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Influence of Motivational Text Messages on Adherence to Continuous Positive Airway Pressure Therapy

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Influence of Motivational Text Messages on Adherence to Continuous Positive Airway Pressure Therapy

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Dedication

I dedicate this dissertation to my wonderful family and friends who have provided love, emotional support and prayers in abundance over the past eight years of my doctoral education. To my wife Beth, you have loved me well through this adventure and served as my compass whenever I lost my way. To Andrew and Will, your patient and continuous encouragement to stay strong and keep going has been great motivation for me in my work. I am proud of the young men you are becoming. Thank you to my parents, John & Janice Dunlap and Marlene Walker for being a listening ear and a safe harbor in the storm. To my Church family, your prayers and presence in my life have been a constant reminder of where I find my identity. To my friends, your constant support and true dedication to my family is something I will cherish always. Thank you to all, I would not have completed my doctoral education without you.

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Abstract

Obstructive sleep apnea (OSA) is a condition affecting approximately 22% of men and 17% of women. Periodic bouts of apneas and hypopneas occur with OSA that negatively impacts sleep quality and neurohormonal function. As a result, individuals with OSA are at increased risk for diseases including diabetes, cancer, stroke, myocardial infarction, and depression. Continuous positive airway pressure (CPAP) therapy is effective but adherence rates are low at an estimated 60%.

The purpose of this pilot study was to determine the feasibility and to examine the effects of a four-week text message-based intervention on an individual's CPAP device adherence, OSA symptom management, and outcome expectations when compared to participants receiving generic text messages. Participants were randomized to an experimental group (EG) (n = 29) or a control group (CG) (n = 28). The EG received one motivational text message designed using the theory of planned behavior (TPB) every week for four weeks. The CG received one text message every week for four weeks that included their weekly CPAP mask-on time. Total mask-on time and CPAP adherence status were measured using CPAP device real-time data. Symptom management and CPAP use expectations were evaluated using Apnea Belief Scale (ABS), Epworth Sleepiness Scale (ESS), and Functional Outcomes of Sleep Questionnaire-10 (FOSQ-10).

There was no significant difference in total mask-on time between the two groups (p = 0.64). The proportion of participants classified as adherent did not differ between the two groups (p = 0.21). Differences in ABS, ESS, and FOSQ-10 scores between groups were also not significant (ABS: p = 0.47; ESS: p = 0.81; FOSQ: p = 0.97).

The pilot study identified trends toward improved CPAP adherence with use of TPB-based text messages. For example, the experimental group's adherence rate was 14.8% higher than control group's adherence rate. The lack of significance for the ABS, ESS, and FOSQ-10 may have occurred because they measured actual behavior (CPAP use) and not what effect the intervention had on changing the behavior. Further research is needed to elucidate the impact of TPB-based text messages on improving CPAP adherence and outcomes for individuals with OSA.

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List of Abbreviations

ABS	Apnea Belief Scale
ACA	Patient Protection and Affordable Care Act
ACS	Acute coronary syndrome
ACTI	Attitudes to CPAP treatment inventory
AHI	Apnea/hypopnea index
AKT	Apnea Knowledge Test
ANOVA	Analysis of variance
AOSATF	The Adult Obstructive Sleep Apnea Task Force of the American Academy of Sleep Medicine
AV	Airview
BAS	Behavioral activation system
BIS	Behavioral inhibition system
CBT	Cognitive behavioral therapy
CG	Control group
CMS	Centers for Medicare and Medicaid Services
CPAP	Continuous positive airway pressure
DM	Diabetes mellitus
DME	Durable medical equipment company
EA	EncoreAnywhere
EG	Experimental group
EPH	Episodes per hour
ESS	Epworth Sleepiness Scale
FOSQ-10	Functional Outcomes of Sleep Questionnaire-10
FOSQ-30	Functional Outcomes of Sleep Questionnaire-30
HADS	Hospital Anxiety and Depression Scale
HBM	Health belief model

HDL	High density lipoprotein
HIPAA	Health Insurance Portability and Accountability Act of 1996
IRB	Institutional review board
LDL	Low density lipoprotein
LV	Left ventricle
MD	Mean difference
ME	Motivational enhancement
MIPS	Merit-based Incentive Payment System
MWT	Maintenance of Wakefulness Test
MSLT	Multiple Sleep Latency Test
NHP	Nottingham Health Profile
NYHA	New York Heart Association
OA	Oral appliance
ONC	The Office of the National Coordinator for Health Information Technology
OSA	Obstructive sleep apnea
PAP	Positive airway pressure
PMT	Protection motivation theory
PI	Principal investigator
RCT	Randomized control trial
REDCap	Research Electronic Data Capture
RR	Relative risk
SD	Standard deviation
SDB	Sleep disordered breathing
SEMSA	Self-Efficacy Measure for Sleep Apnea Scale
SPSS	Statistical Package for the Social Sciences
TBI	Telephone-based interventions
TEP	Text/email/phone

TMBI	Text message-based interventions
TPB	Theory of planned behavior
URL	Uniform Resource Locator
VA	Veterans Administration
VUMC	Vanderbilt University Medical Center
WBE	Web-based education

Chapter 1: Introduction

Obstructive sleep apnea (OSA) is a significant problem in the general population and it is estimated between 9% and 38% have at least mild OSA (Senaratna et al., 2016). In my experience as a primary care nurse practitioner, I have seen the negative effects of OSA in patients and how it affects their quality of life. Continuous positive airway pressure (CPAP) is considered the gold standard and is an effective treatment for OSA. However, for multiple reasons, CPAP device adherence is relatively low with published individual adherence rates between 59% (Wozniak, Lasserson, & Smith, 2014) and 65% (Rotenberg, Murariu, & Pang, 2016). The changes in the quality of life and overall health are especially evident when the individual is not adherent to the prescribed CPAP treatment.

I wanted to explore and expectantly improve CPAP treatment adherence by merging the technology associated with modern CPAP machines, text-based messaging, and the theory of planned behavior (TPB) developed by Icek Ajzen (Ajzen, 1991). Leveraging mobile messaging, which is widely available and convenient, could be a cost-effective method of maintaining contact with the patient immediately after starting CPAP therapy. The text messages sent to the individual were developed using the TPB and supported through real-time CPAP device usage data. The premise was the messages texted to the individuals using a CPAP machine for the treatment of OSA would be a cost-effective and efficacious method to improve patient adherence.

The purpose of this pilot study was to examine the effects of a four-week text message-based intervention (TMBI) on an individual's CPAP device adherence, OSA symptom management, and outcome expectations when compared to participants receiving generic text

messages. Participants were randomized to either an experimental group (EG) receiving the intervention or to a control group (CG). Both groups standard treatment. In addition, the EG received one motivational text message every week for four weeks that was based on concepts derived from the TPB in addition to standard treatment. The CG received one text message every week for four weeks with objective information only (average use in hours per week).

Sleep-disordered breathing (SDB) is a spectrum of disorders associated with breathing impairment that occurs during sleep. These include central sleep apnea, mixed sleep apnea, obesity hypoventilation syndrome, and OSA. Central sleep apnea is characterized by repetitive apneas, with no ventilatory effort, followed by arousal and resumption of respirations and has been identified to be more common in patients with heart failure (Aurora et al., 2012). Mixed sleep apnea was described by Guilleminault, Tilkian, and Dement (1976) as "cessation of airflow and an absence of respiratory effort early in the episode, followed by resumption of unsuccessful respiratory effort in the latter part of the episode" (p. 467). Shetty and Parthasarathy (2015) define obesity hypoventilation syndrome as a state of hypoventilation that occurs in obese persons while awake or asleep that causes arterial carbon dioxide to be elevated. Obstructive sleep apnea, the most common form of SDB occurs when increased airway resistance leads to upper airway collapse during sleep (McEvoy et al., 2016). Obstructive sleep apnea has been linked with significant detrimental health outcomes in the general population including increased risk of cardiovascular disease, stroke, type 2 diabetes mellitus, cognitive decline at an earlier age, and depression (Punjabi, 2008; Stansbury & Strollo, 2015; Young et al., 2009). Unless otherwise stated, this dissertation will the focus on OSA, the most common form of SDB.

In this chapter, the following information will be presented: background of clinical problem, a statement of the problem, purpose of the study, the research hypotheses, a summary

of the TPB used to guide this study, research assumptions, theoretical definitions of concepts, study limitations, and the significance of the study for nursing practice.

Background

Obstructive sleep apnea is characterized by upper airway collapse that occurs during sleep because of increased airway resistance. The upper airway, or pharynx, is a collapsible tube that is involved in respirations, speech, and swallowing (Mannarino, Di Filippo, & Pirro, 2012). The pharynx experiences negative pressures as the lungs inflate during inspiration but this negative pressure is normally counteracted by the dilator muscles of the pharynx that work to maintain patency of the upper airway (Mannarino et al., 2012). Any imbalance between these two opposing influences may result in obstruction of the upper airway that is the hallmark of OSA. An important factor that affects the likelihood of the pharynx becoming obstructed during inspiration is the cross-sectional size of the pharynx. As the pharynx narrows, the velocity of the air flowing passing through during inspiration will be increased. The Venturi effect states that pressure pressing on the walls of a tube will decrease as the velocity of the fluid traveling through the tube increases and, in this case, will increase the likelihood that the pharynx will collapse (Mannarino et al., 2012). The pharynx can narrow as a result of excess fat deposits in the area surrounding the pharynx as well as from tonsillar hypertrophy, tongue hypertrophy, or posterior positioning of the mandible (retrognathia) (Mannarino et al., 2012).

The Adult Obstructive Sleep Apnea Task Force of the American Academy of Sleep Medicine (2009) [AOSATF] released clinical guidelines to aid in the evaluation, management and long-term care of adults with OSA. The Task Force first recommends that a thorough sleep history should include asking a patient if they have had any of the following symptoms or

complaints: snoring while sleeping, witnessed apneas, gasping or choking episodes, unexplained excessive sleepiness, nocturia, morning headaches, insomnia, decreased memory or concentration, decreased libido, or irritability (AOSATF, 2009). These symptoms, along with a physical examination that assesses the cardiovascular, respiratory, and neurologic systems are used to assess OSA risk. The physical assessment should focus on evaluating the upper airway including neck circumference, Mallampati score, and examination of the tonsils, tongue, uvula, hard palate, and nares for any anatomic abnormalities that could potentially narrow the upper airway (AOSATF, 2009). The Mallampati score is determined by asking the patient to open their mouth as wide as they can while emitting no sound: Class I – soft palate and entire uvula are visible; Class II – soft palate and portion of the uvula are visible; Class III – soft palate is visible; and Class IV – soft palate is not visible (Nuckton, Glidden, Browner, & Claman, 2006). In a study of 137 adult patients being evaluated for OSA, Nuckton et al. (2006) determined that the Mallampati score was an independent predictor of the existence and severity of OSA. The researchers discovered that independent of other variables, for every single increase in the Mallampati classification (e.g. Class 1 to Class 2) there was a two-fold increase in the prevalence of OSA and the AHI increased by at least 5 episodes per hour (EPH) as determined by polysomnography (Nuckton et al., 2006).

Currently, there is no systematic program for examining SDB prevalence in the United States but there has been significant research examining the pervasiveness of SDB. Thus, prevalence figures will be described in terms of SDB as no specific data on OSA prevalence has been reported. Using data from the Wisconsin Sleep Cohort Study and the National Health and Nutrition Examination Survey, Peppard et al. (2013) created models that estimate the prevalence of SDB for U.S. adults ages 30 – 70 years old. The researchers estimated that 33.9% of U.S. men

between 30 – 70 years of age had mild SDB which is defined as an apnea-hypopnea index (AHI) between 5 to < 15 EPH and that 13% of U.S. men had moderate to severe SDB defined as an AHI ≥ 15 EPH (Peppard et al., 2013). The prevalence of U.S. women between 30 – 70 years of age with mild SDB was projected to be 17.4% while 5.6% of U.S. women had moderate to severe SDB (Peppard et al., 2013).

In a study by Knauert, Naik, Gillespie, and Kryger (2015), the added burden of untreated OSA on the American healthcare system was estimated to be between $34 and $69 billion annually. This added burden includes the healthcare spending required to treat patients with undiagnosed OSA and their accompanying comorbidities that are caused or worsened by OSA including stroke, hypertension, heart failure, occupational accidents, type 2 diabetes, depression, and coronary artery disease (Knauert et al., 2015; Osorio et al., 2015). As the obesity epidemic continues to rise, this cost will inevitably grow as well. The $34 to $69 billion cost does not consider indirect costs such as transportation accidents brought on by excessive daytime sleepiness that is often a characteristic of OSA. Sassani et al. (2004) performed a meta-analysis that estimated that over 800,000 motor vehicle accidents per year and 1400 resultant deaths are related to OSA at a cost of $15.9 billion annually.

Individuals diagnosed with OSA have symptoms that include excessive daytime sleepiness, fatigue, and/or snoring. Obstructive sleep apnea has been described as an independent risk factor for cardiovascular diseases such as stroke, hypertension, heart failure, dysrhythmias, and coronary heart disease as well as cancer incidence and cancer mortality (Hla et al., 2014; Marshall, Wong, Cullen, Knuiman, & Grunstein, 2014; Somers et al., 2008; Stansbury & Strollo, 2015). Obstructive sleep apnea has also been associated with exacerbating diabetes mellitus, cognition impairment, depression, and reducing or worsening renal function (Hita-Yanez,

Atienza, & Cantero, 2013; Pamidi & Tasali, 2012; Stansbury & Strollo, 2015; Yoshihisa et al., 2013).

According to the Eighth Joint National Committee (JNC 8), hypertension is defined as a blood pressure of 140/90 or greater in patients younger than 60 years of age and blood pressure of 150/90 or greater in patients greater than 60 years of age (James et al., 2014). Hypertension is the most common disease seen in a primary care clinic and, if untreated, can lead to myocardial infarction, stroke, or chronic kidney disease (James et al., 2014). Hypertension can be caused by OSA or it can be exacerbated in OSA through both mechanical and neurohormonal pathways. During an inspiration where the airway is obstructed, as in OSA, the intrathoracic pressure becomes more negative which increases the pressure difference between the pressure within left ventricle (LV) and the pressure around the ventricle (Kasai & Bradley, 2011). This increased LV transmural pressure increases LV afterload (the downstream pressure that the heart must work against to force blood out of the LV during systole) which raises systemic blood pressure (Kasai & Bradley, 2011).

The sympathetic nervous system is activated during periods of apnea or hypopnea. During an apneic or hypopneic episode, the body enters a state of transient hypoxia and carbon dioxide retention that stimulates central and peripheral chemoreceptors that intensifies sympathetic nervous system activity (Kasai & Bradley, 2011). The sympathetic nervous system is also stimulated as a result of arousal from sleep that occurs in OSA (Kasai & Bradley, 2011). Subsequently, the peripheral arteries vasoconstrict to raise blood pressure causing intermittent hypertension. If sleep apnea becomes a chronic condition, then this increase in sympathetic drive persists throughout the day causing hypertension to also last throughout the day (Kasai & Bradley, 2011). An elevation in sympathetic nervous activity has also been shown to be a risk

factor for life-threatening dysrhythmias that could result in sudden cardiac death (Gami et al., 2013).

According to Pamidi and Tasali (2012), it is estimated that over 70% of patients with type 2 diabetes mellitus (DM) who undergo full PSG have at least mild OSA. Sympathetic nervous system activation and activation of inflammation cascade brought on by intermittent hypoxia and sleep fragmentation leads to disruption in glucose metabolism (Pamidi & Tasali, 2012). Transient hypoxia that occurs in OSA has been observed to be a mechanism that alters glucose metabolism and insulin sensitivity (Louis & Punjabi, 2009). Although no causal link was determined, a study by Aronsohn, Whitmore, Van Cauter, and Tasali (2010) concluded that there was a direct association between OSA severity and glucose control in patients with type 2 DM. Poorer glucose control was observed as OSA severity worsened and this was found to be the case independent of the presence of obesity (Aronsohn et al., 2010).

The transient hypoxia episodes experienced in OSA can be severe and reduce oxygen saturation to ≤ 60% (Somers et al., 2008). Somers et al. (2008) also stated that blood pressure during an apneic occurrence can be as high as 240/130 mmHg. These two mechanisms promote systemic vascular inflammation and oxidative stress that result in endothelial dysfunction and lead to atherosclerotic cardiovascular disease if left unchecked. Signs of inflammation associated with patients with OSA include elevated plasma cytokine and C-reactive protein levels as well as enhanced leukocyte activation (Somers et al., 2008). Not only is there worsening endothelial dysfunction in patients with OSA, but OSA has also been linked to increased platelet activation and increased fibrinogen levels that intensify the potential for forming a thrombus which could lead to myocardial infarction, pulmonary embolus, or embolic cerebrovascular accident (Somers et al., 2008). In one study of 1,131 adults, participants with an AHI > 30 EPH were 2.6 times

more likely to have coronary heart disease (unstable angina, revascularization procedure, or myocardial infarction) or heart failure as compared to participants with an AHI < 30 EPH (Hla et al., 2014). Aurora, Crainiceanu, Gottlieb, Kim, and Punjabi (2018) followed 3,265 patients for an average of five years. The researchers evaluating the interaction between OSA occurring mainly during REM sleep and cardiovascular disease with endpoints being non-fatal and fatal events such as heart attack, coronary artery bypass surgery, heart failure, and stroke (Aurora et al., 2018). The authors found there was a significantly higher incidence of the cardiovascular non-fatal and fatal events but only in those individuals with severe OSA (AHI ≥ 30 EPH), and established cardiovascular disease (Aurora et al., 2018). However, two other large studies (Gottlieb et al., 2010; Marshall et al., 2014) demonstrated a non-significant association between OSA and coronary heart disease.

The same endothelial dysfunction that can cause coronary heart disease also negatively impacts the arteries that supply the brain. Similar proinflammatory and prothrombotic mediators are present but there is a much stronger association between OSA and embolic stroke especially in men. In one large study that included 5,422 participants (Redline et al., 2010), it was demonstrated that a higher AHI was associated with a worsening risk of stroke in men. For example, in those men with an AHI greater than 19 EPH (considered to be mild to moderate OSA), there was a threefold increase in the risk of ischemic stroke as compared to those men who had less than 4.1 EPH (Redline et al., 2010). In this study, women with an AHI > 25 EPH were also at increased risk of embolic stroke (Redline et al., 2010). In another study in Australia, 397 participants were followed over 20 years and it was established that those participants, men and women, with an AHI > 15 EPH had a fully adjusted hazard ratio of 3.7 for a stroke as

compared to those with no sleep apnea (Marshall et al., 2014). The univariate association between OSA and stroke was also statistically significant (p = .0004) (Marshall et al., 2014).

Depression is a comorbid condition that is also affected by OSA. In a prospective, longitudinal study, Peppard, Szklo-Coxe, Hla, and Young (2006) examined SDB instead of OSA solely, 1,408 participants were followed for four years and the researchers found that the odds of developing depression were directly associated with the severity of a participant's SDB. A participant with minimal SDB (AHI from 0 to 5 EPH) had a 1.6-fold increase in the odds for development of depression as compared to participants without SDB while participants with mild SDB (AHI from 5 to 15 EPH) had a 2.0-fold increase and those with moderate or worse SDB (AHI > 15 EPH) had a 2.6-fold increase in the odds for development of depression (Peppard et al., 2006). It has been suggested that different OSA mechanisms including transient hypoxia and sleep fragmentation contribute to depression in various ways. Sleep fragmentation has been shown to disrupt the ability to achieve deep, restful sleep and to worsen psychological symptoms (Peppard et al., 2006).

The goals of treating OSA are usually to reestablish normal breathing during sleep and to mitigate the symptoms of OSA such as snoring and excessive daytime sleepiness (AOSATF, 2009). Managing the symptoms of OSA requires a long-term approach. According to AOSATF (2009), it is recommended that the patient play an active role in the decision-making process in determining the most appropriate treatment. Treatment regimens are also guided by the severity of the OSA and include behavioral modalities (e.g., sleep positioning and weight loss), PAP, oral appliances (OAs), and surgery (AOSATF, 2009).

The AOSATF (2009) recommends that sleep positioning, weight loss, alcohol avoidance before bedtime, and sedative avoidance before bedtime be a part of any behavioral treatment for OSA. It has been determined that supine positioning during sleep can worsen especially mild to moderate OSA and that these "positional patients are a dominant phenotype of OSA" (Oskenberg & Gadoth, 2013, p. 208). Although the AOSATF advocates for modifying supine sleep position, there are no known large, randomized, controlled trials that demonstrate statistically significant improvement in OSA or its symptoms with positioning alone. Several small trials have been conducted (Bignold et al., 2009; Heinzer et al., 2012; van Maanen et al., 2013) that showed positional therapy can significantly lower the AHI of participants and even improve excessive daytime sleepiness as demonstrated by statistically significant improvement in Epworth Sleepiness Scale (ESS) scores. It is also important to note that PAP becomes less effective as the severity of the OSA decreases so positional therapy could have benefit to a large number of patients suffering from mild to moderate OSA especially when combined with weight loss (Rosenthal et al., 2000; Joosten et al., 2017).

Obesity is a major risk factor for OSA, and the growing obesity epidemic is likely to increase the prevalence of OSA (Peppard, Young, Palta, Dempsey, & Skatrud, 2000). In fact, an obese person is twice as likely to be diagnosed with OSA as compared to an adult of normal weight (Anandam, Akinnusi, Kufel, Porhomayon, & El-Solh, 2013). Weight change is also important as Peppard et al. (2000) noted in their longitudinal study. The researchers discovered that a 10% increase in weight predicted a 32% increase in AHI and that AHI decreased 26% for a 10% decrease in weight (Peppard et al., 2000). From this finding, it is evident that any OSA treatment plan should include instituting weight reduction measures if obesity is present.

Oral appliances first began as an alternative therapy to those patients with OSA who could not tolerate positive airway pressure (PAP) treatment. The AOSATF (2009) recommends OAs as first-line therapy for patients with mild-to-moderate OSA based on preference, not good candidates for PAP treatment, or for patients who have failed PAP treatment. Oral appliances enlarge the upper airway space by either holding the lower jaw in a more anterior position or by preventing the tongue from collapsing into the airway (Sutherland et al., 2014). Vanderveken et al. (2012) prospectively monitored OA adherence in 51 participants and found that 84% of OA users wore the device for at least 4 hours/night. This adherence rate is much higher than that of PAP treatment which was evaluated in a study by Kribbs et al. (1993). In the study, the adherence of 36 participants was measured over a three-month period and the four-hour adherence rate was calculated to be 52%. The study by Kribbs et al. (1993) is being referenced here because the researchers measured adherence using mask-on-face time which is a more reliable measure of adherence than self-report or even using the CPAP device counter. The improved adherence rates found with OAs led Sutherland et al. (2014) to conclude that OAs and PAP treatment are comparable in improving health outcomes "presumably due to greater overall usage of the OA device compared to CPAP" (p. 223). Improving PAP adherence to a comparable level as OA adherence is a reasonable goal to strive for to improve the health outcomes of patients with OSA.

Surgical interventions, including tracheostomies, were the first methods utilized to treat OSA but are no longer considered as first-line therapy (AOSATF, 2009). There are multiple surgeries performed to alleviate or eliminate the effects of OSA and they include "maxillomandibular advancement, pharyngeal surgeries such as uvulopharyngopalatoplasty, laser assisted uvulopalatoplasty, and radiofrequency ablation" (Caples et al., 2010, p. 1396).

These different surgeries can be performed individually, simultaneously, or in phases to reduce or eliminate apneas and hypopneas (Caples et al., 2010). In their systematic review and meta-analysis, Zaghi et al. (2016) found that maxillomandibular advancement is an effective treatment for OSA substantially reduced the AHI. The most dramatic reductions occurred in patients with an AHI ≥ 60 EPH. Other surgeries including uvulopalatopharyngoplasty, partial glossectomy, and/or nasal surgery have not shown consistent reductions in AHI (Zaghi et al., 2016).

The "gold" standard of OSA treatment for all severity levels has been and continues to PAP treatment with CPAP being the predominant option. The AOSATF (2009) recommends that CPAP be offered to every patient with OSA. Continuous positive airway pressure treatment works by administering air at a positive pressure through a mask that covers either the mouth, nose or both and is connected to a hose that leads to the machine responsible for generating the air pressure. Other forms of PAP include bi-level PAP, and autotitrating PAP. All forms of PAP work to maintain a patent airway by using positive air pressure to open the upper airway and maintain its patency (AOSATF, 2009).

In a systematic review by McDaid et al. (2009), the researchers evaluated 48 studies to see if CPAP treatment improved subjective sleepiness using the ESS and objective sleepiness using the Maintenance of Wakefulness Test (MWT), the Multiple Sleep Latency Test (MSLT) and blood pressure. Continuous positive airway pressure treatment was compared to standard treatment, placebo such as sham CPAP, and OAs. Studies comparing CPAP to placebo and those studies comparing CPAP with standard treatment were pooled together (McDaid et al., 2009). Continuous positive airway pressure treatment significantly reduced subjective sleepiness by a mean difference of -2.7 points on the ESS as compared to the pooled placebo/standard treatment arms while significantly improving MWT where those on CPAP were able to stay awake 3.3

minutes longer than those receiving placebo or standard treatment (McDaid et al., 2009). There was no statistically significant improvement with CPAP on the MSLT compared to placebo/standard treatment (McDaid et al., 2009). Continuous positive airway pressure treatment significantly lowered mean arterial pressure but did not significantly lower systolic or diastolic blood pressure. There were no statistically significant difference in ESS, MWT, MSLT, or blood pressure when comparing CPAP to OAs (McDaid et al., 2009).

In a five-year follow-up study, Martínez-García et al. (2009) evaluated the effect of CPAP on mortality in patients who had experienced an ischemic stroke. One hundred sixty-six patients who were admitted to the hospital for ischemic stroke had a sleep study performed and it was determined that 96 of the patients had an AHI ≥ 20 EPH and CPAP was offered to those persons (Martínez-García et al., 2009). Patients were followed for a total of 5 years and mortality data was recorded. Individuals with an AHI ≥ 20 EPH who did not use CPAP had an increased adjusted risk of mortality (hazard ratio [HR] = 2.69) compared to participants with an AHI less than 20 EPH (Martínez-García et al., 2009). Those same individuals with an AHI ≥ 20 EPH that did not use CPAP also had an increased adjusted risk of mortality (HR = 1.58) when compared with those with an AHI ≥ 20 EPH who were able to tolerate CPAP therapy (Martínez-García et al., 2009).

In a double-blind, placebo-controlled randomized control trial, Sharma et al. (2011) assessed the impact of CPAP on patients with metabolic syndrome. Metabolic syndrome is defined by the National Cholesterol Education Program (2001) as having any three of the following identifying traits: waist circumference > 102 cm for men or > 88cm for women, triglycerides ≥ 150 mg/dL, high density lipoprotein (HDL) < 40 mg/dL for men or < 50 mg/dL for women, blood pressure ≥ 130/ ≥ 85 mmHg, and fasting glucose ≥ 110 mg/dL. The

researchers randomly assigned 86 CPAP naïve patients to use CPAP for three months, wait for one month, then use sham CPAP for three months or vice versa (Sharma et al., 2011). During the study, the investigators measured blood pressure, carotid intima-media thickness using ultrasonography, fasting blood glucose, fasting lipids, hemoglobin A1c, visceral fat using a computed tomographic scan, and waist circumference at the beginning and end of each intervention period (Sharma et al., 2011). It was determined that 75 (87%) of the participants had metabolic syndrome (Sharma et al., 2011). Continuous positive airway pressure treatment was shown to significantly decrease systolic blood pressure by 3.9 mmHg, significantly decrease diastolic blood pressure by 2.5 mmHg, significantly decrease total cholesterol by 13.3 mg/dL, significantly decrease non-HDL cholesterol by 13.3 mg/dL, significantly decrease low density lipoproteins (LDL) by 9.6 mg/dL, significantly decrease triglycerides by 18.7 mg/dL, and significantly decrease hemoglobin A1c by 0.2% (Sharma et al., 2011). The reductions were significant enough to reverse metabolic syndrome in 11 of the 86 patients (13%) (Sharma et al., 2011).

Continuous positive airway pressure equipment can be cumbersome to wear, difficult to clean, and inconvenient to use making CPAP treatment adherence often difficult to achieve. Not only is achieving treatment adherence difficult but even defining what amount of use determines adherence is problematic. Historically, CPAP use of four hours/night on five out of seven days has been considered a commonly accepted definition for adherence, but in a systematic review by Sawyer et al. (2011), the authors make a strong argument for the need for further research to determine what actual level of CPAP use will maximize the machine's effectiveness. Sawyer et al. (2011) contend that the maximum effect is possibly obtained with more than four hours of CPAP use nightly and likely closer to six or seven hours of use per night. As many studies set

four hours per night as the standard for adherence, for the purposes of this dissertation, CPAP treatment adherence was determined as a “mask-on” time of at least four hours for five out of seven nights per week. Modern CPAP machines have the capability to measure adherence by determining “mask-on” time, how much a mask will leak, and even the residual AHI.

Statement of the Problem

Obstructive sleep apnea is a chronic condition that affects an estimated 22% of men and 17% of women (Franklin & Lindberg, 2015). Individuals with OSA have periodic bouts of apneas and hypopneas while sleeping, that negatively impact the quality of their sleep and triggers deleterious neurohormonal responses related to these apneic and hypopneic episodes (Mannarino et al., 2012). As a result of these maladaptive neurohormonal reactions, individuals with OSA are at increased risk for many diseases including diabetes mellitus type 2, cancer, stroke, myocardial infarction, heart failure, and/or depression (Hla et al., 2014; Marshall et al., 2014; Somers et al., 2008; Stansbury & Strollo, 2015). Reported signs and symptoms of OSA include; excessive daytime sleepiness, fatigue, decreased concentration, and irritability (AOSATF, 2009). Continuous positive airway pressure has long been accepted as the gold standard for treatment (AOSATF, 2009). Although CPAP therapy has been shown to be an effective treatment for patients with OSA, adherence rates remain relatively low and range between 59 and 65 percent (Rotenberg et al., 2016; Wozniak et al., 2014).

Purpose of the Study

While it is well-documented that individuals with OSA are often not adherent to effective treatments such as CPAP therapy, the influence of theoretically-based text messages intended to motivate the individual to use the CPAP device has not been well-studied. Therefore, the purpose

of this study was to examine the effects of using the TPB (Ajzen, 1991) to utilize text messages to increase motivation and use of CPAP therapy by persons with OSA.

Individuals newly diagnosed with OSA and prescribed CPAP who agreed to be in the study were randomly assigned to either an EG that received one daily text message per week for four weeks based upon the TPB in addition to standard treatment, or to a CG who received a generic text message stating how many hours of mask-on time were recorded for the previous week plus standard treatment.

Although standard treatment for patients may have varied slightly, standard treatment included a prescription from a sleep specialist for a CPAP device that included appropriate pressure settings. Standard treatment also included using a durable medical equipment company (DME), chosen by the patient from a list provide by their insurance company, to provide the patient with a CPAP device and the necessary supplies. A respiratory technician, provided by the patient's DME, ensured proper mask type and mask fit based on participant's needs and preferences. The DME technician also confirmed the equipment and data links were working properly. Before initiating CPAP therapy, additional education about CPAP therapy was provided by nurses at the sleep clinic, including instructions related to CPAP operation, maintenance, and common troubleshooting tips. The DME customarily followed up with the patient in one to two weeks and sent a CPAP adherence report which contained usage data collected by the CPAP device to the sleep clinic. The follow up with the patient did not always occur due to DME or patient factors. When issues were noted on the adherence report such as inadequate control of apnea or large mask leaks, the DME tech or sleep clinic attempted to contact the patient by phone and/or in person to provide technical and troubleshooting support.

Mask-on time for all participants was measured once per week for four weeks using the pneumotachograph located in the CPAP machine that recorded the rate of airflow during breathing. At the end of each week, participants in the EG received a text message based on their adherence or nonadherence during that particular week. Participants in the CG received a text message with their hours of mask-on time for the week. All participants completed the Apnea Belief Scale (ABS), ESS, and the Functional Outcomes of Sleep Questionnaire-10 (FOSQ-10) survey questionnaires prior to starting CPAP therapy and post-intervention four weeks later (Chasens, Ratcliffe, & Weaver, 2009; Johns, 1991; Smith, Lang, Sullivan, & Warren, 2004).

Hypotheses

Aim 1: Examine the effect of four text messages sent over four weeks on CPAP adherence.

Hypothesis 1: After four weeks of receiving one text message per week, the total mask-on time will differ between the experimental group and the control group.

Hypothesis 2: After four weeks of receiving one text message per week, the proportion of persons classified as adherent will differ between the experimental group and the control group.

Aim 2: Examine the effect of four text messages sent over 4 weeks on OSA symptom management and outcome expectations

Hypothesis 3: After four weeks of receiving one text message per week, changes in the ABS, ESS, and FOSQ-10 will differ between the experimental group and the control group.

Philosophical Perspective

According to Creswell (2009), philosophical worldviews give researchers “a basic set of beliefs that guide action” (p.6). As the purpose of the proposed study is to evaluate an intervention and its impact on CPAP adherence, a cause and effect perspective is required. One such philosophical perspective is postpositivism. Postpositivism reforms logical positivism and views reality as contextual. That is, absolute truth cannot be attained, for example in human behavior, an objective truth in a particular milieu can be pursued and defined using falsifiability instead of verifiability to test hypotheses (Newman, 2009). Postpositivism utilizes a well-defined experimental methodology and includes the following assumptions: (a) knowledge is conjectural, fallible and imperfect and for that reason researchers state that they fail to reject a hypothesis instead of proving a hypothesis; (b) claims are made about theories and research is used to verify, refine, or abandon these claims; (c) knowledge is shaped by the observations and information collected by researchers; (d) the aim of research is to explain causal relationships that are posed in the form of research questions or hypotheses; (e) objectivity is essential to competent inquiry and, therefore, reliability and validity are important aspects to any study design (Creswell, 2009). A postpositivist quantitative study was an appropriate choice to evaluate the effectiveness of using text messages to influence CPAP adherence. The goal was to measure and interpret physiologic changes including CPAP mask-on time and adherence to therapy as well as to objectively measure changes in instruments that included the ABS, ESS, and FOSQ-10.

