

Alicia M. Moran, PERSONALITY CORRELATES OF COMPLIANCE WITH CONTINUOUS POSITIVE AIRWAY PRESSURE FOR TREATMENT OF SLEEP APNEA (Under the direction of Dr. D. Erik Everhart) Department of Psychology, April 2010.

Unlike many chronic illnesses with less than optimal treatment efficacy, the treatment for obstructive sleep apnea (OSA), continuous positive airway pressure (CPAP), is extremely efficacious. However, treatment compliance for OSA is a serious problem for a number of unclear reasons. Because OSA has serious consequences, ranging from daytime sleepiness to life threatening cardiovascular problems, researchers have attempted to identify noncompliant users and to create interventions that promote compliance. Despite the plethora of research, inconsistent and unreplicable results prevail. There appear to be no demographic or personality correlates that consistently predict compliance and researchers have struggled to find an intervention that is practical and effective.

This thesis focuses on identifying personality correlates that may predict treatment compliance. Many traditional, frequently used personality inventories such as the MMPI-2 have been researched in conjunction with CPAP compliance prediction. Other inventories that focus on more specific aspects of personality, such as the BIS/BAS, which measures regulation of inhibitory and appetitive motives, have never been used in research on treatment compliance for any chronic disease. Similarly, the Ways of Coping (WAYS) inventory, which measures coping processes, has been used in one CPAP compliance study. This thesis utilizes the following inventories to predict CPAP compliance: a broad personality inventory that has been researched with chronic treatment regimens other than CPAP, the Mini IPIP, and two less researched and more specific inventories, the BIS/BAS and the WAYS.

PERSONALITY CORRELATES OF COMPLIANCE WITH CONTINUOUS
POSITIVE AIRWAY PRESSURE FOR TREATMENT OF SLEEP APNEA

A Thesis

Presented to the Faculty of the Department of Psychology

East Carolina University

In Partial Fulfillment

of the Requirements for the Degree

Master of Arts in Psychology

by

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April, 2010

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CHAPTER I: INTRODUCTION

Obstructive Sleep Apnea (OSA). Obstructive sleep apnea (OSA), the most common form of sleep apnea, is characterized by episodes of complete or partial pharyngeal obstruction during sleep that results in the interruption of airflow during sleep. Upper airway abnormalities have been described in patients with OSA. A short thick neck, limited head extension, reduced thyromental distance, and oropharyngeal crowding have been associated with OSA (Gentil, Delarminat, Boucherez, & Lienhart, 1994; Horton, Fahy, & Charters, 1989; Peterson et al., 2005).

Diagnostic criteria include an apnea-hypopnea index (AHI) > 5 , and daytime hypersomnolence. An apnea episode is defined as a 10 second time period of cessation in breathing, while a hypopnea episode is defined by a period of 10 seconds where there is at least a 50% reduction in flow of oxygen. The index is calculated by dividing the number of apneas and hypopneas by the number of hours of sleep (Kryger, Roth, & Dement, 2000).

Approximately 4% of men and 2% of women between the ages of 30 and 60 suffer from OSA (Young et al., 1993). Additionally, about 2.5% of children suffer from OSA (Krishnan & Collop, 2006). The strongest risk factors linked to diagnosis of OSA are obesity, age of more than 65 years old, and being male (Kripke et al., 1997). Due to the rapidly rising population that is over 65, and the increasing prevalence of obesity in our society, the prevalence of OSA is expected to rise. Secondary risk factors include alcohol use, race (African American, Mexican Americans, and Pacific Islanders), and disorders such as Down's syndrome and Pierre Robin syndrome (Kryger et al., 2000).

Health professionals regard OSA as a severe disorder due to its high prevalence, increased morbidity, and increased mortality (Nieto et al., 2000; Shahar et al., 2001). Those who suffer from OSA tend to have decreased quality of life, consistently reporting tiredness, fatigue, and lack of energy (Seneviratne & Puvanendran, 2004). Some of the most serious cognitive symptoms include attention deficits, impaired concentration, and memory problems (Quan et al., 2006). Other studies have demonstrated an increased risk for traffic accidents (Masa, Rubio, & Findley, 2000; Young, Blustein, Finn, & Palta, 1997). There is also support for an increase in mood disorders developing in response to OSA (Aloia, Arnedt, Smith et al., 2005; Kryger et al., 2000). Hypertension, asthma, and heart disease are also devastating consequences of OSA (Kryger et al., 2000). Hoekema and colleagues found that untreated OSA is associated with sexual dysfunction (Hoekema et al., 2007). Untreated OSA clearly results in adverse physical, psychological, and socioeconomic consequences that create a serious public health burden, and calls for prompt attention. Fortunately, there is an extremely efficacious treatment available, continuous positive airway pressure (CPAP) therapy for OSA.

Continuous Positive Airway Pressure (CPAP). Continuous positive airway pressure (CPAP) therapy is widely considered the primary treatment for OSA (Kryger et al., 2000). CPAP is applied through a mask that is placed over the nose and/or mouth, and delivers air pressure in order to keep the airway open. It is attached to a CPAP machine, which acts somewhat like an air compressor. Treatment of OSA with CPAP therapy has been shown to decrease daytime sleepiness, improve neurocognitive functioning, decrease blood pressure, and improve quality of life (Budhiraja et al., 2007; Kryger et al., 2000). The importance of regular CPAP use was demonstrated in a

longitudinal study in which adherent patients had a significantly higher survival rate when compared with non-adherent patients (Campos-Rodriguez et al., 2005). For the purpose of this thesis, adherence and compliance are interchangeable terms defined as “obedience to medical advice”.

Although this treatment is considerably more successful than other regimens designed for chronic conditions, compliance has been a significant problem (Wiese et al., 2005). Compliance failure is defined as “use of CPAP for less than 4 hours per night on 70% of the nights and/or lack of symptomatic improvement,” as these criteria support significant improvement in reduction of symptoms (Kryger et al., 2000). Compliance failure ranges from 5% to 50% in the first week to six months (Engleman & Wild, 2003). Other researchers suggest a similarly large interval of compliance rates, ranging from 46% to 89%, and 29% to 89%, respectively (Krishnan et al., 2006; Rolfe, Olson, & Saunders, 1991). Another source estimated that about 25% of patients completely discontinue CPAP use within one year (McArdle et al., 1999).

Since the introduction of the CPAP machine in 1981, researchers have struggled to understand why the compliance rate is low and how to improve it. Research has examined the inconvenience and undesirable chronic regimen the CPAP equipment entails (Kryger et al., 2000). Other researchers hypothesized that there were certain demographic or personality characteristics of compliant versus noncompliant users. Recent research has led to understanding how educational and therapeutic behavioral interventions can promote CPAP compliance.

When newly diagnosed OSA patients were faced with treatment options (weight loss, sleep hygiene, surgery, or CPAP use), only 17% first elected to use CPAP therapy

according to Rosenthal and colleagues (2000). Of patients that do elect CPAP therapy, many often find tolerating the machine and the mask the first challenge. The most common complaint is that they feel “claustrophobic” using the mask (Kribbs et al., 1993). Berthon-Jones and colleagues suggest that the most common reasons for discontinuing CPAP include side effects of treatment, such as mask discomfort, nasal dryness and congestion, and difficulty adapting to the pressure setting (i.e.; difficulty exhaling, sore ribs, or air swallowing) (Berthon-Jones, Lawrence, Sullivan, & Grunstein, 1996). Many users also report the socially undesirable effects of using the machine, such as partner dissatisfaction with noise and embarrassment due to traveling with machine (Zozula & Rosen, 2001). In addition, some women may perceive wearing the mask as being less feminine and is possibly a salient factor in treatment adherence in a shared bed (Richards, Bartlett, Wong, Malouff, & Grunstein, 2007). Although technological advances have worked to make CPAP machines more comfortable and education has attempted to make the machine more socially acceptable, compliance rates have not shown great improvement (Krishnan et al., 2006).

