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Implementation of Yoga to Treat Insomnia in an Adult Population

By

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DNP Scholarly Project Committee

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Dr. Katherine Hinic

Dr. Marcella Frank

Submitted in partial fulfillment of the requirements for the degree of

Doctor of Nursing Practice

Seton Hall University

2021

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Dedication

I dedicate this work to my mother, Patricia Smith, who has always been my source of inspiration as well as my biggest supporter. You are strong and compassionate and never let life's challenges deter you from pursuing your goals. You have taught me to work hard and never give up until success is attained. I feel very blessed to have you as my mother, and words could never truly capture how much I love you.

To my Aunt Cookie; you have offered steadfast support and have always had a calming effect on me during stressful times. I thank you for the love, support, and wisdom that you have given me throughout my life. You truly are my second mom, and I am grateful for your love.

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Seton Hall University
College of Nursing

Approval of Project Defense

Kerri Penders has successfully defended and made necessary modifications to the text of this
Final Scholarly Project for the degree of DNP in Spring 2021.

Dr. Mary Ellen Roberts—Chair

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Date: _____

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Abstract

Background: Insomnia is a highly prevalent disorder with deleterious health consequences, including increased risk of high blood pressure, heart disease, diabetes, anxiety, and depression. Current treatment relies on cognitive behavioral therapy and sedative hypnotics. A non-pharmacological approach is needed to manage insomnia in the long term. *Project Aim:* The present program aimed to determine whether four weeks of yoga improves insomnia and anxiety severity and reduces medication use. *Methods:* This was a quality improvement project with a pre-intervention–post-intervention design. Before intervention, patients received standard cognitive behavioral therapy for insomnia from a sleep provider and, if there was no improvement in their insomnia symptoms, enrolled for four weeks of virtual yoga sessions two to three times a week. A total of eight participants started the program, but one withdrew from the program because of work commitments. All seven participants engaged in the 60-minute classes as directed. Their Insomnia Severity Index (ISI), State-Trait Anxiety Inventory (STAI) score, sleep latency, sleep duration, and medication use were assessed at the baseline and again at the completion of the four weeks of yoga. *Results:* After four weeks of performing yoga exercises, the participants' overall sleep latency improved by 35 minutes on average (49% change), and their sleep duration increased by 1.07 hours on average (18.83% change). Their ISI also improved, with five participants (71%) having subthreshold insomnia and two subjects (29%) exhibiting no clinically significant insomnia. The STAI score is partitioned into the subscales State and Trait; on the State subscale, all participants improved from a median score of 29 before intervention to a median score of 19 post intervention. The Trait subscale score improved, but not markedly, from an average score of 23.71 at the baseline to 20.29 post intervention. There was no significant change in medication dose or frequency post intervention. *Conclusion:* Four weeks of yoga improved insomnia and anxiety symptoms, shortened sleep

latency, and improved sleep duration in women with chronic insomnia. Yoga, in combination with cognitive behavioral therapy for insomnia, may offer providers another non-pharmacological option to make effective and sustainable changes for patients suffering from this sleep disorder.

Keywords: Sleep latency, Sleep duration, Insomnia Severity Index, State-Trait Anxiety Inventory, cognitive behavioral therapy for insomnia

Background

Approximately 50–70 million individuals are estimated to suffer from sleep disorders, with difficulty in sleeping being one of the most common medical complaints reported. Research indicates that poor sleep is associated with declined work performance, increased health care costs, and impaired daytime functioning. Lack of sleep adversely affects one's overall physical and emotional health (Chong et al., 2013; Kessler et al., 2011).

The true incidence of insomnia is not known, but it is estimated that it affects approximately 33–50% of the adult population, depending upon the definition used (Sateia et al., 2017). Individuals suffering from insomnia tend to be educated, older, non-Hispanic White females. The data from the 2017 National Health Interview Survey (N = 26,742) also confirmed these findings (Voib et al., 2019).

The etiology of insomnia is multifactorial, but many believe that it is related to a hyperarousal state of both the central and autonomic nervous systems. Hyperarousal can stem from a psychological, physical, or environmental cause (Folay, 2020). The purpose of therapy is to mitigate any underlying causes that may be contributing to the sleep impairment, with the goal of improving sleep quality and duration. Providers need to identify better alternatives to shift the person's sympathetic drive to more of a parasympathetic state and realize that there may be more than one cause contributing to this complex disorder.

Insomnia is a health concern that has deleterious consequences, including increased risk of high blood pressure, heart disease, diabetes, anxiety, and depression, and is associated with higher morbidity and mortality in the older population (Bhaskar et al., 2016; Colten & Altevogt, 2006; Halpern et al., 2014). Patients with insomnia are also at risk for substance use, poor work performance, daytime sleepiness, and fatal motor vehicle accidents (Laugsand et al., 2014; Saddichha, 2010).

Psychiatric disorders are the most common known causes of insomnia. Anxiety, specifically, can cause insomnia, but insomnia is also known to worsen anxiety, producing a bidirectional effect. Similar to anxiety, depression can also lead to insomnia, with early morning awakenings (American Sleep Association, 2020). Insomnia is a highly prevalent disorder with the ability to impact one's health. The management of insomnia should be an integral component to improve overall disease. It is a public health burden with grave consequences, and there is a need for effective long-term treatment.

Definition of Terms

Insomnia may present itself in different forms; most forms fall into two categories: difficulty with falling asleep and staying asleep. It is not uncommon for patients to present with both forms, which is known as mixed insomnia. Insomnia is also categorized into short-term and chronic insomnia. In short-term insomnia, the patient presents with symptoms that last less than three months, and those with chronic insomnia present with symptoms that occur at least three times a week for at least three months. To be diagnosed with chronic insomnia, a patient must report difficulty with initiating or maintaining sleep and have impaired daytime functioning of cognition, mood, or performance. Additionally, the insomnia should not be related to another sleep disorder, such as obstructive sleep apnea or restless leg syndrome (Sateia et al., 2017; Schutte-Rodin et al., 2008). The impairment of daytime functioning in insomnia is a crucial component that is often overlooked and may manifest in mood disturbances, fatigue or daytime sleepiness, memory difficulties, and behavioral changes (Folay, 2020).

Pandemic and Insomnia

Unfortunately, due to the recent pandemic, the incidence rate of insomnia has increased. The 2019 novel coronavirus disease (COVID-19), first detected in Wuhan, China, in December

2019, has had a notable emotional and physical impact on the general population, and sleep is one of the aspects that have been affected. During the pandemic, patients experienced a loss of routine, social isolation, financial losses, fear of illness, and a sense of helplessness. Changes in the sleep–wake schedules, reduction in sunlight exposure, and increase in the use of electronic devices also contributed to sleep difficulties (Hurley, 2020). Notably, the most common responses to the question “What keeps you up at night?” were finances, overall health, and a feeling of helplessness. The uncertainty inherent to the COVID-19 pandemic compromised the health of these patients further. The pandemic caused patients to change the way they normally performed routine activities. They were essentially required to perform a risk–benefit analysis each time they wanted to step outside. There was also the unknown factor of when the pandemic will end. This constant state of worry heightened the flight-or-flight response, and social isolation compounded these symptoms (Serani, 2020).