Theoretical Framework

The theoretical framework used to guide the development of this study on adherence to using CPAP devices regularly in individuals with newly diagnosed OSA was the TPB developed by Icek Ajzen (see Figure 1) (Ajzen, 1991). The TPB is an extension of the theory of reasoned action (Fishbein & Ajzen, 1977) and is intended to demonstrate the link between beliefs, intention, and behavior (Ajzen, 1991). In TPB, actual behavior is driven by three different beliefs: behavioral beliefs, normative beliefs, and control beliefs. Behavioral beliefs are those beliefs about the probable outcomes of the behavior that, in turn, create a positive or negative attitude towards the behavior (Ajzen, 1991). Normative beliefs are those beliefs about the expectations of those in society that result in peer pressure that Ajzen termed, subjective norm (Ajzen, 1991).

Finally, control beliefs are those beliefs an individual accepts regarding the "presence or absence of requisite resources and opportunities" (Ajzen, 1991, p. 196). Control beliefs directly influence an individual's perceived behavioral control by shaping the perception of how confident they will be in performing the desired behavior. This perception of confidence in performing the desired behavior is known as perceived behavioral control that, according to Ajzen (1991), is "compatible with Bandura's concept of perceived self-efficacy" (p. 184). Perceived behavioral control moderates the influence that both the attitude toward the behavior and subjective norm had on an individual's intention to carry out the actual behavior. Intention is the summation of the motivational factors that influence a behavior. Intentions "are indications of how hard people are willing to try, of how much of an effort they are planning to exert, in order to perform a behavior" (Ajzen, 1991, p. 181). Actual behavioral control refers to the extent to which the actual skills, resources, and opportunities needed to perform the behavior are

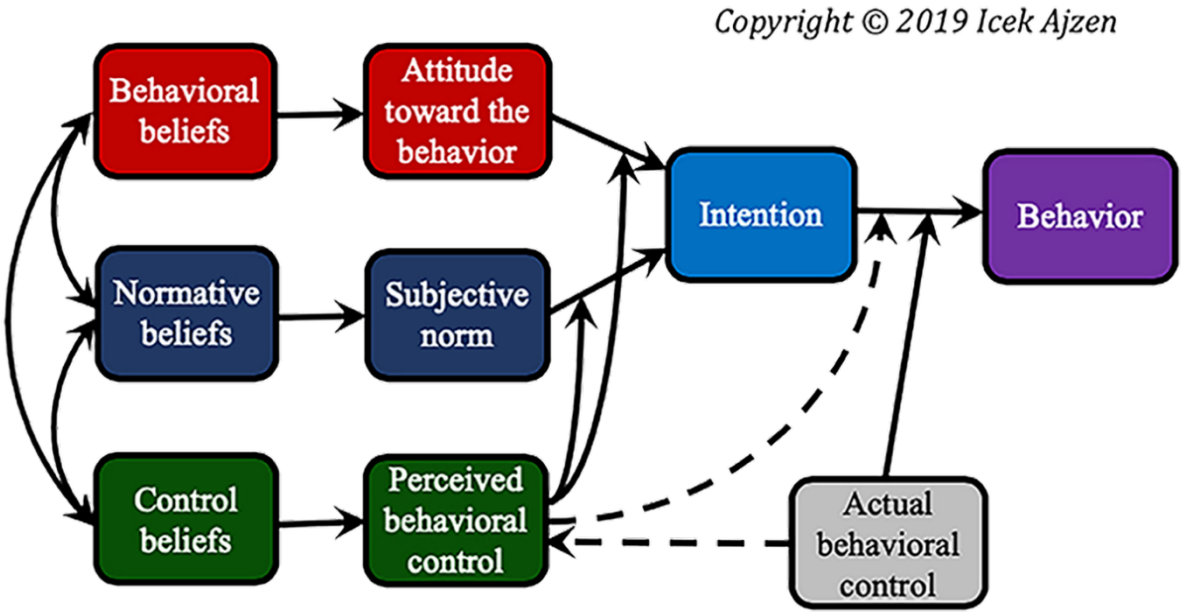


Figure 1. Theory of planned behavior

available to a person (Ajzen, 1987). If there are sufficient skills, resources, and opportunities available then a person may carry out a behavior independent of their intention (Ajzen, 1991).

Appropriately developed text-message based interventions (TMBI) have the potential to heighten the intention to perform a behavior by influencing behavioral beliefs, normative beliefs, and/or control beliefs. During the TMBI, the message sender could theoretically affect behavior beliefs by sending messages that educate the participant about the benefits of adherence. Normative beliefs could theoretically be influenced by stating and emphasizing the value of adherence in a text message. Finally, text messages that assist in solving human-device interface issues (e.g. air leaks or nasal congestion) could empower the participant and theoretically improve their control beliefs. Reported barriers to CPAP adherence includes mask leakage, mask discomfort, reduced freedom, sleep issues, partner sleep disturbance, and claustrophobia among others (Broström, Nilsen et al. 2010). Text-based messaging has the potential to offer a platform for a nurse or other healthcare provider to send messages that provide technical support and encouragement to motivate participants to be adherent to CPAP therapy.

Assumptions

Assumptions of this study based on the theoretical framework included the following:

- Motivation and ability interact to produce effects on behavioral achievement;
- Continual performance of a behavior develops the establishment of a habit;
- The impact of attitudes on behavior is facilitated by intention;
- Perceived behavioral control has motivational significance for behavioral intentions;

- A favorable attitude towards the behavior; a favorable subjective norm, and better perceived behavioral control should reinforce an individual's intention to perform the behavior (Ajzen, 1991).

Conceptual Definitions

Actual behavioral control – "the various internal factors (skills, knowledge, physical stamina, intelligence, etc.) and external factors (legal barriers, money, equipment, cooperation by others, etc.) that are needed to perform the behavior or that can interfere with its performance" (Ajzen, n.d., para. 1).

Adherence

- *Conceptual definition* – "the extent to which a person's behaviour – taking medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a health care provider" (Sabaté, 2003, p. 3).
- *Operational definition* – As the main interest of this study is adherence to CPAP therapy, adherence was defined using the Centers for Medicare and Medicaid Services (CMS) criteria as having a mask-on time at effective pressure for ≥ 4 hours/night for 70% of nights during a consecutive 30-day period (CMS, 2016). Mask-on time was measured using the pneumotachograph located in the CPAP machine that recorded the rate of airflow during breathing and sent it wirelessly to a Health Insurance Portability and Accountability Act of 1996 (HIPAA) compliant cloud-based software program (Respironics EncoreAnywhere or ResMed AirView).

Attitude towards the behavior – "the degree to which a person has a favorable or unfavorable evaluation or appraisal of the behavior in question" (Ajzen, 1991, p. 188).

Behavior – "the coordinated responses of whole living organisms to internal and/or external stimuli" (Dugatkin, 2012, para. 3).

Behavioral beliefs

- *Conceptual definition* – "beliefs about the likely consequences of the behavior" (Ajzen, 2019, page 1).
- *Operational definition* – The ABS was used for all beliefs as it includes outcome expectations of using CPAP for OSA, social support aspects that promote or discourage success with CPAP, and CPAP acceptance (Smith et al., 2004). The ABS is a self-administered questionnaire that takes five to 10 minutes to take (Shahid, Wilkinson, Marcu, & Shapiro, 2012). The ABS has 24 statements that are:

    > designed to assess: perceived impact of OSA (four items); trust in medical staff (two items); outcome expectations (four items); CPAP acceptance (two items); openness to new experiences (two items); commitment to change (four items); willingness to ask for help (two items); attitude to health (two items); and self-confidence (two items). (Smith et al., 2004, p. 361).

The ABS uses a 5-point Likert scale with the answers ranging from agree to disagree and one-half of the 24 statements are negatively worded (and reverse scored) to minimize response bias (Smith et al., 2004). According to Smith et al. (2004), the ABS readability analysis suggests that the ABS can be answered by individuals with sixth grade reading skills. The ABS does not

have subscales and will be applied as a single measure of attitudes toward CPAP adherence. Higher scores on the ABS indicate greater positive attitudes regarding CPAP adherence (Smith et al., 2004). Internal consistency of the ABS has been calculated using Cronbach's α. This test demonstrated modest consistency with $\alpha = 0.75$ (Smith et al., 2004).

Control beliefs – "beliefs about the presence of factors that may facilitate or impede performance of the behavior" (Ajzen, 2019, p. 1).

Intention – "assumed to capture the motivational factors that have an impact on a behavior; they are indications of how hard people are willing to try, of how much of an effort they are planning to exert" (Ajzen, 1987, p. 44).

Normative beliefs – "beliefs about the normative expectations of others" (Ajzen, 2019, p. 1).

Obstructive sleep apnea – "characterized by repetitive episodes of [complete or partial] upper airway obstruction that occur during sleep, usually associated with a reduction in blood oxygen saturation. Although airflow ceases, respiratory muscles continue to work." (Baldwin, 2002, p. 634).

Perceived behavioral control – "the perceived ease or difficulty of performing the behavior and it is assumed to reflect past experience as well as anticipated impediments and obstacles" (Ajzen, 1991, p.188).

Sleep

- *Conceptual definition* – "a behavioral state that alternates with waking, relative to which it is characterized by a heightened threshold to sensory input, attenuation of motor output,

characteristic changes in central and peripheral physiology, and diminished conscious awareness" (Pace-Schott, 2009, p. 11).

- *Operational definition* – As it is cost-prohibitive to monitor sleep state in a person using electroencephalograms or other objective methods, the effects of sleep or lack of sleep on excessive daytime sleepiness and fatigue due to excessive sleepiness on daily activities was measured. The ESS was used to assess the concept of excessive daytime sleepiness (Johns, 1991). The ESS uses a four-point Likert-type scale (0 = would never doze, 1 = slight chance of dozing, 2 = moderate chance of dozing, 3 = high chance of dozing) to rate the chance of dozing in eight different scenarios. Lower ESS scores indicate less excessive daytime sleepiness. The FOSQ-10 measures the impact of excessive sleepiness on functional outcomes related to daily activities and sleep-related quality of life (Chasens et al., 2009). The questionnaire uses a four-point Likert-type scale (1 = extreme difficulty, 2 = moderate difficulty, 3 = a little difficulty, 4 = no difficulty) to rate the difficulty of performing 10 different daily behaviors because of being sleepy or tired. The FOSQ-10 is subdivided into five domains that include general productivity, activity level, vigilance, social outcomes, and intimacy and sexual relationships. A higher score on the FOSQ-10 indicates better functional status. The original FOSQ is a 30-item self-administered questionnaire and likely be a burden but the FOSQ-10 has similar validity and reliability as the FOSQ with an internal consistency of $\alpha = 0.87$ (Chasens et al., 2009).

Subjective norm – "the perceived social pressure to perform or not to perform the behavior (Ajzen, 1991, p. 188).

Limitations

Study limitations included:

- Small sample size obtained from a single university medical center sleep clinic in a large city in the Southeastern United States. Results may not be generalizable to a larger OSA patient population.
- Only CPAP devices from two manufacturers, ResMed and Respironics, were utilized. Results may not be generalizable to individuals using CPAP devices from other manufacturers.
- The TPB does not account for other variables that may influence behavioral intention and motivation such as mental well-being, disposition, or previous experience.
- The TPB does not account for ecological or financial factors that may influence an individual's intention to carry out a desired behavior.

Significance for Nursing

In a meta-analytic review, Armitage and Conner (2001) stated that the TPB accounted for 27% of the variance in behavior and 39% of the variance in intention in 185 studies analyzed by the authors. The TPB has been shown to be an efficacious predictor of behavior and intention and would be an effective framework for designing a nursing intervention to improve CPAP adherence in patients newly diagnosed with OSA. Because a theory explains events by specifying the relationship among variables, using the TPB will allow a nursing researcher to take a systematic approach to understanding behaviors and intention to develop a useful nursing intervention.

As the most trusted profession (Brenan, 2018), nurses play a vital role in caring for patients with chronic conditions such as OSA. The nursing care provided to patients with OSA includes encouraging the patient to follow the agreed upon treatment plan which often feature CPAP therapy. By leveraging cell phone technology owned by 95% of American adults (Pew Research Center, 2018a), nurses can tailor text messages using the TPB to motivate patients just starting CPAP to be adherent to using the machine on a regular basis at a frequency sufficient to provide beneficial effects.

Chapter 2: Literature Review

The literature search was performed using numerous methods to locate research studies relevant to this study. The electronic databases searched include CINAHL, Google Scholar, Ovid, and PubMed. The keywords used included obstructive sleep apnea, continuous positive airway pressure, interface, treatment adherence, treatment adherence measurement, compliance, barriers, side effects, phone, text message, theory of planned behavior, protection motivation theory, and health belief model. Articles selected for this literature review were written in English and published in peer reviewed journals. Articles that solely examined pediatric subjects were excluded. The studies included had publication dates that ranged from 2006 to 2019 except for the articles that studied methods to measure CPAP adherence. Those studies had no limitations on date of publication as none were found written after 1993. After completing the literature search, the relevant studies were divided into four main categories. These categories include:

- Methods to measure CPAP adherence (self-report, machine-on recorded adherence and mask-on recorded adherence),
- Barriers to CPAP adherence (device-human interface factors and psychological factors),
- Adherence treatments for OSA (cognitive behavioral therapy interventions, telephone-based interventions and text message-based interventions) and,
- Theoretical frameworks considered in developing this study (protection motivation theory, health belief model and theory of planned behavior).

Methods to Measure Continuous Positive Airway Pressure Therapy Adherence

Accuracy in reporting any type of medication or device adherence improves the reliability of most studies and this is typically true of measuring CPAP adherence as well. Two studies (Kribbs et al., 1993; Rauscher, Formanek, Popp, & Zwick, 1993) compared self-reporting of CPAP adherence to objective measurements of machine-on time as determined by a time counter on the CPAP machine (Rauscher et al., 1993) and mask-on time as determined by a pressure transducer in the CPAP mask (Kribbs et al., 1993). The study by Rauscher et al. (1993) was a non-randomized, cross sectional, observational study. Data was collected on 63 participants over a six-month period who had been using nasal CPAP therapy for an average of 18 months (Rauscher et al., 1993). The participants answered a 35-item questionnaire that included questions about possible side effects of nasal CPAP as well as daytime sleepiness, and a subjective report of their CPAP adherence (Rauscher et al., 1993). The mean measured time of use was 4.9 hours per night as compared to the reported mean usage time of 6.1 hours which demonstrated a statistically significant over reporting of CPAP usage as compared to machine-on time ($p < .0001$) (Rauscher et al., 1993). Limitations of the study included selecting study participants that had no other serious comorbidities (Rauscher et al., 1993). Another limitation included that the study used a cross sectional design and did not record adherence during different periods of time.

The study by Kribbs et al. (1993) was a non-randomized, prospective, observational study. Data was collected on 35 participants in an urban setting who had been prescribed nasal CPAP by a physician (Kribbs et al., 1993). The participants took an initial questionnaire that consisted of questions regarding concepts such as overall health, daytime sleepiness, and sleep hygiene but the researchers did not state whether the questionnaire was tested for reliability and

validity. The study participants were followed for three months while they kept a log to record how much they used CPAP and the CPAP mask-on time was recorded using a pressure transducer in the CPAP mask without the knowledge of the user (Kribbs et al., 1993). Kribbs et al. (1993) did not state if the participants were CPAP naïve or, if not, how long they had been using the CPAP device. The researchers discovered that the study participants demonstrated reporting bias by overreporting their CPAP use by an average of 69 minutes nightly as compared to actual measured mask-on time ($p < .002$) (Kribbs et al., 1993). Other than not being randomized, other limitations of the study included having a small sample size which would limit generalizability and the study did not measure any objective outcomes such as reduced AHI or other measures.

One advantage of measuring mask-on time as compared to machine-on time as was done in the study by Kribbs et al. (1993) is that mask-on time can detect when a mask leak is occurring. Mask leaks lower the ability of the CPAP machine to maintain the airway open and prevent any obstructions. Another advantage of using mask-on time is that it can differentiate between someone actually wearing the CPAP mask versus using machine-on time where a patient could simply turn on the machine without even wearing the CPAP mask (See Table 1, Row 1).

Barriers to Adherent Continuous Positive Airway Pressure Therapy

According to the AOSATF (2009), CPAP should be the first line of therapy for patients with mild, moderate, or severe OSA. Continuous positive airway pressure has been shown to reduce episodes of apnea and hypopnea during sleep, limit oxyhemoglobin desaturation, and lower cortisol levels associated with arousal incidents among other deleterious effects

Table 1

Study Design Influences

Row	Research Findings	Influence on Study Design
1	Mask-on time found to be more reliable measure of adherence than either machine-on time or self-reporting	Mask-on recorded time was used to measure adherence to CPAP therapy in the participants
2	There are variable adherence rates depending on the type of mask being worn	Mask type data was collected and considered in the data analysis
3	A variety of psychosocial factors have been shown to impact adherence to CPAP therapy	The ABS and FOSQ-10 were used to evaluate psychosocial factors that impact CPAP adherence
4	There is no consensus for what period of time constitutes short-term adherence. The average short-term adherence time period was 27.83 days for six studies reviewed.	The study lasted for four weeks.
5	The various telephone-based intervention studies reviewed did not give clear indication that TBI was superior to standard treatment	CPAP adherence was measured in both the experimental group and the control group to determine effectiveness of the intervention
6	The presence of a sham text message in the control group would help to lessen the impact of any unexpected bias	The control group received text messages that reported the weekly hours of CPAP device usage
7	Automated text messages do not have the ability to determine reasons for nonadherence so that appropriate advice may be provided to the participant	Personalized text messages were sent to the participants in the experimental group based on their adherence or nonadherence to CPAP therapy over a one-week period that included information on how to get assistance

(AOSATF, 2009). A well-documented shortcoming to CPAP is the lack of adherence to therapy which can detract from CPAP therapy effectiveness (Sawyer et al., 2011). Two significant and broad categories that act as barriers to CPAP therapy include device-human interface and psychosocial factors (Sawyer et al., 2011).

There are three main CPAP mask type which include, nasal masks, nasal pillows, and oronasal masks. Nasal masks fit over the nose encompassing the bridge of the nose down to the upper lip and have a triangular shape. Nasal pillows are typically the smallest CPAP masks and rest on the upper lip. The nasal pillow mask delivers the pressurized air through two nasal tubes that cover the nostrils. The oronasal mask is also known as the full-face mask is also triangular shaped and covers both the nose and the mouth making it effective for “mouth breathers”.

Three studies were located that compared the adherence rates of the different CPAP mask types (Borel et al., 2013; Rowland et al., 2018; Ryan, Garvey, Swan, Behan, & McNicholas, 2011). Four different mask types were evaluated for adherence: (a) nasal mask (Borel et al., 2013; Rowland et al., 2018; Ryan et al., 2011), (b) nasal mask plus chinstrap (Rowland et al., 2018), (c) nasal pillows (Borel et al., 2013; Ryan et al., 2011), and (d) oronasal mask (Borel et al., 2013; Rowland et al., 2018). There were no statistical differences in CPAP adherence based on mask type in Rowland et al. (2018) nor Ryan et al. (2011). This was likely due to their sample sizes being too small to detect differences.

The study by Borel et al. (2013) was a large, prospective observational study that included 2311 subjects and included nasal masks, nasal pillows, and oronasal masks. Univariate analysis was used to evaluate the risk of nonadherence with CPAP therapy and it was determined that nasal pillows and oronasal masks both carried a statistically significant higher risk of CPAP

nonadherence when compared to nasal masks when using a p-value $p < .05$ as statistically significant (Borel et al., 2013). Using multivariate analysis, nasal masks were associated with a statistically significant higher rate of CPAP adherence than oronasal masks (Borel et al., 2013). Nasal pillows also showed a higher level of CPAP adherence than oronasal masks but did not achieve statistical significance (Borel et al., 2013). The researchers concluded that nasal masks should be the first choice when determining what type of CPAP mask to choose (Borel et al., 2013). Limitations of the study included no standardized level of treatment was assured as it was an observational study. The generalizability of the study is limited as there were statistically significant demographic differences between those included in the analysis and those who were excluded. Those patients excluded from the study were older, had a lower body mass index (BMI), were more likely to be male, and had less excessive daytime sleepiness as reflected by ESS (Borel et al., 2013).

Rowland et al. (2018) developed a prospective, randomized, crossover trial that compared adherence rates between nasal masks, nasal masks with chinstraps and oronasal masks. The 48 participants involved were patients on a tertiary sleep disorders unit in a hospital who were all considered to have severe sleep apnea (Rowland et al., 2018). All participants wore each mask for a 4-week period, and it was found there was no statistically significant difference in CPAP adherence between the three mask types (Rowland et al., 2018). Differences in subjective findings of mask comfort, sleep quality, and mask preference were statistically significant and favored nasal masks (Rowland et al., 2018).

Ryan et al. (2011) designed a randomized, crossover study to examine adherence using nasal pillows as compared to adherence using nasal masks in 21 participants. According to the researchers, 18 participants were needed to detect a difference with 80% power at the 5%

significance level (Ryan et al., 2011). Participants were assigned to wear either the nasal mask or nasal pillows for a period of four weeks and then change to the other type of mask for another four weeks. There was no statistically significant difference in adherence between nasal masks and nasal pillows, nor was there a clear preference for either mask among the participants (Ryan et al., 2011). In addition to the small number of subjects, limitations of the study included not being able to completely control for the influence of nasal side effects such as nasal congestion (Ryan et al., 2011). Also, the researchers used a questionnaire evaluating side effects that had not been validated and the likelihood of a statistical type 1 error occurring could not be excluded (Ryan et al., 2011).

Five primary studies were found that evaluated mask-related side effects and their impact on adherence. The types of studies included questionnaires (Broström et al., 2009; Fung, Martin, Igodan, Jouldjian, & Alessi, 2012) and three prospective, observational studies by Basoglu, Midilli, Midilli, and Bilgen (2011), Borel et al. (2013) and Ye et al. (2011) that assessed the impact of mask-related side effects of therapy on adherence rates. Basoglu et al. (2011) and Borel et al. (2013) both noted (in studies consisting of 133 and 2311 CPAP naïve participants respectively) that nasal mask, oronasal mask, and nasal pillow related side effects such as mask intolerance, nasal congestion, dry mouth, and choking sensation. All four side effects were statistically significant contributors to CPAP nonadherence (Basoglu et al., 2011; Borel et al., 2013). However, Ye et al. (2011) had 91 participants record 19 mask-related side effects such as dry nose and skin irritation in a diary and the researchers determined that the only mask-related side effect that was a statistically significant contributor to nonadherence was reduced partner intimacy.

Broström et al. (2009) sent out questionnaires and received responses from 350 patients using CPAP therapy for OSA and 105 healthcare personnel that work with this population to compare perceptions regarding different aspects of CPAP therapy including mask-related side effects and their influence on adherence. The type(s) of mask(s) used by the study participants were not stated. Patients considered dry throat, congested nose, mask leaks, and uncomfortable mask pressure the greatest problems that threaten adherence to CPAP therapy (Broström et al., 2009). Tests for significance were not helpful for use in testing adherence as the study compared patient and healthcare personnel opinions on the greatest problems threatening non-adherence.

A qualitative, open-ended questionnaire by (Fung et al., 2012) focused less on the mask-related side effects and concentrated instead on CPAP equipment usage and adherence. The type(s) of CPAP mask(s) used by the study participants was not stated. The authors of the study questioned 148 veterans regarding difficulties they had manipulating different aspects of the CPAP equipment. Examples of questions included, “How much difficulty have you had putting on your continuous positive airway pressure (CPAP) mask?” (Fung et al., 2012, p. 854). The researchers observed no significant relationship between difficulty with CPAP equipment and adherence to CPAP therapy (Fung et al., 2012). Limitations of the study included no use of objective measurements to assess adherence, limited generalizability to younger patients with OSA, and a primarily male sample.

In summary, mask type and mask-related side effects could have an impact on adherence rates. Based on the studies included in this literature review, there is some evidence that nasal masks and/or nasal pillows are associated with slightly better adherence than oronasal masks (Borel et al., 2013; Ryan et al., 2011) and that nasal masks are preferred over nasal masks with chinstraps and oronasal masks (Rowland et al., 2018) (See Table 1, Row 2).

As with any chronic condition requiring long-term management, it is necessary to evaluate not only physical side effects impact on adherence but the psychosocial factors as well. Psychosocial factors such as anxiety using the CPAP machine, claustrophobia, depression or discouragement about wearing the CPAP device long-term, partner not tolerating (no support), or perceived stigma are important factors in impacting the adherence to CPAP therapy. The following eight primary studies were found that focused on psychosocial factors affecting CPAP adherence.

In a mixed, retrospective-observational study by (Law, Naughton, Ho, Roebuck, & Dabscheck, 2014), the authors discovered that depression was independently associated with lower CPAP adherence. Two hundred and forty CPAP naïve participants newly diagnosed with OSA were assessed for depression and anxiety as well as severity of the anxiety and depression and other clinical factors (Law et al., 2014). During the first week of CPAP titration, multiple linear regression determined that depression significantly predicted less CPAP use (Law et al., 2014).

Sawyer, Deatrick, Kuna, and Weaver (2010) carried out a mixed-methods, concurrent, nested, longitudinal study to examine how the beliefs and perceptions differ between CPAP adherers and CPAP non-adherers after the first week of therapy. Thirty interviews were conducted with 15 veterans from an urban Veteran's Administration center prior to starting CPAP therapy for OSA and one week after CPAP therapy was started (Sawyer et al., 2010). This study was one of the few that was based on a conceptual framework and the authors used social cognitive theory to frame the study (Sawyer et al., 2010). Six of the 15 participants were adherent based on an objective measure of mask-on time of $\geq$ 6 hours per night. In the interviews, the six adherent participants reported no barriers after one week of CPAP therapy

(Sawyer et al., 2010). The adherent patients believed that using the CPAP device was important and were confident in their ability to be successful (Sawyer et al., 2010). Conversely, non-adherent study participants focused on barriers rather than facilitators prior to starting CPAP therapy even though few actual barriers were identified one week after using CPAP therapy (Sawyer et al., 2010). Social networks also appeared to be important in determining CPAP adherence. Eight of the nine non-adherent participants identified as either single, divorced, or widowed and did not believe their social networks were important to the OSA diagnosis and to beginning CPAP therapy (Sawyer et al., 2010). However, adherent participants did stress social networks including using friends and families to aid in troubleshooting CPAP issues (Sawyer et al., 2010).

In summary, Sawyer et al. (2010) developed typologies for both the CPAP adherent participants and CPAP non-adherent participants. Non-adherent CPAP users were less able to define the risks associated with OSA and less able to recognize outcome expectations such as hoping adherence to CPAP therapy would improve overall quality of life (Sawyer et al., 2010). Non-adherent CPAP users identified greater barriers and less facilitators to CPAP adherence and had a lower self-efficacy (Sawyer et al., 2010). This finding of low self-efficacy negatively impacting CPAP adherence was also observed in another study by Sawyer et al. (2011) where the authors ascertained that participants expressing low confidence in the ability to use CPAP were at increased risk of being nonadherent to CPAP therapy.

Similar to the study by Sawyer et al. (2010), Broström, Nilsen et al. (2010) conducted a qualitative content analysis using semi-structured interviews to investigate users' experiences of being adherent or non-adherent to CPAP therapy. Twenty-three participants answered the interview questions and using content analysis, the researchers noted several presumed barriers

to CPAP adherence (Broström, Nilsen et al. 2010). Feelings of uncertainty about CPAP therapy led to negative attitudes before therapy was even started (Broström, Nilsen et al. 2010). Broström, Nilsen et al. (2010) also observed that needing to use CPAP therapy and using or showing the CPAP device to other brought about shame to the participants. Other undesirable psychological effects reported by those using CPAP included "reduced freedom, a desire to avoid lifelong treatment, claustrophobic thoughts and anxiety about the technology" (Broström, Nilsen et al. 2010, p. 128). To emphasize the impact of claustrophobia, Sawyer et al. (2011) observed that claustrophobia at therapy initiation was a key factor for putting patients at risk to be nonadherent. In addition to the psychological factors that served as barriers to adherence, the CPAP users also noted that mask-related side effects such as nasal congestion, dry throat, and eye irritation acted to decrease CPAP use (Broström, Nilsen et al. 2010). Because the study used qualitative content analysis, quantification of concepts in order of relative importance could not be performed (Broström, Nilsen et al. 2010). Broström, Nilsen et al. (2010) also noted that the sample was chosen selectively in order to maximize the disparity of the descriptions within the study.

Three other qualitative studies that evaluated psychosocial factors included an inductive content analysis by Dunbar-Jacob, Aloia, Martire, Buysse, and Strollo (2016), a grounded theory study by Rodgers (2013), and a qualitative descriptive study that used the critical incident technique by Elfström et al. (2012). Dunbar-Jacob et al. (2016) interviewed 27 participants about knowledge of OSA, perceived effects of OSA, and facilitators and barriers to CPAP adherence. From their content analysis, the authors determined that a couple-oriented approach to improving CPAP adherence should be considered (Dunbar-Jacob et al., 2016).

In her grounded theory study Rodgers (2013) interviewed 82 participants "who had a wide range of experience with OSA." (p. 186). The theoretical framework developed as a result of the comparative analysis was termed *living in limbo* which was intended to describe the struggle most participants had with living with OSA. As it regards adherence, *living in limbo* described the battle to adhere to CPAP therapy and patients with inadequate personal and professional support as well as poor access to care were less likely to be adherent.

Elfström et al. (2012) used critical incident technique to analyze partners' support to patients with OSA during the initial phase of starting CPAP therapy. The critical incident technique (CIT) "collects specific descriptions of human behavior in defined situations, mainly through semi-structured interviews. A critical incident is the core concept in CIT and represents a major situation of great importance to the person involved." (Elfström et al., 2012, p. 229). The researchers interviewed 25 partners of patients with OSA who were using CPAP therapy and found that shame, complicated routines caring for equipment, and inhibited intimacy were psychosocial factors that negatively affected the partners' support with CPAP therapy. Psychosocial factors positively affecting the partners' support with CPAP therapy included routines that were easily manageable, patient's positive attitude to CPAP, and support from from family, friends and the healthcare team (Elfström et al., 2012).

Baron, Gunn, Wolfe, and Zee (2017) used a mixed-methods study to evaluate relationship factors that impact CPAP adherence. The authors collected quantitative data on 16 women newly diagnosed with OSA including prevalence of depressive symptoms, excessive daytime sleepiness, insomnia symptoms, and apnea severity (Baron et al., 2017). Other data collected included relationship status, relationship quality and level of social support (Baron et al., 2017). Qualitative data included responses to open-ended questions about "helpful" and

"unhelpful" ways partners were involved in CPAP use (Baron et al. 2017, p. 5 of 8). The quantitative data revealed that the presence and severity of relationship conflict negatively impacted adherence to CPAP therapy (Baron et al., 2017). Most participants responding to the qualitative questions reported that the presence or absence of encouragement and support was an important aspect of the ability to be adherent (Baron et al., 2017). The authors concluded that the well-being of partner relationships was highly important to women's CPAP adherence and that a better understanding of "gender and social processes" is needed to aid in understanding reasons for lower CPAP adherence (Baron et al., 2017, p, 6 of 8).

Three prospective, observational cohort studies (Diaz-Abad et al., 2014; Moran et al., 2011; Poulet et al., 2009) are included in this review of literature on psychosocial factors that affect adherence. Diaz-Abad et al. (2014) was unique in their sample selection as they focused solely on determinants of CPAP adherence in Hispanics with OSA. All three studies used different instruments to examine psychosocial factors that predict nonadherence in patients with OSA using CPAP therapy. Diaz-Abad et al. (2014) used a self-developed questionnaire that was not previously tested for reliability nor validity to determine what factors affect CPAP adherence in Hispanic patients with OSA. Seventy-nine consecutive patients were recruited for the study and mailed questionnaires that were printed in both English and Spanish (Diaz-Abad et al., 2014). The researchers found that perceived benefit and improvement in quality of life and health status were the main contributors that predicted adherence – not spoken language or socioeconomic status as was hypothesized (Diaz-Abad et al., 2014). Besides having not performed validity or reliability measures, other limitations of the study included no objective measure of CPAP adherence was used and it utilized a small sample of mainly urban dwelling Puerto Rican immigrants which limited generalizability to all Hispanic patients with OSA.

Moran et al. (2011) used a prospective, observational cohort study to examine if adherence is related to personality traits such as motivation and coping. The researchers recruited 63 participants from a sleep center and asked them to fill out three questionnaires and then monitored adherence using objective data from the CPAP machine via the participant's home healthcare company (Moran et al., 2011). The three instruments included the BIS/BAS inventory that assesses a participant's behavioral inhibition system (BIS) and their behavioral activation system (BAS). A person's BIS is associated with "negative affect and feelings of fear and anxiety" (Moran et al., 2011, p. 688) and BAS is related to "positive affect and feelings of optimism and joy" (Moran et al., 2011, p. 688). The BIS/BAS questionnaire achieved test-retest correlations ranging from 0.59 to 0.72 (Moran et al., 2011). Another instrument used by the researchers included the Ways of Coping (WAYS) questionnaire that is used to evaluate how participants deal with stressful situations using 66 items and was shown to have adequate reliability and validity (Moran et al., 2011).

The final instrument used by Moran et al. (2011) was the mini International Personality Item Pool which was used to measure five personality traits that included "neuroticism, extraversion, intellect/imagination, agreeableness, and conscientiousness" (p. 689) and was demonstrated to show adequate internal consistency across tests with Cronbach's $\alpha \geq 0.6$. From their statistical analysis, the researchers determined that a participant's level of BIS and neuroticism played a statistically significant role in predicting nonadherence (Moran et al., 2011). Limitations of the study included no standardization of the CPAP equipment or mask was used thus, differences in user interface issues and mask comfort may have contributed to outcomes observed. Also, adherence data was not collected for a standard length of time (Moran et al., 2011).

Poulet et al. (2009) utilized a prospective observational cohort design to examine the psychological variables that predict adherence to CPAP therapy. The researchers enrolled 122 patients newly diagnosed with OSA and had them complete four questionnaires prior to initiating CPAP therapy and one month after beginning CPAP therapy (Poulet et al., 2009). The four instruments used included the ABS, the Apnea Knowledge Test (AKT), the Hospital Anxiety and Depression Scale (HADS), and the Nottingham Health Profile (NHP) (Poulet et al., 2009). According to S. Smith, Lang, Sullivan, and Warren (2004), the internal consistency of the AKT was found to be "low to modest" (p. 361) with a Cronbach's alpha of $\alpha = 0.6$. The ABS had reasonable internal consistency with Cronbach's $\alpha = 0.75$ (S. Smith et al., 2004). The HADS is divided into two subscales consisting of an anxiety subscale and a depression subscale; internal consistency of both were tested using Spearman correlation. The internal consistency of the anxiety subscale was found to be $r = 0.54$ and the depression subscale was $r = 0.79$ which were both statistically significant (Zigmond & Snaith, 1983). According to Frank-Stromborg and Olsen (2004), The NHP used criterion validity to determine validity and it was found to be selective in identifying consulters from non-consulters of healthcare. Also, the NHP was found to have test-retest reliability ranging from 0.75 to 0.88 (Frank-Stromborg & Olsen, 2004). Surprisingly, the authors of the study found that participants who were adherent to CPAP therapy were more likely ($p \leq .02$) to be more depressed, have more emotional disorders, to be more fatigued, and to be more socially isolated than participants who were nonadherent to CPAP therapy (Poulet et al., 2009). Two independent predictors of adherence were determined to be the emotional reactions score on the Nottingham Health Profile and the overall score on the ABS (Poulet et al., 2009). Limitations of the study included lack of standardization of education the participants received before initiation of CPAP therapy.

