Ecological Momentary Assessment of Sleep Quality, Daytime Fatigue, and Outcomes in Cardiopulmonary Rehabilitation Patients

by

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Background: Sleep-related difficulties are common among patients with cardiovascular and pulmonary diseases. Positive effects of cardiopulmonary rehabilitation (CVPR) programs on health outcomes have been found. Despite this, participation rates in CVPR programs remain suboptimal. Previous research suggests that CVPR may improve sleep quality and daytime fatigue; however, few studies have examined the association between specific sleep parameters and CVPR participation and outcomes. Ecological momentary assessment (EMA) may provide a unique context for patient adherence to CVPR programming, and may offer a better understanding of how daily changes in sleep patterns may affect CVPR outcomes.

Purpose: The current research seeks to explore the potential impact of specific sleep parameters (subjective sleep quality, sleep duration, sleep latency, sleep disturbances, restfulness, daytime fatigue) on patient engagement and CVPR outcomes. Using an EMA paradigm to examine daily sleep patterns, the association between specific sleep parameters and CVPR participation can be more fully understood.

Methods: The sample for this study consisted of 50 patients at a local CVPR center. Patients were first asked to complete a set of questionnaires assessing subjective sleep quality, fatigue, OSA status, and depression. Then, participants were introduced to a mobile EMA application with which they would track their daily sleep patterns and daytime fatigue over the course of two weeks. The number of sessions, completion status, and health outcomes (change in 6MWT, BMI, BP) were recorded after they finished the program.

Results: Findings from this study suggested that there was a significant momentary association between subjective sleep quality, feelings of restfulness (B=-0.12, t=-0.03, p=.000), and daytime fatigue (B=-0.10, t=-0.03, p=.000). Furthermore, we found that poorer sleep quality (PSQI) at baseline was predictive for poorer perceived restfulness across two weeks (B=-0.02, t=0.01, p=.048). Similarly, we found that higher reported daytime fatigue (CFS) at baseline was predictive of restfulness (B=-0.05, t=0.02, p=.021), as well as perceived fatigue (B=-0.07, t=0.42, p=.003) and number of sleep disturbances at the momentary level (B=-0.03, t=0.01, p=.015). Symptoms of depression (B=-0.79, t=0.06, p=.000) and OSA (B=-0.49, t=0.04, p=.000) were also strong predictors for daytime fatigue. Results from this study did not suggest that there was a significant association between daily sleep patterns and number of sessions attended, completion status, or health outcomes. However, we did observe a statistically significant association between daily self-reported sleep duration and change in systolic (b=7.32, p=.047) and diastolic blood pressure (b=5.31, p=.026) from baseline to program completion.

Discussion: Overall, the results from this study support the idea that EMA reports of sleep quality from the previous night's sleep are associated with restfulness and fatigue later in the day. This suggests that whether a CVPR patient rate themselves as being a good or poor-quality sleeper may be influenced by daytime sleep parameters. However, none of the momentary sleep

predictors were associated with the number of sessions attended or completion status. Similarly, few of the momentary sleep predictors were associated with specific health outcomes. While methodological limitations must be considered, it appears as though daily fluctuations in specific sleep parameters are associated with common difficulties noted by CVPR patients. More research in this area is needed to fully examine whether sleep difficulties may influence CVPR engagement and completion, and to design interventions aimed toward improving daytime functioning may also improve patient's subjective evaluation of sleep quality.

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By

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Introduction

Cardiovascular diseases and chronic pulmonary diseases are among the leading causes of death in the United States (American Heart Association, 2010). Cardiovascular and pulmonary rehabilitation (CVPR) programs are aimed towards improving health outcomes in patients who have experienced an acute exacerbation of a chronic respiratory disease or a cardiac event. CVPR programs focus on providing patients with one-on-one supervised exercise training, and practical advice for stress management, increasing activity, and eating a balanced diet outside of rehabilitation (Balady et al., 2007). To date, there is much research to confirm the beneficial effects of CVPR programs on the physical and psychological health of patients with cardiovascular or chronic respiratory diseases, thereby reducing both mortality as well as the rate of hospital readmissions (Halewijn et al., 2017; Lan et al., 2014; Anderson et al., 2016). Physical improvements, such as marked increases in exercise capacity, are often seen in patients who have completed an exercise-based rehabilitation program (Geffen et al., 2015). Further, CVPR is known to improve mood, sleep quality and illness-related fatigue (Suna et al., 2015; Heerema-Poelman, et al., 2013; Soler et al., 2013; Lacasse et al., 1996).

Although there is much research supporting the effectiveness of CVPR in improving health outcomes, rates of attendance in these programs remains suboptimal (Johnston & Grimmer-Somers, 2010). Although barriers to CVPR completion have already been identified, the potential role for sleep in program engagement remain understudied. Evidence suggests that sleep disturbances and illness-related fatigue are some of the most devitalizing symptoms experienced by patients with cardiovascular and chronic respiratory diseases. Sleep and fatigue-related issues often have a considerable impact on an individual's physical and psychological

wellbeing, thereby reducing overall quality of life (Geffen et al., 2015). Previous studies have linked sleep difficulties to many potential long-term health complications such as immunosuppression, impaired tissue integrity and wound healing, muscle aches and pains, and reduced cardiovascular health (Chandola et al., 2010; Gallagher et al., 2015). Further, there is much evidence for the involvement of prolonged sleep difficulties in the onset and maintenance of depression (Rouleau et al., 2015; Banack et al., 2014). Depression has been identified as an important barrier to CVPR engagement and completion (Rao et al., 2019; Casey et al., 2008; Zellweger et al., 2004). Given the critical role of sleep difficulties in the development of depression, it appears that the management of sleep disturbances is important for improving patient engagement in CVPR programs.

There are many factors contributing to sleep disturbances and illness-related fatigue in patients with cardiovascular and chronic respiratory diseases. For instance, obstructive sleep apnea (OSA) is a common sleep disorder that is often comorbid with cardiovascular or chronic respiratory diseases, affecting nearly half of patients entering cardiovascular rehabilitation programs (Le Grande et al., 2016). Previous research suggests that engaging in regular exercise may decrease the overall risk of adverse health outcomes in patients with OSA (Bartels, 2009). However, excessive daytime fatigue and lack of energy remain important barriers to CVPR engagement and have been shown to reduce exercise tolerance (Banack et al., 2014). Therefore, it may be hypothesized that chronic sleep disturbances and excessive daytime fatigue may lead patients to discontinue CVPR prematurely if not sufficiently addressed at the beginning of rehabilitation (Banack et al., 2014).

Despite the impact illness-related fatigue might have on patient engagement, only two existing studies have examined the severity of fatigue in patients entering cardiovascular or

pulmonary rehabilitation (Weinstein et al., 2013; Margarita et al., 2013). Evidence suggests that patients often experience marked improvements in sleep quality and fatigue following an increase in physical activity (Margarita et al., 2013; Weinstein et al., 2013; Hong & Dimsdale, 2003; Aguillard et al., 1998). Therefore, it appears that improvements in exercise capacity following the completion of exercise-based CVPR programs can thereby improve sleep quality and reduce illness-related fatigue.

It is well-understood that sleep quality and fatigue is a critical component of one's physical and psychological health. However, the impact of fatigue on CVPR engagement has not yet been explored in a combined cardiovascular and pulmonary rehabilitation population. An understanding of how illness-related fatigue may impact patient engagement is necessary for gaining insight into how their sleep patterns can affect outcomes. Assessing the incidence, severity, and timing of sleep difficulties and daytime fatigue is critical for accurately attempting to evaluate the impact of these problems on patient engagement. Ecological momentary assessment (EMA) can provide a real-time, real-world sampling of fatigue in patients in CVPR programs. The proposed study examines the applicability of using a mobile-EMA application to capture the daily experience of sleep disturbances and daytime fatigue in CVPR patients. Furthermore, the primary aim of the proposed study is to examine how changes in sleep patterns and daytime fatigue affect CVPR outcomes. To provide a better understanding of how sleep-related factors can provide a unique context for patient adherence to CVPR programming, the links between cardiopulmonary rehabilitation (CVPR) and patient factors must first be discussed.

Cardiopulmonary Rehabilitation (CVPR)

Cardiac and pulmonary disease refers to conditions that affect the structure and functioning of the heart and lungs. Cardiopulmonary rehabilitation (CVPR) is an evidence-based,

secondary prevention treatment that offers structured exercise, education, counseling, and risk reduction strategies to improve the health and wellbeing of patients who have experienced a recent cardiac event, such as myocardial-infarction (MI), have undergone cardiac surgery, or have developed a heart-related health problem such as cardiovascular disease. In addition, CVPR aims to benefit those who have developed chronic obstructive pulmonary disease (COPD), emphysema, or other lung conditions. CVPR aims to improve the outcomes of patients suffering from these conditions by addressing and reducing post-complications, symptoms, and disabilities that are associated with both cardiac and pulmonary disease. CVPR consists of multifaceted and multidisciplinary interventions that are designed to increase the functional capacity of cardiac and pulmonary patients, so they may return to their former routines of daily living prior to the development of their conditions (Balady et al., 2007). To accomplish this goal, The American Heart Association (AHA) and the American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR) have identified six core components that aim to maximize cardiopulmonary risk reduction, enhance emotional wellbeing, reduce disability, and promote an active lifestyle as well as long-term adherence to health behavior change for patients with cardiopulmonary disease (Balady et al., 2007). Core components include: (1) baseline patient assessment, (2) nutritional counseling and education, (3) risk factor modification (i.e., weight management, diabetes management, blood pressure management, and tobacco cessation), (4) attention to and assessment of psychosocial issues, (5) physical activity counseling, and (6) aerobic exercise and resistance training.

CVPR Outcomes for Cardiac Patients

The benefits of cardiac rehabilitation (CR) have been demonstrated across a wide spectrum of patient groups, including those with cardiac conditions, comorbid diabetes,

overweight or obese patients, those with high or low baseline exercise capacity, and elderly patients (Williams et al., 2002; Vonder et al., 2002; Lavie & Milani, 2000). Recent reviews provide evidence for the effectiveness of CR in optimizing functioning and reducing disability as well as risk for recurrent cardiovascular complications (e.g., sudden cardiac arrest, re-infarction; Halewijn et al., 2017; Anderson et al., 2016; Lan et al., 2014; Conn, Hafdahl, Moore, Nielson, & Brown, 2009; O'Connor et al., 1989; Oldridge, Guyatt, Fisher, & Rimm, 1988; Joliffe et al., 2001; Taylor, Brown & Ebrahim, 2004; Thompson et al., 2007). However, outcomes may differ across various disease states. Overall, it is well-established that cardiac rehabilitation has been shown to reduce cardiovascular and all-cause mortality by approximately 20-25%, and hospital readmissions by 18% for post-MI patients (O'Connor et al., 1989; Oldridge, Guyatt, Fisher & Rimm, 1988). A recent meta-regression analysis of 33 trials comparing outcomes of CR to usual care found that high doses of exercise-based CR (i.e., $\geq$ 36 sessions) was followed by reductions in cardiovascular and all-cause mortality and hospital readmissions when compared to low (< 12 session) and medium dose (12-35 sessions) groups (Santiago de Araujo Pio, Marzolini, Pakosh, & Grace, 2017). These results suggest that at least 36 sessions of exercise-based CR may be needed to achieve reductions in overall mortality and cardiovascular risk.