In a survey that examined 556 adults aged 18–87 years—of whom 48 were infected with COVID-19—using the Insomnia Severity Index (ISI) and the Loneliness Scale, researchers found that COVID-19-related concerns and loneliness were contributing factors in the development of insomnia symptoms, with 19% of the study’s participants meeting the diagnostic criteria for insomnia (Kpolou-Kokou et al., 2020). In another online survey in a Greek population, researchers used the Athens Insomnia Scale, Intolerance to Uncertainty Scale, Loneliness Scale, and Brief Patient Health Questionnaire and found that, of the 2,363 participants aged 18–20 years, 37.6% had insomnia symptoms (Voitsidis et al., 2020). Similar findings were obtained in a study in an Italian population (2,291 participants), with 57.1% reporting poor-quality sleep and 41.8% reporting high anxiety (Casagrande et al., 2020). In the United States, 56% of respondents who reported insomnia and COVID worries also had greater suicidal ideation (Kilgore et al., 2020). The above research indicates high rates of insomnia,

anxiety, and loneliness during the pandemic. The impact is prevalent enough that neurologists have coined the term “COVID-somnia” (Hurley, 2020).

Treatment of Insomnia

Many patients with insomnia, however, are seeking quick treatment options. Between February 16 and March 15, 2020, Express Scripts alone noted a 15% and 34% increase in the use of sleep aids and anti-anxiety medications, respectively, as compared to 2019, and this was before the peak of the pandemic (Express Scripts, 2020). Moreover, 78% of all antidepressant, anti-anxiety, and insomnia medications filled during the second week of March were for new prescriptions (Express Scripts, 2020). Prior to the pandemic, sleep aid use was already on the rise. According to the Centers for Disease Control and Prevention (CDC), there are nine million Americans who use prescription sleep aids, with an increased use of the same seen over the last two decades. The percentage of adults who use prescription sleep aids increases with age, and their use is more commonly seen in individuals who are non-Hispanic white, older, educated females (Chong et al., 2013). The commonly used sleep medications are sedative hypnotics.

The two main categories of sedative hypnotics are the benzodiazepines and the Z-drugs (non-benzodiazepines); both are recommended for short-term use. However, it is more common to find patients who visit sleep centers to be on one of these medications for months or even years, despite research demonstrating a poor safety profile of these drugs. The known adverse cognitive and psychomotor events associated with these medications, which is well documented in the literature are memory loss, daytime drowsiness, and increased fall rates. Sedative hypnotics may also lead to a physical dependency, with a potential for addiction (McMillan et al., 2013).

In 2011, there were over 30,000 emergency room visits related to the nonmedical use of Zolpidem (a Z-drug), and data from 2012 suggests that 21% of patients who abused sleep aids

contemplated suicide (Juergens, 2020). As the pandemic continues to unfold, and the prevalence of insomnia continues to grow, we may see future studies documenting an increased need of sleep aids. Providers need to identify non-pharmacological treatment options for patients with insomnia. Medication is only a short-term solution for a disorder that needs long-term management. Given the drawbacks of the medication currently prescribed for insomnia, safe, non-pharmacological approaches that are sustainable for long-term use are warranted.

Sleep education in the form of cognitive behavioral therapy for insomnia (CBT-I) is one of the first-line treatment methods and has been recommended by the American Academy of Sleep Medicine (AASM) since 2016, as well as The American College of Physician (ACP) (Folay, 2020; Koefel et al., 2018). CBT-I is a multi-component approach that looks at the connection between thoughts and behaviors and the impact these have on sleep. The structured program of CBT-I includes providing education on the misconceptions about sleep and eliminating those maladaptive behaviors of patients that perpetuate their insomnia. The cognitive part of the therapy focuses on recognizing and restructuring the negative beliefs and thoughts that affect the individual's ability to sleep. The common aspects that are typically addressed involve anxiety related to sleep, unrealistic expectations about sleep, and worry about performance caused with missed sleep. The goal of cognitive therapy is to educate patients about sleep norms, encourage them to set realistic goals about their sleep, and implement cognitive practices that will calm their mind and improve the repetitive negative thinking that influences their ability to sleep (Mayo Clinic, 2021; Newsom, 2020).

The behavioral part of the CBT-I looks at the patient's behaviors that are impacting their sleep ability. Typically, patients complete a two-week sleep log to document their bedtime, wake time, sleep duration, and sleep quality, daytime activity, and use of medications. These sleep logs provide a visual sleep-wake pattern and highlight areas that need to be modified to improve the

insomnia symptoms. The provider, for example, can then determine whether a patient has a variable sleep schedule that may be contributing to the insomnia symptoms or whether their medications are contributing to a prolonged sleep latency. Additional behavioral education includes minimizing or avoiding naps and eliminating behaviors that disrupt sleep (stimulus control), such as watching television or paying bills in bed. Sleep restriction is also a useful strategy to help consolidate sleep. Many patients spend too much time in bed trying to sleep, which results in the patients' sleep opportunity exceeding their sleep ability (Edinger et al., 2021). In sleep restriction treatment, the patient's total sleep time is calculated from sleep logs, and they are advised to limit their time in bed to that amount of time plus 30 minutes. For example, if a patient reports sleeping five hours a night, they are advised to limit the time they spend in bed to five and a half hours. Once all their time in bed is spent sleeping, they are then advised to gradually increase their total time in bed to their desired goal. The goal with sleep restriction is to increase the patient's sleep drive to help consolidate sleep (Edinger, 2021; Newsom, 2020).

There are additional behavioral strategies that are part of the CBT-I approach that providers can implement to improve insomnia symptoms and this is in the area of complementary alternative medicine (CAM). Examples of these activities are deep breathing, yoga, meditation, and tai chi. Research has shown that these practices can slow the heart rate and respiratory rate and decrease stress and anxiety, but, unfortunately, these practices are not usually recommended or implemented for insomnia outside of sleep center practices (Bertisch et al., 2012; Newsom, 2020).

Not only does the AASM recommend these supplemental practices as part of the CBT-I education, but The National Heart, Lung and Blood Institute (2020) also supports these techniques to target the hyperarousal state of insomnia. Data collected from the National Health

Interview Study (N= 23,358) indicated that although 23% of the included patients used relaxation techniques (deep-breathing exercises, progressive muscle relaxation, biofeedback, and guided imagery), and 45% used CAM practices (homeopathy, tai chi, energy healing, and yoga), fewer than 2% of the adults surveyed used CAM practices specifically for mitigating insomnia symptoms (Bertisch et al., 2012). This indicates that although these are acceptable practices they are not used for insomnia. Both relaxation techniques and CAM practices are underutilized in the treatment of insomnia symptoms and should be encouraged as a part of the CBT-I training. If there was more of a focus on healthier treatment options, there may be less reliance on prescription medication, which is currently the most common treatment for insomnia (Naiman, 2015). CBT-I, overall, is a highly effective approach and there is evidence to support the addition of supplemental practices to improve insomnia symptoms (Edinger, 2021; Newsom, 2020).

Yoga and Health

Yoga is an ancient Indian practice that focuses on physical movements, rhythmic breathing, and meditation to balance the mind, body, and spirit (Gothe et al., 2019). Yoga practice is a well-suited treatment option to compliment the current CBT for insomnia. Yoga, through its meditative practices, engages the parasympathetic response, which leads to a calmer, less stressed state, as evidenced by a lower blood pressure, heart rate, and lower levels of the stress hormone cortisol. In contrast, the activation of the sympathetic nervous system prepares the body for a “fight or flight” reaction, with opposing reactions. When the parasympathetic system is activated, it cancels out the sympathetic system and calms the body, which is a precursor to sleep (Kennedy, 2014; McCall, 2007). Yoga teaches the insomnia patient to be present and slows down their ruminating thoughts and characteristics that are often presented in insomnia (Folay, 2020).

Research has shown that practicing yoga enhances overall health and has therapeutic benefits. It reduces blood pressure, stress, and obesity and is shown to increase flexibility, strength, and balance. Furthermore, it improves diabetes and cardiovascular function and is believed to be neuroprotective (Gothe et al., 2019; McCall, 2007; Park & Han, 2017; Rioux & Howerter, 2019).