The Use of Demographic Variables to Predict CPAP Compliance. Studies focused on using demographic characteristics to predict compliance have been ambiguous. Gender differences in CPAP use are inconclusive, with some studies demonstrating higher compliance in men and others showing higher compliance in women (Budhiraja et al., 2007; Krishnan et al., 2006; Pelletier-Fleury, Rakotonanahary, & Fleury, 2001; Richards et al., 2007). Similarly, a study predicting race differences was found to be inconclusive (Heurtin-Roberts & Reisin, 1992). One study conducted by Budhiraja and colleagues suggests that African Americans were significantly less

compliant than Caucasians, although the authors suggest this interpretation is limited in the absence of any socioeconomic, cultural, biological, or education indexes (2007). Budhiraja and colleagues also found that older people are more likely to be compliant than younger people, but Pelletier-Fluery and colleagues (2001) found no difference when researchers controlled for confounding variables. One study suggests that those patients with overweight body-mass indexes (BMIs) were more likely to participate in long-term compliance (Edinger, Carwile, Miller, Hope, & Mayti, 1994). Body-mass index, a statistical composite relating a person's height to weight, determines in which category a person belongs – underweight, healthy weight, overweight, obese, or extremely obese. Pelletier-Fluery and colleagues found a nonsignificant trend that those patients with lower BMI's were more compliant (2001). Both the objective apnea severity (AHI index) and subjective severity (sleepiness) of OSA appears to be unrelated to compliance according to Budhiraja (2007). However, alternative research suggests that those persons with higher AHI's tend to be more compliant because there is a more drastic reduction in subjective sleepiness present (Pelletier-Fleury et al., 2001; Sforza & Lugaresi, 1995). An early study suggested that income, marital status, and knowledge about health care were thought to be unrelated to compliance (Stoudemire & Thompson, 1983).. Findings suggest there are no definitive demographic characteristics that can predict those patients who will comply with CPAP therapy.

Early Compliance Predicts Future Compliance. Some researchers have approached the question of compliance without investigating individual differences. Actually, the series of events that immediately follow initiation of CPAP treatment may be more useful in determining if there will be a long-term commitment to compliance

among patients than personality factors. Several studies have demonstrated that the first few weeks of objective compliance data are sufficient to predict future compliance at 6 months or sooner (Aloia, Arnedt et al., 2007; Delguste & Rodenstein, 2000; Janson, Noges, Svedberg-Brandt, & Lindberg, 2000; Rosenthal et al., 2000). Two other studies suggest long-term adherence to CPAP therapy can be predicted as early as 3 and 4 days after the initiation of CPAP therapy (Budhiraja et al., 2007; Weaver et al., 1997).

Of interest, European patients may have fewer issues with noncompliance because they spend extra nights in the hospital after initial CPAP titration in order to provide an opportunity for further education and also to intervene if any compliance issues arise (Hoy, Vennelle, Kingshott, Engleman, & Douglas, 1999). Therefore, providing instructions and interventions when CPAP machines are first received is vital to starting patients out on the right step towards ongoing compliance. Although past behavior is valuable in predicting future behavior, many theorists believe that understanding CPAP compliance involves a much more cognitively complex process.

Social-Cognitive Theory and the Transtheoretical Model. Research by Stepnowsky et al. suggests that Social-Cognitive Theory and the Transtheoretical model can explain CPAP adherence. Utilizing the social cognitive theory, Stepnowsky and colleagues hypothesize that patients with higher perceived self-efficacy, outcome expectancies, functional social support, and knowledge about OSA and CPAP will be more compliant. Basing their hypothesis off of the transtheoretical model, these researchers hypothesize that those patients who find more pros than cons to using their CPAP will be more adherent to therapy (Stepnowsky, Marler, Palau, & Annette Brooks, 2006). These models have been used to develop some interesting interventions that are

under investigation. For example, the motivational enhancement therapy that has operated under theories of behavior change focuses on patients weighing out the pros and cons of CPAP therapy in order to enhance self-efficacy, a strong predictor of long-term adherence (Aloia et al., 2004; Aloia, Arnedt, Stepnowsky et al., 2005).

Interventions to Improve CPAP Compliance: Education and Therapy. Success of educational therapy supports the notion of the above listed theories. Researchers have used the components of the social cognitive and transtheoretical theories to create interventions ranging from simple one-time educational clinics to use of multiple sessions of CBT. Wiese et al. found that showing a patient an educational video at the initial visit significantly improved the rate of return for the first follow-up visit, and was therefore a factor in retention of patients in treatment (2005). Similarly, it was demonstrated that a 2-hour clinic designed to educate and encourage patient compliance significantly increased CPAP compliance that was sustained over years (Likar, Panciera, Erickson, & Rounds, 1997).

One study completed in China reported contradictory findings. Despite supplementing basic instruction with an educational 15-minute videotape, a longer CPAP education session by nurses, telephone supporting the first 3 months, and early follow-up, CPAP compliance was not significantly increased among our new CPAP users (Hui et al., 2000). Perhaps there is a cultural element that plays a role in these differential findings, or a Type II error was committed. Also unique to this study, 97 out of the 108 patient participants were men. Further research examining culture and gender relative to receptiveness of educational therapy is needed.

More demanding and complex behavioral interventions have also been examined. A randomized, controlled, parallel-group study compared intensive support (including hospital CPAP supervision) to standard CPAP instruction and support. The intensive support group had increased CPAP usage by almost 2 hours per night (Hoy et al., 1999). Most recently, a group cognitive behavioral therapy (CBT) intervention based on correcting distorted beliefs, promoting positive feedback, promoting a positive outlook to treatment, and using catchphrases, such as “sleep safely using CPAP,” resulted in a significant increase in adherence after 28 days (Richards et al., 2007). Patients were reinforced with praise after increasing adherence. Authors suggest this study was limited to a broad population that did not differentiate compliance by gender, race, or other demographic variables.

Aloia and colleagues compared one session of traditional education therapy (i.e.; didactic presentation of pathophysiology of apnea, consequences of apnea) to two sessions of motivational enhancement therapy (i.e.; client centered intervention based on theories of behavior change and self-efficacy) (Aloia, Smith et al., 2007). Although both groups were significantly more compliant than the control group, there was no significant difference between therapies. This particular study by Aloia and colleagues suggested that perhaps simple education is adequate and more expensive and/or time-consuming therapy is unnecessary. Ten years prior to Aloia’s research Chervin and colleagues suggested that “simple interventions” were all that were necessary to significantly increase CPAP use (1997). One group of subjects received weekly phone calls to uncover any problems and encourage use while another received written information about sleep apnea and the importance of regular CPAP use. Contrary to Aloia’s research, there was no difference

between the two treatment groups, and neither group had higher compliance than the control group (1997). Further research on solely educational approaches compared to more complex and demanding behavioral interventions is necessary.

A similar study to Chervin's first intervention was based on positive reinforcement via a regular phone call from a CPAP nurse. This earlier study also did not find that usage was increased (Fletcher & Luckett, 1991). This may be because this intervention lacked a group format and the educational component evident in the successful studies above.

Due to the socially undesirable factors that play a role in CPAP compliance, it was hypothesized that social support from the user's spouse or family member would increase compliance. But Richards et al. demonstrated that having one's partner present during CBT did not play a role in CPAP usage (2007). However, patients with CPAP-using relatives were shown in one study to benefit more from educational interventions and to have higher rates of compliance (Chervin, Theut, Bassetti, & Aldrich, 1997). A number of the successful interventions mentioned above had a group format where patients were encouraged to discuss expectations, experiences, etc. among each other, which suggests support from fellow users is helpful (Hoy et al., 1999; Likar et al., 1997; Richards et al., 2007).

Typically, CPAP machines store precise usage data that health professionals can access. Even when patients are knowledgeable that their physician has access to specific usage data, they still tend to considerably overestimate daily CPAP use (Rauscher, Formanek, Popp, & Zwick, 1993). Further research with these objective data demonstrated consistent patient overestimation of CPAP use (Engleman, Martin, &

Douglas, 1994). According to Smith and colleagues, most patients that believe they are being compliant are actually using their machine less than the prescribed amount (1994). Therefore, some patients may believe they are much more compliant to treatment than they actually are. This is often addressed during educational interventions.