In a study by Platt et al. (2010), the authors used a retrospective cohort study to assess if health-promoting behaviors such as medication adherence were associated with adherence to CPAP therapy when controlling for age, race, and clinical factors. One hundred seventeen participants newly prescribed CPAP therapy who were already on lipid-lowering medications were recruited for the study (Platt et al., 2010). To determine medication adherence, the researchers used a Veterans Administration (VA) electronic pharmacy database to keep track of medication refills for lipid-lowering medications and CPAP adherence was determined by the objective measure of using machine mask-on time as determined by the CPAP machine (Platt et al., 2010). From the study, Platt et al. (2010) concluded that patients who were more adherent to taking lipid-lowering medications were significantly more likely to be adherent to CPAP therapy and termed this behavior "so-called 'healthy-user' effect" (p. 105). Because 97% of the participants recruited to the study were male this limits the generalizability of the study. Another limitation was the method in which medication adherence was determined. The refills of a medication may not directly correlate to the actual ingestion of the medicine and may have affected the statistical analysis. In summary, a variety of psychosocial factors have been shown to impact adherence to CPAP therapy including depression (Law et al., 2014), outcome expectations (Broström, ÅRestedt et al., 2010; Diaz-Abad et al., 2014; Sawyer et al., 2010) partner intimacy and support (Baron et al., 2017; Elfström et al., 2012), and social networks (Broström, ÅRestedt et al., 2010; Elfström et al., 2012; Rodgers, 2013; Sawyer et al., 2010). These psychosocial factors are quantitatively measured in the ABS and the FOSQ-10 (see Table 1, Row 3)

Interventions to Improve Continuous Positive Airway Pressure Adherence for the Treatment of Obstructive Sleep Apnea

As previously stated, CPAP is known to be an effective treatment for OSA that reduces the AHI, improves oxygen saturation, and reduces respiratory related arousals (AOSATF, 2009). There is currently no consensus on what short-term CPAP adherence timeframe is predictive of long-term CPAP adherence despite being studied by multiple researchers (Budhiraja et al., 2007; Campos-Rodriguez et al., 2019; Naik, Kreinin, & Kryger, 2019; Somiah et al., 2012; Turnbull, Bratton, Craig, Kohler, & Stradling, 2016; Weaver et al., 1997). The criterion for short-term adherence and long-term adherence varied in every study reviewed. The average short-term adherence period that was determined to be predictive of long-term adherence for all six studies was 27.83 days (Budhiraja et al., 2007; Campos-Rodriguez et al., 2019; Naik et al., 2019; Somiah et al., 2012; Turnbull et al., 2016; Weaver et al., 1997) (See Table 2). Based on the literature review, a 4-week long study is a reasonable amount of time to evaluate short-term adherence (See Table 1, Row 4).

According to Sudak (2006), cognitive behavioral therapy (CBT) interventions are "relatively short-term, goal-directed, problem-focused treatments that are fundamentally based on the model that changing cognitions is possible and leads to behavioral change" (p. *i*). For many years, CBT has been used with success for psychiatric disorders such as depression, generalized anxiety disorder, and posttraumatic stress disorder. However, in recent years, CBT interventions have been used in other situations such as chronic pain, marital distress, sleep disturbances in the elderly, and CPAP adherence (Butler, Chapman, Forman, & Beck, 2006). Three studies that include four randomized control trials (RCT) and one Cochrane Review from

2006 until the present were included in the literature review that evaluated CBT interventions designed to improve CPAP adherence in OSA.

Four studies demonstrated that CBT techniques were successful in improving CPAP adherence in participants with OSA when compared to standard treatment (Bakker et al., 2016;

Table 2

CPAP Adherence Timeframes

Study	**Short-term Adherence Time Period**	**Long-term Adherence Time Period**
Budhiraja et al. (2007)	3 days & 7 days	1 month
Campos-Rodriguez et al. (2019)	1 month	57.6 months
Naik et al. (2019)	3 months	1 year
Somiah et al. (2012)	2 weeks	2 months
Turnbull et al. (2016)	2-4 weeks	6 months
Weaver et al. (1997)	1 week	9 weeks
Average time (days)	27.83	404.33

Richards, Bartlett, Wong, Malouff, & Grunstein, 2007; Sedkaoui et al., 2015; Sparrow, Aloia, Demolles, & Gottlieb, 2010). Standard treatment in the four RCTs consisted of familiarizing participants with both the CPAP equipment and procedures to follow at bedtime (Bakker et al., 2016; Richards et al., 2007; Sedkaoui et al., 2015; Sparrow et al., 2010). Bakker et al. (2016) evaluated a behavioral intervention called motivational enhancement (ME) to see if its use would improve adherence to CPAP. Of the 83 participants, 41 received the ME intervention during two separate psychologist appointments and six phone calls over an eight-month period (Bakker et al., 2016). The researchers discovered that those receiving standard treatment plus ME significantly improved their adherence to CPAP ($P = .003$). Richards et al. (2007) used a group setting to deliver the CBT intervention and showed that CBT led to increased adherence at 1 month with a large effect size of $d = 1.09$ (Stepnowsky, Zamora, Edwards, Liu, & Agha, 2013). Sedkaoui et al. (2015) used a telephone-based communication to deliver five counselling sessions over 90 days. Of the 379 participants in the study, the 188 in the experimental group had a statistically significant higher adherence rate as compared to the control group at four months ($\chi^2 = 3.97$) (Sedkaoui et al., 2015). Sparrow et al. (2010) also utilized a telephone-based communications system to provide the CBT intervention and determined that CBT increased CPAP use 2 hours per night higher at 12 months as compared to standard treatment and a statistically significant impact on CPAP adherence ($p = .006$). In a systematic review, Wozniak, Lasserson, and Smith (2014) analyzed six studies that totaled 584 participants in all and noted that those participants in the behavioral intervention groups used CPAP 1.71 hours per night mean difference more than those in the control groups (test for overall effect $Z = 2.79$ ($P = .0053$)).

There were noteworthy differences in determining how CPAP adherence was measured in the three RCTs and the systematic review (Richards et al., 2007; Sedkaoui et al., 2015; Sparrow et al., 2010; Wozniak et al., 2014) which made evaluation of the studies more difficult. According to Sawyer et al. (2011), a commonly accepted benchmark of CPAP adherence has been to use four hours per night on 70% of nights but this standard was used in only one of the three RCTs (Sedkaoui et al., 2015). Richards et al. (2007) measured mask-on time at 28 days to determine the mean hours of CPAP therapy. Sparrow et al. (2010) simply used > 4 hours per night of CPAP usage to determine CPAP adherence without providing how many nights per week were needed. Finally, Wozniak et al. (2014) measured CPAP machine usage, either machine-on time or mask-on time but no other information.

While these studies showed that CBT improved CPAP adherence, the definition of adherence among the studies was variable and most did not follow the established guidelines of > 4 hours for 70% of nights during a consecutive 30-day period as set by the CMS (2013). To provide a more accepted definition of CPAP adherence, this present study set the threshold for CPAP adherence as ≥ 4 hours per night on 70% of nights as set by CMS (2013). It does need to be clarified that according to the American Thoracic Society [ATS] (Schwab et al., 2013), setting CPAP adherence at ≥ 4 hours/night for 70% of nights during a consecutive 30-day period was arbitrarily assigned by CMS and that this “criteria assume that CPAP treatment has a threshold effect and therefore and do not address whether outcomes may have a linear response with much lower levels of CPAP use” (p. 617). However, despite this statement by the ATS, they have also established that patients are considered adherent if they use their CPAP for ≥ 4 hours per night (Schwab et al., 2013). For the purposes of this current study, CPAP adherence was operationalized as using CPAP for ≥ 4 hours per night for 70% of nights.

Cognitive behavioral therapy has shown to be effective improving CPAP adherence and usage and decreasing CPAP discontinuation in group settings (Richards et al., 2007), by using telephone-based counselling sessions (Sedkaoui et al., 2015) as well as automated phone calls (Sparrow et al., 2010). However, CBT requires a trained therapist to administer the interventions making it costly, time intensive, and labor intensive. Even in the Sedkaoui et al. (2015) and Sparrow et al. (2010) studies, a significant amount of time was required for participants to interact with the counsellor or to answer the automated prompts that would aid in selecting the appropriate intervention message to be played over the phone.

The telephone continues to be an integral part in the life most individuals in the United States and other industrialized nations even as we have become more mobile. Cell phones and electronic messaging have also increased in the healthcare sector as a means of reducing the number of expensive office visits and nurse home visits. As a result, attempts to improve adherence have found their way to the telephone in different areas including contraception use (C. Smith, Gold, Ngo, Sumpter, & Free, 2015), smoking cessation (Whittaker, McRobbie, Bullen, Rodgers, & Gu, 2016), secondary prevention of coronary heart disease (Chen et al., 2016), as well as CPAP adherence (Fox et al., 2012; Sparrow et al., 2010; Taylor, Eliasson, Andrada, Kristo, & Howard, 2006; Woehrle et al., 2017). Four studies that include three RCTs and one matched cohort, prospective study from 2006 until the present were included in the literature review that evaluated TBIs designed to improve CPAP adherence in OSA (Fox et al., 2012; Sparrow et al., 2010; Taylor et al., 2006; Woehrle et al., 2017).

The most prevalent theme noted in this portion of the literature review was that both CPAP adherence and CPAP therapy termination improved as a result of TBI when compared to standard treatment (Fox et al., 2012; Sparrow et al., 2010; Woehrle et al., 2017). Two of the three

RCTs demonstrated that TBI was successful in improving CPAP adherence in participants with OSA when compared to standard treatment (Fox et al., 2012; Sparrow et al., 2010). Standard treatment in the two RCTs was similar to standard treatment in the CBT interventions (sleep lab familiarized participants with both the CPAP equipment, procedures to follow at bedtime and help with troubleshooting equipment issues) (Fox et al., 2012; Sparrow et al., 2010). The matched cohort, prospective study by Woehrle et al. (2017) did not actually measure CPAP adherence but did show that TBI improved the long-term PAP therapy termination rate when compared to standard treatment. The decision not to measure specific usage data in the standard treatment group is a limitation in the study by Woehrle et al. (2017). Standard treatment in the trial performed by Woehrle et al. (2017) varied by insurance but included being told to contact their primary care provider or the sleep lab with any issues and PSG after six months or as necessary to evaluate CPAP effectiveness. However, the RCT conducted by Taylor et al. (2006) did not show improved CPAP usage, functional status, or client satisfaction as compared to standard treatment. Standard treatment in the Taylor et al. (2006) study allowed the participants to access the care provider over the telephone or by doing walk-in visits in addition to a scheduled visit at one month. The evidence that TBI is more effective than standard treatment is contradictory and therefore it is important that CPAP adherence intervention studies compare the intervention to standard treatment (See Table 1, Row 5).

There is evidence that telephone intervention increases adherence but the studies to date demonstrated several drawbacks to TBI. For instance, one study showed a significant increase in labor resources where an additional 67 minutes of staff time was spent on participants in the telemedicine arm compared with the standard treatment arm ($p = .0001$) (Fox et al., 2012). In the Taylor et al. (2006) study, the authors noted that it was often difficult to reach participants once

CPAP related problems were identified. The authors also observed that conversations were sometimes delayed for several days when the participant and the provider were not able to connect by telephone (Taylor et al., 2006).

According to the Pew Research Center (2018a), 95% of Americans own some type of cellphone including 99% of adults 30-49 year of age and 97% of Americans 50-64 years of age. The Cellular Telecommunications and Internet Association is a trade organization that represents the cellular communications industry in the United States. The organization estimated that 1.9 trillion text messages were exchanged in the United States in 2015 (Cellular Telecommunications and Internet Association, 2016). These statistics demonstrate the extent to which cellphones and text messages are now an integral part of our daily lives. Text messaging has become an efficient and accepted means of communication including being used for healthcare purposes. In a study published in Journal of the American Medical Association, Chow, Redfern, Hillis, and et al. (2015) sent four text messages per week for four weeks to an intervention group in order to modify cardiovascular risk factors. The authors reported that most participants found the text messages to be useful (91%), easy to understand (97%), and appropriate in frequency (86%) (Chow et al., 2015). This integration and acceptance of text messaging into our daily lives can be leveraged into improving adherence to clinical treatments such as CPAP device usage.

Five RCTs utilizing TMBI were included in this literature review that were either designed to improve medication adherence (Chow et al., 2015; Khonsari et al., 2015; Wald, Bestwick, Raiman, Brendell, & Wald, 2014) or to improve CPAP adherence (Hwang et al., 2018; Munafo et al., 2016). A separate Cochrane review was also included that evaluated the effects TMBI on adherence to hypertension medications, adherence to peak expiratory flow in patients

with asthma, and adherence to diabetes treatment across multiple studies (de Jongh, Gurol-Urganci, Vodopivec-Jamsek, Car, & Atun, 2012). Two clear themes emerged as a result of the literature review including TMBIs are shown to improve adherence in a variety of chronic diseases, but they do not have the capability to assess reasons for nonadherence.

The three RCTs that evaluated cardiovascular medication adherence and the Cochrane Review study all demonstrated a statistically significant improvement in outcomes when an intervention group receiving TMBI was compared to a control group (Chow et al., 2015; de Jongh et al., 2012; Khonsari et al., 2015; Wald et al., 2014). Chow et al. (2015) enrolled 710 patients in their study and randomized the participants to either a TMBI group that received four automated text messages each week for 6 months or a control group that received standard treatment (unspecified). The primary outcome was LDL levels at six months and secondary outcomes measured included smoking status, systolic blood pressure, BMI, and physical activity (Chow et al., 2015). The study showed a statistically significant lower LDL levels in the intervention group when compared to the control group ($p = .04$) as well as improvements in smoking status (relative risk [RR] = 1.33), physical activity (RR = 2.39), and blood pressure (RR = 1.44) (Chow et al., 2015). The authors concluded the study showed a modest effect size, but no actual value was documented (Chow et al., 2015). Limitations of the study included recruiting participants from only one hospital thereby limiting generalizability and the inability to completely blind the trial. Other limitations included the inability of automated text messages to determine reasons for nonadherence so that appropriate advice could be provided and the absence of a sham text message in the control group which would help to lessen the impact of any unidentified bias (See Table 1, Row 6).

de Jongh et al. (2012) conducted a meta-analysis of four moderate quality RCTs with a total of 182 participants to determine the impact of TMBI to facilitate self-management of chronic diseases. Three of the four studies specifically looked at the effect of TMBI on medication adherence in hypertension, asthma, and diabetes mellitus and included 142 participants (de Jongh et al., 2012). The authors determined that the medication adherence of participants that received text messages in the hypertension study was higher by a statistically significant amount ($p = .045$) with a RR = 0.73 that a participant's blood pressure was not under control as compared to the control group (de Jongh et al., 2012). However, there were no statistically significant differences in adherence in either the diabetes adherence study ($p = 0.63$) or the asthma study ($p = 0.16$) (de Jongh et al., 2012). Effect sizes were documented in terms of mean difference (MD) including hypertension adherence at 6 months (MD = 8.90), adherence with peak expiratory flow measurement in patients with asthma (MD = 4.90), and diabetes medication adherence using a visual analog scale (MD = 6.80) (de Jongh et al., 2012). Limitations of this study included the overall small number of participants used to analyze the data which limited the quality of the evidence. Another limitation was the inability of automated text messages to determine reasons for nonadherence so that appropriate advice could be provided. (See Table 1, Row 7).

Khonsari et al. (2015) investigated using TMBI to improve medication adherence in those patients discharged from a hospital following acute coronary syndrome (ACS) with the primary outcome being medication adherence and secondary outcomes being heart functional status, ACS-related hospital readmissions, and death. The researchers consented 62 participants to either a control group that received standard treatment or an intervention group that received text messages every time a cardiac medication was scheduled to be taken (Khonsari et al., 2015).

The authors found that there was a statistically significant higher medication adherence level in the intervention group as compared to the control group ($p < .001$) with a RR = 4.09 that favored the intervention group and that heart functional status (as measured by using the New York Heart Association (NYHA) functional classification) was higher in the intervention group ($p < .01$) (Khonsari et al., 2015). However, there was no statistically significant difference between the two groups regarding hospital readmissions ($p = .056$) or death (p = .246) (Khonsari et al., 2015). Effect size for the study was reported in terms of Cramer's Phi ($\varphi = 0.548$) and relative risk of being *low adherent* in the control group was 4.09 times that of the intervention group (Khonsari et al., 2015). Limitations of the study included having a small sample size, recruiting from only one center, and obtaining medication adherence from a self-report using a questionnaire. Another limitation included determining heart functional status using NYHA functional classification which is based on a patient's symptoms rather than an objective measure of heart functional status. Other limitations included the inability of automated text messages to determine reasons for nonadherence so that appropriate advice could be provided and, the absence of a sham text message in the control group.

Finally, Wald et al. (2014) evaluated using TMBI to improve medication adherence to blood pressure and lipid-lowering medications. The researchers utilized a novel approach to recruit participants by using an electronic database of patients to text 6,884 patients across seven primary care practices who were on both a blood pressure and lipid-lowering medication and also had a cellphone number (Wald et al., 2014). From this group and from another 120 patients asked to participate while at one of the primary care practices, 303 participants were consented to take part in the study (Wald et al., 2014). Participants were randomly assigned to being sent text messages to remind them to take their medicines or a control group who received standard

treatment but did not receive text messages. Using an automated computer program, those participants receiving text messages were sent one text message daily for two weeks, then every other day for two weeks, and finally, one weekly text message for 22 weeks (Wald et al., 2014). Participants were randomly assigned to receive text message reminders to take medications or to a control group who received standard treatment and no text messages (Wald et al., 2014). Adherence was determined to be medication use exceeding 80% of prescribed regimen and, based on this threshold, those participants receiving text messages had a statistically significant higher likelihood of being adherent when compared to the group that received no text messages ($p < .001$) (Wald et al., 2014). Limitations including using a recruiting technique that likely biased the sample towards engaged participants more likely to adhere and there was no objective outcome measured such as blood pressure or cholesterol levels. Other limitations included the inability of automated text messages to determine reasons for nonadherence so that appropriate advice could be provided and the absence of a sham text message in the control group.

Only two studies were identified that evaluated the effects of TMBI on adherence to CPAP therapy (Hwang et al., 2018; Munafo et al., 2016). Hwang et al. (2018) used a four-arm, randomized, factorial design clinical trial to evaluate the effectiveness of telemedicine-based education and feedback messaging on CPAP adherence in 1,455 participants. The first of the two interventions developed for the study was a web-based education (WBE) that discussed the negative effects of OSA as well as teaching how to use the CPAP machine and explaining the benefits of CPAP (Hwang et al., 2018). The second intervention was a TMBI and involved sending one of three generic text messages to the participants based on provider-defined CPAP usage thresholds (Hwang et al., 2018). CPAP adherence was statistically significantly higher

than standard treatment in both the TMBI only and the TMBI+WBE arms but not the WBE only arm (Hwang et al., 2018).

Munafo et al. (2016) followed 122 CPAP naïve participants at two centers and randomized them into a TMBI group or a control group that received standard treatment. Participants in both groups received a one-hour education session with a respiratory therapist about the pathophysiology of OSA, proper use and care of the CPAP device and mask, and the potential benefits of CPAP therapy (Munafo et al., 2016). Participants in both groups also received telephone follow up calls from registered sleep technicians (Munafo et al., 2016). Participants in the control group received standard treatment consisting of phone calls on day 1, 7, 14, and 30 and other phone calls and return office visits as necessary based on CPAP usage and efficacy data (Munafo et al., 2016). The TMBI group received automated text messages or e-mails at an unspecified frequency that were generated by preset conditions such as not wearing the CPAP for two consecutive days, CPAP usage < 4 hours for three consecutive nights, and having a large air leak among other conditions (Munafo et al., 2016). Per the authors, "When usage falls, e-mail and text messages are sent to encourage patients to use CPAP more regularly." (Munafo et al., 2016, p. 2) and emails were also sent to the participant's healthcare provider concurrently. The study did not demonstrate a statistically significant difference in CPAP adherence between the TMBI group and the standard treatment group where CPAP adherence was defined as > 4 hours of CPAP usage each night for 70% of nights over 30 consecutive days any time within the first 90 days of CPAP therapy initiation ($p = 0.17$) or daily usage for any length of time ($p = 0.24$).

In summary, the use of TMBI to improve adherence has shown success in improving medication adherence (Chow et al., 2015; de Jongh et al., 2012; Khonsari et al., 2015; Wald et

al., 2014) and has shown success in one CPAP adherence trial (Hwang et al., 2018) but not others (Munafo et al., 2016). However, the body of work evaluating TMBI in CPAP adherence is currently limited in amount, often has small sample sizes, and does not discuss the use of a theoretical framework to design the content of the text messages.

This current pilot study was intended to evaluate the feasibility of designing a research trial that will more reliably determine if TMBI is an effective intervention in influencing CPAP adherence. Design improvements included text messages based on a theoretical framework and tailored to individual participants in the intervention group based on their adherence or nonadherence to CPAP therapy including information on how to get technical support. This study also used generalized text messages in the control group.

Theoretical Frameworks

Creswell (2009) defines a theory as "an interrelated set of constructs (variables) formed into propositions, or hypotheses, that specify the relationship among variables (typically in terms of magnitude or direction)" (p.51). By understanding how and why an independent variable can be used to influence or predict a dependent variable, theory can be used to further knowledge or develop interventions in a particular field of study. In their review of health behavior interventions that were delivered using mobile technologies, Riley et al. (2011) describes the value in using a theory to develop an appropriately worded text message. In their analysis, it was observed that text messages developed without using a theoretical framework were relatively direct, consistent with the *cue to action* component of multiple behavior theories (Riley et al., 2011). This direct approach does not take into account the assumptions of many behavioral

theories that behavior change is not straightforward but rather a complex action that has multiple variables (Riley et al., 2011).

In this current study, the researcher hopes to modify actual behavior, therefore, it is appropriate to use a psychological theory in designing the study as it is the science of mind and behavior. Three psychology-based theories were evaluated in designing this study and they include the health belief model, protection motivation theory, and the TPB. In the following sections, several different factors were considered including the theoretical assumptions of each theory, the measures, if any, tied to the particular theory, how the theory fits with the planned intervention, and the limitations of each theory.

In the 1950s, the United States Public Health Service developed the health belief model (HBM) (see Figure 2) with the goal of increasing the use of preventive services such as immunizations screening for tuberculosis (Hochbaum, Rosenstock, & Kegels, 1952). The psychologists theorized that taking an action involved an individual performing an internal assessment to determine the benefit of taking action or not taking action (Champion & Skinner, 2008). The HBM identifies four concepts that influence the internal assessment: perceived susceptibility of the illness, perceived severity of the illness, and perceived barriers to taking action (Champion & Skinner, 2008). Self-efficacy was later added to the HBM in an attempt to better explain individual differences in health behaviors (Champion & Skinner, 2008). Modifying factors in the HBM include demographic, psychosocial, and structural variables that may indirectly influence health-related behavior (Champion & Skinner, 2008). Other modifying factors are cues that are thought to trigger an action but no cues to action have been systematically studied (Champion & Skinner, 2008). For years, cognitive theorists have assumed that behavior is “a function of the subjective value of an outcome and the subjective expectation

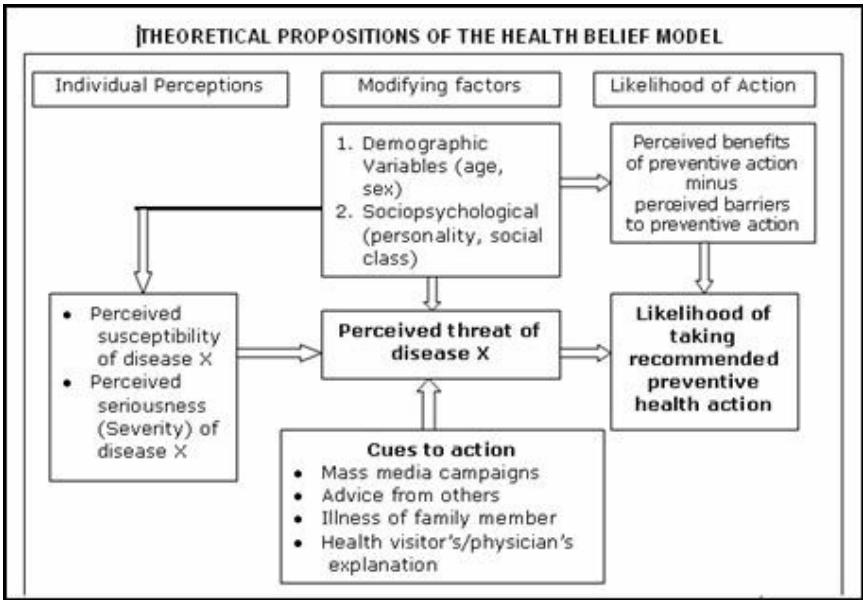


Figure 2. Health belief model

that a particular action will achieve that outcome" (Champion & Skinner, 2008, p. 46). When these concepts were placed in the context of health-related behavior within the HBM, the assumptions became individuals: 1) value avoiding illness and, 2) expect that a specific health action will prevent or reduce the severity of illness (Champion & Skinner, 2008).

There are several limitations to the utility of the HBM in predicting health-related behaviors. Limitations including the low predictive capacity (average of $R^2 < 0.21$) of the variables in the HBM, the small effect size of the individual variables, and the lack clear relationships between the individual variables led Orji, Vassileva, and Mandryk (2012) to extend the HBM to address these limitations. Further, the HBM fails to account for the attitudes, beliefs, or emotions and their influence on behavior. Other limitations include the assumption that everyone has the same access to information on the illness and non-consideration of social pressures and other non-health related reasons for performing a health-related behavior.

Protection motivation theory (PMT) (see Figure 3) developed by Rogers (1983) proposes that intention to protect oneself is the primary determinant of health behavior that is organized into two mediating concepts named coping appraisal and threat appraisal. Whether to implement or maintain a recommended protective health behavior is determined by the coping appraisal (Rogers & Prentice-Dunn, 1997). The intention to stop or avoid a negative health behavior is determined by the threat appraisal (Rogers & Prentice-Dunn, 1997). The major assumptions of PMT state that motivation must first be established to initiate the coping process in a positive linear function consisting of four values: 1) there is a perception of a severe threat, 2) the person perceives they vulnerable to the threat, 3) the capability to cope with the threat is available and efficacious, and 4) the individual's perceived ability to begin and be successful with the recommended protective behavior (Rogers, 1983). According to (Rogers, 1975), "fear may also

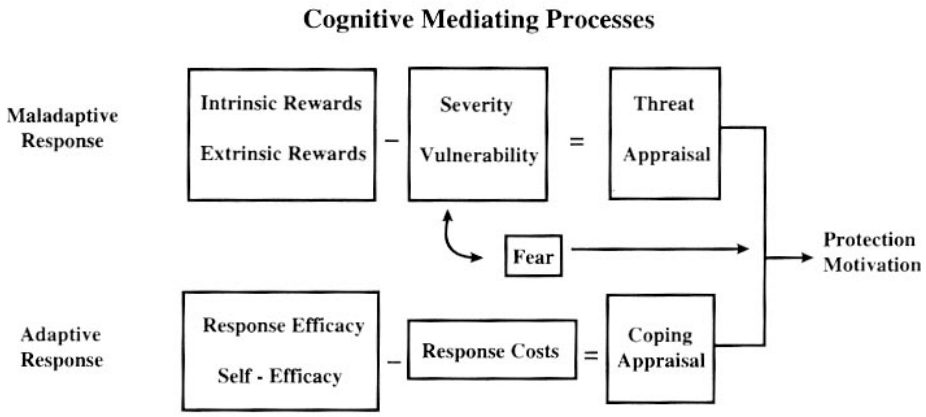


Figure 2. Cognitive mediating processes of protection motivation theory.

Figure 3. Protection motivation theory

be considered a relational construct, aroused in response to a situation that is judged as dangerous and toward which protective action is taken" (p. 96). In PMT, fear plays an indirect role in the threat appraisal by affecting the perceived severity of the danger.

Limitations to PMT include its linear design that does not readily allow for ongoing feedback as intention results in behavior that may improve the perception of self-efficacy. Another limitation is the homogenous effects of the variables that influence threat appraisal and coping appraisal. Depending on the nature of the threat and available coping resources, variables will have different levels of influences. One suggestion to minimize the homogeneity and linearity of PMT is to integrate PMT with the transtheoretical model (Block & Keller, 1998). The integration of two complementary yet separate theoretical models would add undue complications in designing a study to evaluate CPAP adherence and therefore will not be applied in designing this study.

The TPB (see Figure 1), was developed by Icek Ajzen (Ajzen, 1985, 1991, 2002b, 2019) and is an extension of the theory of reasoned action (Fishbein & Ajzen, 1977). The theory was developed to predict behavior under incomplete volitional control and to understand the behavior's psychological determinants (Ajzen, 1991). Ajzen (1991) postulated that actual behavior is determined by an individual's intention to perform the behavior. Intention, in turn, is driven by three diverse beliefs: behavioral beliefs, normative beliefs, and control beliefs (Ajzen, 1991). Behavioral beliefs are those beliefs about the probable outcomes that, in turn, create a positive or negative *attitude towards the behavior* (Ajzen, 1991). Normative beliefs are those beliefs about the expectations of those in society that result in peer pressure termed as *subjective norm* (Ajzen, 1991). Finally, control beliefs are those beliefs that directly influence an individual's *perceived behavioral control* by shaping the perception of how confident the

individual will be in performing the desired behavior (Ajzen, 1991). The TPB proposes that the intention to perform a certain behavior is more likely when there is a more positive attitude toward the behavior and subjective norm, as well as a greater perceived behavioral control.

Another assumption of TPB is that "to the extent that perceived behavioral control is veridical, it can serve as a proxy for actual control and contribute to the prediction of the behavior in question" (Ajzen, 2019, p. 1). The TPB also assumes that a concept known as actual behavioral control describes the extent to which the actual skills, resources, and opportunities needed to perform the behavior are available to a person (Ajzen, 1987). If there are sufficient skills, resources, and opportunities available then a person may carry out a behavior independent of their intention (Ajzen, 1991). Another supposition is that all behavior is not under volitional control so the intention to *try* to perform a particular behavior does not always equate to carrying out the behavior (Ajzen, 1985). Incomplete volitional control can result from both internal and external factors. Internal factors that may limit volitional control includes an individual's reduced confidence to carry out the desired behavior (perceived behavioral control), lack of required information or skills, lack of will power, and negative emotional experiences (Ajzen, 1985). External factors that adversely incomplete volitional control include lack of time and opportunity to perform the behavior and dependence on others (Ajzen, 1985).

One limitation of the TPB is the assumption that an individual will act rationally while a second limitation is the inability to account for the impact of emotions or established beliefs on the behavior (Munro, Lewin, Swart, & Volmink, 2007). Another limitation of the TPB is its limited predictive validity which is affected by the time between the measurement of intention and the observation of the behavior, during which intervening events can alter an individual's behavioral, normative, or control beliefs and feasibly modify intentions (Ajzen, 2011).

The decision to use the TPB to frame this study was based on several factors. Factors included the results of three meta-analyses (Armitage & Conner, 2001; McEachan, Conner, Taylor, & Lawton, 2011; Rich, Brandes, Mullan, & Hagger, 2015) and one systematic integrative literature review (Ward, Hoare, & Gott, 2014). Attitudes and social support were found to be predictive factors of CPAP adherence – these are concepts in the TPB that influence the actual behavior of using or not using CPAP therapy (Ward et al., 2014). The meta-analyses (Armitage & Conner, 2001; McEachan et al., 2011; Rich et al., 2015) examined the effectiveness of the TPB in explaining the variance in behavior and intention. Depending on the construct being evaluated, the variance accounted for by the TPB ranged from 9% (behavior in treatment adherence) to 44% (intention in health behaviors) (McEachan et al., 2011; Rich et al., 2015). The three meta-analyses (Armitage & Conner, 2001; McEachan et al., 2011; Rich et al., 2015) found that effect sizes between the TPB concepts and health behaviors, including adherence, were typically small to medium. Rich et al. (2015) noted that the TPB effect sizes "show the theory of planned behavior compares favorably when considering meta-analyses of social-cognitive models that have been applied to adherence, such as the health belief model and common-sense model" (p. 683).

Practically, another influential reason to use the TPB to design the study was clearly defined causal relationships hypothesized among the theory's concepts. This clarity allows the TPB to be a useful framework for designing interventions that target key behavioral, normative, and control beliefs. If the interventions are effective, they can affect attitudes, subjective norms, and perceived behavioral control to produce changes in intentions and, therefore, actual behaviors.

The final aspect of the TPB that influenced the decision was the wide-ranging impact that the TPB has had on the study of human social behavior. In a review of Google Scholar citations, it was noted that Ajzen's seminal work (1991) has been cited over 64,000 times as of February 2019 (Google Scholar, 2019) and considered "as having the highest scientific impact score among US and Canadian psychologists" (Ajzen, 2011, p. 1113).

Chapter Summary

This literature review assessed the published research regarding the methods to measure CPAP adherence, barriers to CPAP adherence, interventions to improve CPAP adherence, as well theoretical frameworks that would be appropriate in framing a study design to evaluate interventions to improve CPAP adherence. It was determined that the most reliable and quantitative measure of CPAP adherence was mask-on time as measured by the CPAP device. Barriers to CPAP adherence included human-device interface issues such as poor mask fit, air leaks, and nasal congestion. Psychosocial factors that may act as barriers to CPAP adherence included anxiety using the CPAP machine, claustrophobia, depression and poor social support.

Multiple themes regarding interventions to improve CPAP adherence became evident during the review of the available literature. One theme noted was the discrepancy in the definition of CPAP adherence and, based on the most common definition, this study used CMS criteria. Another clear theme was that CBT interventions are effective, but it was found they were costly, time intensive, and labor intensive. The literature review also found that both CPAP adherence and CPAP therapy termination improved as a result of TBI when compared to standard treatment.