A recent meta-analysis of exercise-based CR by Anderson and colleagues included 63 randomized controlled trials and examined outcomes for cardiac patients (N = 14,486) with a wide range of cardiovascular diagnoses including post-MI, revascularization (i.e., coronary artery bypass grafting or percutaneous coronary intervention), angina pectoris, or coronary heart disease (Anderson et al., 2016). Results demonstrated reductions in cardiovascular mortality by approximately 7-10%, and hospital readmissions by 26-30% following 22 to 37 sessions of exercise-based CR. Much of the observed reductions in cardiovascular risk and mortality can be

attributed to the positive influence CR has in reducing risk factors such as smoking, hypertension, and hypercholesterolemia (Lawler et al., 2011; Taylor, Unal, Critchley, & Capewell, 2006).

Much of the reductions in cardiovascular mortality, hospital readmissions, and recurrent complications can be attributed to the positive influences of exercise-based CR on physical fitness. Recent systematic reviews and meta-analyses have confirmed the beneficial effects of CR in improving aerobic exercise capacity and reducing dyspnea. For example, a meta-analysis of 31 published studies examining improvements in physical fitness found that patients (N = 3,827) can expect marked improvements in exercise tolerance by approximately 1.5 metabolic equivalents (METs) following >36 sessions of exercise-based CR (Sandercock, Hurtado, & Cardoso, 2013). Such improvements in exercise tolerance and cardiorespiratory fitness (e.g., MET increases) have been found to be associated with an approximately 2-12% reduction in cardiovascular mortality in both the general population and cardiac patients (Kavanagh et al., 2006; Vanhees, Fagard, Thijs, & Amery ,1995; Myers et al., 2002; Dorn, Naughton, Imamura, & Trevisan, 1999).

Beyond improvements in physical fitness, CR has been proven to be an effective tool for increasing functional capacity and independence, thereby improving quality of life (QOL) in cardiac patients. For example, a recent meta-analysis examining 20 randomized-controlled trials (RCTs) of exercise-based CR found that 14 of the 20 published studies found marked improvements in health-related QOL when compared with a control group (i.e., no additional exercise group; Anderson et al., 2016). Such increases in health-related QOL and exercise capacity have been observed across a range of cardiac conditions, particularly for heart failure patients enrolled in exercise-based CR (Davies et al., 2010). These studies provide evidence for

the effectiveness of exercise-based CR in improving outcomes across various disease states, thereby highlighting the importance of identifying and understanding factors that may interfere with attendance and completion of CVPR programming.

CVPR Outcomes for Pulmonary Patients

Pulmonary rehabilitation (PR) is recognized as an effective treatment modality in reducing disability and improving health-related QOL of patients with various chronic respiratory diseases (CRDs; Lacasse, Maltais, & Goldstein, 2004; Coventry & Hind, 2007; Lacasse, Goldstein, Lasserson, & Martin, 2006). Despite this, PR outcomes of patients with CRDs remains understudied in comparison to CR outcomes. Several studies have demonstrated that PR can effectively decrease dyspnea and increase aerobic exercise capacity for patients with CRDs (McCarthy et al., 2015; Maltais et al., 2016). Further, a meta-analysis of 14 RCTs found that 4 weeks of PR led to improvements in health-related QOL, dyspnea, and functional exercise capacity as measured by the 6-minute walk test for patients with COPD (Lacasse et al., 1996). There is also evidence of improved outcomes for patients with idiopathic pulmonary fibrosis and interstitial lung disease. For example, a systematic review and meta-analysis by Cheng et al., (2018) found several studies demonstrating that PR could significantly decrease dyspnea, increase health-related QOL, and reduce hospital readmissions and healthcare costs for patients with COPD and interstitial lung diseases (McCarthy et al., 2015; Maltais et al., 2016; Dowman Hill, & Holland, 2014).

Although PR has been associated with improved health-related QOL, dyspnea, and aerobic capacity in patients with CRDs, the evidence on PR outcomes influencing survival is less clear. According to a recent review by Hakamy, Bolton, & McKeever (2017) two randomized controlled trials have examined the mortality of patients following PR. One RCT examining

survival rates in 62 COPD patients found no statistically significant difference in 3-year survival rates when compared to non-PR controls ($N = 62$; Ries, Kaplan, Limberg, & Prewitt, 1995). Further, the second RCT showed that PR led to improvements in 1-year survival rates in patients with COPD ($N = 92$) when compared to controls ($N = 90$), however, this difference was not statistically significant (Griffiths et al., 2000). Overall, these results provide evidence for the effectiveness of PR programming in improving functional outcomes for patients with CRDs, but little evidence for improving mortality.

Referral, Attendance and Completion Rates

Despite its proven benefits in addition to the fact that these services are often covered by Medicare, CVPR remains considerably underutilized due to issues related to enrollment and attendance. A key component to utilization is the appropriate and timely referral of patients to an outpatient CVPR program. However, there are many instances in which providers fail to provide such a referral or when patients decidedly fail to follow through with the referral. A review by Brown et al. (2009) found that 56% of patients hospitalized for recent MI, percutaneous coronary intervention (PCI), or coronary artery bypass graft (CABG) procedure were referred to CR at discharge. Referrals to PR also remain suboptimal, with only an estimated 3-16% of eligible patients with COPD referred (Azarisman et al., 2008; Bourbeau et al., 2008; Lange et al., 2007; Yawn & Wollan, 2008). Further, a recent systematic review by Milner, Boruff, Beaurepaire, Ahmed, & Janaudis-Ferreira (2017) examining referrals to PR found that referrals rates across 35 studies ranged from 0-85% with a median referral rate of 17% for patients with COPD.

Given the low rates of referral, it is perhaps unsurprising that CVPR participation rates also remain at suboptimal levels. It is estimated that fewer than 30% of eligible patients utilize CR services following a cardiac event (e.g., CABG, PCI, cardiac valve surgery, heart

transplantation, central sleep apnea in heart failure, following MI), with the lowest participation rates occurring in the Southern states (Thomas et al., 2010; Suaya et al., 2007). Further, a recent meta-analysis of 14 studies examining CR enrollment and participation found that patient adherence (N = 8176) ranged from 36.7-84.6% of prescribed sessions (i.e., minimum 8 weeks duration, 1 to 3 sessions per week; Oosenbrug et al., 2016). One study of discharged cardiac patients (N = 526) found that the majority (58%) of the patients completed their prescribed CR sessions (i.e., 24 to 36 sessions, 2 to 3 times per week), with 63% of non-completers discontinuing due to nonmedical reasons (e.g., "not interested", "too busy", "can do it at home"; Sanderson, Phillips, Gerald, DiLillo, & Bittner, 2003).

Similar to CR, referral and enrollment rates in PR have also been recognized as suboptimal, considering the substantial health benefits associated with participation. A retrospective analysis of patients (N = 711) diagnosed with COPD found that 157 (31.8%) patients failed to attend a single session of PR, whereas 393 (70.9%) patients attended at least 63% of prescribed session in PR (Hayton et al., 2012). These results indicate that rates of CVPR referral, enrollment, and attendance tend to vary considerably and have shown little improvement in recent years. Further research is needed for a better understanding of the possible predictors for poor adherence to CVPR programming to identify ways in which these patient-level factors can be addressed over the course of treatment.

Barriers to CVPR Attendance and Completion

The extent to which CVPR can effectively improve outcomes may depend on the patient's willingness or ability to attend prescribed sessions and adhere to the recommended health behavior changes that are necessary to achieve the desired benefits (Sanderson et al., 2003; Burke, Dunbar-Jacob, & Hill, 1997; Haynes, 2001; Miller, Hill, Kottke, & Ockene, 1997).

Given the low participation rates in CVPR, many studies have examined barriers to adherence and completion of CVPR programs. While many patients are not able to attend due to medical reasons, studies have shown that a larger proportion of patients may drop-out due to non-medical reasons including the psychological wellbeing of the patient as well as other psychosocial factors (Sanderson et al., 2003). With respect to medical reasons, previous studies have reported that disease severity appears to negatively affect adherence to physical activity, such that patients with more intense symptoms tend to be less adherent to an exercise-based program due to greater impairment and decreased functional capacity (Heerema-Poelman, Stuive, & Wempe, 2013). Further, patients with greater comorbidities, including type II diabetes and overweight and obesity, are found to be less likely to complete CVPR programs, suggesting that medical factors outside of cardiac and pulmonary diagnoses also appear to be important factors related to attendance and completion (Sanderson et al., 2003).

Beyond medical reasons for nonadherence, several patient-oriented factors, health-care system factors, and environmental factors appear to be related to CVPR participation. Lack of referral of CR is the leading system-level predictor of poor CR attendance whereas being female is the leading patient-specific predictor (Becki & Beckstead, 2011). Among 48,993 coronary artery disease patients from 365 hospitals across the United States between 2003 and 2009, only 40% of eligible patients receive CR referrals, and females were 12% less likely to be referred than males (Shanshan et al., 2018). Regarding CR attendance, a recent meta-analysis found that among 8,176 CR patients (27.3% women), more than half of patients adhered to two-thirds of prescribed sessions, with men (68.6%) attending 5% more of prescribed sessions than women (64.2%; Oosenbrug et al., 2016). In addition, age- and sex-specific differences in CR participation have been observed such that attendance is lower for patients older than 70-years

(OR = -0.95 per 1-year increase) and the odds of participation are higher for men (OR = 1.93; Dunlay et al., 2009).

Other factors associated with poor CR attendance include being less educated, socioeconomically disadvantaged and minority status. A recent meta-analysis of 21 studies examining socioeconomic factors related to CR attendance found that a post-high school education (OR = 0.67; 95% CI = 0.50-0.91) and full- or part-time employment (OR = 1.45; 95% CI = 1.08-1.95) is associated with increased likelihood of participating (Sun et al., 2017). Further, patients with an annual gross income greater than $27,000 in addition to being insured (OR = 0.32; 95% CI = 0.14-0.71) have greater odds of participating in CR (Graversen et al., 2017; Sun et al., 2017). Racial and ethnic disparities in CR referral and participation have also been observed, with Black, Hispanic, and Asian patients being 20%, 36%, and 50%, respectively, less likely than White patients to report instruction to attend CR (Shanshan et al., 2018).While fewer studies have examined socioeconomic factors related to adherence to pulmonary rehabilitation, these services tend to be underutilized by women, patients of older age (> 70-years), and those with less education (Hayton et al., 2012).

