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td>Child seems to stop breathing during sleep</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Child snorts and/or gasps during sleep</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Child has trouble sleeping away from home (visiting relatives, vacation)</td>
<td>☐</td>
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</table>
### Waking During the Night

<table>
<thead>
<tr>
<th>Event</th>
<th>Usually (5-7)</th>
<th>Sometimes (2-4)</th>
<th>Rarely (0-1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Child awakens during night screaming, sweating, and inconsolable</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Child awakens alarmed by a frightening dream</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Morning Waking**

Write in the time of day child usually wakes in the morning:

- **Weekdays**: [ ] [ ] [ ]
- **Weekends**: [ ] [ ] [ ]

<table>
<thead>
<tr>
<th>Event</th>
<th>Usually (5-7)</th>
<th>Sometimes (2-4)</th>
<th>Rarely (0-1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Child wakes up by him/herself</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Child wakes up in negative mood</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adults or siblings wake up child</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Child has difficulty getting out of bed in the morning</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Child takes a long time to become alert in the morning</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Daytime Sleepiness

<table>
<thead>
<tr>
<th>Event</th>
<th>Usually (5-7)</th>
<th>Sometimes (2-4)</th>
<th>Rarely (0-1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Child seems tired</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

During a usual week has your child appeared sleepy or fallen asleep during the following (check all that apply):

<table>
<thead>
<tr>
<th>Activity</th>
<th>Very Sleepy</th>
<th>Falls Asleep</th>
<th>Not Applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Watching TV</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Riding in a car</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
The next section lists items that describe children. For each item please choose the response that best describes your child from: very often true, quite often true, sometimes true, seldom true or if it is not true at all. Please answer all the items as well as you can, even if some do not seem to apply to your child.

<table>
<thead>
<tr>
<th></th>
<th>NOT True at All</th>
<th>Seldom True</th>
<th>Sometimes True</th>
<th>Quite Often True</th>
<th>Very Often True</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Has difficulty stopping him/herself from worrying....</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>2. Is tense, restless or irritable due to worrying</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>3. Is reluctant to go to sleep without you or to sleep away from home</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>4. Has trouble sleeping due to worrying</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>5. Worries that something bad will happen to his/her parents</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>6. Spends a large part of each day worrying about various things</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>7. Worries that something bad might happen to him/her (e.g., getting lost or kidnapped), so he/she won’t be able to see you again</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>8. Becomes distressed about your leaving him/her at preschool/school or with a babysitter</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>9. Has nightmares about being apart from you</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>10. Asks for reassurance when it doesn’t seem necessary</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>
Spence Children’s Anxiety Scale  
(Parent Report)

The next section lists items that describe children. For each item please choose the response that best describes your child from: very often true, quite often true, sometimes true, seldom true or if it is not true at all. Please answer all the items as well as you can, even if some do not seem to apply to your child.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th>Never</th>
<th>Sometimes</th>
<th>Often</th>
<th>Always</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. My child worries about things.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. When my child has a problem, she/he complains of having a funny feeling in his/her stomach.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. My child would feel afraid of being on his/her own at home.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. My child worries about being away from us/me.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. My child worries that something awful will happen to someone in our family.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. My child is scared if she/he has to sleep on his/her own.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. My child has trouble going to school in the mornings because she/he feels nervous or afraid.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. When my child has a problem, she/he complains of his/her heart beating really fast.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. My child worries that something bad will happen to him/her.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11. When my child has a problem, she/he feels shaky.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12. My child would feel scared if she/he had to stay away from home overnight.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13. Is there anything else that your child is really afraid of?</td>
<td>YES</td>
<td>NO</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Please write down what it is, and fill out how often she/he is afraid of this thing:
Post Hospital Behaviours
I am now going to read you some items related to your child’s behaviour. For each, I would like you to rate the extent to which each behaviour changed in frequency as compared with PRIOR to your child being hospitalized. Response options are: 1) Much less than before, 2) Less than before, 3) Not changed, 4) More than before, and 5) Much more than before. Please answer all the items as well as you can, even if some do not seem to apply to your child.