Emerging themes regarding TMBI included the consensus that TMBI improves adherence in a variety of chronic diseases, including OSA, but that it does not have the capability to assess the reasons for nonadherence. The four studies reviewed that used TMBIs to influence CPAP adherence lacked details including any mention of a theoretical framework, as well as any specific descriptions of the content in the text messages. Besides not finding any studies that used theoretical frameworks in TMBIs, other gaps in the literature included the absence of trials that compared an experimental group receiving a TMBI to a control group receiving sham text messages to reduce unexpected biases. Also, no studies were found where text messages influenced by the TPB were sent to participants based on their adherence or nonadherence to CPAP therapy over a given period of time. Research in these areas will add to the body of knowledge in caring for patients with OSA.

Chapter 3: Methods

The purpose of this prospective, randomized controlled pilot study was to examine the effects of a four-week long TMBI on an individual's CPAP device adherence, OSA symptom management and outcome expectations of using CPAP therapy when compared to participants receiving generic text-based messages. This chapter contains a synopsis of the study design, procedures for the text-based message intervention, sampling and recruitment of participants, risks and protection of study participants, data collection and analysis methods, and threats to validity.

Study Design

This research study applied a quantitative, true-experimental design. A pilot study is not normally used to test hypotheses or determine effect sizes (Leon, Davis, & Kraemer, 2011). However, for this doctoral dissertation study, hypotheses were tested, and effect sizes were determined in this pilot study. A pilot study was also conducted because the intervention to be utilized and examined is a novel approach and its feasibility unknown. It is this student's plan to continue this line of research after graduation and the lessons learned will prove useful in designing larger studies. Because a pilot study is meant to "test the performance characteristics and capabilities of study designs, measures, procedures, recruitment criteria, and operational strategies" (Moore, Carter, Nietert, & Stewart, 2011, p. 332), the experience gathered will be valuable. Another rationale for doing a pilot study was the scarcity of studies whose objective was to utilize text messages to improve adherence to CPAP therapy in patients with OSA. The literature review completed included two RCTs that evaluated CPAP adherence (Hwang et al., 2018; Munafo et al., 2016). The study by Munafo et al. (2016) did not demonstrate a statistically

significant difference in CPAP adherence between the text-based message experimental group and the standard treatment group. The authors concluded that a high dropout rate of 15% may have affected the ability to detect differences in CPAP adherence (Munafo et al., 2016). Hwang et al. (2018) demonstrated that CPAP adherence using text-message based interventions and text-message based interventions in combination with web-based education interventions was statistically significantly higher than standard treatment.

In this pilot study, in addition to standard treatment, participants were randomized to an EG or to a CG. The EG received one motivational text message every week for four weeks based on concepts derived from the TPB. The CG received one text message every week for four weeks with objective information consisting of average use in hours per week only. Although standard treatment for patients being prescribed CPAP therapy may vary slightly from one sleep center to another, the following list describes the consistent care following the diagnosis of sleep apnea:

1. Patients suspected to be at risk for sleep apnea are evaluated by board certified sleep specialists. During this consultation, the sleep medicine physician reviews the pathophysiology of sleep apnea and describes its impact on sleep quality, daytime alertness, and long-term health consequences of untreated sleep apnea. The physician describes treatment options that include CPAP, mandibular advancement device, surgery, and weight loss. While advantages and disadvantages of each treatment modality are discussed, CPAP therapy is emphasized as the most effective treatment.
2. The patient then undergoes a sleep study that includes PSG. Once OSA is diagnosed, the sleep physician recommends CPAP therapy, if appropriate, considering the patient's

preferences. The physician chooses appropriate pressure settings and orders the equipment through a DME.

3. The DME provides the patient with a CPAP device, necessary supplies and a DME respiratory technician ensures proper mask type and mask fit based on participant's needs and preferences. The DME technician also confirms the equipment and data links are working properly.
4. Before initiating CPAP therapy, additional education is provided to patients starting CPAP therapy. Nurses at the sleep clinic deliver the information that includes instructions related to CPAP operation, maintenance, and common troubleshooting tips such as improving CPAP mask fit, CPAP machine cleaning, and CPAP machine settings.
5. The patient is then advised to contact the DME or the sleep clinic with all problems related to CPAP therapy.
6. The DME customarily follows up with the patient in one to two weeks and sends a CPAP adherence report which contains usage data collected by the CPAP device to the sleep clinic. The follow up with the patient does not always occur due to DME or patient factors.
7. When issues are noted on the adherence report such as inadequate control of apnea or large mask leaks, the DME tech or sleep clinic will contact the patient and provide technical and troubleshooting support.
8. Patients follow up with the sleep clinic approximately three months after starting CPAP therapy and further technical and troubleshooting support is provided at that time.

Aims and Hypotheses

The specific aims of this pilot study were to examine the effect of one text message sent every week over a four-week period on: a) CPAP device adherence, b) OSA symptom management and outcome expectations of using CPAP therapy. The hypotheses tested in this pilot study were: 1) after four weeks of receiving one text message per week, the total mask-on time will differ between the experimental group and the control group; 2) after four weeks of receiving one text message per week, the proportion of persons classified as adherent will differ between the experimental group and the control group; and 3) after four weeks of receiving one text message per week, changes in the ABS, ESS, and FOSQ-10 will differ between the experimental group and the control group.

Variables

The independent variable was the motivational text messages developed using TPB and the control text messages that were sent one time per week for four weeks. The dependent variables included total mask-on time and CPAP adherence rates that were measured objectively by the CPAP device. CPAP adherence was defined as having at least four hours of mask-on time on 70% of nights (20 nights) over four weeks. Other dependent variables included aspects of symptom management such as excessive daytime sleepiness as measured by ESS and the impact of sleepiness on the ability to conduct daily activities as measured by FOSQ-10 (Chasens, Ratcliffe, & Weaver, 2009; Johns, 1991). The final dependent variable measured was outcome expectations as measured by ABS (Smith, Lang, Sullivan, & Warren, 2004).

Study Sample

Owing to the lack of information in the literature on effect size, in this pilot study, participants were serially recruited for five months from the Vanderbilt Sleep Clinic that is responsible for two separate sleep centers in middle Tennessee associated with Vanderbilt University Medical Center (VUMC). Study participants were English speaking adults, 18 years of age or older, newly diagnosed with OSA at one of the two VUMC Sleep Centers and CPAP naïve.

Study Setting

All study participants were recruited from the Vanderbilt Sleep Clinic where professional staff oversee and conduct diagnostic sleep studies at two sleep centers associated with VUMC. Vanderbilt University Medical Center is a non-profit, university affiliated, teaching hospital located in middle Tennessee that serves a region including southern Kentucky and northern Alabama. One VUMC Sleep Center is in Nashville, TN at the Marriot Hotel at Vanderbilt University while the second VUMC Sleep Center is in Franklin, TN at the Hyatt Place Franklin/Cool Springs. Both locations combine to provide a total of 16 hotel rooms to diagnose and treat various sleep disorders including OSA, periodic limb movement disorder, insomnia, and narcolepsy. The experimental and control text messages used were identical, regardless of the sleep center utilized.

Inclusion and Exclusion Criteria

Inclusion requirements for enrollment were that participants must: a) be at least 18 years of age or older; b) be CPAP naïve with a new diagnosis of at least mild OSA using PSG with an AHI $\geq$ 5 EPH; c) be able to read and write in English at a level sufficient to answer instruments

and to read experimental and control text messages; d) be prescribed a Respironics CPAP device or a ResMed CPAP device; e) have insurance that ensures patients will have DME confirm proper setup and verify modem or wi-fi access in home where CPAP device will be worn; f) have access to a mobile device that can send and receive text messages as well as voice communication; g) have an active e-mail address; and h) have use of a device containing a web browser for accessing the internet to enter information including electronically signing an informed consent.

Exclusion criteria included a charted diagnosis of: a) pulmonary or cardiac comorbidities which may impair oxygen exchange such as chronic obstructive pulmonary disease, asthma or decompensated heart failure; b) cognitive or physical impairments which interferes with independent operation of the CPAP device and mask or participation in the study; c) anatomical abnormalities which obstruct airflow such as nasal obstruction or enlarged tonsils or; d) any planned travel requiring overnight stays that may impact ability of participant to effectively use CPAP device.

Recruitment of Study Participants

Participants were enrolled through one of two methods:

- When an individual was diagnosed with OSA (whether using PSG or home sleep test), depending on the physician's recommendations and the patient's preferences, CPAP therapy was often prescribed. A nurse in the sleep clinic would then call the individual to arrange setup for their CPAP device through a DME selected by the individual or their insurance. During that call and when it was appropriate, the patient was also asked if they

could be contacted by the principal investigator (PI) by phone about being in a research study involving text messages.

- Individuals were sometimes seen in the Vanderbilt Sleep Clinic by a healthcare provider for various reasons after they had been diagnosed with OSA but before they started using their CPAP device. During that visit, a member of the clinic staff asked permission for the PI to contact the individual by phone about being in a research study involving text messages. Occasionally, when the clinic staff had the opportunity, the patients were sometimes given a recruitment flyer (see Appendix A) with information about the study.

After the individual agreed to be contacted by either of the two methods, a member of the sleep clinic staff then messaged the PI through eStar, the HIPAA compliant electronic health record utilized by VUMC. The PI then called the patient to determine if they met inclusion and exclusion criteria.

Once it had been determined the patient met criteria, had all their questions answered and they agreed to participate in the pilot study, participants electronically signed an informed consent form sent to them using an e-mail address they gave to the PI. See the **Ethical Considerations** section for details on use of an electronic informed consent. The planned recruitment strategy (see Figure 4) and retention during the recruitment period was based on estimated recruitment information from the sleep clinic medical director as well as the literature review of similar studies (Chow, Redfern, Hillis, & et al., 2015; Khonsari et al., 2015; Munafo et al., 2016; Pew Research Center, 2016, 2017; Upender, 2017). Participants were alternately assigned to groups with a random start (coin toss). For instance, if the coin toss indicated that the first individual who agreed to participate was assigned to the EG, then the next

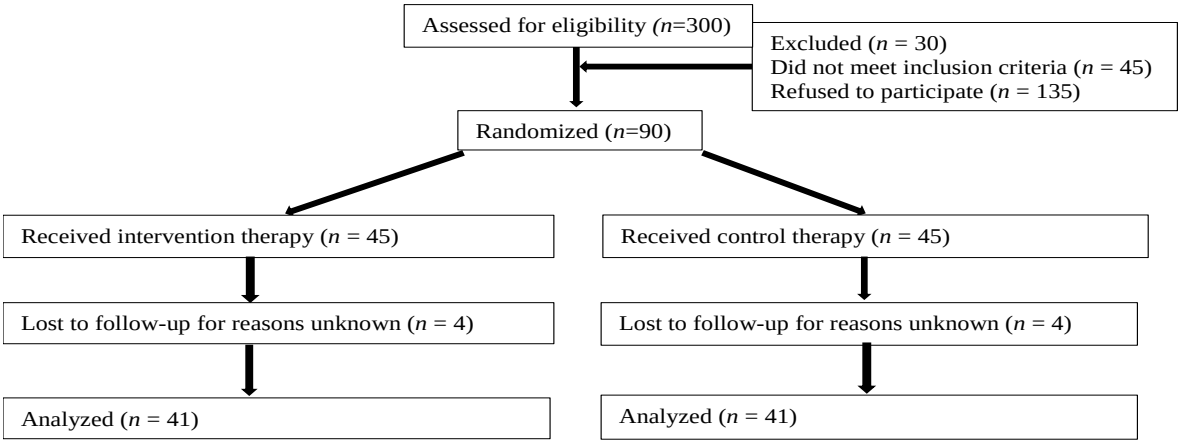


Figure 4. Planned recruitment strategy

participant was assigned to the CG, and so on. No individual was excluded based on ethnicity, gender identification, religion, sexual orientation, or socioeconomic status. Participants were notified that anyone completing all questionnaires would be entered to receive one of two $100 gift cards purchased by the PI using private funds.

Instruments

The ABS (See Appendix B) is an instrument used to measure the concepts of outcome expectations of CPAP, social support as it relates to success or failure of using CPAP, and CPAP acceptance (Smith et al., 2004). Items in the ABS are based on a literature review by the authors of the study and consultation with sleep experts (Smith et al., 2004). The ABS is a self-administered questionnaire that takes 5 to 10 minutes to complete (Shahid, Wilkinson, Marcu, & Shapiro, 2012a). The ABS has 24 statements that are:

> designed to assess: perceived impact of OSA (four items); trust in medical staff (two items); outcome expectations (four items); CPAP acceptance (two items); openness to new experiences (two items); commitment to change (four items); willingness to ask for help (two items); attitude to health (two items); and self-confidence (two items). (Smith et al., 2004, p. 361).

A five-point Likert scale is used with the answers ranging from agree to disagree. Twelve of the 24 statements are negatively worded (reverse scored) to minimize response bias (Smith et al., 2004). The ABS has no subscales and was applied as a single measure of attitudes toward CPAP adherence. Higher scores on the ABS indicate greater positive attitudes regarding CPAP adherence (Smith et al., 2004).

According to Smith et al. (2004), the ABS readability analysis suggests that the ABS can

be answered by individuals with sixth grade reading skills. Internal consistency of the ABS was calculated using Cronbach's α that demonstrated modest consistency with α = 0.75 (Smith et al., 2004). To examine ABS validity, an independent samples *t*-test was used that compared adults diagnosed with OSA who were willing to start CPAP and healthy adults with no diagnosis of a sleep disorder (Smith et al., 2004). Smith et al. (2004) rationalized that those individuals needing CPAP therapy would have a more positive attitude regarding CPAP usage than healthy individuals. The *t*-test results did show a significant difference between ABS scores ($p < .01$) with higher scores present in those individuals with a diagnosis of OSA (Smith et al., 2004). E-mail approval to use the ABS is Appendix C.

The ESS (See Appendix D) is a sleep instrument designed to measure sleep propensity that is influenced by the construct *excessive daytime sleepiness* where the construct was "derived from observation about the nature and occurrence of daytime sleepiness and sleepiness" (Johns, 1991, p. 541). The ESS is a self-administered questionnaire that asks about the "chance of dozing" (p. 541) during eight low stimulation scenarios including sitting and reading, watching TV, and sitting "in a car while stopped for a few minutes in the traffic" (p. 541). A higher score indicates a higher level of excessive daytime sleepiness. Conversely, an extremely low overall score of 0 may reflect a sleeping disorder such as insomnia as one question asks what the chances of dozing would be when "lying down to rest in the afternoon when circumstances permit" (p. 541). In these situations, it would be expected that even normal sleepers would answer that there would be a slight chance (scores as a 1) or moderated chance (scores as a 2) of dozing. According to (Shahid, Wilkinson, Marcu, & Shapiro, 2012b), the ESS takes two to five minutes to complete.

Validity of the ESS instrument was correlated with the MSLT. The relationship between ESS and MSLT was tested using Pearson correlation coefficients and linear regression. There was significant correlation between the 27 patients who had ESS and MSLT ($p < .001$) (Johns, 1991). However, a later, larger study of 237 patients showed that the association between ESS and MSLT was not statistically significant (Chervin & Aldrich, 1999). Within the study by Chervin and Aldrich (1999), there was a statistically significant relationship between self-rated concept *problem sleepiness* and the ESS ($p < .0001$). Strengths and weaknesses of instrument validity are not addressed in the articles by Johns (1991; 1992) but are addressed by Chervin and Aldrich (1999) and as a result Chervin and Aldrich do not recommend that the ESS be used as a surrogate for the MSLT.

Test-retest reliability used Pearson correlation and internal consistency was tested using Cronbach's α (Johns, 1992). The Pearson correlation coefficient was 0.822 ($p < .001$) and the Cronbach's α was reasonable at a 0.88 for 150 patients with various sleep disorders and 0.73 for third year medical students who were "ostensibly healthy although no attempt was made to investigate their general health or sleep habits in detail" (p. 377). Construct validity was tested using factor analysis. All eight factors loaded on one main dimension in both patients and medical students except items 6 and 8 for the medical students. These two items "sitting and talking to someone" (p. 379) and "in a car, while stopped for a few minutes in traffic" (p. 379) had very little variance as there were so few students who stated they would doze in those situations. The User Agreement to use the ESS is Appendix E.

The FOSQ-10 (See Appendix F) is a self-administered instrument used for measuring the impact of sleep on the concept *functional status* (Chasens et al., 2009). The FOSQ-10 consists of 10 questions that are used to evaluate five domains of *functional status* that includes "General

Productivity, Activity Level, Vigilance, Social Outcomes, and Intimate and Sexual Relationships" (Chasens et al., 2009, pp. 915-916). Participants answering each question on the FOSQ-10 select one response from a four-point rating scale ranging from no difficulty to extreme difficulty with a lower score indicating a higher functional status. According to Shahid, Wilkinson, Marcu, and Shapiro, 2012c, the original Functional Outcomes of Sleep Questionnaire (FOSQ-30) takes 10 to 15 minutes to administer and the FOSQ-10 takes less time than the FOSQ-30.

Before the advent of the FOSQ-10, the FOSQ-30 was considered the gold-standard for measuring the impact of sleep on functional status. The FOSQ-30 has a readability at a fifth-grade reading level and the FOSQ-10 has not modified the ten questions used (Chasens et al., 2009; Weaver et al., 1997). To evaluate internal consistency of the FOSQ-10, Chasens et al. (2009) used Cronbach's α and obtained a score of $\alpha = 0.87$. Correlations between the FOSQ-10 and the FOSQ-30 total scores 90 days post-treatment with CPAP were highly related with $r = 0.97$ (Chasens et al., 2009). To evaluate FOSQ-10 validity, individuals with OSA were compared to individuals with no sleep disorder diagnosis and scores differed significantly ($p < .0001$). A signed letter of agreement to use the FOSQ-10 is Appendix G.

Study Procedures

Authorization to have participants take part in the pilot study was contained within the informed consent (See Appendix H). The ABS, ESS, FOSQ-10, and a demographics survey (see Appendix I) were electronically completed by both the EG and the CG at baseline before they began using their CPAP device using the Research Electronic Data Capture (REDCap) data management software that will be explained in the **Data Collection** section. The participants

were also given the choice to answer the questions over the phone. In this case, the PI entered their answers electronically in REDCap. Another method of completing the consent form was for the consent form to be mailed to them and returned in a self-addressed stamped envelope provided by the PI. After four weeks using the CPAP device, the participants were sent a Uniform Resource Locator (URL) link through REDCap to again answer the ABS, ESS, and FOSQ-10. If not completed within four days, the PI called participants to request they answer the questionnaire. If still not completed after another 4 days, a text message reminder was sent to them. Finally, a last reminder was either sent via e-mail, text, or phone to the participants and they were removed from the study if they still did not complete the post-intervention questionnaires.

Continuous positive airway pressure device mask-on time measurements were downloaded on a weekly basis using the EncoreAnywhere (EA) patient data management programs or the Airview (AV) patient data management software. Both EA and AV patient data management programs are explained in the **Data Collection** section. The PI sent a text message to the participants in both groups once weekly for four weeks based on the adherence data obtained from EA or AV. The CG received text messages that reported the weekly hours of CPAP device usage. For example, “You wore your CPAP device for a total of 10 hours between 06/01/2018 and 06/07/2018.” Participants in the EG received text messages that are described in the next section. As a requirement of most insurance companies, insured patients must have technology to send data for at least the first 90 days of use to demonstrate CPAP adherence. Most insurance companies use the Centers for Medicare and Medicaid Services (2016) objective definition of CPAP adherence which is, “use of a PAP device for 4 or more hours per night on 70% of nights during a consecutive 30-day period anytime during the first 3 months of initial

use" (p. 5). The DME assisted the patient in setting up their connection and assisted to troubleshoot any issues with sending data.

Intervention

This quantitative, randomized controlled pilot study tested the effects of participation in a text-based message program on CPAP adherence rates over a four-week timeframe. According to Broström, Nilsen et al. (2010) and Shapiro and Shapiro (2010), factors that negatively impact CPAP adherence includes attitudes such as claustrophobia, a feeling of insufficient knowledge on the need for CPAP therapy, and shame admitting CPAP use to others. Practical problems with CPAP therapy include improper mask fit, waking from sleep, skin breakdown, mask leakage, noisy CPAP devices, sleep position difficulties, and nasal congestion (Broström, Nilsen et al., 2010; Shapiro & Shapiro, 2010).

Based on the above conditions, participants in the EG received text messages that were tailored to address these factors using TPB which was developed by Icek Ajzen (see Table 3) (Ajzen, 1991, 2019). The TPB is an extension of the theory of reasoned action (Fishbein & Ajzen, 1977) and is intended to demonstrate the link between beliefs, intention, and behavior (Ajzen, 1991). In TPB, actual behavior is assumed to be driven by three different beliefs: behavioral beliefs, normative beliefs, and control beliefs. Behavioral beliefs are those beliefs about the probable outcomes of the behavior that, in turn, create a positive or negative attitude towards the behavior (Ajzen, 1991). Normative beliefs are those beliefs about the expectations of those in society that result in peer pressure termed by Ajzen as subjective norm (Ajzen, 1991). Finally, control beliefs are those beliefs that an individual embrace about "the presence or absence of requisite resources and opportunities" (Ajzen, 1991, p. 196). Control beliefs directly

influence an individual's perceived behavioral control by shaping the perception of how confident the individual will be in performing the desired behavior. This perception of confidence in performing the desired behavior is known as perceived behavioral control that, according to Ajzen (1991), is "compatible with Bandura's concept of perceived self-efficacy" (p. 184). Actual behavioral control refers to the extent to which the actual skills, resources, and opportunities needed to perform the behavior are available to a person (Ajzen, 1987). If there are sufficient skills, resources, and opportunities available then a person may carry out a behavior independent of their intention (Ajzen, 1991). Intention is the summation of the motivational factors that influence a behavior and intentions and "are indications of how hard people are willing to try, or how much of an effort they are planning to exert, in order to perform a behavior" (Ajzen, 1991, p. 181).

Appropriately developed text-message based interventions (TMBI) have the potential to heighten the intention to perform a behavior by influencing behavioral beliefs, normative beliefs, and/or control beliefs. During the text-based messaging intervention, the message sender could theoretically affect behavioral beliefs by sending messages that educate the participant about the benefits of adherence. Normative beliefs could theoretically be influenced by stating and emphasizing the value of adherence in a text message. Finally, text messages sent that assist in solving human-device interface issues (e.g. air leaks or nasal congestion) can empower the participant and theoretically improve their control beliefs. Reported barriers to CPAP adherence includes mask leakage, reduced freedom, sleep issues, and claustrophobia among others (Broström, ÅRestedt et al., 2010). Therefore, text messages were developed to address the most commonly identified barriers found in the literature based on concepts derived from TPB. Text messages included the following four text messages for those who were adherent in a particular

week (See Table 3). Adherence over one week was defined as using CPAP for four hours per night for 70% of nights (5 nights). This measure of adherence over one week is separate from the measurement of CPAP adherence over four weeks which was used as the independent variable to test the Hypothesis 2. The text messages in Table 4 were sent to those participants in the EG who did not meet the adherence criteria. Participants received the weekly text messages based on their adherence or nonadherence during a particular week. For example, if a participant was adherent for weeks one and two then they received the first two weeks' adherent text messages. Then in week three, if they were nonadherent, they received the nonadherent text message for week three because this was the third week they had participated in the study. If the participant was again adherent in week four, they received the fourth adherent text message as this was the fourth week they have been in the study. There was one exception to which text message the participant would receive. For the first week they were adherent, whether it was week one, two, three, or four, they received the week 1 adherent message (see Table 3).

Data Collection

Data collected during the study included: a) demographics consisting of first and last name, mobile device number where text messages were to be received, e-mail addresses where the URL links to the instruments and electronic informed consent were to be sent, age, gender identification, sleep partner (if any), level of education, level of income, severity of OSA in terms of AHI, and type of mask to be worn; b) ABS; c) ESS; d) FOSQ-10; and e) CPAP device mask-on time as measured using the pneumotachograph located in the CPAP machine that recorded the rate of airflow during breathing. Demographic data were collected only pre-intervention. Continuous positive airway pressure data were transmitted electronically where the

Table 3

Adherent Text Messages

Week adherent	Factor affecting adherence	Theoretical Construct	Appropriate text message	Rationale for Text Message Content
1	No perceived behavioral control	Control belief	Congratulations! You have been adherent for 1 week! To stay on track, plan for problems like a poorly fitting mask. Please call your durable medical equipment (DME) company for help	To avoid technical complications that may negatively impact perceived behavioral control and may reduce adherence
2	Not valuing adherence	Normative belief	Well done! Regularly wearing your CPAP will help you be more alert and less likely to be in an accident on the job or while driving	To illustrate the value of wearing CPAP on a regular basis
3	Lack of knowledge of benefits of CPAP therapy	Behavioral belief	Way to go!! Regularly wearing your CPAP mask has been shown to reduce the risk of having diabetes and being depressed	Diabetes and depression are two significant comorbidities that can substantially impact an individual's quality of life and overall health
4	Lack of knowledge of benefits of CPAP therapy	Behavioral belief	Excellent job!! You are well on your way to lowering your blood pressure which will help to reduce your risk of heart attack and stroke	Cardiovascular disease is the leading cause of death in men and women in the United States

Table 4

Nonadherent Text Messages

Week nonadherent	Factor affecting adherence	Theoretical Construct	Appropriate text message	Rationale for text message content
1	No perceived behavioral control	Control belief	How is your mask fitting? Do you feel comfortable using the CPAP machine? Please call your durable medical equipment (DME) company for help	Technical complications can negatively impact perceived behavioral control and may reduce adherence
2	Lack of knowledge of benefits of CPAP therapy	Behavioral belief	It's important to use your CPAP at least 4 hours every night. It reduces your risk of heart attack & stroke by lowering your blood pressure	Cardiovascular disease is the leading cause of death in men and women in the United States
3	Not valuing adherence	Normative belief	Don't give up on using your CPAP. Remember CPAP's benefits. You will feel more rested and have the energy to do the things you want to do	To remind the participant the value of wearing CPAP on a regular basis
4	Lack of knowledge of benefits of CPAP therapy	Behavioral belief	Sleep apnea is KNOWN to increase the risk of getting diabetes, having a stroke, and being depressed. Please don't give up wearing your CPAP	Diabetes, stroke, and depression are significant comorbidities that can substantially impact an individual's quality of life and overall health

PI could access the information using either the EA or AV patient data management programs.

EncoreAnywhere is a HIPAA compliant web-based program developed by Philips Healthcare. The program provides a central patient data management system that collects and analyzes adherence and therapy data. The system can generate reports about the data that are accessible using a compatible internet web browser. To ensure HIPAA compliance, EA includes access security as well as the security of transmitted data. No adherence or therapy data were stored on the password-protected laptop as the data were stored on secure EA cloud servers that are also HIPAA compliant.

The second data management program is AV patient management program developed by ResMed. AirView is HIPAA compliant and provides a central patient data management system that collects and analyzes adherence and therapy data. The program can generate reports about the data that are accessible using a compatible internet web browser. No adherence or therapy data was stored on the password-protected laptop as the data was stored on secure AV cloud servers that are also HIPAA compliant and hosted in a secure data center located in the ResMed-owned facility in San Diego, California. Further security for AV was provided by password protection, role-based access and data encryption.

Participant identification numbers, rather than names, were used on all data collection instruments. The PI kept a list that matched participants with their identification numbers that were assigned sequentially; this list was kept as a data file on a password-protected laptop computer and this computer was kept in a secured location and only the PI had access to this information. Only the PI had access to the names, research data, e-mail addresses and telephone numbers of the individuals who participated. Uniform Resource Locator links to the pre-

intervention and post-intervention online surveys were sent to participants using the HIPAA compliant data management software developed by Vanderbilt University known as REDCap (Research Electronic Data Capture) (Harris et al., 2009). Study data were also collected and managed using REDCap electronic data capture tools hosted at Vanderbilt University (Harris et al., 2009). Research Electronic Data Capture is a secure, web-based application designed to support data capture for research studies, providing 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources. REDCap supports surveys in a web browser that can be easily distributed via a public or private URL (Harris et al., 2009). Data can be downloaded as: (a) a Statistical Package for the Social Sciences (SPSS); (b) CSV; (c) TXT; (d) or Excel file (Harris et al., 2009). REDCap surveys use encryption that is HIPAA compliant and requires a two-step verification process to access the data (Harris et al., 2009). No informed consent forms or questionnaire data was stored on the password-protected laptop as the data was stored on secure REDCap cloud servers that are also HIPAA compliant. The data was backed up daily to prevent loss of data.

The PI and the project statistician conducted ongoing monitoring and evaluation of the data. Survey responses were independently reviewed by the PI for completeness. Data from all instruments were downloaded directly into SPSS from REDCap using participant identification numbers on all records. Data cleaning was conducted by the PI. Any partial data from participants who did not complete the study were removed from the data used for analysis and the master data file.

Data Analysis

Data were analyzed using SPSS version 25 (2018). The following statistical methods were used for each hypothesis:

Hypothesis 1: If assumptions were met, an independent samples *t*-test was performed to test the hypothesis, “after four weeks of receiving one text message per week, the total mask-on time will differ between the experimental group and the control group.”

Hypothesis 2: If assumptions were met, a cross tabulation chi-square analysis was performed to test the hypothesis, “after four weeks of receiving one text message per week, the proportion of persons classified as adherent will differ between the experimental group and the control group.”

Hypothesis 3: If the assumptions were met, three repeated measures analysis of variance (ANOVA) calculations were performed to test the hypothesis, “after four weeks of receiving one text message per week, changes in the ABS, ESS, and FOSQ-10 will differ between the experimental group and the control group.”

A two-tailed test was used for the three non-directional hypotheses and statistical significance was set at $p \leq .05$. For the repeated measures ANOVA in Hypothesis 3, effect size and observed power was obtained. For any marginal findings, a power analysis was performed to determine how much larger the sample needs to be to detect the differences observed in the sample.

Risks and Protections

The risks of participation in this study were considered minimal. Participants were informed there was a slight psychological or emotional risk, in answering the questionnaires could make them uncomfortable. If items on the questionnaire were uncomfortable or too stressful to answer, the participant could choose not to answer those items or to withdraw from the study. Patients with OSA are comprised of potentially vulnerable populations including women and racial minorities. Thus, individuals in the prospective study samples are collectively often subject to discrimination, stigmatization, unequal legal protections, and economic disadvantage. Many individuals are under- or uninsured and belong to subpopulations with patterns of persistent health disparities. Participation in research is often perceived as risky, engendered by mistrust often related to historical negative representation or general mischaracterization in research findings and conclusions drawn. For example, some past research has perpetuated stereotypes.

The PI is a licensed advanced practice nurse in the State of Tennessee and is certified as an Adult Nurse Practitioner by the American Nurses Credentialing Center. All participants for this study were recruited from patients seen at the Vanderbilt Sleep Clinic that operates a Vanderbilt Sleep Center in Nashville, TN and another Vanderbilt Sleep Center in Franklin, TN. When possible, trained staff at the sleep clinic asked all patients newly diagnosed with OSA if they would be interested in participating in a study. If the patients were interested, the sleep clinic staff determined eligibility by basic inclusion and exclusion criteria. The staff then referred the patients to the PI who verified their eligibility and willingness to participate in the study.

Ethical Considerations

After a thorough explanation of the pilot study, time was provided for participants to ask questions regarding the study through various methods of communication including text messaging, telephone calls, or video conferencing with the PI. To ensure full disclosure, an informed consent (see Appendix H) was reviewed and electronically signed by all individuals who agreed to be in the study using REDCAP eConsent once all their questions had been answered to their satisfaction. The signed eConsent was stored on the HIPAA compliant REDCap cloud servers with access only available to the PI. A URL link was sent to the study participant, using an email address designated by the participant, at the time of enrollment that allowed the participant to access a copy of the electronically signed Informed Consent at their convenience.

REDCap eConsent is a template found in the REDCap data management software that allows an individual to review the consent information anywhere they have internet access such as their place of residence. eConsent supports the use of text, images, audio, video, and other interactive capabilities to explain the study to the prospective participant. eConsent also has the capability to allow patients to electronically "sign" their consents by typing their name, signing their name via stylus or by using their finger and the State of Tennessee (2015) gives an electronic signature the same legal effect as a manual signature.

The research protocols were reviewed by the Vanderbilt University institutional review board (IRB). The Vanderbilt University IRB reviews all prospective studies related to human subject research at both Vanderbilt University and VUMC. The IRB reviewed this pilot study to verify: (a) risks to participants were minimized; (b) the study used appropriately credentialed and

trained personnel as well as appropriate study monitoring procedures; (c) risks to participants were reasonable when compared to anticipated benefits; (d) informed consent was appropriately documented; (e) participant privacy and confidentiality of data were maintained; (f) the study used appropriate review, testing, and study debriefing procedures and; (g) the least vulnerable population possible was used in the study.

Participants were instructed that participation was voluntary and they could withdraw from the study at any time without threat of alteration in treatment or care. Health Insurance Portability and Accountability Act and the Vanderbilt Notice of Privacy Practices (see Appendix J), signed by all patients at VUMC clinics and practices, allows disclosures of protected health information for research, authorizing the initial case reviews and communication required to identify potential participants. Participants were not be excluded from the study based on ethnicity, gender identification, religion, sexual orientation, or socioeconomic status.

Threats to Validity

Threats to the study's validity included: a) maturation of participants over time in response to their adherence or nonadherence to CPAP therapy, b) participants agreed (selected) to be in the study as they were motivated to succeed and would use any available method that would promote being adherent, c) experimental mortality that occurred during the study such as serious illness, death, and no longer willing to participate in the study. To minimize the threats to validity, steps taken the PI included: a) randomization of study participants into control and experimental groups, b) selected a length of time that was intended to minimize experimental mortality such that only two participants dropped out of the study as a result of unrelated health

issues, c) selected a length of time between testing that decreased participant recall of item responses.

Chapter Summary

The purpose of this study was to examine the effects of a four-week long text-based message intervention on an individual's CPAP device adherence, OSA symptom management, and outcome expectations when compared to participants receiving control text messages. This pilot study was a quantitative, true-experimental design with an EG and a CG. The EG received one weekly motivational text message for four weeks based on concepts derived from the TPB in addition to standard treatment. All study participants were recruited at a sleep clinic that utilizes two sleep centers situated in separate geographic locations 16 miles apart. Participants who met inclusion/exclusion criteria for the study and provided informed consent were enrolled in the study. Demographic data was collected, and participants were asked to answer the ABS, ESS, and FOSQ-10 survey questionnaires pre-intervention and post-intervention. CPAP device usage was also measured, and data analyzed to look for significant differences in the EG and the CG. Risk protections, ethical considerations, and threats to validity were also discussed and a comprehensive plan of how to manage each topic was reviewed.