Research suggests that rural inhabitants are less likely to participate in CR due to barriers that are geographic in nature, including limited access and long travel distances to CR site location. Suaya et al (2007) used patients' residence zip codes to calculate the distance to the closest CR site, and found that patients with a mean distance of 31.8 miles (the furthest quintile group) were 71% less likely to participate in CR. Travel distance has also been recognized as an important predictor of patient utilization of PR, such that driving distances greater than 36 miles have been identified as a risk factor for nonadherence in outpatient PR programs (Fan et al., 2008). Moreover, limited access to transportation, employment obligations and subsequent time

conflicts, and financial constraints surrounding the out-of-pocket costs for co-pays have been recognized as significant barriers to participation in CVPR, particularly for patients with low socioeconomic status (Clark et al., 2012; De Vos et al., 2013; Suaya et al., 2007; Boyden, Rubenfire, & Franklin, 2010; Mazzini et al., 2008). In addition, environmental barriers affecting CR participation among rural patients includes the quality of roadways in addition to harsh weather conditions (Curnier, Savage, & Ades, 2005; Cooper, Jackson, Weinman, & Horne, 2002).

Sleep quality and CVPR non-completion

Getting adequate sleep is an important aspect of maintaining good physical health. Evidence suggests that a restful night's sleep can promote efficient wound healing, including the repair of the heart and blood vessels following a cardiac event (Chandola et al., 2010). Sleep is also involved in important modulatory processes that regulates the immune system, reduces inflammation, and manages pain and hormonal levels (Gallagher et al., 2015). Over time, getting inadequate sleep can affect how we perform in our day-to-day activities and can have a major impact on our overall physical health and quality of life. Poor sleep has been linked with heart disease, hypertension, diabetes, heart failure, heart disease, obesity, heart attack, stroke, and other chronic conditions including impaired cognition, fatigue, lethargy, and depression (Gallagher et al., 2015; Khayat & Pleister, 2018; Lan et al., 2014). Given the high prevalence and potentially fatal consequences of chronic sleep disturbance, increased efforts are needed to recognize and treat poor sleep quality in patients entering cardiovascular and pulmonary rehabilitation (CVPR).

Psychosocial factors such as sleep quality (i.e., subjective sleep quality, habitual sleep efficiency, sleep latency, sleep duration, sleep disturbances, use of sleep medication, and daytime

dysfunction) may also be important factors affecting CVPR attendance and adherence. Poor sleep quality, difficulties initiating sleep and maintaining a consistent sleep-wake schedule, sleep disorders (e.g., chronic obstructive sleep apnea), and daytime fatigue are commonly reported among patients recovering from a recent cardiovascular event (e.g., post-MI, CABG procedure; Izawa et al., 2018; Yilmaz & Iskesen, 2007; Iskesen et al., 2009; Yilmaz & Iskesen, 2007). For example, a study conducted by Banack et al. (2014) evaluating the prevalence of sleep disturbances among 259 patients enrolled in an exercise-based CR program found that 52% of participants reported poor sleep quality. Moreover, Banack et al. (2014) observed an association between sleep quality and depressive symptoms such that 47% of participants also reported experiencing at least mild depressive symptoms, with poor sleep quality occurring more often in those reporting depressive symptoms (77%). Within the sample, women reported higher levels of depressive symptoms as well as poorer quality sleep than did men such that the odds of experiencing sleep disturbances was 3.38 times higher for women with depression relative to men (Banack et al., 2014).

Poor sleep quality and depressive symptoms are also commonly reported among patients with COPD, with as many as 61-75% reporting difficulty initiating and maintaining sleep and an increased number of sleep disturbances during sleep (Soler, Diaz-Piedra, & Ries, 2013; Chou-\Chin et al., 2014; Klink & Quan, 1987; Nunes et al., 2009). Further, objective measures have demonstrated that sleep disturbances are often related to symptoms of COPD including cough, sputum production, and nocturnal oxygen desaturation (Soler, Diaz-Piedra, & Ries, 2013; Krachman, Minai, & Scharf, 2008; Kwon, Wolfe, Lu, & Kalhan, 2009). Even patients ($N = 52$) with mild-to-moderate COPD have been shown to have overall lower sleep efficiency, shortened

sleep duration, and severe airflow obstruction compared to age, gender, and bodyweight matched controls without COPD (Vallpour, Lavie, Lothaller, Mikulic, & Burghuber, 2011).

There is much research supporting the effectiveness of CVPR in improving health outcomes including depression, however, it is possible that sleep disturbances may precipitate nonadherence to CVPR programming. For example, sleep-disordered breathing is an increasingly recognized sleep disturbance that is highly prevalent among cardiopulmonary patients. In comparison to other sleep disorders, obstructive sleep apnea (OSA) has been frequently studied due to its high prevalence among older adults as well as its relationship to cardiopulmonary disease. OSA is characterized by intermittent obstruction of the upper airway during sleep, which disrupts the delivery of oxygen to the body, including the brain, and interferes with the normal sleep-wake cycle. Common symptoms of OSA include loud snoring, gasping or observable episodes of breathing cessation during sleep, and excessive daytime sleepiness or fatigue (Quan & Gersh, 2004). OSA is highly prevalent among the general population (37% of men and 50% of women; Quan & Gersh, 2004), however, the incidence is dramatically higher among cardiopulmonary patients, affecting more than three-quarters of this population (Marzolini et al., 2016; Le Grande et al., 2016; Kohli, Balachandran, & Malhotra, 2015; Lancaster et al., 2009). In addition to being more common among cardiopulmonary patients, OSA is increasingly being connected to cardiovascular disease both in terms of shared risk factors and physiological mechanisms. For example, factors including obesity, hypertension, male gender, and increasing age are recognized as major risk factors for both OSA and cardiovascular disease (Quan & Gersh, 2004).

Given the high prevalence of this sleep disorder, many researchers have sought to understand the degree to which OSA contributes to the progression of cardiopulmonary disease

as well as the beneficial effects of OSA treatment on long term health outcomes. OSA is associated with numerous risk factors for cardiovascular disease, including hypertension, coronary artery disease, arrhythmias, heart failure, and stroke (Bradley & Floras, 2009). Furthermore, it is common for patients with comorbid OSA to report an exacerbation of pulmonary symptoms, including increased shortness of breath and excessive daytime fatigue (Bartels, 2009). Extensive research on this disorder has led to a successful intervention, known as continuous positive airway pressure (CPAP), and has been shown to have a beneficial impact on long-term health outcomes. However, despite being a highly prevalent disorder among cardiopulmonary patients, one study of cardiac patients ($N = 295$) found that only 16.6% were prescribed CPAP and compliance to treatment was poor (63.3%) with discomfort being the greatest barrier (Marzolini et al., 2016). Therefore, despite the high efficacy of CPAP in improving health outcomes, treatment effectiveness is limited by variable adherence to prescribed treatment (Weaver & Grunstein, 2008).

Among cardiopulmonary patients, evidence suggests that the perceived burden of symptoms as well as daily functioning are important factors in determining adherence to prescribed treatment (Weaver & Grunstein, 2008). Furthermore, one study of 242 heart failure patients found the interaction between older age with poorer sleep quality and higher comorbid conditions, including cardiopulmonary disease, to be predictive of poor adherence to prescribed treatments, including CPAP (Knafl & Riegel, 2014; Weaver & Grunstein, 2008). Therefore, it is conceivable that sleep-related factors may also influence adherence to CVPR programming. More research is needed to examine patient-level predictors of poor CVPR adherence, including sleep-related factors such as sleep quality and daytime fatigue.

Fatigue and CVPR non-completion

Poor quality sleep often accumulates a sleep dept that leads to difficulties staying alert as well as mental and physical tiredness that may progress to chronic fatigue (Banks & Dinges, 2007; Elmenhorst et al., 2008; Bonnet & Arand, 2003). Moreover, chronic fatigue has also been associated with numerous adverse health outcomes, including recurrent cardiovascular events, reduced health-related quality of life, as well as higher rates of depression and anxiety among those patients diagnosed with cardiovascular and pulmonary disease (Banack et al., 2014; Mai & Buysse, 2008; Norra et al., 2012). Previous research also indicates that chronic fatigue can also have a negative impact on cardiac patients' daily activities such that daytime dysfunction often leads to exercise intolerance, which also contributes to poorer health outcomes (Chu, Valencia, Garvert & Montoya, 2018; Cvejic et al., 2017; Evangelista et al., 2008).

Among patients diagnosed with cardiovascular disease, daytime fatigue is among the most prominent symptoms of cardiovascular disease, with as many as 69-82% of cardiac patients reporting difficulties staying alert and awake throughout the day (Bartels, 2009; Anderson et al., 2001; Nordgren & Sorensen, 2003), and it is also common among patients with pulmonary disease, with the prevalence of such dysfunction ranging from 68-80% (Bartels, 2009; Skilbeck et al., 1998). Among cardiopulmonary patients, the issue of central versus peripheral causes of fatigue must be addressed when considering the underlying mechanisms of daytime dysfunction. It is clearly established that hypoperfusion, altered metabolism, hypoxemia, and hypercapnia seen in cardiopulmonary disease are common symptoms associated with peripheral fatigue that often result in perceived fatiguing of the muscles themselves, known as physical fatigue. However, fewer researchers have examined other dimensions of fatigue, such as central or mental fatigue, which can also be relevant to disease prognosis and is largely unexplained by

physical symptoms of cardiopulmonary disease. For example, depression and anxiety are thought to be central causes of fatigue seen in patients with cardiopulmonary disease.

In comparison to healthy subjects, research has shown fatigue to most often be the result of pathogenic mechanisms underlying cardiopulmonary disease, including advanced airflow limitation (Antonela-Antoniu et al., 2016). Furthermore, daytime sleepiness is often quite severe among patients with comorbid OSA, and are often related to depression as well as cognitive impairment including deficits in attention, concentration, and memory (Quan & Gersh, 2004). Evidence suggests that an increase in activity can drastically reduce fatigue and can mitigate health complications associated with OSA (Bartels, 2009; Hong & Dimsdale, 2003; Aquillard et al., 1998). However, excessive fatigue can reduce exercise tolerance and may lead patients to discontinue CVPR if not sufficiently addressed at the beginning of rehabilitation. More research is needed to understand the manner in which sleep-disordered symptoms are related to adherence to CVPR.

Ecological Momentary Assessment

For years, psychological research has largely relied on cross-sectional/retrospective assessment as the primary means to gather information about subjects. There is strong evidence suggesting that retrospective self-reports are subject to recall biases that challenge both their reliability and validity (Trull & Ebner-Priemer, 2009). Further, discrepancies between real-time assessments and retrospective self-reports of mood symptoms and behaviors have been identified across a range of mental and physical health problems, including depression and disordered sleep (Trull & Ebner-Priemer, 2009; Solhan, Trull, Jahng, & Wood, 2009; Stone & Broderick, 2007; Fahrenberg et al., 2007; Ben-Zeev & Young, 2010; Grandner, 2016). Ecological momentary assessment (EMA) has received increasing attention over the years as a method for addressing

these limitations through repeated sampling of subjects' current behaviors and experiences in real time, within the subjects' natural environments (Shiffman, Stone, & Hufford, 2008).

