

THE EFFECT OF EARPLUGS ON PERCEIVED SLEEP QUALITY OF ACUTE
CARE PATIENTS

by

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ABSTRACT

The purpose of this study was to evaluate the use of earplugs to improve perceived sleep quality in hospitalized patients. Sleep disruption is a common problem for hospitalized patients and has been shown to lead to physical and emotional complications. A variety of factors such as pain, illness, stress, worry, noise, lights and patient care activities contribute to disturbed sleep. Studies on sound in hospitals have shown that levels exceed recommendations by the Environmental Protection Agency. Limited research has shown that earplugs are a cost-effective, non-pharmacologic intervention with clinical usefulness to improve sleep quality.

The study design was a quasi-experimental pilot study using a pre-test and post-test with the participants serving as their own control. Participants were recruited from a telemetry unit at St. Vincent Healthcare in Billings, Montana. The Verran and Snyder-Halpern Sleep Scales were selected to measure sleep quality. Ten participants were able to complete the two nights of study. The proposed hypothesis was supported for the sleep characteristic, soundness of sleep, with an improvement greater than 15 mm on the night with the ear plugs. Subjective findings identified positive comments with only one participant unable to tolerate the earplugs.

The improvement in sleep was clinically significant for these participants. Hospitals should consider creating a sleep promotion policy and re-evaluating their night care practices. Earplugs could be included as an option for patients, and patients experiencing sleep difficulties should be encouraged to try earplugs. Further research is needed with a variety of populations and a large sample size. Research should also be done on nurses' knowledge and beliefs regarding sleep and sleep interventions. This information could provide useful information on areas where additional education is needed.

CHAPTER 1

INTRODUCTION

Many patients consider disturbed sleep a normal part of their hospital experience, and this could be said to be especially true in the intensive care unit. “Sleep is a basic need, much as food and water are for human survival” (Honkus, 2003, p. 179). Sleep impairment can eventually lead to sleep deprivation. Disturbed sleep has multiple negative effects including altered immune function, altered metabolic and endocrine function, altered wound healing, fatigue, impaired daytime functioning, impaired short-term memory, altered mood, low motivation, and impaired social and family interactions (Lee, 2003). Many factors can contribute to impaired sleep in the acute care setting. Noise, lights, therapeutic interventions, pain, medications, and psychological stress are just a few of the different factors that contribute to sleep impairment in the hospital (BaHammam, 2006). Patients who are critically ill are exposed to the same factors and experience more frequent patient care disturbances secondary to the severity of their illness including vital signs, x-rays, phlebotomy and medication administration (Weinhouse & Schwab, 2006). Often, the influence of these factors on sleep could be mitigated with simple interventions.

Noise, in particular, is known to affect sleep even in the best of circumstances. Sound levels in the hospital setting exceed recommendations set by the Environmental Protection Agency for hospital sound levels, and various studies have examined the effect that noise-reducing interventions have on sleep (Kahn, Cook, Carlisle, Nelson, Kramer & Millman, 1998; Monsen & Edell-Gustafsson, 2005; Moore, et al., 1998; Stanchina, Abu-

Hijleh, Chaudhry, Carlisle & Millman, 2005; Olson, Borel, Laskowitz, Moore & McConnell, 2001; Wallace, Robins, Alvord & Walker, 1999). This study evaluated if the use of earplugs by patients in the acute care environment improves perceived sleep quality.

Background and Significance

Basic information on the mechanisms of sleep is essential to understand the importance of sleep. Friedman (1999) stated that sleep is experienced from the sleeper's point of view as "(1) being the deliberate initiation of a change or reduction in consciousness lasting an average of 8 hours, (2) commencing about the same time each 24-hour period, and (3) usually resulting in a feeling of restored physical, emotional and intellectual energy" (p. 347).

Sleep has physiologic importance and adequate sleep is necessary for the maintenance of good health and well-being. Sleep is considered a necessary process in which the body is allowed time to repair and restore itself (BaHammam, 2006). Although the exact functions of overall sleep are poorly understood, certain theories have been proposed. One theory is that sleep plays a role in energy conservation (Neubauer, 2003). In this theory, sleep may provide an opportunity to restore energy stores by allowing a decrease in glucose and oxygen use in deep sleep, and an accumulation of brain glycogen stores and adenosine. Adenosine has a role in energy throughout the body by way of the ATP cycle (Neubauer, 2003). Adenosine antagonists, caffeine and theophylline, inhibit sleep and adenosine agonists enhance sleep. This supports the theory that adenosine plays a role in sleep.

Researchers have defined two distinct categories of sleep through electroencephalogram (EEG): non-rapid eye movement (NREM) sleep and rapid eye movement (REM) sleep. Non-rapid eye movement sleep can be divided into four stages (Lee, 1997). Stage 1 is the first stage of the sleep process, and is a transitional state between wakefulness and sleep. In this stage, an individual is still aware of the surroundings but is drowsy and relaxed, and is easily awakened by sensory stimulation. Myoclonic jerks of the face, hands and feet may be noticed, and body temperature and vital signs start to decrease (Honkus, 2003). Electroencephalogram (EEG) measurements during Stage 1 reveal a disappearance of the alpha pattern and a general slowing of the background rhythm and there may continue to be theta activity and sharp waves at the vertex (Neubauer, 2002). This stage typically lasts no more than a few minutes. Stage 2 of NREM sleep is considered a transition stage to deeper NREM or REM sleep (Honkus, 2003). The individual is not aware of his surroundings, and metabolism and vital signs continue to decrease (Lee, 1997). EEG measurements in Stage 2 are characterized by K-complexes and sleep spindles, and are made up of mixed-frequency low-amplitude activity (Neubauer, 2003). This stage constitutes 50-55% of normal sleep time. Stages 3 and 4 are much deeper sleep, and vital signs, body temperature, and metabolism continue to decrease (Honkus, 2003). EEG measurements in Stage 3 and 4 consist of slow-wave or delta waves (Neubauer, 2003). If 20% of the epoch (30 second groupings) consists of delta activity, then it is staged as Stage 3. If delta waves constitute 50% of the epoch, then it is coded as Stage 4. Stage 4 is the deepest sleep and the individual is very difficult to awaken (Lee, 1997). During Stage 4 vital signs and metabolism are at their lowest. Stages

3 and 4 are important to physically restore a person and it is during this stage that growth hormone is secreted, and protein synthesis and tissue healing is promoted (Honkus, 2003).

Rapid eye movement (REM) sleep is another phase of sleep. REM sleep is different because this is a very active stage of sleep in which cerebral blood flow is increased, and some researchers believe that memory storage and consolidation occur during this phase (Honkus, 2003). Physiologically, when in REM sleep, the breathing becomes more rapid, irregular, and shallow, the eyes jerk rapidly in various directions, and limb muscles become paralyzed (National Institute of Neurological Disorders and Stroke, 1998). The heart rate also increases and the blood pressure rises (National Institute of Neurological Disorders and Stroke, 1998). REM sleep is also characterized by remarkable skeletal muscle atonia which results from active inhibition that prevents stimulation of the cerebral cortex motor area from being transmitted to the muscles (Neubauer, 2003). Electrophysiological measurements found during REM sleep reveal a mixed-frequency, low-amplitude tracing which makes this stage difficult to discern with EEG alone. However, distinct rapid eye movements are detected on the electroculogram (EOG) tracing, and the electromyogram (EMG) leads register decreased muscle tone. Most individuals dream during REM sleep and this process is thought to restore the individual mentally (Honkus, 2003). REM sleep becomes progressively longer as the night progresses (Huether & Defriez, 2006).

Each cycle of REM and NREM sleep lasts about 90 to 110 minutes and a person typically has 4 to 5 cycles each night. Sleep cycles vary from night-to-night and there is also individual variation in the pattern (Neubauer, 2003). Honkus (2003) stated that if an

individual is awakened from sleep frequently, they will get little or no REM sleep because after awakening the individual must start the cycle at Stage 1 again.

A generally accepted model of sleep hypothesizes that two physiologic processes regulate sleep, the circadian and homeostatic mechanisms. The two processes work together in a complementary manner that optimizes the ability of people to sleep effectively (Neubauer, 2003). The homeostatic component monitors the need for sleep (Campbell & Murphy, 2007). A proposed model for this component is that during waking, a sleep pressure begins to accumulate which will enhance sleep onset as bedtime approaches (Neubauer, 2003). At that time sleep is initiated and then this component depletes until it reaches a lower threshold at which time sleep is terminated (Campbell & Murphy, 2007). This pressure results from the overall balance of sleep and waking (Neubauer, 2004).

The second mechanism, a circadian process, is thought to govern the variations in sleepiness and alertness across the 24 hour day (Campbell & Murphy, 2007). This circadian rhythm has an approximately 24 hour repeating pattern with a peak time when sleep is most likely to occur and a trough when sleep is least likely to occur. The circadian process is a biologic clock which regulates several physiological, behavioral, and biochemical rhythms including hormone secretion and body temperature (Parthasarathy & Tobin, 2004). The circadian process is determined by the body's response to light and darkness. Light exposure decreases melatonin secretion. Melatonin is a hormone which increases with darkness and is associated with feelings of increased drowsiness (National

Institute of Neurological Disorders and Stroke, 1998). This circadian process contributes to the cycling of sleep and wakefulness.

The homeostatic and circadian processes work together to allow a person to sleep effectively for approximately 8 hours and remain awake for approximately 16 hours (Neubauer, 2003). The homeostatic process alone would not maintain sleep for eight hours as the sleep pressure is discharged within the first few hours of sleep. However, later in the night, circadian sleepiness enhances continued sleep. The opposite occurs during the daytime. Early alertness is associated with low homeostatic pressure to sleep and alertness later in the day is associated with the circadian pattern of increased alertness. Thus, the circadian and homeostatic processes have an interactive relationship which regulates sleeping and waking.

Sleep architecture changes throughout the adult lifespan. These changes include less time spent in deep sleep and more time spent in lighter, Stage 2 sleep (Kryger, Monjan, Bliwise & Ancoli-Israel, 2004). Campbell & Murphy (2007) found in their study of sleep across the lifespan, an increase in sleep maintenance difficulties, reduced sleep duration, lowered arousal threshold, earlier bedtimes, and earlier rising times in adults over 60 years of age. Kryger et al. (2004) made a point in stating that aging is not synonymous with sleep complaints. Sleep problems in the aging can also be attributed to co-morbidities which can disrupt the sleep cycle (Kryger, et al., 2004). Changes in the circadian controls of sleep, such as an earlier decrease in core body temperature and an increase in melatonin levels, could also contribute to age-related changes in sleep. This causes the person to feel sleepier earlier and then to waken earlier. Campbell and Murphy

(2007) also found that older individuals over the age of 59 years have significantly poorer daytime recovery sleep after being exposed to a 25 hour sleep deprivation period. Thus, older patients in the hospital could have a harder time recovering from sleep disruption than young and middle aged patients. The lowered arousal threshold could also indicate that older individuals may be more sensitive to noise than younger individuals.

Sleep provides the person with multiple physical and emotional benefits which are evidenced by examining what occurs when the body has insufficient sleep. Most of the information on the benefits of sleep has been derived from studying the effects of sleep impairment and deprivation. Sleep deprivation and disruption are common problems in the hospital setting (Dogan, Ertekin & Dogan, 2005; Freedman, Kotzer & Schwab, 1999; Honkus, 2003; Redeker, 2000; Tranmer, Minard, Fox & Rebelo, 2003). Sleep impairment can lead to multiple physiologic and psychological problems which are listed in Table 1 (Hodgson, 1991; Honkus, 2003; Lee, 2003; Weinhouse & Schwab, 2006). In addition to the effects listed in Table 1, other signs and symptoms of sleep deprivation can include behavioral changes, apathy, speech deterioration, ptosis, poor judgment, or lack of energy. (Dines-Kalinowski, 2002). The behavioral changes can include agitation, restlessness, paranoia, or poor impulse control. (Dines-Kalinowski, 2002).

Table 1. Effects of Sleep Impairment

Physiologic: • Decreased immune response • Increased levels of thyroid hormone • Increased levels of cortisol • Increased levels of norepinephrine • Decreased growth hormone • Decreased pain tolerance • Upper airway musculature dysfunction • Blunting of the hypercapneic and hypoxic ventilatory responses Psychologic: • Aggression • Irritability • Anti-social behavior • Memory Loss • Delusions • Hallucinations

From “Sleep in the critically ill patient” by G. L. Weinhouse and R. J. Schwab, 2006, *Sleep*, 29 (5), pp. 711-712.