The sleep benefits provided by yoga have been documented in randomized control trials in cancer survivors (Garcia et al., 2018; Mustian et al., 2013) and in the elderly (Chen et al., 2010; Hariprasad et al., 2013; Manjunath & Telles, 2004). In non-randomized control trials, yoga improved sleep duration, sleep latency, and sleep efficiency and reduced anxiety and depression symptoms (Halpern et al., 2014; Khalsa et al., 2014). Similarly, Kohn and colleagues (2013) noted that yoga decreased stress and improved anxiety. Yoga has the potential to optimize every system in your body, manage insomnia symptoms in the long term, and carries far lower risks and less side effects than medications (Kennedy, 2014; McCall, 2007). The above literature indicates that yoga, through its psychophysical practices, improves both the mind–body connection, improves insomnia symptoms, and has the potential to improve one’s overall health in the adult population.

Objectives of the Project

This project had three main objectives:

1. To determine whether four weeks of yoga is an effective treatment option for patients with insomnia using the ISI, sleep latency, and sleep duration
2. To determine whether yoga improves anxiety symptoms in patients with chronic insomnia using the State-Trait Anxiety Inventory (STAI)
3. To determine whether four weeks of yoga decreases the use of sleep aids for patients with chronic insomnia

Benefits of the Project

Insomnia is a highly prevalent sleep disorder with a high financial and medical burden on society. The total costs to treat insomnia—both direct (healthcare provider visits and prescription medications, etc.) and indirect costs (decreased work performance, missed work days, work accidents, etc.)—are estimated to be between \$ 30–107.5 billion (Roy, 2014). The long-term effects of sleep loss may have deleterious health consequences as well, including increased risk of diabetes, hypertension, obesity, mood disorders, and cardiac events. Clinicians need to identify better approaches to incorporate long-term management in the treatment of insomnia to prevent further complications. Insomnia is a highly prevalent disorder that can have grave health and financial consequences on society, and it is often overlooked and undertreated (Colten & Altevogt, 2006).

The existing data does support that CBT-I has the ability to reduce costs. McCrae and colleagues (2014) conducted a retrospective chart review of 84 patients and found that patients who attended more than three treatment encounters had a \$ 196.86 lower post-treatment current procedural terminology (CPT) cost, fewer office visits ($p < 0.05$), lower estimated total costs ($p < 0.05$), and a slightly lower outpatient cost by \$ 39.04 ($p < 0.07$). Adding yoga to the already existing CBT-I may alleviate the financial and health burden associated with this disease.

Literature Review

This literature review was conducted from October 2020 to March 2021 using the electronic databases PubMed, Medline, ScienceDirect, Elsevier, CINAHL, American Academy of Sleep Medicine, and Seton Hall Library. The keywords utilized in the search were “yoga” and “insomnia.” Most of the research on yoga and insomnia has focused on individuals with cancer and menopausal women. There were, however, several studies that showed the health benefits of yoga in the elderly population. In a study conducted by Chen et al. (2010), 69 elderly residents

were randomized into either a yoga or a control group in a quasi-experimental pre-intervention–post-intervention design. Thirty-eight subjects performed yoga three times a week for six months. The sleep quality, depression, and perception of health improved in the yoga group, and results were maintained at a six-month follow up ($p < 0.05$). In a similar randomized control study conducted by Manjunath and Telles (2004), 120 residents from a nursing home were randomly assigned to receive no treatment (control group), receive herbal sleep medication (Ayurveda), or perform an hour of yoga six days a week. The yoga group showed significantly shorter sleep latency (by 10 min; $p < 0.05$) and significantly higher sleep durations (by 1 h; $p < 0.05$). The other two groups showed no significant change post intervention. In another study in this population, Hariprasad et al. (2013) found that the yoga intervention group—which performed supervised yoga for three months (daily for one month and weekly up to three months) and unsupervised yoga for three months—showed an improved quality of life ($p < 0.001$) and sleep quality ($p = 0.001$) as compared to the wait-list group (control group).

In another exploratory randomized control trial (RCT), which focused more on restless leg syndrome (RLS) and yoga in an adult population, researchers randomly assigned 41 participants to either watch an educational film on RLS or enroll in a 12-week yoga class (the intervention group). For the first four weeks, the participants engaged in a 75-minute class twice every week and then a weekly 75-minute class for the remaining eight weeks. In addition to the RLS improvement, investigators found that yoga improved the sleep quality, mood, and quality of life of these subjects (Innes et al., 2020).

A meta-analysis conducted by Chen et al. (2020), which included studies up to August 2019, analyzed 497 patients in seven RCTs, examined the impact of mindfulness-based stress reduction (MBSR) techniques, including yoga, and found that the MBSR group showed significantly improved sleep quality ($p = 0.002$) and anxiety ($p = 0.003$). In another meta-

analysis published in 2019, the data from the RCTs was used to analyze the effects of yoga specifically on women with insomnia. Nineteen full-text articles with 1,832 female participants were included in this qualitative analysis. Yoga improved sleep ($p = 0.001$), with patients with non-cancer diseases and non-menopausal patients showing the greatest improvement. Sixteen RCTs revealed improvement in sleep quality for women ($p = 0.003$), whereas the other three RCTs showed no improvement in sleep with yoga when compared with the control group (Bankar et al., 2013; Wang et al., 2020).

In contrast, in a meta-analysis looking specifically at hatha yoga (where the focus is more on breath work and poses), 13 RCTs were analyzed to determine whether yoga was an effective treatment for acute or chronic mood and anxiety disorders. The findings showed no significant effect of hatha yoga on the symptoms of anxiety when compared with the control group (Vollbehr et al., 2018). Although these RCTs showed no improvement, this discrepancy might be due to methodological differences; these studies focused specifically on hatha yoga, and it is possible that other forms of yoga may be more beneficial, specifically meditative yoga.

Several nonrandomized studies conclude that yoga is beneficial for sleep. In a study by Halpern et al. (2014), in which a nonrandomized, wait-list control group was included, yoga was implemented twice every week for 12 weeks by 67 older individuals (aged ≥ 60 years). The authors noted a significant improvement in the yoga group compared with patients who received standard care in factors such as sleep quality ($p = 0.002$), sleep efficiency ($p = 0.450$), sleep duration ($p = 0.020$), sleep latency ($p = 0.040$), depression or anxiety symptoms ($p = 0.010$), and general wellbeing ($p = 0.080$). Khalsa (2004) also found similar improvements in sleep efficiency, sleep duration, sleep latency, and wake after sleep onset following eight weeks of yoga exercises at home. Additionally, research conducted by Kohn and colleagues (2013) indicates that practicing yoga once a week for 12 weeks significantly reduced stress and anxiety

and improved the perception of one's overall health in patients with stress-related symptoms.

This is important because poor sleep is a risk factor for insomnia, and patients with insomnia are 20 times more likely to develop anxiety (Neckelmann et al., 2007).

Insomnia is highly prevalent in patients with cancer and menopausal patients, and most of the studies reviewed were from this patient population. Anywhere from 30–90% of cancer patients suffer from impaired sleep quality post treatment, which, in turn, has the potential to increase patients' morbidity and mortality rates. Mustian and colleagues (2013) determined that four weeks of yoga improved sleep quality and reduced daytime dysfunction in 410 cancer survivors. Additionally, the yoga group decreased their sleep medication use by 21% per week, whereas the control group actually increased their sleep medication use by 5%. In the intervention group, 90% of the patients found that yoga improved their sleep quality. Yoga also improved sleep quality, quality of life, and reduced menopausal symptoms in women after they performed daily mindfulness and relaxation training for eight weeks (Garcia et al., 2018). In an online survey administered to 29 oncologists, respondents believed that practicing yoga during treatment would reduce the patients' fear and anxiety during treatment and improve their quality of life (McCall et al., 2015).