Numerous technological methods have been used to record subject experiences at varying time intervals including written diaries, electronic diaries, physiological sensors, telephones, and mobile applications. One advantage of EMA is that it is less influenced by retrospective memory biases and highly sensitive to fluctuating environmental factors involved in real-world contexts. EMA focuses on the subjects' subjective experience in-the-moment (e.g., subjective feelings of tiredness at the time of assessment) without drastically changing or influencing their daily routine. Through strategic selection of times of assessment, EMA allows for the examination of day-to-day, or moment-to-moment changes in variables of interest (Shiffman, Stone, & Hufford, 2008). In this way, EMA can help researchers better understand how behaviors and subjective experiences may vary across time and contexts.

Given the variability in daily experiences, an EMA approach appears to be ideal for the assessment of sleep quality and fluctuations in fatigue throughout the day. Furthermore, evidence suggests that nightly comparisons of sleep quality may prove more useful relative to averaged data (e.g., over the past month), as night-by-night variability in sleep-related factors have been associated with greater sleep complaints among older adults (Kay, Dzierzewski, Rowe, & McCrae, 2013). Lemola, Ledermann, & Friedman (2013) found that greater day-to-day variability in sleep duration was associated with self-reported poorer sleep quality and subjective well-being; however, average sleep duration, sleep latency, and wake after sleep onset were not related to subjective well-being. McCrae et al. (2008) found that lower self-reported sleep quality was associated with more negative affect, but these associations fell short of significance for objective sleep measures (i.e., actigraphy). Further, Russel et al. (2016) completed a daily diary

study investigating the dynamic relationship between subjective and objective sleep measures and symptoms of fatigue in patients with chronic fatigue syndrome. Their findings revealed that subjective, but not objective, measures of sleep were predictive of next-day fatigue. Furthermore, they found that negative mood in the morning mediated the association between subjective sleep quality and next-day fatigue (Russel et al., 2016).

Parsey & Schmitter-Edgecombe (2019) more recently used objective sleep measures as predictors of momentary (i.e., morning, midday, afternoon, and evening) measures of cognition, mood, and fatigue in older adults. They found that EMA reports of fatigue and daytime sleepiness or drowsiness were related to the previous night's sleep such that objectively measured poor sleep efficiency was related to greater sleepiness or drowsiness at the morning time block and levels of fatigue at the morning and midday time blocks but not at the afternoon and evening time blocks (Parsey & Schmitter-Edgecombe, 2019). Interestingly, shortened sleep duration, wake after sleep onset, and prolonged sleep latency fell short of statistical significance as predictors of EMA measures of sleepiness or drowsiness and fatigue the following morning. Further, objective sleep measures did not appear to be predictive of momentary mood and perceived cognitive abilities (e.g., feelings of grogginess or perception of less cognitive clarity in the morning), may have been due to minimal within-person variations in the EMA data for these questions (i.e., mostly average reports; Parsey & Schmitter-Edgecombe, 2019). These findings are consistent with the research of previous studies suggesting that subjective, but not objective sleep quality is associated with mood (e.g., poorer sleep quality correlates with more negative affect; Martin et al., 2010; McCrae et al., 2008).

In summary, these findings suggest that fatigue may be context-specific, and daytime factors (e.g., naps, consumption of caffeine) may influence perceived sleep quality and fatigue

throughout the day. Momentary measures may better capture the contextual effects of sleep quality on fatigue over the course of the day in naturalistic settings. Given the impact of subjective sleep quality on functional capacity and quality of life (Vardar-Yagli, et al., 2015), it is critical to understand how these experiences may influence health behaviors in naturalistic settings, including patient engagement in CVPR.

Aims and Hypotheses

The **first aim** for this study is to use an EMA paradigm to examine within-person correlates, antecedents, and consequences of self-reported sleep quality and daytime fatigue. We hypothesize that:

a. Subjective sleep quality (reported soon after awakening) will be negatively correlated with daytime fatigue (reported at afternoon and evening) such that poorer quality sleep the previous night will be associated with higher daytime fatigue the following day.

b. The within-person association between momentarily reported poor quality sleep and daytime fatigue will be stronger for participants with poorer self-reported sleep quality at baseline (measured using the PSQI).

c. The within-person association between poor quality sleep and daytime fatigue will be stronger for participants with higher depressive symptoms at baseline (measured using the PHQ-9).

d. The within-person association between poor quality sleep and daytime fatigue will be stronger for participants with a positive screening for obstructive sleep apnea at baseline (measured using the STOP questionnaire).

The **second aim** of the study is to examine if subjective sleep quality and daytime fatigue are associated with attendance to CVPR programming. The total number of sessions will be calculated from baseline to CVPR program completion. Our hypotheses include:

a. Poor quality sleep (averaged across two full weeks) will be associated with lower rates of attendance to CVPR programming (i.e., fewer total number of sessions attended).

b. Higher daytime fatigue (averaged across two full weeks) will be associated with lower rates of attendance to CVPR programming.

c. The interaction between poor quality sleep and daytime fatigue will be significantly associated with lower rates of attendance to CVPR programming.

    a. The inverse association will be observed for good sleep quality and lower daytime fatigue.

The **third aim** for the study is to determine whether subjective sleep quality and daytime fatigue are associated with CVPR outcomes (i.e., rates of completion, change in 6-minute walk test, change in blood pressure, change in body mass index). CVPR outcomes will be calculated from baseline to program completion (T1 to T2) and will only include participants who have completed CVPR programming given that measurements at T2 will not be possible for non-completers. We hypothesize that:

a. Poorer quality sleep and higher daytime fatigue will be negatively associated with program completion.

b. Poorer quality sleep and higher daytime fatigue will be associated with lower positive change in CVPR outcomes.

Chapter 2: Methods

Participants

The proposed study is part of an ongoing, collaborative research project designed to examine context-specific predictors of CVPR adherence and health outcomes. Participants are being recruited at the Cardiovascular & Pulmonary Rehabilitation (CVPR) program at Vidant Health and will include both cardiac and pulmonary patients. There are no specific exclusion criteria for age, gender, or race/ethnicity; however, the ability to read and speak English will be required for patients to participate in the study. Patients will not be excluded based on whether they own a smartphone but rather will be provided with a mobile device for the duration of the study. Alternatively, paper versions will be available upon request if interested participants were to express concerns or difficulties in using mobile technology. Participants using paper versions of the daily monitoring forms will be asked to complete the forms on the same schedule as those using their smartphone devices. Regardless of monitoring modality (i.e., smartphone devices, paper forms), participants will be provided with a study information worksheet detailing their daily monitoring schedule (e.g., 9:00 AM, 2:00 PM, 6:00 PM) as well as their specific dates of participation.

A power analysis was completed using MLPowSim software (Brown, Lahi, & Parker, 2009) to determine how many participants would be needed to achieve adequate power for multilevel analyses. Based on the power analysis and previous multilevel findings by Wenze and colleagues (2018) using EMA methodology, it was determined that 40 participants completing at least 28 EMA prompts (i.e., 2 responses per day for 14 days) would achieve 80% power. Given that we do not anticipate all participants to complete 2 responses each day for the duration of the study, it was determined that 50 participants would provide adequate power for our study.

Furthermore, the simulation using MLPowSim indicated that 89% power would be achieved even if 50 participants completed approximately 50% of EMA prompts.

Measures

Baseline sleep quality. Subjective sleep quality will be measured using Pittsburgh Sleep Quality Index (PSQI). The PSQI is a questionnaire that contains 19 self-report items measuring subjective sleep quality during the past month. The PSQI assesses several factors related to sleep including subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleep medication, and daytime dysfunction over the last month on a scale from 0 (*Not during the past month*) to 3 (*Three or more times a week*). The scores are summed and then are grouped into seven individual components of sleep (i.e., sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbance, use of sleeping medication, daytime dysfunction). Further, the total sum of scores are calculated to derive a global PSQI score ranging from 0-21 with scores greater than 5 reflecting poor sleep quality.

Previous research has proven the PSQI to be a good measure of subjective sleep quality, but not a precise measure of objective sleep quality. Polysomnography is considered to be among the most accurate forms of objective measures of sleep quality; however, it has been found that the PSQI does not significantly correlate with polysomnography (Littner et al., 2003; Buysse et al. 1989). It has been suggested that this limitation may be due to the retrospective nature of the PSQI (Buysse et al., 1989), given that respondents are required to subjectively assess their sleep quality over the course of one month. Wrist-worn actigraphy has been widely accepted as an acceptable alternative to polysomnography (Kushida et al., 2001; Kanady et al., 2011; Marino et al., 2013), and is commonly used to objectively measure sleep quality in one's natural environment (Littner et al., 2003). Previous research comparing subjective and objective

measures of sleep quality has found the PSQI to be weakly correlated with actigraphy (Landry, Best, Liu-Ambrose, 2015). Results from these studies suggest that perceived d sleep quality is quite different from objective reality such that the PSQI is a valuable tool for assessing subjective aspects of sleep quality including depth or restfulness of sleep (Landry, Best, Liu-Ambrose, 2015; Carpenter & Andrykowski, 1998; Backhaus et al., 2002).

Baseline fatigue. Subjective symptoms of fatigue will be measured using the Chalder Fatigue Scale (CFS). The CFS is a self-report measure that was developed as a brief assessment tool to be used in both primary and secondary care (Chalder et al. 1993). The CFS consists of 11-items assessing symptoms of fatigue including tiredness, sleepiness, lack of energy, lack of strength in the muscles, and difficulties in concentration and memory over the past month using a scale from 0 (*Less than usual*) to 3 (*Much more than usual*). The scores are then summed to calculate a total score ranging from 0 to 33 with scores greater than 14 reflecting greater overall fatigue.

Baseline OSA symptoms. The STOP questionnaire is a brief, self-report measure that was developed to meet the need for a reliable, concise, and easy-to-use screening tool for symptoms of chronic obstructive sleep apnea (OSA; Chung et al., 2008). The four-item STOP questionnaire is a self-report, forced-choice (yes/no) scale that consists of the following four questions: S – "Do you Snore loudly (louder than talking or loud enough to be heard through closed doors)", T – "Do you often feel Tired, fatigued, or sleep during the daytime?", O – "Has anyone Observed you stop breathing during your sleep?", and P – "Do you have or are you being treated for high blood Pressure?". A score of 1 is given for each affirmative response and scores are summed to calculate the total score ranging from 0 to 4 with scores greater than 2 reflecting high risk for moderate to severe OSA.

Baseline depressive symptoms. Symptoms of depression will be assessed using the Patient Health Questionnaire – 9 (PHQ-9). The PHQ-9 is a brief, self-report measure that is commonly used to assess the severity of depression for patients in clinical or research settings (Kroenke, Spitzer, & Williams 2002). The PHQ-9 requires participants to rate the degree to which they have experienced each of the nine DSM-IV diagnostic criteria for depression over the past two weeks with scores ranging from 0 (*Not at all*) to 3 (*Nearly every day*). These scores are then totaled, with higher scores reflecting greater levels of depressive symptoms (i.e., scores of 10 or higher indicate mild depression, scores of 15 or higher indicate moderate depression, scores of 20 or higher indicate severe depression).