It is clear that educational and therapeutic interventions can be beneficial to CPAP patients. It is also evident that improvements among these interventions are needed, and with the variability in results there are likely additional factors that influence who is receptive to treatment as well as who is a candidate for an educational and/or therapeutic intervention. Demographic characteristics have been researched for the past two decades, but inconclusive findings have prevailed. Researchers suggested that personality factors may help predict CPAP compliance.

Personality Correlates of CPAP Compliance. The body of literature pertaining to personality factors and CPAP compliance is much more limited than the demographic and intervention research, and so current findings may be even less conclusive. Specifically, it is suggested that certain personality traits may predict CPAP compliance. For example, the MMPI-2 has been used to examine personality factors associated with CPAP compliance. Lower scores on the Depression (D) and Hypochondriasis (Hs) scales were found prior to treatment among individuals who were compliant (Chervin et al., 1997; Edinger et al., 1994). The D scale measures various aspects of depression including personal worth, psychomotor retardation, withdrawal, and lack of interest in one's surroundings. The Hs scale measures the degree of somatic concern a person has with him or herself. Another body of literature suggests that the type D personality is associated with noncompliance (Brostrom et al., 2007). Type D personality is defined as

the joint tendency towards negative affectivity and social inhibition. Despite this limited research examining CPAP compliance and personality factors, compliance research is available for other chronic disease states.

Personality Correlates of Compliance to other Chronic Treatment Regimens.

There is some literature examining compliance with other chronic medical regimens that may pertain to CPAP compliance. For example, there is ample research using personality inventories to predict compliance with treatment for chronic pain patients. Like OSA, chronic pain is a chronic condition that is typically not curable and requires prolonged treatment or therapy. Additionally, the educational and therapeutic qualities in CPAP intervention are evident in chronic pain management as well. Research using the MMPI-2 found that the total number of clinical scale elevations was incrementally predictive of treatment dropout among chronic pain patients (Minnix et al., 2005). Similarly, Evans and Blanchard found that the more psychopathology present, the less likely a patient would remain in a chronic pain treatment program (Evans & Blanchard, 1988). The Personality Assessment Inventory (PAI) has similarly been used to predict compliance. It was demonstrated that the Treatment Process Index (TPI) was significantly lower for individuals who were compliant (Hopwood, Ambwani, & Morey, 2007). The Treatment Process Index is a configuration of several PAI scales linked to treatment amenability, with higher scores representing lower willingness to be treated (Karlin et al., 2005). However, the Negative Treatment Indicator scale on the MMPI-2, which measures a similar construct as the TRI index, was not significantly associated with treatment compliance (Minnix et al., 2005).

Another example is compliance to interferon therapy for those with chronic hepatitis C. Compliance among this patient population has been low due to the flu-like side effects and expense. Kraus and colleagues used the Inventory of Interpersonal Problems (IIP-C) to predict compliance among hepatitis C patients. Using a logistic regression to predict noncompliance, Kraus found that those with the following problems according to the IIP-C were most likely not to be compliant: anger-hostility, depression, phobic anxiety, and intrusiveness (Kraus et al., 2001). Research focused on glaucoma patients, who also have a chronic treatment regimen, and suggested that high levels of hostility and depression were predictors of poor treatment compliance (Pappa et al., 2006).

A body of literature using the Five-factor Theory of Personality to predict treatment to chronic regimens has also been inconclusive. The five-factor theory is a purely descriptive model of personality that was developed through lexical analysis. The five factors, Openness, Conscientiousness, Extraversion, Agreeableness, and Neuroticism, are each main factors that consist of more specific facets that correlate together. Conscientiousness is the tendency to show self-discipline, act dutifully, and aim for achievement. Some studies suggest that conscientiousness is a robust predictor for treatment compliance in patients who were on treatment regimens, such as high cholesterol treatment and renal dialysis (Christensen & Smith, 1995; Stilley, Sereika, Muldoon, Ryan, & Dunbar-Jacob, 2004). Both of these studies found no other significant Five-factor dimensions to be significantly related to compliance. Other studies have reported that conscientiousness is either unrelated to compliance or that higher levels of this trait may actually be associated with poorer compliance among some patients

(Moran, Christensen, & Lawton, 1997; Wiebe & Christensen, 1997). However, these studies pertained to renal dialysis, and the findings were observed only among subgroups of patients who had the highest perceived severity of disease. The reliability of this research may also not be as strong as other chronic regimens (such as CPAP), due to the difficult nature of compliance measurement (Christensen, 2000; Christensen et al., 1995; Moran et al., 1997). Perhaps CPAP treatment for OSA would be ideal to research using the Five-Factor Theory of Personality.

The Five-Factor Theory of Personality. It is possible that the relationship between treatment and Five-factor predictors is more complex than a single factor, conscientiousness, being associated with compliance. Some researchers believe that other factors in the context of compliance, such as perceived self-efficacy, task discipline, and coping mechanisms, may interact with personality factors (Christensen, 2000; Christensen, Wiebe, Benotsch, & Lawton, 1996; Rosenbaum & Smira, 1986). Furthermore, Christensen has proposed that the Five-factor theory may play different roles in compliance in chronic treatment regimens depending on whether the regimen is a patient-directed or provider-controlled (2000). Therefore, research using the Five-factor Theory and CPAP compliance could enhance understanding chronic patient-directed regimens. Also, predicted high levels of conscientiousness and compliance would be consistent with the MMPI-2 research reviewed above, which suggested compliant individuals handle stress well and tend to be responsible (related to conscientiousness). An additional reason to perform this research using the OSA patient population is that measures of CPAP compliance are more easily obtained and much more reliable than other chronic treatment plans that require self-report.

Although findings are somewhat inconsistent, noncompliance to chronic treatments appears to be associated with overall psychopathology, depression, and hostility upon review of personality inventories. Measures of conscientiousness and ease of treatment may also be useful in predicting compliance, but further research is needed. With the proliferation of more domain specific personality inventories, the opportunity for further research is immense.

The BIS/BAS Model of Personality. Despite the research on frequently used personality inventories such as the MMPI-2 and the inventories based on the Big-5, there is no body of literature pertaining to compliance and the BIS/BAS model of personality. This theory is based on the idea that there are two general motivational systems that underlie behavior. There is a behavioral activation system (BAS), which is believed to regulate appetitive motives, and a behavioral inhibition system (BIS), which is believed to regulate aversive motives (Carver & White, 1994). The goal of BAS is to move towards something desired, while the goal of BIS is to move away from something aversive. BIS is sensitive to punishment and nonreward, and BAS is sensitive to reward, nonpunishment, and escape from punishment (Amodio, Master, Yee, & Taylor, 2008). BAS is associated with positive affect and feelings of optimism and joy (Gable, Reis, & Elliot, 2000). BIS is related with negative affect and feelings of fear and anxiety (Depue & Iacono, 1989; Fowles, 1994). Physiologically, greater left sided frontal cortical activity is associated with high BAS scores (Harmon-Jones, 2003). However, BIS does not appear to be associated with frontal asymmetry (Coan & Allen, 2003). Frontal asymmetry may be relevant to research utilizing overnight PSGs and compliance data.

BIS and BAS are proposed to be relevant to CPAP compliance in a multitude of ways. As addressed above, CPAP treatment is very effective when patients are compliant. Daytime sleepiness is relieved, and the risk for heart disease and other comorbid diseases is greatly reduced in compliant CPAP users. These benefits can be seen as a reward component, suggesting that the BIS/BAS model is relevant to compliance research. Because the goal of BIS is to move away from something aversive, and the BIS system is also associated with negative affect and feelings of fear and anxiety, it is predicted that there is a relationship between strong levels of BIS and noncompliance in CPAP use. Due to the socially undesirable attributes of the CPAP mask and invasive, chronic nature of the CPAP machine, it is not unreasonable to suggest that fear and anxiety play a role in noncompliance for these patients. This prediction is further supported by research pertaining to Type D personality (which involves negative affectivity and social inhibition) being associated with noncompliance. Furthermore, patients with a low BAS level experience a weakened drive towards appetitive motives, such as relief from OSA symptoms. Decreased BAS strength is also associated with depressive symptoms, and depressive symptoms are related to noncompliance, as suggested by the personality based literature reviewed above (Depue et al., 1989) Therefore, low levels of BAS may play a role in noncompliance as well. The BIS/BAS model is a very specific tool that investigates motivational components of personality. However, CPAP compliance has proved to be a complex topic, and understanding additional domains of personality, such as coping processes, may be vital to fully understanding compliance.