<table>
<thead>
<tr>
<th>Item</th>
<th>Much Less than before</th>
<th>Less than before</th>
<th>Not Changed</th>
<th>More than before</th>
<th>Much More than before</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Does your child make a fuss about going to bed at night?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>2. Does your child make a fuss about eating?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>3. Does your child spend time just sitting or lying and doing nothing?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>4. Does your child need a pacifier?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>5. Does your child seem to be afraid of leaving the house without you?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>6. Is your child uninterested in what goes on around him/her?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>7. Does your child wet the bed at night?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>8. Does your child bite his/her fingernails?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>9. Does your child get upset when you leave him/her alone for a few minutes?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>10. Does your child need a lot of help doing things?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>11. Is it difficult to get your child interested in doing things (like playing games, with toys, and so on?)</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>12. Does your child seem to avoid or be afraid of new things?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>13. Does your child have difficulty making up his or her mind?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>14. Does your child have temper tantrums?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>15. Is it difficult to get your child to talk to you?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>16. Does your child seem to get upset when someone mentions doctors or hospitals?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>17. Does your child follow you everywhere around the house?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>18. Does your child spend time trying to get or hold your attention?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>19. Is your child afraid of the dark?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>20. Does your child have bad dreams or wake up and cry?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>21. Is your child irregular in his/her bowel movements?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>22. Does your child have trouble getting to sleep at night?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>23. Does your child seem to be shy or afraid around strangers?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>
24. Does your child have a poor appetite?  
25. Does your child tend to disobey you?  
26. Does your child break toys or other objects?  
27. Does your child suck his/her fingers or thumbs?

<p>| | | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td></td>
</tr>
</tbody>
</table>

Participant Satisfaction
The next few questions are about your experiences as a participant in the RELAX TO SLEEP study.

1. What did you like about being in the RELAX TO SLEEP study? (mark all that apply)
   - Contacts with the research team.
   - Randomized to the group I wanted.
   - Being in the RELAX TO SLEEP study helped me feel reassured.
   - Helped to find answer to an important research question.
   - There was nothing I liked about being a participant in the RELAX TO SLEEP study.
   - Other ________________

2. What did you dislike about being in the RELAX TO SLEEP study (check all that apply)
   - Contacts with the research team.
   - Not randomized to the group I wanted.
   - Participating in the RELAX TO SLEEP study caused me to feel worried.
   - Disliked the extra demands on my time.
   - Disliked nothing
   - Other ___________________

3. If you had the decision to make again, would you choose to be in the study? (choose only one).
   - Definitely yes
   - Probably yes
   - Probably not
   - Definitely not
   - Not sure

Actigraphy Device
The next questions are about your child’s experiences with the Actigraph Device. Based on the 3 days that your child was wearing the actigraph please rate the extent to which you agree or disagree with the following statements.

1. The actigraph caused my child discomfort.
   - Strongly Disagree
   - Disagree
   - Neither Agree nor Disagree
   - Agree
   - Strongly Agree

2. Wearing the actigraph interfered with my child’s activities.
   - Strongly Disagree
   - Disagree
   - Neither Agree nor Disagree
   - Agree
   - Strongly Agree
3. Wearing the actigraph caused my child to worry.
   - □  Strongly Disagree
   - □  Disagree
   - □  Neither Agree nor Disagree
   - □  Agree
   - □  Strongly Agree

4. My child had problems with the actigraph not working properly.
   - □  Strongly Disagree
   - □  Disagree
   - □  Neither Agree nor Disagree
   - □  Agree
   - □  Strongly Agree

This concludes the end of the questionnaire. We would like to thank you for your time and effort during your participation in the RELAX TO SLEEP study. Are there any other comments about the study that you would like to make?