Chapter 4: Results

This chapter presents the research hypotheses tested and shares the study results for each hypothesis. The chapter also provides a description of the study's sample and presents the statistical methods used for data analysis. The chapter closes with a summary of the study findings.

Description of Sample

Recruitment of participants in this prospective, randomized controlled pilot study took place at the Vanderbilt Sleep Clinic in Nashville, TN and was conducted using two different methods. In the first method, when an individual underwent a sleep study and was diagnosed with OSA, a nurse from the sleep clinic would call the individual to notify them of the sleep study results and inform them they have OSA. If CPAP therapy was ordered by the sleep specialist and the patient agreed to begin therapy, the nurse would ask if they could be contacted by the researcher. In the second method, individuals diagnosed with OSA would often have sleep clinic appointments before they began CPAP therapy. During that visit, a member of the clinic staff would ask if the researcher could contact the individual and they would be offered a recruitment flyer (see Appendix A) describing the study.

Of the 135 individuals who agreed to be contacted, 73 completed the informed consent (see Appendix H). Of those, 68 individuals completed the pre-intervention questionnaires (see Appendices B, D, F, and I) and 65 were alternately assigned to either the EG (n = 33) or CG (n = 32) with a random start based on a coin flip. Of those 65 individuals, 57 received all four text messages and completed the post-intervention questionnaires. Of the 33 participants assigned to the EG, 29 completed the study. Twenty-eight out of 32 individuals in the CG completed the

study (see Figure 5). Demographic data collected included age, ethnicity, race, gender, sleep status, educational level, annual income, CPAP mask type, and AHI measured in EPH. Of the 65 participants randomized to a group, eight (4.6%) did not provide ethnicity information on the demographic form. One participant (1.5%) did not provide race information, and eight (12.3%) did not provide annual income information. Ten individuals (15.4%) did not report AHI while seven (10.8%) reported an AHI < 5 EPH. To be prescribed CPAP therapy, an OSA diagnosis needs to be made and one criterium is an AHI ≥ 5 EPH. As all participants had an OSA diagnosis, these seven values were not included in the statistical calculations as they were believed to be inaccurate. Seven (10.8%) did not provide CPAP mask type information (see Tables 5 & 6).

Participants ranged in age from 29 to 75 years (Mean = 48.65, standard deviation (SD) = 10.87). Of those participants providing information, 60 (92.3%) reported they were not of Hispanic or Latino ethnicity while three (4.6%) answered “Unknown/Not Reported”. Nine participants (13.8%) identified as black and 53 (92.3%) as white. Thirty-two participants (49.2%) were female and 33 (50.8%) were male. Thirty-eight participants (58.5%) lived with their significant other and slept in the same bed, 19 (29.2%) slept alone, and eight (12.3%) lived with their significant other and slept in the separate beds. The median participant education level was “College graduate”. One participant (1.5%) had some high school education, eight (12.3%) were high school graduates, 14 (21.5%) had some college, two (3.1%) had trade/technical/vocational training, 20 (30.8%) were college graduates, three (4.6%) had done some post-graduate work, and 17 (26.2%) had post-graduate degrees. The median participant income level was $60,000 to $79,999 and included two participants (3.1%) who made less than $20,000, 13 (20.0%) made between $20,000 and $39,999, eight (12.3%) made between $40,000 and $59,999, 12 (18.5%)

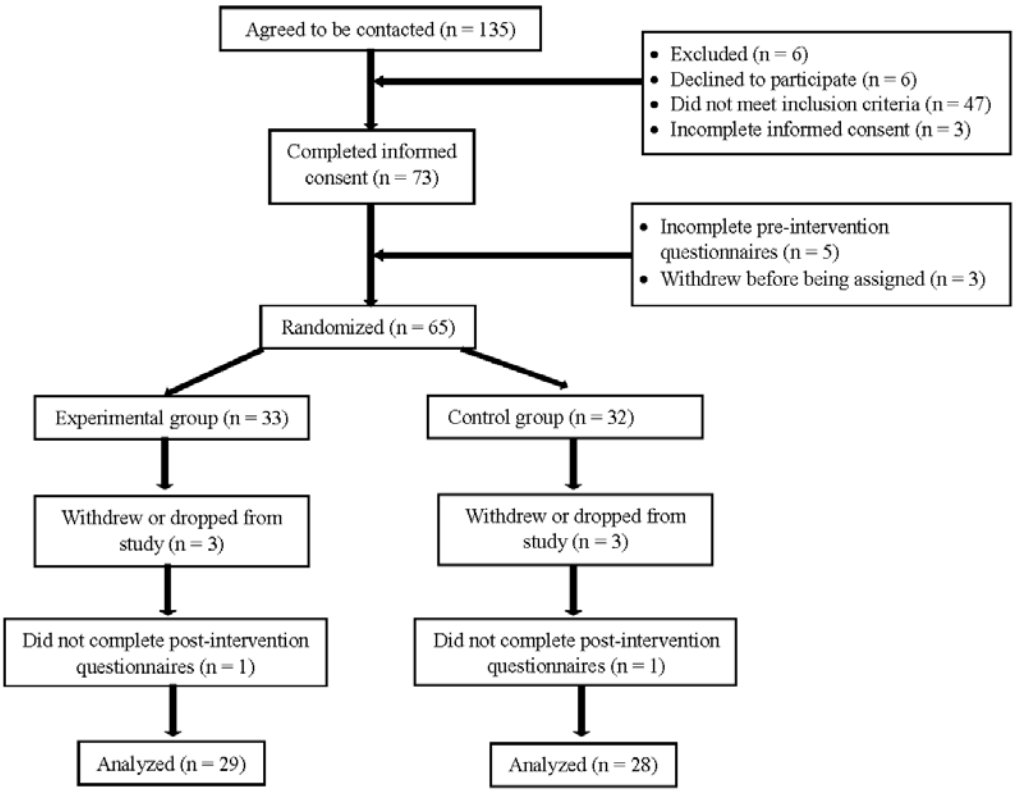


Figure 5. Research study flow

Table 5

Sample Demographics Independent Samples t-test

	Group	N	Mean	Std. Deviation	Std. Error Mean	t	df	Sig. (2-tailed)
Age	CG	32	48.72	11.277	1.994	.053	63	.958
	EG	33	48.58	10.630	1.850			
Ethnicity	CG	31	1.03	.180	.032	-.556	61	.580
	EG	32	1.06	.246	.043			
Race	CG	31	3.87	.341	.061	-.313	61	.755
	EG	32	3.91	.530	.094			
Gender	CG	32	.50	.508	.090	-.120	63	.905
	EG	33	.52	.508	.088			
Sleep Status	CG	32	1.91	.734	.130	.956	63	.343
	EG	33	1.76	.502	.087			
Education Level	CG	32	3.59	1.898	.336	-.362	63	.719
	EG	33	3.76	1.751	.305			
Income	CG	32	3.50	2.342	.414	-.691	63	.492
	EG	33	3.91	2.429	.423			
Apnea/Hypopnea Index	CG	21	28.576	20.6405	4.5041	-1.170	53	.247
	EG	27	27.874	20.9280	4.0276	.116	46	.908

Note: CG=control group; EG=experimental group; N=sample size

Table 6

Baseline Sample Demographics by Group

Category	Characteristic	Control Group	Experimental Group	Pearson Chi-Square
Ethnicity	NOT Hispanic or Latino	30	30	0.573
	Hispanic or Latino	0	0	
	Unknown/not reported	2	3	
Race	American Indian/Alaska Native	0	0	0.573
	Asian	0	0	
	Native Hawaiian or other Pacific Islander	0	0	
	Black or African American	4	5	
	White	27	26	
	More than one race	0	0	
	Unknown/not reported	0	1	
Gender	Male	16	16	0.903
	Female	16	17	
Sleep Status	Sleep alone	9	11	0.069
	Live with significant other and sleep in same bed	16	21	
	Live with significant other and sleep in separate beds	7	1	
Education	Some high school	1	0	0.671
	High school graduate	4	4	
	Some college	7	7	
	Trade/technical/vocational training	1	1	
	College graduate	10	10	
	Some postgraduate work	0	3	
	Post graduate degree	9	8	
Annual Income	Prefer not to answer	4	4	0.321
	Less than $20,000	2	0	
	$20,000 to $39,999	6	7	
	$40,000 to $59,999	3	5	
	$60,000 to $79,999	9	3	
	$80,000 to $99,999	3	5	
	$100,000 to $119,999	0	3	
	$120,000 to $139,999	2	3	
	$140,000 or more	3	3	

made between $60,000 and $79,999, eight (12.3%) made between $80,000 and $99,999, three (4.6%) made between $100,000 and $119,999, five (7.7%) made between $120,000 and $139,999, and six (9.2%) made $140,000 or more. Apnea/hypopnea indices ranged from 5 to 85 EPH (Mean = 28.18, SD = 20.58). Independent sample *t*-tests and chi-square analyses were conducted with no statistically significant differences noted between groups.

Research Hypotheses

Listed below are the aims of the study as well as the research hypotheses for each aim.

Aim 1: Examine the effect of four text messages sent over four weeks on CPAP adherence.

Hypothesis 1: After four weeks of receiving one text message per week, the total mask-on time will differ between the EG and CG.

Hypothesis 2: After four weeks of receiving one text message per week, the proportion of persons classified as adherent will differ between the EG and CG.

Aim 2: Examine the effect of four text messages sent over 4 weeks on OSA symptom management and outcome expectations.

Hypothesis 3: After four weeks of receiving one text message per week, changes in the ABS, ESS, and FOSQ-10 will differ between the EG and CG

Null Hypotheses

The study had three null hypotheses.

Null hypothesis 1: After four weeks of receiving one text message per week, there will be no difference in the total mask-on time between the EG and CG.

Null hypothesis 2:After four weeks of receiving one text message per week, there will be no difference in the proportion of persons classified as adherent between the EG and CG.

Null hypothesis 3:After four weeks of receiving one text message per week, there will be no difference in the ABS, ESS, and FOSQ-10 between the EG and CG.

Hypothesis Testing

Ajzen's theory of planned behavior (1991) provided the framework for study development. The TPB is intended to demonstrate the link between beliefs, intention, and behavior (Ajzen, 1991). According to TPB, actual behavior is driven by three different beliefs: behavioral beliefs, normative beliefs, and control beliefs (Ajzen, 1991). In this study, the ABS was intended to evaluate the effect of behavioral beliefs, normative beliefs, and control beliefs. The ESS and FOSQ-10 instruments were intended to measure any change in OSA symptom management and outcome expectations. Actual behavior was measured using objective CPAP device data collected weekly for four weeks.

Hypothesis 1 stated that after four weeks of receiving one text message per week, the total mask-on time will differ between the EG and CG. To test this hypothesis, participants in both groups received one text message per week for four weeks and objective CPAP usage data was collected. The CG received text messages that reported the weekly hours of CPAP device usage. Participants in the EG received text messages tailored to address behavioral beliefs, normative beliefs, and control beliefs described in TPB (Ajzen, 1991) (see Tables 3 & 4). The TPB designed text messages were further customized based on the participant's adherence or nonadherence to CPAP therapy. Weekly adherence was defined as using CPAP for four hours or greater per night for 70% of nights (five nights), based on the CMS definition of CPAP

adherence therapy (CMS, 2016). CPAP device mask-on time was measured using the pneumotachograph located in the CPAP machine that recorded the rate of airflow during breathing and reported the time used in minutes. At the end of the four weeks, each participant's mask-on time data for the entire four-week time period was collected. An independent samples *t*-test was used to test for differences in the mean mask-on times between the EG and CG. A Levene's Test for Equality of Variances demonstrated no significance allowing equal variances to be assumed. With the significance set at an alpha level of 0.05, the independent samples *t*-test results demonstrated no significant differences in the mean scores for the EG (M = 5.89 hours/night, SD = 1.50 hours/night) and CG (M = 5.67 hours/night, SD = 2.03 hours/night); $t(55) = -0.47$, $p = 0.64$. The null hypothesis was not rejected. Effect size ($\eta p2$) magnitude was determined using .01 as a small effect, .06 as a medium effect, and 0.14 as a large effect (Cohen, 1988). The effect size between the EG and CG was negligible $\eta p2 = .004$.

Hypothesis 2 stated that after four weeks of receiving one text message per week, the proportion of persons classified as adherent will differ between the EG and CG. The definition of adherence according to CMS states, "Objective evidence of adherence to use (defined as use of PAP devices for 4 or more hours per night on 70% of nights during a consecutive 30-day period anytime during the first 3 months of initial use) of the PAP device, reviewed by the treating physician." (CMS, 2016, p. 5). To adapt the CMS definition to fit this study, adherence for 28 days was defined as use of the CPAP device for 4 or more hours per night on 20 of 28 days. The proportion of participants classified as adherent did not differ between the EG (86.2%) and CG (71.4%), $\chi^2 = 1.87$, df = 1, $p = 0.21$. The null hypothesis was not rejected. Effect size (ϕ) magnitude was determined using 0.1 as a small effect, 0.3 as a medium effect, and 0.5 as a large effect (Cohen, 1988). The effect size between the EG and CG was small ($\phi = 0.18$).

Hypothesis 3 stated after four weeks of receiving one text message per week, changes in the ABS, ESS, and FOSQ-10 will differ between the EG and CG. The ABS is a 24-item survey instrument used to measure the concepts of outcome expectations of CPAP, social support as it relates to success or failure of using CPAP, and CPAP acceptance (Smith, Lang, Sullivan, & Warren, 2004). The ABS does not have subscales and was applied as a single measure of attitudes toward CPAP adherence. Higher scores on the ABS indicate greater positive attitudes regarding CPAP adherence (Smith et al., 2004). The ESS is an 8-item survey instrument asks individuals their likelihood of falling asleep while engaged in different activities (Johns, 1991). The resulting score is that person's average tendency to have daytime sleepiness with a higher score indicating a higher level of daytime sleepiness (Johns, 1991). The FOSQ-10 is a 10-item survey instrument that is used to evaluate how sleep affects functional status (Chasens, Ratcliffe, & Weaver, 2009).

A repeated measures ANOVA was used to test for differences in mean scores for ABS, ESS, and FOSQ-10 at pre- and post-intervention between the EG and CG. All three instruments demonstrated acceptable reliability: a) ABS pre-intervention $\alpha = 0.88$, ABS post-intervention $\alpha = 0.78$; b) ESS pre-intervention $\alpha = 0.84$, ESS post-intervention $\alpha = 0.83$; c) FOSQ-10 pre-intervention $\alpha = 0.83$, FOSQ-10 post-intervention $\alpha = 0.79$. With significance set at an alpha of .05, the repeated measures ANOVA revealed no significant effect between groups for ABS mean scores, [$F(1, 55) = 0.52$, $p = 0.47$, $\eta p2 = 0.22$], change in ESS mean scores [$F(1, 55) = .06$, $p = 0.81$, $\eta p2 = 0.39$]; and FOSQ-10 mean scores [$F(1, 55) = .002$, $p = 0.97$, $\eta p2 = 0.33$]. Effect size ($\eta p2$) magnitude was determined using .01 as a small effect, .06 as a medium effect, and 0.14 as a large effect (Cohen, 1988). The effect size between groups was small for all three instruments. The null hypothesis was not rejected for each test between groups. A main effect of time was

found to be statistically significant for ABS [F(1, 55) = 15.80, p < .001, ηp2 = .009], ESS [F(1, 55) = 35.29, p < .001, ηp2 = .001] and FOSQ-10 [F(1, 55) = 26.46, *p* < .001, ηp2 = .000] indicating that both groups improved similarly over time. The within group effect size was negligible for all three instruments.

Chapter Summary

Statistical test results were achieved using parametric tests as well as one non-parametric test, chi-square. An independent samples *t*-test was used to compare the EG and CG at baseline to test homogeneity of variance. There was no statistically significant difference in the total mask-on time between the EG and CG. There was also no statistically significant difference in the proportion of persons classified as adherent between the EG and CG. Finally, there were no statistically significant differences in the scores for the ABS, ESS, and FOSQ-10 between the two groups. Study findings are discussed in detail in Chapter 5.

Chapter 5: Discussion

This randomized control pilot study examined the effects of using the theory of planned behavior to design text messages to motivate individuals newly diagnosed with OSA to be more adherent to using CPAP therapy. The theoretical framework used to guide the development of this study was the TPB developed by Icek Ajzen (Ajzen, 1991). The demographic characteristics and study findings are reviewed in this chapter. Implications for the theoretical framework, healthcare policy, nursing clinical practice, and future research are also discussed. This chapter will conclude with a summary of the study and findings.

Demographic Characteristics

Comparison of demographic characteristics for the CG and EG showed no significant differences between the two at baseline (see Tables 5 & 6). Of the 65 participants who were randomized to either the CG or EG, 62 answered the demographic and pre-intervention instruments and received at least one text message. Fifty-seven participants were able to complete the study and answer the post-intervention instruments. The participation rate was 91.9% which is higher than recent studies that evaluated sleep and OSA by Haba-Rubio et al. (2017) (71%) and Munks et al. (2019) (56.6%). Within the groups, the age range for the CG was 29 to 75 with a mean of 48.7 years and an age range of 31 to 72 in the EG with a mean of 48.6 years, which were similar. For those reporting ethnicities, 96.8% in the CG identified as “NOT Hispanic or Latino” while 93.8% in the EG identified as “NOT Hispanic or Latino”, which were also similar. One participant in the CG and two participants in the EG chose to report their ethnicities as “Unknown/Not Reported”. One participant in each group did not provide answers to ethnicity. For those reporting race, 12.9% of the CG and 15.6% of the EG identified as “Black

or African American". Those participants identifying as "White" included 87.1% in the CG and 81.3% in the EG. No participants in the CG and one participant in the EG chose to report their races as "Unknown/Not Reported". One participant in each group did not provide answers to race. There was no significant racial difference between the two groups. Fifty percent of the CG participants identified as female while 51.5% of the EG identified as female, which were similar. Regarding sleep status, 28.1% of the CG and 33.3% of EG report they "Sleep Alone". Fifty percent of the CG and 63.6% of the EG chose "Live with significant other and sleep in same bed". "Live with significant other and sleep in separate beds" was the choice for 21.9% of the CG and 3% of the EG. There was no significant difference in sleep status between the two groups.

One participant in the CG did not complete high school while every participant in the EG at least completed high school. High school graduates included 12.5% of the CG and 12% of the EG. Seven CG participants (21.9%) and seven EG participants (21.2%) reported they attained "Some college" but did not graduate from college. One participant from each group (CG = 3.1%; EG = 3.0%) reported "Trade/technical/vocational training". Ten participants from each study group (CG = 31.3%; EG = 30.3%) identified themselves as college graduates. No CG participants chose "Some postgraduate work" while 9.1% of EG reported "Some post graduate work". Nine CG participants (28.1%) and eight EG participants (24.2%) reported earning a postgraduate degree. There was no significant difference in education level between the two groups.

Four participants in each group (CG = 12.5%; EG = 12.1%) preferred not to answer the demographic item "Annual Income". Two CG participants (6.3%) and no EG participants reported making less than $20,000 annually. Nine CG participants (28.2%) and 12 EG

participants (36.4%) reported making between $20,000 and $60,000 annually. Twelve CG participants (37.5%) and eight EG participants (24.3%) reported incomes between $60,000 and $100,000 annually. Five CG participants (15.7%) and nine EG participants (27.3%) claimed incomes $100,000 and greater. There was no significant difference in annual income between the two groups.

A total of 17 participants (26.1%) did not report a baseline AHI which included 11 in the CG (17.9%) and six in the EG (9.2%). For those CG participants reporting AHI, the range was between five and 85 EPH with a mean of 28.6. For EG group participants, the AHI range was between five and 84 EPH with a mean of 27.9. There was no significant difference in AHI between the two groups.

Overall, the participants were predominantly white (81.5%), not of Hispanic or Latino ethnicity (92.3%), female (50.8%), lived with significant other and slept in same bed (58.4%), were college graduates or higher (61.5%), made more than $60,000 annually (56.9%), and were considered to have severe OSA as determined by their AHI (28.2 EPH). The study population ranged in age from 29 to 75 with a mean of 48.7 years. Several of these demographic characteristics approximate the U.S. Census Bureau's *2013-2017 American Community Survey 5-Year Estimates* for the state of Tennessee (U.S. Census Bureau, 2017). Within Tennessee in 2017, the population was predominantly white (77.8%), not of Hispanic or Latino ethnicity (94.8%), female (51.3%), and made more than $50,000 annually per household (67.5%). Differences in demographic characteristic within Tennessee as compared to the study population, included age (median of 38.6 years), and college degree or higher (33.1%), (U.S. Census Bureau, 2017). Within both groups, it was also noted that most participants lived with their significant other and slept in the same bed (EG = 67%; CG = 50%; $\chi^2 = .06$). Study population

underrepresentation included minorities, younger individuals, those with less education than a college degree, and individuals with mild or moderate OSA. As a result, a limitation of this study is the limited generalizability of findings to non-white ethnicity, younger individuals, less educated individuals, and individuals with mild or moderate OSA.

Study Findings

Hypothesis 1 stated that after four weeks of receiving one text message per week, the total mask-on time will differ between the EG and the CG. The results showed no significant difference between the EG and CG after an independent samples *t*-test was performed ($p = 0.64$) as well as a negligible effect size between the two groups ($\eta p2 = .004$). As stated in Chapter 3, a pilot study was chosen because the intervention was a new approach to affecting adherence to CPAP therapy and the procedures needed to be tested. The small sample size used in the pilot study made it easier to test the study design and operational characteristics. However, the smaller sample size in this study did make it more difficult to test the hypotheses and determine a reliable effect size.

Although the CGs' text messages only included weekly CPAP mask-on time, participants may still have perceived this communication as being supportive of adherence. This is endorsed by the higher adherence rate in this study's CG (71.4%) as compared to a 2014 Cochrane review that found adherence for those receiving standard treatment to be 59% (Wozniak, Lasserson, & Smith, 2014). Sixteen participants (57.1% of CG), responded to the informational text messages with questions and comments concerning a variety of different issues. Examples, with emojis, included: "I really appreciate your support as I started CPAP. There should be one of you for new person! 😊"; "So far, I have been able to sleep without waking up more than a couple of

times during the night. It does take a fair amount of time to go to sleep."; "My man I thank you for checking in on me I do. I'm still trying to work through my difficulties with the CPap. I need to change the mask asap. I was on vacation last week & didn't use. As soon as I get mask changed I will give it my all."; and "What constitutes a successful night?". There was discussion with my dissertation committee whether it would be considered unethical to ignore the CGs' requests for information or assistance and it was agreed that it would be unethical. It was also agreed that any replies provided would be limited to short answers to simple questions and comments, if necessary, that were not guided by the TPB. For more complex troubleshooting issues, participants were referred to the DME supplier or the Vanderbilt Sleep Center.

Hypothesis 2 stated that after four weeks of receiving one text message per week, the proportion of persons classified as adherent will differ between the EG and the CG. For this study, adherence for 28 days was defined as use of the CPAP device for 4 or more hours per night on 20 of 28 days. The results showed no statistically significant difference between the EG and CG ($p = 0.21$). The effect size between the EG and CG was small ($\phi = 0.18$). Despite having no statistically significant difference between the two groups, there was a trend towards the EG having a greater proportion adherent (86.2%) versus the CG (71.4%). This equates to 14.8% more EG participants being adherent to CPAP than in the CG.

Hypothesis 3 stated after four weeks of receiving one text message per week, changes in the ABS, ESS, and FOSQ-10 will differ between the EG and the CG. Three repeated measures ANOVA tests were used to test for differences in mean scores for ABS, ESS, and FOSQ-10 at pre- and post-intervention between the CG and EG. The analyses revealed no significant differences between CG and EG for ABS mean scores ($p = 0.47$), ESS mean scores ($p = 0.81$),

and FOSQ-10 mean scores (p = 0.97). The effect size between groups was small for the ABS (ηp2 = 0.22), ESS (ηp2 = 0.39), and FOSQ-10 (ηp2 = 0.33).

However, the instruments selected were not ideal to evaluate the effectiveness of the TMBI designed using the TPB. This would explain the lack of any significant differences between the mean scores of the two groups for the ABS, ESS, and FOSQ-10. Despite no significant difference *between groups*, there was a statistically significant *main effect over time* for each individual group for the ABS (p = .002), ESS (p = .000), and FOSQ-10 (p = .000). This change over time demonstrates, what has been clearly established in numerous studies, that CPAP therapy is effective in alleviating symptoms (ESS), improving functional outcomes (FOSQ-10), and improving outcome expectations and acceptance of using CPAP therapy (ABS). These three instruments evaluated the *results* of the behavior (using or not using the CPAP device) and not the *effect*, if any, that the TPB-based intervention had on changing an individual's attitudes, subjective norms, or perceived behavior control about using CPAP therapy to treat their OSA.

As the TPB is intended to identify interactions between beliefs, intention, and behavior (Ajzen, 1991), instruments that detect changes in attitudes towards the behavior, subjective norms, and perceived behavior control would have been more appropriate to measure the intervention's efficacy. For instance, the attitudes to CPAP treatment inventory (ACTI) was designed to measure the attitudes an individual has towards the behavior of using their CPAP device and may have been a more suitable choice to evaluate the intervention (Broström, Ulander, Nilsen, Svanborg, & ÅRestedt, 2011). According to Ajzen (1991), perceived behavioral control is "compatible with Bandura's concept of perceived self-efficacy" (p. 184). Therefore, an appropriate instrument to evaluate any change in a participant's perceived behavioral control

would be the Self-Efficacy Measure for Sleep Apnea (SEMSA) (Weaver et al., 2003). Finally, according to Ajzen (1991), normative beliefs influence the subjective norm which is the individual's own assessment of the social pressure to perform or not perform a behavior. Because the estimated social pressure for every conceivable behavior is difficult to estimate, Ajzen (2002a) suggests developing a TPB questionnaire "for different behaviors and for different research populations" (p.4). An example of a subjective norm item on a CPAP adherence TPB questionnaire would be, "Most people who are important to me think that I should use my CPAP device for at least 4 hours every night." (Ajzen, 2002a). Ajzen's (2002a) proposal of constructing TPB questionnaires is not limited to subjective norms but also applies to attitude towards the behavior, perceived behavior control, and intention. Any instruments designed using this method would need to be validated (Ajzen, 2002a).

Implications for Theoretical Framework

This study was the first of its kind to use text messages designed using the TPB (Ajzen, 1991) to influence an individual's beliefs about using CPAP therapy to manage their OSA. Despite being a pilot study, there was a trend towards the EG being significantly more adherent to CPAP therapy than the CG when using CMS-based definition of CPAP adherence. This finding supports the need of further development and testing of TPB-based interventions in promoting CPAP adherence.

Rich, Brandes, Mullan, and Hagger (2015) conducted a meta-analysis of the TPB's validity in predicting treatment adherence in chronic illness. The meta-analysis included studies that evaluated the TPB-based interventions and their ability to influence adherence to medications, diet, exercise, and self-care (Rich et al., 2015). In their introduction and summary,

Rich et al. (2015) stated the TPB is effective in "explaining substantial amounts of variance in both intentions and behavior in health domains from a relatively parsimonious set of predictors" (p. 675). The authors also noted that the TPB compares favorably to other social-cognitive theories like the health belief model (Rich et al., 2015). In the conclusion, the authors observed the ability of the TPB to predict adherence in the treatment of chronic illnesses was limited (Rich et al., 2015). As the TPB was never designed to explain adherence to a prescribed therapy, the authors recommended the use of models specifically designed to understand adherence (Rich et al., 2015). However, Rich et al. (2015) also remarked the options for such models are limited and that they pertain only to medication adherence. The authors concluded that other theories need to be developed and tested that are more valid in predicting adherence and interventions based on these theories be developed and test as well (Rich et al., 2015). Despite the documented limitations, the TPB continues to be a widely used method of understanding human social behavior. The TPB's clearly defined concepts and hypothesized causal relationships provides a useful framework for designing interventions that improve therapy adherence and should be thoughtfully considered in being used to design and test interventions to improve CPAP therapy.

Implications for Clinical Practice

One immediate implication from this study suggests that text messages, in any form, may improve adherence to CPAP therapy. As stated earlier, the adherence rate in this pilot study for both the EG (86.2%) and the CG (71.4%) was higher as compared to a 2014 Cochrane Review that found EG adherence to be 75% and CG adherence to be 59% (Wozniak et al., 2014). These findings indicate that the simple act of sending a text message about an individual's CPAP usage may influence their beliefs about the value other people place on using a CPAP device to treat OSA (subjective norm) (Ajzen, 1991). The technology is available to have automated messages

that report CPAP usage and studies have been performed that demonstrate they are effective in significantly lowering the long-term rate of therapy termination (Woehrle et al., 2017) and improving CPAP adherence (Hwang et al., 2018). This method of sending automated text messages has the potential to be a cost-effective way of engaging patients using CPAP therapy. Based on this pilot study and if monetarily feasible, designating a trained staff member to respond to any appropriate text messages related to CPAP therapy questions or concerns may be beneficial as well. A total of 26 out of the 57 participants (45.6%) who completed the study sent text messages asking questions or making comments that necessitated a reply like the examples listed in the discussion section of **Hypothesis 1**. The value of being heard cannot be understated and may improve attitude towards the behavior, subjective norm, and a patient's perceived behavioral control.

Another implication of this study is the emphasis on the utility of the TPB in designing different types of interventions that have the potential to change a behavior. This flexibility in design advances the idea of establishing nurse-led interventions in outpatient settings that employ the TPB in their designs. Such interventions may include educating patients on the negative effects of OSA on overall health and how CPAP therapy reduces or negates those negative effects (attitude towards the behavior) (Ajzen, 1991). Another intervention may emphasize the value of CPAP therapy to the individual and society such as lower risk of depression as well as reduces MVA and workplace injury risk (subjective norms) (Ajzen, 1991). A third intervention may be one that is intentional in ensuring appropriate technical support is in place and that sufficient amounts of the proper equipment are accessible to the patient (perceived behavioral control) (Ajzen, 1991).

Implications for Future Policy

Policy implications for advancing health-promoting behaviors, such as CPAP adherence, can be drawn from this pilot study. Given the growing obesity epidemic that is likely to increase the prevalence of OSA (Peppard, Young, Palta, Dempsey, & Skatrud, 2000), any policy changes promoting CPAP adherence will likely have a significant impact. With the full implementation of the Patient Protection and Affordable Care Act (ACA) in 2014, there have been far-reaching healthcare policy changes including health insurance reforms (U.S. Congress, 2010). An aspect of the ACA insurance changes involves connecting payments to a value-based care model and away from the traditional fee-for-service model. This move is designed to emphasize improved healthcare quality and improved healthcare delivery by focusing on population health, health-promoting behaviors, and preventive services while reducing the overall cost of healthcare (Vincent & Reed, 2014). For these changes to be successful, there will need to be significant paradigm shifts to innovative care delivery methods. Such methods include patient-centered medical homes, accountable care organizations, and greater use of health information technology to reduce fragmented care and improve communication with patients in different settings. As a result of the holistic care provided by nurses in a modern, technology-driven culture, the profession is well-positioned to act as change agents in several different spheres of influence including the advancement of health-promoting behaviors. However, it is vital to demonstrate the effectiveness of health-promoting behaviors by having their outcomes measured and reimbursed appropriately.

Health-promoting behaviors are a necessary element of organizational efforts at different levels including state and federal governments, payors, and healthcare providers to improve overall health of the entity's populations of interest. For example, the CMS measures the

performance of Medicare Advantage and Part D plans using the *Star Rating System* (CMS, 2019). One purpose of the Star Ratings is to encourage improving the care given to individuals through performance-based monetary incentives and public accountability (CMS, 2019). The different Medicare Advantage and Part D plans collect data on up to 46 unique performance and quality measures in five areas including managing chronic (long-term) conditions (CMS, 2019). Currently, there are 15 sub-categories under the *managing chronic (long-term) conditions* category but no sub-category addresses promoting health behaviors such as adherence to therapy (medication, device, diet, exercise, etc.). Incorporating adherence, including CPAP therapy, as a sub-category would be prudent as numerous studies have shown that adherence to therapy improves patient outcomes while non-adherence worsens patient outcomes (Giles et al., 2006; Krass, Schieback, & Dhippayom, 2015; Raparelli et al., 2017; Ruppar, Cooper, Mehr, Delgado, & Dunbar-Jacob, 2016).

Another area where health policy changes can support health-promotion behaviors is through the Merit-based Incentive Payment System (MIPS). The Medicare Access and CHIP Reauthorization Act of 2015 required CMS implement the Quality Payment Program which is a payment incentive program consisting of the Advanced Alternative Payment Models, and the MIPS (Casalino, 2017). The MIPS provides for payment incentives that are determined by performance measure in four areas, cost, improvement activities, promoting interoperability, and quality. The MIPS began collecting the performance measures in January 2017 with 91% of eligible clinicians participating in the system (Verma, 2018). One quality measure of interest to this current pilot study is QPP #279 (Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy) (American Academy of Sleep Medicine, 2018). The criteria for this quality performance measure is the, “Percentage of visits for patients aged 18 years and older with a

diagnosis of obstructive sleep apnea who were prescribed positive airway pressure therapy who had documentation that adherence to positive airway pressure therapy was objectively measured" (CMS, 2017, p.1). If this TPB-based TMBI is shown to be effective, the intervention has the potential to improve payments to the organization through the MIPS by improving CPAP therapy adherence. For this reason, healthcare organization policy-makers should consider funding nurse-led intervention programs to provide weekly motivational text messages as a means for promoting adherence to CPAP therapy. Specially-trained nurses will be needed in providing technical support that improves an individual's perceived behavioral control (Ajzen, 1991). The nurses will also have the potential to provide multimodal patient education regarding the positive effects of CPAP therapy and the negative effects of OSA (attitude towards the behavior) as well as the value of CPAP adherence to the individual as well as his referent group (subjective norm) (Ajzen, 1991).

Implications for Future Research

A reasonable course for future research is to design a more robust randomized control trial taking in to account the lessons learned from this pilot study. An example of a lesson learned includes choosing different instruments to measure the effects of the intervention. As stated previously, the instruments used were not effective in measuring changes in attitudes, subjective norms, or perceived behavior control pre- and post- intervention. As a result, further research is needed to determine the effectiveness of using the TPB in designing TMBIs using more suitable instruments like the ACTI, a TPB questionnaire that measures subjective norm, and the SEMSA. Other adjustments, not previously discussed, may include altering the inclusion criteria to allow for those individuals who were on CPAP therapy in the past, had failed, and are now interested in going back on CPAP therapy.