Many physiological, psychological, and environmental factors contribute to the incidence of sleep deprivation for the hospitalized patient. The primary physiologic factors documented in the literature are pain, medications, and illness (Weinhouse & Schwab, 2006). Stress and worry are the primary psychological factors which disrupt sleep (Honkus, 2003). Environmental factors include noise, lights, and patient care activities (Celik, Oztekin, Akyolcu & Issever, 2005; Freedman et al., 1999; Honkus, 2003; Redeker, 2000). Patient care activities that can disturb sleep include vital signs, phlebotomy, assessments, nursing interventions, and diagnostic tests (Freedman et al., 1999). Environmental factors and patient care activities can be manipulated to decrease patient disruption and therefore, prevent sleep disturbance.

Sound levels in the hospital setting are higher than recommendations of the Environmental Protection Agency for hospital rooms (Freedman, Gazendam, Levan, Pack & Schwab, 2001; Topf, Bookman & Arand, 1996). The Environmental Protection Agency and the World Health Organization have recommended a maximum sound level of 35 dB for the hospital setting during anytime of the day. Studies measuring sound levels on hospital wards consistently show that sound levels often exceed this recommendation by approximately 15-40 dB (Busch-Vishniac, et al., 2005; Kahn, et al., 1998; Moore, et al., 1998; Topf, 2000). When Busch-Vishniac et al. (2005) plotted sound measurements versus time of day they found that sound decreased by approximately 10 dB at night. Moore et al. (1998) found a slightly greater difference of 20 dBs between day and nighttime recordings.

Noise is an environmental factor that contributes to sleep impairment and has been examined in various research studies of hospitalized patients. (Christensen, 2005; Cornock, 1998; Kahn, et al., 1998; Moore, et al., 1998). Noise can be reduced using simple interventions such as turning down the volume on alarms, closing patient doors, and the use of earplugs. Research into improving sleep for inpatients in the hospital setting needs to be done to help prevent the complications that arise from sleep impairment. The use of earplugs to decrease noise disruption should be studied as a way to help improve sleep quality for acutely ill patients in the hospital setting.

Problem

Sleep disruption is one of the most frequent complaints among patients who have been discharged from the hospital and noise plays a part in this disruption (BaHammam,

2006; Weinhouse & Schwab, 2006). The use of earplugs to decrease perceived noise could be helpful in improving sleep quality for patients in the hospital.

Purpose

The main purposes of this study were to 1) assess whether patients' perceived sleep quality improves with the use of earplugs in the acute care setting, and 2) evaluate the availability and willingness of the hospitalized patients to use ear plugs and the viability of the intervention.

Hypothesis

The hypothesis for this study is as follows:

Patients in the acute care setting will demonstrate a 15 mm improvement in sleep scores on the Verran and Snyder-Halpern Sleep Scales with the use of earplugs when compared to sleep quality without earplugs. To test this hypothesis, perceived sleep quality with the use of earplugs is compared to perceived sleep quality without the use of earplugs.

Definitions of Terms for the Purpose of this Study

Certain terms must be more clearly defined. These terms include sleep, sleep deprivation, sleep disruption and noise.

Sleep

Sleep is defined as "the natural periodic suspension of consciousness of which the powers of the body are restored" (Merriam-Webster Online, 2007). Although there is a suspension of awareness the brain is still active during this time. Honkus (2003) stated

that “sleep is a complex, active process that is programmed by man’s circadian rhythm” and is based on a light-dark cycle, which programs humans to sleep at night and be awake during the day (p. 179).

Sleep Deprivation

Sleep deprivation is defined as an inadequate amount of sleep (Lee, 2003). Signs and symptoms of sleep deprivation can vary from person to person.

Sleep Disruption

Sleep disruption is defined as fragmented sleep (Lee, 2003).

Noise

Noise can be classified by measuring the level of sound. Noise will be considered “any sound that is loud, unpleasant, unexpected or undesired” (The Free Dictionary, 2007). A sound is “transmitted vibrations of any frequency which stimulates the organs of hearing (The Free Dictionary, 2007). Each person will have a different concept of what noise is to them.

Conceptual/Theoretical Framework

Roy’s Adaptation Model (Roy & Zahn, 2006) was used as the framework for examining the relationship between a person and their environment. In this model, “humans are viewed as biopsychosocial adaptive systems who cope with environmental change through the process of adaptation” (Polit & Beck, 2004, p. 12). In Roy’s model,

the role of nursing is to promote client adaptation and regulation of stimuli affecting adaptation (Polit & Beck, 2004).

Roy's theory focuses on two primary coping processes, the regulator and cognator subsystems. The regulator subsystem focuses on the physiological processes and the response is innate (Cunningham, 2002, p. 50). The regulator subsystem is a coping process involving the neural, chemical and endocrine system. The cognator subsystem focuses on the cognitive and emotional processes. The cognator subsystem is a coping process involving four cognitive-emotive channels: perceptual and information processing, learning, judging and emotion. These two processes govern how individuals respond to external stimuli. An individual is exposed to a stimulus and the cognator and regulator processes function to produce a behavioral response. The coping processes are theories and have not been tested scientifically.

Intertwined with the primary coping processes in Roy's model are the four adaptation modes: physiological, interdependence, role function and self-concept/group identity. The physiological mode includes basic needs such as oxygenation, nutrition, elimination, activity and rest, and protection (Roy, n.d.). The interdependence mode involves a person's support systems, developmental stage, dependency, and interdependency (Butcher, 2001). The role function mode focuses on what different tasks the individual takes part in (Butcher, 2001). The self-concept mode focuses on the individual's participation in different tasks (Butcher, 2001). According to Roy, the behavioral response to external stimuli is a result of the primary processes and the four adaptation modes (Butcher, 2001). In Roy's model, research focuses on the person as an

adaptive system, including the adaptive processes, adaptive modes, and adaptation related to health (Roy & Zhan, 2006, p. 271).

Roy's Adaptation Model (Roy & Zhan, 2006) provides a new perspective for examining the issues of noise and sleep disruption, and was chosen because the noise in the acute care environment is an environmental change in which the patient needs to adapt to allow for adequate sleep. The use of earplugs would help to mitigate noise stimulation which may be affecting a patient's ability to adapt to the hospital environment. If the intervention is found to be successful, this will be considered a positive environmental change.

Summary

Sleep impairment is a common problem for patients in the hospital (Dogan, et al., 2005; Freedman et al., 1999; Honkus, 2003; Redeker, 2000; Tranmer et al., 2003). As stated previously, impaired sleep can lead to multiple physical and psychological complications and behavioral changes for the healthy patient (see Figure 1), and sleep needs are increased for patients requiring acute care. One of the primary environmental factors contributing to sleep disruption in the hospital is noise. The use of earplugs to decrease noise disruption could be helpful in improving sleep quality for patients in the hospital. It is important to further study this intervention's effectiveness in improving perceived sleep quality because sleep impairment is a common problem with serious complications which impact multiple aspects of a patient's health.

CHAPTER 2

REVIEW OF LITERATURE

Introduction

The importance of sleep is not a new concept. However, sleep disruption continues to be a problem in hospitals. In previous studies, patients have indicated poorer sleep than at home with more awakenings, difficulty falling asleep, shorter duration of sleep, poor quality sleep, and an increased need for sleeping pills (Freedman et al., 1999; Gabor et al., 2003; Redeker, 2000).

The purpose of this review is to establish the current knowledge on sleep and noise in the acute care setting and what interventions have been attempted to improve sleep quality. This review will also identify any gaps which may exist in the current knowledge. Topics which will be covered include sleep in the acute care setting, factors contributing to sleep disruption, and interventions to decrease noise. In addition, sleep measurement will be evaluated as this is an important factor in sleep research. The Cumulative Index to Nursing and Allied Health Literature (CINAHL) and Public/Publisher MEDLINE (PubMed) were the primary search engines used in this literature review.

The Acute Care Setting and Sleep

Patients in the acute care setting experience altered sleep throughout their hospitalizations. Tranmer et al. (2003) stated that, “the type of sleep loss, the duration of

the loss, the factors contributing to the loss, and the impact of the loss are uniquely experienced by each patient”. This statement emphasizes the unique nature of sleep. These researchers examined the sleep experiences of both medical ($n=54$) and surgical ($n=56$) patients and found that sleep perceptions changed throughout the course of the hospitalization. Average sleep time for all participants was 9.16 hours in a 24 hour period. No information was available on pre-hospitalization sleep time in this study for comparison. Medical patients reported decreased sleep effectiveness scores as their stay progressed. Surgical patients reported more disturbances on the first night and less sleep effectiveness across all nights. Sedative medication was used in this study as a sleep promotion strategy which decreased sleep disturbances but did not increase sleep effectiveness scores. The authors stated that their findings indicate that sleep promotion strategies need to vary throughout the hospitalization to balance the changes found in sleep effectiveness throughout the hospitalization (Tranmer et al., 2003).

Three separate studies found that patients in the acute care setting suffer from sleep pattern disturbances. Fontaine (1989) studied 20 trauma patients in the intensive care unit over one night. This study found that participants slept an average of 6.5 hours a night and were awakened frequently throughout the night (Fontaine, 1989). Frighetto et al. (2004) studied 100 patients on a general medical ward and found that their sleep, using the Verran and Snyder-Halpern Sleep Scales scores, was almost as impaired as people experiencing chronic insomnia. Dogan et al. (2005) found that the sleep scores for 150 patients in the acute care setting were poorer (7.9 ± 0.33) than those of the 50 non-

hospitalized in the control group (4.4+/- 0.52). Scores above 5 indicated poor sleep quality. These studies support that hospitalizations are often characterized by poor sleep.

A comparison study of nurses' and patients' perceptions done by Cochran & Ganong (1989) found that patients ranked not being able to sleep as the fourth highest ranking of environmental stressors in the intensive care unit, following the top three stressors that included: 1) having tubes in the nose and mouth, 2) being stuck with needles, 3) being in pain. Nurses ranked not being able to sleep as the fifth highest ranking stressor. In this study, a sample of 20 patients and 23 nurses participated (Cochran & Ganong, 1989). In a duplicate study done by Cornack (1998) with 71 patients almost 10 years later, not being able to sleep was ranked by the patient as the fifth highest of environmental stressors. Both studies indicate that not being able to sleep continued to be a stressor for patients in the intensive care unit. Further research would be needed to generalize these findings to all hospitalized patients.

Factors Contributing to Sleep Disruption

Factors contributing to sleep disturbance in the acute care setting can be classified as physiological and psychological. Physiological factors that have been identified include pain, increased intracranial pressure, altered central nervous system pathology, and decreased nutrition (Hodgson, 1991). Pain is also indicated as a contributing factor by Honkus (2003) and Redeker (2000). Other physiological factors identified by Redeker (2000) include age and previous sleep disorders. Weinhouse and Schwab (2006) stated patient medications may contribute to sleep impairment. Bennett (2003) pointed out that the discomfort of invasive lines and tubes are also physical barriers to sleep. The

psychological factors that are listed most frequently are stress and worry (Celik et al., 2005; Honkus, 2003; Redeker, 2000).

Sleep in the hospital can also be disrupted by environmental factors. Light is one of the environmental factors that can contribute to sleep problems in acute care patients. Bright lights over the nurses' station and lights that are not dimmed in patient care areas are disruptive to a patient's sleep (Honkus, 2003; Richardson, Allsop, Coghill & Turnock, 2007). It is unclear how the lights over the nurses' station disrupted the patients' sleep. Redeker (2000) stated lights can be used in the acute care environment to improve the circadian rhythm. Lee (2003) stated that light and dark are the most powerful stimuli that allow for wake to alternate with sleep, and that without exposure to light changes, patients cannot maintain a regular day/night pattern. Different temperatures, pillows, mattresses and sleeping situations may also interfere with sleep for hospitalized patients. No research was found on how these environmental changes may alter sleep.

Patient care activities also contribute to sleep disruption on night shift. A study performed in Turkey in a 15-bed intensive care unit with 60 participants provided insight into patient care activities during the night shift (Celik et al., 2005). An average of 51 activities was performed per patient per night with the activities occurring more frequently between 0200 and 0500 (Celik et al., 2005). During this time, 62% of the patients were bathed, and patient monitoring, such as vital signs and urine output measurements, often occurred hourly. Other activities which contribute to patient disturbances include repositioning, interventions to improve oxygenation, mouth care, nasogastric tube aspiration, and medication administration (Celik et al., 2005; Redeker,

2000; Tamburri et al., 2004). Tamburri et al. (2004) performed a retrospective study of patients ($n=50$) who were in the critical care unit over a period of 147 nights. In 94% of the study nights, the maximum uninterrupted sleep time was three hours with most patients being awakened every hour to two hours for care. They also found only one episode of sleep-promoting interventions during the nights of study (Tamburri et al., 2004). In this instance, one nurse had charted she had given the patient a back rub to promote sleep. This data was limited because it was gathered retrospectively from patient charts and some sleep promoting interventions may not have been documented.