The Ways of Coping Model. Stepnowsky and colleagues performed a comprehensive study examining personality factors, stress responses, and coping strategies (depression, anxiety, stress, social support, and anger/hostility). Results suggest that coping strategies are the best predictor of compliance, with lead these authors to believe that understanding prior coping mechanisms may be useful in predicting subsequent CPAP compliance (Stepnowsky, Bardwell, Moore, Ancoli-Israel, & Dimsdale, 2002). Specifically, this study suggested that the Planful Problem Solving and Confrontive Coping subscales of the Active Coping scale were most strongly associated with compliance. Confronting Coping describes aggressive efforts to alter the situation and suggests some degree of hostility and risk-taking, while Planful Problem Solving describes deliberate problem-focused efforts to alter the situation, coupled with an analytic approach to solving the problem. However, the basic compliance rate in this particular study was higher than the overall compliance rates reported in other research (Kribbs et al., 1993; Krishnan et al., 2006; Rolfe et al., 1991). Replication of these findings would help determine whether these findings apply to a broader population of OSA patients, rather than just more consistent users as this study suggests.

Summary and Hypotheses. In summary, obstructive sleep apnea (OSA) is a serious sleep condition with devastating consequences. Although continuous positive airway pressure (CPAP) is an efficacious treatment, compliance is a serious issue. Psychologists have attempted to predict who will be compliant with CPAP treatment, but results are ambiguous. Beneficial educational and therapeutic interventions have been developed, but identifying demographic or personality factors that predict compliance has proved challenging. The purpose of this study is to examine to what extent compliance

can be predicted from three inventories (Mini-IPIP, BIS/BAS, WAYS) that measure different domains or aspects of personality, including basic descriptive traits, motivation, and coping. Specifically, the following predictions are made for this study: (1) high levels of conscientiousness will be associated with high levels of compliance (2) low BAS and high BIS will be associated with low compliance, and (3) there will be a positive association among the Confrontive Coping and Planful Problem Solving subscales on the Ways of Coping questionnaire and CPAP compliance.

CHAPTER II: CPAP COMPLIANCE PREDICTED BY PERSONALITY VARIABLES

Method

Participants. Data were collected from 63 adults recruited from the Pitt County Memorial Sleep Center in Greenville, NC. Participants were patients with follow-up appointments at the sleep center. All participants gave informed consent to the protocol, which was approved by the East Carolina University Institutional Review Board.

Procedure. Participants were asked to participate in the study after a scheduled clinic appointment. After consent was obtained, participants completed the 1) Mini IPIP questionnaire, 2) Ways of Coping questionnaire, and 3) the BIS/BAS questionnaire. This process took approximately 20 minutes. Additional demographic information was collected from medical records, as stated in consent document.

Compliance was obtained from an online database provided by the patient's home healthcare company or via faxed request to home healthcare company. Compliance was defined as >4 hours per night on 70% of the nights, as these criteria support significant improvement in reduction of symptoms (Kryger et al., 2000).

The treatment period was defined by the first available compliance report from start of treatment, which ranged from 30-171 days.

Apparatuses. Participants' apparatuses were one of the following machines: CPAP (continuous positive airway pressure), BiPAP (Bilevel Positive Airway Pressure), or APAP (Automatic Positive Airway Pressure). A CPAP machine works by pushing air through the airway passage at a set pressure high enough to prevent apneas. A BiPAP machine is a technological advancement of CPAP, providing two levels of pressure:

Inspiratory Positive Airway Pressure (IPAP) and a lower Expiratory Positive Airway Pressure (EPAP) for easier exhalation, as well as three different modes the patient can control. APAP is the most recent technological advancement in positive airway pressure. The APAP machine incorporates pressure sensors and a computer that continuously monitors the patient's breathing performance. The pressure is continuously adjusted, increasing it when the user is attempting to breathe but cannot, and decreasing it when the pressure is higher than necessary.

Measures. BIS/BAS questionnaire. BIS and BAS was assessed using Carver and White's (1994) questionnaire, with BIS items (7) and BAS items (13) intermixed. Carver and White's original research suggested BAS has three subscales (Reward Responsiveness, Drive, and Fun Seeking) with reliabilities ranging from .66 to .76 (Carver et al., 1994). For the purpose of our research, we considered BAS as three subscales as well as a single scale. In contrast, BIS is a single scale. Participants were asked to read each question individually and decide if the question is true or false on a self-report scale (1 = very true for me, 2 = somewhat true for me, 3 = somewhat false for me, 4 = very false for me) (Carver et al., 1994).

Ways of Coping Questionnaire (Planful Problem Solving, Confrontive Coping, and Escape-Avoidance subscales). The Ways of Coping questionnaire (WAYS) by Folkman and Lazarus contains 66 items that measure the thoughts and actions people use to handle stressful encounters (1984). There are eight coping factors measured by the WAYS: Confrontive Coping, Distancing, Self-Controlling, Seeking Social Support, Accepting Responsibility, Escape-Avoidance, Planful Problem Solving, and Positive Reappraisal. Alphas ranged from .61 to .79, with Planful Problem Solving, Confrontive

Coping and Escape-Avoidance having alphas of .68, .70, and .72 respectively (Lazarus & Folkman, 1984). With permission, a document was constructed with only questions pertaining to Confrontive Coping, Planful Problem Solving, and Escape-Avoidance subscales (original items 1, 49, 26, 39, 48, 52, 46, 7, 17, 28, 34, 6, 11, 16, 33, 40, 47, 50, 58, and 59). Loadings of these items ranged from .30 to .71. Individuals responded to each item on a four-point self-report scale, indicating frequency with which each strategy is used (0 = does not apply and/or not used, 1 = used somewhat, 2 = used quite a bit, 3 = used a great deal).

Mini IPIP. The Mini-IPIP is a 20-item short form of the 50-item International Personality Item Pool – Five-Factor Model measure created by Goldberg in 1999 (Goldberg, 1999). The Mini-IPIP contains four items for each of the Big Five traits (Neuroticism, Extraversion, Intellect/Imagination, Agreeableness, and Conscientiousness), and has consistent and acceptable internal consistencies across studies (alpha at or $>.60$) (Donnellan, Oswald, Baird, & Lucas, 2006). Individuals responded to each item on a five-point self-report scale, indicating to what degree the statement applies to themselves (Very Inaccurate = 1, Moderately Inaccurate = 2, Neither inaccurate nor accurate = 3, Moderately Accurate = 4, Very accurate = 5).

Other measures were collected from participants' medical charts, including age, gender, ethnicity, BMI, and AHI.

Statistical Analyses. The primary analysis performed was a logistic regression predicting compliance (> 4 hours 70% of the nights) as defined by Kryger and colleagues (2002) from the three questionnaires distributed and various demographics (age, gender,

ethnicity, BMI). Alpha level was set at .05 in tests of statistical significance. Data analyses were performed using PASW for Windows v.16.0.

Results

Analyses based on hypotheses. Thirty-two women and thirty-one men participated. This sample was composed of Caucasians (65.5%) and African Americans (34.5%), and the mean age of participants was 57.1 years. The average BMI of a 37.6 falls in the range of Class II obesity, though the sample included a range of average to class III obesity individuals (BMI range 21-70). A vast majority of the individuals were using CPAP (76.2%) at the time of data collection. Some participants were using BiPAP (14.5%), and the remaining participants were prescribed AutoPAP (also referred to as APAP) (9.7%). Data were collected on gender and age as well. There were no significant differences in compliance among men and women, $t(61) = -.854, p = .397$, and ethnicity did not play a role in compliance either, $t(53) = 1.93, p = .087$.