Momentary sleep quality ratings. Subjective sleep quality will be momentarily assessed using a 6-item measure of sleep quality (see Appendix A). The measure includes items derived from the Pittsburgh Sleep Quality Index (PSQI; Buysse et al., 1989). Participants will be asked to rate the quality and restfulness of their sleep on a Likert scale ranging from 0 to 3, with higher scores reflecting poorer overall sleep quality. Participants will also be asked to estimate their sleep/wake times (i.e., "What time did you go to bed last night?", "What time did you wake up this morning?") in order to calculate total sleep duration.

Momentary fatigue ratings. Participants will be asked to respond to the following question to assess momentary fatigue: "How tired (sleep/drowsy, low energy, problems thinking clearly) do you feel right now?" with responses ranging from 1 (*Not at all tired*) to 6 (*Extremely tired*).

Procedure

The study will be conducted at the Cardiovascular and Pulmonary Rehabilitation (CVPR) program at Vidant Health. Patients who are within their first two weeks ($\leq$ 6 sessions) of the

program will be approached by members of the research team as well as nursing staff at CVPR and asked if they might be interested in participating in the study. Patients who express interest in participating in the study will be invited to participate in a baseline session with a member of the research team. This session is expected to last approximately 15-20 minutes in which participants will be provided with informed consent. Participants will also be given the opportunity to ask questions regarding the study. Interested participants who do not own a smartphone device will be given the opportunity to borrow a device for the duration of the study or to complete paper versions of the momentary assessments. After providing informed consent, participants will be introduced to the EMA mobile application and will be instructed on the procedures for responding to daily assessment prompts. The Personalized Analytics Companion (PACO) is an open-source data collection platform that was designed for ecological momentary assessment. To orient themselves to the app, participants will be asked to complete an initial measure of sleep quality and will be given the opportunity to ask questions. As part of a joint research study, participants will also be asked to complete momentary assessments of mood and experiential avoidance. Participants at the CVPR program at Vidant Medical Center would have already completed the PHQ-9 during their initial CVPR session, prior to enrolling in the study.

Momentary Assessments. Participants will be asked to respond to prompts three times per day (i.e., morning, afternoon, evening) for two full weeks (i.e., 14 days). Each morning, participants will be asked to respond to six questions related to their perceived sleep quality the previous night. Participants will also be asked to rate their current mood, experiential avoidance, perceived stress, and level of fatigue during the afternoon and evening prompts. Following two weeks of monitoring, each participant will be asked to return their mobile device or completed paper forms. Participants will be monetarily compensated at the beginning of their participation

in the study (i.e., during the baseline assessment session) by being provided a gift card to a local vendor amounting in five dollars.

Post-EMA session. Following two weeks of data collection, participants will be given the opportunity to participate in a post-EMA session lasting approximately 10-15 minutes. During this session, they will be provided with feedback regarding their sleep quality and mood ratings over the past two weeks as well as handouts regarding sleep hygiene and stress management skills. Participants will also be given the opportunity to ask questions regarding their perceived sleep quality and mood throughout the duration of the study. The post-EMA session is optional to participants, however, it is included in this study as a means of further incentivizing participation through a mild psycho-educational intervention. Participants will also be provided with an additional gift card to a local vendor (i.e., five dollars) for participating in this optional session.

CVPR Registry Outcomes. As part of standard care, patients are regularly monitored as they progress through the CVPR program at Vidant Health. Once patients have completed the program or have discontinued attendance, their medical record will be reviewed and entered into the American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR) online registry by CVPR staff members as part of standard procedure. The AACVPR registry includes patient demographic information as well as health outcome data related to their progress in the CVPR program at Vidant Health. Of interest for the current study, outcome data will be reviewed by members of the research team including the total number of sessions prescribed and attended, and whether they completed the CVPR program. Rates of completion are determined by whether the patient met their treatment goals set by the patient and CVPR staff members. Additionally, outcome data including pre- and post-measures of body mass index, blood

pressure, and 6-minute walk test times will also be reviewed by members of the research team. To protect the patients' confidentiality, registry data will be matched to their EMA data and will then be deidentified by deleting any identifying information not deemed pertinent to the study including first and last names, dates of birth, and zip codes.

Planned Data Analyses

The preliminary aim of this study is to examine the potential momentary association between subjective sleep quality and daytime fatigue. To do this, multilevel linear regression will be employed to examine the within-person correlates between overall sleep quality and daytime fatigue. To explore these within-person relationships, demographic covariates (level 1) will be nested within individuals (level 2), to examine the correlations between the variables of interest and demographic characteristics (i.e., age, sex, race/ethnicity). The variables of interest (level 1) will be nested within individuals (level 2), allowing for the estimation of a unique relationship between momentary sleep quality and daytime fatigue for each participant. Baseline sleep quality, fatigue, OSA symptoms, and depressive symptoms will also be nested within individuals (level 2), to examine how these variables interact with the within-person correlates of momentary sleep quality and fatigue. For example, we hypothesize that self-reported sleep quality at baseline (level 2) will significantly interact with the within-person associations between momentarily reported poor quality sleep and daytime fatigue (level 1).

The secondary and tertiary aim of this study is to examine the potential role of subjective sleep quality and daytime fatigue in determining outcomes for CVPR (i.e., total number of sessions attended, rates of completion, change in 6-minute walk test, change in blood pressure, change in body mass index). The within-person association between momentary sleep quality and fatigue and CVPR outcomes will be examined using multiple linear regression. Similar to

the first aim, all variables of interest will be entered at level 1 and outcome variables will be entered at level 2 (within individuals). Outcome variables will be continuous whereas rates of completion as an outcome variable will be dichotomized (i.e., completed vs. not completed).

Anticipated Methodological Limitations

There are several potential methodological limitations that must be considered with the proposed methodological approach. First, we anticipate that some patients will express disinterest or apprehensiveness related to using a mobile app for daily monitoring. Specifically, many patients may have limited exposure to using mobile technology, given the older age and rurality of the majority of the current patient population at CVPR at Vidant Health. To address these issues, we will be providing mobile devices to individuals who do not currently own a device, and will be offering paper versions of the daily diary forms to those who express disinterest in borrowing a mobile device. We also plan to walk each patient through the process of completing an EMA prompt as well as to allow the opportunity for patients to ask questions regarding the EMA mobile app before agreeing to participate.

Our primary aims of the study include examining whether momentary sleep quality and fatigue is related to CVPR attendance and outcomes. However, it is possible that patients who express interest in participating in the study will be more likely to be regular attendees. Therefore, it is possible that we may be unable to detect whether sleep quality and fatigue predicts the total number of sessions attended. However, we plan to address this issue by recruiting participants within their first two weeks of CVPR programming when they are more susceptible to lower attendance and dropout (Casey et al., 2008). Lastly, we expect that patients who experience more difficulties with attendance may be less likely to adhere to daily monitoring prompts. However, despite these potential limitations of the proposed study, these

methodological considerations provide valuable insight regarding the feasibility of using mobile technology to predict outcomes in a CVPR setting.

Chapter 3: Results

Demographics of the Sample

The sample for this study consisted of 50 participants. Overall, the sample contained 30 women (57.7%) and 20 men (38.5%), with an age range of 28- to 89-years (*M*=63.82, *SD*=11.63; three participants did not report age). The sample was predominantly non-Hispanic White or Caucasian (76.9%, *n*=40), with eight (15.4%) Black or African American participants, and one (1.9%) non-white Hispanic or Latino participant (one participant did not report race). Education level was dichotomized into those who obtained less than a college degree and those with a college degree or above. Twenty-nine participants (55.8%) reported an educational level below that of a college graduate, whereas thirteen participants (25.0%) endorsed being a college graduate or having post-graduate education; ten (19.2%) did not report an education level. The majority of the sample largely consisted of cardiac patients (78.8%, *n*=41), while the remaining nine participants (17.3%) were classified as being pulmonary patients. Demographic information is presented in Table 1, which contrasts demographic information between individuals who completed and did not complete the CVPR program.

Table 1: Demographics of completers and non-completers and of the overall sample.

Demographics	Completers (*N*=32)	Non-Completers (*N*=13)	Total Sample (*N*=45)
Sex			
Male	14 (70.0%)	3 (15.0%)	20 (38.5%)
Female	17 (56.7%)	10 (33.3%)	30 (57.7%)
Race			
White or Caucasian	12 (30.0%)	28 (70.0%)	40 (76.9%)
Black or African American	8 (100.0%)*	0 (0.0%)	8 (15.4%)
Hispanic or Latino	0 (0.0%)	1 (100.0%)	1 (1.9%)
Age			
Mean Age	65.81 $\pm$ 12.36	58.54 $\pm$ 8.57	63.82 $\pm$ 11.63
Education Level			
Below College Graduate	19 (65.5%)	10 (34.5%)	29 (55.8%)
College Graduate or Above	11 (84.6%)	2 (15.4%)	13 (25.0%)
Patient Classification			
Cardiac	24 (58.5%)	12 (29.3%)	41 (78.8%)
Pulmonary	8 (88.9%)	1 (11.1%)*	9 (17.3%)

First, analyses were conducted to determine whether there were significant differences in the demographic characteristics of those who completed CVPR programming versus those who did not complete. Chi-square analyses were utilized for categorical demographics (race, education level, and patient classification) and t-tests were used for continuous demographics (age). Older age (t=3.392, p=.001), patient classification (X^2=205.370, p=.000), higher level of education (X^2=305.625, p=.000), and sex (X^2=10.186, p=.012) were found to be significantly associated with completion status (Table 2).

Table 2: Association between demographics and completion status

	Completion Status
Demographics	
Sex	X^2=10.186*
Race	X^2=220.510**
Education Level	X^2=305.625**
Patient Classification	X^2=205.370**
Age	t=3.392**

**Significant at the p<.05 level **Significant at the p<.01 level*

Then, analyses were conducted to determine the interrelationship between the predictor variables in the study. As such, a correlation table was created, and Pearson correlation coefficients were examined. The correlation table for the main predictor variables (i.e., daily self-reported sleep latency, sleep disturbances, sleep quality, restfulness, sleep duration, daytime fatigue averaged across two full weeks) is shown below (Table 3). These predictor variables were averaged across two full weeks of data collection for ease of interpretation. Results indicated that several of the predictor variables were significantly correlated with other

predictors in the sample. Specifically, nightly sleep disturbances were significantly correlated with sleep duration (p=.016) and perceived feelings of restfulness upon awakening (p=.014). In addition, daily self-reported sleep quality was also significantly associated with perceived feelings of restfulness upon awakening (p=.000).

Table 3: Correlations for interrelationship of predictors

	Sleep Latency	Sleep Disturbances	Sleep Quality	Restfulness	Sleep Duration	Daytime Fatigue
Sleep Latency						
Pearson Correlation		.255	-.279	-.353	.260	.174
Significance		p=.077	p=.052	.p=.052	p=.071	p=.271
N		49	49	49	49	42
Sleep Disturbances						
Pearson Correlation	.		-.230	-.350	.343	.176
Significance			p=.112	p=.014*	p=.016*	p=.266
N			49	49	49	42
Sleep Quality						
Pearson Correlation				.749	.093	-.202

Significance				p=.000*	p=.524	p=.195
N				50	49	43
Restfulness						
Pearson Correlation					.113	-.274
Significance					p=.438	p=.076
N					49	43
Sleep Duration						
Pearson Correlation						-.085
Significance						p=.592
N						42

**Significant at the p<.05 level*

Aim #1: Daily interplay Between Sleep Quality and Daytime Fatigue

Using multilevel linear regression, we examined the influence of daily self-reported sleep quality, sleep duration, sleep latency, and sleep disturbances based on last night's sleep as well as perceived feelings of restfulness upon awakening on daytime fatigue throughout the day (measured twice daily). We found a statistically significant association between perceived sleep quality (*B*=-0.10, *t*=-0.03, *p*=.000), and feelings of restfulness upon awakening (*B*=-0.12, *t*=-0.03, *p*=.000) and fatigue. All other momentary sleep predictors fell short of statistical significance. These results are presented below in Table 4.