It is difficult to draw significant clinical conclusions on the basis of the literature review. Studies were done in a variety of populations, assessors were not blinded to treatment allocation, sample sizes were insufficient, and there was a lack of heterogeneity of yoga techniques and in the study protocols designs, making definitive conclusions difficult.

At present, research suggests that yoga is plausible as a treatment option for improving insomnia symptoms. This quality improvement (QI) project will shed light on the need for additional research and assess whether yoga is a useful treatment option for patients with insomnia.

Theoretical Framework

Dorothea Orem's self-care deficit theory consists of three interlocking theories: the theory of self-care, theory of self-care deficit, and theory of nursing systems. The *theory of self-care* describes the activities that one undertakes to maintain their health and wellbeing. When a patient's needs exceed their abilities to perform the acts to meet those needs, a *self-care deficit* occurs. When this deficit occurs, nursing care is needed to bring the individual to a state of independence. The third theory, *the theory of nursing systems*, incorporates the trusting relationship established between nurse and patient, which is needed for a successful health outcome (Orem, 1991). Orem's self-care theory is useful in various clinical and educational settings and in all stages of life. The goal of Orem's theory is to teach and guide patients to promote personal development and independence, which, in turn, will improve patient outcomes (Trimmins & Horan, 2007). Orem's self-care theory is therefore an applicable theoretical framework that can be used in the management of patients with insomnia, and it offers guidance in providing patients with the opportunity to become independent healthy individuals.

Orem's theory discusses the importance of a three-step nursing process to determine whether a health care deficit exists, whether nursing care is needed, and how the patient is going to attain self-reliance. In the first step, data is collected to determine the self-care deficit, and health goals are established. A decision is then made to construct the patient's treatment plan (Health Research Funding, 2019; Orem, 1991).

This first step is similar to how providers currently practice medicine in the sleep center. The data is collected on the basis of the patient's chief complaint (i.e., subjective data) and previous objective data. The provider assesses the patient's sleep goals, analyzes the information presented, including both subjective and objective data, and then often makes a clinical diagnosis.

The second step in Orem's nursing process involves creating an educational treatment plan to eliminate the self-care deficit (Health Research Funding, 2019; Orem, 1991). This is the goal of insomnia management: to ensure that patients are self-reliant and equipped with healthy practices to manage their insomnia symptoms. This is accomplished by providing written and verbal educational information from the AASM and following the designated insomnia practice parameters.

The final and third step in this process involves implementing the devised health care plan, evaluating whether these techniques are useful, and then modifying the plan as needed for patient success (Health Research Funding, 2019; Orem, 1991). Although there are practice parameters in place to help guide the treatment plan, each patient is a unique individual, and, therefore, the treatment plan is always individualized to meet the patient's needs.

When patients arrive at a sleep center, they have a self-care deficit and are seeking assistance to improve the duration and quality of their sleep. We assess the patient's sleep disturbances, diagnose the type of sleep disorder, and provide suggestions based on the assessment, all while establishing a patient-provider relationship. As providers, we offer the patients the necessary tools, support, and education to become independent and self-reliant, with the goal of minimizing their sleep disturbances and improving their overall health and wellbeing.

This QI project involves offering yoga to interested patients to further improve their insomnia symptoms. The concepts of self-care and self-reliance to improve wellbeing are integral to yoga practice (McCall, 2007). This is the cornerstone of Orem's theory and, therefore, fitting for this project.

Orem's nursing theory has several components that influence the care of an individual: *health, person, nursing, and environment*. Yoga practitioners and others who look to Orem's theory for guidance believe that *health* is not only the physical absence of disease but also a

balance between the physical, psychological, and emotional aspects of an individual (McCall, 2007; Orem, 1991).

The World Health Organization (WHO) (2019, p. 1), the organization concerned with national health, also believes that “Health is a state of complete physical, mental, and social wellbeing and not merely the absence of disease and infirmity.” Those who practice medicine are beginning to realize that health is defined not only by the physical being but also by the emotional and spiritual parts of a person; each of these aspects is intertwined with the others and affects overall health.

It is well known that insomnia is multifactorial and that all of these aspects within *health* have the potential to interfere with one’s sleep. If, for example, a patient is psychologically stressed or physically feeling anxious, this may impact the patient’s ability to initiate sleep. It is not uncommon for patients with stress or anxiety to ruminate on their thoughts. This often leads to difficulty falling asleep and difficulty reinitiating sleep once aroused (Folay, 2020).

Additionally, patients who do not sleep well are often more irritable, less focused, and more prone to anxiety than patients who do (National Health Service [NHS], 2018; Neckelmann et al., 2007). Clinicians can no longer focus solely on the physical body when we define health if we want patients to be truly healthy.

Orem (1991) describes the next concept of *person* as the recipient of care and as the one who has self-knowledge and the ability to learn, develop, and interpret experiences. Patients must be able to receive and comprehend the information being provided and then modify the information such that it can be incorporated into their daily lifestyles. Everything an individual does has the potential to positively or negatively impact their sleep.

Nursing, the next component of Orem’s theory, is described as the specialized health care services that an individual receives to improve and meet self-care needs. Nursing is a process

that involves the ability to make decisions about what can and should be done for the patient and which factors need to be changed for the patient for them to gain independence. It is these nursing processes and actions that prevent self-care deficits (Orem, 1991). Educating patients about the health benefits of yoga practice (e.g., improvement in conditions such as insomnia symptoms, anxiety disorders, back disorders, diabetes, heart disease, menopausal symptoms, and obesity) will hopefully engage and motivate patients to strive for healthier lifestyles. This, in turn, should improve sleep symptoms; sleep quality may be a factor that affects quality of life (McCall, 2007).

Environment, the last component of the theory, is described as the external factors that may affect the patient's care (Orem, 1991). Assessing the environment of patients with insomnia is crucial. There are many external factors that contribute to poor sleep and affect the sleep-wake cycle. Light, for example, affects the internal or biological clock, which regulates our sleep-wake cycle. The brain decides on the basis of light signals whether it is time to sleep or stay awake. Bedrooms should be devoid of all electronics devices; the light from these devices can decrease the production of melatonin, the naturally occurring sleep hormone. Temperature is another external factor that affects one's sleep. Most people prefer a cooler room, but this is person-specific. The bed should be comfortable, and ambient noise should be limited (American Sleep Association, n.d.). The four major components of Orem's theory—*health*, *person*, *nursing*, and *environment*—are consistent with what we are trying to assess at our sleep center. All of the above concepts have the potential to influence sleep, and our primary focus is to improve patients' insomnia symptoms. Our goal, similar to Orem's, is to have patients initiate and continue to practice activities that improve their overall quality of life, health, and wellbeing.

The six assumptions of Orem's theory are also instrumental in the QI project:

- *Individuals should be self-reliant and are responsible for their care.* As providers, we provide patients with the necessary tools to self-manage their insomnia symptoms. Patients, in turn, need to follow through with the provided therapeutic measures to be successful.
- *Each individual is a unique human being.* Not all insomnia symptoms require the same treatment management, and each patient is assessed and managed as an individual.
- *Nursing is an interaction between two people.* In the sleep center practice, it is imperative that a trusting relationship exists between patient and provider. If patients trust this relationship, they will be more open when sharing their personal and medical information and following through with the treatment plan. Providers, in turn, need to be effective communicators, trust the information being received, and be empathetic toward the patient's concerns.
- *Patients need to successfully meet the self-care requisites.* Orem defines these as the processes needed to maintain life (e.g., sufficient intake of air, food, and water and maintenance of a balance between rest and activity). The staff at a sleep center promote activities that maintain wellbeing because good-quality sleep is needed to maintain health.
- *Patients need to be aware of health problems and seek the care needed.* Patients who arrive at a sleep center have already acknowledged that they need care and are seeking remedies to improve their health.
- *Self-care is learned.* Sleep providers know that self-building can occur, and improvement in sleep symptoms occurs with the right information and encouragement (Health Research Funding, 2019).