Table 1 shows the descriptive statistics of the scores on the personality and coping subscales administered.

Table 1

Descriptive Statistics on Personality and Coping Subscales

Subscale	Mean	<i>s</i>
BIS	18.49	3.67
BAS	34.4	7.25
Reward Responsiveness	12.21	3.78
Drive	12.29	3.53
Fun Seeking	10.05	2.61

BIS-BAS Ratio	.557	.173
Extraversion	11.72	3.58
Openness	12.67	3.26
Conscientiousness	13.85	2.66
Neuroticism	11.36	3.19
Agreeableness	14.72	3.21
Confrontive Coping	7.23	3.53
Planful Problem Solving	9.37	3.59
Escape Avoidance	7.48	4.66

Overall, 61.9% of participants were compliant with CPAP treatment. Logistic regression analysis was employed to predict the probability that a participant would be compliant. Prior to logistic regression analyses, Pearson correlations between predictor variables and compliance were examined. The predictor variables were the Behavioral Inhibition Scale (BIS), the BIS/BAS ratio, ethnicity, conscientiousness, neuroticism, agreeableness, and the escape-avoidance scale of the Ways of Coping (WAYS). Only those predictors which were significant at the .10 level were retained in subsequent models. Among those variables dropped were the following – conscientiousness ($r = -.118, p = .429$), BAS ($r = -.010, p = .946$), Planful Problem Solving ($r = .035, p = .816$) and Confrontive Coping ($r = .037, p = .806$). Table 2 shows correlation coefficients for compliance (0 = noncompliant, 1 = compliant) and other personality subscales.

Table 2

Pearson Correlations between Compliance and Personality Scales

Personality Subscale	Compliance (yes or no)
BIS	-.452**
BAS	.010
Reward Responsiveness	-.138
Drive	.070
Fun Seeking	.046
BIS/BAS ratio	-.241
Extraversion	.048
Openness	.008
Conscientiousness	-.118
Neuroticism	-.296*
Agreeableness	-.127
Confrontive Coping	.037
Planful Problem Solving	.035
Escape-Avoidance	-.182

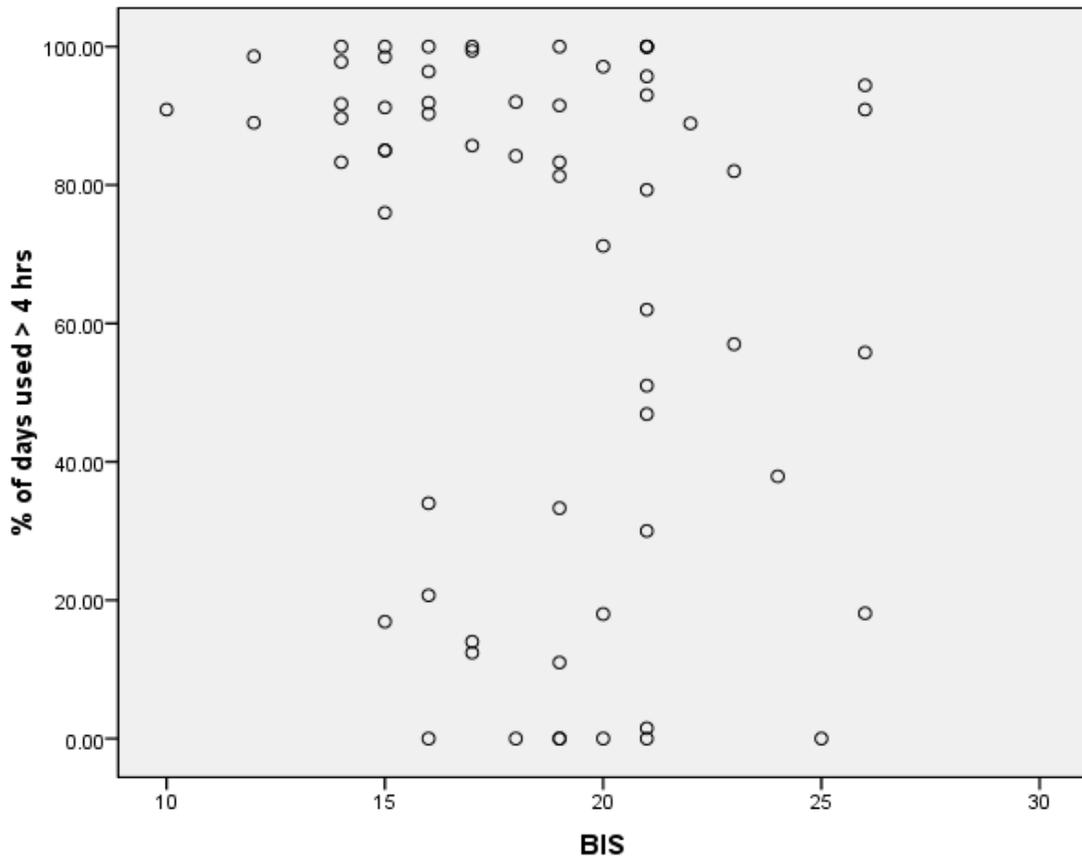
* = $p < .05$.

** = $p < .001$.

Similarly, the Pearson correlation between compliance measured as a continuous variable (% of days used > 4 hrs) and BIS was significant, $r = -.472$, $p = .001$. Figure 1 represents the scatter plot of this relationship.

Figure 1

BIS Score and % of days used > 4 hours



A test of the full logistic model versus a model with intercept only was statistically significant, $\chi^2(7, N = 63) = 18.66$, $p = .009$. The model was able to correctly classify 61.9% of those who were not compliant and 80.6% of those who were compliant, for an overall success rate of 73.1%. A standard .5 cutoff for classification was used.

Table 3 shows sensitivity, specificity, and false positive and negative rates. The Nagelkerke R Square suggests that these predictors can explain approximately 41% of the variance in compliance.

Table 3

Sensitivity, Specificity, False Negative and Positive Rates for Full Model

Sensitivity (Compliance)	80.6%
Specificity (Noncompliance)	61.9%
False Positive Rate	24.2%
False Negative Rate	31.6%

Table 4 shows the logistic regression coefficient, Wald test, and odds ratio for each of the predictors. Employing a .05 criterion of statistical significance, BIS had a significant partial effect. A one-point increase on the four-point BIS scale is associated with the odds of being compliant decreasing by a multiplicative factor of .770. Although neuroticism is significantly correlated with compliance ($r = -.296, p = .043$), neuroticism does not significantly contribute to the overall model as it does not have a significant partial effect ($p = .301$). A model using BIS as the only predictor variable was significant, $\chi^2(1, N = 63) = 7.32, p = .012$. The model was able to correctly classify 89.7% of those participants that were compliant, but only 20.8% of those participants who were not compliant, for an overall success rate of 63.5%. Therefore, the additional 6 predictor variables in the full model can correctly classify approximately 10% of cases than BIS alone.

The odds ratio for ethnicity indicates when holding all other variables constant, an African American participant is .354 times as likely to be compliant than is a Caucasian participant.