Noise in the Acute Care Setting

Noise has been studied as a contributing factor in sleep disturbances. Christensen (2005) showed that sound levels on the general acute care units were less than that found in the intensive care setting, although levels still averaged over 40 dBs during the daytime on the general units (Christensen, 2005). This same study found that increased noise levels had a positive correlation with the number of staff on the units (Christensen, 2005). A study was done to examine sound levels in Johns Hopkins Hospital on multiple wards including adult oncology, adult medical/surgical, pediatric medical/surgical and pediatric intensive care unit (Busch-Vishniac et al., 2005). This study found that minimal measurements ranged from 40-50 dBs and maximum measurements ranged between 60-70 dBs (Busch-Vishniac et al., 2005). The highest noise levels were found in the pediatric intensive care unit, 50-70 dBs, and the lowest noise levels were found on the pediatric medical/surgical floor, 40-60 dBs (Busch-Vishniac et al., 2005). Moore et al. (1999) found sound levels in the adult intensive care unit at the University of Virginia Health

System similar to the intensive care findings at Johns Hopkins Hospital. They measured sound levels in the adult intensive care unit over three 24-hour periods and found levels which ranged between 56-62 dBs (Moore et al., 1999). In comparison to these findings, the Environmental Protection Agency and the World Health Organization have recommended a maximum sound level of 35 dB for the hospital setting during anytime of the day. Some variance in findings could be attributed to the use of different sound measurement devices used in each study.

Topf et al. (1996) evaluated the effects of recorded intensive care sounds on the subjective quality of sleep for participants in a sleep lab. This study was done with a control group ($n=27$) and a noise group ($n=33$) who were exposed to a tape recording of sounds and noises recorded in a critical care unit. Statistically significant differences ($P < 0.05$) were noted between the control group and noise group for 6 of 7 sleep variables measured. Subjects exposed to critical care unit sounds and noises: a) took longer to fall asleep, b) spent less time sleeping, c) experienced more awakenings, and d) used fewer positive adjectives describing sleep than the control group (Topf et al. 1996).

Gabor et al. (2003) and Freedman et al. (2001) also found noise contributed to sleep disturbances for intensive care patients. Both found that, although noise did contribute to sleep disruptions, patient disturbances accounted for at least as many sleep disruptions. Gabor et al. (2003) studied sleep disruption in patients on mechanical ventilation. In this study, the participants' sleep ($n=14$) was monitored using continuous polysomnography and the participants' environment was monitored using a sound meter and infrared camera. Noise and sleep data were then compared, and it was found that

noise peaks accounted for more arousals than baseline sound levels. Freedman et al. (2001) also performed continuous polysomnography and sound readings on their study sample ($n=22$) of intensive care patients. They found that there was no difference in sound levels in the daytime and nighttime hours, and that the sound levels exceeded the EPA recommendations for peak levels for both daytime and nighttime levels in hospitals (Freedman et al., 2001). No difference was noted between daytime and nighttime levels and mean levels were 59.1 ± 6.1 dBs. Busch-Vishniac et al. (2005) state the overwhelming number of alarms was a major source of irritation for patients, and yet these alarms are often not acted upon by the health care team. This indicates an area where change could occur by more judiciously using alarms for patient safety and decreasing noise disturbance (Busch-Vishniac, et al., 2005).

When intensive care nurses' knowledge regarding the detrimental effects of noise was evaluated in a study by Christensen (2005), nurses were found to have a significant knowledge deficit. In this study, nurses in the United Kingdom were given a multiple choice questionnaire that encompassed three aspects of the effects of noise: a) political, b) psychological, and c) physiological. Political questions in this study were related to the United Kingdom's Health and Safety Executive's and the World Health Organization's policy on noise limitations in the work environment and psycho-physiological questions were focused on the effects of excessive noise exposure on humans (Christensen, 2005). In each area, nurses were found to have a limited amount of knowledge (Christensen, 2005). This study was done in the United Kingdom and further study of nurses'

knowledge should be done in the United States. Further research should be done to help guide nursing education on the importance of sleep.

Behavior Modification to Decrease Noise

Study of behavioral modification to reduce noise levels and improve sleep produced mixed results (Kahn et al., 1998; Monsen & Edell-Gustafsson, 2005; Moore, et al., 1999; Olson, Borel, Laskowitz, Moore & McConnell, 2001). In the studies by Kahn et al. (1998) and Monsen and Edell-Gustafsson (2005), behavior modification programs were established after first evaluating sound levels in their respective intensive care units. The behavior modification program used by Monsen and Edell-Gustafsson (2005) involved staff education regarding sleep, sleep disturbances, and noise effects on humans. Changes were discussed with staff and included non-disturbance periods. Non-disturbance periods were instituted between the hours of 1300-1500 and 0000-0500. In the study by Kahn et al. (1998), behavior modifications that were instituted included: turning pagers to vibrate, turning off TVs in the patients' rooms, turning down the volume of the overhead speakers and adhering strictly to visitors' hours. Both studies found that their behavior modification programs were clinically successful. The modifications introduced by Kahn et al. (1998) were successful in reducing noise peaks by 12% after behavior modification. The non-disturbance periods and behavior modification program introduced by Monsen and Edell-Gustafsson (2005) did not provide a statistically significant decrease in sound levels.

Two other studies evaluating the use of quiet times and the limiting of extraneous sound also produced mixed results (Moore, et al., 1998; Olson et al., 2001). Olson et al.

(2001) studied 843 participants in an intensive care unit that instituted two hour quiet times, one in the afternoon and one in the early morning. They found that institution of quiet times did result in decreased mean sound and light levels, but not in increased sleep as measured by trained observers (Olson et al., 2001). They also stated that staff had a difficult time adhering to the quiet time and stated they just wanted to “check” on their patients (Olson et al., 2001). A limitation to this study was the use of trained observers to measure sleep rather than an objective or subjective sleep measurement. A second limitation was the varied compliance by the staff. The intervention by Moore et al. (1998) was unsuccessful in terms of improving sleep. This study focused on behavior modification on an acute care unit and intensive care unit including limiting phone calls and turning pagers to vibrate as well as instituting a one hour quiet time in the afternoon. No change was found in sound levels after the staff education and quiet time institution. Another interesting finding in this study was that closing patient doors in the intensive care unit did not decrease sound levels in the patient’s room. The authors stated that they felt this was because a significant amount of sound was generated inside the room.

Other Interventions to Improve Sleep

Interventions other than behavioral modifications that can be used to improve sleep in the hospital include unit re-design, white noise and relaxation techniques. One way to reduce noise is to redesign the patient care unit, general ward and/or intensive care unit, to make acoustical improvements. However, other strategies do not require construction. These strategies encompass various interventions which can be done by staff and are listed in Table 2 (Topf, 2000).

Table 2. Noise Reduction Strategies

Noise Reduction Strategies
·Assign patients to available beds farthest from the desk ·Limit the number of visitors at the bedside at one time ·Lower unit lights to keep noise level down ·Discontinue radio and television or provide headphones ·Turn off unused suctioning and oxygen equipment ·Restrict unnecessary louder bedside communication with signs ·Organize care so patients have fewer nighttime sounds at one point in time ·Isolate patients who emit disturbing verbal sounds ·Unwrap supplies and prepare treatments away from bedside

Use of white noise in patients exposed to ICU noise has been examined and a decrease in sleep disruptions was noted (Stanchina, Abu-Hijleh, Chaudhry, Carlisle & Millman, 2005). These researchers exposed one group of subjects to recorded ICU sounds and the other group to recorded ICU sound and continuous white noise. Mean baseline noise levels for the ICU were 57.9 +/- 0.3 dBs. Combined white noise and ICU noise levels were 61.1 +/- 0.2 dBs. The addition of white noise to a subject's room substantially decreased sleep disruptions induced by ICU noise. Sleep was measured by continuous polysomnography monitoring for sleep disruptions and continuous sound monitoring. The authors speculated that the decrease in disruptions was due to increased arousal thresholds in the subjects exposed to continuous white noise.

The effect of relaxation techniques on sleep quality of patients in the intensive care unit has also been evaluated. Richards (1998) evaluated the use of back massage and relaxation techniques on the sleep of male subjects ($n=69$, ages 55-79). Subjects were assigned to either a back massage, relaxation instruction session, or an audiotope of muscle relaxation, mental imagery, and relaxing background music. Back massage lead

to an increased length of sleep but patients were still awakened as much as control subjects and they had a decreased percentage of REM sleep. The relaxation audiotape did not lead to improved sleep scores when compared to healthy control subjects. The results of this study are limited due to the exclusion of women from the study sample.

Additionally, Richardson (2003) evaluated the use of relaxation and imagery on patients ($n=36$) in the critical care unit. This study used a repeated measures experimental design in which participants in the intervention group practiced the intervention for two nights. No statistical difference was found in the overall sleep scores between the intervention and control group. Although the intervention was not statistically significant, the researcher stated that the intervention was clinically effective for 25 % of participants and, therefore, warrants merit as a possible sleep promotion intervention.

The Use of Earplugs to Improve Sleep Quality

The purpose of the first study identified using earplugs as a sleep promotion intervention was to identify if quality and quantity of sleep improved with earplug use (Haddock, 1994). In this study, the researcher compared the participants' sleep when using earplugs with their previous night's sleep without earplugs and the researcher also compared the earplug wearers' sleep to non-earplug wearers' sleep. This study had a small sample of 18 women on a general medical/surgical ward. The earplugs chosen for this study were the soft, foam type which can be worn for multiple nights and were chosen because they were assumed to have high noise protection and were relatively inexpensive. Participants wearing earplugs reported more improvement in quality and quantity of sleep than the participants not wearing earplugs. Participants reported the

earplugs were easy to apply, comfortable to wear, and easy to remove. After one study night, three participants chose not to take sedative medication at night and only one of the three reported a decline in her sleep when compared to the previous night with the sedative medication. Haddock (1994) concluded that earplugs could be used as an acceptable sleep intervention and may be used as an alternative to sleep medications for patients when appropriate.

Wallace, Robins, Alvord and Walker (1999) examined the use of earplugs on simulated intensive care noise with healthy volunteers as participants in a two part study conducted in a sleep center. The first part of the study evaluated different noise-reduction devices for comfort, effectiveness, ease of application, cost, and ability to stay in place during repositioning. The devices evaluated were the Bose aviation headset, Bose ANR-1 prototype, passive hearing protection headset, a Quiet Band (ear pads with chin band), and various brands and types of earplugs. The Bose aviation headset was the superior device for decreasing noise; however, the headsets were difficult to keep in place when patients were repositioned. Super soft foam earplugs were chosen for the study because they were effective noise-reducers, inexpensive, comfortable, easy to apply, and stayed in place during positioning.

The next part of the study evaluated the effect of earplugs on sleep. This study used a repeated measures design with a sample size of six participants with an average age of 25 +/- 3 years. After one night of adaptation, participants were divided into two groups: the first group (3) wore earplugs and the second group (3) did not. Both groups slept in a sleep center for the nights of participation. Each group spent one night in a quiet

environment and one night in the “noise” environment with recorded ICU sounds, and polysomnographic data was collected during each night. No differences in sleep were found between the earplug group and the control group on the quiet night. For participants using earplugs, REM latency (time to enter REM sleep) decreased significantly, and the use of earplugs significantly increased the percentage of REM sleep. The researchers concluded that their pilot study provided a reasonable basis for further examination of the use of earplugs on noise reduction on critically ill patients (Wallace, Robins, Alvord & Walker, 1999).

Richardson et al. (2007) evaluated the use of earplugs and eye masks to improve sleep quality for critical care patients. The pilot study ($n=64$) evaluated factors which influenced sleep and the usefulness of earplugs and eye masks to improve sleep over one night of study. Participants in this study, who were divided into intervention and non-intervention groups, identified tiredness, eye mask, earplugs, lack of noise, no sleep the night before, and analgesia as factors which helped them go to sleep. Factors which prevented participants from sleeping included: noise, feeling too hot, general discomfort, pain, light, blood draws, previous sleep problems, anxiety, and general environment. The intervention group identified that they slept longer periods of time than the non-intervention group. Because the interventions were used together, there is no way to know if one intervention was more helpful than the other. Nevertheless, this small study does support the use of earplugs as a possible sleep intervention in the acute care setting.