The goal for all providers is to treat diseases and illnesses more effectively. Dorothea Orem's self-care theory is an applicable theoretical framework that can be used in clinical practice and is useful for guiding the management of patients with insomnia. A sleep center is a patient-centered system where patients are responsible, in part, for their own care.

Methodology

Approval Process

The approval process began after the topic of interest was identified in 2019. Multiple meetings occurred with stakeholders within the community hospital. Because all yoga classes were offered online, due to the pandemic, this QI initiative did not qualify as human subjects research and did not require Institutional Review Board (IRB) oversight. Once the topic was defined, a meeting was secured with the stakeholders, including the current and former Medical Directors of the sleep center, , , the office manager, and the owner of the yoga center. All of the aforementioned members approved this project.

All the information collected from the program was kept confidential. The data of each participant was coded anonymously. All laptops were issued by the medical center and were password-protected and stored in a locked cabinet inside a locked office.

Project Risks

A strengths, weaknesses, opportunities, and threats (SWOT) analysis was done to determine whether the project goals were realistic and attainable. The SWOT analysis includes internal variables (strengths and weaknesses), which can be controlled by the project manager, and external variables (opportunities and threats), which are beyond the project manager's control (Pearce & Robinson, 2007; Roberts, 2019).

The strengths of this project were the committed, educated, and experienced employees of the sleep center. The staff is well versed in treating patients with insomnia and has worked in

this field for over 20 years. The center has an excellent reputation and an extensive referral source. It is also the largest accredited sleep center in New Jersey. The patients were recruited from the sleep center itself, thus creating a built-in referral source.

The identifiable weaknesses of the project were related to the time constraints for the patients to complete the program, the overall program design, and the lack of continuity of care. Each participant was required to attend a one-hour appointment with the APN at the start and the end of the program. Weekly follow-ups via text messages or email ensured that the participants were adhering to the four-week program. This was not a quick-treatment solution, which is what the majority of the patients were seeking.

There were a few external variables noted in the QI initiative. First, only female patients participated. The program included the recruitment of both male and female patients, but all eight participants were women. There is a higher prevalence of insomnia in females, and the recruitment of only female participants is not unexpected, but may lead to a gender bias. Another noteworthy weakness identified by the SWOT analysis was the lack of evidence-based guidelines for yoga in the literature, and the type of yoga to be utilized was unclear. The pandemic occurring simultaneously with this project may have also influenced the outcomes of the project, since it likely created higher insomnia and anxiety scores pre-yoga. Another external threat to the QI project was the possibility that the patients changed their behaviors because they knew they were being evaluated throughout the program. Last, the patients were probably more comfortable with the author and familiar with the forms after four weeks of interaction, and this may have influenced the scores in the post-yoga period.

Project Timeline

The project proposal began in January 2020. The first participant began the program in July 2020. This six-month delay was due to the numerous meetings with the sleep center staff and

hospital delays stemming from the current pandemic. During the pandemic for example, most of the sleep center staff were mandated to other areas within the hospital, and the administration believed that the QI project should begin with a fully functional staff. The last participant completed the program in January 2021; thus, the project required six months for completion. The post-intervention analysis occurred from January 2021 to February 2021.

Project Budget

When doing a post-expenditure analysis, it was determined that the costs associated with the project were minimal. The STAI form was purchased (Spielberger, 1983), and the voucher scorecards were created at minimal costs (Appendix B). Because this was a school project, there was no cost associated with presenting the information to my colleagues, and the participants were not reimbursed for the project. All forms were printed using the hospital copier, and, therefore, there were no additional costs. All patients were seen by the author through regular follow-ups and on nonworking days so as not to bill patients for an office visit or take away appointment times from a busy practice. Emails and texts were convenient and cost-effective approaches to staying in touch with the patients throughout the process. There was no participation cost for the patients, and all yoga sessions were complimentary.

Project Description

For this QI project, the Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-V) was used for conceptual definitions (American Psychiatric Association [APA], 2013). Insomnia was defined as difficulty in initiating or maintaining sleep three times a week for at least three months. The sleep difficulty occurred despite an opportunity to sleep and the impairment of daytime functioning was evident. The daytime impairment usually manifests in different ways, but common symptoms included daytime sleepiness, memory impairment, and mood disorders (APA, 2013; Folley, 2020).

To recruit participants, a flyer was placed in each of the six examination rooms, informing the patients about the availability of a QI project; the flyer is provided in Appendix A. This was a pilot project, and, therefore, only eight patients were asked to participate. The inclusion/exclusion conditions for the project are outlined below. To be considered for the program, patients needed to fulfill the following conditions:

- Chronic insomnia and over 18 years of age
- No improvement in insomnia symptoms with the standard CBT-I strategies
- Ability to engage in floor activities and absence of significant orthopedic issues
- Participation in the CBT-I strategies provided by one of the sleep providers, prior to enrollment

Patients were not included if they had the following conditions:

- Patients with untreated sleep-related breathing disturbances, movement disorders (e.g., restless leg or periodic limb movement disorders), or circadian rhythm disorders
- Patients with insomnia that is related to substance use
- Patients unable to download the yoga application on an electronic device
- Patients unable to actively participate in yoga sessions (e.g., patients in advanced pregnancies, with orthopedic issues, or at high risk of falls)
- Patients who currently practice yoga on a regular basis, as minimal benefit would be obtained

All participants were required to see a sleep specialist and participate in the standard CBT-I practices. If, after this treatment phase, patients wished to further improve their insomnia symptoms, they were seen by the APN and were asked to participate in a voluntary four-week yoga program. If the patients were interested, an informed consent was obtained (Appendix B).

During the same visit, two forms were administered: the ISI questionnaire (Appendix D) and the STAI short form (Appendices E and F). The ISI questionnaire includes seven questions pertaining to sleep patterns, the degree to which the insomnia interferes with daily life, the extent to which the insomnia is noticeable to others, and the impact of the insomnia on the quality of life. The responses are based on a five-point Likert scale and represent the following score ranges: 0–7 = no insomnia, 8–14 = subthreshold insomnia, 15–21 = moderately severe clinical insomnia, and 22–28 = severe clinical insomnia. Higher scores indicate more acute symptoms of insomnia (Bastien et al., 2001).

The short STAI form is a self-reported questionnaire with twenty questions and is based on a four-point Likert scale ranging from 1 (not at all) to 4 (very much). The questions measure two aspects of anxiety: a temporary form of anxiety that fluctuates across situations and focuses on how the patient feels at the current moment (the State subscale) and the stable, general personality traits that predispose individuals to anxiety (the Trait subscale). The combined responses to both STAI subscales assist sleep specialists in identifying current or recurring symptoms that may impact sleep patterns. The scores of each subscale were tallied to provide the total score (Spielberger, 1983). Both the ISI and the STAI are self-administered forms and are reliable and valid tools, as determined by Cronbach's alpha (Bastien et al., 2001; Glen, 2014; Spielberger, 1983).