Table 4

Logistic Regression Predicting Compliance

Predictor	<i>B</i>	Wald χ^2	<i>p</i>	Odds Ratio
BIS	-.264	4.29	.038	.770
BIS/BAS ratio	.216	.009	.925	1.24
Neuroticism	-.129	1.071	.301	.879
Conscientiousness	-.117	.416	.519	.889
Agreeableness	-.066	.289	.591	.936
Escape-Avoidance	-.039	.170	.680	.961
Ethnicity	-1.04	1.86	.173	.354

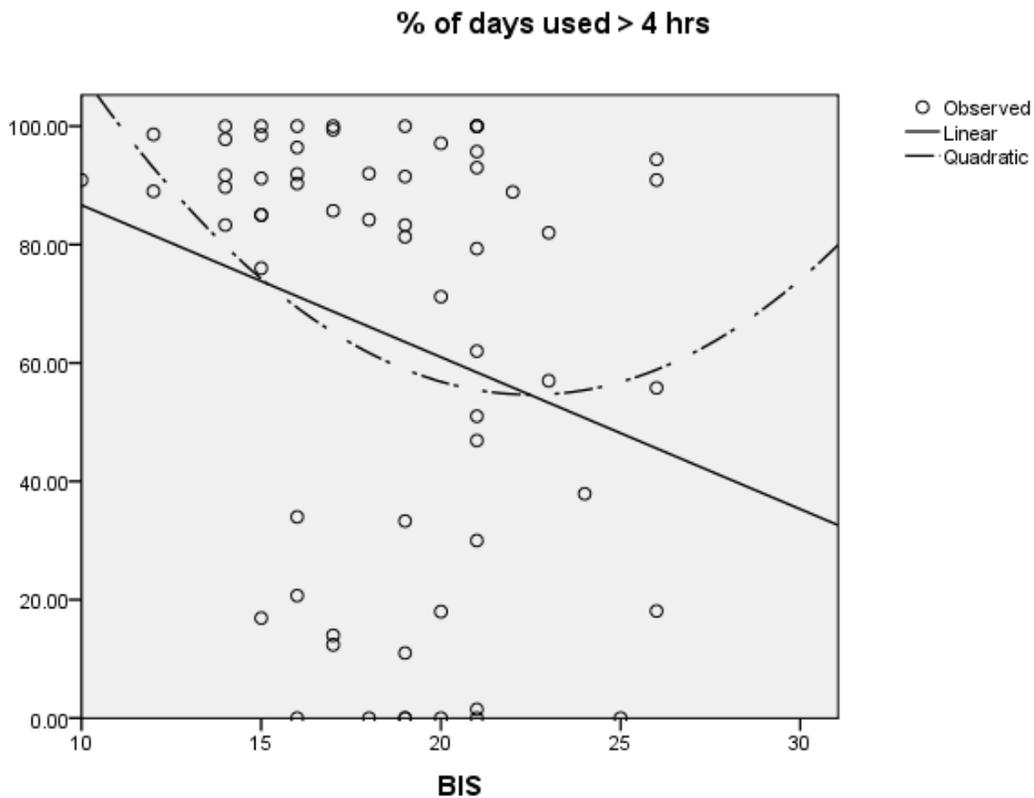
The Pearson correlations between compliance (dichotomized into yes and no) and two scales, BIS and neuroticism, were significant at a .05 criterion of statistical significance ($r = -.472, p = .001$ and $r = -.296, p = .043$, respectively). Furthermore, the correlation between neuroticism and BIS was significant, $r = .335, p = .021$.

Exploratory Analyses. Due to the appearance of the BIS and compliance scatter plot, it was hypothesized that the relationship between BIS and compliance was curvilinear rather than linear. There was a significant linear relationship between BIS and compliance, $r^2 = .067, F(1, 60) = 4.227, p = .043$. Adding a quadratic component to

the model did not significantly increase the fit of model to data, increase in $r^2 = .020$, $F(1, 59) = 1.269$, $p = .26$. These findings can be seen in Figure 2.

Figure 2

Curvilinear and Linear model of BIS Score and % of days used > 4 hours



Upon further observation, it appeared that there were few participants who fell in the middle range for % of days used > 4 hours. While 61.9% of participants met criteria for being compliant (used >4 hours 70% of days), only 6.3% of the sample was compliant between 50-69.9% of the time. The remaining 31.8% of people were considered compliant less than half of the time. These data suggest the existence of two groups that can be thought of as separate populations with possibly distinct personality profiles.

When examining overall compliant individuals, those who were compliant 70-100% of days, as a separate group, there is no significant relationship between BIS and compliance (% of days used > 4 hrs), $r = -.058$, $p = .724$. Despite a visible trend, there was no significant relationship between compliance and BIS for the individuals who were compliant less than 50% of the time, $r = -.068$, $p = .775$.

However, there were other significant relationships involving compliance. Of those participants who are considered overall compliant, percentage of days compliant was significantly correlated with conscientiousness, $r = .377$, $p = .022$, and openness, $r = .458$, $p = .004$, which suggests that those who are more consistent with using their machine are more conscientiousness and open. For those participants who were compliant less than 50% of the time, usage and frequency of feeling depressed were significantly correlated, $r = .563$, $p = .015$, which suggests that among those with low to moderate compliance, those who reported depressed feelings more frequently were more compliant than those less often depressed.

CHAPTER III: DISCUSSION

Because obstructive sleep apnea (OSA) has serious health consequences, researchers have attempted to identify noncompliant users and to create interventions that promote compliance. This thesis focused on utilizing personality variables and coping strategies to predict compliance of continuous positive airway pressure (CPAP).

A logistic regression correctly predicted compliance status for 73.1% of participants. The following predictors were used: the Behavioral Inhibition Scale (BIS), the BIS/BAS ratio, ethnicity, conscientiousness, neuroticism, agreeableness, and the Escape-Avoidance scale of the Ways of Coping (WAYS). However, the success rate was in large predicted by a single predictor, BIS. Although neuroticism was found to be significantly related to compliance, this variable did not have a significant partial effect in the model, and did not help explain much variance in the model. This could be explained by the overlap of BIS and neuroticism, as they were moderately correlated. This overlap would be expected, as BIS is related to negative affect and feelings of fear and anxiety as is neuroticism (Depue et al., 1989; Fowles, 1994)

A model with BIS only correctly classified 63.5% of cases, while a composite model of personality variables and ethnicity predicted 73.1%. The only significant predictor was BIS. Consistent with our hypothesis, this model suggests that BIS score increases as compliance decreases. High levels of BIS are associated with avoidance and movement away from aversive stimuli – in this case perhaps the socially undesirable attributes and invasiveness of the CPAP apparatus. Furthermore, this invasive and undesirable nature of the CPAP increases fear and anxiety consistent with those individuals who score high on BIS, which results in noncompliance. These findings are

consistent with our research suggesting high levels of neuroticism is associated with noncompliance and past research indicating Type D personality (characterized by negative affectivity and social inhibition) is associated with noncompliance (Brostrom et al., 2007). However, the Escape-Avoidance subscale of the WAYS was not related to compliance, despite measuring somewhat similar constructs as BIS, Type D personality, and neuroticism.

Although a scatter plot of the relationship between BIS and compliance appeared curvilinear, further analysis suggested that it was a linear model, but there were few observations in the middle range of compliance. While 61.9% of participants were met criteria for being compliant (used >4 hours 70% of days), only 6.3% of the sample was compliant between 50-69.9% of the time. The remaining 31.8% of people were considered compliant less than half of the time. This data pattern suggests that we may be dealing with two different populations, rather than a more continuous and uniform distribution of compliance in individuals ranging from 0-100%. It appears there are two distinct groups – a group that uses their CPAP machine almost daily, above and beyond the necessary minimum criteria for compliance, and the group that rarely or never uses their CPAP machine. This is consistent with the notion that humans conform to a routine or “get in the habit” of performing a particular task, such as either wearing a CPAP mask regularly or never using the machine.

Perhaps these findings can help explain why there has been considerable difficulty in replicating research utilizing personality inventories with CPAP compliance. Perhaps it may be more fruitful to conduct this type of research by examining these two distinct groups separately. In the current study we found that when examining only those

patients who meet criteria for being compliant, there was a moderate-sized positive correlation between usage and conscientiousness. In other words, within compliant individuals those who are more self-disciplined, careful, and deliberate use their machines more consistently. Similarly, when isolating compliant individuals, there is also a significant positive relationship between usage and openness. Individuals who are open and receptive to new ideas and open to trying new things, may also be more receptive to using their CPAP consistently. On the other hand, when isolating noncompliant individuals, compliance increased with frequency of self-reported depression. Past research suggests that depressed individuals are less compliant (Chervin et al., 1997; Edinger et al., 1994). So this may be a spurious correlation, or warrants further investigation. Interestingly, Stepnowsky and colleagues identified predictors with using an isolated compliant group, as discussed below (2002). This findings provide a rationale for why researchers may want to analyze their data as two separate groups (highly compliant group and noncompliant group) in addition to the overall group.