Text-message based studies could also evaluate the text messages themselves. Aspects of text messages including the timing of text messages during the day and the frequency of the text messages should be studied. The timing of the text message was not consistent in this pilot study, however, the time of day may play an important role as an individual's perception of the text message may change depending on when it was received. Determining the optimal frequency of text messages would also be beneficial. The optimal frequency may be influenced by issues such as the total time the individual will be receiving the messages as well as the type and morbidity of the chronic illness in question. The urgency of the disease may allow the individual with the chronic disease to be more receptive to receiving text-based messages at an increased frequency.

As discussed previously in chapter two, mask type and mask-related side effects may have an impact on adherence rates. Borel et al., 2013 and Ryan et al., 2011 both observed that nasal masks and/or nasal pillows are associated with slightly better adherence than oronasal masks. Another study found a significantly higher preference for nasal masks over nasal masks with chinstraps and oronasal masks (Rowland et al., 2018). These studies indicate the importance of the mask type chosen and CPAP mask usage, access, and adverse effects needs to be studied in greater detail

Other opportunities for future research include evaluating the use of social media platforms such as Facebook, Snapchat, and Twitter as modes of communication to deliver TPB-designed adherence messages to individuals on chronic therapy for conditions including OSA. According to Pew Research Center (2018b), 68% of Americans use Facebook, 27% use Snapchat, and 24% use Twitter. When broken down into those between 18-29 years of age, usage increases appreciably. 80% of Americans between 18-29 use Facebook, approximately 67% use Snapchat, and roughly 40% use Twitter (Pew Research Center, 2018b). As individuals

in this age group grow older and experience chronic illnesses and the therapies that accompany them, these social media platforms can be leveraged as effective communication methods to deliver motivational messages designed to improve therapy adherence.

Another burgeoning means of communication is healthcare organization-based patient portals. According to The Office of the National Coordinator for Health Information Technology (ONC) (n.d.), a patient portal is a secure website that gives individuals access to their personal health information. Some patient portals allow for active interaction with their healthcare team including requesting prescription refills and scheduling appointments as well the ability to send and receive secure messages (ONC, n.d.). In a systematic review by Kruse, Bolton, and Freriks (2015), the authors noted, regarding the use of patient portals, that "improvements were identified in medication adherence and the management of chronic disease, disease awareness, improved self-care, general "clinically relevant benefits", and a decrease in the number of office visits" (p.5). Using the TPB to design adherence promoting messages sent via patient portals is one more application of technology that has the opportunity to improve patient outcomes and lower costs is an area that also needs to be studied in future research.

Conclusion

In conclusion, this theoretically-derived, randomized controlled pilot study examined the effects of using the TPB to design text messages to motivate individuals with OSA to be more adherent to CPAP therapy. Results showed no significant difference in adherence, mask-on time, symptom management, and outcome expectations between participants who received text messages designed using the TPB and those receiving text messages with data usage only but there were trends towards significance for CPAP therapy adherence. This study added to

healthcare knowledge base by evaluating the effects of TMBIs designed using the TPB on adherence to therapy. Implications for clinical practice include designing nurse-led interventions, including TMBIs, based on the TPB to improve adherence to therapy. Implications for Future policy derived from this study includes the need for theoretically-based interventions that utilize technology to improve adherence to CPAP therapy which, in turn, may improve quality measures and improve value-based payments. Finally, the implications for future research are vast and include improving this study design, as well as to evaluate leveraging social media platforms and patient portals to potentially improve adherence to therapy, including CPAP therapy.

References

Adult Obstructive Sleep Apnea Task Force of the American Academy of Sleep Medicine. (2009). Clinical guideline for the evaluation, management and long-term care of obstructive sleep apnea in adults. *Journal of Clinical Sleep Medicine, 5*(3), 263-276. Retrieved from http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2699173/

Ajzen, I. (1985). From intentions to actions: A theory of planned behavior. In J. Kuhl & J. Beckmann (Eds.), *Action control: From cognition to behavior* (pp. 11-39). Berlin, Heidelberg: Springer Berlin Heidelberg

Ajzen, I. (1987). Attitudes, traits, and actions: Dispositional prediction of behavior in personality and social psychology. *Advances in Experimental Social Psychology, 20*(1), 1-63. doi:10.1016/S0065-2601(08)60411-6

Ajzen, I. (1991). The theory of planned behavior. *Organizational Behavior and Human Decision Processes, 50*(2), 179-211.

Ajzen, I. (2002a). Constructing a TPB questionnaire: Conceptual and methodological considerations. Retrieved from http://chuang.epage.au.edu.tw/ezfiles/168/1168/attach/20/pta_41176_7688352_57138.pdf

Ajzen, I. (2002b). Perceived behavioral control, self-efficacy, locus of control, and the theory of planned behavior. *Journal of Applied Social Physiology, 32*(4), 665-683. doi:doi:10.1111/j.1559-1816.2002.tb00236.x

Ajzen, I. (2011). The theory of planned behaviour: Reactions and reflections. *Psychology & Health, 26*(9), 1113-1127. doi:10.1080/08870446.2011.613995

Ajzen, I. (2019). Behavioral interventions based on the theory of planned behavior. Retrieved from http://people.umass.edu/aizen/pdf/tpb.intervention.pdf

Ajzen, I. (n.d.). Frequently asked questions. Retrieved from http://people.umass.edu/aizen/faq.html

American Academy of Sleep Medicine. (2018). CMS finalizes removal of two sleep apnea measures from MIPS for 2019. *Clinical Resources.* Retrieved from https://aasm.org/cms-finalizes-removal-of-two-sleep-apnea-measures-from-mips-for-2019/

Anandam, A., Akinnusi, M., Kufel, T., Porhomayon, J., & El-Solh, A. (2013). Effects of dietary weight loss on obstructive sleep apnea: a meta-analysis. *Sleep and Breathing, 17*(1), 227-234. doi:10.1007/s11325-012-0677-3

Armitage, C. J., & Conner, M. (2001). Efficacy of the theory of planned behaviour: A meta-analytic review. *British Journal of Social Psychology, 40*(4), 471-499.

Aronsohn, R. S., Whitmore, H., Van Cauter, E., & Tasali, E. (2010). Impact of untreated obstructive sleep apnea on glucose control in type 2 diabetes. *American Journal of Respiratory Critical Care Medicine, 181*(5), 507-513. doi:10.1164/rccm.200909-1423OC

Aurora, R. N., Chowdhuri, S., Ramar, K., Bista, S. R., Casey, K. R., Lamm, C. I., . . . Tracy, S. L. (2012). The treatment of central sleep apnea syndromes in adults: Practice parameters with an evidence-based literature review and meta-analyses. *Sleep, 35*(1), 17-40. doi:10.5665/sleep.1580

Aurora, R. N., Crainiceanu, C., Gottlieb, D. J., Kim, J. S., & Punjabi, N. M. (2018). Obstructive sleep apnea during REM sleep and cardiovascular disease. *American Journal of Respiratory and Critical Care Medicine, 197*(5), 653-660.

Bakker, J. P., Wang, R., Weng, J., Aloia, M. S., Toth, C., Morrical, M. G., . . . Redline, S. (2016). Motivational enhancement for increasing adherence to CPAP. *Chest, 150*(2), 337-345. doi:10.1016/j.chest.2016.03.019

Baldwin, C. M., & Quan, S. F. (2002). Sleep disordered breathing. *Nursing Clinics of North America, 37*(4), 633-654. Retrieved from http://www.sciencedirect.com/science/article/pii/S0029646502000300. doi:10.1016/S0029-6465(02)00030-0

Baron, K. G., Gunn, H. E., Wolfe, L. F., & Zee, P. C. (2017). Relationships and CPAP adherence among women with obstructive sleep apnea. *Sleep Science and Practice, 1*(1), 10. doi:10.1186/s41606-017-0011-x

Basoglu, O., Midilli, M., Midilli, R., & Bilgen, C. (2011). Adherence to continuous positive airway pressure therapy in obstructive sleep apnea syndrome: effect of visual education. *Sleep and Breathing*, 1-8. doi:10.1007/s11325-011-0631-9

Bignold, J. J., Deans-Costi, G., Goldsworthy, M. R., Robertson, C. A., McEvoy, D., Catcheside, P. G., & Mercer, J. D. (2009). Poor long-term patient compliance with the tennis ball technique for treating positional obstructive sleep apnea. *Journal of Clinical Sleep Medicine, 5*(5), 428.

Block, L. G., & Keller, P. A. (1998). Beyond protection motivation: An integrative theory of health appeals. *Journal of Applied Social Psychology, 28*(17), 1584-1608. doi:10.1111/j.1559-1816.1998.tb01691.x

Borel, J. C., Tamisier, R., Dias-Domingos, S., Sapene, M., Martin, F., Stach, B., . . . Series, F. (2013). Type of mask may impact on continuous positive airway pressure adherence in apneic patients. *PLoS ONE, 8*(5), e64382.

Brenan, M. (2018). Nurses again outpace other professions for honesty, ethics. Retrieved from https://news.gallup.com/poll/245597/nurses-again-outpace-professions-honesty-ethics.aspx

Broström, A., ÅRestedt, K. F., Nilsen, P. E. R., Strömberg, A., Ulander, M., & Svanborg, E. V. A. (2010). The side-effects to CPAP treatment inventory: the development and initial validation of a new tool for the measurement of side-effects to CPAP treatment. *Journal of Sleep Research, 19*(4), 603-611. doi:10.1111/j.1365-2869.2010.00825.x

Broström, A., Nilsen, P., Johansson, P., Ulander, M., Strömberg, A., Svanborg, E., & Fridlund, B. (2010). Putative facilitators and barriers for adherence to CPAP treatment in patients with obstructive sleep apnea syndrome: A qualitative content analysis. *Sleep Medicine, 11*(2), 126-130. Retrieved from http://www.sciencedirect.com/science/article/pii/S1389945709004316. doi:10.1016/j.sleep.2009.04.010

Broström, A., Strömberg, A., Ulander, M., Fridlund, B., Mårtensson, J., & Svanborg, E. (2009). Perceived informational needs, side-effects and their consequences on adherence — A

comparison between CPAP treated patients with OSAS and healthcare personnel. *Patient Education and Counseling, 74*(2), 228-235.

Broström, A., Ulander, M., Nilsen, P. E. R., Svanborg, E. V. A., & ÅRestedt, K. F. (2011). The attitudes to CPAP treatment inventory: development and initial validation of a new tool for measuring attitudes to CPAP treatment. *Journal of Sleep Research, 20*(3), 460-471. doi:10.1111/j.1365-2869.2010.00885.x

Budhiraja, R., Parthasarathy, S., Drake, C. L., Roth, T., Sharief, I., Budhiraja, P., . . . Hudgel, D. W. (2007). Early CPAP use identifies subsequent adherence to CPAP therapy. *Sleep, 30*(3), 320-324.

Butler, A. C., Chapman, J. E., Forman, E. M., & Beck, A. T. (2006). The empirical status of cognitive-behavioral therapy: a review of meta-analyses. *Clinical Psychology Review, 26*(1), 17-31.

Campos-Rodriguez, F., Navarro-Soriano, C., Reyes-Nuñez, N., Torres, G., Caballero-Eraso, C., Lloberes, P., . . . Martinez-Garcia, M. A. (2019). Good long-term adherence to continuous positive airway pressure therapy in patients with resistant hypertension and sleep apnea. *Journal of Sleep Research, Epub ahead of print*(e12805), 1-8. Retrieved from https://onlinelibrary.wiley.com/doi/abs/10.1111/jsr.12805. doi:10.1111/jsr.12805

Caples, S. M., Rowley, J. A., Prinsell, J. R., Pallanch, J. F., Elamin, M. B., Katz, S. G., & Harwick, J. D. (2010). Surgical modifications of the upper airway for obstructive sleep apnea in adults: a systematic review and meta-analysis. *Sleep, 33*(10), 1396-1407.

Casalino, L. P. (2017). The Medicare Access and CHIP Reauthorization Act and the corporate transformation of American medicine. *Health Affairs, 36*(5), 865-869. Retrieved from https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2016.1536. doi:10.1377/hlthaff.2016.1536

Cellular Telecommunications and Internet Association. (2016). Wireless Quick Facts. Retrieved from https://www.ctia.org/industry-data/wireless-quick-facts

Center for Medicare & Medicaid Services. (2016). Positive airway pressure (PAP) devices: Complying with documentation & coverage requirements. Retrieved from https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/PAP_DocCvg_Factsheet_ICN905064.pdf

Center for Medicare & Medicaid Services. (2017). *Quality ID #279: Sleep apnea: Assessment of adherence to positive airway pressure therapy – National quality strategy domain: Effective clinical care*. Retrieved from https://qpp.cms.gov/docs/QPP_quality_measure_specifications/Claims-Registry-Measures/2018_Measure_279_Registry.pdf

Center for Medicare & Medicaid Services. (2019). Star ratings. Retrieved from https://www.medicare.gov/find-a-plan/staticpages/rating/planrating-help.aspx

Champion, V. L., & Skinner, C. S. (2008). The health belief model. In K. Glanz, B. K. Rimer, & K. Viswanath (Eds.), *Health behavior and health education: Theory, research, and practice* (4 ed., pp. 45-62). San Francisco, CA: John Wiley & Sons.

Chasens, E. R., Ratcliffe, S. J., & Weaver, T. E. (2009). Development of the FOSQ-10: a short version of the Functional Outcomes of Sleep Questionnaire. *Sleep, 32*(7), 915-919.

Chen, S., Gong, E., Kazi, D. S., Gates, A. B., Karaye, K. M., Girerd, N., . . . Yan, L. L. (2016). Development of a mobile phone-based intervention to improve adherence to secondary prevention of coronary heart disease in China. *Journal of Medical Engineering & Technology, 40*(7-8), 372-382. doi:10.1080/03091902.2016.1213904

Chervin, R. D., & Aldrich, M. S. (1999). The Epworth Sleepiness Scale may not reflect objective measures of sleepiness or sleep apnea. *Neurology, 52*(1), 125-125.

Chow, C. K., Redfern, J., Hillis, G. S., & et al. (2015). Effect of lifestyle-focused text messaging on risk factor modification in patients with coronary heart disease: A randomized clinical trial. *Journal of the American Medical Association, 314*(12), 1255-1263. doi:10.1001/jama.2015.10945

Cohen, J. (1988). *Statistical power analysis for the behavioral sciences* (2nd ed.). United States of America: Lawrence E Erlbaum Associates.

Creswell, J. W. (2009). *Research design: Qualitative, quantitative, and mixed methods approaches* (3rd ed.). Los Angeles, CA: Sage publications.

de Jongh, T., Gurol-Urganci, I., Vodopivec-Jamsek, V., Car, J., & Atun, R. (2012). Mobile phone messaging for facilitating self-management of long-term illnesses. *Cochrane Database of Systematic Reviews, 12,* Cd007459. doi:10.1002/14651858.CD007459.pub2

Diaz-Abad, M., Chatila, W., Lammi, M. R., Swift, I., Alonzo, G. E., & Krachman, S. L. (2014). Determinants of CPAP adherence in Hispanics with obstructive sleep apnea. *Sleep Disorders, 2014,* 6. doi:10.1155/2014/878213

Dugatkin, L. A. (2012). What is "behavior" anyway?: What do animal behaviorists mean by the word "behavior?". Retrieved from https://www.psychologytoday.com/blog/the-prince-evolution/201207/what-is-behavior-anyway

Dunbar-Jacob, J., Aloia, M. S., Martire, L. M., Buysse, D. J., & Strollo, P. J. (2016). Patient and partner experiences with obstructive sleep apnea and CPAP treatment: A qualitative analysis. *Behavioral Sleep Medicine, 14*(1), 67-84. doi:10.1080/15402002.2014.946597

Elfström, M., Karlsson, S., Nilsen, P., Fridlund, B., Svanborg, E., & Broström, A. (2012). Decisive situations affecting partners' support to continuous positive airway pressure–Treated patients with obstructive sleep apnea syndrome: A critical incident technique analysis of the initial treatment phase. *Journal of Cardiovascular Nursing, 27*(3), 228-239. doi:10.1097/JCN.0b013e3182189c34

Fishbein, M., & Ajzen, I. (1977). Belief, attitude, intention, and behavior: An introduction to theory and research.

Fox, N., Hirsch-Allen, A., Goodfellow, E., Wenner, J., Fleetham, J., Ryan, C. F., . . . Ayas, N. T. (2012). The impact of a telemedicine monitoring system on positive airway pressure adherence in patients with obstructive sleep apnea: a randomized controlled trial. *Sleep, 35*(4), 477-481.

Frank-Stromborg, M., & Olsen, S. J. (2004). *Instruments for clinical health-care research*: Jones & Bartlett Learning.

Franklin, K. A., & Lindberg, E. (2015). Obstructive sleep apnea is a common disorder in the population—a review on the epidemiology of sleep apnea. *Journal of Thoracic Disease, 7*(8), 1311.

Fung, C. H., Martin, J. L., Igodan, U., Jouldjian, S., & Alessi, C. (2012). The association between difficulty using positive airway pressure equipment and adherence to therapy: a pilot study. *Sleep and Breathing, 17*(2), 853-859. doi:10.1007/s11325-012-0779-y

Gami, A. S., Olson, E. J., Shen, W. K., Wright, R. S., Ballman, K. V., Hodge, D. O., . . . Somers, V. K. (2013). Obstructive sleep apnea and the risk of sudden cardiac death: A longitudinal study of 10,701 adults. *Journal of the American College of Cardiology, 62*(7), 610-616. Retrieved from http://www.sciencedirect.com/science/article/pii/S0735109713022511. doi:10.1016/j.jacc.2013.04.080

Giles, T. L., Lasserson, T. J., Smith, B. J., White, J., Wright, J., & Cates, C. J. (2006). Continuous positive airways pressure for obstructive sleep apnoea in adults. *Cochrane Database Systematic Review*(1), CD001106. doi:10.1002/14651858.CD001106.pub2

Google Scholar. (2019). Theory of planned behavior. Retrieved from https://scholar.google.com/scholar?q=theory+of+planned+behavior&btnG=&hl=en&as_sdt=0%2C43

Gottlieb, D. J., Yenokyan, G., Newman, A. B., O'Connor, G. T., Punjabi, N. M., Quan, S. F., . . . Shahar, E. (2010). Prospective study of obstructive sleep apnea and incident coronary heart disease and heart failure: The sleep heart health study. *Circulation, 122*(4), 352-360. Retrieved from http://circ.ahajournals.org/content/122/4/352.abstract. doi:10.1161/circulationaha.109.901801

Guilleminault, C., Tilkian, A., & Dement, W. C. (1976). The sleep apnea syndromes. *Annual Review of Medicine, 27*(1), 465-484. Retrieved from http://www.annualreviews.org/doi/abs/10.1146/annurev.me.27.020176.002341. doi:doi:10.1146/annurev.me.27.020176.002341

Haba-Rubio, J., Marti-Soler, H., Tobback, N., Andries, D., Marques-Vidal, P., Waeber, G., . . . Popp, J. (2017). Sleep characteristics and cognitive impairment in the general population. *The HypnoLaus study, 88*(5), 463-469. Retrieved from https://n.neurology.org/content/neurology/88/5/463.full.pdf. doi:10.1212/wnl.0000000000003557

Harris, P. A., Taylor, R., Thielke, R., Payne, J., Gonzalez, N., & Conde, J. G. (2009). Research electronic data capture (REDCap)--a metadata-driven methodology and workflow process for providing translational research informatics support. *Journal of Biomedical Informatics, 42*(2), 377-381. doi:10.1016/j.jbi.2008.08.010

Heinzer, R. C., Pellaton, C., Rey, V., Rossetti, A. O., Lecciso, G., Haba-Rubio, J., . . . Lavigne, G. (2012). Positional therapy for obstructive sleep apnea: an objective measurement of patients' usage and efficacy at home. *Sleep Medicine, 13*(4), 425-428.

Hita-Yanez, E., Atienza, M., & Cantero, J. L. (2013). Polysomnographic and subjective sleep markers of mild cognitive impairment. *Sleep, 36*(9), 1327-1334.

Hla, K.M., Young, T., Hagen, E.W., Stein, J.H., Finn, L.A., Nieto, F.J. and Peppard, P.E., 2015. Coronary heart disease incidence in sleep disordered breathing: the Wisconsin Sleep Cohort Study. *Sleep, 38*(5), 677-684.

Hochbaum, G., Rosenstock, I., & Kegels, S. (1952). Health belief model. *United States Public Health Service*, W432W8784.

Hwang, D., Chang, J. W., Benjafield, A. V., Crocker, M. E., Kelly, C., Becker, K. A., . . . Derose, S. F. (2018). Effect of telemedicine education and telemonitoring on continuous positive airway pressure adherence: The tele-OSA randomized trial. *American Journal of Respiratory and Critical Care Medicine, 197*(1), 117-126. doi:10.1164/rccm.201703-0582OC

James, P. A., Oparil, S., Carter, B. L., Cushman, W. C., Dennison-Himmelfarb, C., Handler, J., . . . Ortiz, E. (2014). 2014 evidence-based guideline for the management of high blood pressure in adults: report from the panel members appointed to the Eighth Joint National Committee (JNC 8). *Journal of the American Medical Association, 311*(5), 507-520. doi:10.1001/jama.2013.284427

Johns, M. W. (1991). A new method for measuring daytime sleepiness: the Epworth Sleepiness Scale. *Sleep, 14*(6), 540-545.

Johns, M. W. (1992). Reliability and factor analysis of the Epworth Sleepiness Scale. *Sleep, 15*(4), 376-381.

Johnson, D. A., Guo, N., Rueschman, M., Wang, R., Wilson, J. G., & Redline, S. (2018). Prevalence and correlates of obstructive sleep apnea among African Americans: the Jackson Heart Sleep Study. *Sleep, 41*(10), 1-9. Retrieved from https://doi.org/10.1093/sleep/zsy154. doi:10.1093/sleep/zsy154

Joosten, S. A., Khoo, J. K., Edwards, B. A., Landry, S. A., Naughton, M. T., Dixon, J. B., & Hamilton, G. S. (2017). Improvement in obstructive sleep apnea with weight loss is dependent on body position during sleep. *Sleep, 40*(5), zsx047.

Kasai, T., & Bradley, T. D. (2011). Obstructive sleep apnea and heart failure: Pathophysiologic and therapeutic implications. *Journal of the American College of Cardiology, 57*(2), 119-127. Retrieved from http://www.sciencedirect.com/science/article/pii/S0735109710043354. doi:10.1016/j.jacc.2010.08.627

Khonsari, S., Subramanian, P., Chinna, K., Latif, L. A., Ling, L. W., & Gholami, O. (2015). Effect of a reminder system using an automated short message service on medication adherence following acute coronary syndrome. *European Journal of Cardiovascular Nursing, 14*(2), 170-179. doi:10.1177/1474515114521910

Knauert, M., Naik, S., Gillespie, M. B., & Kryger, M. (2015). Clinical consequences and economic costs of untreated obstructive sleep apnea syndrome. *World Journal of Otorhinolaryngology-Head and Neck Surgery*. Retrieved from http://www.sciencedirect.com/science/article/pii/S2095881115300081. doi:10.1016/j.wjorl.2015.08.001

Krass, I., Schieback, P., & Dhippayom, T. (2015). Adherence to diabetes medication: a systematic review. *Diabetic Medicine, 32*(6), 725-737.

Kribbs, N. B., Pack, A. I., Kline, L. R., Smith, P. L., Schwartz, A. R., Schubert, N. M., . . . Dinges, D. F. (1993). Objective measurement of patterns of nasal CPAP use by patients with obstructive sleep apnea. *American Review of Respiratory Disease, 147*(4), 887-895. Retrieved from http://dx.doi.org/10.1164/ajrccm/147.4.887. doi:10.1164/ajrccm/147.4.887

Kruse, C. S., Bolton, K., & Freriks, G. (2015). The effect of patient portals on quality outcomes and its implications to meaningful use: A systematic review. *Journal of Medical Internet Research, 17*(2), 1-8.

Law, M., Naughton, M., Ho, S., Roebuck, T., & Dabscheck, E. (2014). Depression may reduce adherence during CPAP titration trial. *Journal of Clinical Sleep Medicine, 10*(02), 163-169.

Leon, A. C., Davis, L. L., & Kraemer, H. C. (2011). The role and interpretation of pilot studies in clinical research. *Journal of Psychiatric Research, 45*(5), 626-629. doi:10.1016/j.jpsychires.2010.10.008

Louis, M., & Punjabi, N. M. (2009). Effects of acute intermittent hypoxia on glucose metabolism in awake healthy volunteers. *Journal of Applied Physiology, 106*(5), 1538-1544. Retrieved from http://jap.physiology.org/jap/106/5/1538.full.pdf. doi:10.1152/japplphysiol.91523.2008

Mannarino, M. R., Di Filippo, F., & Pirro, M. (2012). Obstructive sleep apnea syndrome. *European Journal of Internal Medicine, 23*(7), 586-593. Retrieved from http://www.sciencedirect.com/science/article/pii/S0953620512001525. doi:10.1016/j.ejim.2012.05.013

Marshall, N. S., Wong, K. K., Cullen, S. R., Knuiman, M. W., & Grunstein, R. R. (2014). Sleep apnea and 20-year follow-up for all-cause mortality, stroke, and cancer incidence and mortality in the Busselton Health Study cohort. *Journal of Clinical Sleep Medicine, 10*(4), 355-362. doi:10.5664/jcsm.3600

Martínez-García, M. Á., Soler-Cataluña, J. J., Ejarque-Martínez, L., Soriano, Y., Román-Sánchez, P., Illa, F. B., . . . Durán-Cantolla, J. (2009). Continuous positive airway pressure treatment reduces mortality in patients with ischemic stroke and obstructive sleep apnea: a 5-year follow-up study. *American Journal of Respiratory and Critical Care Medicine, 180*(1), 36-41.

McDaid, C., Durée, K. H., Griffin, S. C., Weatherly, H. L., Stradling, J. R., Davies, R. J., . . . Westwood, M. E. (2009). A systematic review of continuous positive airway pressure for obstructive sleep apnoea–hypopnoea syndrome. *Sleep Medicine Reviews, 13*(6), 427-436.

McEachan, R. R. C., Conner, M., Taylor, N. J., & Lawton, R. J. (2011). Prospective prediction of health-related behaviours with the Theory of Planned Behaviour: a meta-analysis. *Health Psychology Review, 5*(2), 97-144. doi:10.1080/17437199.2010.521684

McEvoy, R. D., Antic, N. A., Heeley, E., Luo, Y., Ou, Q., Zhang, X., . . . Anderson, C. S. (2016). CPAP for prevention of cardiovascular events in obstructive sleep apnea. *New*

England Journal of Medicine, 375(10), 919-931. Retrieved from https://www.nejm.org/doi/full/10.1056/NEJMoa1606599. doi:10.1056/NEJMoa1606599

Moran, A., Everhart, D., Davis, C., Wuensch, K., Lee, D., & Demaree, H. (2011). Personality correlates of adherence with continuous positive airway pressure (CPAP). *Sleep and Breathing, 15*(4), 687-694. doi:10.1007/s11325-010-0422-8

Munafo, D., Hevener, W., Crocker, M., Willes, L., Sridasome, S., & Muhsin, M. a. (2016). A telehealth program for CPAP adherence reduces labor and yields similar adherence and efficacy when compared to standard of care. *Sleep and Breathing*, 1-9. doi:10.1007/s11325-015-1298-4

Munks, R., Knuiman, M., Hunter, M., Hillman, D., Divitini, M., & James, A. (2019). Healthcare-seeking behaviour and utilization of treatment in a community-based screening study for obstructive sleep apnoea in Busselton, Western Australia. *Sleep Health, 5*(1), 91-100. Retrieved from http://www.sciencedirect.com/science/article/pii/S2352721818301888. doi:https://doi.org/10.1016/j.sleh.2018.10.009

Munro, S., Lewin, S., Swart, T., & Volmink, J. (2007). A review of health behaviour theories: how useful are these for developing interventions to promote long-term medication adherence for TB and HIV/AIDS? *BMC Public Health, 7*, 104-104. doi:10.1186/1471-2458-7-104

Naik, S., Kreinin, I., & Kryger, M. (2019). Centers for Medicare and Medicaid Services positive airway pressure adherence criteria may limit treatment to many medicare beneficiaries. *Journal of Clinical Sleep Medicine, 15*(2), 245-251.

National Cholesterol Education Program. (2001). Executive Summary of The Third Report of The National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, And Treatment of High Blood Cholesterol In Adults (Adult Treatment Panel III). *Journal of the American Medical Association, 285*(19), 2486-2497.

Newman, M. A. (2009). Prevailing paradigms in nursing. In P. G. Reed & N. B. Crawford Shearer (Eds.), *Perspectives on nursing theory* (5th ed., pp. 221-226). Philadelphia, PA: Lippincott, Williams, & Wilkins.

Nuckton, T. J., Glidden, D. V., Browner, W. S., & Claman, D. M. (2006). Physical examination: Mallampati score as an independent predictor of obstructive sleep apnea. *Sleep, 29*(7), 903-908.

Orji, R., Vassileva, J., & Mandryk, R. (2012). Towards an effective health interventions design: An extension of the health belief model. *Online Journal of Public Health Informatics, 4*(3), ojphi.v4i3.4321. doi:10.5210/ojphi.v4i3.4321

Osorio, R. S., Gumb, T., Pirraglia, E., Varga, A. W., Lu, S.-e., Lim, J., . . . de Leon, M. J. (2015). Sleep-disordered breathing advances cognitive decline in the elderly. *Neurology, 84*(19), 1964-1971. Retrieved from https://n.neurology.org/content/neurology/84/19/1964.full.pdf. doi:10.1212/wnl.0000000000001566

Pace-Schott, E. F. (2009). Sleep architecture. In R. Stickgold & M. P. Walker (Eds.), *The neuroscience of sleep* (pp. 11-17). Spain: Elsevier, Inc.

Pamidi, S., & Tasali, E. (2012). Obstructive sleep apnea and type 2 diabetes: is there a link? *Frontiers in Neurology, 3*(126), 1-13.

Peppard, P., Szklo-Coxe, M., Hla, K. M., & Young, T. (2006). Longitudinal association of sleep-related breathing disorder and depression. *Archives of Internal Medicine, 166*(16), 1709-1715. doi:10.1001/archinte.166.16.1709

Peppard, P., Young, T., Barnet, J. H., Palta, M., Hagen, E. W., & Hla, K. M. (2013). Increased prevalence of sleep-disordered breathing in adults. *American Journal of Epidemiology, 177*(9), 1006-1014. Retrieved from http://aje.oxfordjournals.org/content/177/9/1006.abstract. doi:10.1093/aje/kws342

Peppard, P., Young, T., Palta, M., Dempsey, J., & Skatrud, J. (2000). Longitudinal study of moderate weight change and sleep-disordered breathing. *Journal of the American Medical Association, 284*(23), 3015-3021.

Pew Research Center. (2016). 13% of Americans don't use the internet. Who are they? *FactTank: News in the numbers.* Retrieved from http://www.pewresearch.org/fact-tank/2016/09/07/some-americans-dont-use-the-internet-who-are-they/

Pew Research Center. (2018a). Mobile technology fact sheet. *Fact Sheet.* Retrieved from http://www.pewinternet.org/fact-sheet/mobile/

Pew Research Center. (2018b). Social media use in 2018. Retrieved from http://www.pewinternet.org/2018/03/01/social-media-use-in-2018/

Platt, A. B., Kuna, S. T., Field, S. H., Chen, Z., Gupta, R., Roche, D. F., . . . Asch, D. A. (2010). Adherence to sleep apnea therapy and use of lipid-lowering drugs: a study of the healthy-user effect. *Chest, 137*(1), 102-108. doi:10.1378/chest.09-0842

Poulet, C., Veale, D., Arnol, N., Lévy, P., Pepin, J. L., & Tyrrell, J. (2009). Psychological variables as predictors of adherence to treatment by continuous positive airway pressure. *Sleep Medicine, 10*(9), 993-999. doi:http://dx.doi.org/10.1016/j.sleep.2009.01.007

Punjabi, N. M. (2008). The epidemiology of adult obstructive sleep apnea. *Proceedings of the American Thoracic Society, 5*(2), 136-143. Retrieved from http://www.atsjournals.org/doi/abs/10.1513/pats.200709-155MG. doi:10.1513/pats.200709-155MG

Raparelli, V., Proietti, M., Cangemi, R., Lip, G. Y., Lane, D. A., & Basili, S. (2017). Adherence to oral anticoagulant therapy in patients with atrial fibrillation. *Thrombosis and Haemostasis, 117*(02), 209-218.

Rauscher, H., Formanek, D., Popp, W., & Zwick, H. (1993). Self-reported vs measured compliance with nasal CPAP for obstructive sleep apnea. *Chest, 103*(6), 1675-1680. doi:10.1378/chest.103.6.1675

Redline, S., Yenokyan, G., Gottlieb, D. J., Shahar, E., O'Connor, G. T., Resnick, H. E., . . . Geraghty, E. M. (2010). Obstructive sleep apnea–hypopnea and incident stroke: the sleep heart health study. *American Journal of Respiratory and Critical Care Medicine, 182*(2), 269-277.

Rich, A., Brandes, K., Mullan, B., & Hagger, M. S. (2015). Theory of planned behavior and adherence in chronic illness: a meta-analysis. *Journal of Behavioral Medicine, 38*(4), 673-688. doi:10.1007/s10865-015-9644-3

Richards, D., Bartlett, D. J., Wong, K., Malouff, J., & Grunstein, R. R. (2007). Increased adherence to CPAP with a group cognitive behavioral treatment intervention: a randomized trial. *Sleep, 30*(5), 635-640.

Riley, W. T., Rivera, D. E., Atienza, A. A., Nilsen, W., Allison, S. M., & Mermelstein, R. (2011). Health behavior models in the age of mobile interventions: are our theories up to the task? *Translational Behavioral Medicine, 1*(1), 53-71.

Rodgers, B. (2013). Breaking through limbo: Experiences of adults living with obstructive sleep apnea. *Behavioral Sleep Medicine, 12*(3), 183-197. doi:10.1080/15402002.2013.778203

Rogers, R. W. (1975). A protection motivation theory of fear appeals and attitude change. *The Journal of Psychology, 91*(1), 93-114.

Rogers, R. W. (1983). Cognitive and physiological processes in fear appeals and attitude change: A revised theory of protection motivation. In J. Cacioppo & R. Petty (Eds.), *Social psychophysiology: A sourcebook* (pp. 153-177). New York, NY: Guilford.

Rogers, R. W., & Prentice-Dunn, S. (1997). Protection motivation theory. In D. Gochman (Ed.), *Handbook of health behavior research: Determinants of health behavior: Personal and social* (Vol. 1, pp. 113-132). New York, NY: Plenum Press.