Table 4: The associations between last night's sleep predictors and next-day fatigue

	Estimate (B)	Std. Error	Significance
Momentary Sleep Predictors			
Sleep Quality	-0.10	0.03	p=.000*
Sleep Duration	-0.01	0.02	p=.514
Sleep Latency	0.06	0.05	p=.220
Sleep Disturbances	0.05	0.05	p=335
Restfulness	-0.12	0.03	p=.000*

**Significant at the p<.05 level*

A linear regression was utilized to examine whether baseline sleep quality (Pittsburgh Sleep Quality Index) and fatigue (Chalder Fatigue Scale) are associated with daily self-reported sleep quality, sleep duration, latency to fall asleep, sleep disturbances, restfulness, and daytime fatigue over the following two weeks. Predictor variables were averaged across the two full weeks of data collection, whereas baseline measures were administered prior to momentary assessment. These results are presented below in Table 5. As previously mentioned, higher scores on the PSQI and CFS are thought to be indicative of poorer subjective sleep quality and daytime fatigue, respectively. We found that higher baseline scores on the PSQI were significantly associated with perceived feelings of restfulness upon awakening across the subsequent two full weeks of data collection (B=-0.02, t=0.01, p=.048). None of the other outcome variables were significantly associated with baseline PSQI scores. Baseline CFS scores, on the other hand, were significantly associated with perceived fatigue (B=-0.07, t=0.42, p=.003), restfulness (B=-0.05, t=0.02, p=.021), and number of sleep disturbances (B=-0.03, t=0.01, p=.015) across two full weeks. These results suggest that participants with higher PSQI

and CFS scores may be more likely to experience more frequent sleep disturbances as well as higher daytime fatigue and poorer perceived restfulness upon awakening.

Table 5: Association between baseline sleep quality (PSQI) and fatigue (CFS) and momentary sleep predictors

	Estimate (B)	Std. Error	Significance
PSQI Total Score			
Daytime Fatigue	0.04	0.01	p=.070
Sleep Quality	-0.02	0.01	p=.114
Sleep Duration	-0.03	0.02	p=.899
Sleep Latency	0.03	0.01	p=.685
Sleep Disturbances	0.01	0.04	p=.832
Restfulness	-0.02	0.01	p=.048*
CFS Total Score			
Daytime Fatigue	0.07	0.42	p=.003*
Sleep Quality	-0.01	0.03	p=.656
Sleep Duration	0.02	0.06	p=.708
Sleep Latency	0.01	0.02	p=.688
Sleep Disturbances	0.03	0.01	p=.015*
Restfulness	-0.05	0.02	p=.021*

**Significant at the p<.05 level*

It is well-known that subjective sleep quality and daytime fatigue can be confounded by other variables that potentially affect both sleep quality and fatigue. For example, disruptions in mood, including symptoms of depression, and comorbid medical conditions such as OSA are

both known to affect both sleep quality and fatigue. In order to examine whether our results were affected by symptoms of depression or OSA, a multiple linear regression was utilized to examine the effect of these symptoms on daytime fatigue across two full weeks. Of note, multilevel analyses were not utilized given that baseline measures for depression and OSA were administered prior to momentary data collection. Daily self-reported fatigue was averaged across two full weeks of data collection for ease of interpretation. The results can be seen in Table 6 below. We found that participants who screened positive for depression at baseline reported significantly higher rates of daytime fatigue across two full weeks (B=-0.79, t=0.06, p=.000). Similarly, a positive screening for OSA was also found to be significantly associated with daytime fatigue (B=-0.49, t=0.04, p=.000). These results suggest that symptoms of depression and OSA are significantly predictive for daytime fatigue at the independent level.

Multiple linear regressions were then utilized to examine whether the association between perceived sleep quality and daytime fatigue was influenced by these common confounders (symptoms of depression and OSA). Symptoms of depression were measured at baseline using scores from either the PHQ-9 or Center for Epidemiological Studies – Depression Scale (CES-D). When available, PHQ-9 scores were prioritized over CES-D scores. Total scores were then calculated using cut-off scores (score 10 or greater for PHQ-9; score of 16 or greater for CES-D) for depression assessment, and participants were dichotomized in a non-depressed or depressed group. Additionally, OSA symptoms were measured at baseline and responses were dichotomized using the STOP self-report measure in which participants were considered to screen positive for OSA if they obtained a total score of 2 or greater. Table 6 describes these confounds and their correlations with momentary sleep predictors. We found that the association

between perceived sleep quality and daytime fatigue was no longer significant after accounting for symptoms of depression and OSA.

Table 6: Association between momentary sleep predictors and daytime fatigue in the presence of potential confounders

	Estimate (B)	Std. Error	Significance
Positive Depression Screening Alone			
Daytime Fatigue	0.79	0.06	p=.000*
Positive OSA Screening Alone			
Daytime Fatigue	0.49	0.04	p=.000*
Positive Depression Screening + Momentary Sleep Predictors			
Sleep Quality	0.01	0.09	p=.926
Sleep Duration	0.01	0.08	p=.895
Sleep Latency	0.01	0.09	p=.775
Sleep Disturbances	-0.72	0.44	p=.114
Restfulness	-0.75	0.44	p=.103
Positive OSA Screening + Momentary Sleep Predictors			
Sleep Quality	0.02	0.07	p=.782
Sleep Duration	0.02	0.07	p=.792
Sleep Latency	0.02	0.07	p=.775
Sleep Disturbances	-0.03	0.40	p=.934
Restfulness	-0.15	0.39	p=.697

*Significant at the p<.05 level

Aim #2: Momentary Sleep Predictors and Number of Sessions Attended

A linear regression was utilized to examine the effect of daily self-reported sleep quality, sleep duration, latency to fall asleep, sleep disturbances, restfulness, and daytime fatigue on the number of CVPR sessions attended. These variables were averaged across the two full weeks of data collection for ease of interpretation. The results are presented below in Table 7. Briefly, none of the predictors were found to be significantly associated with the number of CVPR sessions attended.

Table 7: Linear regression results for total number sessions attended

Predictors	Unstandardized Beta Weights (*b*)	Significance
Momentary Sleep Predictors		
Sleep Quality	2.06	p=.420
Sleep Duration	-0.64	p=.776
Sleep Latency	-0.65	p=.816
Sleep Disturbances	1.06	p=.837
Restfulness	-2.97	p=.390
Daytime Fatigue	1.56	p=.378

**Significant at the p<.05 level*

Aim #3: Sleep Quality and Daytime Fatigue and CVPR Outcomes

A multiple linear regression was also utilized to examine the association between daily self-reported sleep quality, sleep duration, latency to fall asleep, sleep disturbances, restfulness, and daytime fatigue and participant outcomes for the CVPR program. These variables were

averaged across the two full weeks of data collection. CVPR outcomes (completion status, change in 6MWT, BP, BMI) were calculated from baseline to program completion (T1 to T2). Of note, these analyses only include participants who have completed CVPR programming (*N*=32), given that measurements at T2 were not possible for non-completers. The results can be seen below in Table 8.

Table 8: Association between momentary sleep predictors and CVPR outcomes

Predictors	Unstandardized Beta Weights (*b*)	Significance
Completion Status		
Sleep Quality	0.10	p=.366
Sleep Duration	0.14	p=.130
Sleep Latency	0.07	p=.545
Sleep Disturbances	0.00	p=.989
Restfulness	-0.01	p=.924
Daytime Fatigue	-0.08	p=.318
Association with Increase in Walk Distance (6MWT)		
Sleep Quality	13.12	p=.712
Sleep Duration	-91.31	p=.850
Sleep Latency	54.80	p=.375
Sleep Disturbances	239.06	p=.461
Restfulness	1.34	p=.988
Daytime Fatigue	-12.92	p=.811

Association with Decrease Systolic BP		
Sleep Quality	-4.09	p=.278
Sleep Duration	7.32	p=.047*
Sleep Latency	1.76	p=.698
Sleep Disturbances	-1.72	p=.641
Restfulness	-7.03	p=.172
Daytime Fatigue	-3.05	p=.321
Association with Decrease in Diastolic BP		
Sleep Quality	-4.86	p=.054
Sleep Duration	5.31	p=.026*
Sleep Latency	0.28	p=.922
Sleep Disturbances	0.01	p=.999
Restfulness	-0.51	p=.872
Daytime Fatigue	-1.58	p=.415
Association with Decrease in BMI		
Sleep Quality	21.93	p=.804
Sleep Duration	-43.48	p=.467
Sleep Latency	-38.99	p=.617
Sleep Disturbances	46.76	p=.707
Restfulness	-12.52	p=.909
Daytime Fatigue	-33.74	p=.528

**Significant at the p<.05 level*

As with the total number of sessions completed, none of the predictor variables were statistically significant predictors for completion status. Furthermore, the predictor variables were also not significant predictors for change in walk distance (6MWT) and BMI from baseline to completion. While the predictor variables were not significant predictors for change in 6MWT and BMI, sleep duration was a significant predictor for change in systolic (b=7.32, p=.047) and diastolic BP (b=5.31, p=.026) from baseline to program completion. These results suggest that participants with longer sleep duration experienced statistically significant reductions in systolic and diastolic BP from baseline to program completion than those with shorter sleep duration.

Chapter 4: Discussion

Review of the Results

The current study sought to examine the role of daily perceived sleep quality and daytime fatigue on completion and outcomes in a cardiopulmonary rehabilitation program. For the primary aim of the study, an EMA paradigm was used to examine within-person correlates, antecedents, and consequences of subjective sleep parameters. Our findings indicated that perceived sleep quality and feelings of restfulness upon awakening were predictors for daytime fatigue later in the day (afternoon and evening). Additionally, we found that subjective sleep quality (PSQI) at baseline was predictive for poorer perceived feelings of restfulness upon awakening across two full weeks. Similarly, we found that higher reported daytime fatigue (CFS) at baseline was predictive of restfulness, as well as perceived fatigue and number of sleep disturbances at the momentary level. This is consistent with previous findings which have suggested that an individual's judgement of subjective sleep quality is often influenced by their memories of what happened during sleep (e.g., self-reported sleep disturbances) and their experience upon awakening (e.g., feeling refreshed upon awakening; Parsey & Schmitter-Edgecombe, 2019). These findings also suggested that whether an individual rate themselves as being a good or poor-quality sleeper may be largely influenced by daytime sleep parameters such as tiredness upon awakening and throughout the day. This is consistent with findings by Parsey & Schmitter-Edgecombe (2019) , which found that subjective sleep quality was associated with EMA reports of daytime fatigue. Interestingly, combinations of these sleep parameters are similar to some of the statements featured in the Dysfunctional Beliefs and Attitudes about Sleep (DBAS) scale (Morin, Vallières, & Ivers, 2007). For example, "I need 8-hours of sleep to feel refreshed and function well during the day." It is possible that endorsement of rigid, unhelpful

sleep beliefs may have a direct or indirect effect on people's judgement of sleep quality and restfulness, which may have influenced the present findings. Furthermore, this effect on people's judgement may also apply to those experiencing symptoms of depression and obstructive sleep apnea, which are commonly reported by CVPR patients.