Sleep Instrumentation

An important component to sleep research is the selection of the proper instrument to measure sleep. Multiple methods are used to evaluate sleep quality and quantity and it is important to evaluate each method for reliability, validity and clinical usefulness.

Polysomnography was used by multiple researchers to measure sleep. Polysomnography is a method to measure and record electrical potentials from the brain, the outer canthus of the eye, and the mental and submental muscles beneath the chin. This method is considered the most accurate objective measure of sleep and is used to gauge the validity of all other objective methods of sleep measurement. After each sleep study, the data gathered is then analyzed by specially trained individuals. This is the only method to identify specific sleep stages defined by the electroencephalogram (Bourne, Minelli, Mills & Kandler, 2007). This method provides accurate measurement of sleep quantity but requires special equipment and specially trained individuals to evaluate the data.

Actigraphy is yet another method of sleep measurement. Actigraphs are small, computerized devices that are worn like an ordinary watch or bracelet, and most often record movements from the non-dominant wrist or an ankle (Shilo et al., 2000). This assessment is an activity-based sleep assessment which has been found to be reliable and valid when compared to polysomnography (Kroon & West, 2000). The data gathered using the actigraph is downloaded into a computerized sleep-scoring algorithm (Kroon & West, 2000). Bourne et al. (2007) stated that actigraphy is best for monitoring patient rest-activity. Limitations to actigraphs can be found in patients with decrease movement, such as in coma or paralysis, and may lead to an overestimation of sleep. Actigraphs were

found to be a more cost-effective measurement of sleep than polysomnography by Kroon & West (2000), but do still require specialized equipment and training.

Another method of sleep measurement is observation. This method was used in the study on the effectiveness of quiet time to improve sleep (Olson et al., 2001). In this study observers were specially trained by the researchers to be able to effectively evaluate sleep. Parthasarathy and Tobin (2004) state that judgments based on observation consistently overestimate sleep time and do not detect sleep disruption. This can occur if the sleeper is lying quietly with the eyes closed and not asleep but the observer is not aware that the person is awake. Others have also reported that observations of sleep have been found to be inaccurate in comparison to polysomnographic data (Bourne et al., 2007; Kroon and West, 2000). Additionally, nurse observations were found to be inaccurate when compared with patient's self-assessment of sleep (Richardson et al., 2007). Only one study found that observation was a valid method of sleep quality measurement (Fontaine, 1989). In this study, the Echols' Patient's Sleep Behavior Observation Tool was used and this tool shows an inter-rater reliability of 96%. The researcher compared results from this tool to subjective results from the Verran and Snyder-Halpern Sleep Scales and continuous polysomnography and found convergent validity ($p < 0.05$). Observation requires specialized training and has been shown to be less reliable in some studies.

A final method for sleep measurement is self-assessment using sleep questionnaires. This method is attractive for measuring subjective sleep because patients are best positioned to relate their own sleep quality and quantity (Bourne et al., 2007).

Kroon and West (2000) used the Verran/Snyder-Halpern (VSH) Sleep Scales for subjective sleep measurement in their study comparing the difference between objective, subjective, and physiological assessment of sleep. Actigraphy was used for objective sleep measurement and the Echols' Patient Sleep Behavior Observational Tool was used for objective sleep measurement. The VSH sleep scales use a visual analogue scale to facilitate an increased variability of response and were reliable and valid in comparison to polysomnography (Kroon & West, 2000). These scales consist of 15 questions related to sleep characteristics and use a 100 cm visual analogue response line (Snyder-Halpern & Verran, 1987). Bourne et al. (2007) state that advantages to this questionnaire include it is quick to complete and baseline sleep quality can be compared to current sleep quality. A disadvantage would be the limited usefulness in cognitively impaired individuals.

A sleep questionnaire evaluated by Richardson et al. (2007) in their study of sleep assessment tools was the St. Mary's Hospital Sleep Questionnaire. This questionnaire is a fourteen item multiple choice and short answer tool which examines an individual's previous night's sleep. In this same study, the researchers created three new sleep assessment tools for use in critical care units (Richardson et al., 2007). These tools were simple questionnaires with only one question each which evaluated length of sleep, comparison of current sleep to normal sleep, and quality of sleep, respectively (Richardson et al., 2007). These tools were labeled Tool One, Tool Two and Tool Three, and no information was provided on reliability or validity. Participants of the study found all three tools easy to use which may support the possibility of clinical usefulness.

Lastly, the Pittsburgh Sleep Quality Index is a questionnaire that consists of 24 questions, 19 of which are self-rating questions. The other five questions are answered by the roommate or partner of the participant. Questions cover a range of subjects including quality of sleep, sleep latency, length of sleep, sleeping habits, sleep disorders, use of sleeping pills and daytime activity disorder (Dogan, Ertekin & Dogan, 2005). This questionnaire evaluates sleep for the past month so it is not useful for the study of one or two nights of sleep.

Summary

Sleep is an important aspect of the healing process, yet sleep impairment has been established as a common occurrence in the acute care environment (Hodgson, 1989; Honkus, 2003; Redeker, 2000). Research on multiple noise reduction strategies to help improve sleep had mixed results in acute care settings. (Kahn, et al., 1998; Monsen & Edell-Gustafsson, 2005; Moore, et al., 1999; Olson et al., 2001; Stanchina et al., 2005; Wallace et al., 1999). Additional research needs to be done to further evaluate noise reduction strategies. Further research should also be done on the use of noise reduction interventions such as behavior modification and earplugs for patients on general medical wards as limited research has been done on these units. Only three studies have evaluated the use of earplugs to improve sleep quality in the acute care environment. Of the three studies discussed, one was done in a clinical laboratory and one of them combined earplugs with eye masks. The studies all supported the use of earplugs as a possible intervention to reduce noise and thereby improve sleep. Further research is needed to support these findings in the clinical setting.

Various sleep measures include polysomnography, actigraphy, observation, and self-rating questionnaires. Polysomnography and actigraphy require special equipment and training to operate and this can limit the feasibility in the clinical setting. Observation has limited usefulness due to difficulty assessing sleep and inter-rater reliability issues. Self-rating questionnaires provide important subjective information about sleep. Because various sleep questionnaires and sleep measurement tools are available, the proper instrument must be selected based on the patient population, the purpose of the study and the availability of equipment and resources.

CHAPTER 3

METHODS

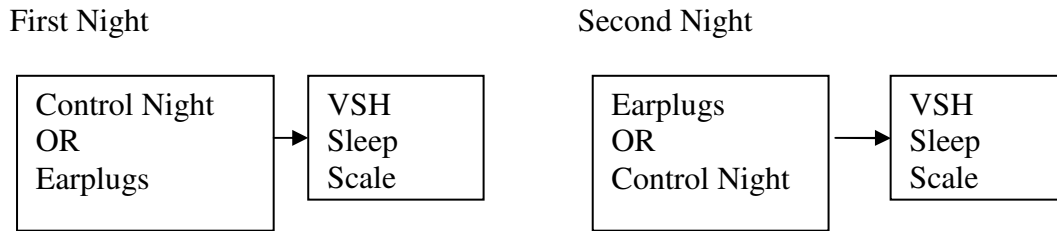
Introduction

The purpose of this quantitative study was to determine if the use of earplugs would improve perceived sleep quality for patients in the hospital setting when compared to sleep quality without the use of earplugs. Another objective was to evaluate the availability and willingness of the hospitalized patients to use ear plugs and the viability of the intervention. This study was a pilot study and used a quasi-experimental design. Participants were recruited from the telemetry floor and intensive care unit of a local hospital. Study design will be explained in detail in the following paragraphs.

Design

This pilot study used a quasi-experimental design with a pre-test and post-test and the participants served as their own control. The dependent variable was perceived sleep quality. The independent variable was use of earplugs. Sleep quality was measured subjectively using the Verran/Snyder-Halpern Sleep Scales (Snyder-Halpern & Verran, 1987). This pilot study will provide information on the availability and willingness to participate of the patient population, the feasibility of this intervention in this population, and data collection limitations. Participants will sleep with earplugs one night and will sleep without earplugs one night as demonstrated in Figure 1. This study was done using repeated measures with randomization of control and intervention nights.

Figure 1. Study Design



Instrumentation

Sleep Scale Selection: The Verran and Snyder-Halpern Sleep Scales were selected as the tool for this study. A questionnaire was selected as the best choice because it is easy for participants to use and is less costly than technical equipment needed to measure sleep. The Verran and Snyder-Halpern Sleep Scales were selected because this tool requires minimal time to administer and allows for greater variability of response.

Physiologic measurement was not used in this study for various reasons. This research question is focused on the participant's perception of the quality of their sleep rather than the quantity of sleep. Polysomnography and actigraphy require specific equipment and some degree of training to effectively use these items. More importantly, physiologic measurements don't measure the subjective quality of sleep and may be more disturbing to participants as they are additional attached equipment (Richardson et al., 2007; Snyder-Halpern & Verran, 1987).

Verran and Snyder-Halpern Sleep Scale Description: The third version of the Verran and Snyder-Halpern Sleep Scales, which is designed to characterize overall self-reported sleep quality by using three sleep characteristic scales, was used in this study. The scales utilizes a 100 mm visual analogue response line (Verran & Snyder-Halpern,

1990). The 100 mm visual analogue scale line was selected for this model as it allows for greater variability of response (Kroon & West, 2000). The VSH Sleep Scales consist of 15 questions divided into the three separately-scored scales (see Appendix D). A sixteenth characteristic is calculated by adding two other characteristics. Verran and Snyder-Halpern (1990) do not recommend a total score as each scale measures a different concept.

The sleep characteristic scales include disturbance, effectiveness and supplementation (Verran & Snyder-Halpern, 1990). Disturbance questions include the following characteristics: 1) mid-sleep awakening, 2) wake after sleep onset, 3) movement during sleep, 4) soundness of sleep, 5) quality of disturbance, 6) sleep latency and 7) quality of latency. Effectiveness questions include the following characteristics: 1) rest upon awakening, 2) subjective quality of sleep, 3) sleep sufficiency evaluation, 4) total sleep time and 5) total sleep period, calculated by adding total sleep time and wake after sleep onset. Supplementation questions include the following characteristics: 1) daytime sleep, 2) morning sleep, 3) afternoon sleep and 4) wake after final arousal.

Verran and Snyder-Halpern Sleep Scale Performance: The Verran and Snyder-Halpern (VSH) Sleep Scales have been tested and found to be both a reliable and valid as a sleep measurement tool for perceived sleep in hospitalized patients. In initial testing of this tool, the creators found that it had a reliability coefficient of .82 (theta) (Snyder-Halpern & Verran, 1987). Psychometric testing has also been done in healthy adults in their usual sleep environment, adults with insomnia, hospitalized adults in the United States, and hospitalized adults in Taiwan (Verran & Snyder-Halpern, 1990). The results

of this testing indicated adequate reliability for the disturbance and effectiveness scales and inconsistent reliability for the supplementation scale (Verran & Snyder-Halpern, 1990). In comparison with scores of two other sleep scales, St. Mary's Hospital Sleep Questionnaire and the Baekeland and Hoy Sleep Log, convergent validity was supported for the VSH scales (Topf & Thompson, 2001).

The Verran and Snyder-Halpern (VSH) Sleep Scales have been tested in the hospital setting and found to have some limitations (Richardson et al., 2007). Limitations included difficulty seeing or reading the tool, and difficulty writing secondary to limited range of motion (Richardson et al., 2007). The scale was tested once in the critical care environment with quadriplegics, and was found to be useful but only with assistance completing the form from a researcher (Richardson et al., 2007). These potential limitations will be addressed by having the researcher assist participants with completing the questionnaire if needed.

Earplug Selection: The earplugs used in this study were selected by examining noise reduction, previous research, cost, and availability. Noise reduction rates are required by the EPA for all hearing protection devices, and noise reduction rates describe the average noise level reduction which any hearing protection device provides in a laboratory setting (3-M Education, 2000). Only foam earplugs were evaluated since this type of earplug had previously been found to be the easiest and most comfortable to use (Haddock, 1994; Wallace et al., 1999). In the study by Wallace et al. (1999), various noise protection devices were placed on the patient and the ease of use and comfort were evaluated. The foam earplugs were chosen by the patients because they stayed in place

during positioning and were comfortable throughout the night (Wallace et al., 1999). See Table 3 for comparison of noise reduction rates and costs of the six foam earplugs which were evaluated for this research project. The Howard Leight Max-1 was chosen for this study due to a higher Noise Reduction Rating and low cost. No research data was available on comfort of earplugs although each manufacturer stated that their earplugs were comfortable for extended periods of time.