Although our hypothesis regarding BIS was supported, there was no evidence that BAS was a useful predictor for compliance. By definition BIS and BAS seem to compliment each other. However, BIS and BAS are independent constructs, and it is not unusual that only one is a good predictor of compliance (Carver et al., 1994).

The results of this study were inconsistent with the study by Stepnowsky and colleagues in 2002. Results from Stepnowsky and colleagues suggested that the Planful Problem Solving and Confrontive Coping subscales of the Active Coping scale were positively associated with compliance. The present study found no relationship among these scales and compliance. However, there are a number of differences between these

two studies that could contribute to differences in findings. First, the methodology and statistical analysis was different. Stepnowsky and colleagues used a design in which they controlled for types of machine and time frame of usage, and the current study collected observational data. Stepnowsky's study utilized a hierarchical regression, while the present study used a logistic regression with additional personality variables involved. However, there were no significant bivariate correlations between compliance and either of these two subscales.

Secondly, there were clear differences in the samples. Aside from the difference in sample size (there were 23 participants in Stepnowsky's study), there are qualitative differences in the sample. Stepnowsky's sample was mostly men, while the present study had a fairly even number of men and women. Past research has suggested compliance differences among men and women, but our research did not support these findings (Budhiraja et al., 2007; Krishnan et al., 2006; Pelletier-Fleury et al., 2001; Richards et al., 2007). Gender may play a role in these differences found. Our sample captured a much larger age range (26-80) than Stepnowsky's study (age range 32-60). This difference is of interest, as some elderly patients in this study reported difficulty with identifying a stressful situation they experienced in the past week, which is necessary to complete the WAYS. This occurrence is further discussed in the limitations sections. Data from the current study and Stepnowsky's were also collected in different regions of the United States, and education and socioeconomic status were not collected for either of these studies.

Finally, the participants in Stepnowsky's study were all CPAP-naïve patients, and data were collected for only the first week of usage. The current study used a large range

of data, from the initial month of usage to first 171 days of usage. In Stepnowky's study all patients had been recently titrated to the same machine. Finally, all patients were considered "compliant" in Stepnowsky's study, as all participants used their machine 4.4-7.7 hours per day. This is much different from the current study in which a broad range of compliance was observed. In order to obtain a much larger sample size in the current study, controlled variables (time of data collection, type of machine, etc.) evident in Stepnowsky's study were sacrificed in our observational study.

The final main hypothesis in the current study was that conscientiousness would be positively associated with compliance. Similar to other studies examining the relationship between compliance to chronic medical regimens and conscientiousness, we found no significant relationship in our sample (Moran et al., 1997; Wiebe et al., 1997). Conscientiousness was found to be a significant predictor in the consistency of compliance in individuals who met criteria for compliance, as addressed above.

There were a number of limitations within this study and challenges in collecting data with this patient population. In an effort to collect a large sample size, patients differed on a number of variables that could impact the findings in this study. For example, participants were using different types of machines with different masks that differ in comfort level. Furthermore, there was no screening to determine if patients were currently noncompliant due to a necessary change in pressure or a mask that did not correctly fit. Despite collecting a number of demographic variables, some variables that were utilized in the logistic regression, such as ethnicity, may be confounded by uncollected variables, such as socioeconomic status (SES) and education.

The amount of time that compliance data was collected differed among participants, with a range of 30-171 days post initial use. Exact number of days were not recorded specifically, but rather recorded as a 30-day interval, or greater than one month of data. We are uncertain on how this range could impact compliance, although current research suggests that the first few weeks of objective compliance data are sufficient to predict future compliance at 6 month follow ups or less (Aloia, Arnedt et al., 2007; Delguste et al., 2000; Janson et al., 2000; Rosenthal et al., 2000). Two other studies suggest long-term adherence to CPAP therapy can be predicted as early as 3 and 4 days after the initiation of CPAP adherence, respectively (Budhiraja et al., 2007; Weaver et al., 1997). Problems could also arise with data collection for long periods of time. For example, a patient may be compliant the first two months of treatment, but after a weight change the pressure is no longer adequate and the patient has a difficult time using the machine until it can be readjusted. Therefore, this person could appear less compliant than he or she would have been predicted to be based on personality variables.

The issue of consistency in data collection is difficult to control when studying a clinic population for a sample rather than conducting a controlled study that utilizes identical machines individually titrated, with a set window of compliance on CPAP-naïve patients. Machine capabilities vary greatly. There are some CPAP machines that do not collect compliance data, and those that do are typically not sophisticated enough to download compliance data into particular time frames. Furthermore, some patients do not return for follow-up appointments or mail in data cards that are required to obtain usage data. Although some health professionals would assume this indicates that the patient is not compliant with CPAP usage, this may not always be the case.

Another obstacle lies within obtaining downloads from different home healthcare companies. There are companies that are not cooperative with research efforts, and some companies that use self-report data rather than an objective measure of compliance. Some companies prefer not to release information despite appropriate consent documents provided. In the present study, two home healthcare companies requested payment for data release and one home healthcare company faxed self-report measures of compliance rather than data recorded by the CPAP machine.

A potential limitation pertains to the completion of the WAYS. Though just observational, there were reports of difficulty identifying a stressful situation that occurred in the past weeks. We received statements such as “I’m retired, there’s no stress,” and “my stressor can’t be changed so I don’t use any of these.” Although the reading level of this inventory was 7th grade, to complete this inventory validly a considerable amount of cognitive effort and ability is needed. We did not screen for cognitive impairment, despite having several individuals in the age group prone to cognitive decline. This may be a factor in the inability to replicate Stepnosky et al. 2002.

As a result of these challenges, our sample size was approximately half the targeted number based upon a power analysis. Despite this limitation, we were still able to find a moderate effect of BIS on compliance. The analyses conducted may have lacked sufficient power to find smaller effects. Future research would benefit from replication with a bigger sample size with increased efforts to preserve internal validity. Furthermore, It is possible that the BIS/BAS model may be applicable to other chronic treatment regimens. Like CPAP therapy, many patients do not comply or adhere to treatment regimens due to the aversive side effects, pain, discomfort, or even cost.

Perhaps BIS can identify those individuals who are likely to experience more negative feelings associated with a new treatment regimen, as a first step towards intervention.

In addition to BIS and neuroticism identifying noncompliant individuals, these findings provide information about these patients' personalities and coping strategies to some degree. This information can be valuable to developing efficacious interventions designed to increase compliance. For example, transtheoretical model hypothesizes that those patients that find more pros than cons to using their CPAP will be more adherent to therapy (Stepnowsky et al., 2006). Because those patients high on BIS and neuroticism are thought to be avoidance of aversive stimuli and overcome by negative emotionality, perhaps having them undergo motivational enhancement therapy, which focuses on pros and builds self efficacy, may increase positive emotions associated with CPAP and treatment (Aloia et al., 2004; Aloia, Arnedt, Stepnowsky et al., 2005). It has been established that neuroticism is linked to low health behavior self-efficacy (Muris, 2001; Williams, 2004).

Furthermore, it is important for future research to identify what these patients who score highly on BIS identify as "aversive". For example, a common complaint patients have is that they feel "claustrophobic" with the CPAP mask on (Kribbs et al., 1993). We hypothesize that this negative and fearful feeling would be associated with high neuroticism and BIS. Perhaps these patients would benefit from a type of desensitization treatment.

The BIS/BAS scales are unique in that they are correlated with frontal lobe cortical activity (Coan et al., 2003; Harmon-Jones, 2003). Although there is less evidence that BIS is directly associated with cortical activity, there is an abundance of

research that suggests general negative affect and withdrawal motivation is associated with resting right hemisphere cortical activity (Coan et al., 2003; A. J. Tomarken, Davidson, R. J., & Henriques, J. B., 1990; A. J. Tomarken, Davidson, R. J., Wheeler, R. E., & Doss, R., 1992). Furthermore, lack of right frontal lobe activity has been associated with negative affect and depression (Gotlib, 1998). Future research could focus on examining compliance as related to frontal lobe activity. This information could potentially be useful in predicting compliance from resting EEG activity. This information is practical to gather, as a polysomnogram is ordered to diagnose sleep apnea in patients.