For the primary aim of the study, it was hypothesized that symptoms of depression and OSA may be highly associated with the momentary relationship between perceived sleep quality and daytime fatigue given that previous literature has suggested heightened levels of fatigue and poorer sleep quality. We found that symptoms of depression and OSA at baseline were strong predictors for daytime fatigue. Given that daytime fatigue is often viewed as a common symptom of depression (Banack et al., 2014) and OSA (Quan & Gersh, 2004), these results are relatively unsurprising. The findings from the present study also found that the association between daily self-reported sleep quality and daytime fatigue was no longer significant after accounting for symptoms of depression and OSA. This result suggests that the presence of OSA or depressive symptoms may determine whether an individual tends to report poorer sleep quality and higher levels of fatigue on average. It is possible that including momentary measures of mood would have resulted in a better view of the influence of negative mood symptoms on the temporal relationship between sleep quality and mood and resulted in different findings.

The secondary aim of the study was to examine momentary sleep quality and daytime fatigue as predictors of attendance to CVPR programming. However, results from the present study did not support the idea that daily sleep-related factors were predictive of the number of sessions attended. Neither momentarily reported subjective sleep quality nor daytime fatigue were associated with number of sessions attended. This result is surprising given that previous studies have shown that subjective sleep quality and daytime fatigue is often associated with

exercise intolerance, which has been linked to lesser likelihood of CVPR adherence and completion (Banack et al., 2014). While there is not much previous literature on using momentary measures of sleep quality and fatigue as predictors of CVPR attendance, it was hypothesized that individuals who experienced poorer sleep quality and higher levels of fatigue may be less likely to engage in CVPR programming. Given that CVPR has been shown to be effective at improving sleep quality and fatigue (Weinstein et al., 2013), it is possible that participants who experienced sleep-related difficulties at the beginning of the program began to feel better from engaging in CVPR programming, which reinforced them to attend more sessions.

The third aim of the study was to determine whether momentary sleep parameters were associated with specific health outcomes following CVPR program completion. Similar to the total number of sessions completed, daily self-reported sleep quality and daytime fatigue were not associated with outcomes following engagement in CVPR programming. For the exploratory hypothesis of including momentary sleep quality and daytime fatigue as predictors for participant outcomes, results did not support the idea that these momentary measures would be predictive of completion status, as well as increase in walk distance and decrease in BMI over the course of CVPR programming. Interestingly, results did show that daily self-reported sleep duration was associated with change in systolic and diastolic blood pressure from baseline to CVPR program completion. While there is not much previous literature on using momentary measures of sleep duration as predictors for changes in blood pressure, this corroborates previous findings by Grandner and colleagues (2018) which indicate that short sleep duration is associated with hypertension risk. Of note, the third aim of the study only included those who completed CVPR programming (N=32). Therefore, to check whether our non-significant results were due to a lack

of statistical power, a post hoc power analysis was conducted using GPower (Faul, Erdfelder, Lang, & Buchner, 2007). Based on this power analysis, it was determined that 98 participants would be needed to achieve 80% power for this particular aim. Therefore, it is possible that our non-significant findings may be due to our limited sample size.

Limitations of the Current Research

As noted above, some of the results of this study appear to be inconsistent with results typically found within literature in this area. Therefore, it is possible that some of the limitations of the methodology of the current study may have affected the results. In the final sample, about 71% of the participants in the study completed the CVPR program, which reflects significantly higher rates of completion than previous research has found (36%, Oosenbrug et al., 2016). This finding is somewhat surprising, given that participants in the present study attended approximately 22-30 sessions, on average. According to AACVPR guidelines, a complete course of CVPR programming is typically considered attending ≥36 supervised sessions. Of note, at our facility, patients may graduate from CVPR programming in fewer than 36 sessions, depending on their assessed level of risk and their progress over time. Therefore, it is possible that some of the results were influenced by the variability in the number of sessions required for patients to complete CVPR programming at our facility.

It is also possible that the current sample was not representative of the population of CVPR patients. In the final sample, nearly 45% of pulmonary patients and 64% of cardiac patients who were enrolled in the present study identified as being female, which reflects different sex distributions than the AACVPR online registry indicates (i.e., compared to 50% pulmonary patients and 28.2% cardiac patients nationwide). Additionally, our final sample comprised of 22.2% of pulmonary patients and 14.6% cardiac patients who identified as being

Black or African American, which also reflects different racial/ethnic distributions when compared to nationwide AACVPR patient demographics (i.e., 6.5% pulmonary patients, 4.2% cardiac patients).

There are several possible explanations for why the sample in this study may not generalize to other previous studies. Firstly, patients were recruited by members of the research team as well as nursing staff at Vidant CVPR. While the ultimate goal was to approach all eligible patients (i.e., those within their first two weeks of CVPR programming), it is possible that some patients were not approached to participate. Given that previous research has suggested that most patients who drop out of CVPR programming will do so early (Casey et al., 2008), we decidedly recruited patients within their first two weeks of the program. It is possible that patient engagement in CVPR programming may be been indirectly affected by participating in the present study, which may have influenced our findings. Additionally, some patients declined to participate when approached with information about the study; therefore, although data were not collected on those who declined to participate, it is possible that those who voluntarily participated in this study experienced fewer sleep-related difficulties and were more amenable to CVPR programming, and therefore less likely to drop out. Furthermore, the sample size in the present study was smaller than many other studies involving the CVPR population; therefore, it is possible that some of the results which were approaching statistical significance would have been observable with a larger sample size.

There were several other potential limitations to the current study which should be considered when interpreting the results, in addition to sample size. First, this study does not include an objective measure of sleep, such as actigraphy. Though several studies suggest that sleep indices obtained through self-report are better predictors for daytime functioning than

objective measures (Parsey & Schmitter-Edgecombe, 2019; Russel et al., 2016). An important limitation in the use of event-based monitoring is that there is often no way to independently assess or verify compliance. In other words, momentary reports are subject to error resulting from poor compliance or falsification. In a previous study conducted by Russel and colleagues (2016), sleep diary entries have been compared to records made by actigraphy devices, and have suggested that subjective estimates of sleep parameters (e.g., sleep duration, number of sleep disturbances) tend to significantly differ from objective report. Furthermore, research has demonstrated that subjective sleep quality is a better predictor for daytime fatigue than objective measures of sleep duration (Parsey & Schmitter-Edgecombe, 2019; Russel et al., 2016). Therefore, despite potential methodological limitations, our findings appear to be consistent with previous studies showing that perceptions of sleep quality and restfulness upon waking are different from what is objectively measured but can provide important information regarding daytime functioning.

The primary aim of this study was to determine whether day-to-day fluctuations in subjective sleep quality and daytime fatigue is related to CVPR attendance and outcomes. Instead of asking participants to give a standard rating of their sleep quality, we asked them to report on each night's sleep over the course of two full weeks. As previously discussed, it is difficult to determine what the defining feature of sleep quality is. Sleep is considered to be a behavioral state of reduced activity with which people typically remember little of what happened during the hours of sleep (Perlis et al., 2001). In contrast, the feelings an individual has upon waking and their evaluations of their own restfulness and alertness during the day are relatively more accessible information. It is feasible that participants in the present study may have drawn upon their experience during the morning (i.e., ease of waking, overall mood,

excitement about the day's activities) to judge their current feelings of fatigue. The nature of momentary assessment also raises several interesting possibilities for future investigation. First, an individual's judgement of restfulness upon awakening may vary depending on the time of day the question is presented and the amount of relevant information that is readily accessible. It is possible that one's judgement of sleep quality can potentially be altered by systematically restructuring a person's daytime experience or by introducing negative attentional biases in their evaluation of their sleep and daytime functioning.

Secondary goals of the study were to investigate the influence of momentary sleep parameters on CVPR outcomes. To reduce patient burden in filling out questionnaires, it was decided that baseline depression scores (PHQ-9) would be obtained via chart review of patient outcomes. As previously discussed, patients are regularly monitored as they progress though the CVPR program at Vidant Medical Center, and their medical records are then reviewed and entered into the American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR) online registry by CVPR staff members as part of standard procedure. It is important to note that procedural delays in entering this data into the AACVPR registry created some challenges in collecting baseline depression and outcomes data for the present study. Namely, patients were administered either the CES-D or PHQ-9 rather than a single, standard measure for depressive symptoms. Therefore, when available, PHQ-9 scores were prioritized over CES-D scores and these scores were dichotomized in a non-depressed or depressed group for ease of interpretation. This is an important limitation to the present study, which likely influenced the findings. Finally, we cannot exclude the possibility of additional unmeasured confounders in our analyses, such as specific medications, as well as medical and psychiatric comorbidities which

could have directly or indirectly influenced our findings. Overall, the limitations to this study should be carefully considered when examining the results.

Strengths and Future Directions

The current study exhibited several notable strengths. Concerning EMA, we were able to demonstrate that mobile EMA applications are feasible tools for examining daily perceptions of sleep parameters. In the present study, adherence to EMA monitoring was high, with 84.61% completion of morning prompts and 75% completion of afternoon and evening prompts (78.2% combined). Previous research has demonstrated the benefits of EMA, including the ability to reduce retrospective biases that may characterize other research methods. In the present study, the combined use of baseline and momentary measures of sleep quality and daytime fatigue to examine the differences between abstract ratings of sleep quality and momentary ratings resonates with previous work which suggests that certain aspects of sleep may be more important predictors for daytime fatigue. To our knowledge, the current study is the first to use a mobile EMA application to examine the temporal nature of associations between subjective sleep quality and daytime fatigue in a CVPR population and its possible association to outcomes.

The association between daily self-reported restfulness and daytime fatigue suggests that if the participants did not feel refreshed in the morning, they would be disproportionately more likely to conclude that they are feeling excessively tired later in the day. Furthermore, if the participants somehow feel refreshed upon waking, whether or not they have slept through the night, had longer sleep duration, or felt that they had "good quality sleep" the previous night would not be as important in predicting daytime fatigue. This finding raises the possibility that subjective sleep quality may not be a prerequisite to feeling refreshed the next morning and experiencing less fatigue throughout the day. Similar to judgements of sleep quality, feeling

refreshed is a relatively non-specific subjective judgment that can be influence by a number of factors related to the sleep experience, such as a person's mood or ability to look forward to certain activities or excitement for the day.