Table 3. Foam Earplug Comparison

Name	Noise Reduction Rating	Cost per pair
Elvex Blue	29 dB	\$0.15 (Elvex.com)
E-A-R Soft Fx	33 dB	\$0.21 (EarInc.com)
E-A-R TaperFit2	32 dB	\$0.21 (EarInc.com)
Soft Foam Ear Plugs	33 dB	\$1.68 (Apex Healthcare)
Howard Leight Max-1	33 dB	\$0.09 (Amazon.com)
Physician's Choice Soft Foam Earplugs	29 dB	\$0.15 (Ear-Mart.com)

Earplug Description: The Howard Leight Max-1 earplug is designed for single use. This earplug comes with the highest noise reduction rate available. These earplugs are made from polyurethane with a smooth, soil-resistant skin which prevents dirt build-up. They are bell-shaped for comfort and are designed to be easy to insert with reduced tendency to back out of the ear. They come in one size fits all so they should be usable for a variety of ear sizes (Howard Leight, n.d.). No information is available on adaptation to earplugs.

Sample

A convenience sampling procedure was used to select participants who met selected criteria. Participants were eligible from the intensive care unit and telemetry unit at St. Vincent Healthcare, in Billings, Montana. St. Vincent Healthcare is a 230 bed hospital with a 23 bed intensive care unit, and a 35 bed telemetry unit. As will be discussed, although a power analysis was performed and a sample size was determined, after consideration of multiple factors, a minimum of ten participants was set with a maximum sample of twenty.

Sample Size: To determine sample size, a power analysis was performed. In order to perform this analysis, the effect size, significance level, and power level had to be determined. Duffy, Munro and Jacobsen (2005) state that a small effect would be 0.2 standard deviation, a moderate effect would be 0.5 standard deviation, and a large effect would be 0.8 standard deviation. A moderate effect was chosen. Normative data for hospital patients in the United States provided by Verran and Snyder-Halpern (1990) was used to determine the standard deviation. A standard deviation of 30 was used because 30 was in the middle of the range of standard deviations for the normative data for the sleep characteristics in each of the three scales: disturbance, effectiveness, and supplementation. Using the calculation provided by Duffy et al. (2005), the effect size was calculated by multiplying 0.5 times 30 (standard deviation). This provided an effect size of 15 mm.

The next step was to determine the significance level. A significance level of 0.05 was chosen indicating that there is a 5 in 100 chance that the effect occurred by chance

alone (Duffy et al., 2005). Lastly, an 80% power level is adequate for statistical significance (Duffy et al., 2005). A power level of 90% was used to calculate the sample size.

The power analysis revealed that a sample size of 140 would be needed to achieve power of 90%. This was calculated using the GPower.exe, 2.0 (1998) program which was downloaded by the primary researcher from the Internet. The power analysis was important to provide a basis for sample size.

Due to time and human resource limitations, a smaller sample size was selected. This determination was made in consultation with the thesis committee and was felt to be appropriate because this was a pilot study. It was then decided that the minimum sample size would be ten and the maximum sample would be twenty.

Sample Criteria: Criteria for inclusion in the study included the following: The participant must 1) be at least 18 years of age, 2) be oriented to time and place, 3) have had one previous night on the unit during this hospital stay, 4) be able to read, speak, and hear English, 5) be at least 48 hours post-operative, if a surgical patient, and 6) be able to consent to participate in the study. Participants were excluded from the study if there was 1) history of brain damage (traumatic or pathologic) or chronic sleep problems, 2) ear injury or hearing impairment requiring use of aids, or 3) allergy to polyurethane.

Protection of Human Participants

The study was approved by the Montana State University Institutional Review Board (IRB) and the Institutional Review Board (IRB) of Billings to conduct the study.

In meeting the requirements of the Montana State University IRB and the IRB of Billings, the researcher had to successfully complete the Human Participant Protections: Education for Research program provided by the National Institutes of Health. This program provided the researcher with background information on how to develop and implement ethical research. Part of this process included how to create an informed consent form. Approval letters from the Montana State University IRB and the IRB of Billings can be found in Appendix A.

Prior to beginning the study, each participant was asked to complete an informed consent form after receiving an explanation of the study provided by the researcher. The consent form included information on the expectations of the study, risks, benefits and maintenance of confidentiality (Appendix B). Participants were exposed to a possible risk of ear irritation or allergy from the earplugs. No payments were provided for participating. Participants were also informed of the potential benefit of improved sleep. Participants were reassured that they could withdraw from the study at any time and that data will only be accessed by the researcher and her committee. In addition to the consent form, each participant also signed a privacy authorization form (Appendix C) required by the Billings IRB. This form provided information on how any information collected will be used and protected. No names or other identifying data were included in the results or report and only aggregate data were reported.

Data Collection

Data collection began in January 2008 and continued through March 2008. An informational session was provided for the hospital staff which included nurses and

certified nursing aides, and an information poster was posted with contact information to notify the researcher of possible participants. During the informational service, staff were informed about the nature of the study, inclusion and exclusion criteria, risks, benefits and how to approach possible participants. If the staff were unable to attend the in-service, an e-mail was sent with the same information that was provided during the informational session. In addition, they were provided with a narrative to use when approaching patients to help eliminate any risk of coercion (Figure 2). The researcher made daily trips to the units to provide information to the staff and evaluate for possible participants.

Figure 2. Hospital Staff Script

“You are eligible to take part in a research project that is being done on this unit. The purpose is to determine if earplugs will improve your sleep quality. If you choose to take part, you will participate for two nights and wear earplugs on one night. Are you interested in participating in this study? If so, I will have the nurse researcher come and discuss this with you further.”

Staff were also informed on the application and care of the earplugs as participants may require assistance with this task. If the earplugs come out inadvertently, the participant can re-apply the earplugs if awake but should not be awakened to do so. If the participant removes the earplugs, they can choose to replace them or leave them out. Data will be analyzed from participants only if they were able to wear plugs for greater than half of the sleep time as self-reported. Questions about the research study were encouraged by staff and possible participants.

Demographic data was collected for each participant. This data included sex, age, marital status, medication history, and primary diagnosis. This data was used to determine eligibility and to assess comparability of participants. No names were used on the data collection sheets (Appendix E) so that only the researcher and the patient's care providers on the nights of the study knew the identities of the participants. A master list of patients was kept in the researcher's file.

Procedure

Hospital staff nurses made initial contact with the possible participant. The staff initially screened participants for inclusion and exclusion criteria. The staff approached the patient about their possible participation in the study and received permission for the researcher to visit with the possible participant using the provided narrative. Staff contacted the researcher who made a same day visit to the patient. The researcher was then responsible for performing final determination about inclusion and exclusion criteria. The researcher then discussed the expectations and time commitment, and received informed consent. After informed consent was obtained, the researcher arranged the time for the study to begin.

Patients were randomly assigned to earplug use on either the first or second night. To do this, the researcher selected one of two folded pieces of paper. One piece read control and one read earplugs. The same procedure was repeated for each participant. After randomization, the researcher discussed attempting to go to sleep around 10 pm, earlier if desired, and attempting to stay in bed throughout the night as able until 06 am. The researcher returned prior to 0900 am after each study night to

administer the VSH Sleep Scale questionnaire (Appendix D). The researcher discussed the study with the participant's nurse. The nurse was encouraged to continue with care as usual. A note was above the bed notifying staff of patient's participation in the study. No other measures, such as shutting doors, turning off of TVs, or decreasing monitor alarm levels, were taken to decrease the noise in the environment. This prevented introduction of additional changes to the environment and controlled for any extraneous reasons for decreased noise. This procedure was the same for both intervention and control nights with the exception of earplug instruction on the intervention night.

On the intervention night, the researcher instructed the participant on insertion of the earplugs. If the participant did not think that he would be able to insert the earplugs, the researcher instructed the nurse on application. The earplugs were placed around 10 pm and removed only as necessary for comfort or care. The earplugs were removed upon awakening, but the participant was not awakened to remove the plugs. On the control night, the researcher did not visit the participant in the evening and the participant slept without earplugs. No other measures were taken to decrease noise in the environment.

Data Analysis

Demographic data was reported and bivariate correlation and regression analysis were used to evaluate for any response variance due to the demographics. Descriptive analysis and independent samples t-testing were done to analyze for statistical significance between intervention and control nights.

Data from the VSH Sleep Scales was analyzed using individual sleep characteristics, and scores for each sleep scale (disturbance, effectiveness and

supplementation) will be calculated. To test the hypothesis that sleep characteristic scores would improve 15 mm with the use of earplugs, scores on the intervention night were compared to scores without the intervention. The three scale mean totals, disturbance, effectiveness, and supplementation, were compared for the control and intervention nights. No normative data for scale totals was provided by the scale authors therefore it is unknown what the effect size should be for the scale totals. Descriptive analysis was used to compare results to normative data of hospitalized patients in the United States. Bivariate correlations and linear regressions were done to rule out the effects of demographics on response variance. Independent samples t-tests were done to identify any statistical difference between intervention and control sleep scores.

Summary

The study was designed with the intent of protecting the rights of the human participants. This study was approved by the Montana State University IRB and the IRB of Billings. A quasi-experimental design was selected for this pilot study and a sample size of ten to twenty participants was determined in consultation with the thesis committee. Participants were recruited from the intensive care unit and telemetry floor at St. Vincent Healthcare. Participants were initially screened by the hospital staff and then screened again by the researcher. The Verran and Snyder-Halpern Sleep Scales were chosen as the sleep tool. Sample criteria were determined by examining previous sleep research in the hospital setting.

The study population consisted of alert, oriented hospitalized patients that met all of the inclusion criteria. After consent was attained, participants were randomly assigned

for control or intervention for the first night of study. Subjects received instruction on proper use of the earplugs and no other attempts were made to control noise. The Verran and Snyder-Halpern Sleep Scales were administered after each night of study. Hypothesis testing was performed by comparing intervention and control scores for each sleep characteristic for an effect size of 15 mm. Correlations were performed to evaluate for any response variance related to the demographic data.

CHAPTER 4

RESULTS

Introduction

The purpose of this study was to evaluate if acute care patients perceived sleep improved with the use of earplugs and this was evaluated using the Verran and Snyder-Halpern Sleep Scales. Ten participants were able to complete both study nights. Hypothesis testing was done to evaluate for an effect size of 15 mm.

Sample Description

Thirty-five patients were identified as possible participants by the unit staff over a three month period. Fourteen of these consented to participate in this research study. Ten of the fourteen were able to complete the two nights of study. Reasons for not participating in the study included discharge from the hospital, transfer from the unit, worsening illness, and inability to tolerate ear plugs. The mean age of the ten participants was 66 years old (SD = 11.29) with a range of 55-92 years old. Six participants were men and four participants were women. Five participants were married, three were widowed, one was single and one was divorced. Upon enrollment the mean length of hospitalization was 5.7 days (SD = 9.02) with a range of 2-31 days. One participant used sleep medication every night at home. Other routine sleep assistance methods reported by participants included watching television, reading, using CPAP and wearing earplugs. On the nights of study, intervention and control, only one participant had taken a sleeping

pill. Four participants were on narcotic pain medication on the nights of study and no participants were administered a hypnotic such as benzodiazepines.

Data Findings

After the completion of data collection, questionnaires were scored according to tool instructions. These data were then entered into the Statistical Package for the Social Sciences (SPSS) data analysis program (Version 15.0 for Windows) along with the demographic data.

Perceived Sleep Quality

The hypothesis that the use of earplugs would improve perceived sleep quality as evidenced by an effect size of 15 mm was supported for soundness of sleep. The means of each sleep characteristic were compared for the intervention and control nights. There was a 15.1 mm decrease in the mean score for soundness of sleep (SS). Total means for each scale, disturbance, effectiveness, and supplementation were calculated. Total means did not meet the requirements for an effect size change for each sleep scale. The means for each sleep characteristic are identified in Figures 3 through 5 and the total means for each sleep scale are identified in Figure 6. Descriptive statistics are provided for the disturbance, effectiveness and supplementation scale scores in Table 4.