After these forms were completed, the sleep schedule or logs for each patient were evaluated with a focus on their current sleep latency (the time it takes a patient to fall asleep) and

their current sleep duration (the period for which the patient slept the previous night) before and after the four weeks of yoga, along with their medication use. The yoga application was downloaded in the office for the convenience of the patient, and its use was reviewed. Each patient agreed to participate in two–three virtual yoga sessions per week for four weeks. Once a patient virtually attended a class, they checked the box on a provided scorecard to keep track of their attendance. These scorecards served as a visual cue for patients to keep track of classes attended (Appendix C) and were reviewed weekly.

There are a variety of yoga classes; however, for consistency, each patient virtually participated in a meditation/Roots class and a Gentle yoga class. The Roots class was a 60-minute class that focuses on breathing, posture, and body alignment; this class simplified the language and practice of yoga. The Gentle yoga class was also 60 minutes in duration; it focused on slower movements, breath work, stretching, and relaxation. After attending the class, patients marked the voucher scorecards. They were encouraged to attend a minimum of eight and a maximum of 12 classes for four consecutive weeks. This author was able to verify class attendance through the yoga application. Participants were advised to participate in the class and the time of day that that would best suit their interest.

At the completion of the four weeks of yoga, patients were required to complete both the ISI and the STAI questionnaires. Medication usage was reviewed again using electronic medical records (EMRs), and any noted changes were documented. The sleep schedule/logs were reviewed once again with a specific focus on sleep latency and sleep duration. All surveys and reviews of the EMRs were performed by the author. All information was stored on secure password-protected laptops. The patient information was de-identified, and each patient was assigned a code number; only the author had access to the code key. All paper forms were held in a locked cabinet in the author's locked office.

PICO Framework

The PICO (patient population, intervention, comparison, outcome) framework was utilized to guide this QI project: In adult patients with chronic insomnia, how effective is four weeks of gentle yoga in improving insomnia severity, sleep initiation, sleep duration, anxiety symptoms, and decreasing the use of sleep aids?

Setting

This project was conducted in the outpatient sleep center, which is a part of a community-based hospital system in central New Jersey. The project was conducted online through the yoga application after patients were seen at the sleep center. The patient population for the QI project primarily included older adult females, which is consistent with the patient populations used in recent studies (Nguyen et al., 2019; U.S. Department of Health and Human Services, 2018). The patient age ranged from 38–62 years with one outlier—a 19-year-old female. Six of the eight subjects were White, one was of Indian descent, and one subject was Asian.

Recipients

Patients who did not have significant improvement in their insomnia symptoms with standard CBT-I strategies and wished to engage in yoga exercises were included. All eight patients had been on a sleep aid for anywhere from six months to three years before they came to the sleep center.

QI Model

This QI project used a pre-intervention–post-intervention design, using standardized questionnaires. The ongoing enrollment occurred over a six-month period from July 2020 to January 2021. Before the intervention, all patients received standard CBT-I, which consisted of sleep restriction, stimulus control, and sleep hygiene. Pre-intervention and post-intervention surveys and chart reviews using EMRs were used for the analyses.

Results

A total of eight female patients who fulfilled the criteria for insomnia provided signed consent and enrolled in the QI project. Only seven participants completed the program; one participant withdrew from the project owing to her work commitments as a nurse. The sleep latency, sleep duration, ISI, STAI score, and changes in sleep medication usage were assessed before and after four weeks of yoga. All eight patients arrived at the sleep center having been on sleep aids for a duration ranging from six months to three years, and none of the participants had received CBT-I prior to arriving at the sleep center.

The ACP and the AASM recommends CBT-I as the first-line treatment for insomnia and acknowledges that it improves sleep symptoms and reduces the risk of reliance on sedative hypnotics. However, in clinical practice, the primary care settings are not following evidence-based practices. Previous research documents that the barriers to CBT-I in the primary care setting are related to the fact that clinicians are encumbered by the time required to properly assess sleep issues, lack knowledge pertaining to CBT-I treatments, and a lack the motivation needed to treat insomnia patients, as it is deemed a low priority when compared to other health conditions. In contrast to the ACP and AASM guidelines, sedative hypnotics with simple sleep hygiene suggestions (e.g., avoiding stimulants at bedtime and keeping the room cool, quiet, and dark) are still the most commonly used treatment choices (Folay, 2020 ;Koeffel et al., 2018).

In reviewing the data, it was determined that the pre-intervention and post-intervention sleep latency was 30–180 min (average 64.29 min) and 10–60 min (average 29.29 min), respectively; the mean change in sleep latency was 35 minutes (a 49% change). Even after excluding the single statistical outlier (Patient 7 with a sleep latency of 180 min.), the data showed an improvement of 21 minutes, a 47% change.

The pre-intervention and post-intervention sleep duration was 5–7 h and 6–8 h, respectively, showing a mean improvement of 1 hour (a 19% change). Participant 4 showed the smallest improvement in sleep duration (30 min), whereas participants 5 and 7 showed the greatest improvement in sleep duration (1.5 hours).

All seven participants showed significant improvement in the ISI. At the baseline, three subjects (43%) exhibited severe insomnia and four subjects (57%) exhibited moderately severe insomnia. Following the four weeks of yoga, five subjects (71%) had subthreshold insomnia, and two subjects (29%) had no clinically significant insomnia. Participant 2 showed the greatest improvement in the ISI and went from severe insomnia to no insomnia following the four-week yoga program.

For the STAI questionnaire, all participants showed improvement in the State subscale, with mean pre-intervention and post-intervention scores of 29 and 19, respectively. The normative value for the State subscale for females is based on age; the age group norm for the first six respondents was 18.17, and that for participant 7 was 18.42 (Spielberger, 1983). The baseline data indicated that each subject started at a higher value—between 26 and 34—than the norms at the baseline, indicating that these respondents were more anxious. Participant 3 had the most significant improvement, with a pre-intervention score of 34 and a post-intervention score of 20.

The analysis of the Trait subscale showed no significant change between the pre-intervention and post-intervention scores. The mean baseline score was 23.71, whereas the mean post-intervention score was 20.29. Because this subscale measures the qualities that predispose an individual to anxiety, the results suggest that four weeks of yoga did not significantly affect the inherent qualities that predispose an individual to anxiety.

All seven participants were on sedative hypnotics before their initial sleep consultation and remained on these medications throughout the program. There was no change in the dose or frequency of medication usage.

Discussion

Worrying about sleep can inhibit one's ability to initiate sleep. Yoga teaches you to build better connectivity between the mind and body and changes the balance between the hypervigilant sympathetic system and the more relaxing, meditative parasympathetic system. The parasympathetic system is more calming; it lowers the heart rate, decreases the blood pressure, and lowers the stress hormone cortisol (McCall, 2007; Thirthalli et al., 2013). Insomniacs show higher levels of cortisol and tend to respond more intensely to stressful events than others. When the flight-or-fight system is constantly active, the threshold to manage stressful events is considerably lower. Yoga teaches one to be present and realize that stress can often be managed (McCall, 2007).

This initiative has the potential to create many opportunities, the first and foremost of which is the improvement of patients' insomnia symptoms. This change, in turn, has the ability to improve patients' anxiety symptoms, which impacts their general wellbeing. Patients with insomnia want nothing more than a good night's sleep; they commonly complain that they are tired of being tired. Furthermore, this program may lead to additional research that may improve how primary care providers manage and treat patients with insomnia, which will hopefully lead to fewer written prescriptions for sedative hypnotics. The implementation of yoga is effective, is less costly, and is a more accessible option to decrease the overall medical expenditures and work-related costs. In the context of ever-evolving health care changes, it is imperative that providers continue to provide quality care while being cognizant of the overall cost of the care being delivered.