It may be important to explore ways to help people feel more refreshed in the morning in order to examine factors that could improve individual perceptions of sleep-related experiences. For example, it may be helpful to assist individuals in developing strategies to reverse or diffuse attentional biases toward negative sleep cues and increase attention toward positive aspects of sleep to inform their sleep quality judgement. Furthermore, it may be helpful for individuals to place greater emphasis on pleasant experiences upon waking instead of focusing exclusively on nighttime experience. Based on the findings of the present study, improved perceptions of restfulness upon waking can influence a person's overall perception of their functioning during the day, which can influence one's willingness and ability to perform certain health behaviors.

Final Conclusions

Overall, the results from this study support the idea that EMA reports of sleep quality and restfulness from the previous night's sleep are associated with daytime fatigue. However, none of the momentary sleep parameters, including daily self-reported sleep quality and daytime fatigue were significantly associated with the number of CVPR sessions attended or completion status. Similarly, few of the momentary sleep parameters were associated with health outcomes, except daily self-reported sleep duration, which was found to be associated with decreases in blood pressure following CVPR program completion. These results should be interpreted cautiously, given that the current study had some considerable limitations. Taken together, however, it appears as though day-to-day variations in specific sleep parameters such as subjective sleep quality and restfulness are associated with some of the common difficulties

noted by CVPR patients (e.g., increased daytime fatigue, higher rates of depression and OSA). Furthermore, our findings also suggest that sleep quality judgements may be determined by not only what happened during sleep (e.g., sleep disturbances) but also what happens after awakening (e.g., feeling tired upon waking and throughout the day). It is possible that interventions aimed toward improving functioning during the day may improve people's subjective evaluation of sleep quality. More research in this area is needed in order to examine sleep-related factors that may influence CVPR engagement and completion, and to design interventions to improve sleep-related functioning in these individuals.

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APPENDIX A – Momentary Assessment of Sleep Quality

1. What time did you fall asleep last night? (please round to the nearest hour)
    a. Please specify AM or PM
2. What time did you wake up this morning? (please round to the nearest hour)
    b. Please specify AM or PM
3. How long did it take you to fall asleep last night? (please select one)

0	1	2	3
0-10 minutes	10-20 minutes	30 minutes-1 hour	Over 1 hour

4. How many times did you wake up last night?

0	1	2	3
I did not wake up	1-2 times	3-4 times	5 or more times

5. Please rate the overall quality of your sleep last night.

0 = “Very bad” ---------1---------2---------3---------4---------5--------- 6= “Very good”

6. Please rate how rested you feel this morning.

0 = “Not at all rested” ---------1---------2---------3---------4---------5--------- 6= “Extremely rested”

APPENDIX B – Momentary Assessment of Daytime Fatigue

1. How tired (sleepy/drowsy, low energy, problems thinking clearly) do you feel right now?

0 = “Not at all tired” ---------1---------2---------3---------4---------5--------- 6= “Extremely tired”

APPENDIX C: IRB Approval Letter

RX: Your study has been approved

umcirb@ecu.edu <umcirb@ecu.edu>
Tue 09/25/2018 01:54 PM
To: Midgette, Emily Paige <midgettee13@students.ecu.edu>

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Notification of Initial Approval: Expedited

From: Biomedical IRB
To: Jordan Ellis
CC: Matthew Whited
Date: 9/25/2018
Re: UMCIRB 18-001542
Sleep and Mood in Cardiopulmonary Rehabilitation

I am pleased to inform you that your Expedited Application was approved. Approval of the study and any consent form(s) is for the period of 9/24/2018 to 9/23/2019. The research study is eligible for review under expedited category #5,7. The Chairperson (or designee) deemed this study no more than minimal risk.

Changes to this approved research may not be initiated without UMCIRB review except when necessary to eliminate an apparent immediate hazard to the participant. All unanticipated problems involving risks to participants and others must be promptly reported to the UMCIRB. The investigator must submit a continuing review/closure application to the UMCIRB prior to the date of study expiration. The Investigator must adhere to all reporting requirements for this study.

Approved consent documents with the IRB approval date stamped on the document should be used to consent participants (consent documents with the IRB approval date stamp are found under the Documents tab in the study workspace).

The approval includes the following items:

Name	Description
Application-for-Waiver-Form CVPR2 (8_29_18).pdf	HIPAA Authorization
chalder fatigue scale.pdf	Surveys and Questionnaires
CVPR_EMA_Paper Form_#1 9.9.18.docx	Surveys and Questionnaires
CVPR_EMA_Paper Form_#2 (9.7.18).docx	Surveys and Questionnaires
CVPR_EMA_Paper Form_#3 (9.7.18).docx	Surveys and Questionnaires
Dissertation Proposal_Ellis (IRB).docx	Study Protocol or Grant Application
HIPAA-Research-on-Decedents-Information-Form-4-10-2012.pdf	HIPAA Authorization
Informed-Consent (9.7.18).docx	Consent Forms

APPENDIX D: Informed Consent Document

Informed Consent to Participate in Research
Information to consider before taking part in research that has no more than minimal risk.

Title of Research Study: Sleep and Mood in Cardiopulmonary Rehabilitation

Principal Investigator: Jordan M. Ellis, MA and Emily Midgette, BA (Person in Charge of this Study)
Faculty Supervisor: Matthew C. Whited, Ph.D., Associate Professor of Psychology at East Carolina University
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Telephone #: 252-328-1069

Participant Full Name: _____ Date of Birth: _____
Please PRINT clearly

Researchers at East Carolina University (ECU) and Vidant Cardiopulmonary Rehabilitation study issues related to society, health problems, environmental problems, behavior problems and the human condition. To do this, we need the help of volunteers who are willing to take part in research.

Why am I being invited to take part in this research?

The purpose of this research is to understand the relationships between mood, stress, sleep, and daytime sleepiness on participation and outcomes in cardiopulmonary rehab. You are being invited to take part in this research because you are currently a patient enrolled in cardiopulmonary rehab at Vidant. The decision to take part in this research is yours to make. By doing this research, we hope to learn about barriers to participation in cardiopulmonary rehab, and how programming may be changed to reduce these barriers.

If you volunteer to take part in this research, you will be one of about 50 people to do so.

Are there reasons I should not take part in this research?

You should not participate in this research if you are under 18 years of age or cannot speak English.

What other choices do I have if I do not take part in this research?

You can choose not to participate. Choosing not to participate will not affect your cardiac or pulmonary rehabilitation program. If you choose not to participate, you will receive the same cardiac or pulmonary rehabilitation program as anyone else in the program.

Where is the research going to take place and how long will it last?

The research will be conducted at the Vidant Medical Center Cardiovascular and Pulmonary Rehabilitation program. You will need to meet with our research team twice during the study, while attending your normal rehab sessions. You will also be answering brief series of questions on a mobile device three times per day for 2 weeks. These surveys only take 2-5 minutes to complete. The total amount of time you will be asked to volunteer for this study is a total of approximately 4 hours over the next 2 weeks.

What will I be asked to do?

You will be asked to do the following:

- You will complete a brief measure about your current sleep patterns and quality. We will also be assessing depressive symptoms through a measure you have already completed as a regular part of cardiopulmonary rehabilitation.
- Using your personal smartphone, we will assist you in downloading a mobile application, which will allow us to ask you questions throughout the day regarding your sleep habits, stress, and mood.
- If you do not have a smartphone, you will be provided with one to use for the duration of the study.
- At the end of the 14 days you will meet briefly (10-15 minutes) with the us, and will be provided with resources related to sleep hygiene and mood/stress management.

What might I experience if I take part in the research?
We don't know of any risks (the chance of harm) associated with this research. Any risks that may occur with this research are no more than what you would experience in everyday life. We don't know if you will benefit from taking part in this study. There may not be any personal benefit to you but the information gained by doing this research may help others in the future. You may benefit from learning more about yourself through the monitoring process.

Will I be paid for taking part in this research?
We will be able to pay you for the time you volunteer while being in this study. You will receive a $5.00 gift card for participating in the initial session. You will also receive a second $5.00 gift card after the 14 days of mobile monitoring.

Will it cost me to take part in this research?
It will not cost you any money to be part of the research; however, the Personal Analytics Companion (PACO) mobile app does involve minimal data usage (<5 MB). Access to WiFi will eliminate the need to use data on your smartphone.

Who will know that I took part in this research and learn personal information about me?
ECU and the people and organizations listed below may know that you took part in this research and may see information about you that is normally kept private. With your permission, these people may use your private information to do this research:

- Any agency of the federal, state, or local government that regulates human research. This includes the Department of Health and Human Services (DHHS), the North Carolina Department of Health, and the Office for Human Research Protections.
- The University & Medical Center Institutional Review Board (UMCIRB) and its staff have responsibility for overseeing your welfare during this research and may need to see research records that identify you.
- People designated by Vidant Medical Center and Vidant Health
- If you are a patient at ECU or Vidant, a copy of this form will be placed in your medical records.
- Members of the research team.

If information is shared, it will not be individual data and will be averages of data across research participants.

How will you keep the information you collect about me secure? How long will you keep it?
Data collected from this study will be kept securely for 6 years. All identifying information (e.g., your name and email address) will be separated from responses after completing the mobile monitoring and destroyed prior to the end of the 7-year period.

What if I decide I don't want to continue in this research?
You can stop at any time after it has already started. There will be no consequences if you stop and you will not be criticized. You will not lose any benefits that you normally receive.

Who should I contact if I have questions?
The people conducting this study will be able to answer any questions concerning this research, now or in the future. You may contact the Principal Investigators at 252-375-3916 (days, between 8am and 5pm), or by email at ellisjo15@students.ecu.edu or midgettee@students.ecu.edu. You may also contact the Faculty Supervisor, Dr. Matthew Whited by email at whitedm@ecu.edu or by phone at 252-328-6308. You will be provided with a copy of this form after you decide whether or not to sign it.

If you have questions about your rights as someone taking part in research, you may call the Office of Research Integrity & Compliance (ORIC) at phone number 252-744-2914 (days, 8:00 am-5:00 pm). You may also call the Vidant Health Center for Research and Grants at 252-847-1177. If you would like to report a complaint or concern about this research study, you may call the Director of the ORIC, at 252-744-1971 and the Vidant Health Risk Management Office at 252-413-4473.

Is there anything else I should know?
Most people outside the research team will not see your name on your research record. This includes people who try to get your information using a court order. One exception is if you agree that we can give out research information with your name on it. Other exceptions are information about child abuse or neglect and harm to yourself or others.

I have decided I want to take part in this research. What should I do now?
The person obtaining informed consent will ask you to read the following and if you agree, you should sign this form:

- I have read (or had read to me) all of the above information.
- I have had an opportunity to ask questions about things in this research I did not understand and have received satisfactory answers.
- I know that I can stop taking part in this study at any time.
- By signing this informed consent form, I am not giving up any of my rights.
- I have been given a copy of this consent document, and it is mine to keep.

_____ _____

Participant's Name (PRINT) **Signature** **Date**

Person Obtaining Informed Consent: I have conducted the initial informed consent process. I have orally reviewed the contents of the consent document with the person who has signed above, and answered all of the person's questions about the research.

_____

Person Obtaining Consent (PRINT) **Signature** **Date**