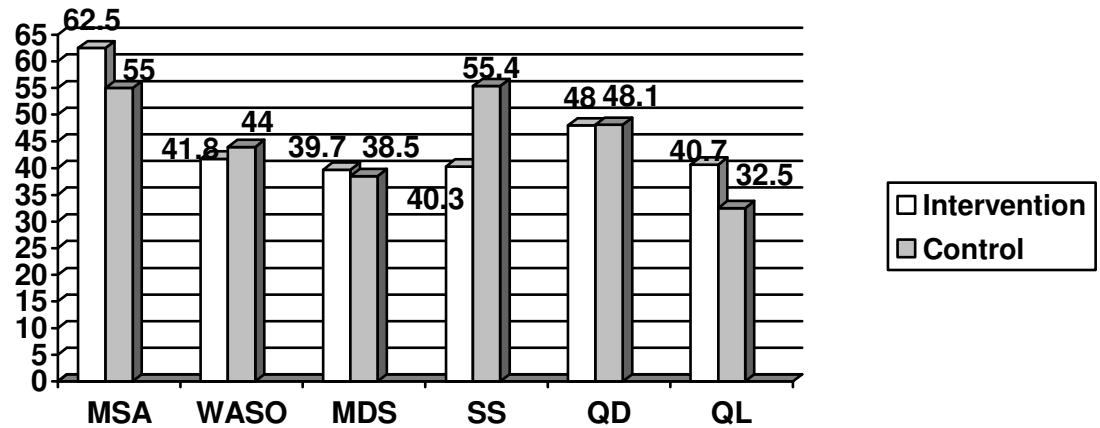


Figure 3. Disturbance Scale Mean Scores for Intervention and Control Nights:
 MSA=Mid-Sleep Awakening, WASO=Wake after Sleep Onset, MDS=Movement during Sleep, SS=Soundness of Sleep, QD=Quality of Disturbance, SL=Sleep Latency, QL=Quality of Latency

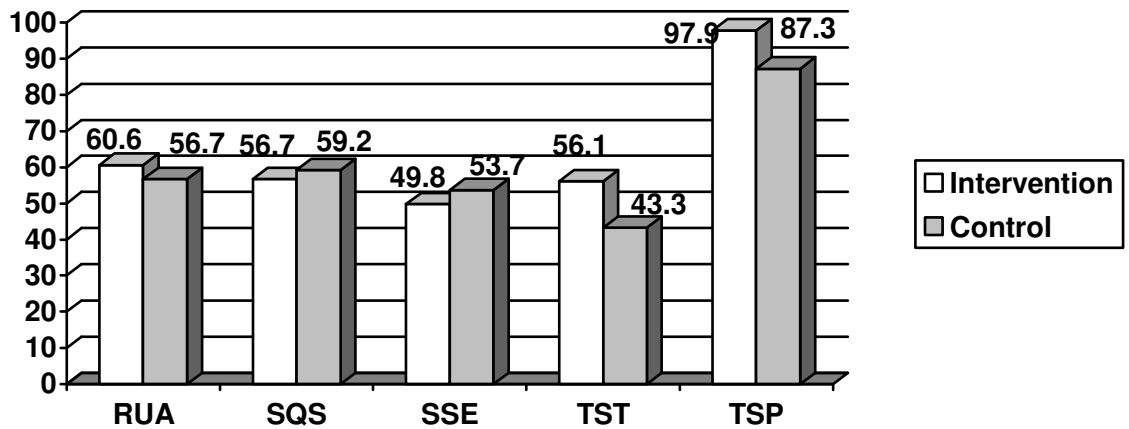


Figure 4. Effectiveness Scale Mean Scores for Intervention and Control Nights:
 RUA=Rest Upon Awakening, SQS=Subjective Quality of Sleep, SSE=Sleep Sufficiency Evaluation, TST=Total Sleep Time, TSP=Total Sleep Period

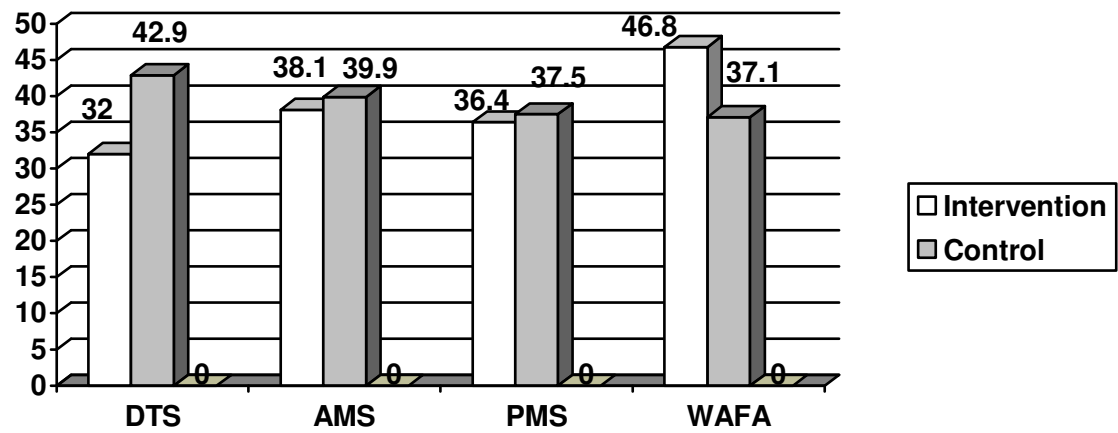


Figure 5. Supplementation Scale Mean Scores for Intervention and Control Nights:
DTS=Daytime Sleep, AMS=Morning Sleep, PMS=Afternoon Sleep, WAFA= Wake after
Final Arousal

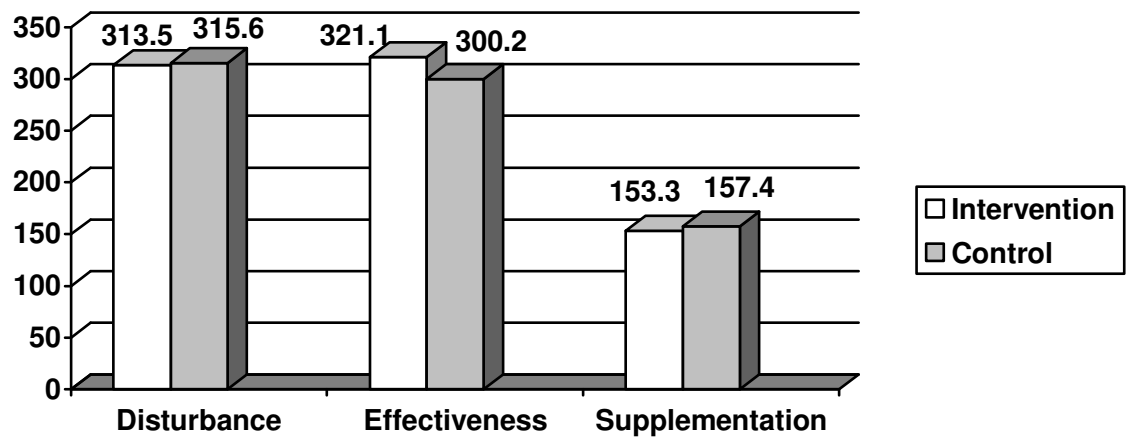


Figure 6. Disturbance, Effectiveness and Supplementation Means for Intervention and
Control

Table 4. Descriptive Statistics for Disturbance, Effectiveness and Supplementation Scales

	Minimum	Maximum	Mean
Disturbance – Intervention	99	437	313.5
Disturbance – Control	46	474	315.6
Effectiveness – Intervention	147	466	321.1
Effectiveness – Control	180	431	300.2
Supplementation – Intervention	28	256	153.3
Supplementation - Control	45	226	157.4

Scores

Independent samples t-tests were completed to determine if a statistically significant difference existed between the control and intervention nights. No statistical significance was noted between intervention and control nights for any of the sleep characteristics. No statistical significance was noted between control and intervention nights for the total mean scores for each scale.

Bivariate correlations and linear regression testing did not reveal any response variance attributable to demographic data. Total sleep scores were determined for each sleep scale: disturbance, effectiveness, and supplementation. These scores were correlated with the age, normal total sleep hours, and length of hospitalization, demonstrating no statistical effect on control or intervention nights. Regression analysis was used to examine the relationship between the dependent sleep variables, disturbance, effectiveness, and supplementation scores, and the confounding, dichotomous variables, sex, narcotic pain medication use, sleep medication use, chronic sleep medication use,

and routine sleep assistance. This resulted in no statistical significance between dependent and confounding variables for control or intervention nights.

Descriptive analysis was done to compare data to normative data for hospitalized patients in the United States as provided by the Verran and Snyder-Halpern (1989). This information is summarized in Tables 5, 6, and 7. When comparing the data, the difference in sample sizes should be acknowledged.

Table 5. Mean Scores for Sleep Disturbance by Group

Characteristic	Intervention Night Mean (SD)	Control Night Mean (SD)	Hospital-US (Normative Data) Mean (SD)
Sample Size	10	10	151
Mid-Sleep Awakening (MSA)	62.5 (19.2)	55.0 (22.3)	58.2 (30.0)
Wake after Sleep Onset (WASO)	41.8 (23.3)	44.0 (19.6)	44.0 (25.7)
Movement During Sleep (MDS)	39.7 (20.2)	38.5 (20.8)	45.7 (28.2)
Soundness of Sleep (SS)	40.3 (24.9)	55.4 (30.4)	54.5 (31.1)
Quality of Disturbance (QD)	48.0 (26.3)	48.1 (28.9)	46.7 (31.8)
Sleep Latency (SL)	40.5 (21.1)	42.1 (24.2)	41.9 (30.2)
Quality of Latency (QL)	40.7 (29.4)	32.5 (18.4)	40.3 (33.2)

Table 4. Mean Scores for Sleep Effectiveness by Group

Characteristic	Intervention Mean (SD)	Control Mean (SD)	Hospital-US (Normative Data) Mean (SD)
Sample Size	10	10	151
Rest upon Awakening (RUA)	60.6 (21.0)	56.7 (17.4)	55.0 (29.2)
Subjective Quality of Sleep (SQS)	56.7 (25.6)	59.2 (27.0)	51.8 (31.3)
Sleep Sufficiency Evaluation (SSE)	49.8 (26.9)	53.7 (25.5)	57.3 (33.2)
Total Sleep Time (TST)	56.1 (23.8)	43.3 (20.7)	55.7 (23.5)
Total Sleep Period (TSP)	97.9 (15.07)	87.2 (20.4)	99.4 (27.0)

Table 5. Mean Scores for Sleep Supplementation by Group

Characteristic	Intervention Mean (SD)	Control Mean (SD)	Hospital-US (Normative Data) Mean (SD)
Sample Size	10	10	151
Daytime Sleep (DTS)	32.0 (19.9)	42.9 (18.9)	22.5 (23.2)
Morning Sleep (AMS)	38.1 (31.0)	39.9 (26.7)	33.2 (33.7)
Afternoon Sleep (PMS)	36.4 (26.3)	37.5 (28.0)	30.1 (32.1)
Wake after Final Arousal (WAFA)	46.8 (23.1)	37.1 (24.3)	32.5 (32.5)

Participant Comments or Verbal Responses

During data collection, participant comments were recorded in clinical notes.

Qualitative data were not originally planned but the comments provided by the participants provided insight into the clinical usefulness of the earplug intervention. Most of the comments provided were positive. One participant stated that the earplugs created “a quiet world” that was “somehow comforting”. Another participant stated that she felt

that she was able to get back to sleep after being weighed at 0400 due to the earplugs because this was usually a noisier time on the unit. Another participant commented that the earplugs helped to block the noise in the room from his intravenous pump and his oxygen humidifier. Only two participants had negative feedback regarding the earplugs. One of the participants who did not finish the study stated that she was unable to tolerate the earplugs because they made her feel claustrophobic. Another participant had to remove his earplugs part way through the night because he stated that he became fixated on his own breathing. He stated that he had been congested that night and wanted to wear the earplugs the next night when he wasn't congested. The next night he reported that he found them helpful in blocking out the noise at the nurses' station and did not have any difficulty with his breathing.

Summary

Descriptive analysis, bivariate correlation, linear regression, and independent samples t-testing were done using SPSS. No relationship was found between the demographics and the sleep scores. No statistical significance ($\alpha \geq 0.05$) was identified between the intervention and the control night for any sleep characteristics. An effect size greater than 15 mm was identified for soundness of sleep but was not identified for any other sleep characteristic. Expected effect size changes were not seen for total sleep scale scores. The proposed hypothesis is supported for the sleep characteristic soundness of sleep but is not supported for any other sleep characteristic or total sleep scale scores. Subjective findings identified primarily positive comments with one person reporting

difficulty tolerating the earplugs. The data analysis provides essential information for this pilot study although the small sample size makes generalization of the findings difficult.