Limitations

This QI project had several limitations. The limited number of participants restricts the power and generalizability of these findings. After the completion of this QI initiative, the author believes that an RCT with a larger sample size is needed to change the current practice standards and validate the effects of yoga on insomnia. The participants and the author were aware of the goals of the project, and the participants may have modified their behavior, which is known as the Hawthorne effect (Parsons, 1974). The treatment expectations may have influenced the outcomes, and, because the assessments mostly used questionnaires, the data was subjective. The patients received CBT-I from varying providers, and this lack of consistency may have influenced the results. Only female patients, with the majority being White Non-Hispanics (six of eight patients) completed the program. In the current literature, females are more commonly affected by insomnia, and it is usually more prevalent in Blacks and Hispanic groups as compared to White groups (Nguyen et al., 2019; U.S. Department of Health and Human Services, 2018). All patients attended the eight to twelve yoga classes, and this was verified through the yoga application. Nevertheless, it is possible that, although the video was on, the participant did not engage in the activity but rather simply viewed the exercises. There were two participants who did not complete four consecutive weeks owing to illness, which may have also interfered with their overall improvement. Last, the current pandemic may have led to higher baseline scores for both insomnia and anxiety and, thus, influenced the project results.

Sustainability

Yoga is a safe and cost-effective complementary treatment option for insomnia. Most yoga studios have online versions, making it convenient to practice at home. Many yoga centers offer free or low-cost on-demand and live-streaming classes. In this project, all patients preferred to attend online sessions, as opposed to in-person classes, because it allowed for more flexibility,

and the patients were able to work around their family and work commitments. The participants also considered it a safer environment with a lower likelihood of becoming ill with regard to the pandemic. Yoga is a safe, affordable, sustainable, and non-pharmacological treatment option for those suffering from insomnia.

Conclusion

This pre-intervention–post-intervention design QI project demonstrated that four weeks of yoga significantly reduced insomnia and anxiety symptoms and improved the sleep latency and duration for patients but had no effects on their medication use. There are many different types of therapies for treating insomnia, and yoga may be an additional treatment option for patients to pursue. The findings of this QI project suggest that yoga offers a safe and viable complement to standard CBT-I practices and provides an alternative to pharmacological treatment for patients suffering with insomnia. Given these promising findings, further investigation, including rigorously designed research studies, is warranted.

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Appendix A



ARE YOU OVER THE AGE OF 18
AND HAVE DIFFICULTY
FALLING ASLEEP OR STAYING
ASLEEP?

HAVE YOU TRIED ALL OF THE
SLEEP STRATEGIES BUT DON'T
FEEL BETTER?

ARE YOU INTERESTED IN FREE
YOGA SESSIONS TO SEE IF THIS
IMPROVES YOUR SLEEP?

WE MAY HAVE THE ANSWER.

Please see Kerri Penders, CSH,APN, our Nurse
Practitioner for details.
She may be reached at 609 584-5150

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Appendix B



Capital Health Consent to determine if Yoga improves sleep

You are being asked to participate in a quality improvement program because you have been diagnosed with chronic insomnia. This is a voluntary yoga program. You may stop participating in the yoga sessions at any point in time. Please read the consent form carefully and take your time to make your decision.

Name of Principal Investigator: Kerri Penders, CCSH, APN

Name of Sponsor: Honor Yoga

This informed consent form has two parts:

- **Information sheet (to share information about the research with you)**
- **Certificate of consent (for signatures if you agree to participate)**

You will be given a copy of the full informed consent form.

PART I: Information Sheet

Introduction

My name is Kerri Penders; I am a nurse practitioner at Capital Health. I have been working at the Sleep Center for 15 years. In my practice, we have noticed that insomnia is a highly common disorder and is not always easily treated. We are interested in determining the impact that yoga may have on your sleep. I am going to give you information and invite you to participate in the program. Please read the consent form carefully. You do not have to decide today whether you will participate. Before you decide, you may wish to talk it over with your primary care physician, friends, or family members. If there are words or phrases that you do not understand, please ask me, and I will take the time to explain them. If questions should arise throughout the yoga program, please feel free to reach out to me. I am here to help. My contact information is provided below.

Purpose of the Project

Insomnia is a highly common disorder and affects approximately 33–50% of adults. The symptoms affect the emotional and physical health of the individuals affected. Previous research indicates that insomnia may have serious health consequences, including increased risk of high blood pressure, heart disease, diabetes, and mood disorders. We are trying to find healthier alternatives

to treat patients with insomnia. Yoga may be the answer. It is easily accessible, can be performed easily in different locations, and is cost effective.

Requirement of the Project

This project will require that you virtually attend two to three sessions of yoga weekly. The virtual classes that are available to you are the Roots class or the Gentle yoga session. The Roots class is a 60-minute class that focuses on breathing, posture, and body alignment. This class simplifies the language and practice of yoga. The Gentle yoga class is also 60 minutes in duration. The class will focus on slower movements, breath work, stretching, and relaxation. After you have attended the complimentary yoga sessions, please mark your voucher scorecard, indicating that you have attended the same. You should then contact me via text or email about your progress each week.

Participant Selection

We are inviting all adults with chronic insomnia to participate in the free yoga sessions. We are accepting only eight patients, as this is a pilot program.

Voluntary Participation

Your participation is entirely voluntary. It is your choice whether to participate. Whether you choose to do so, all the services you receive from Capital Health or within the Sleep Center will not change. If you choose not to participate in this project, you will continue to receive the standard care from Capital Health and the Sleep Center.

Description of the Process

After the consent form is signed, you will be asked to complete two surveys, the Insomnia Severity Index and the State-Trait Anxiety Inventory. It should take no more than 15–20 minutes to complete both. You will then download the free Honor Yoga application, and, at your convenience, choose 8–12 virtual sessions you wish to participate in. Please mark the scorecard at the end of your completed session. They will be collected at the completion of the project. Please use the Honor Yoga application only for yourself. Please do not begin the program until you can dedicate attending a minimum of two sessions—preferably, three sessions per week—for four consecutive weeks. You will be required to email me or text me weekly to let me know how you are progressing through the program. At the completion of the program, you will meet with me again to see how the program has impacted your sleep and if there are any changes in your medication use. I will ask you again to complete the initial two surveys, the Insomnia Severity Index and the State-Trait Anxiety Inventory, to document if there is any change.

Duration

The project will take place over a four-week period. I will meet with you in person at the start of the program and at the end of the fourth week. We will stay in touch via email or text weekly.

Side Effects/Risks

As with any exercise, you may experience pain, muscle discomfort, lightheadedness, nausea, or a feeling of faintness. You may stop the exercises at any point in time if you feel any discomfort.

Benefits

There are many documented health improvements with yoga, specifically reduced stress, improved flexibility, improved balance and strength, lowered blood pressure, reduced weight, improved

cardiovascular health, improved mood, and improved emotional wellness. We believe that yoga will also improve your sleep, decrease your anxiety (if present), and reduce the need for sleep aids.

Reimbursements

There is no reimbursement for this project. You will receive 12 complimentary yoga sessions.

Confidentiality

We will not share your identity with those participating in the program. The owner of Honor Yoga will know that there are eight participants who have joined the program, but they will not be able to identify you through the application. The information that we collect from the program will be kept confidential. Any information about you, with regard to the program, will have a number, not a name. Only I will know the number code, and this information will be kept under lock and key.

Sharing the Results

The knowledge that we obtain through conducting this quality improvement initiative will be presented through community meetings before it is made available to the public. Confidential information will not be shared.

Right to Refuse or Withdraw

This is a reconfirmation that participation is voluntary and includes the right to withdraw. You may withdraw from the program at any point in time. This will not affect the care you receive from Capital Health or the Sleep Center. All your rights will continue to be respected.