For Researcher: Please indicate the attempts that you tried to reach this family below:

<table>
<thead>
<tr>
<th>Attempt</th>
<th>Date</th>
<th>Time</th>
<th>Comments/Notes:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1&lt;sup&gt;st&lt;/sup&gt;</td>
<td>0□□□□ / □□ / □□</td>
<td>□□□□</td>
<td>24hr clock</td>
</tr>
<tr>
<td></td>
<td>year month day</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2&lt;sup&gt;nd&lt;/sup&gt;</td>
<td>0□□□□ / □□ / □□</td>
<td>□□□□</td>
<td>24hr clock</td>
</tr>
<tr>
<td></td>
<td>year month day</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3&lt;sup&gt;rd&lt;/sup&gt;</td>
<td>0□□□□ / □□ / □□</td>
<td>□□□□</td>
<td>24hr clock</td>
</tr>
<tr>
<td></td>
<td>year month day</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4&lt;sup&gt;th&lt;/sup&gt;</td>
<td>0□□□□ / □□ / □□</td>
<td>□□□□</td>
<td>24hr clock</td>
</tr>
<tr>
<td></td>
<td>year month day</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Date Questionnaire Completed: 0□□□□ / □□ / □□
                                   year       month       day
This questionnaire asks you to evaluate the RELAX TO SLEEP program, which you received by the researcher during your participation in the RELAX TO SLEEP study at SickKids. The program consisted of a discussion with the researcher about sleep, a booklet that you were given to keep, and a relaxation technique from a CD or a book. We are interested in knowing which parts of the program you used and how often, and how helpful they were to you for your hospital stay. Please answer as honestly as you can.

**Educational Booklet**
The next few questions are about the educational booklet you received from the researcher. Based on your meeting with the researcher and the booklet she/he provided, please rate the extent to which you agree or disagree with the following statements.

1. I enjoyed the one-on-one discussion with the researcher.
   - [ ] Strongly Agree
   - [ ] Agree
   - [ ] Neither Agree nor Disagree
   - [ ] Disagree
   - [ ] Strongly Disagree

2. The information provided during the one-on-one discussion helped me to learn more about sleep and sleep issues during hospitalization.
   - [ ] Strongly Agree
   - [ ] Agree
   - [ ] Neither Agree nor Disagree
   - [ ] Disagree
   - [ ] Strongly Disagree

3. The educational booklet was easy to read and understand.
   - [ ] Strongly Agree
   - [ ] Agree
   - [ ] Neither Agree nor Disagree
   - [ ] Disagree
   - [ ] Strongly Disagree

4. The tips provided in the educational booklet were helped my child sleep during their hospital stay.
   - [ ] Strongly Agree
   - [ ] Agree
   - [ ] Neither Agree nor Disagree
   - [ ] Disagree
   - [ ] Strongly Disagree
Relaxation Breathing
The next few questions are about the relaxation breathing exercise. Based on your child’s use of the relaxation breathing exercise over the course of hospitalization, please rate the extent to which you agree or disagree with the following statements.

1. The _______(read only one – book or CD) was easy to use.
   - Strongly Agree
   - Agree
   - Neither Agree nor Disagree
   - Disagree
   - Strongly Disagree

2. The instructions were easy to follow.
   - Strongly Agree
   - Agree
   - Neither Agree nor Disagree
   - Disagree
   - Strongly Disagree

3. My child enjoyed using the relaxation breathing exercise.
   - Strongly Agree
   - Agree
   - Neither Agree nor Disagree
   - Disagree
   - Strongly Disagree

4. I found that relaxation breathing helped my child calm down in stressful situations.
   - Strongly Agree
   - Agree
   - Neither Agree nor Disagree
   - Disagree
   - Strongly Disagree

5. I found that relaxation breathing helped my child relax and fall asleep easily.
   - Strongly Agree
   - Agree
   - Neither Agree nor Disagree
   - Disagree
   - Strongly Disagree

6. I would recommend relaxation breathing to other parents with children who are hospitalized.
   - Strongly Agree
   - Agree
   - Neither Agree nor Disagree
   - Disagree
   - Strongly Disagree

7. I would use relaxation breathing exercises with my child again in the future.
   - Strongly Agree
   - Agree
   - Neither Agree nor Disagree
   - Disagree
   - Strongly Disagree
Below are a list of the sleep tips that were covered in your session with the researcher and the booklet that you were given. Thinking of your hospital stay, we are interested in knowing, which tips you used and whether these tips were helpful.