Rosenthal, L., Gerhardstein, R., Lumley, A., Guido, P., Day, R., Syron, M. L., & Roth, T. (2000). CPAP therapy in patients with mild OSA: implementation and treatment outcome. *Sleep Medicine, 1*(3), 215-220.

Rotenberg, B. W., Murariu, D., & Pang, K. P. (2016). Trends in CPAP adherence over twenty years of data collection: a flattened curve. *Journal of Otolaryngology - Head & Neck Surgery, 45*(1), 43. doi:10.1186/s40463-016-0156-0

Rowland, S., Aiyappan, V., Hennessy, C., Catcheside, P., Chai-Coezter, C. L., McEvoy, R. D., & Antic, N. A. (2018). Comparing the efficacy, mask leak, patient adherence, and patient preference of three different CPAP interfaces to treat moderate-severe obstructive sleep apnea. *Journal of Clinical Sleep Medicine, 14*(1), 101-108. doi:10.5664/jcsm.6892

Ruppar, T. M., Cooper, P. S., Mehr, D. R., Delgado, J. M., & Dunbar-Jacob, J. M. (2016). Medication adherence interventions improve heart failure mortality and readmission rates: Systematic review and meta-analysis of controlled trials. *Journal of the American Heart Association, 5*(6), e002606.

Ryan, S., Garvey, J. F., Swan, V., Behan, R., & McNicholas, W. T. (2011). Nasal pillows as an alternative interface in patients with obstructive sleep apnoea syndrome initiating continuous positive airway pressure therapy. *Journal of Sleep Research, 20*(2), 367-373.

Sabaté, E. (2003). *Adherence to long-term therapies: Evidence for action*: World Health Organization.

Sassani, A., Findley, L. J., Kryger, M., Goldlust, E., George, C., & Davidson, T. M. (2004). Reducing motor-vehicle collisions, costs, and fatalities by treating obstructive sleep apnea syndrome. *Sleep, 27*(3), 453-458.

Sawyer, A. M., Deatrick, J. A., Kuna, S. T., & Weaver, T. E. (2010). Differences in perceptions of the diagnosis and treatment of obstructive sleep apnea and continuous positive airway pressure therapy among adherers and nonadherers. *Qualitative Health Research, 20*(7), 873-892. doi:10.1177/1049732310365502

Sawyer, A. M., Gooneratne, N. S., Marcus, C. L., Ofer, D., Richards, K. C., & Weaver, T. E. (2011). A systematic review of CPAP adherence across age groups: Clinical and empiric insights for developing CPAP adherence interventions. *Sleep Medicine Reviews, 15*(6), 343-356. Retrieved from http://www.sciencedirect.com/science/article/pii/S1087079211000050. doi:http://dx.doi.org/10.1016/j.smrv.2011.01.003

Schwab, R. J., Badr, S. M., Epstein, L. J., Gay, P. C., Gozal, D., Kohler, M., . . . Weaver, T. E. (2013). An official American Thoracic Society statement: continuous positive airway pressure adherence tracking systems. The optimal monitoring strategies and outcome measures in adults. *American Journal of Respiratory and Critical Care Medicine, 188*(5), 613-620. doi:10.1164/rccm.201307-1282ST

Sedkaoui, K., Leseux, L., Pontier, S., Rossin, N., Leophonte, P., Fraysse, J.-L., & Didier, A. (2015). Efficiency of a phone coaching program on adherence to continuous positive airway pressure in sleep apnea hypopnea syndrome: a randomized trial. *BMC Pulmonary Medicine, 15*(1), 102. doi:10.1186/s12890-015-0099-7

Senaratna, C. V., Perret, J. L., Lodge, C. J., Lowe, A. J., Campbell, B. E., Matheson, M. C., . . . Dharmage, S. C. (2016). Prevalence of obstructive sleep apnea in the general population: A systematic review. *Sleep Medicine Reviews,* 1-12. Retrieved from http://www.sciencedirect.com/science/article/pii/S1087079216300648. doi:10.1016/j.smrv.2016.07.002

Shahid, A., Wilkinson, K., Marcu, S., & Shapiro, C. (2012a). Apnea Belief Scale. In A. Shahid, K. Wilkinson, S. Marcu, & C. Shapiro (Eds.), *STOP, THAT and one hundred other sleep scales* (pp. 47-48). New York: Springer.

Shahid, A., Wilkinson, K., Marcu, S., & Shapiro, C. (2012b). Epworth Sleepiness Scale. In A. Shahid, K. Wilkinson, S. Marcu, & C. Shapiro (Eds.), *STOP, THAT and one hundred other sleep scales* (pp. 149-150).

Shahid, A., Wilkinson, K., Marcu, S., & Shapiro, C. (2012c). Functional Outcomes of Sleep Questionnaire. In A. Shahid, K. Wilkinson, S. Marcu, & C. Shapiro (Eds.), *STOP, THAT and one hundred other sleep scales* (pp. 179-180).

Shapiro, G., & Shapiro, C. (2010). Factors that influence CPAP adherence: an overview. *Sleep and Breathing, 14*(4), 323-335. doi:10.1007/s11325-010-0391-y

Sharma, S. K., Agrawal, S., Damodaran, D., Sreenivas, V., Kadhiravan, T., Lakshmy, R., . . . Kumar, A. (2011). CPAP for the metabolic syndrome in patients with obstructive sleep apnea. *New England Journal of Medicine, 365*(24), 2277-2286.

Shetty, S., & Parthasarathy, S. (2015). Obesity hypoventilation syndrome. *Current Pulmonology Reports, 4*(1), 42-55. doi:10.1007/s13665-015-0108-6

Smith, C., Gold, J., Ngo, T. D., Sumpter, C., & Free, C. (2015). Mobile phone-based interventions for improving contraception use. *Cochrane Database of Systematic Reviews*(6), Cd011159. doi:10.1002/14651858.CD011159.pub2

Smith, S., Lang, C., Sullivan, K., & Warren, J. (2004). Two new tools for assessing patients' knowledge and beliefs about obstructive sleep apnea and continuous positive airway pressure therapy. *Sleep Medicine, 5*(4), 359-367. Retrieved from http://www.sciencedirect.com/science/article/pii/S1389945704000590. doi:10.1016/j.sleep.2003.12.007

Somers, V. K., White, D. P., Amin, R., Abraham, W. T., Costa, F., Culebras, A., . . . Young, T. (2008). Sleep apnea and cardiovascular disease: an American Heart Association/American College of Cardiology Foundation Scientific Statement from the American Heart Association Council for High Blood Pressure Research Professional Education Committee, Council on Clinical Cardiology, Stroke Council, and Council on Cardiovascular Nursing. *Circulation, 118*(10), 1080-1111. Retrieved from http://circ.ahajournals.org/content/118/10/1080.short. doi:10.1161/circulationaha.107.189420

Somiah, M., Taxin, Z., Keating, J., Mooney, A. M., Norman, R. G., Rapoport, D. M., & Ayappa, I. (2012). Sleep quality, short-term and long-term CPAP adherence. *Journal of Clinical Sleep Medicine, 8*(5), 489-500.

Sparrow, D., Aloia, M., Demolles, D. A., & Gottlieb, D. J. (2010). A telemedicine intervention to improve adherence to continuous positive airway pressure: a randomised controlled trial. *Thorax, 65*(12), 1061-1066. doi:10.1136/thx.2009.133215

State of Tennessee. (2015). 47-10-107. Legal recognition of electronic records, electronic signatures, and electronic contracts. *Laws, Policy, and Guides.* Retrieved from https://www.tn.gov/lawsandpolicies/article/47-10-107.-legal-recognition-of-electronic-records-electronic-signatures-an

Stepnowsky, C., Zamora, T., Edwards, C., Liu, L., & Agha, Z. (2013). Interventions to improve CPAP adherence and outcomes: Role of theory and behavioral change techniques. *Journal of Sleep Disorders and Therapy, 2*(133), 2167-0277.1000133.

Stansbury, R. C., & Strollo, P. J. (2015). Clinical manifestations of sleep apnea. *Journal of Thoracic Disease, 7*(9), E298-E310. Retrieved from http://www.jthoracdis.com/article/view/5253

State of Tennessee. (2015). 47-10-107. Legal recognition of electronic records, electronic signatures, and electronic contracts. *Laws, Policy, and Guides.* Retrieved from https://www.tn.gov/lawsandpolicies/article/47-10-107.-legal-recognition-of-electronic-records-electronic-signatures-an

Sudak, D. M. (2006). *Cognitive behavioral therapy for clinicians*. Philadelphia, PA: Lippincott Williams & Wilkins.

Sutherland, K., Vanderveken, O., Tsuda, H., Marklund, M., Gagnadoux, F., Kushida, C., & Cistulli, P. (2014). Oral appliance treatment for obstructive sleep apnea: an update. *Journal of Clinical Sleep Medicine, 10*(2), 215-227.

Taylor, Y., Eliasson, A., Andrada, T., Kristo, D., & Howard, R. (2006). The role of telemedicine in CPAP compliance for patients with obstructive sleep apnea syndrome. *Sleep and Breathing, 10*(3), 132-138.

The Office of the National Coordinator for Health Information Technology. (n.d.). What is a patient portal? Retrieved from https://www.healthit.gov/faq/what-patient-portal

Turnbull, C. D., Bratton, D. J., Craig, S. E., Kohler, M., & Stradling, J. R. (2016). In patients with minimally symptomatic OSA can baseline characteristics and early patterns of CPAP usage predict those who are likely to be longer-term users of CPAP. *Journal of Thoracic Disease, 8*(2), 276-281. Retrieved from https://www.ncbi.nlm.nih.gov/pubmed/26904268. doi:10.3978/j.issn.2072-1439.2016.01.54

Upender, R. (2017) *Interview with Dr. Upender regarding recruitment estimates/Interviewer: J. T. Dunlap*.

U.S. Census Bureau. (2017). 2013-2017 American community survey 5-year estimates. Retrieved from https://factfinder.census.gov/faces/nav/jsf/pages/index.xhtml

U.S. Congress. (2010). *Patient Protection and Affordable Care Act*. Washington, D.C.: U.S. Congress Retrieved from https://www.congress.gov/bill/111th-congress/house-bill/3590

van Maanen, J. P., Meester, K. A., Dun, L. N., Koutsourelakis, I., Witte, B. I., Laman, D. M., . . . de Vries, N. (2013). The sleep position trainer: A new treatment for positional obstructive sleep apnoea. *Sleep and Breathing, 17*(2), 771-779.

Vanderveken, O. M., Dieltjens, M., Wouters, K., De Backer, W. A., Van de Heyning, P. H., & Braem, M. J. (2012). Objective measurement of compliance during oral appliance therapy for sleep-disordered breathing. *Thorax*, thoraxjnl-2012-201900.

Verma, S. (2018). Quality payment program exceeds year 1 participation goal. *Blog.* Retrieved from https://www.cms.gov/blog/quality-payment-program-exceeds-year-1-participation-goal

Vincent, D., & Reed, P. G. (2014). Affordable Care Act:Overview and implications for advancing nursing. *Nursing Science Quarterly, 27*(3), 254-259. Retrieved from https://journals.sagepub.com/doi/abs/10.1177/0894318414534494. doi:10.1177/0894318414534494

Wald, D. S., Bestwick, J. P., Raiman, L., Brendell, R., & Wald, N. J. (2014). Randomised trial of text messaging on adherence to cardiovascular preventive treatment (INTERACT trial). *PLoS ONE, 9*(12), e114268. doi:10.1371/journal.pone.0114268

Ward, K., Hoare, K. J., & Gott, M. (2014). What is known about the experiences of using CPAP for OSA from the users' perspective? A systematic integrative literature review. *Sleep Medicine Reviews, 18*(4), 357-366.

Weaver, T. E., & Grunstein, R. R. (2008). Adherence to continuous positive airway pressure therapy: The challenge to effective treatment. *Proceedings of the American Thoracic Society, 5*(2), 173-178. doi:10.1513/pats.200708-119MG

Weaver, T. E., Kribbs, N. B., Pack, A. I., Kline, L. R., Chugh, D. K., Maislin, G., . . . Dinges, D. F. (1997). Night-to-night variability in CPAP use over the first three months of treatment. *Sleep, 20*(4), 278-283.

Weaver, T. E., Laizner, A. M., Evans, L. K., Maislin, G., Chugh, D. K., Lyon, K., . . . Dinges, D. F. (1997). An instrument to measure functional status outcomes for disorders of excessive sleepiness. *Sleep, 20*(10), 835-843.

Weaver, T. E., Maislin, G., Dinges, D. F., Younger, J., Cantor, C., McCloskey, S., & Pack, A. I. (2003). Self-efficacy in sleep apnea: instrument development and patient perceptions of obstructive sleep apnea risk, treatment benefit, and volition to use continuous positive airway pressure. *Sleep, 26*(6), 727-734.

Weaver, T. E., & Sawyer, A. M. (2010). Adherence to continuous positive airway pressure treatment for obstructive sleep apnea: implications for future interventions. *The Indian Journal of Medical Research, 131*, 245.

Whittaker, R., McRobbie, H., Bullen, C., Rodgers, A., & Gu, Y. (2016). Mobile phone-based interventions for smoking cessation. *Cochrane Database of Systematic Reviews, 4*, Cd006611. doi:10.1002/14651858.CD006611.pub4

Woehrle, H., Ficker, J. H., Graml, A., Fietze, I., Young, P., Teschler, H., & Arzt, M. (2017). Telemedicine-based proactive patient management during positive airway pressure therapy. *Somnologie,* 1-7. doi:10.1007/s11818-016-0098-9

Wozniak, D. R., Lasserson, T. J., & Smith, I. (2014). Educational, supportive and behavioural interventions to improve usage of continuous positive airway pressure machines in adults

with obstructive sleep apnoea. *The Cochrane Library*(1), CD007736. doi:10.1002/14651858.CD007736.pub2

Ye, L., Pack, A. I., Maislin, G., Dinges, D., Hurley, S., McCloskey, S., & Weaver, T. E. (2011). Predictors of continuous positive airway pressure use during the first week of treatment. *Journal of Sleep Research, 21(4),* 419-426. doi:10.1111/j.1365-2869.2011.00969.x

Yoshihisa, A., Suzuki, S., Owada, T., Iwaya, S., Yamauchi, H., Miyata, M., . . . Nakazato, K. (2013). Short-term use of adaptive servo ventilation improves renal function in heart failure patients with sleep-disordered breathing. *Heart and Vessels, 28*(6), 728-734.

Young, T., Palta, M., Dempsey, J., Peppard, P. E., Nieto, F. J., & Hla, K. M. (2009). Burden of sleep apnea: rationale, design, and major findings of the Wisconsin Sleep Cohort study. *WMJ, 108*(5), 246-249.

Zaghi, S., Holty, J.-E. C., Certal, V., Abdullatif, J., Guilleminault, C., Powell, N. B., . . . Camacho, M. (2016). Maxillomandibular advancement for treatment of obstructive sleep apnea: a meta-analysis. *JAMA Otolaryngology–Head & Neck Surgery, 142*(1), 58-66.

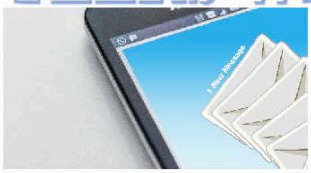
Zigmond, A. S., & Snaith, R. P. (1983). The Hospital Anxiety and Depression Scale. *Acta Psychiatrica Scandinavica, 67*(6), 361-370. doi:10.1111/j.1600-0447.1983.tb09716.x

Appendices

Appendix A

Recruitment Flyer

VOLUNTEERS WANTED



Text Messages for CPAP Users

Are you over the age of 18 and think you may use CPAP if you are diagnosed with sleep apnea? My name is Travis Dunlap and I am conducting a research study about sending text messages to individuals who are using a CPAP device.

If you are interested, please contact me at **(615) 592-1262** or by e-mail at travis.dunlap@vanderbilt.edu . You can also let the staff in the sleep clinic know that it is OK I contact you.

Benefits you may receive from being in the study include better management of your sleep apnea.

If you are diagnosed with sleep apnea and agree to participate in the study:

- You will receive an email with a link asking you to answer 4 short questionnaires (takes about 20 minutes). You may also answer the questionnaires over the phone if you choose.
- After you begin using the CPAP device, you will receive 1 text message a week for 4 weeks.
- After 4 weeks, you will get another email message with a link asking you to answer 3 of the previous questionnaires again. You may also answer the questionnaires over the phone if you choose.
- After answering the 3 questionnaires, you will be finished with the study.

Participants who complete all of the questionnaires will be entered to receive one of two $100 Visa electronic gift cards

THANK YOU for your help in this study!!!

This research is conducted under the direction of Dr. Raghu Upender of the Vanderbilt Sleep Clinic.
(IRB number: #180131)

Appendix B

Apnea Belief Scale

Confidential

Apnea Belief Scale

Please complete the survey below.

Answer each of these questions by selecting the number that represents your answer.

1)	Sleep apnea has no effect on my life	◯ Strongly disagree ◯ Disagree ◯ Not sure / neutral ◯ Agree ◯ Strongly agree
2)	If things become too much I generally don't go through with them	◯ Strongly disagree ◯ Disagree ◯ Not sure / neutral ◯ Agree ◯ Strongly agree
3)	CPAP is "the answer" to my sleep apnea	◯ Strongly disagree ◯ Disagree ◯ Not sure / neutral ◯ Agree ◯ Strongly agree
4)	Sleep apnea gets in the way of my friendships	◯ Strongly disagree ◯ Disagree ◯ Not sure / neutral ◯ Agree ◯ Strongly agree
5)	I intend to use the CPAP machine all night every night.	◯ Strongly disagree ◯ Disagree ◯ Not sure / neutral ◯ Agree ◯ Strongly agree
6)	I believe using the CPAP mask will be a nuisance	◯ Strongly disagree ◯ Disagree ◯ Not sure / neutral ◯ Agree ◯ Strongly agree
7)	I am willing to ask for help when it is required	◯ Strongly disagree ◯ Disagree ◯ Not sure / neutral ◯ Agree ◯ Strongly agree
8)	CPAP is the best treatment for my health problems	◯ Strongly disagree ◯ Disagree ◯ Not sure / neutral ◯ Agree ◯ Strongly agree

9)	I am willing to follow the directions of medical staff "to the letter"	◯ Strongly disagree ◯ Disagree ◯ Not sure / neutral ◯ Agree ◯ Strongly agree
10)	I believe that using CPAP is very confusing	◯ Strongly disagree ◯ Disagree ◯ Not sure / neutral ◯ Agree ◯ Strongly agree
11)	Wearing the CPAP mask will make falling asleep hard	◯ Strongly disagree ◯ Disagree ◯ Not sure / neutral ◯ Agree ◯ Strongly agree
12)	Once I make a decision, I stick with that decision	◯ Strongly disagree ◯ Disagree ◯ Not sure / neutral ◯ Agree ◯ Strongly agree
13)	Wearing the CPAP mask will improve the quality of my sleep	◯ Strongly disagree ◯ Disagree ◯ Not sure / neutral ◯ Agree ◯ Strongly agree
14)	I find it stressful to use new machinery or technology	◯ Strongly disagree ◯ Disagree ◯ Not sure / neutral ◯ Agree ◯ Strongly agree
15)	Good health is secondary to being able to do what I want in life	◯ Strongly disagree ◯ Disagree ◯ Not sure / neutral ◯ Agree ◯ Strongly agree
16)	I enjoy trying new things, like snorkeling	◯ Strongly disagree ◯ Disagree ◯ Not sure / neutral ◯ Agree ◯ Strongly agree
17)	I don't believe I have a sleep problem	◯ Strongly disagree ◯ Disagree ◯ Not sure / neutral ◯ Agree ◯ Strongly agree
18)	I find it embarrassing to ask for help	◯ Strongly disagree ◯ Disagree ◯ Not sure / neutral ◯ Agree ◯ Strongly agree

19)	Sleep apnea is my major health problem	◯ Strongly disagree ◯ Disagree ◯ Not sure / neutral ◯ Agree ◯ Strongly agree
20)	I believe that CPAP will make little difference to my sleep	◯ Strongly disagree ◯ Disagree ◯ Not sure / neutral ◯ Agree ◯ Strongly agree
21)	I want to improve my health	◯ Strongly disagree ◯ Disagree ◯ Not sure / neutral ◯ Agree ◯ Strongly agree
22)	I am confident that I will be able to use the CPAP machine as taught	◯ Strongly disagree ◯ Disagree ◯ Not sure / neutral ◯ Agree ◯ Strongly agree
23)	I would try anything that I thought might help my sleep apnea	◯ Strongly disagree ◯ Disagree ◯ Not sure / neutral ◯ Agree ◯ Strongly agree
24)	I believe that I know what is the best treatment for me	◯ Strongly disagree ◯ Disagree ◯ Not sure / neutral ◯ Agree ◯ Strongly agree

Appendix C

ABS Permission E-mail from Author

Dunlap, Travis (Travis Dunlap)

From: Simon Smith <simon.smith@qut.edu.au>
Sent: Monday, March 27, 2017 9:59 PM
To: Dunlap, John Travis (Travis Dunlap)
Subject: Re: Permission to use Apnea Belief Scale
Attachments: Apnea Beliefs Scale_2017_2.doc

Hi Travis,

Thanks you for your interest in our work. You are free to use the ABS as published, just acknowledge us where appropriate. I've attached a version with the reverse-scored items noted in red.
April Shapiro is completing her PhD in nursing at West Virginia University and has done a factor analysis of the scale, it might be worth contacting her about that.
All the best for your studies,

Regards

Simon

New email: simon.smith@uq.edu.au
Recover Injury Research Centre
The University of Queensland

From: Dunlap, John Travis (Travis Dunlap) <jdunlap9@vols.utk.edu>
Sent: 28 March 2017 04:24:47
To: Simon Smith
Subject: Permission to use Apnea Belief Scale

Dr. Smith,
I am a PhD nursing student at the University of Tennessee, Knoxville in the United States and I would like to use the Apnea Belief Scale (ABS) in my dissertation study. I am interested in evaluating outcome expectations of using CPAP for OSA, social support aspects that promote or discourage success with CPAP, and CPAP acceptance. Would you be able to tell me how I get permission to use the ABS? Thank you for your time,
Travis Dunlap

J. Travis Dunlap MSN, ANP-BC
PhD Nursing Student
College of Nursing
University of Tennessee, Knoxville
Big Orange. Big Ideas.

Appendix D

Epworth Sleepiness Scale

Confidential

Link to Surveys

Please complete the survey below.

EPWORTH SLEEPINESS SCALE

- How likely are you to doze off or fall asleep in the following situations, in contrast to feeling just tired?
- This refers to your usual way of life in recent times.
- Even if you have not done some of these things recently try to work out how they would have affected you.
- Use the following scale to choose the most appropriate number for each situation:

1) Sitting and Reading

◯ 0 = would never doze
◯ 1 = slight chance of dozing
◯ 2 = moderate chance of dozing
◯ 3 = High chance of dozing

2) Watching TV

◯ 0 = would never doze
◯ 1 = slight chance of dozing
◯ 2 = moderate chance of dozing
◯ 3 = High chance of dozing

3) Sitting, inactive in a public place (e.g. a theatre or a meeting)

◯ 0 = would never doze
◯ 1 = slight chance of dozing
◯ 2 = moderate chance of dozing
◯ 3 = High chance of dozing

4) As a passenger in a car for an hour without a break

◯ 0 = would never doze
◯ 1 = slight chance of dozing
◯ 2 = moderate chance of dozing
◯ 3 = High chance of dozing

5) Lying down to rest in the afternoon when circumstances permit

◯ 0 = would never doze
◯ 1 = slight chance of dozing
◯ 2 = moderate chance of dozing
◯ 3 = High chance of dozing

6) Sitting and talking to someone

◯ 0 = would never doze
◯ 1 = slight chance of dozing
◯ 2 = moderate chance of dozing
◯ 3 = High chance of dozing

7) Sitting quietly after a lunch without alcohol

◯ 0 = would never doze
◯ 1 = slight chance of dozing
◯ 2 = moderate chance of dozing
◯ 3 = High chance of dozing

8) In a car, while stopped for a few minutes in the traffic

◯ 0 = would never doze
◯ 1 = slight chance of dozing
◯ 2 = moderate chance of dozing
◯ 3 = High chance of dozing

Appendix E

ESS User Agreement

User agreement Special Terms

Mapi Research Trust, a non-for-profit organisation subject to the terms of the French law of 1st July 1901, registered in Carpentras under number 453 979 346, whose business address is 27 rue de la Villette, 69003 Lyon, France, hereafter referred to as "MRT" and the User, as defined herein, (each referred to singularly as a "Party" and/or collectively as the "Parties"), do hereby agree to the following User Agreement Special and General Terms:

Mapi Research Trust
PROVIDE™
27 rue de la Villette
69003 Lyon
France
Telephone: +33 (0)4 72 13 65 75

Recitals

The User acknowledges that it is subject to these Special Terms and to the General Terms of the Agreement, which are included in Appendix 1 to these Special Terms and fully incorporated herein by reference. Under the Agreement, the Questionnaire referenced herein is licensed, not sold, to the User by MRT for use only in accordance with the terms and conditions defined herein. MRT reserves all rights not expressly granted to the User.

The Parties, in these Special Terms, intend to detail the special conditions of their partnership.

The Parties intend that all capitalized terms in the Special Terms have the same definitions as those given in article 1 of the General Terms included in Appendix 1.

In this respect, the Parties have agreed as follows:

Article 1. Conditions Specific to the User

Section 1.01 Identification of the User

User Name	John Dunlap
Legal Form	Student
Address	1200 Volunteer Blvd Tennessee 37996 Knoxville
Country	United States of America
Email address	jdunlap9@vols.utk.edu

Section 1.02 Identification of the Questionnaire

Title	Epworth Sleepiness Scale (ESS)

Author(s)	Johns Murray W, MB, BS, BSc, PhD
Owner	Johns Murray W.
Copyright	ESS © MW Johns 1990-1997. Used under License.
Original bibliographic references	Johns MW. The clinical assessment of daytime sleepiness in patients with obstructive sleep apnea. In:Surgery for snoring and obstructive sleep apnea syndrome, ed. Fabiani M. Kugler publications, The Hague, 2003: 283-295 Johns MW. Sensitivity and specificity of the multiple sleep latency test (MSLT), the maintenance of wakefulness test and the epworth sleepiness scale: failure of the MSLT as a gold standard. J Sleep Res. 2000 Mar;9(1):5-11 (PubMed abstract) Johns MW. Sleepiness in different situations measured by the Epworth Sleepiness Scale. Sleep. 1994 Dec;17(8):703-10 (PubMed abstract) Johns MW. Daytime sleepiness, snoring, and obstructive sleep apnea. The Epworth Sleepiness Scale. Chest. 1993 Jan;103(1):30-6 (PubMed abstract) Johns MW. Reliability and factor analysis of the Epworth Sleepiness Scale. Sleep. 1992 Aug;15(4):376-81 (PubMed abstract) Johns MW. A new method for measuring daytime sleepiness: the Epworth sleepiness scale. Sleep. 1991 Dec;14(6):540-5 (PubMed abstract)

Article 2. Rights to Use

Section 2.01 Context of the Use of the Questionnaire

The User undertakes to only use the Questionnaire in the context of the Study as defined hereafter.

Context of Use	Clinical project or study
Title	Does the use of text based messages based on the TPB improve adherence rates in CPAP users newly diagnosed with OSA?
Disease or condition	obstructive sleep apnea
Type of research	Clinical trial
Number of patients expected	150
Number of submissions to the questionnaire for each patient	two
Term of clinical follow-up for each patient	one month
Start	07/2017
End	01/2018
Mode of administration	E-application

Section 2.02 Conditions for Use

The User undertakes to use the Questionnaire in accordance with the conditions for use defined hereafter.

(a) Rights transferred
Acting in the Owner's name, MRT transfers the following limited, non-exclusive rights, to the User (the "Limited Rights")
(i) to use the Questionnaire, only as part of the Study; this right is made up exclusively of the right to communicate it to the Beneficiaries only, free of charge, by any means of communication and by any means of remote distribution known or unknown to date, subject to respecting the conditions for use described hereafter; and

(ii) to reproduce the Questionnaire, only as part of the Study; this right is made up exclusively of the right to physically establish the Questionnaire or to have it physically established, on any paper, electronic, analog or digital medium, and in particular documents, articles, studies, observations, publications, websites whether or not protected by restricted access, CD, DVD, CD-ROM, hard disk, USB flash drive, for the Beneficiaries only and subject to respecting the conditions for use described hereafter; and

(iii) Should the Questionnaire not already have been translated into the language requested, the User is entitled to translate the Questionnaire or have it translated in this language, subject to informing MRT of the same beforehand by the signature of a Translation Agreement indicating the terms of it and to providing a copy of the translation thus obtained as soon as possible to MRT.

The User acknowledges and accepts that it is not entitled to amend, modify, condense, adapt, reorganise the Questionnaire on any medium whatsoever, in any way whatsoever, even minor, without MRT's prior specific written consent.

(b) Specific conditions for the Questionnaire

- Use in Individual clinical practice or Research study / project

User shall:

- Cite the reference publications
- never duplicate, transfer or publish the Questionnaire without indicating the Copyright Notice
- Insert the Owner's copyright notice on all pages/screens on which the Questionnaire will be presented
- Mention the following information: "The Questionnaire contact information and permission to use: Mapi Research Trust, Lyon, France – Internet: https://eprovide.mapi-trust.org "
- In case of use of an IT Company (e-vendor), User shall check with Mapi Research Trust that the IT Company has signed the necessary License Agreement with Mapi Research Trust before developing the electronic version of the Questionnaire

In the case of use of an electronic version of the Questionnaire in academic studies, the User undertakes to respect the following special obligations:

- Submit the screenshots of all the Pages where the Questionnaire appears to Mapi Research Trust before release for approval and to check that the above-mentioned requirements have been respected.

In the case of use of an electronic version of the Questionnaire in commercial studies / projects, the User undertakes to respect the following special obligations:

- For the first migration of the Questionnaire (generally the original version) into a specific electronic device

- Review of screenshots:

After implementation of the Questionnaire into the device, the user and/or IT Company will generate screen captures (screenshots) of the original questionnaire as displayed in the device. These will be reviewed by Mapi to check that they are consistent with the original paper version in terms of presentation, content and completion except for specific instructions related to the electronic administration. Corrections that may be needed will be reported to the user and/or IT Company. In this case, screenshots after correction will be generated for another round of review by Mapi until all screenshots are approved.

- Usability testing:

Usability testing is a methodology which aims to examine whether respondents are able to use a device and associated software as intended. Major issues of concern in usability testing typically include device complexity, navigation and response selection for example.

The objective of this investigation is to ensure that the electronic version of the questionnaire as included in the device meets usability criteria, focusing on functional aspects and respondents' understanding of instructions. Usability testing consists in interviews with patients where patients will complete the electronic version of the Questionnaire on the device and comment on their understanding of the instructions, ease of use and handiness of the device. A Usability testing report presenting results will be produced. If any changes are recommended, these will be implemented by the user and/or IT Company. If issues raised by respondents are rated as major, the user and/or IT Company may need to perform additional developments and another round of interviews may be needed.

The review of screenshots is mandatory. The usability testing is highly recommended by Mapi, however should the User and/or IT Company decide not to perform this step, Mapi Research Trust shall not be held responsible for any consequence and expense associated with this decision which shall remain the User and/or IT Company's sole liability.

The review of screenshots and usability testing, when and if performed, shall be performed exclusively by Mapi and shall be sponsored by the User.

The performance of the review of screenshots and usability testing will result in a certification of the electronic device original version of the Questionnaires by Mapi for future licenses.

- For the migration of other language versions of the Questionnaire on an existing certified specific electronic device

- Update version

After the electronic device original version of the Questionnaire is fully ready, the Questionnaire's language versions developed for paper administration will be updated to reflect the changes in wording of instructions implemented in the electronic device original version of the questionnaire.

Native speakers of the languages will reflect the changes made to the electronic device original version of the Questionnaire and will provide English equivalents of all changes made for Mapi's quality control.

- Review of screenshots:

After implementation of the Questionnaire into the device, the user and/or IT Company will generate screen captures (screenshots) of the original questionnaire as displayed in the device. These will be reviewed by Mapi to check that they are consistent with the original paper version in terms of presentation, content and completion except for specific instructions related to the electronic administration. Corrections that may be needed will be reported to the user and/or IT Company. In this case, screenshots after correction will be generated for another round of review by Mapi until all screenshots are approved.

The update of version and review of screenshots are mandatory. These steps shall be performed exclusively by Mapi and shall be sponsored by the User.

The performance of the update of version and review of screenshots will result in a certification of the electronic device language version of the Questionnaires by Mapi for future licenses.

- Use in a publication or on a website with unrestricted access:

In the case of a publication, article, study or observation on paper or electronic format of the Questionnaire, the User undertakes to respect the following special obligations:

- not to include any full copy of the Questionnaire, but a protected version with the indication "sample copy, do not use without permission"
- to indicate the name and copyright notice of the owner
- to include the reference publications of the Questionnaire
- to indicate the details of MRT for any information on the Questionnaire as follows: contact information and permission to use: Mapi Research Trust, Lyon, France – Internet: https://eprovide.mapi-trust.org/
- to provide MRT, as soon as possible, with a copy of any publication regarding the Questionnaire, for information purposes
- to submit the screenshots of all the Pages where the Questionnaire appears to MRT before release to check that the above-mentioned requirements have been respected.

- Use for dissemination:

- On a website with restricted access:

In the case of publication on a website with restricted access, the User may include a clean version of the Questionnaire, subject to this version being protected by a sufficiently secure access to only allow the Beneficiaries to access it.

The User undertakes to also respect the following special obligations:

- to indicate the name and copyright notice of the owner
- to include the reference publications of the Questionnaire
- to indicate the details of MRT for any information on the Questionnaire as follows: contact information and permission to use: Mapi Research Trust, Lyon, France – Internet: https://eprovide.mapi-trust.org/
- to submit the screenshots of all the Pages where the Questionnaire appears to MRT before release to check that the above-mentioned requirements have been respected.

- On promotional / marketing documents

In the case of publication on promotional/marketing documents, the User undertakes to respect the following special obligations:

- to indicate the name and copyright notice of the Owner
- to include the reference publications of the Questionnaire
- to indicate the details of MRT for any information on the Questionnaire as follows: contact information and permission to use: Mapi Research Trust, Lyon, France – Internet: https://eprovide.mapi-trust.org/
- to provide MRT, as soon as possible, with a copy of any publication regarding the Questionnaire, for information purposes
- to submit the screenshots of all the Pages where the Questionnaire appears to MRT before release to check that the above-mentioned requirements have been respected.