Liability

You agree that neither Honor Yoga or Capital Health officers, directors, employees, agents, volunteers, committees, and boards shall be liable or responsible for any injuries resulting from participation in the yoga and meditation programs. By signing this consent, you expressly release and discharge Capital Health from all claims, actions, judgments, and expenses and costs of every kind and character, the likes of which you or your heirs, executors, administrators, or assignees may have or claim to have as a result of any injury or other damages that may occur in connection with the participation in the yoga and meditative program. By signing this consent, this release shall be binding.

Whom to Contact

If you have any questions, you may ask them now or later, even after the program has started. You may contact Kerri Penders, CCSH, APN at kpenders@capitalhealth.org or on the cell number 917 855-7601.

PART II: Certificate of Consent

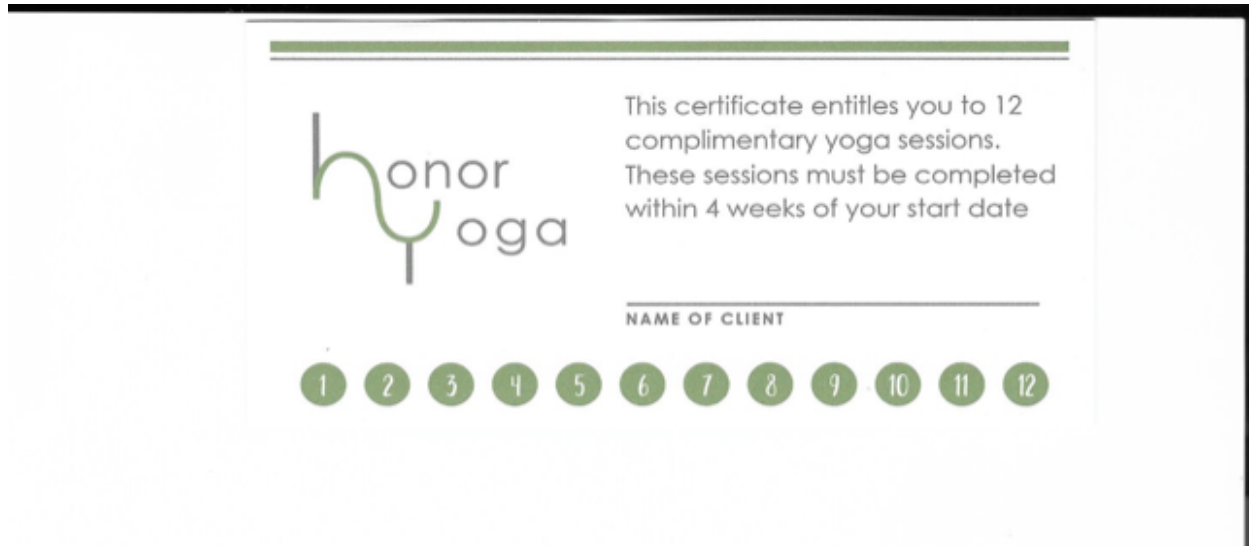
I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it, and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this quality improvement initiative.

Print Name of Participant _____

Signature of Participant _____

Date _____

Appendix C



Appendix D

Insomnia Severity Index

The Insomnia Severity Index has seven questions. The seven answers are added up to get a total score. When you have your total score, look at the 'Guidelines for Scoring/Interpretation' below to see where your sleep difficulty fits.

For each question, please CIRCLE the number that best describes your answer.

Please rate the *CURRENT* (i.e. *LAST 2 WEEKS*) *SEVERITY* of your insomnia problem(s).

Insomnia Problem	None	Mild	Moderate	Severe	Very Severe
1. Difficulty falling asleep	0	1	2	3	4
2. Difficulty staying asleep	0	1	2	3	4
3. Problems waking up too early	0	1	2	3	4

4. How SATISFIED/DISSATISFIED are you with your CURRENT sleep pattern?

Very Satisfied Satisfied Moderately Satisfied Dissatisfied Very Dissatisfied
 0 1 2 3 4

5. How NOTICEABLE to others do you think your sleep problem is in terms of impairing the quality of your life?

Not at all
 Noticeable A Little Somewhat Much Very Much Noticeable
 0 1 2 3 4

6. How WORRIED/DISTRESSED are you about your current sleep problem?

Not at all
 Worried A Little Somewhat Much Very Much Worried
 0 1 2 3 4

7. To what extent do you consider your sleep problem to INTERFERE with your daily functioning (e.g. daytime fatigue, mood, ability to function at work/daily chores, concentration, memory, mood, etc.) CURRENTLY?

Not at all
 Interfering A Little Somewhat Much Very Much Interfering
 0 1 2 3 4

Guidelines for Scoring/Interpretation:

Add the scores for all seven items (questions 1 + 2 + 3 + 4 + 5 + 6 + 7) = _____ your total score

Total score categories:

0–7 = No clinically significant insomnia

8–14 = Subthreshold insomnia

15–21 = Clinical insomnia (moderate severity)

22–28 = Clinical insomnia (severe)

Appendix E

For use by Kerri Penders only. Received from Mind Garden, Inc. on September 29, 2019

Self-Evaluation Questionnaire STAIAD Short Form Y-1

Please provide the following information:

Name _____ Date _____ S _____
Age _____ Gender (Circle) M F T _____

Directions: A number of statements which people have used to describe themselves are given below. Read each statement and then circle the appropriate number to the right of the statement to indicate how you feel *right* now, that is, *at this moment*. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feelings best. Use the following scale:

NOT AT ALL – SOMEWHAT – MODERATELY SO – VERY MUCH SO

NOT AT ALL
 SOMEWHAT
 MODERATELY SO
 VERY MUCH SO

- | | | | | |
|--|---|---|---|---|
| 1. I feel calm | 1 | 2 | 3 | 4 |
| 2. I am tense..... | 1 | 2 | 3 | 4 |
| 3. I feel at ease..... | 1 | 2 | 3 | 4 |
| 4. I am presently worrying over possible misfortunes | 1 | 2 | 3 | 4 |
| 5. I feel frightened..... | 1 | 2 | 3 | 4 |
| 6. I feel nervous..... | 1 | 2 | 3 | 4 |
| 7. I am jittery..... | 1 | 2 | 3 | 4 |
| 8. I am relaxed..... | 1 | 2 | 3 | 4 |
| 9. I am worried..... | 1 | 2 | 3 | 4 |
| 10. I feel steady..... | 1 | 2 | 3 | 4 |

Appendix F

For use by Kerri Penders only. Received from Mind Garden, Inc. on September 29, 2019

SELF-EVALUATION QUESTIONNAIRE

STAIAD Short Form Y-2

Name _____ Date _____

Directions: A number of statements which people have used to describe themselves are given below. Read each statement and then circle the appropriate number to the right of the statement to indicate how you *generally* feel.

Use the following scale:

ALMOST NEVER – SOMETIMES – OFTEN – ALMOST ALWAYS

	ALMOST NEVER	SOMETIMES	OFTEN	ALMOST ALWAYS
11. I feel nervous and restless	1	2	3	4
12. I feel satisfied with myself	1	2	3	4
13. I wish I could be as happy as others seem to be	1	2	3	4
14. I feel like a failure	1	2	3	4
15. I worry too much over something that really doesn't matter	1	2	3	4
16. I lack self-confidence	1	2	3	4
17. I feel secure	1	2	3	4
18. I feel inadequate	1	2	3	4
19. I am a steady person	1	2	3	4
20. I get in a state of tension or turmoil as I think over my recent concerns and interests.....	1	2	3	4