Please rate how helpful each of the tips were for your child’s sleep in hospital:

(Please mark an answer for each tip).

<table>
<thead>
<tr>
<th>TIPS</th>
<th>Not used</th>
<th>Not helpful</th>
<th>Helped a little</th>
<th>Very helpful</th>
</tr>
</thead>
<tbody>
<tr>
<td>Child had same bedtime each night.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Child had same wake-up time each morning.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Child slept in a quiet room.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Child slept in a dark room.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Child slept in a cool room.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Child was exposed to bright light during the day (e.g., went for a walk, or opened up the window shades)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Child had no caffeine to eat or drink after lunchtime.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Child avoided stimulating activity such as watching television or playing video games prior to bedtime.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Child engaged in a calming bedtime routine.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Relaxation Breathing**

The next few questions are about the relaxation breathing exercise. Based on your child’s use of the relaxation breathing exercise over the course of hospitalization, please indicate how often the relaxation breathing technique was used.

<table>
<thead>
<tr>
<th>Relaxation Breathing</th>
<th>NEVER (0 times)</th>
<th>RARELY (1 time per day)</th>
<th>SOMETIMES (2-3 times per day)</th>
<th>OFTEN (&gt;3 times a day)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Child used relaxation breathing during their hospital stay.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Child used relaxation breathing if they were awoken in the middle of the night by a health care professional or a loud noise.</td>
<td></td>
<td></td>
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<tr>
<td>Child used relaxation breathing during stressful situations (e.g., needle, or vital signs).</td>
<td></td>
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<tr>
<td>Child used the relaxation breathing technique using the book or CD provided.</td>
<td></td>
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</tbody>
</table>
To be completed at follow-up with *Final Questionnaire* over the telephone.

This questionnaire asks you to evaluate the RELAX TO SLEEP program, which you received by the researcher during your participation in the RELAX TO SLEEP study at SickKids. The program consisted of a discussion with the researcher about sleep, a booklet that you were given to take home, and a relaxation technique from a CD or a book. We are interested in knowing which parts of the program you used and how often, and how helpful they were to you once you went home. Please answer as honestly as you can.

Below are a list of the sleep tips that were covered in your session with the researcher and the booklet that you were given. Thinking of when you went home, rate how helpful each of the tips were for your child’s sleep at home: *(Please mark an answer for each tip).*

<table>
<thead>
<tr>
<th>TIPS</th>
<th>Not used</th>
<th>Not helpful</th>
<th>Helped a little</th>
<th>Very helpful</th>
</tr>
</thead>
<tbody>
<tr>
<td>Child had same bedtime each night.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Child had same wake-up time each morning.</td>
<td></td>
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<tr>
<td>Child slept in a quiet room.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Child slept in a dark room.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Child slept in a cool room.</td>
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<td></td>
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<tr>
<td>Child was exposed to bright light during the day (e.g., went for a walk, or opened up the window shades)</td>
<td></td>
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<tr>
<td>Child had no caffeine to eat or drink after lunchtime.</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Child avoided stimulating activity such as watching television or playing video games prior to bedtime.</td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>Child engaged in a calming bedtime routine.</td>
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</tbody>
</table>

The next few questions are about the relaxation breathing exercise. Based on your child’s use of the relaxation breathing exercise at home, please indicate how often the relaxation breathing technique was used.

<table>
<thead>
<tr>
<th>Relaxation Breathing</th>
<th>NEVER (0 times)</th>
<th>RARELY (1 time per day)</th>
<th>SOMETIMES (2-3 times per day)</th>
<th>OFTEN (&gt;3 times a day)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Child used relaxation breathing once they were discharged home.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Child used relaxation breathing as part of a bedtime routine at home.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Child used the relaxation breathing technique using the book or CD provided in the home.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Did you share any of the information from the RELAX TO SLEEP program with another family while your child was hospitalized at SickKids?

Yes □

No □

This concludes the end of the questionnaire. We would like to thank you for your time and effort during your participation in the RELAX TO SLEEP study. Are there any other comments about the study that you would like to make?