For any other use not defined herein, please contact MRT for the specific conditions of use and access fees (if applicable).

Article 3. Term

- For Clinical Trials and Study Projects:

MRT transfers the Limited Rights to use the Questionnaire as from the date of delivery of the Questionnaire to the User and for the whole period of the Study.

- For Clinical Practice and Dissemination purpose:

MRT transfers the Limited Rights to use the Questionnaire as from the date of delivery of the Questionnaire to the User and for a period of 3 years.

- For a publication in a book:

MRT transfers the Limited Rights to use the Questionnaire as from the date of delivery of the Questionnaire to the User and for a period of 10 years.

Article 4. Beneficiaries

The Parties agree that the User may communicate the Questionnaire in accordance with the conditions defined above to the Beneficiaries involved in the Study only, in relation to the Study defined in section 2.01.

Article 5. Territories and Languages

MRT transfers the Limited Rights to use the Questionnaire on the following territories and in the languages indicated in the table below:

Questionnaire	Language
ESS	English for the USA

Article 6. Price and Payment Terms

The User undertakes in relation to MRT to pay the price owed in return for the availability of the Questionnaire, according to the prices set out below, depending on the languages requested and the costs of using the Questionnaire, in accordance with the terms and conditions described in section 6.02 of the General Terms included in Appendix 1.

ROYALTY FEES*	Commercial users	Cost per study	1 100 € (use in commercial epidemiologic / observational / marketing studies: please consult the User Agreement)
		Cost per language	550 €
	Funded academic research	Cost per study	300 €
		Cost per language	50 €
	Not funded academic users	Cost per study	Free
		Cost per language	Free

DISTRIBUTION FEES*	Commercial users	Cost per study	1 000 €
		Cost per language	500 €
	Funded academic research	Cost per study	300 €
		Cost per language	50 €
	Not funded academic users	Cost per study	Free
		Cost per language	Free

Agreed and acknowledged by

John Dunlap

01-May-2017

Appendix F

Functional Outcomes of Sleep Questionnaire

Confidential

Functional Outcomes of Sleep Questionnaire-10

Please complete the survey below.

•Some people have difficulty performing everyday activities when they feel tired or sleepy.
•The purpose of this questionnaire is to find out if you generally have difficulty carrying out certain activities because you are too sleepy or tired.
•In this questionnaire, when the words "sleepy" or "tired" are used, it means the feeling that you can't keep your eyes open, your head is droopy, that you want to "nod off", or that you feel the urge to take a nap.
•These words do not refer to the tired or fatigued feeling you may have after you have exercised.

DIRECTIONS: Please select an answer to each question. Select only one answer for each question. Please try to be as accurate as possible. All information will be kept confidential.

1)	Do you have difficulty concentrating on the things you do because you are sleepy or tired?	◯ No difficulty ◯ Yes, a little difficulty ◯ Yes, moderate difficulty ◯ Yes, extreme difficulty
2)	Do you generally have difficulty remembering things, because you are sleepy or tired?	◯ No difficulty ◯ Yes, a little difficulty ◯ Yes, moderate difficulty ◯ Yes, extreme difficulty
3)	Do you have difficulty operating a motor vehicle for short distances (less than 100 miles) because you become sleepy or tired?	◯ I don't do this activity for other reasons ◯ No difficulty ◯ Yes, a little difficulty ◯ Yes, moderate difficulty ◯ Yes, extreme difficulty
4)	Do you have difficulty operating a motor vehicle for long distances (greater than 100 miles) because you become sleepy or tired?	◯ I don't do this activity for other reasons ◯ No difficulty ◯ Yes, a little difficulty ◯ Yes, moderate difficulty ◯ Yes, extreme difficulty
5)	Do you have difficulty visiting with your family or friends in their home because you become sleepy or tired?	◯ I don't do this activity for other reasons ◯ No difficulty ◯ Yes, a little difficulty ◯ Yes, moderate difficulty ◯ Yes, extreme difficulty
6)	Has your relationship with family, friends or work colleagues been affected because you are sleepy or tired?	◯ I don't do this activity for other reasons ◯ No difficulty ◯ Yes, a little difficulty ◯ Yes, moderate difficulty ◯ Yes, extreme difficulty
7)	Do you have difficulty watching a movie or videotape because you become sleepy or tired?	◯ I don't do this activity for other reasons ◯ No difficulty ◯ Yes, a little difficulty ◯ Yes, moderate difficulty ◯ Yes, extreme difficulty
8)	Do you have difficulty being as active as you want to be in the evening because you are sleepy or tired?	◯ No difficulty ◯ Yes, a little difficulty ◯ Yes, moderate difficulty ◯ Yes, extreme difficulty

9)	Do you have difficulty being as active as you want to be in the morning because you are sleepy or tired?	◯ No difficulty ◯ Yes, a little difficulty ◯ Yes, moderate difficulty ◯ Yes, extreme difficulty
10)	Has your desire for intimacy or sex been affected because you are sleepy or tired?	◯ I don't engage in sexual activity for other reasons ◯ No ◯ Yes, a little ◯ Yes, moderately ◯ Yes, extremely

Appendix G

FOSQ-10 Signed Letter of Agreement

FUNCTIONAL OUTCOMES OF SLEEP QUESTIONNAIRE (FOSQ)
CONDITIONS OF AGREEMENT

This instrument is copyrighted, therefore no question, format or portion of the FOSQ can be adapted or used apart from the instrument as a whole without the express written consent of the author's.

I/we agree to the following conditions for the use of the Functional Outcomes of Sleep Questionnaire (FOSQ) in my/our practice or research:

1. Sign the two enclosed letters of agreement
2. If the FOSQ is being used in research please return the following upon completion of your research (whether published or unpublished):
   a. How the FOSQ will/was be applied in your research
   b. Paragraph stating purposes of your study
      1. Instruments used in study
      2. Sample/population to include size, characteristics (i.e., gender, age, health status, where the sample was obtained), and type (e.g., random, convenience, etc.)
      3. Descriptive and inferential statistical results of your study especially, those findings relevant to the FOSQ (including graphs and/or tables if available)
3. If the FOSQ is being applied in practice, please briefly describe the clinic population in which it is being used, and any recommendations that you may have.

Sign and send one copy of this agreement to:

Dr. Terri E. Weaver
University of Pennsylvania
School of Nursing
Philadelphia, PA 19104-6096
215/573-7496 (fax)

The scoring scheme will be sent to you upon receipt of the agreement.

Name: JOHN TRAVIS DUNLAP (type or print)

Address: 8111 BRENTHAVEN DRIVE

BRENTWOOD, TN 37027

Signature: John T Dunlap Date: 5/1/17

Terri E. Weaver, Ph.D., RN, CS, FAAN Date: _____

Appendix H

Informed Consent Form

Confidential

CPAP Adherence Study eConsent

Vanderbilt University Institutional Review Board
Informed Consent Document For Research

Principal Investigator: John Travis Dunlap
Study Title: "Use of weekly text-based messages to influence sleep apnea management"
Institution/Hospital: Vanderbilt University
Revision Date: 02-27-2018

This informed consent applies to healthy volunteers.

* The following information is provided to inform you about the research project and your participation in it. Please read this form carefully and feel free to ask any questions you may have about this study and the information given below. You will be given an opportunity to ask questions, and your questions will be answered. Also, you will be given a copy of this consent form.

** If you decide not to take part in this research study, it will not affect your treatment, payment, or enrollment in any health plans or affect your ability to get benefits.

Participants wishing to see the entire consent document before continuing with the consent process can download and view it by clicking on the link below.

[Attachment: "Stamped-REDCap informed consent.pdf"]

Consent Material

Please carefully read the following consent form. After reading the form, you will be asked to answer a few short questions confirm your understanding of the material presented:

Your participation in this research study is voluntary. You may choose not to participate and receive alternative treatments without affecting your healthcare/services or other rights. You are also free to withdraw from this study at any time. In the event new information becomes available that may affect the risks or benefits associated with this research study or your willingness to participate in it, you will be notified so that you can make an informed decision whether or not to continue your participation in this study.

Continue to review consent?

◯ Yes
◯ No

A. What is the purpose of this study?

You are being asked to participate in this research study because you have recently been diagnosed with obstructive sleep apnea and have been asked by the sleep specialist to start using a continuous positive airway pressure (CPAP) device to help treat the sleep apnea. The purpose of this study is to examine the effects of sending one motivational text message per week for 4 weeks on an individual's CPAP device adherence, sleep apnea symptom management, and outcome expectations when compared to participants receiving generic text messages.

The plan is to recruit 100 people to participate in the study.

Study Procedures:

1.) You will receive an email with a link asking you to answer 4 short questionnaires (takes about 20 minutes). You may also answer the questionnaires over the phone if you choose.
2.) After you begin using the CPAP device, you will receive 1 text message a week for 4 weeks.
3.) After 4 weeks, you will get another email message with a link asking you to answer 3 of the previous questionnaires again. You may also answer the questionnaires over the phone if you choose.
4.) After answering the 3 questionnaires, you will be finished with the study.

C. Costs to you if you take part in this study:

The only expense will be the fee your cellphone carrier will charge, if any, for the 4 text messages you will receive.

Continue to review consent? ◯ Yes ◯ No

D. Side effects and risks that you can expect if you take part in this study:

There is a slight risk that answering the questionnaires may make you uncomfortable. Should items on the questionnaire be uncomfortable or too stressful to answer, you may choose not to answer those items or to withdraw from the study.

For those who are pregnant or who may become pregnant during the study, the risk to the fetus is caused solely by interventions that hold out the prospect of direct benefit for the woman or the fetus.

There is a slight risk of time inconvenience as a result of the duration of time to answer the questionnaires.

There is also a slight risk of confidentiality breach.

E. Compensation in case of study-related injury:

If it is determined by Vanderbilt and the Investigator that an injury occurred as a direct result of the tests or treatments that are done for research, then you and/or your insurance will not have to pay for the cost of immediate medical care provided at Vanderbilt to treat the injury.

There are no plans for Vanderbilt to pay for any injury caused by the usual care you would normally receive for treating your illness or the costs of any additional care. There are no plans for Vanderbilt to give you money for the injury.

F. Good effects that might result from this study:

a) The benefits to science and humankind that might result from this study include determining methods to improve sleep apnea management.

b) The benefits you might get from being in this study are better management of your sleep apnea

Continue to review consent? ◯ Yes ◯ No

G. Other treatments you could get if you decide not to be in this study:

Standard care that is offered to all patients who are starting CPAP. Standard care includes:

1.) A medical equipment company will provide you with a CPAP device, supplies and someone to make sure your mask and equipment functions properly.

2.) Nurses at the sleep clinic will give you instructions about CPAP operation, maintenance, and troubleshooting.

3.) You contact the medical equipment company or the sleep clinic with any problems.

4.) If the medical equipment company or sleep clinic notices you are having issues with your CPAP, they will contact you.

5.) You will follow up with the sleep clinic in about 3 months.

H. Payments for your time spent taking part in this study:

You will be entered to win 1 of 2 $100 Visa electronic gift cards. The odds of winning 1 of the gift cards is 1 in 50. The gift card winners will be determined once data collection has ended and the winners will be notified and receive the Visa electronic gift cards by e-mail.

I. Reasons why the principal investigator, Travis Dunlap, may take you out of this study:

A reason will be given to the participant, should PI remove participant from the study. For example, the PI may withdraw a participant from the study if they are not able to complete all of the questionnaires.

What happens if you choose to withdraw from study participation?

If you decide you don't want to continue, you should tell the Principal Investigator. Your participation in this study is voluntary. You may end participation without affecting your health care/services or other rights.

Information on Emergency Contact Information

Who to call for any questions or in case you are injured:

If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact me (Travis Dunlap) at (615) 592-1262 or Dr. Raghu Upender at (615) 936-0060.

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the Vanderbilt University Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Information on Confidentiality

All efforts, within reason, will be made to keep your personal information in your research record confidential but total confidentiality cannot be guaranteed.

Participant identification numbers, rather than names, will be used on all data collection instruments. Travis Dunlap will keep a list that matches participants with their identification numbers; this list will be kept as a data file on a password-protected laptop computer and this computer will be kept in a secured location and only Travis Dunlap will have access to this information. Only Travis Dunlap will have access to the names, research data, e-mail addresses and telephone numbers of the individuals who participate.

The principal investigator, Travis Dunlap, will be the only individual with access to your personal health information. CPAP data will be transmitted electronically and can be accessed using either the EncoreAnywhere (EA) patient data management software developed by Philips Healthcare or the AirView (AV) patient data management software developed by ResMed. Both EA and AV are Health Insurance Portability and Accountability Act (HIPAA) compliant and provide central patient data management systems that collect, analyze adherence and therapy data, and provide reports about the data that is accessible using a compatible internet web browser. To ensure HIPAA compliance, both EA and AV include access security as well as the security of transmitted data. No adherence or therapy data will be stored on the password-protected laptop as the data will be stored on secure EA cloud servers or AV cloud servers that are both HIPAA compliant. EA and AV are both currently used by the Vanderbilt Sleep Clinic.

Uniform Resource Locator links to the pre-intervention and post-intervention online surveys will be sent to participants using the HIPAA compliant data management software developed by Vanderbilt University known as REDCap. No data will be stored on the password-protected laptop as the data will be stored on secure REDCap cloud servers that are also HIPAA compliant. The data will be backed up on a daily basis to prevent loss of data.

Vanderbilt may share your information, without identifiers, to others or use it for other research projects not listed in this form. Vanderbilt, Travis Dunlap and his staff will comply with any and all laws regarding the privacy of such information. There are no plans to pay you for the use or transfer of this de-identified information.

Proceed to review of confidentiality, HIPAA authorization and agreement to participate in study?

- ◯ Yes
- ◯ No

Information on Authorization to Use/Disclose Protected Health Information

All efforts, within reason, will be made to keep your protected health information (PHI) private. PHI is your health information that is, or has been gathered or kept by Vanderbilt as a result of your healthcare. This includes data gathered for research studies that can be traced back to you. Using or sharing ("disclosure") such data must follow federal privacy rules. By signing the consent for this study, you are agreeing ("authorization") to the uses and likely sharing of your PHI. If you decide to be in this research study, you are also agreeing to let the study team use and share your PHI as described below.

As part of the study, Vanderbilt University Medical Center may share the results of your study and/or non-study linked sleep study, as well as parts of your medical record, to the groups named below. These groups may include people from the Federal Government Office for Human Research Protections, the VUMC Institutional Review Board, and Vanderbilt University. Federal privacy rules may not apply to these groups; they have their own rules and codes to assure that all efforts, within reason, will be made to keep your PHI private.

Vanderbilt may give or sell your health data, without identifiers, to others or use it for other research projects not listed in this form. Vanderbilt, Travis Dunlap and his staff will comply with any and all laws regarding the privacy of such information. There are no plans to pay you for the use or transfer of this de-identified information.

The study results will be kept in your research record for at least six years after the study is finished. At that time, the research data that has not been put in your medical record will be kept for an unknown length of time. Any research data that has been put into your medical record will be kept for an unknown length of time. The data will be retained for potential reuse in future studies. After the six years has passed, any identifying information will be destroyed.

Unless told otherwise, your consent to use or share your PHI does not expire. If you change your mind, we ask that you contact Travis Dunlap in writing and let him know that you withdraw your consent. His mailing address is:
461 21st Ave. South
367 Frist Hall
Nashville, TN 37240-1119
At that time, we will stop getting any more data about you. But, the health data we stored before you withdrew your consent may still be used for reporting and research quality.

You have the right to see and copy the PHI we gather on you for as long as the principal investigator or research site holds this data. To ensure the scientific quality of the research study, you will not be able to review some of your research data until after the research study is finished.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

Participant Information and Consent

Statement by individual regarding whether to be in this study or not:	◯ I have read and/or viewed this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in the associated study. ◯ I choose not to participate in this research study
THANK YOU for your willingness to participate in this research project.	
Signature of Participant: * Please click "add signature". * For computers, sign using your cursor, for portable electronic devices, please sign using a stylus or your finger. * Once signed, please click "accept signature".	_____
Participant Name	_____ (First Name Last Name)
Email address you regularly use. Links to the questionnaires will be sent to this email address.	_____
Today's Date	_____ (MM-DD-YYYY)
Participant's Age (at time of consent)	_____ (Years)

Information of Person Obtaining Consent	
Consent obtained by (please enter full name).	_____ (Completed by study personnel at time of consent.)
Consent obtained by (please enter full name): * Please click "add signature". * For computers, sign using your cursor, for portable electronic devices, please sign using a stylus or your finger. * Once signed, please click "accept signature".	_____

Appendix I

Demographics Survey

Confidential

Link to Surveys

Please complete the survey below.

Participant Information	
First Name	_____
Last Name	_____
Phone number where text messages will be received	_____ (Include Area Code xxx-xxx-xxxx)
Active e-mail address where questionnaire links will be sent.	_____ (Please enter the same email address that was entered on the Consent Form)
Today's date	_____ (MM-DD-YYYY)
Date of birth	_____ (MM-DD-YYYY)
Age (years)	_____
Ethnicity	◯ Hispanic or Latino ◯ NOT Hispanic or Latino ◯ Unknown / Not Reported
Race	◯ American Indian/Alaska Native ◯ Asian ◯ Native Hawaiian or Other Pacific Islander ◯ Black or African American ◯ White ◯ More Than One Race ◯ Unknown / Not Reported
Gender with which you identify	◯ Female ◯ Male

Other information	
Sleep Status	◯ Sleep alone ◯ Live with significant other and sleep in same bed ◯ Live with significant other and sleep in separate beds
What is the highest level of education you have completed?	◯ Some high school ◯ High school graduate ◯ Some college ◯ Trade/technical/vocational training ◯ College graduate ◯ Some postgraduate work ◯ Post graduate degree
Annual Income Level	◯ Prefer not to answer ◯ Less than $20,000 ◯ $20,000 to $39,999 ◯ $40,000 to $59,999 ◯ $60,000 to $79,999 ◯ $80,000 to $99,999 ◯ $100,000 to $119,999 ◯ $120,000 to $139,999 ◯ $140,000 or more
Apnea hypopnea index (AHI) at diagnosis	_____ (How many times were you told you stopped breathing every hour?)
Mask type	◯ Nasal mask ◯ Nasal pillow ◯ Full mask ◯ Other type
Please specify "Other" type of mask:	_____

Appendix J

Vanderbilt Notice of Privacy Practices

Notice of Privacy Practices

Effective January 1, 2017

This Notice tells how your medical information may be used or shared. It also tells how you can get your information. Please read it carefully. Ask us if you have any questions. Or call the Privacy Office at (615) 936-3594.

Why We Keep Information about You

We keep medical information about you to help care for you and because the law requires us to.

The law also says we must:

- protect your medical information
- give you this Notice
- follow what the Notice says.

What the Words We Use Mean

- "Notice" means this Notice of Privacy Practices.
- "VUMC" means Vanderbilt University Medical Center, its staff, and any affiliated organizations covered by the Notice. (Covered entities are listed at the end of the Notice.)
- "We," "our," or "us" means one or more VUMC organizations, providers, or staff.
- "You" means the patient that the medical information is about.
- "Medical information" means all the paper and electronic records related to a patient's physical and mental health care—past, present, or future. These records tell who the patient is and include information about billing and payment.
- "Use" means sharing or using medical information within VUMC.
- "Share" means giving medical information, or access to information, to someone outside VUMC.

How We May Use and Share Information about You

We use electronic record systems to manage your care. These systems have safeguards to protect the information in them. We also have policies and training that limit the use of information to those who need it to do their job.

Doctors and other people who are not employed by VUMC may share information they have about you with our employees in order to care for you.

Hospitals, clinics, doctors, and other caregivers, programs, and services may share medical information about you without your consent for many reasons. Here are just a few examples:

For Health Information Exchanges (HIEs)

We will send your health information to any of the Health Information Exchanges (HIEs) that Vanderbilt participates in. A Health Information Exchange (HIE) is a secure electronic system that helps health care providers and entities such as

health plans and insurers manage care and treat patients. We will send your health information to the Vanderbilt Health Affiliated Network (VHAN) HIE, the Epic Care Everywhere HIE, and other HIEs we choose to participate in. Information about your past medical care and current medical conditions and medicines is available not only to us but also to non-VUMC health care providers who participate in the HIE. You have the right to opt out of the HIE. However, even if you do, some of your health information will remain available to certain health care entities as permitted by law.

If you have questions or would like to opt out of any of the HIEs, contact the Privacy Office at (615) 936-3594.

For Treatment

We may use and share medical information to treat you. For example, a doctor treating you for a broken leg will need to know if you have diabetes because diabetes can slow healing. The doctor may need to tell food services that you have diabetes so the right meals can be prepared for you.

We may also share medical information about you so that you can get

- medicine, medical equipment, or other things you need for your health care
- lab tests, x-rays, transportation, home care, nursing care, rehab, or other health care services.

Medical information may also be shared when needed to plan for your care after you leave VUMC.

For Billing and Payment

We may use and share your information so that we and others who have provided services to you can bill and collect payment for these services. For example, we may share your medical information with your health plan:

- so your health plan will pay for care you got at VUMC
- to get approval before doing a procedure
- so your health plan can make sure they have paid the right amount to VUMC.

We may also share your information with a collection agency if a bill is overdue.

For Business Reasons

We may use and share information about you for business reasons. When we do this, we may, if we can, take out information that identifies who you are.

Some of the business reasons we may use or share your medical information include:

- to follow laws and regulations
- to train and educate
- for credentialing, licensure, certification, and accreditation
- to improve our care and services
- to budget and plan
- to do an audit
- to maintain computer systems
- to evaluate our staff
- to decide if we should offer more services
- to find out how satisfied our patients are
- to bill and collect payment.

We may also allow access to your information to those health care providers and their authorized representatives that are members of an organized health care arrangement with VUMC. The members of such an arrangement are operationally or clinically integrated and may participate jointly in utilization review, quality assessment and improvement, or payment activities. Anyone we share information with in order to do these tasks on behalf of or in partnership with us must also protect and restrict the use of your medical information.

To Contact You about Appointments, Insurance, and Other Matters

We may contact you by mail, phone, text, or email for many reasons, including to:

- remind you about an appointment
- register you for a procedure
- give you test results
- ask about insurance, billing, or payment
- follow up on your care
- ask you how well we cared for you.

We may leave voice messages at the telephone number you give to us. If you choose to have us contact you by text, texting charges may apply.

To Tell You about Treatment Options or Health-related Products and Services

We may use or share your information to let you know about treatment options or health-related products or services that may interest you.

For Fundraising

We may use your name, address, phone number, the dates and places you got services at VUMC, and the names of your doctors to contact you to try to raise money for VUMC. You have the right to ask not to be contacted for fundraising. If we contact you, we will tell you how to prevent future contact if you wish.

For the Hospital Directory

If you are admitted to the hospital, your name, where you are in the hospital, your general condition (such as "fair" or "stable"), and your religion is included in the patient directory at the information desk. This helps family, friends, and clergy visit you and learn your condition. Except for your religion, this information may be shared with visitors or phone callers who ask for you by name. Unless you tell us not to, your religion may be shared with a member of the clergy, such as a priest or rabbi, even if you aren't asked for by name.

If you ask us to take your name from the directory, we will not share your information even if you are asked for by name.

To Inform Family Members and Friends Involved in Your Care or Paying for Your Care

We may share information about you with family members and friends who are involved in your care or paying for your care. Whenever possible, we will allow you to tell us who you would like to be involved in your care. However, in emergencies or other situations in which you are unable to tell us who to share information with, we will use our best judgment and share only information that others need to know. We may also share information about you with a public or private agency during a disaster so that the agency can help contact your family or friends to tell them where you are and how you are doing.

For Research

We may use and share medical information about you for the research we do to improve public health and develop new knowledge. For example, a research project may compare the health and recovery of patients who received one medicine for an illness to those who received a different medicine for the same illness. We use and share your information for research only as allowed by federal and state rules. Each research project is approved through a special process that balances the research needs with the patient's need for privacy. In most cases, if the research involves your care or the sharing of medical information that can identify you, we will first explain to you how your information will be used and ask your consent to use the information. We may access your medical information before the approval process to design the research project and provide the information needed for approval. Health information used to prepare a research project does not leave VUMC.

To Stop a Serious Threat

We may share your medical information to prevent a serious and urgent threat to the health and safety of you or someone else. For example, a threat to harm another person may be reported to the police.

For Organ, Eye, and Tissue Donation

We share medical information about organ, eye, and tissue donors and about the patients who need the organs, eyes, and tissues with others involved in getting, storing, and transplanting the organs, eyes, and tissues.

With Military Authorities

If you are a member or veteran of the armed forces, we may share your medical information with the military as authorized or required by law. We may also share information about foreign military personnel to the proper foreign military authority.

For Workers' Compensation

We may share medical information about you with those who need it in order to provide benefits for work-related injuries or illness.

For Health Oversight and Public Health Reporting

We may share information for audits, investigations, inspections, and licensing with agencies that oversee health organizations.

We may also share your medical information in reports to public health agencies.

Some reasons for this include:

- to prevent or control disease and injuries
- to report certain kinds of events, such as births and deaths
- to report abuse or neglect of children, elders, or dependent adults
- to report reactions to medicines or problems with medical products
- to tell people about recalls of medical products they may be using
- to let someone know that they may have been exposed to a disease or may spread a disease
- to notify the authorities if we believe a patient has been the victim of abuse, neglect, or domestic violence.

For Lawsuits and Disputes

We may share your medical information as directed by a court order, subpoena, discovery request, warrant, summons, or other lawful instructions from a court or public body when needed for a legal or administrative proceeding.

With Law Enforcement and Other Officials

We may share your medical information with a law enforcement official as authorized or required by law:

- in response to a court order, subpoena, warrant, summons, or similar process
- to identify or find a suspect, fugitive, material witness, or missing person
- if you are suspected to be a victim of a crime. (We generally do this with your permission)
- because of a death we believe may have been caused by a crime
- because of criminal conduct at the hospital
- in an emergency: to report a crime; the location of the crime or victims; or the identity, description, or location of the person who committed the crime
- if you are under the custody of the police or other law enforcement official.

We May Also Share Your Medical Information with:

- coroners, medical examiners, and funeral directors, so they can carry out their duties
- federal officials for national security and intelligence activities
- federal officials who provide protective services for the President and others, such as foreign heads of state, or to conduct special investigations
- a correctional institution if you are an inmate
- a school to confirm that you have been immunized.

Other Uses of Your Medical Information

We will not use or share your medical information for reasons other than those described in this Notice unless you agree to this in writing. For example, you may want us to give medical information to your employer. We will do this only with your written approval. Likewise, we would not use your information for marketing, sell your information, or share psychotherapy notes without your written approval. You may revoke the approval in writing at any time, but we cannot take back any medical information that has already been shared with your approval.

Your Rights Regarding Your Medical Information

The records we create and maintain using your medical information belong to VUMC, but you have the following rights:

Right to Review and Get a Copy of Your Medical Information

You have the right to look at and get a copy of your medical information, including billing records. You must make your request in writing to Health Information Management at the address listed at the end of this Notice. We may charge a fee to cover copying, mailing, and other costs and supplies. In rare cases, we may deny your request for certain information. If we deny your request, we will give you the reason why in writing. In some cases, you may ask that the denial be reviewed by a licensed health care professional chosen by VUMC.

Right to Ask for a Change in Your Medical Information

If you think our information about you is not correct or complete, you may ask us to correct your record by writing to Health Information Management at the address listed at the end of this Notice. Your written request must say why you are asking for the correction. We will respond in 60 days.

If we agree, we will tell you and correct your record. We cannot take anything out of the record. We can only add new information to complete or correct the existing information. With your help, we will notify others who have the incorrect or incomplete medical information.

If we deny your request, we will tell you why in writing. You will then have the right to submit a written statement of 250 words or less that tells what you believe is not correct or is missing. We will add your written statement to your records and include it whenever we share the part of your medical record that your written statement relates to.

Right to Ask For a List of When Your Medical Information Was Shared

You have the right to ask for a list of when your medical information was shared without your written consent.

This list will NOT include uses or sharing:

- for treatment, payment, or business reasons
- with you or someone representing you
- with those who ask for your information as listed in the hospital directory
- with family members or friends involved in your care
- in those very few instances where the law does not require or permit it
- as part of a limited data set with direct identifiers removed
- released before April 14, 2003.

You must request this list in writing from the Privacy Office at the address listed at the end of this Notice. Your request must state the time period for which you want the list. The time period may not be longer than 6 years from the date of your request. The first list you ask for within a 12-month period will be free. You may be charged a fee if you ask for another list in that same 12-month period.

Right to Notice in Case of a Breach

You have a right to know if your information has been breached (not treated according to our rules). We will follow what the privacy laws require to let you know if your information has been shared in error.

Right to Ask for Limits on the Use and Sharing of Your Medical Information

You have the right to ask that we limit the use or sharing of information about you for treatment, payment, or business reasons. You also have the right to ask us to limit the medical information we share about you with someone involved in your care or paying for your care, such as a family member or friend. For example, you could ask that we not share information about a surgery you had. Except for the sharing of information with health plans described in the next section, we reserve the right to accept or reject your request. Generally, we will not accept limits for treatment, payment, or business

reasons. We will let you know if we do not agree to your request. If we do agree, our agreement must be in writing, and we will follow your request unless the information is needed to treat you in an emergency. We are allowed to end a limit if we tell you. If we end a limit, only medical information that was created or received after we notify you will be affected.

You must make your request to limit the use and sharing of your medical information in writing to the Privacy Office at the address listed at the end of this Notice. In your request, you must tell us

- what information you want to limit
- whether you want to limit our use or sharing of the information, or both
- AND to whom you want the limits to apply.

Right to Limit Sharing of Information with Health Plans

If you paid in full for your services, you have the right to limit the information that is shared with your health plan or insurer. To do this, you must ask before you receive any services. Let us know you want to limit sharing with your health plan when you schedule your appointment.

Any information shared before we receive payment in full, such as information for pre-authorizing your insurance, may be shared. Also, because we have a medical record system that combines all your records, we can limit information only for an episode of care (services given during a single visit to the clinic or hospital). If you wish to limit information beyond an episode of care, you will have to pay in full for each future visit as well.

Right to Ask for Confidential Communications

You have the right to ask us to communicate with you in a certain way or at a certain place. For example, you can ask that we contact you only at work or only using a post office box. You must make your request in writing to the Privacy Office at the address listed at the end of this Notice. You do not need to tell us the reason for your request. Your request must say how or where you wish to be contacted. You must also tell us what address to send your bills for payment. We will accept all reasonable requests. However, if we are unable to contact you using the ways or locations you have requested, we may contact you using any information we have.

Right to Get a Paper Copy of This Notice

You have the right to get a paper copy of this Notice, even if you have agreed to receive it electronically. You may get a copy:

- at any of our facilities
- by contacting the Privacy Office at the number listed at the end of this Notice
- at VanderbiltHealth.com.

Changes to this Notice

We have the right to change this Notice at any time. Any change could apply to medical information we already have about you, as well as information we receive in the future. The effective date of this Notice is on the first page of the Notice. A copy of the current Notice is posted throughout VUMC and at VanderbiltHealth.com.

How to Ask a Question or Report a Complaint

If you have questions about this Notice or want to talk about a problem without filing a formal complaint, please contact the Privacy Office at (615) 936-3594. If you believe your privacy rights have been violated, you may file a complaint with us. Please send it to the VUMC Privacy Official at the address listed at the end of this Notice. You may also file a complaint with VUMC Patient Relations or the Office of Civil Rights at the addresses listed at the end of this Notice. You will not be treated differently for filing a complaint.

VUMC Operations and Affiliates That Will Follow the Rules of this Notice:

- Vanderbilt University Hospital
- Vanderbilt Psychiatric Hospital
- Monroe Carell Jr. Children's Hospital at Vanderbilt
- Vanderbilt Medical Group
- VUMC clinics and practices (a detailed list is available on request)
- VUMC Outpatient Pharmacies
- Members of the VUMC medical staff while practicing at VUMC
- Members of the Vanderbilt School of Medicine when covered functions involve the use or disclosure of protected health information
- Members of the Vanderbilt School of Nursing when covered functions involve the use or disclosure of protected health information
- VUMC Administration when covered functions involve the use or disclosure of protected health information
- Other designated health care components of VUMC

Vanderbilt Health Services Affiliated Covered Entities

- Cool Springs Imaging (Williamson Imaging)
- Gateway-Vanderbilt Cancer Treatment Center
- One Hundred Oaks Imaging
- Spring Hill Imaging Center
- Vanderbilt Health and Williamson Medical Center Clinics and Services
- Vanderbilt Home Care Services
- Vanderbilt Imaging Services (VIS)
- Vanderbilt Integrated Providers (VIP)
- Vanderbilt-Maury Radiation Oncology
- VIP MidSouth, LLC

Organized Health Care Arrangements

- Vanderbilt Health Affiliated Network (VHAN)

This list may be updated from time to time. For a current list, contact the VUMC Privacy Office.

How to Contact Us

VUMC Privacy Office
4560 Trousdale Drive, Suite 101, Nashville, TN 37204-4538; (615) 936-3594
privacy.office@vanderbilt.edu

VUMC Health Information Management
4560 Trousdale Drive, Suite 101, Nashville, TN 37204-4538; (615) 322-2062

VUMC Patient Relations
1817 The Vanderbilt Clinic, Nashville, TN 37232-5612; (615) 322-6154

Office for Civil Rights, Region IV, DHHS
Atlanta Federal Center, 61 Forsyth Street SW, Suite 3B70, Atlanta, GA 30323

Vita

John “Travis” Dunlap was born in Maryville, TN to Johnny and Marlene Dunlap. He attended Heritage High School in Maryville, TN. After graduation, Travis joined the U.S. Navy and served six years as a nuclear reactor operator on the fast attack submarine, USS Albany (SSN-753). After the Navy, Travis attended the University of Tennessee, Knoxville and then attended Vanderbilt University School of Nursing (VUSN) where he graduated with his Master of Science in Nursing (MSN) in 2002. After working as a nurse practitioner in heart failure and heart transplant at Vanderbilt University Medical Center, Travis returned to VUSN in 2005 where he currently holds the rank of assistant professor. Travis coordinates several MSN didactic classes and also maintains an active NP practice at several clinical sites affiliated with Vanderbilt Medical Group that include four walk-in clinics as well as a faculty-led NP clinic. His areas of clinical interest include CPAP adherence in patients with sleep apnea, handheld mobile technology, urgent care, and heart failure. Travis is pursuing his PhD in Nursing at the University of Tennessee, Knoxville and will complete the degree requirements in August 2019.