CHAPTER 5

DISCUSSION

Research Findings

The purpose of this pilot study was to evaluate the usefulness of earplugs and to evaluate the availability and willingness of hospitalized patients to use ear plugs towards evaluating the feasibility of the intervention. The hypothesis was that patients in the acute care setting will demonstrate a 15 mm improvement in sleep characteristic scores on the Verran and Snyder-Halpern Sleep Scales with the use of earplugs when compared to sleep quality without earplugs. The sleep characteristic, soundness of sleep, demonstrated a greater than 15 mm change between the intervention and control night. This finding indicates that the participants perceived sleeping more soundly with the earplugs than without the earplugs. However, for 14 other sleep characteristics the use of earplugs did not produce a change in sleep scores of greater than 15 mm. It is unknown if 15 mm is appropriate to correctly represent sleep improvement because individuals characterize sleep improvement differently. It may be difficult to determine a single value to measure adequate sleep improvement for all participants.

Evaluation of the change in sleep scores between intervention and control nights revealed no statistical significance. Sleep scores may not have changed due to various factors. One possibility is that the earplugs did not effectively decrease the sound for some individuals. Other possibilities are that patients were unable to sleep or had

disrupted sleep because of illness, pain, anxiety, lights, the unfamiliar environment, or patient care disturbances.

Regression analysis and bivariate correlations revealed that the demographic data did not have a statistically significant effect on sleep scores. This may have been due to a variety of factors such as anxiety, pain or patient care disturbances. Data from this study was compared to normative data for hospitalized patients in the United States.

Similarities did exist in mean scores between the study controls and normative data. The difference in sample sizes could limit the value of this information.

Subjective information indicated that the earplugs were clinically useful, although it was not reflected in the statistical analysis. The participants found the earplugs were helpful in assisting them get back to sleep after being awakened and block sounds within their rooms such as IV pumps and humidity bottles. Previous research supports these findings and the clinical significance warrants further investigation into the use of earplugs to improve sleep in the hospital setting.

Research Process

The second goal of this study was to evaluate the availability and willingness of participants to use earplugs and to determine the viability of the intervention. The study took place on the telemetry unit and intensive care unit of St. Vincent Healthcare over a three month period. Research notes were kept regarding possible participants and reasons for refusal but no specific data was gathered regarding recruitment and patient willingness to participate. During the study period, only 35 patients were identified as possible participants. Only one possible participant was in the intensive care unit. One

reason for the low number of possible participants was the need for the participant to be on the same floor for a total of three nights. The nurses on the telemetry unit repeatedly stated that their patients would be discharged within one to two days after admission. In the intensive care unit, if patients were eligible, they would not be spending more than one or two nights in the unit. The other reasons for exclusion included being unable to consent due to confusion, being hard of hearing, and a history of stroke. There were several patients who were willing to participate but were excluded from eligibility because they wore hearing aids or were deaf in one ear. In addition, several patients were disqualified because they were unable to consent to take part in the study due to confusion. These findings indicate that the availability of participants on the telemetry floor and intensive care unit at St. Vincent Healthcare is limited.

Another difficulty with availability of participants was that the unit nurses were relied upon to initially identify and approach possible participants. This is a common problem encountered by researchers in healthcare settings. Information regarding the study was provided to the staff via staff meetings, e-mails, and posters. Contact information for the researcher was available, and the researcher made site visits daily to speak with staff about possible participants. For the first three weeks, no participants were identified on either unit. During this time, the researcher met resistance of some staff to approach patients regarding participation. The researcher also found it difficult to engage all staff members during unit visits which could be attributed to the fast pace of the unit. It is also unclear if the staff fully understood the inclusion and exclusion criteria and if this understanding decreased the number of possible participants. It was noted a nurse would

state one patient did not meet the criteria and the next nurse would believe the same patient did qualify. These difficulties may have contributed to fewer possible participants identified than were actually available.

In addition to inadequate availability of patients, there also appeared to be limited willingness of patients to wear earplugs. Of the thirty-five eligible participants, only fourteen agreed to participate in the study. The primary reason for refusal was unwillingness to wear earplugs. The researcher did not make initial contact and, therefore, no further information was given for why the patients did not want to wear earplugs. Other reasons for refusal included chronic sleep problems, pain, frequent nocturia, and feeling too sick. Two participants who originally consented to the study had to withdraw due to worsening illness and inability to tolerate the earplugs. Of the ten who were able to complete the study, all of them found the earplugs to be an acceptable intervention. Although, a narrative was provided to staff for approaching patients about participation, staff bias may have been perceived by the patients and this could have also affected participation. Medical, oncology, surgical and orthopedic units should be evaluated for increased availability and willingness to participate in future research.

Conceptual Framework

The conceptual framework chosen for this study was Roy's Adaptation Model. For study purposes, the person was viewed as the adaptive system. Roy's theory is centered on the belief that adaptive responses support health (Roy & Zhan, 2006). Roy's model describes the role of the nurse as regulating stimuli affecting adaptation. The use of earplugs was a nursing intervention to help minimize noise, an environmental stimulus.

In this study, the intervention was initiated by the nurse researcher but the use of ear plugs could be initiated by the nurse. The clinical usefulness of the earplugs indicates positive adaptation to the environment and that earplugs may be an effective sleep intervention for select patients. Roy's Adaptation Model was an appropriate conceptual framework for this sleep study.

Limitations

Due to time and human resource limitations, a small sample size (N=10) was selected. The small sample prevents generalizing the results to all patients in the acute care setting. The sample in this study was likely too small to lead to any statistically significant results. With a small sample, any unusual results have a greater affect on the study results which may result in a type II error. To decrease the likelihood of a type II error, a larger sample should be used (Duffy et al., 2005).

Another limitation on generalization of the findings is that participants were only recruited from one specialty floor of the hospital as no participants were obtained from the intensive care unit. The effectiveness of the intervention is unknown with a medical, surgical, or intensive care population. In addition, the study only took place in one hospital in Billings, Montana.

Another limitation to this study was use of the Verran and Snyder-Halpern Sleep Scales. During the study, several participants had difficulty understanding the use of the Verran and Snyder-Halpern Sleep Scales. Participants frequently asked where to mark on the line to correctly represent their sleep. One participant stated that she felt that the visual analogue scale was too vague and subjective.

Confounding variables may have affected the sleep score results. One patient stated that he would have slept better if he wasn't up every two hours urinating. Another patient expressed his frustration at being frequently disturbed for vital signs and phlebotomy. Other confounding variables include pain, worry, lights, different staff and room assignment. No testing or interventions were done to control for these variables and it is unknown if these may have influenced the study results.

Implications for Clinical Practice

Earplugs are an inexpensive, non-pharmacologic sleep intervention shown to improve soundness of sleep in this study. In addition, participants found the earplugs comforting and helpful for blocking out hallway noise which may have prevented them from going back to sleep during the night. This clinical significance is an important finding and is consistent with previous researchers' findings (Haddock, 1994; Richardson et al., 2007). Patients who are having difficulty with sleep should be encouraged to try earplugs, and proper insertion should be demonstrated. This could be incorporated into routine bedtime care and certified nursing aides could be responsible for instruction.

Hospital policy changes and staff education are also important components to improve sleep quality. Previous research supports the importance of staff knowledge regarding the negative effects of sleep impairment and noise (Freedman et al., 2001; Gabor et al., 2003; Topf et al. 1996). It is also important for staff to be educated on various methods to help decrease the noise on the unit. One patient discussed that after she was weighed at 0400, it was too noisy to go back to sleep without the earplugs. Patient care changes may be needed based on patients' statements. Another patient mentioned that he was not sure if

earplugs would help because he was disturbed by staff so frequently. Previous research supports that patient care disturbances are another serious problem for hospitalized patients (Celik et al., 2005; Tamburri et al., 2004). The hospital should be encouraged to examine the routine night duties to limit patient disturbances and noise and to promote improved sleep quality.

Recommendations for Research

Further earplug research is recommended based on the clinical significance of the findings and the positive effect size findings for soundness of sleep. A variety of populations should be evaluated for increased eligibility and willingness to participate. Medical, surgical, oncology, and orthopedic patients should be studied as part of larger study with a heterogenous and larger sample. This study could be replicated with a larger sample size and different populations.

Further study of nursing knowledge and beliefs regarding sleep in the hospital setting should be done. Identifying any gaps in nursing knowledge could be used to guide sleep education. A previous study of nurses' knowledge regarding the effects of noise showed a knowledge deficit (Christensen, 2005). Another study found that after staff education regarding sleep importance and promotion interventions, nurses still were unable to leave patients undisturbed for two hours (Olsen et al., 2001). A study of nurses' feelings toward sleep interventions would provide information on obstacles which may be encountered when attempting to implement a sleep intervention.

Future research should attempt to control confounding variables. Distance from the nurses' station could be evaluated for any response variance on sleep scores. In the

hospital setting, researchers would be faced with challenges when attempting to control for variable such as pain, stress and illness.

Summary

The aim of this study was to evaluate earplugs as an intervention to promote sleep in acute care patients. Study results indicated that earplugs have clinical usefulness to improve perceived sleep quality consistent with previous research. Hospitals should evaluate their bedtime routine and consider adding earplugs as an option for patients to use to facilitate sleep. The positive effect size findings for soundness of sleep and the clinical usefulness support further study with a larger sample to substantiate these findings and to evaluate for statistical significance.

The study findings have clinical implications and help guide future research. Hospital sleep practices should be evaluated and earplugs should be considered as a sleep promotion intervention. A larger study should be done to validate the findings in this study and should control for confounding variables.. Nursing knowledge and beliefs should also be evaluated to help guide education. This study has provided useful information for future sleep research.

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APPENDICES

APPENDIX A

INSTITUTIONAL REVIEW BOARD APPROVAL LETTERS

INSTITUTIONAL REVIEW BOARD OF BILLINGS

SERVING

Billings Clinic

Montana Cancer Consortium

St. Vincent Healthcare

Other Independent Investigators & Institutions

February 4, 2008

Kristy Martin, BSN, RN
927 Burlington Ave
Billings MT 59101

Dear Ms. Martin,

An amendment to add Billings Clinic as a study conduct site for the following minimal risk nursing study was approved using expedited review procedures by the Institutional Review Board of Billings on February 4, 2008, using criteria from CFR 46.110 (b)(2) "Minor changes in previously approved research during the period for which approval is authorized":

**MONTANA STATE UNIVERSITY-BOZEMAN COLLEGE OF NURSING - BILLINGS CAMPUS
ST VINCENT HEALTHCARE / Kristy Martin RN, PI**

07.21 The Use of Earplugs to Improve Sleep Quality in the Intensive Care Unit

Approved conduct sites: St. Vincent Healthcare
Billings Clinic

Materials reviewed included but were not limited to: Billings Clinic letter of invitation to conduct research and revised Consent Form.

Please note that approval by the IRB of Billings is not a substitute for approval from the institutional review board of Montana State University Bozeman.

A stamped, approved consent form for the above-numbered protocol study is enclosed. Please notify the IRB office if additional information is required.

Sincerely,



James A. Patten, Chairman

Enclosure: Approved consent form for IRB 07.21

*Required Notice: Copy to Billings Clinic Research Center

The Institutional Review Board of Billings is in compliance with the regulations of the Food and Drug Administration, effective July 27, 1981, and all amendments thereto, contained in Title 21 of the Code of Federal Regulations, Parts 31 and 32.

Tel (406) 238-5657 ~ Fax (406) 238-5669
1020 North 27th Street, Suite 120 Billings, MT 59101-0760

INSTITUTIONAL REVIEW BOARD OF BILLINGS

SERVING

Billings Clinic

Montana Cancer Consortium

St. Vincent Healthcare

Other Independent Investigators & Institutions

November 14, 2007

Kristy Martin, BSN, RN
 927 Burlington Ave
 Billings MT 59101

Dear Ms. Martin,

The following new nursing study with consent form presented a less-than-minimal risk and was approved using expedited procedures on November 9, 2007, by the Institutional Review Board of Billings:

**MONTANA STATE UNIVERSITY-BOZEMAN COLLEGE OF NURSING - BILLINGS CAMPUS
 ST VINCENT HEALTHCARE / Kristy Martin RN, PI**

*Approved, Initial Review:***07.21** The Use of Earplugs to Improve Sleep Quality in the Intensive Care Unit

Materials reviewed included: Cover letter, 10/29/07; curriculum vitae; MSU-Bozeman IRB completed application; (Revised) Verran and Snyder-Halpern Sleep Scale Questionnaire; Visual Analog Sleep Scale form; Data Collection form (Subject Information Questionnaire Chart Form); Consent Form; and Addendum to consent form: Privacy Authorization

Please note that approval by the IRB of Billings is not a substitute for approval from the institutional review board of Montana State University-Bozeman.