Strengths of this study include a diverse sample that is representative of patients with OSA. This sample captures a broad range of ages and includes both Caucasian and African American participants. This sample represents the population of OSA patients well in terms of BMI distribution.

Despite lack of control over compliance time period, CPAP titration, comfort and other variables that impact internal validity, there is significant external validity in this study. Despite noting different CPAP machines and masks among participants as a limitation in this study, it also serves as a strength. CPAP patients typically use different masks before finding one that is comfortable, and it is not unusual that pressure needs change across time. Due to restrictions placed by insurance companies many patients do not have the choice of using the top-of-the-line machine.

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CONSENT DOCUMENT

Title of Research Study: Coping and Treatment
Principal Investigator: Alicia Moran
Institution: East Carolina University
Address: 237 Rawl Building, Department of Psychology, East Carolina University
Telephone #: (252) 328-1069

PURPOSE AND PROCEDURES

The purpose of this research study is to understand how patients may cope with treatment of health conditions, and in this particular case, Obstructive Sleep Apnea.

In participating in this research, you will be asked to do the following things:

- Read and sign this informed consent document
- Complete 3 questionnaires
- Permit researchers to review information pertaining to your medical history, current medical records, polysomnogram (overnight sleep study) results, and information pertaining to treatment of sleep apnea for one year following the completion of the polysomnogram.

POTENTIAL RISKS AND DISCOMFORTS

There is a very slight chance that you may experience unwanted emotions from answering the questionnaires.

POTENTIAL BENEFITS

There is no personal benefit from your participation. However, the information obtained from this study may be helpful in understanding how individuals cope with obstructive sleep apnea.

SUBJECT PRIVACY AND CONFIDENTIALITY OF RECORDS

Your privacy and confidentiality will be maintained in the following ways. The records of this research will be kept private. In any sort of report we might publish, we will not include any information that will make it possible to identify a participant. Research records will be kept in a locked file, and access will be limited to the researchers, the University review board responsible for protecting human participants, and regulatory agencies.

PERSON ADMINISTERING CONSENT: I have conducted the consent process and orally reviewed the contents of the consent document. I believe the participant understands the research.

Person Obtaining consent (PRINT)	Signature	Date
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Principal Investigator's (PRINT)	Signature	Date
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BIS/BAS

Directions: Below is a series of statements that people might use to describe how they generally feel. Read each statement and decide whether it reflects your thoughts, with 1=strongly agree and 4=strongly disagree.

	Strongly Agree			Strongly Disagree
	4	3	2	1
_____	1			
_____	2			
_____	3			
_____	4			
_____	5			
_____	6			
_____	7			
_____	8			
_____	9			
_____	10			
_____	11			
_____	12			
_____	13			
_____	14			
_____	15			
_____	16			
_____	17			
_____	18			
_____	19			
_____	20			

The Mini-IPIP

On the following pages, there are phrases describing people's behaviors. Please use the rating scale below to describe how accurately each statement describes **you**. Describe yourself as you generally are now, not as you wish to be in the future. Describe yourself as you honestly see yourself, in relation to other people you know of the same sex as you are, and roughly your same age. So that you can describe yourself in an honest manner, your responses will be kept in absolute confidence. Please read each statement carefully, and then write the number in the blank that corresponds with the Response Options scale.

Response Options

1: Very Inaccurate

2: Moderately Inaccurate

3: Neither Inaccurate nor Accurate

4: Moderately Accurate

5: Very Accurate

1. Am the life of the party. _____
2. Sympathize with others' feelings. _____
3. Get chores done right away. _____
4. Have frequent mood swings. _____
5. Have a vivid imagination. _____
6. Don't talk a lot. _____
7. Am not interested in other people's problems. _____
8. I often forget to put things back in their proper place. _____
9. Am relaxed most of the time. _____
10. Am not interested in abstract ideas. _____
11. Talk to a lot of different people at parties. _____
12. Feel others' emotions. _____
13. Like order. _____
14. Get upset easily. _____
15. Have difficulty understanding abstract ideas. _____
16. Keep in the background. _____
17. Am not really interested in others. _____
18. Make a mess of things. _____
19. Seldom feel blue. _____
20. Do not have a good imagination. _____

The Ways of Coping (CC/PPS)

Instructions

To respond to the statements in this questionnaire, you must have a specific stressful situation in mind. Take a few moments and think about the most stressful situation that you have experienced in the *past week*.

By "stressful" we mean a situation that was difficult or troubling for you, either because you felt distressed about what happened, or because you had to use considerable effort to deal with the situation. The situation may have involved your family, your job, your friends, or something else important to you. Before responding to the statements, think about the details of this stressful situation, such as where it happened, who was involved, how you acted, and why it was important to you. While you may still be involved in the situation, or it could have already happened, it should be the most stressful situation that you experienced during the week. As you respond to each of the statements, please keep this stressful situation in mind.

Read each statement carefully and indicate, by circling 0, 1, 2 or 3, to what extent you used it in the situation.

Key:

0 =Does not apply or not used

1 =Used somewhat

2 =Used quite a bit

3 =Used a great deal

Please try to respond to every question.

1. I did something that I didn't think would work, but at least I was doing something.**0 1 2 3**
2. I just concentrated on what I had to do next—the next step.....**0 1 2 3**
3. I made a plan of action and followed it.....**0 1 2 3**
4. Wished that the situation would go away or somehow be over with.....**0 1 2 3**
5. I changed something so things would turn out all right.....**0 1 2 3**
6. Hoped a miracle would happen.....**0 1 2 3**
7. I stood my ground and fought for what I wanted.....**0 1 2 3**
8. Had fantasies or wishes about how things might turn out.....**0 1 2 3**
9. Tried to make myself feel better by eating, drinking, smoking, using drugs or medications, etc.....**0 1 2 3**
10. I drew on my past experiences; I was in a similar situation before.....**0 1 2 3**
11. I tried to get the person responsible to change his or her mind.....**0 1 2 3**
12. I expressed anger to the person(s) who caused the problem.....**0 1 2 3**
13. Avoided being with people in general.....**0 1 2 3**
14. I knew what had to be done, so I doubled my efforts to make things work.....**0 1 2 3**
15. I took a big chance or did something very risky to solve the problem....**0 1 2 3**
16. I let my feelings out somehow.....**0 1 2 3**
17. I came up with a couple of different solutions to the problem.....**0 1 2 3**
18. Refused to believe that it happened.....**0 1 2 3**
19. Took it out on other people.....**0 1 2 3**
20. Slept more than usual.....**0 1 2 3**



University and Medical Center Institutional Review Board

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Chair and Director of Biomedical IRB: L. Wiley Nifong, MD
Chair and Director of Behavioral and Social Science IRB: Susan L. McCammon, PhD

TO: Alicia Moran, Student, c/o Dr. Erik Everhart, Dept of Psychology, ECU—104 Rawl Building

FROM: UMCIRB

DATE: March 25, 2009

RE: Expedited Category Research Study

TITLE: "Personality Correlates of CPAP Compliance"

AM

UMCIRB #09-0280

This research study has undergone review and approval using expedited review on 3.16.09. This research study is eligible for review under an expedited category because it is a research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.) It is also a research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

The Chairperson (or designee) deemed this **unfunded** study **no more than minimal risk** requiring a continuing review in **12 months**. 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.

The above referenced research study has been given approval for the period of **3.16.09** to **3.15.10**. The approval includes the following items:

- Internal Processing Form
- Informed Consent, Version 1.1 (dated 2.23.09)
- Survey
- Letter of Support (dated 3.10.09)
- COI Disclosure Form (dated 3.10.09)

The Chairperson (or designee) does not have a potential for conflict of interest on this study.

The UMCIRB applies 45 CFR 46, Subparts A-D, to all research reviewed by the UMCIRB regardless of the funding source. 21 CFR 50 and 21 CFR 56 are applied to all research studies under the Food and Drug Administration regulation. The UMCIRB follows applicable International Conference on Harmonisation Good Clinical Practice guidelines.

AM