No deviations from or changes to the above-named and numbered protocol study should be initiated without prior written IRB approval, except to eliminate an apparent immediate hazard to subjects. Please advise the IRB of any serious and unexpected adverse event that is associated with a study procedure, according to IRB policies for investigator reporting of adverse events.

The approval period for the above-named and numbered study is one year: A periodic review is due on or before October 10, 2008. Please note this date on your calendar: Compliance with periodic review is the responsibility of the Principal Investigator.

A stamped, approved consent form for the above-numbered new protocol study is enclosed. Please notify the IRB office if additional information is required.

Sincerely,



James A. Patten, Chairman

Enclosure: Approved consent form for IRB 07.21

The Institutional Review Board of Billings is in compliance with the regulations of the Food and Drug Administration, effective July 27, 1981, and all amendments thereto, contained in Title 21 of the Code of Federal Regulations, Parts 50 and 56

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 1020 North 27th Street, Suite 120 Billings, MT 59101-0760



INSTITUTIONAL REVIEW BOARD
For the Protection of Human Subjects
FWA 00000165

960 Technology Blvd. Room 127
 c/o Veterinary Molecular Biology
 Montana State University
 Bozeman, MT 59718
 Telephone: 406-994-6783
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Chair: Mark Quinn
 406-994-5721
 mquinn@montana.edu
Administrator:
 Cheryl Johnson
 406-994-6783
 cherylj@montana.edu

MEMORANDUM

TO: Kristy Martin

FROM: Mark Quinn *Mark Quinn CJ*
 Chair, Institutional Review Board for the Protection of Human Subjects

DATE: October 23, 2007

SUBJECT: *The Effect of Earplugs in Acute Care Patients to Improve Perceived Sleep Quality* [KM102307]

The above proposal was reviewed by expedited review by the Institutional Review Board and approved as submitted for a period of up to five years with yearly renewals.

Please keep track of the number of subjects who participate in the study and of any unexpected or adverse consequences of the research. If there are any adverse consequences, please report them to the committee as soon as possible. If there are serious adverse consequences, please suspend the research until the situation has been reviewed by the Institutional Review Board.

Any changes in the human subjects aspects of the research should be approved by the committee before they are implemented

It is the investigator's responsibility to inform subjects about the risks and benefits of the research. Although the subject's signing of the consent form, documents this process, you, as the investigator should be sure that the subject understands it. Please remember that subjects should receive a copy of the consent form and that you should keep a signed copy for your records. You can download a copy of the consent form format from our web site at: http://www.montana.edu/wwwami/IRB/instructions_for_writing.htm.

In one year, you will be sent a questionnaire asking for information about the progress of the research. The information that you provide will be used to determine whether the committee will give continuing approval for another year. After initial approval, if the research is still in progress beyond a 5-year period, a completely new application will be required.



INSTITUTIONAL REVIEW BOARD
For the Protection of Human Subjects
FWA 00000165

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Chair: Mark Quinn
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Administrator:
 Cheryl Johnson
 406-994-6783
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MEMORANDUM

TO: Kristy Martin

FROM: Mark Quinn *Mark Quinn CH*
 Chair, Institutional Review Board for the Protection of Human Subjects

DATE: January 31, 2008

SUBJECT: *The Effect of Earplugs in Acute Care Patients to Improve Perceived Sleep Quality* [KM102307]

This is to acknowledge receipt of the request dated January 31, 2008 for a minor modification to the above proposal. The request for the following modification(s) is/are approved:

- Addition of another facility (Billings Clinic) and revision of consent form to include the Billings Clinic

APPENDIX B

SUBJECT CONSENT FORM

SUBJECT CONSENT FORM
FOR
PARTICIPATION IN HUMAN RESEARCH AT
MONTANA STATE UNIVERSITY

PROJECT TITLE: The Effect of Earplugs on Perceived Sleep Quality of Acute Care Patients.

PARTICIPATION: You are being asked to participate in a study of sleep and the use of earplugs to improve sleep quality while in the hospital.

PURPOSE: Sleep is an important factor in the healing process and in maintaining emotional well-being. Sleep quality can be impaired while people are in the hospital and noise is one reason for the sleep impairment. This research may help us to understand whether sleep in acute care patients could be improved with this simple intervention. This study is being done as part of the requirements for the Master of Nursing program through Montana State University in Bozeman. The study will take place on the Telemetry Unit and Intensive Care Unit at St. Vincent Healthcare.

PROCEDURES:

If you agree to participate in this study, you will be asked to report your sleep quality for two nights. One night you will be asked to wear foam earplugs and the other night you will not wear ear plugs. The order in which you wear the earplugs will be randomly selected so that neither you nor the investigator will decide which comes first. During the study, you will be encouraged to go to sleep around 10 pm and to sleep until 06 am, as able. You will wear the earplugs during this time. Prior to the use of the earplugs, the investigator will explain proper application, care, and removal of the earplugs. This will take less than five minutes. After each night of sleep, you will be asked to complete a sleep questionnaire about the quality of your sleep. The questionnaire takes approximately five minutes to complete. The earplugs may be removed if necessary for your care or for any discomfort. You may also choose to withdraw from the study at any time. If you are transferred or discharged from the unit prior to completion of the study, you will no longer take part in the study. The researcher will review your medical record to gather information about your medical history.

RISKS: The risks are minimal, but include a potential for irritation of the ear or an allergic reaction to the earplugs. Because the earplugs are made of soft foam, irritation is not likely to occur. Allergies to the foam are rare.

BENEFITS: This study may benefit you by improving your sleep quality when you wear the earplugs. **ALTERNATIVES AVAILABLE:** If you decide not to participate there will be no change in your usual medical or nursing care.

COST: You will have no costs for this study. The earplugs are provided free of charge and you may keep them. You will not be paid for participating in this study.

RIGHTS OF PARTICIPANT: Taking part in this study is voluntary. You may choose to withdraw from this study at any time by removing the earplugs or telling your nurse or the investigator.

CONFIDENTIALITY OF RECORDS: All information about you will be kept confidential. Information about your medical history will be gathered as well as the sleep questionnaires. The

signed consent form(s) may be reviewed by qualified individuals at St. Vincent Healthcare, and by agencies that ensure that the rights of human participants are maintained such as the Institutional Review Board (IRB) of Billings and the Montana State University IRB. These agencies may also review the information provided to evaluate the data collected or for other purposes allowed by law. The information shared in this study may be used in nursing journals but no individual identifying data will be included. Results of this study will be reported for the group, without identifying individuals. Signed consent forms are kept on file at Montana State University College of Nursing for five years in a locked cabinet and then destroyed.

ADDITIONAL QUESTIONS: Additional questions regarding this study can be answered by Kristy Martin, principal investigator, (406) 252-5972 or (406) 788-3432 or Susan Luparell, thesis chairperson, (406) 771-4459.

For additional information on the rights of human subjects in research, or if you have any comments, questions or concerns, you may contact the chairman of the Montana State University Institutional Review Board, Mark Quinn, (406) 994-5721. You may also contact the Institutional Review Board (IRB) of Billings at (406) 238-5657, if you have any questions, comments or concerns about this study. This board is a community regulatory board whose mission is to protect human subjects from research risk and act as a research subject advocate.

AUTHORIZATION: I have read and understand the above information and have had my questions answered to my satisfaction at this time. I understand any benefits and risks associated with participation in this study. I, _____ agree to participate in this research. I understand that I may later refuse to participate, and that I may withdraw from the study at any time.

I have received a copy of this consent form for my own records.

Yes _____ No _____

Signed: _____

Witness: _____

Investigator: _____

Date: _____

APPENDIX C

ADDENDUM TO CONSENT FORM: PRIVACY AUTHORIZATION

Addendum to Consent Form: Privacy Authorization
for Protocol 07:21, The Effect of Earplugs on Perceived Sleep Quality of Acute Care
Patients.

Explanation and Background

Records – Use and Disclosure This attachment to the information and consent form provides additional information about how your medical records and health information (together, your “records”) will be used and disclosed for this study. Your records may include information about your blood samples, physical examinations, medical history and any other data collected or reviewed during the course of the study as described in the consent form.

This form allows the principal investigator identified in the consent to use your records to carry out the study described in the consent form. By signing this form you allow the principal investigator to disclose your records to the sponsor identified in the consent and the sponsor’s representatives. The sponsor will use the information to review the results of the study. The data sent by the principal investigator to the sponsor will not include your name, address or social security number.

All of your records, the signed consent form (s), and this form also might be reviewed or copied by St. Vincent Healthcare or by the Institutional Review Boards (IRB) of Billings, or by the Montana State University IRB or by other regulatory agencies in this country. These agencies might review your records to check the information collected in this study, to check how the study was conducted or for other uses allowed by law.

Possibility for Re-Disclosure Federal and state laws require the principal investigator to protect the privacy of your records; however, absolute confidentiality cannot be guaranteed because of the need to disclose information as described above. In addition, after the principal investigator discloses your records to others, then the law may no longer protect the privacy of the information. If you would like to know how the sponsor will protect the privacy of your records, ask the principal investigator how to obtain this information. If you would like to know how the IRB will protect the privacy of your records, you can contact the IRB at the telephone number listed in the consent form.

Authorization Requirement for Participation If you do not sign this authorization, you cannot participate in the study. You can cancel this authorization at any time by giving a written notice to the principal investigator. If you cancel this authorization, then you no longer will be able to participate in the study. If you cancel this authorization then the principal investigator will no longer use or disclose your records unless the principal investigator needs to do so in order to preserve the scientific integrity of the study. The principal investigator may still use the information that has already been collected.

Participant’s Initials _____ Date _____

Duration of Authorization This authorization does not have an expiration date. If you do not cancel this authorization, then it will remain in effect indefinitely.

Privacy Authorization

I authorize the release of my medical records and health information related to this study, including my signed consent form and this addendum, to the sponsor and its representatives, St. Vincent Healthcare, IRB of Billings, Montana State University IRB and other regulator agencies as described above.

By signing this form, I have not given up any of my legal rights as a research participant. I understand that I will receive a signed copy of this authorization for my records.

Printed Name of Participant

Signature of Participant

Date

APPENDIX D

VERRAN AND SNYDER-HALPERN SLEEP SCALES

VISUAL ANALOG SLEEP SCALES

Directions: Answer each question by placing a vertical mark across the answer line at a point which **BEST REFLECTS YOUR OPINION.**

Example: Happy _____ | _____ Sad

Answer all of the following questions about your last night's sleep. Consider the night's sleep to begin from the time you first tried to go to sleep to the time you were finally "up" in the morning.

- | | | |
|---|-------|--|
| 1. Did not awaken | _____ | Was awake ten hours |
| 2. Had no sleep | _____ | Excluding time awake, had ten hours of sleep |
| 3. Did not sleep during the day yesterday | _____ | Slept ten hours during the day |
| 4. Did not sleep yesterday morning | _____ | Slept off and on yesterday morning |
| 5. Did not sleep yesterday evening | _____ | Slept off and on yesterday evening |
| 6. Fell asleep immediately | _____ | Did not fall asleep |
| 7. Slept lightly | _____ | Slept deeply |
| 8. Had no trouble with disrupted sleep | _____ | Had a lot of trouble with disrupted sleep |
| 9. Didn't wake at all | _____ | Was awake off and on all night |
| 10. Had no trouble falling sleep | _____ | Had a lot of trouble falling asleep |
| 11. Didn't move | _____ | Tossed all night |

- | | | |
|-----------------------------------|-------|---|
| 12. Awoke exhausted | _____ | Awoke refreshed |
| 13. After morning
stayed awake | _____ | After morning awakening, dozed off and on |
| 14. Had a bad night's sleep | _____ | Had a good night's sleep |
| 15. Had enough sleep | _____ | Did not have enough sleep |

APPENDIX E

SUBJECTIVE INFORMATION QUESTIONNAIRE

SUBJECT INFORMATION QUESTIONNAIRE
Revised from Verran and Snyder-Halpern

Directions: Please circle or fill in the one correct response.

SUBJECT NUMBER: _____

1. What is your sex? A. Female B. Male
2. What is your age? _____
3. What is your marital status? _____
4. What are your normal sleeping hours: ____ to ____
5. Do you have any routine assistance for achieving sleep; **YES** **NO**
 e.g., a radio, TV, reading, etc. If YES, please list below:

6. In your opinion, are you currently experiencing any stress **YES** **NO**
 which might disrupt your normal sleep patterns?
7. Day of Hospitalization: _____
8. Day of Week _____
9. Diagnosis: _____
10. Service: 1. Medical 2. Surgical
11. Sleeping medication night study: **YES** **NO**
 Medication: _____
 Dose: _____
 Time: _____

